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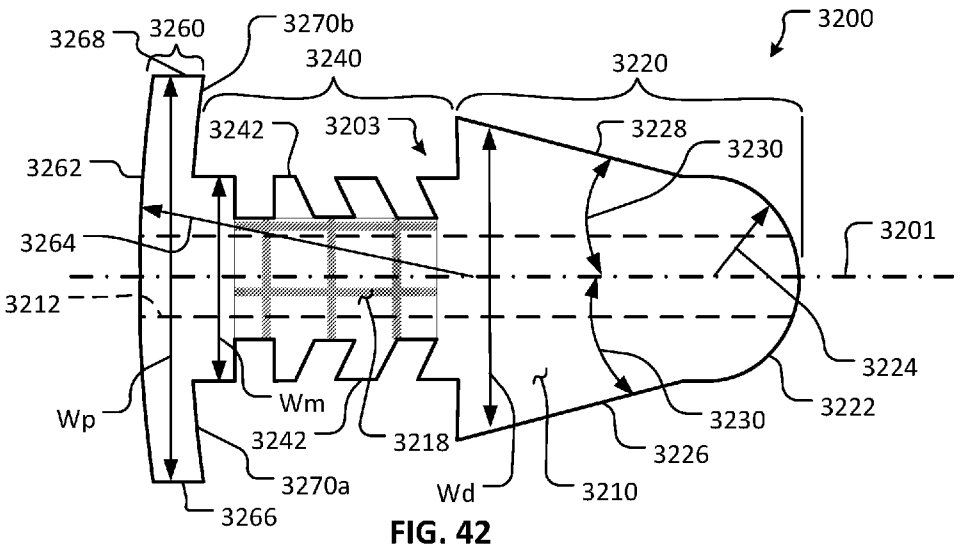


FIG. 42

(57) Abstract: Devices can be implanted in an eye to treat glaucoma and/or dry eye. The devices described herein include a body defining a lumen and having first and second ends and external and lumenal surfaces. The body has a length sufficient to provide fluid communication between the anterior chamber and tear film of the eye through the lumen when the device is implanted in the sclera. The body can include a radiused distal edge. A distal end portion of the body can be laterally flared. The body can include a mid-body portion that is laterally narrower than distal and proximal end portions of the body. Methods of treating glaucoma and/or dry eye, wherein the device is implanted in the sclera of an afflicted eye, are also described.

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GLAUCOMA TREATMENT DEVICES AND METHODS

CROSS REFERENCE TO RELATED APPLICATIONS

This application claims the benefit of U.S. Provisional Application No. 62/359,044, filed July 6, 2016. The disclosure of the prior application is considered part of and is incorporated by reference in the disclosure of this application.

BACKGROUND

1. Technical Field

This document relates to devices and methods for the treatment of glaucoma. For example, this document provides devices configured for implantation into the sclera of an afflicted eye to allow aqueous humor to flow from the anterior chamber of the afflicted eye through a lumen of the device and into the tear film, as well as methods for using such devices to treat glaucoma. This outflow of aqueous humor into the tear film can reduce the intraocular pressure of an afflicted eye in addition to providing moisture and lubrication on to the surface of the eye.

2. Background Information

Glaucoma is the leading cause of irreversible blindness in the world. About 105 million people worldwide have glaucoma, and nearly 10 million are bilaterally blind from this disease. In the United States, over 3 million people suffer from glaucoma, and it is the third most common reason for adults to visit a medical doctor. Elevated intraocular pressure is the outstanding risk factor for the development of glaucoma, and the main reason for progression of the disease. Accordingly, one mode for treatment of glaucoma is directed to lowering the intraocular pressure in the affected eye.

Dry eye syndrome is a common condition that occurs when a person's tears are not produced properly, or when the tears are not of the correct consistency and evaporate too quickly. Inflammation of the surface of the eye may occur along with dry eye. If left untreated, this condition can lead to pain, ulcers, or scars on the cornea, and some loss of vision.

SUMMARY

This document provides devices and methods for the treatment of glaucoma. For example, this document provides devices configured for implantation into the sclera of an afflicted eye to allow aqueous humor to flow from the anterior chamber of the afflicted eye through a lumen of the device and into the tear film, as well as methods for using such devices to treat glaucoma. By the strategic selection of particular materials of construction, and/or by controlling the shape and size of the lumen, in some embodiments, a device provided herein can be filterless, or can be designed to include a filter. A filterless glaucoma treatment device described herein, or a glaucoma treatment device having a filter as described herein, can be designed to prevent bacterial ingress and to provide a desired level of outflow resistance to achieve a desired intraocular pressure (typically a low to normal, or slightly above normal intraocular pressure) in glaucoma patients. Simultaneously, moisture and lubrication is provided to the surface of the eye to alleviate the dry eye symptoms commonly associated with glaucoma.

Hence, this document also provides devices and methods for the treatment of dry eye conditions. For example, this document provides devices configured for implantation into the sclera of an afflicted eye to allow aqueous humor to flow from the anterior chamber of the afflicted eye through a lumen of the device and into the tear film, as well as methods for using such devices to treat dry eye conditions. This outflow of aqueous humor into the tear film can provide moisture and lubrication to the surface of the eye. The devices and methods described herein can be used for treatment of dry eye conditions in conjunction with glaucoma treatments, or specifically directed to dry eye alone (without simultaneously treating glaucoma).

In one aspect, the disclosure is directed to a device for treating glaucoma in an eye that includes a body having a distal end portion and a proximal end portion. The body defines a lumen extending between the distal end portion and the proximal end portion. The body has external and lumenal surfaces. The body has a longitudinal length sufficient to provide fluid communication between an anterior chamber and a tear film of the eye through the lumen when the device is implanted in a sclera of the eye. A distal edge of the distal end portion has a radius.

Such a device for treating glaucoma in an eye may optionally include one or more of the following features. The radius of the distal edge may be centered on a longitudinal axis of the device. The radius of the distal edge may extend along an arc

from a first lateral edge of the distal end portion to a second lateral edge of the distal end portion. The radius of the distal edge may be between 0.2 mm to 0.8 mm.

In another aspect, this disclosure is directed to a device for treating glaucoma in an eye that includes a body having a distal end portion and a proximal end portion. The body defines a lumen extending along a longitudinal axis of the body between the distal end portion and the proximal end portion. The body has external and lumenal surfaces. The body has a longitudinal length sufficient to provide fluid communication between an anterior chamber and a tear film of the eye through the lumen when the device is implanted in a sclera of the eye. The distal end portion is laterally flared.

Such a device for treating glaucoma in an eye may optionally include one or more of the following features. A lateral width of the laterally flared distal end portion may increase along the distal end portion toward the proximal end portion. A lateral width of the laterally flared distal end portion may increase by a total of between 0.3 mm to 1.0 mm along the distal end portion toward the proximal end portion. The laterally flared distal end portion may include a first lateral edge and a second lateral edge. The first lateral edge and the second lateral edge may each be nonparallel with the longitudinal axis. The first lateral edge and the second lateral edge may each define angles in relation to the longitudinal axis between 5 degrees and 30 degrees.

In another aspect, this disclosure is directed to a device for treating glaucoma in an eye. The device includes a body having a distal end portion, a proximal end portion, and a mid-body portion extending between the distal end portion and the proximal end portion. The body defines a lumen extending along a longitudinal axis of the body between the distal end portion and the proximal end portion. The body has external and lumenal surfaces. The body has a longitudinal length sufficient to provide fluid communication between an anterior chamber and a tear film of the eye through the lumen when the device is implanted in a sclera of the eye. The mid-body portion is laterally narrower than some portions of each the distal end portion and the proximal end portion.

Such a device for treating glaucoma in an eye may optionally include one or more of the following features. A maximum total lateral width of the mid-body portion may be at least 0.3 mm less than a maximum total lateral width of the distal end portion. The maximum total lateral width of the mid-body portion may be at least

0.5 mm less than a maximum total lateral width of the proximal end portion. The mid-body portion may include a plurality of lateral protrusions. At least some edges of the lateral protrusions may extend laterally along angles that are non-orthogonal in relation to the longitudinal axis.

In another aspect, this disclosure is directed to a device for treating glaucoma in an eye. The device includes a body having a distal end portion and a proximal end portion. The body defines a lumen extending between the distal end portion and the proximal end portion. The body has external and lumenal surfaces. The body has a longitudinal length sufficient to provide fluid communication between an anterior chamber and a tear film of the eye through the lumen when the device is implanted in a sclera of the eye. A proximal edge of the proximal end portion has a radius.

Such a device for treating glaucoma in an eye may optionally include one or more of the following features. The radius of the proximal edge may be centered on a longitudinal axis of the device. The radius of the proximal edge may extend along an arc from a first lateral edge of the proximal end portion to a second lateral edge of the proximal end portion. The radius of the proximal edge may be between 5.0 mm to 10.0 mm. The radius of the proximal edge may be a first radius, and a distal edge of the proximal end portion may have a second radius. The distal edge of the proximal end portion may abut an outer surface of the eye when the device is implanted in the sclera of the eye. The second radius may be between 5.0 mm to 10.0 mm. The first radius may be between 5.0 mm to 10.0 mm.

In another aspect, this disclosure is directed to a device for treating glaucoma in an eye. The device includes a body having a distal end portion and a proximal end portion. The body defines a lumen extending along a longitudinal axis of the body between the distal end portion and the proximal end portion. The body has external and lumenal surfaces. The body has a longitudinal length sufficient to provide fluid communication between an anterior chamber and a tear film of the eye through the lumen when the device is implanted in a sclera of the eye. A maximum longitudinal length of the body in comparison to a maximum lateral width of the body is a ratio between 1:1 to 3:1.

Any one or more of the device implementations described above may optionally include one or more of the following features. The proximal end portion may include at least one suture attachment feature configured for receiving a suture to attach the body to the eye. The lumen may be open from the first end to the second

end and configured to maintain a desired intraocular pressure without a porous element inside the lumen. The body may include one or more ribs extending longitudinally through at least a portion of the lumen. The lumenal surface of the device may include a hydrophilic material. The hydrophilic material may include polyethylene glycol. The external surface of the device may be coated with a hetero-bifunctional crosslinker to stimulate collagen binding. The hetero-bifunctional crosslinker may be 5-azido-2-nitrobenzoic acid N-hydroxysuccinimide. In some embodiments, a porous element (e.g., a filter material and the like) is positioned in the lumen.

In another implementation, a method for treating glaucoma includes providing any one of the devices described herein, and implanting the device in the sclera of the eye such that aqueous humor flows from the anterior chamber to the tear film of the eye.

Such a method may optionally include one or more of the following features. After implanting the device, the second end may protrude from the eye by a distance in the range from about 100 μm to about 500 μm, or from about 50 μm to about 1000 μm. Such protrusion can be tolerated by a patient, as with each blink the rectus muscles retract the eyeball by about 1000 μm. A portion of the second end may be flared or otherwise extended, and a surface of the flared or extended portion may be in contact with the eye and generally follow a contour of the eye.

Particular embodiments of the subject matter described in this document can be implemented to realize one or more of the following advantages. In some embodiments, the devices provided herein drain aqueous humor into the tear film, rather than into the subconjuctival space. Therefore, no conjunctival bleb is formed, and therefore there is no potential to scar. Aqueous humor can be expelled into the tear film, thereby enhancing moisture and lubrication to the surface of the eye. Drainage of aqueous humor from the subject device into the tear film can alleviate dry eye symptoms in the glaucoma patients in which it is implanted. In some embodiments, the lumen of the devices provided herein is sized and/or provided with a surface chemistry to resist bacteria ingress. In addition, the geometry of the lumen can be selected to provide a particular aqueous humor outflow resistance that yields desirable intraocular pressure. By the selection of such a geometry, a filterless construct is facilitated in some embodiments. In some embodiments, a filter or filter-like element is included in the lumen. In some embodiments, the materials used to

make a device provided herein can be selected to provide bulk biocompatibility by seeking to match scleral rigidity, and/or by providing a porous cellular ingrowth surface on the portion of the device that is in contact with eye tissue. In some embodiments, naturally occurring extracellular matrix proteins such as collagen type 1, laminin, fibronectin, or other cell adhesion peptides (CAPs) can be grafted onto the outer surface to promote biointegration. In some cases, the inner or outer surfaces of the device can be coated with materials such as polymer coatings or biologically active molecules, to promote surface biocompatibility and/or immobilization of the implanted device. Biointegration and scleral rigidity matching can serve to limit inflammation by limiting micromotion of the device. In some embodiments, suture attachment features can be included to allow for device stabilization before and during biointegration. In some embodiments, a protruding portion of the devices provided herein can be flanged or otherwise extended.

Unless otherwise defined, all technical and scientific terms used herein have the same meaning as commonly understood by one of ordinary skill in the art to which this invention pertains. Although methods and materials similar or equivalent to those described herein can be used to practice the invention, suitable methods and materials are described herein. All publications, patent applications, patents, and other references mentioned herein are incorporated by reference in their entirety. In case of conflict, the present specification, including definitions, will control. In addition, the materials, methods, and examples are illustrative only and not intended to be limiting.

The details of one or more embodiments of the invention are set forth in the accompanying drawings and the description herein. Other features, objects, and advantages of the invention will be apparent from the description and drawings, and from the claims.

DESCRIPTION OF THE DRAWINGS

FIG. 1 is a sagittal cross-sectional schematic diagram of an eye with one embodiment of a device illustrative of the devices provided herein implanted in the eye.

FIG. 2 is a perspective view of an example device for treating glaucoma in accordance with some embodiments.

FIG. 3 is a longitudinal cross-sectional view of the device of FIG. 2.

FIG. 4 is a schematic drawing of a sagittal cross-section of an eye (dividing the nasal and temporal halves of the eye) that shows example geometric relationships between the eye and an implanted device for treating glaucoma.

FIG. 5 is a perspective view of another example device for treating glaucoma in accordance with some embodiments.

FIG. 6 is a perspective view of another example device for treating glaucoma in accordance with some embodiments.

FIG. 7 is a side view of the device of FIG. 6.

FIG. 8 is a sagittal cross-sectional schematic diagram of an eye with the device of FIG. 6 implanted in the eye.

FIG. 9 is a perspective view of another example device for treating glaucoma in accordance with some embodiments.

FIG. 10 is a side view of the device of FIG. 9.

FIG. 11 is a perspective view of another example device for treating glaucoma in accordance with some embodiments.

FIG. 12 is a side view of the device of FIG. 11.

FIG. 13 is a perspective view of another example device for treating glaucoma in accordance with some embodiments.

FIG. 14 is a side view of the device of FIG. 13.

FIG. 15 is a plan view of another example device for treating glaucoma in accordance with some embodiments. An enlarged view of a portion of the lumenal structure is illustrated.

FIG. 16 is a plan view of another example device for treating glaucoma in accordance with some embodiments. An enlarged view of a portion of the lumenal structure is illustrated.

FIG. 17 is a plan view of another example device for treating glaucoma in accordance with some embodiments. An enlarged view of a portion of the lumenal structure is illustrated.

FIG. 18 is a plan view of another example device for treating glaucoma in accordance with some embodiments. An enlarged view of a portion of the lumenal structure is illustrated.

FIG. 19 is a plan view of another example device for treating glaucoma in accordance with some embodiments. An enlarged view of a portion of the lumenal structure is illustrated.

FIG. 20 is a plan view of another example device for treating glaucoma in accordance with some embodiments. An enlarged view of a portion of the lumenal structure is illustrated.

FIG. 21 is a plan view of another example device for treating glaucoma in accordance with some embodiments. An enlarged view of a portion of the lumenal structure is illustrated.

FIG. 22 is a plan view of another example device for treating glaucoma in accordance with some embodiments. An enlarged view of a portion of the lumenal structure is illustrated.

FIG. 23 is a plan view of another example device for treating glaucoma in accordance with some embodiments. An enlarged view of a portion of the lumenal structure is illustrated.

FIG. 24 is a plan view of another example device for treating glaucoma in accordance with some embodiments. An enlarged view of a portion of the lumenal structure is illustrated.

FIG. 25 is a plan view of another example device for treating glaucoma in accordance with some embodiments. An enlarged view of a portion of the lumenal structure is illustrated.

FIG. 26 is a plan view of another example device for treating glaucoma in accordance with some embodiments. An enlarged view of a portion of the lumenal structure is illustrated.

FIG. 27 is an exploded perspective view of another example device for treating glaucoma in accordance with some embodiments.

FIG. 28 is a side view of the device of FIG. 27.

FIG. 29 is an exploded perspective view of another example device for treating glaucoma in accordance with some embodiments.

FIG. 30 is a side view of the device of FIG. 29.

FIG. 31 is a sagittal cross-sectional schematic diagram of an eye with another embodiment of a device illustrative of the devices provided herein implanted in the eye.

FIG. 32 is a perspective view of another example device for treating glaucoma in accordance with some embodiments.

FIG. 33 is a perspective view of another example device for treating glaucoma in accordance with some embodiments.

FIG. 34 is a photograph of an example eye shortly after receiving an implantation of two devices in accordance with some embodiments.

FIG. 35 is a photograph of the eye of FIG. 34 two weeks after the implantation.

FIG. 36 is a photograph of the eye of FIG. 34 one month after the implantation.

FIG. 37 is an exploded perspective view of another example device for treating glaucoma in accordance with some embodiments.

FIG. 38 is a side view of the device of FIG. 37.

FIG. 39 is a sagittal cross-sectional schematic diagram of an eye with the device of FIG. 37 implanted in the eye.

FIG. 40 is an exploded plan view of an example deployment tool and a device for treating glaucoma.

FIG. 41 is an exploded side view of the example deployment tool and the device for treating glaucoma of FIG. 40.

FIG. 42 is a plan view of another example device for treating glaucoma in accordance with some embodiments.

FIG. 43 is a lateral side elevation view of the device of FIG. 42.

FIG. 44 is a plan view of another example device for treating glaucoma in accordance with some embodiments.

FIG. 45 is a lateral side elevation view of the device of FIG. 44.

FIG. 46 is a plan view of another example device for treating glaucoma in accordance with some embodiments.

FIG. 47 is a lateral side elevation view of the device of FIG. 46.

FIG. 48 is a plan view of another example device for treating glaucoma in accordance with some embodiments.

FIG. 49 is a lateral side elevation view of the device of FIG. 48.

FIG. 50 is a plan view of another example device for treating glaucoma in accordance with some embodiments. The device is shown in a first configuration.

FIG. 51 is a plan view of the device of FIG. 50 in a second configuration.

FIG. 52 is a plan view of an example insertion tool.

FIG. 53 is a side view of the insertion tool of FIG. 52.

Like reference numbers represent corresponding parts throughout.

DETAILED DESCRIPTION

This document provides devices and methods for the treatment of glaucoma and/or dry eye conditions. For example, this document provides devices configured for implantation into the sclera of an afflicted eye to allow aqueous humor to flow from the anterior chamber of the afflicted eye through a lumen of the device and into the tear film, as well as methods for using such devices to treat glaucoma and/or dry eye. By the strategic selection of particular materials of construction, and/or by controlling the shape and size of the lumen, in some embodiments, a device provided herein can be filterless, or can be designed to include a filter. A filterless glaucoma treatment device described herein, or a glaucoma treatment device having a filter as described herein, can be designed to prevent bacterial ingress and to provide a desired level of outflow resistance to achieve a desired intraocular pressure (typically a low to normal, or slightly above normal intraocular pressure) in glaucoma patients. The flow of aqueous humor from the anterior chamber also provides moisture and lubrication to the surface of the eye to alleviate the dry eye symptoms commonly associated with the use of eye drops for treating glaucoma.

Referring to **FIG. 1**, an example device 1 is shown implanted in an afflicted eye 20 for the purpose of treating glaucoma and/or dry eye of afflicted eye 20. The depicted anatomical features of eye 20 include an anterior chamber 2, a sclera 6, a tear film 4, an iris 23, a ciliary body 25, and a cornea 21. Device 1 includes a body 3 that defines a lumen 5. Body 3 includes a first end 7 and a second end 9. Body 3 has an external surface 10, and a lumenal surface 12.

As depicted, device 1 is configured such that, according to some implementations, device 1 can be surgically implanted in sclera 6 of eye 20. Device 1 has a length sufficient to provide fluid communication between anterior chamber 2 and tear film 4 of eye 20 when device 1 is implanted in sclera 6. As described further herein, in some embodiments, lumen 5 can be sized and configured to provide an appropriate outflow resistance to modulate aqueous humor flowing through lumen 5, without an element that provides additional flow resistance (e.g., a filter or a porous element). In doing so, lumen 5 functions to maintain a desired intraocular pressure (IOP) to treat a glaucoma-afflicted eye 20, while also providing moisture and lubrication to the surface of eye 20 and tear film 4. In other words, aqueous humor is shunted directly to tear film 4. According to some implementations, no conjunctival bleb is formed. Additionally, no episcleral venous pressure (EVP) is created that

could raise nocturnal IOP. EVP is unaffected by the use of the devices and methods provided herein. In some cases, a device provided herein can define a lumen that includes a filter or a porous element.

In some cases, to provide fluid communication between anterior chamber 2 and tear film 4, device 1 has a length of about 2.5 mm. In some embodiments, device 1 has a length of between about 2.5 mm and about 5.0 mm, or between about 3.5 mm and about 6.0 mm. The length of at least about 2.5 mm will reduce the possibility of blockage of the lumenal opening in anterior chamber 2 by iris 23. The length of device 1 within the scleral tract would preferably be greater than the scleral thickness, because insertion would not be perpendicular to sclera 6 (but more tangential) to be parallel to iris 23.

In some cases, device 1 is designed such that the modulus of elasticity of device 1 is essentially equal to the modulus of elasticity of sclera 6. Such a matching of the moduli of elasticity of device 1 to sclera 6 is advantageous for at least the following reasons. When an implant is placed in the body, for best results the implant should handle local mechanical loads in a same or very similar way as the surrounding tissue. If the modulus of elasticity of the implant is significantly higher than the surrounding tissue, it will take over the load bearing and the surrounding tissue will start to die. This causes the implant to loosen, and eventually fall out. Alternatively, when the modulus of elasticity of the implant is significantly lower than the tissue, it can cause excess load on the tissue, again leading to a loose implant which may eventually fall out. The best approach in designing a biomaterial is to match the surrounding tissue's modulus of elasticity. The surrounding tissue will experience stress loading in much the same way it did before the implant, leading to good healing, with significantly reduced micromotion when compared to the same implant with a mismatched modulus. Such matching of the moduli of elasticity of device 1 to sclera 6 can be achieved through material selection and/or the mechanical design of device 1.

Referring also to **FIGS. 2 and 3**, additional details and features of example device 1 are visible therein. FIG. 3 is a longitudinal cross-sectional view of device 1 along section line 3-3 as shown in FIG. 2. It should be understood that one or more (or all) of the details and features described herein in reference to example device 1 are also applicable to the other device embodiments provided herein.

In some embodiments, the main structure of body 3 is formed of a material such as, but not limited to, SU-8, parylene, thiolene, silicone, acrylic, polyimide, polypropylene, polymethyl methacrylate, polyethylene terephthalate (PET), polyethylene glycol (PEG), thermoplastic polyurethane (TPU), polyurethane, and expanded polytetrafluoroethylene (e.g., denucleated and coated with laminin). In some embodiments, the main structure of body 3 is formed of a combination of two or more materials. For example, in some embodiments, a layer of PEG is sandwiched between an upper layer of PET and a lower layer of PET. The PEG can be used to define lumen 5, in some embodiments. The use of PEG for the surfaces of the lumen can be advantageous because PEG resists bacterial, protein, and cell adherence. In some embodiments, materials that prevent or resist bio-fouling can be incorporated into device 1 (and the other devices described herein). For example, in some embodiments triethylene glycol, Poly(ethylene) glycol, zwitterionic polymers (e.g. poly(carboxybetaine methacrylate)), poly(2-oxaline)s (e.g. poly(2-ethyl-2-oxaline)), poly(hydroxyfunctional acrylates) (e.g. poly(2-hydroxyethyl methacrylate)), poly(vinylpyrrolidone), peptides or peptoids (e.g. poly(amino acid) or poly(petoid)) can be incorporated into one or more portions of, or an entirety of, device 1.

In some embodiments, a portion of external surface 10 of body 3 is coated with a coating such as a silicone coating or other type of coating. In some embodiments, substantially the entire external surface 10 is coated with a coating such as a silicone coating or other type of coating. In particular embodiments, one portion of external surface 10 may be coated with silicone, and other one or more portions may be coated with another type or types of coatings. Embodiments that include a silicone coating on portions or all of external surface 10 may be coated with a layer of silicone about 50 μm thick, or within a range from about 40 μm to about 60 μm thick, or within a range from about 30 μm to about 70 μm thick, or within a range from about 20 μm to about 80 μm thick, or thicker than about 80 μm.

In some embodiments, external surface 10 of body 3 includes a porous cellular ingrowth coating on at least a portion thereof. In some embodiments, the portion of external surface 10 that is coated with the cellular ingrowth coating corresponds substantially to the portion of body 3 in contact with eye tissue (e.g., sclera 6) following scleral implantation. Such porous cellular ingrowth coatings have been described with respect to other ophthalmic implants, and can be made of silicone with a thickness of about 0.04 mm, in some examples. In some embodiments, surface laser

engraving can be used to make depressions in a portion of the body surface to allow cellular ingrowth. Selected growth factors may be adsorbed on to this coating to enhance cellular ingrowth. Coating external surface 10 with a hetero-bifunctional crosslinker allows the grafting of naturally occurring extracellular matrix proteins such as collagen type 1, laminin, fibronectin, or other cell adhesion peptides (CAPs) to external surface 10. These can attract fibroblasts from the episclera to lead to collagen immobilization of device 1. One example of a hetero-bifunctional crosslinker that is useful for such a purpose is 5-azido-2-nitrobenzoic acid N-hydroxysuccinimide.

In some embodiments, one or more portions of body 3 may be configured to inhibit conjunctival overgrowth. For example, second end 9 (of which at least a portion thereof extends exterior to cornea 21) can be configured to inhibit conjunctival overgrowth. Preventing such conjunctival overgrowth can advantageously facilitate patency of lumen 5. In some such embodiments, a coating such as a PEG coating can be applied to second end 9 to inhibit conjunctival overgrowth.

In some embodiments, a bio-inert polymer is included as a liner of lumen 5. That is, in some embodiments, lumenal surface 12 includes a bio-inert polymer material. For example, in some embodiments, a material such as, but not limited to, polyethylene glycol (PEG), phosphoryl choline (PC), or polyethylene oxide (PEO) can be used for the lumenal surface 12 of lumen 5. Such bio-inert surfaces may be further modified with biologically active molecules such as heparin, spermine, surfactants, proteases, or other enzymes, or other biocompatible chemicals amendable to surface immobilization or embedding. Some such materials are advantageously hydrophilic. For example, in some embodiments, the hydrophilic properties of lumenal surface 12 can help prevent bacterial contamination of device 1.

In some embodiments, a filter or filter-like porous member is included in the device's flow path (e.g., lumen 5) for the aqueous humor. In some embodiments, no filter or porous member is present in lumen 5 for the purpose of resisting ingress of bacteria. In some cases, the surface chemistry of lumen 5 of a device provided herein can be used to prevent bacterial ingress. For example, the high molecular weight PEG lining lumen 5 can be very hydrophilic and can attract a hydration shell. The motility of the PEG side chains, and steric stabilization involving these side chains, also can repulse bacteria, cells, and proteins. In some cases, the shear stress of the laminar

flow of the aqueous humor as it leaves eye 20 can resist ingress of bacteria into device 1. Experiments demonstrated that when perfusing device 1 into an external broth with 10^8 bacteria per mL, no bacteria entered device 1. Tears are usually quite sterile and have IgA, lysozyme, lactoferrin, and IgG/complement if inflamed. In some cases, tears can be used to clear an infection.

In some embodiments, device 1 is constructed using bulk and surface micro-machining. In some embodiments, device 1 is constructed using 3D micro-printing. In particular embodiments, external surface 10 is textured such as by stippling, cross-hatching, waffling, roughening, plasma etching, photo etching, chemical etching, placing backwards facing barbs or protrusions, and the like. One way to accomplish this external surface texturing is by laser engraving. Such featuring can stabilize device 1 *in situ* and also can increase the visibility of device 1 by making it less transparent. The featuring of the external surface 10 can make device 1 more visible to a surgeon, thereby making the handling and deployment process of device 1 more efficient and convenient.

In some embodiments, the width W of device 1 is in a range from about 0.1 mm to about 0.4 mm, or from about 0.3 mm to about 0.6 mm, or from about 0.5 mm to about 0.8 mm, or from about 0.7 mm to about 1.0 mm, or from about 0.9 mm to about 1.2 mm, or from about 1.1 mm to about 1.4 mm, or from about 1.3 mm to about 1.6 mm, or from about 1.5 mm to about 1.8 mm, or greater than about 1.8 mm.

In the depicted embodiment, body 3 flares and/or extends out around at least part of second end 9. The flaring of body 3 at its second end 9 provides a number of advantages. For example, flaring of body 3 at its second end 9 aids in the surface mounting of device 1 in eye 20 by providing an endpoint of insertion as device 1 is pushed into sclera 6 during surgery. Additionally, the flaring of body 3 at its second end 9 provides structural support to bolster the portion of device 1 that protrudes from eye 20. Such structural support can help maintain patency of lumen 5 by resisting deflection of the protruding portion, which may tend to occur from the forces exerted by an eyelid, for example. For instance, such a posteriorly placed flare/extension bolsters the device against posterior pressures. In some cases, the flaring/extending of body 3 at its second end 9 provides additional resistance to growth of conjunctiva over the exposed second end 9. For example, the additional surface area provided by the flared portion may tend to make growth of conjunctiva over the exposed second end 9 less likely to occur, thereby helping to maintain patency of lumen 5.

In some cases, device 1 can be anteriorly beveled at its first end 7 to assist in implantation and to keep the iris from plugging the inner lumenal opening.

In the depicted embodiment, lumen 5 is a narrow slit with a generally rectangular cross-section. This narrow slit may contain a number of longitudinal channels, which themselves may be square, rectangular, circular, or the like, and combinations thereof. In some embodiments, the total width of lumen 5 is about 0.5 mm. In some embodiments, the total width of lumen 5 is in a range from about 0.4 mm to about 0.6 mm, or about 0.3 mm to about 0.7 mm, or about 0.2 mm to about 0.8 mm. The height, effective width, configuration, and length of lumen 5 can be selected to provide a total resistance so that a desirably low IOP from about 8 mm Hg to about 12 mm Hg is maintained. This IOP is sometimes called the threshold pressure, which is the IOP at which pressure does not contribute to loss of retinal ganglion cells over and above the normal age-related loss. The devices provided herein for providing glaucoma and/or dry eye treatment can be configured to attain the threshold pressure, without inducing hypotony.

The effective width of lumen 5 is that width obtained after subtracting the total width of all the device support ribs 13 (as shown in FIG. 2). In some implementations, it is desirable to achieve a normal aqueous humor outflow resistance of about 3.2 mmHg×min/μL. In some implementations, there is some tolerance in the system, since the aqueous humor outflow even in a glaucomatous eye is rarely zero. In fact, the main natural aqueous humor outflow of the eye, the conventional or trabecular meshwork pathway, is IOP dependent and can modify IOP swings. Poiseuille's equation for laminar flow though a porous media (R = 8 x viscosity x channel length / channel number x π x channel radius to the fourth power) can be used to determine the combination of lumen dimensions to give the proper resistance to provide the desired IOP.

In the depicted embodiment, device 1 includes a suture attachment feature 11. In the depicted embodiment, suture attachment feature 11 is a through-hole that extends completely through body 3. Suture attachment feature 11 can receive a suture therethrough, whereby body 3 is attached to eye 20. In some implementations, such suture(s) can stabilize device 1 in eye 20 prior to bio-integration of device 1 with eye 20. In some embodiments, one or more other types of suture attachment features are included such as a flange, a slot, a projection, a clamp, and the like. In the depicted embodiment, suture attachment feature 11 is a rectangular hole. In some

embodiments, suture attachment feature 11 is a circular hole, ovular hole, or another shape of hole.

In some embodiments, suture attachment feature 11 is sized large enough to receive a 10-0 spatula needle. For example, in some embodiments, the dimensions of suture attachment feature 11 is about 300 μm by about 200 μm. Other appropriate sizes for suture attachment feature 11 can be used.

In some embodiments, one or more longitudinal support ribs 13 is included within lumen 5. Support rib 13 can add structural rigidity to help maintain patency of lumen 5. In some embodiments, support rib 13 includes a series of short discontinuous ribs that are disposed along lumen 5. In some embodiments, no support rib 13 is included.

In some embodiments, longitudinal support ribs 13 can divide lumen 5 into two or more portions (e.g., channels). That is, in some embodiments, lumen 5 of body 3 includes two or more channels (e.g., two, three, four, five, six, or more than six channels). Aqueous outflow can occur through these channels, which may be square, rectangular, circular, and the like, and combinations thereof.

In some embodiments, the portion of body 3 that is in contact with eye tissue following implantation includes one or more barbs designed to engage with tissue upon implantation and provide stability to implanted device 1. The one or more barbs may be formed as part of device body 3 during manufacture, or may be fused or bonded to device body 3 using any appropriate technique.

It should be understood that one or more (or all) of the details and features described herein in reference to example device 1 are also applicable to the other device embodiments provided herein. Moreover, one or more of the device details and features described herein can be combined with one or more other device details and features described herein to create hybrid device constructions, and such hybrid device constructions are within the scope of this disclosure.

Referring also to **FIG. 4**, certain geometric aspects of device 1 in relation to eye 20 can be described. Device 1 is shown implanted at the limbus of eye 20 in accordance with some example implant techniques. The dimension X is the anterior protrusion of device 1 from the scleral surface, and the dimension Y is the posterior protrusion of device 1 from the scleral surface. In the depicted implementation, dimensions X and Y are about the same because flare bevel angle Z follows the contour of eye 20 (e.g., angle θ is about 40° to 45° in the depicted implementation).

The posterior flare and/or extension also follows the contour of eye 20. Protrusion of device 1 from the scleral surface can prevent conjunctival overgrowth. In some cases, this advantage should be balanced with the fact that increased protrusion may tend to make for increased micromotion in some cases. In some embodiments, protrusion dimensions X and Y are in a range from about 50 μm to about 1000 μm, or from about 50 μm to about 200 μm, or from about 100 μm to about 300 μm, or from about 200 μm to about 400 μm, or from about 300 μm to about 500 μm, or from about 400 μm to about 600 μm, or from about 500 μm to about 700 μm, or from about 600 μm to about 800 μm, or from about 700 μm to about 900 μm, or from about 800 μm to about 1,000 μm.

Dimension A in FIG. 4 is the thickness of device 1. Dimension B is the frontal view thickness of the flared portion of device 1. In some embodiments, facial dimensions A and B are about 200 μm. Dimension B can vary in correspondence to variations in selected protrusion dimensions X and Y.

In some cases, device 1 is implanted in eye 20 at a position that is at about 12 o'clock relative to eye 20 (when viewed from the front of the eye). In other words, in some cases, device 1 is implanted at the limbus of eye 20 in the most superior position possible. In other cases, device 1 is implanted at the limbus of eye 20 at a position that is at least somewhat lateral from the most superior 12 o'clock position. For example, when viewed from the front of the eye, device 1 can be implanted between the 9 o'clock and 11 o'clock positions, or between the 10 o'clock and 12 o'clock positions, or between the 11 o'clock and 1 o'clock positions, or between the 12 o'clock and 2 o'clock positions, or between the 1 o'clock and 3 o'clock positions, or between the 10 o'clock and 2 o'clock positions, or between the 9 o'clock and 3 o'clock positions.

As an alternative to implantation of device 1 via the limbus of eye 20, in some cases device 1 can be implanted farther away from the cornea of eye 20. For example, in some cases device 1 can be implanted under the subconjunctiva. To implant device 1 under the subconjunctiva, a subconjunctiva bleb would be created in which the protruding portion of device 1 would reside. Such a bleb would be located under an eyelid such as the upper eyelid of the lower eyelid. For example, in some cases device 1 is implanted under the subconjunctiva of eye 20 at a position that is at about 12 o'clock relative to eye 20 (when viewed from the front of the eye). In some cases, when viewed from the front of the eye, device 1 can be implanted under the

subconjunctiva of eye 20 between the 9 o'clock and 11 o'clock positions, or between the 10 o'clock and 12 o'clock positions, or between the 11 o'clock and 1 o'clock positions, or between the 12 o'clock and 2 o'clock positions, or between the 1 o'clock and 3 o'clock positions, or between the 10 o'clock and 2 o'clock positions, or between the 9 o'clock and 3 o'clock positions.

Referring to **FIG. 5**, another example device 100 in accordance with some embodiments provided herein is illustrated. Device 100 includes a body 103 that defines a lumen 105. Body 103 includes a first end 107 and a second end 109. Body 103 has an external surface 110 and a lumenal surface 120.

Device 100 can be constructed using any of the materials and techniques as described above in reference to device 1. In some cases, device 100 can be configured and used as described above in reference to device 1. Device 100 differs from device 1, at least in regard to, the addition of lateral wings 110a and 110b. Further, in the depicted embodiment of device 100, device 100 does not include suture attachment feature 11 as included in device 1. Rather, device 100 includes suture attachment features 111a and 111b that are disposed in wings 110a and 110b, respectively. Each of suture attachment features 111a and 111b can be configured like suture attachment feature 11 of device 1 as described above.

A first method for installing the devices provided herein is as follows. Sometime before installation, the eye is irrigated with 1-5% Betadine solution, and topical antibiotic and non-steroidal anti-inflammatory drops (NSAID) are applied to the operative eye. These can be continued for about one week postoperatively four times a day. The NSAID helps stabilize the blood-aqueous barrier.

Each of the embodiments of the device illustrated herein may be inserted under topical anesthesia, possibly supplemented subconjunctivally. In general, the devices provided herein may be inserted into the sclera and under the conjunctiva, using an operative procedure. The location of insertion of a device provided herein can be in the sclera at about the posterior surgical limbus. In some cases, a device provided herein can be inserted at any site around the limbus. In some cases, a device provided herein can be inserted at the superior or temporal limbus. In some cases, a device provided herein can be inserted under the subconjunctiva such that the protruding portion of the device resides within a bleb created in the subconjunctiva.

In some cases, the insertion procedure can begin by excising a small amount of conjunctiva at the site of the anticipated insertion, exposing the underlying sclera.

In some cases (as described further below), the insertion procedure is performed without the excision of conjunctiva. Any bleeding can then be cauterized. For embodiments of the device as shown in FIG. 5, a groove incision can be made at the site of insertion with a diamond blade with a depth guard to a depth sufficient to cover the entire length of wings 110a and 110b when the device is in place. Wings 110a and 110b can provide an end-stop for insertion, so the flare at end 109 of device 100 is optional. This groove incision can be made at or near the posterior surgical limbus and can be parallel to the iris plane. For the embodiment of device 1 of Fig. 2, no groove incision is needed, since this is only necessitated by wings 110a and 110b. In some cases, for device 1, only a straight stab incision is used, with the end-stop for insertion depth provided by the flare/extension at the outer end of the device. In some cases, for device 1, insertion can be made through intact conjunctiva.

Approximately 1-2 mm posterior to the limbus, at the site of the now exposed sclera, a diamond blade can be used to make a stab incision into the anterior chamber, while held roughly parallel to the iris. This blade is of a size predetermined to make an opening into the anterior chamber sized appropriately for the introduction of the device. This stab incision is made gently, but relatively quickly, assiduously avoiding any and all intraocular structures. Such an uneventful paracentesis has been found not to disrupt the blood-aqueous barrier in most cases. In any event, any disruption of this barrier is usually of less than 24 hours duration without continued insult.

The device is next picked up and held with a non-toothed forceps. The lips of the stab incision wound may be gaped with a fine, toothed forceps. The pointed tip of the tube element would then be gently pushed through the scleral tract of the stab incision and into the anterior chamber, with the device lying above and parallel to the iris, with the bevel up (i.e., anteriorly). The flare/extension in the embodiments of device 1 and device 100 provide for a definite endpoint to the depth of insertion. For embodiments of the device having a beveled first end, the bevel is oriented anteriorly to minimize the potential for blockage of the lumenal opening by the iris. The scleral barb(s) or other outer surface features (if included) stabilize the device until the biointegration with the sclera is complete. This biointegration is a function of its porous cellular ingrowth surface, possibly enhanced by adsorbed growth factors and/or grafted extracellular matrix proteins. In addition, in some implementations, one or more sutures may be added using the device's suture attachment features to stabilize the device prior to biointegration. For example, in the embodiments of

device 1 and device 100, a 10-0 nylon suture on a broad spatula needle may be used to suture the device the sclera, providing additional stability to the device until the biointegration is complete. This suture may then be easily removed at a later time if needed. An alternative insertion technique would have the device pre-loaded into an insertion holder or cartridge, to limit the needed handling of the device by the surgeon. A properly sized sharp blade could be at the leading edge of the inserter, such blade acting also as a guide for implanting the device. Alternatively, the paracentesis could be made with a separate blade, followed by controlled insertion with an inserter.

After insertion of the device, an ocular shield can be placed over the eye. The implanted device will bio-integrate with the sclera, thereby reducing the risks of infections such as tunnel infection.

Referring to **FIGS. 6 and 7**, another example device 600 in accordance with some embodiments provided herein is illustrated. Device 600 includes a body 603 that defines a lumen 605. Body 603 includes a first end 607 and a second end 609. Body 603 has an external surface 610 and a lumenal surface 612.

Device 600 can be constructed using any of the materials and techniques as described herein in reference to device 1. Also, device 600 can be configured and used in any of the manners described herein in reference to device 1.

In the depicted embodiment, first end 607 is generally orthogonal in relation to the longitudinal surfaces of external surface 610. In contrast, second end 609 of the depicted embodiment is beveled in relation to the longitudinal surfaces of external surface 610. It should be understood that, in some embodiments of device 600 and the other devices provided herein, both ends 607 and 609 may be beveled (e.g., like second end 609), both ends 607 and 609 may be orthogonal (e.g., like first end 607), or either one of ends 607 or 609 may be beveled while the other one of ends 607 or 609 is orthogonal.

In the depicted embodiment, lumen 605 includes a first longitudinal rib 613a and a second longitudinal rib 613b. While in the depicted embodiment, the ribs 613a and 613b extend continuously from first end 607 to second end 609, in some embodiments, ribs 613a and 613b may be made of multiple individually shorter segments and/or other arrangements. It should be understood that lumen 605 may be configured with any of the lumenal constructs provided herein (e.g., FIGS. 15–26, and others), and combinations thereof.

In the depicted embodiment, second end 609 includes a first flange portion 614a and a second flange portion 614b that extend laterally in relation to the longitudinal axis of body 603. In some implementations, surfaces of flange portions 614a and 614b contact the surface of the cornea and provide mechanical stabilization of device 600 in relation to the eye. The outermost lateral surfaces of flange portions 614a and 614b are radiused (contoured) in the depicted embodiment. In some embodiments, the outermost lateral surfaces of flange portions 614a and 614b are planar and parallel to the longitudinal surfaces of external surface 610. In some embodiments, the outer lateral surfaces of flange portions 614a and 614b are planar and unparallel or askew in relation to the longitudinal surfaces of external surface 610.

In some embodiments, one or more suture attachment features are included on device 600 (and the other devices provided herein). In the depicted embodiment, second end 609 includes a first suture attachment structure 616a and a second suture attachment structure 616b. The suture attachment structures 616a and 616b are slots in the depicted embodiment. In some embodiments, other types of suture attachment structures can be alternatively or additionally included. While the depicted embodiment includes two suture attachment structures 616a and 616b, in some embodiments, zero, one, three, four, or more than four suture attachment structures are included.

One or more portions of external surface 610 can be configured for enhanced friction with eye tissue (e.g., the cornea or sclera). Advantageous mechanical stability and/or migration resistance of the device 600 (and the other devices provided herein) in relation to the eye can be facilitated by such portions. For example, in the depicted embodiment, a surface portion 618 includes an enhanced texture (roughness) in comparison to other portions of external surface 610. In the depicted embodiment, surface portion 618 is a waffled surface (cross-hatched). In some embodiments, other types of texturing configurations can be alternatively or additionally included. For example, such texturing configurations can include, but are not limited to, stippling, knurling, inclusion of one or more barbs, and the like, and combinations thereof. In some embodiments, the surface portion 618 is created by techniques such as, but not limited to, laser machining, chemical etching, 3D printing, photo etching, plasma etching, and the like.

Referring to **FIG. 8**, device 600 is shown implanted in afflicted eye 20 for the purpose of treating glaucoma and/or dry eye of afflicted eye 20. The depicted anatomical features of eye 20 include anterior chamber 2, sclera 6, tear film 4, iris 23, ciliary body 25, and cornea 21. Device 600 includes body 603 that defines lumen 605. Body 603 includes first end 607 and a second end 609. Body 603 has an external surface 610, and a lumenal surface 612.

As depicted, device 600 (and the other devices provided herein) is configured to be surgically implanted in sclera 6 of eye 20. Device 600 has a length sufficient to provide fluid communication between anterior chamber 2 and tear film 4 of eye 20 when device 600 is implanted in sclera 6. As described further below, in some embodiments lumen 605 is sized and configured to provide an appropriate outflow resistance to modulate aqueous humor flowing through lumen 605, without the need for an element that provides additional flow resistance (e.g., a filter or a porous element). In doing so, lumen 605 functions to maintain a desired IOP to treat a glaucoma afflicted eye 20, while also providing moisture and lubrication to the surface of eye 20 and tear film 4. In some embodiments, a filter or filter-like porous element is includes in lumen 605.

In general, to provide fluid communication between anterior chamber 2 and tear film 4, in some embodiments, device 600 has a length of about 2.5 mm. In some embodiments, device 600 has a length of from about 2.5 mm to about 5.0 mm, or from about 3.5 mm to about 6.0 mm. The length of at least about 2.5 mm will reduce the possibility of blockage of the lumenal opening in anterior chamber 2 by iris 23. The length of device 600 within the scleral tract would preferably be greater than the scleral thickness, because insertion would not be perpendicular to sclera 6 (but more tangential) to be parallel to iris 23.

Referring to **FIGS. 9 and 10**, another example device 700 in accordance with some embodiments provided herein is illustrated. Device 700 includes a body 703 that defines a lumen 705. Body 703 includes a first end 707 and a second end 709. Body 703 has an external surface 710 and a lumenal surface 712.

Device 700 can be constructed using any of the materials and techniques as described herein in reference to device 1. Also, device 700 can be configured and used in any of the manners described herein in reference to device 1.

In the depicted embodiment, first end 707 is beveled in relation to the longitudinal surfaces of external surface 710. Second end 709 of the depicted

embodiment is also beveled in relation to the longitudinal surfaces of external surface 710. It should be understood that, in some embodiments of device 700 (and the other devices provided herein), both ends 707 and 709 may be beveled (e.g., as shown), both ends 707 and 709 may be orthogonal, or either one of ends 707 or 709 may be beveled while the other one of ends 707 or 709 is orthogonal.

In the depicted embodiment, lumen 705 includes a plurality of ovular pillars 713 that are spaced apart from each other. It should be understood that lumen 705 may be configured with any of the lumenal constructs provided herein (e.g., FIGS. 15–26, and others), and combinations thereof.

In the depicted embodiment, second end 709 includes a first flange portion 714a and a second flange portion 714b. In some implementations, flange portions 714a and 714b contact the surface of the cornea and provide mechanical stabilization of device 700 in relation to the eye. The outer lateral surfaces of flange portions 714a and 714b include planar and chamfered portions in the depicted embodiment. In some embodiments, the outer lateral surfaces of flange portions 714a and 714b are radiused (contoured) in relation to the longitudinal surfaces of external surface 710.

In some embodiments, one or more suture attachment features are included on device 700 (and the other devices provided herein). In the depicted embodiment, second end 709 includes a suture attachment structure 716. The suture attachment structure 716 is a slot in the depicted embodiment. In some embodiments, other types of suture attachment structures can be alternatively or additionally included. While the depicted embodiment includes one suture attachment structure 716, in some embodiments, zero, two, three, four, or more than four suture attachment structures are included.

One or more portions of external surface 710 can be configured for enhanced friction with eye tissue (e.g., the cornea or sclera). Such portions can provide advantageous mechanical stability and/or migration resistance of the device 700 (and the other devices provided herein) in relation to the eye. For example, in the depicted embodiment, a surface portion 718 includes an enhanced texture (roughness) in comparison to other portions of external surface 710. In the depicted embodiment, surface portion 718 is a stippled surface. In some embodiments, other types of texturing configurations can be alternatively or additionally included. For example, such texturing configurations can include, but are not limited to, cross-hatching, knurling, inclusion of one or more barbs, and the like, and combinations thereof. In

some embodiments, the surface portion 718 is created by techniques such as, but not limited to, laser machining, chemical etching, 3D printing, plasma etching, photo etching, and the like.

Referring to **FIGS. 11 and 12**, another example device 800 in accordance with some embodiments provided herein is illustrated. Device 800 includes a body 803 that defines a lumen 805. Body 803 includes a first end 807 and a second end 809. Body 803 has an external surface 810 and a lumenal surface 812.

Device 800 can be constructed using any of the materials and techniques as described herein in reference to device 1. Also, device 800 can be configured and used in any of the manners described herein in reference to device 1.

In the depicted embodiment, first end 807 is beveled. Second end 809 of the depicted embodiment is also beveled in relation to the longitudinal surfaces of external surface 810. It should be understood that, in some embodiments of device 800 and the other devices provided herein, both ends 807 and 809 may be orthogonal in relation to the longitudinal surfaces of external surface 810, or either one of ends 807 or 809 may be beveled while the other one of ends 807 or 809 is orthogonal.

In the depicted embodiment, lumen 805 includes a longitudinal rib 813. While in the depicted embodiment, the rib 813 extends continuously from first end 807 to second end 809, in some embodiments, rib 813 may be made of multiple individually shorter segments and/or other arrangements. It should be understood that lumen 805 may be configured with any of the lumenal constructs provided herein (e.g., FIGS. 15–26, and others), and combinations thereof.

In the depicted embodiment, second end 809 includes a first flange portion 814a and a second flange portion 814b. In some implementations, one or more surfaces of flange portions 814a and 814b contact the surface of the cornea and provide mechanical stabilization of device 800 in relation to the eye. The outer lateral surfaces of flange portions 814a and 814b are planar and parallel to the longitudinal surfaces of external surface 810 in the depicted embodiment. In some embodiments, the outer lateral surfaces of flange portions 814a and 814b are contoured. In some embodiments, the outer lateral surfaces of flange portions 814a and 814b are planar and unparallel or askew in relation to the longitudinal surfaces of external surface 810.

In some embodiments, one or more suture attachment features are included on device 800 (and the other devices provided herein). In the depicted embodiment,

second end 809 includes a first suture attachment structure 816a and a second suture attachment structure 816b. The suture attachment structures 816a and 816b are holes in the depicted embodiment. In some embodiments, other types of suture attachment structures can be alternatively or additionally included. While the depicted embodiment includes two suture attachment structures 816a and 816b, in some embodiments, zero, one, three, four, or more than four suture attachment structures are included.

One or more portions of external surface 810 can be configured for enhanced friction with eye tissue (e.g., the cornea or sclera). Advantageous mechanical stability and/or migration resistance of the device 800 (and the other devices provided herein) in relation to the eye can be facilitated by such portions. For example, in the depicted embodiment, a plurality of protrusions 818 provide an enhanced texture (greater roughness) in comparison to other portions of external surface 810. In the depicted embodiment, protrusions 818 are disposed on opposing surfaces of external surface 810. It should be understood that protrusions 818 can be located in any desired location(s) on external surface 810. In some embodiments, other types of texturing configurations can be alternatively or additionally included. For example, such texturing configurations can include, but are not limited to, cross-hatching, stippling, knurling, inclusion of one or more barbs, and the like, and combinations thereof. In some embodiments, the surface portion 818 is created by techniques such as, but not limited to, laser machining, plasma etching, chemical etching, 3D printing, photo etching, and the like.

Referring to **FIGS. 13 and 14**, another example device 900 in accordance with some embodiments provided herein is illustrated. Device 900 includes a body 903 that defines a lumen 905. Body 903 includes a first end 907 and a second end 909. Body 903 has an external surface 910 and a lumenal surface 912.

Device 900 can be constructed using any of the materials and techniques as described herein in reference to device 1. Also, device 900 can be configured and used in any of the manners described herein in reference to device 1.

In the depicted embodiment, first end 907 is not beveled. Rather, first end 907 is generally orthogonal in relation to the longitudinal surfaces of external surface 910. Second end 909 of the depicted embodiment is beveled in relation to the longitudinal surfaces of external surface 910. It should be understood that, in some embodiments of device 900 (and the other devices provided herein), both ends 907 and 909 may be

beveled (e.g., like second end 909), both ends 907 and 909 may be orthogonal (e.g., like first end 907), or either one of ends 907 or 909 may be beveled while the other one of ends 907 or 909 is orthogonal.

In the depicted embodiment, lumen 905 includes a first longitudinal rib 913a and a second longitudinal rib 913b. While in the depicted embodiment, the ribs 913a and 913b extend continuously from first end 907 to second end 909, in some embodiments, ribs 913a and 913b may be made of multiple individually shorter segments and/or other arrangements. It should be understood that lumen 905 may be configured with any of the lumenal constructs provided herein (e.g., FIGS. 15–26, and others), and combinations thereof.

In the depicted embodiment, second end 909 includes a first flange portion 914a and a second flange portion 914b. In some implementations, flange portions 914a and 914b contact the surface of the cornea and provide mechanical stabilization of device 900 in relation to the eye. The outer lateral surfaces of flange portions 914a and 914b are planar and parallel to the longitudinal surfaces of external surface 910 in the depicted embodiment. In some embodiments, the outer lateral surfaces of flange portions 914a and 914b are nonplanar (e.g., radiused, chamfered, contoured, etc.). In some embodiments, the outer lateral surfaces of flange portions 914a and 914b are planar and unparallel or askew in relation to the longitudinal surfaces of external surface 910.

In some embodiments, one or more suture attachment features are included on device 900 (and the other devices provided herein). In the depicted embodiment, second end 909 includes a first suture attachment structure 916a and a second suture attachment structure 916b. The suture attachment structures 916a and 916b are slots in the depicted embodiment. In some embodiments, other types of suture attachment structures can be alternatively or additionally included. While the depicted embodiment includes two suture attachment structures 916a and 916b, in some embodiments, zero, one, three, four, or more than four suture attachment structures are included.

One or more portions of external surface 910 can be configured for enhanced friction with eye tissue (e.g., the cornea or sclera). Advantageous mechanical stability and/or migration resistance of the device 900 (and the other devices provided herein) in relation to the eye can be facilitated by such portions. For example, in the depicted embodiment, one or more lateral barbs 918 are included on opposing surfaces of

external surface 910. In the depicted embodiment, lateral barbs 918 are triangular protrusions with atraumatic tips (e.g., truncated tips, radiused tips, and the like). In some embodiments, no such lateral barbs 918 are included. In some embodiments, other types of texturing configurations can be alternatively or additionally included. For example, such texturing configurations can include, but are not limited to, stippling, knurling, cross-hatching, and the like, and combinations thereof. In some embodiments, the surface portion 918 is created by techniques such as, but not limited to, laser machining, chemical etching, plasma etching, 3D printing, photo etching, and the like.

FIGS. 15–26 depict various example lumenal structures that can be incorporated in the devices provided herein. It should be understood that the lumenal structures depicted are not an exhaustive compilation of structures that can be used for configuring the lumenal passageways of the devices provided herein. Moreover, the features of one or more of the depicted lumenal structures can be combined with the features of one or more other depicted lumenal structures to create many different combinations, which are within the scope of this disclosure.

The example lumenal structures can be sized and configured to provide an appropriate outflow resistance to modulate aqueous humor flowing through the lumen without the need for an element that provides additional flow resistance (e.g., a filter or a porous element). In doing so, the lumen functions to maintain a desired IOP to treat a glaucoma afflicted eye, while also providing moisture and lubrication to the surface of eye and tear film. In some embodiments, a filter or filter-like porous element is included in the devices provided herein.

Referring to **FIG. 15**, an example device 1000 can include a lumenal structure 1005 that includes one or more longitudinal ribs 1013. In the depicted embodiment, eight longitudinal ribs 1013 are included. In some embodiments, zero, one, two, three, four, five, six, seven, nine, ten, eleven, twelve, or more than twelve longitudinal ribs 1013 are included. Such longitudinal ribs 1013 serve to divide overall lumen 1005 into two or more longitudinal portions.

Referring to **FIG. 16**, an example device 1100 can include a lumenal structure 1105 that includes one or more longitudinal rib portions 1113. Such longitudinal rib portions 1113 serve to divide overall lumen 1105 into some segments having two or more longitudinal portions, and some segments that are undivided by longitudinal rib portions 1113. In the depicted embodiment, eight longitudinal rib portions 1113 are

included. In some embodiments, zero, one, two, three, four, five, six, seven, nine, ten, eleven, twelve, or more than twelve longitudinal rib portions 1113 are included. Any suitable number of groupings of longitudinal rib portions 1113 can be included.

Referring to **FIG. 17**, an example device 1200 can include a lumenal structure 1205 that includes one or more longitudinal rib portions 1213. Such longitudinal rib portions 1213 serve to divide overall lumen 1205 into some segments having two or more longitudinal portions, and some segments that are undivided by longitudinal rib portions 1213. In addition, in the depicted embodiment, alternating groupings of longitudinal rib portions 1213 are laterally offset from adjacent groupings of longitudinal rib portions 1213. In the depicted embodiment, eight longitudinal rib portions 1213 are included. In some embodiments, zero, one, two, three, four, five, six, seven, nine, ten, eleven, twelve, or more than twelve longitudinal rib portions 1213 are included. Any suitable number of groupings of longitudinal rib portions 1213 can be included.

Referring to **FIG. 18**, an example device 1300 can include a lumenal structure 1305 that includes one or more longitudinal ribs 1313. In the depicted embodiment, six longitudinal ribs 1313 are included. In some embodiments, zero, one, two, three, four, five, seven, eight, nine, ten, eleven, twelve, or more than twelve longitudinal ribs 1313 are included. Such longitudinal ribs 1313 serve to divide overall lumen 1305 into two or more longitudinal portions. Longitudinal ribs 1313 can be made to have any suitable width.

Referring to **FIG. 19**, an example device 1400 can include a lumenal structure 1405 that includes one or more longitudinal rib portions 1413. Such longitudinal rib portions 1413 serve to divide overall lumen 1405 into some segments having two or more longitudinal portions, and some segments that are undivided by longitudinal rib portions 1413. In the depicted embodiment, six longitudinal rib portions 1413 are included. In some embodiments, zero, one, two, three, four, five, seven, eight, nine, ten, eleven, twelve, or more than twelve longitudinal rib portions 1413 are included. Any suitable number of groupings of longitudinal rib portions 1413 can be included. Longitudinal ribs 1313 can be made to have any suitable width.

Referring to **FIG. 20**, an example device 1500 can include a lumenal structure 1505 that includes one or more longitudinal rib portions 1513. Such longitudinal rib portions 1513 serve to divide overall lumen 1505 into some segments having two or more longitudinal portions, and some segments that are undivided by longitudinal rib

portions 1513. In addition, in the depicted embodiment, alternating groupings of longitudinal rib portions 1513 are laterally offset from adjacent groupings of longitudinal rib portions 1513. In the depicted embodiment, six longitudinal rib portions 1513 are included. In some embodiments, zero, one, two, three, four, five, seven, nine, eight, ten, eleven, twelve, or more than twelve longitudinal rib portions 1513 are included. Any suitable number of groupings of longitudinal rib portions 1513 can be included. Longitudinal ribs 1313 can be made to have any suitable width.

Referring to **FIG. 21**, an example device 1600 can include a lumenal structure 1605 that includes one or more longitudinal ribs 1613. In the depicted embodiment, three longitudinal ribs 1613 are included. In some embodiments, zero, one, two, four, five, six, seven, eight, nine, ten, eleven, twelve, or more than twelve longitudinal ribs 1613 are included. Such longitudinal ribs 1613 serve to divide overall lumen 1605 into two or more longitudinal portions. Longitudinal ribs 1613 can be made to have any suitable width.

Referring to **FIG. 22**, an example device 1700 can include a lumenal structure 1705 that includes one or more longitudinal rib portions 1713. Such longitudinal rib portions 1713 serve to divide overall lumen 1705 into some segments having two or more longitudinal portions, and some segments that are undivided by longitudinal rib portions 1713. In the depicted embodiment, three longitudinal rib portions 1713 are included. In some embodiments, zero, one, two, four, five, six, seven, eight, nine, ten, eleven, twelve, or more than twelve longitudinal rib portions 1713 are included. Any suitable number of groupings of longitudinal rib portions 1713 can be included. Longitudinal ribs 1713 can be made to have any suitable width.

Referring to **FIG. 23**, an example device 1800 can include a lumenal structure 1805 that includes one or more longitudinal rib portions 1813. Such longitudinal rib portions 1813 serve to divide overall lumen 1805 into some segments having two or more longitudinal portions, and some segments that are undivided by longitudinal rib portions 1813. In addition, in the depicted embodiment, alternating groupings of longitudinal rib portions 1813 are laterally offset from adjacent groupings of longitudinal rib portions 1813. In the depicted embodiment, three longitudinal rib portions 1813 are included. In some embodiments, zero, one, two, four, five, six, seven, nine, eight, ten, eleven, twelve, or more than twelve longitudinal rib portions 1813 are included. Any suitable number of groupings of longitudinal rib portions

1813 can be included. Longitudinal ribs 1313 can be made to have any suitable width.

Referring to **FIG. 21**, an example device 1900 can include a lumenal structure 1905 that includes a plurality of circular pillars 1913. Such circular pillars 1913 serve to constrict lumen 1905 but not prevent all flow of fluid through lumen 1905. Circular pillars 1913 can be made to have any suitable size (e.g., diameter). In the depicted embodiment, circular pillars 1913 are longitudinally aligned in rows.

Referring to **FIG. 22**, an example device 2000 can include a lumenal structure 2005 that includes a plurality of circular pillars 2013. Such circular pillars 2013 serve to constrict lumen 2005 but not prevent all flow of fluid through lumen 2005. Circular pillars 2013 can be made to have any suitable size (e.g., diameter). In the depicted embodiment, circular pillars 2013 are laterally offset from longitudinally adjacent circular pillars 2013.

Referring to **FIG. 23**, an example device 2100 can include a lumenal structure 2105 that includes a plurality of ovular pillars 2113. Such ovular pillars 2113 serve to constrict lumen 2105 but not prevent all flow of fluid through lumen 2105. Ovular pillars 2113 can be made to have any suitable size (e.g., length and width). In the depicted embodiment, ovular pillars 2113 are laterally offset from longitudinally adjacent ovular pillars 2113.

Referring to **FIGS. 27 and 28**, another example device 2200 in accordance with some embodiments provided herein is illustrated. Device 2200 includes a body 2203 that defines a lumen 2205. Body 2203 includes a first end 2207 and a second end 2209. Body 2203 has an external surface 2210, and a lumenal surface 2212. Device 2200 also includes a bolster portion 2204. Bolster portion 2204 can be mated with body 2203. In some cases, second end 2209 of body 2203 can be coupled with receptacle 2218 of bolster portion 2204. In some embodiments, a compression fit (interference fit) exists between body 2203 and bolster portion 2204, such that body 2203 and bolster portion 2204 are held together and effectively function as a monolithic device prior to and after implantation into an eye.

Bolster portion 2204 and body 2203 can be constructed using any of the materials and techniques as described herein in reference to device 1. In addition, in some embodiments, bolster portion 2204, or portions thereof, is made of silicone. In some embodiments, bolster portion 2204, or portions thereof, is made of PET. Device

2200 can be configured and used in any of the manners described herein in reference to device 1.

Bolster portion 2204 provides a stable footing for device 2200 when device 2200 is implanted in an eye. In some cases, at least a portion of bolster portion 2204 contacts the surface of the eye, thereby mechanically stabilizing the device 2200 in relation to the eye. In some cases, bolster portion 2204 can serve to prevent or inhibit tipping of device 2200 in relation to the eye. Other device design features and device use techniques to prevent or inhibit tipping of device 2200 (and the other devices provided herein) in relation to the eye are also envisioned. For example, the inclusion of design features such as barbs, textured surfaces, projections, and other mechanical aspects can be included to prevent or inhibit tipping. Further, in some cases the angle of insertion of the device 200 (and the other devices provided herein) can be selected and/or optimized so prevent or inhibit tipping.

While in the depicted embodiment, bolster portion 2204 is rectangular, in some embodiments, bolster portions with other shapes are used. Such shapes can include, but are not limited to, circles, ovals, squares, parallelograms, and the like. Bolster portion 2219 can be oriented at an angle 2219 in relation to body 2203. In some embodiments, angle 2219 is about a 45° angle. In some embodiments, angle 2219 is within the range from about 40° to about 50°, or from about 35° to about 45°, or from about 45° to about 55°, or from about 30° to about 60°, or from about 20° to about 70°, or from about 10° to about 80°, or from about 0° to about 90°, or greater than about 90°.

In the depicted embodiment, first end 2207 is beveled. In some embodiments, first end 2207 is generally orthogonal in relation to the longitudinal surfaces of external surface 2210. Second end 2209 of the depicted embodiment is not beveled in relation to the longitudinal surfaces of external surface 2210. It should be understood that, in some embodiments of device 2200 and the other devices provided herein, both ends 2207 and 2209 may be beveled (e.g., like first end 2207), both ends 2207 and 2209 may be orthogonal (e.g., like second end 2209), or either one of ends 2207 or 2209 may be beveled while the other one of ends 2207 or 2209 is orthogonal.

In the depicted embodiment, second end 2209 extends beyond bolster portion 2204. In some embodiments, second end 2209 is flush or slightly recessed in relation to bolster portion 2204.

In the depicted embodiment, lumen 2205 includes a longitudinal rib 2213. While in the depicted embodiment, rib 2213 extends continuously from first end 2207 to second end 2209, in some embodiments, rib 2213 may be made of multiple individually shorter segments and/or other arrangements. It should be understood that lumen 2205 may be configured with any of the lumenal constructs provided herein (e.g., FIGS. 15–26, and others), and combinations thereof.

In the depicted embodiment, second end 2209 includes a first flange portion 2214a and a second flange portion 2214b. In some implementations, flange portions 2214a and 2214b contact the surface of the cornea and provide mechanical stabilization of device 2200 in relation to the eye. In addition, in this two-piece construct of device 2200, flange portions 2214a and 2214b engage within recesses of bolster portion 2204 to provide a sturdy mechanical connection therebetween. In the depicted embodiment, flange portions 2214a and 2214b protrude from bolster portion 2204. In some embodiments, flange portions 2214a and 2214b are flush or slightly recessed in relation to bolster portion 2204.

In some embodiments, one or more suture attachment features are included on device 2200 (and the other devices provided herein). In the depicted embodiment, bolster portion 2204 includes a first suture attachment structure 2216a and a second suture attachment structure 2216b. The suture attachment structures 2216a and 2216b are holes in the depicted embodiment. In some embodiments, other types of suture attachment structures can be alternatively or additionally included. While the depicted embodiment includes two suture attachment structures 2216a and 2216b, in some embodiments, zero, one, three, four, or more than four suture attachment structures are included.

One or more portions of external surface 2210 can be configured for enhanced friction with eye tissue (e.g., the cornea or sclera) to improve mechanical stability and/or migration resistance of the device 2200 (and the other devices provided herein) in relation to the eye. In some embodiments, configurations of external surface 2210 can include, but are not limited to, stippling, knurling, cross-hatching, inclusion of one or more barbs, and the like, and combinations thereof. In some embodiments, some such configurations are created by techniques such as, but not limited to, laser machining, chemical etching, plasma etching, 3D printing, photo etching, and the like.

Referring to **FIGS. 29 and 30**, another example device 2300 in accordance with some embodiments provided herein is illustrated. Device 2300 includes a body

2303 that defines a lumen 2305. Body 2303 includes a first end 2307 and a second end 2309. Body 2303 has an external surface 2310 and a lumenal surface 2312. Device 2300 also includes a bolster portion 2304. Bolster portion 2304 can be mated with body 2303. In some cases, body 2303 can be coupled with receptacle 2318 of bolster portion 2304 such that flange portions 2314a and 2314b are positioned in contact with bolster portion 2304. In some embodiments, a compression fit (interference fit) exists between body 2303 and bolster portion 2304, such that body 2303 and bolster portion 2304 are held together and effectively function as a monolithic device prior to and after implantation into an eye.

Bolster portion 2304 and body 2303 can be constructed using any of the materials and techniques as described herein in reference to device 1. In addition, in some embodiments, bolster portion 2304, or portions thereof, is made of silicone. In some embodiments, bolster portion 2304, or portions thereof, is made of PET. Device 2300 can be configured and used in any of the manners described herein in reference to device 1.

Bolster portion 2304 provides a stable footing for device 2300 when device 2300 is implanted in an eye. In some cases, at least a portion of bolster portion 2304 contacts the surface of the eye, thereby mechanically stabilizing the device 2300 in relation to the eye. In some cases, bolster portion 2304 can serve to prevent or inhibit tipping of device 2300 in relation to the eye.

While in the depicted embodiment, bolster portion 2304 is ovular, in some embodiments, bolster portions with other shapes are used. Such shapes can include, but are not limited to, circles, rectangles, squares, parallelograms, and the like. Bolster portion 2319 can be oriented at an angle 2319 in relation to body 2303. In some embodiments, angle 2319 is about a 45° angle. In some embodiments, angle 2319 is within the range from about 40° to about 50°, or from about 35° to about 45°, or from about 45° to about 55°, or from about 30° to about 60°, or from about 20° to about 70°, or from about 10° to about 80°, or from about 0° to about 90°, or greater than about 90°.

In the depicted embodiment, first end 2307 is not beveled. Rather, first end 2307 is generally orthogonal in relation to the longitudinal surfaces of external surface 2310. Second end 2309 of the depicted embodiment is also not beveled in relation to the longitudinal surfaces of external surface 2310. It should be understood that, in some embodiments of device 2300 and the other devices provided herein, both ends

2307 and 2309 may be beveled, both ends 2307 and 2309 may be orthogonal, or either one of ends 2307 or 2309 may be beveled while the other one of ends 2307 or 2309 is orthogonal.

In the depicted embodiment, second end 2309 extends beyond bolster portion 2304. In some embodiments, second end 2309 is flush or slightly recessed in relation to bolster portion 2304.

In the depicted embodiment, lumen 2305 includes a longitudinal rib 2313. While in the depicted embodiment, rib 2313 extends continuously from first end 2307 to second end 2309, in some embodiments, rib 2313 may be made of multiple individually shorter segments and/or other arrangements. It should be understood that lumen 2305 may be configured with any of the lumenal constructs provided herein (e.g., FIGS. 15–26, and others), and combinations thereof.

In the depicted embodiment, second end 2309 includes first flange portion 2314a and second flange portion 2314b. In this two-piece construct of device 2300, flange portions 2314a and 2314b engage with bolster portion 2304 to provide a sturdy mechanical connection therebetween. In the depicted embodiment, flange portions 2314a and 2314b protrude from bolster portion 2304. In some embodiments, flange portions 2314a and 2314b are flush or slightly recessed in relation to bolster portion 2304.

In some embodiments, one or more suture attachment features are included on device 2300 (and the other devices provided herein). In the depicted embodiment, bolster portion 2304 does not include any such suture attachment features. In some embodiments, when bolster portion 2304 is made of silicone, bolster portion 2304 can be pierced by a needle to allow sutures to be threaded through bolster portion 2304 (despite the lack of specific suture attachment features). While the depicted embodiment includes no suture attachment structures, in some embodiments, one, two, three, four, or more than four suture attachment structures are included.

One or more portions of external surface 2310 can be configured for enhanced friction with eye tissue (e.g., the cornea or sclera) to improve mechanical stability and/or migration resistance of the device 2300 (and the other devices provided herein) in relation to the eye. In some embodiments, configurations of external surface 2310 can include, but are not limited to, stippling, knurling, cross-hatching, inclusion of one or more barbs, and the like, and combinations thereof. In some embodiments,

some such configurations are created by techniques such as, but not limited to, laser machining, chemical etching, 3D printing, plasma etching, photo etching, and the like.

Referring to **FIG. 31**, an example device 2400 is shown implanted in afflicted eye 20 for the purpose of treating glaucoma and/or dry eye of afflicted eye 20. The depicted anatomical features of eye 20 include anterior chamber 2, sclera 6, tear film 4, iris 23, ciliary body 25, and cornea 21.

Device 2400 includes body 2403 that defines lumen 2405. Body 2403 includes first end 2407 and a second end 2409. Body 2403 has an external surface 2410, and a lumenal surface 2412.

In the depicted embodiment, device 2400 also includes a longitudinal extension member 2420 that is attached to body 2403. An anchor member 2422 is attached to the opposite end of the extension member 2420. Anchor member 2422 can be a structure such as, but not limited to, a barb, a hook, a screw, a clamp, and the like. Anchor member 2422 can be implanted within or attached to cornea 21 or sclera 6. In some cases, extension member 2420 and anchor member 2422 serve to stabilize mechanically device 2400 in relation to eye 20.

In some embodiments, extension member 2420 is a wire member, or another type of elongate member. In some embodiments, extension member 2420 and anchor member 2422 are made of a metallic material such as nitinol or stainless steel. Alternatively or additionally, in some embodiments, extension member 2420 and anchor member 2422 are made of a polymeric material.

Referring to **FIG. 32**, another example device 2500 in accordance with some embodiments provided herein is illustrated. Device 2500 includes a body 2503 that defines a lumen 2505. Body 2503 includes a first end 2507 and a second end 2509. Body 2503 has an external surface 2510 and a lumenal surface 2512.

Device 2500 can be constructed using any of the materials and techniques as described herein in reference to device 1. Also, device 2500 can be configured and used in any of the manners described herein in reference to device 1.

In the depicted embodiment, first end 2507 is beveled. In some embodiments, first end 2507 is generally orthogonal in relation to the longitudinal surfaces of external surface 2510. Second end 2509 of the depicted embodiment is not beveled in relation to the longitudinal surfaces of external surface 2510. It should be understood that, in some embodiments of device 2500 and the other devices provided herein, both ends 2507 and 2509 may be beveled (e.g., like first end 2507), both ends 2507 and

2509 may be orthogonal (e.g., like second end 2509), or either one of ends 2507 or 2509 may be beveled while the other one of ends 2507 or 2509 is orthogonal.

In the depicted embodiment, lumen 2505 is open continuously from first end 2507 to second end 2509. In some embodiments, lumen 2505 can be configured with any of the other lumenal constructs provided herein (e.g., FIGS. 15–26, and others), and combinations thereof.

In the depicted embodiment, second end 2509 includes a first flange portion 2514a and a second flange portion 2514b. In some implementations, flange portions 2514a and 2514b contact the surface of the cornea and provide mechanical stabilization of device 2500 in relation to the eye. The outer lateral surfaces of flange portions 2514a and 2514b are radiused (contoured) in the depicted embodiment. In some embodiments, the outer lateral surfaces of flange portions 2514a and 2514b are planar and parallel to the longitudinal surfaces of external surface 2510. In some embodiments, the outer lateral surfaces of flange portions 2514a and 2514b are planar and unparallel or askew in relation to the longitudinal surfaces of external surface 2510.

In some embodiments, one or more suture attachment features are included on device 2500 (and the other devices provided herein). In the depicted embodiment, second end 2509 includes a first suture attachment structure 2516a and a second suture attachment structure 2516b. The suture attachment structures 2516a and 2516b are grooves in the depicted embodiment. In some embodiments, other types of suture attachment structures can be alternatively or additionally included. While the depicted embodiment includes two suture attachment structures 2516a and 2516b, in some embodiments, zero, one, three, four, or more than four suture attachment structures are included.

One or more portions of external surface 2510 can be configured for enhanced friction with eye tissue (e.g., the cornea or sclera). Advantageous mechanical stability and/or migration resistance of the device 2500 (and the other devices provided herein) in relation to the eye can be facilitated by such portions. For example, in the depicted embodiment, a surface portion 2518 includes an enhanced texture (roughness) in comparison to other portions of external surface 2510. In the depicted embodiment, surface portion 2518 is a stippled surface. In some embodiments, other types of texturing configurations can be alternatively or additionally included. For example, such texturing configurations can include, but are not limited to, cross-hatching,

knurling, inclusion of one or more barbs, and the like, and combinations thereof. In some embodiments, the surface portion 2518 is created by techniques such as, but not limited to, laser machining, plasma etching, chemical etching, 3D printing, photo etching, and the like.

Referring to **FIG. 33**, another example device 2600 in accordance with some embodiments provided herein is illustrated. Device 2600 includes a body 2603 that defines a lumen 2605. Body 2603 includes a first end 2607 and a second end 2609. Body 2603 has an external surface 2610, and a lumenal surface 2612.

Device 2600 can be constructed using any of the materials and techniques as described herein in reference to device 1. Also, device 2600 can be configured and used in any of the manners described herein in reference to device 1.

In the depicted embodiment, device 2600 is generally configured in the arrangement as device 2500 of FIG. 32. Device 2600 differs from device 2500 in that second end 2609 is extended beyond flange portions 2614a and 2614b by a distance 2620. In some embodiments, distance 2620 is about 300 μm. In some embodiments, distance 2620 is in a range from about 200 μm to about 400 μm, or from about 100 μm to about 500 μm, or from about 0 μm to about 600 μm.

Referring to **FIG. 34**, example devices 2700 and 2800 can be implanted in an eye 20 that is afflicted with glaucoma.

A second method for installing the devices provided herein is as follows. Sometime before installation, the eye is irrigated with 1-5% Betadine solution, and topical antibiotic and non-steroidal anti-inflammatory drops (NSAID) are applied to the operative eye. These can be continued for about one week postoperatively four times a day. The NSAID can help stabilize the blood-aqueous barrier. All embodiments of the device illustrated herein may be inserted under topical anesthesia, possibly supplemented subconjunctivally.

This insertion procedure can be conducted without excising conjunctiva at the site of the anticipated insertion. Approximately 1-2 mm posterior to the limbus, a diamond blade can be used to make a stab incision into the anterior chamber, while held roughly parallel to the iris. The blade can be of a size predetermined to make an opening into the anterior chamber sized appropriately for the introduction of the device. This stab incision can be made gently, but relatively quickly, assiduously avoiding any and all intraocular structures.

The device is next picked up and can be held with a non-toothed forceps. The lips of the stab incision wound may be gaped with a fine, toothed forceps. The distal end (which may or may not be a pointed/beveled tip) of the tube element would then be gently pushed through the scleral tract of the stab incision and into the anterior chamber, with the device lying above and parallel to the iris, with the bevel up (i.e., anteriorly). The lateral flanges in the embodiments so configured provide for a definite endpoint to the depth of insertion. For embodiments of the device having a beveled first end, the bevel is oriented anteriorly to minimize the potential for blockage of the lumenal opening by the iris. The scleral barb(s) or other outer surface features (if included) can stabilize the device until the biointegration with the sclera is complete. This biointegration is a function of its porous cellular ingrowth surface, possibly enhanced by adsorbed growth factors and/or grafted extracellular matrix proteins. In some implementations, one or more sutures may be added using the device's suture attachment features to stabilize the device prior to biointegration. For example, a 10-0 nylon suture on a broad spatula needle may be used to suture the device the sclera, providing additional stability to the device until the biointegration is complete. This suture may then be easily removed at a later time if needed. An alternative insertion technique can include having the device pre-loaded into an insertion holder or cartridge, to limit the needed handling of the device by the surgeon. A properly sized sharp blade could be at the leading edge of the inserter, such blade acting also as a guide for implanting the device. Alternatively, the paracentesis can be made with a separate blade, followed by controlled insertion with an inserter.

After insertion of the device, an ocular shield can be placed over the eye. The implanted device can bio-integrate with the sclera, thereby reducing the risks of infections such as tunnel infection.

Referring to **FIG. 35**, eye 20 is shown after devices 2700 and 2800 have been implanted for a period of approximately two weeks. The end portions of devices 2700 and 2800 have not been overgrown with conjunctival tissue. Hence, the lumens of devices 2700 and 2800 are patent and can function to reduce IOP, thereby treating glaucoma in a safe and effective manner.

Referring to **FIG. 36**, eye 20 is shown after devices 2700 and 2800 have been implanted for a period of approximately one month. The end portions of devices 2700 and 2800 still have not been overgrown with conjunctival tissue. Hence, the

lumens of devices 2700 and 2800 are patent and can function to reduce IOP, thereby treating glaucoma in a safe and effective manner. In addition, the photo shows that the prior irritation (redness) of the tissue has subsided. Hence, devices 2700 and 2800 have been successfully integrated by the patient in this example.

Prevention of conjunctival tissue overgrowth to sustain patency of the device's lumen has been found to be effected by a number of various design factors such as, but not limited to, material selection, coatings, physical distance and geometry of the projection of the device from the surface of the eye, and the angle of the projecting end relative to the eye. For example, from animal experimentation, the relationships between time and projection distance (distance from the eye's surface to the end of the device) shown in Table 1 below have been observed.

TABLE 1: Amount of Conjunctival Overgrowth

Projection Distance	1 Week after Implantation	2 Weeks after Implantation	1 Month after Implantation	2 Months after Implantation
200 μm	none	partial	full	full
800 μm	none	none	none	none

Referring to **FIGS. 37 and 38**, another example device for treating glaucoma and/or dry eye in accordance with the techniques provided herein is a two-piece device 2900. Two-piece device 2900 includes a collar 2910 and a cartridge 2940. Collar 2910 is configured to slidably receive cartridge 2940, such that collar 2910 and cartridge 2940 are releasably coupleable.

During normal use, collar 2910 and cartridge 2940 are coupled together (as shown in FIG. 38). In that coupled arrangement, two-piece device 2900 can be implanted in a sclera of an afflicted eye to allow aqueous humor to flow from the anterior chamber of the afflicted eye through two-piece device 2900, and into the tear film (as shown in FIG. 39). This outflow of aqueous humor into the tear film can treat glaucoma by reducing the intraocular pressure of the afflicted eye, in addition to providing moisture and lubrication to the surface of the eye. Such functionality is consistent with that of other device embodiments described herein.

Along with the ability to reduce intraocular pressure, two-piece device 2900 provides added functional advantages related to the fact that collar 2910 and cartridge 2940 are releasably coupleable. For example, as described further herein, while collar

2910 remains implanted in the sclera of an afflicted eye, a used cartridge 2940 can be removed from engagement with the implanted collar 2910, and a new cartridge 2940 can be reinstalled into the implanted collar 2910. In some cases, such a procedure for installing a new cartridge 2940 is not as extensive as would be the procedure for installing an entire new single piece device. Hence, two-piece device 2900 can in some cases provide functional advantages related to the fact that collar 2910 and cartridge 2940 are releasably coupleable.

Collar 2910 and cartridge 2940 can be constructed using any of the materials and techniques as described herein in reference to device 1 and other devices provided herein. In addition, in some embodiments, collar 2910 and/or cartridge 2940, or portions thereof, are made of silicone. In some embodiments, collar 2910 and/or cartridge 2940, or portions thereof, are made of PET. Two-piece device 2900 can be configured and used in any of the manners described herein in reference to device 1. In some cases, the inner and/or outer surfaces of the two-piece device 2900 can be coated with materials such as polymer coatings or biologically active molecules, to promote surface biocompatibility and/or immobilization of the implanted device.

Collar 2910 includes a body 2912. In the depicted embodiment, body 2912 includes barbs 2912a and 2912b. One or more portions of body 2912 can be configured for enhanced friction with eye tissue (e.g., the cornea or sclera). Advantageous mechanical stability and/or migration resistance of the device two-piece 2900 (and the other devices provided herein) in relation to the eye can be facilitated by such portions. For example, in the depicted embodiment, one or more lateral barbs 2912a and 2912b are included on opposing surfaces of body 2912. In the depicted embodiment, lateral barbs 2912a and 2912b are triangular protrusions with sharp tips. Other types of shapes may be used for lateral barbs 2912a and 2912b. In some embodiments, lateral barbs 2912a and 2912b are configured to be atraumatic (e.g., truncated tips, radiused tips, and the like). In some embodiments, multiple barbs are used on one or more particular surfaces of body 2912. In some embodiments, no such lateral barbs 2912a and 2912b are included. The barbs 2912a and 2912b may be formed as part of body 2912 during manufacture, or may be fused or bonded to body 2912 using any appropriate technique.

In the depicted embodiment, a surface portion 2918 of body 2912 includes an enhanced texture (roughness) in comparison to other surface portions of body 2912. In the depicted embodiment, surface portion 2918 is a cross-hatched surface. In some

embodiments, other types of texturing configurations can be alternatively or additionally included. For example, such texturing configurations can include, but are not limited to, stippling, knurling, inclusion of one or more barbs, and the like, and combinations thereof. In some embodiments, the surface portion 2918 is created by techniques such as, but not limited to, laser machining, chemical etching, plasma etching, 3D printing, photo etching, and the like. Such texturing can be located on all external surfaces of body 2912 in some embodiments. In specific embodiments, texturing may be located on some external surfaces of body 2912, but not on others. In some embodiments, no such texturing is included on any external surfaces of body 2912.

Body 2912 defines a lumen 2914. Lumen 2914 can extend entirely through body 2912 from a proximal end to a distal end of body 2912. In some embodiments, lumen 2914 is sized for press-fit coupling with cartridge 2940. That is, in some embodiments a dimensional interference between the sizes of lumen 2914 and cartridge 2940 may facilitate a mechanical coupling therebetween. Alternatively, or additionally, in some embodiments other mechanical coupling techniques between body 2914 and cartridge 2940 can be used. Such techniques can include, but are not limited to, use of adhesives, snap-fitting, use of welding techniques, threading, clamping, and the like, and combinations thereof.

PEG can be used to define lumen 2914, in some embodiments. The use of PEG for the surfaces of lumen 2914 can be advantageous because PEG resists bacterial, protein, and cell adherence. In some embodiments, low molecular weight PEG can be used. In some cases, the PEG is photo-polymerized. In some cases, the PEG is not photo-polymerized.

In order to facilitate a desired coupling arrangement between cartridge 2940 and lumen 2914, in some embodiments the outer dimensions of cartridge 2940 are inconsistent along the longitudinal length of cartridge 2940. For example, in some embodiments a distal portion of cartridge 2940 has smaller outer dimensions than a proximal portion of cartridge 2940. That way, when cartridge 2940 is inserted into lumen 2914, the distal portion of cartridge 2940 will slide through lumen 2914, while the proximal portion of cartridge 2940 will become coupled with lumen 2914 due to a dimensional interference therebetween.

Cartridge 2940 includes a body 2943 that defines a lumen 2945. Body 2943 includes a first end 2947 and a second end 2949. Body 2943 has an external surface

2210, and a lumenal surface 2212. Device 2200 also includes a bolster portion 2204. Bolster portion 2204 can be mated with body 2203. In some cases, second end 2209 of body 2203 can be coupled with receptacle 2218 of bolster portion 2204.

In the depicted embodiment, lumen 2945 includes a longitudinal rib 2953. While in the depicted embodiment, rib 2953 extends continuously from first end 2947 to second end 2949, in some embodiments, rib 2953 may be made of multiple individually shorter segments and/or other arrangements. It should be understood that lumen 2945 may be configured with any of the lumenal constructs provided herein (e.g., FIGS. 15–26, and others), and combinations thereof.

While in the depicted embodiment, the cross-sectional shapes of collar 2910 and cartridge 2940 are rectangular, in some embodiments, other cross-sectional shapes are used. Such cross-sectional shapes can include, but are not limited to, circles, ovals, squares, parallelograms, and the like.

In the depicted embodiment, first end 2947 is not beveled. Rather, first end 2947 is generally orthogonal in relation to the longitudinal external surfaces of body 2943. Second end 2949 of the depicted embodiment is beveled in relation to the longitudinal external surfaces of body 2943. It should be understood that, in some embodiments of two-piece device 2900 and the other devices provided herein, both ends 2947 and 2949 may be beveled, both ends 2947 and 2949 may be orthogonal, or either one of ends 2947 and 2949 may be beveled while the other one of ends 2947 and 2949 is orthogonal.

In the depicted embodiment, second end 2949 extends beyond collar 2910 (in the coupled arrangement of FIG. 38). For example, in some embodiments second end 2949 extends beyond collar 2910 by about 200 μm. In some embodiments, second end 2949 extends beyond collar 2910 by a distance in a range from about 50 μm to about 1000 μm, or from about 50 μm to about 200 μm, or from about 100 μm to about 300 μm, or from about 200 μm to about 400 μm, or from about 300 μm to about 500 μm, or from about 400 μm to about 600 μm, or from about 500 μm to about 700 μm, or from about 600 μm to about 800 μm, or from about 700 μm to about 900 μm, or from about 800 μm to about 1,000 μm. In some embodiments, while in the coupled arrangement, second end 2949 is flush or slightly recessed in relation to collar 2910.

In some embodiments, one or more suture attachment features are optionally included on two-piece device 2900 (and the other devices provided herein). For example, in some embodiments suture attachment features may be included on collar

2910. The suture attachment features can be holes, slots, flanges, and the like, and combinations thereof. in the depicted embodiment.

Referring to **FIG. 39**, two-piece device 2900 is shown implanted in an afflicted eye 20 for the purpose of treating glaucoma and/or dry eye of afflicted eye 20. The depicted anatomical features of eye 20 include an anterior chamber 2, a sclera 6, a tear film 4, an iris 23, a ciliary body 25, and a cornea 21. Two-piece device 2900 includes collar 2910 and cartridge 2940. Cartridge 2940 includes first end 2947 and second end 2949.

As depicted, two-piece device 2900 is configured to be surgically implanted in sclera 6 of eye 20. Two-piece device 2900 has a length sufficient to provide fluid communication between anterior chamber 2 and tear film 4 of eye 20 when two-piece device 2900 is implanted in sclera 6. As described further herein, in some embodiments, lumen 2945 can be sized and configured to provide an appropriate outflow resistance to modulate aqueous humor flowing through lumen 2945, without an element that provides additional flow resistance (e.g., a filter or a porous element). In doing so, lumen 2945 functions to maintain a desired IOP to treat a glaucoma-afflicted eye 20, while also providing moisture and lubrication to the surface of eye 20 and tear film 4. In other words, aqueous humor is shunted directly to tear film 4. No conjunctival bleb is formed. Additionally, no EVP is created that could raise nocturnal IOP. Rather, EVP is unaffected. In some cases, lumen 2945 includes a filter or a porous element.

In some cases, collar 2910 can be implanted so that the proximal end of collar 2910 is generally flush with the outer surface of eye 20. Collar 2910 can be configured with a length such that when generally flush with the outer surface of eye 20, the distal end of collar 2910 extends beyond sclera 6, just into anterior chamber 2.

In some cases, to provide fluid communication between anterior chamber 2 and tear film 4 (via lumen 2945), two-piece device 2900 has a total length of about 2.5 mm. In some embodiments, two-piece device 2900 has a total length of between about 2.5 mm and about 5.0 mm, or between about 3.5 mm and about 6.0 mm. The length of at least about 2.5 mm will reduce the possibility of blockage of the lumenal opening in anterior chamber 2 by iris 23. The length of two-piece device 2900 within the scleral tract would preferably be greater than the scleral thickness, because insertion would not be perpendicular to sclera 6 (but more tangential) to be parallel to iris 23.

As described in reference to FIGS. 37 and 38, two-piece device 2900 is configured such that cartridge 2940 can be removed from the collar 2910 while collar 2910 remains implanted in sclera 6. Thereafter, a new cartridge 2940 can be readily installed in collar 2910. Such a feature can be advantageous in various circumstances. In one example circumstance, over a period of time lumen 2945 of a used cartridge 2940 may become partially or fully occluded by biomaterials, for example. Therefore, it may become desirable or necessary to remove used cartridge 2940, and to install a new cartridge 2940. In such a case, a clinician can remove used cartridge 2940 (while leaving collar 2910 in its implanted position) and then install a new cartridge 2940 into a coupled arrangement with collar 2910.

In another example circumstance, two-piece device 2900 is configured to be adaptable to a patient's needs over time by facilitating the use of cartridges 2940 of differing flow resistances in accordance with the patient's needs. For example, physicians can prescribe different resistance levels if the patient needs more or less AH flow to treat the patient's glaucoma. When a cartridge 2940 with a different resistance level is needed by the patient, the old cartridge 2940 can be removed and the new cartridge 2940 can be installed, using the advantageous techniques (while leaving collar 2910 in its implanted position) accommodated by two-piece device 2900.

Referring to **FIGS. 40 and 41**, in some cases a deployment tool 3000 can be used to assist in the implantation of the glaucoma and/or dry eye treatment devices provided herein (such as the depicted example device 3100). The use of deployment tool 3000 can be advantageous because the minute size of glaucoma and/or dry eye treatment device 3100 can make glaucoma and/or dry eye treatment device 3100 otherwise challenging for a clinician to handle and manipulate as needed during the implantation process.

Deployment tool 3000 includes a grasping portion 3010, a shaft 3020, and a distal end 3030 that is configured to releasably engage with device 3100. In the depicted embodiment, distal end 3030 includes a slot 3032 that is configured to releasably engage with a proximal end of device 3100. For example, in some embodiments a light interference fit can be provided between slot 3032 and proximal end of device 3100. In some embodiments, other releasable engagement techniques between distal end 3030 and device 3100 can be used. For example, in some embodiments distal end 3030 can include retractable tabs that a clinician can retract

after device 3100 has been implanted in the eye of a patient. Other releasable engagement techniques are also contemplated.

In some cases, an end user clinician may receive deployment tool 3000 and device 3100 in a coupled arrangement, in a sterile package. To perform the implant procedure, the clinician would remove the coupled combination of deployment tool 300 and device 3100 from the sterile package, and use deployment tool to implant device 3100 in accordance with the implant techniques described herein. When device 3100 is implanted in the patient's eye as desired, the clinician can uncouple deployment tool 3000 from implanted device 3100.

Referring to **FIGS. 42 and 43**, another example device 3200 in accordance with some embodiments provided herein is illustrated. Device 3200 includes a body 3203 that defines a lumen 3205 and a longitudinal axis 3201. Body 3203 includes a distal end portion 3220, a mid-body portion 3240, and a proximal end portion 3260. Body 3203 includes a distal edge 3222 and a proximal edge 3262. Body 3203 has an external surface 3210 and a lumenal surface 3212.

Body 3203 has a maximum longitudinal length L extending longitudinally between distal edge 3222 and proximal edge 3262. Body 3203 has lateral widths (e.g., as defined in FIG. 42 by Wd, Wm, and Wp) extending orthogonally in relation to axis 3201. Body 3203 has a thickness T.

Device 3200 can be constructed using any of the materials and techniques as described herein in reference to device 1. Also, device 3200 can be configured and used in any of the manners described herein in reference to device 1. Thickness T can be, without limitation, between about 0.5 mm to about 3.0 mm, or about 0.8 mm to about 2.5 mm, or about 1.0 mm to about 2.0 mm, or about 1.2 mm to about 1.8 mm.

In the depicted embodiment, lumen 3205 does not include ribs. In some embodiments, lumen 3205 includes one or more ribs. Such ribs may extend continuously between distal edge 3222 and proximal edge 3262, or, in some embodiments, such ribs may be made of multiple individually shorter segments and/or other arrangements. It should be understood that lumen 3205 may be configured with any of the lumenal constructs provided herein (e.g., FIGS. 15–26, and others), and combinations thereof.

In the depicted embodiment, distal end portion 3220 includes a radiused distal edge 3222 having a radius 3224, a first lateral edge 3226, and a second lateral edge 3228. Radiused distal edge 3222 extends along an arc between first lateral edge 3226

and second lateral edge 3228. In some cases, a radiused distal edge 3222 can facilitate a less forceful insertion technique as compared to a non-radiused distal leading edge.

In the depicted embodiment, radius 3224 is centered on axis 3201 such that body 3203 is symmetrical about axis 3201, but such centering and axial symmetry is not required in all embodiments. In some embodiments, radius 3224 is between about 0.2 mm and about 0.8 mm. In some embodiments, without limitation, radius 3224 is between about 0.2 mm and about 0.6 mm, or about 0.3 mm and about 0.6 mm, or about 0.4 mm and about 0.6 mm, or about 0.2 mm and about 1.0 mm, or about 0.2 mm and about 0.9 mm, or about 0.2 mm and about 0.7 mm, or about 0.2 mm and about 0.5 mm.

In the depicted embodiment, distal end portion 3220 is laterally flared. That is, first lateral edge 3226 and second lateral edge 3228 can each be non-parallel to axis 3201. While in the depicted embodiment first lateral edge 3226 and second lateral edge 3228 define equal non-parallel angles 3230 in relation to axis 3201, in some embodiments first lateral edge 3226 and second lateral edge 3228 define dissimilar non-parallel angles in relation to axis 3201. In some embodiments, first lateral edge 3226 and/or second lateral edge 3228 define angle 3230 in relation to axis 3201 at between about 5 degrees and about 30 degrees. In some embodiments, without limitation, angle 3230 is between about 0 degrees to about 80 degrees, or about 0 degrees to about 60 degrees, or about 0 degrees to about 45 degrees, or about 10 degrees and about 35 degrees, or about 10 degrees and about 25 degrees, or about 10 degrees and about 20 degrees.

The lateral width Wd of the laterally flared distal end portion increases along the distal end portion 3220 toward the proximal end portion 3260. In some embodiments, without limitation, lateral width Wd of the laterally flared distal end portion increases by a total of between about 0.2 mm to about 1.2 mm, or about 0.3 mm to about 1.0 mm, or about 0.4 mm to about 0.9 mm, or about 0.5 mm to about 0.8 mm, or about 0.5 mm to about 0.7 mm.

Mid-body portion 3240 extends between proximal portion 3260 and distal portion 3220. Mid-body portion 3240 has a lateral width Wm. In the depicted embodiment, lateral width Wm is laterally narrower than some portions of each proximal portion 3260 and distal portion 3220. In some embodiments, a maximum lateral width Wm is at least about 0.3 mm less than a maximum lateral width Wd. In

some embodiments, without limitation, a maximum lateral width Wm is at least about 0.1 mm less, or about 0.2 mm less, or about 0.4 mm less, or about 0.5 mm less, or about 0.6 mm less, or about 0.8 mm less, or about 1.0 mm less, or about 1.2 mm less than a maximum lateral width Wd.

In some embodiments, maximum lateral width Wm is at least about 0.5 mm less than a maximum lateral width Wp of proximal portion 3260. In some embodiments, without limitation, a maximum lateral width Wm is at least about 0.1 mm less, or about 0.2 mm less, or about 0.3 mm less, or about 0.4 mm less, or about 0.6 mm less, or about 0.7 mm less, or about 0.8 mm less, or about 0.9 mm less, or about 1.0 mm less, or about 1.2 mm, or about 1.4 mm less than a maximum lateral width Wp.

In the depicted embodiment, mid-body portion 3240 includes a plurality of lateral protrusions 3242. Such lateral protrusions 3242 can improve the anchoring strength of device 3200 to tissue, and thereby help facilitate migration resistance of device 3200. In some embodiments, such as the depicted embodiment, at least some edges of lateral protrusions 3242 extend laterally along angles that are non-orthogonal in relation to longitudinal axis 3201. In some embodiments, without limitation, edges of lateral protrusions 3242 can extend laterally along angles between about 0 degrees to about 80 degrees, or about 10 degrees to about 80 degrees, or about 30 degrees to about 80 degrees, or about 40 degrees and about 70 degrees, or about 50 degrees and about 70 degrees, or about 40 degrees and about 60 degrees in relation to the longitudinal axis 3201.

One or more portions of external surface 3210 can be configured for enhanced friction with eye tissue (e.g., the cornea or sclera). Advantageous mechanical stability and/or migration resistance of the device 3200 (and the other devices provided herein) in relation to the eye can be facilitated by such portions. For example, in the depicted embodiment, a surface portion 3218 includes an enhanced texture (roughness) in comparison to other portions of external surface 3210. In the depicted embodiment, surface portion 3218 is a waffled surface (cross-hatched engravings). In some embodiments, other types of texturing configurations can be alternatively or additionally included. For example, such texturing configurations can include, but are not limited to, etching, stippling, knurling, inclusion of one or more barbs, and the like, and combinations thereof. In some embodiments, the surface portion 3218 is

created by techniques such as, but not limited to, laser machining, chemical etching, plasma etching, 3D printing, photo etching, and the like.

In the depicted embodiment, proximal end portion 3260 includes a radiused proximal edge 3262 having a radius 3264, a first lateral edge 3266, and a second lateral edge 3268. Radiused proximal edge 3262 extends along an arc between first lateral edge 3266 and second lateral edge 3268. In some cases, a radiused proximal edge 3262 can facilitate a uniform projection of device 3200 from an eye surface as compared to a non-radiused distal leading edge.

In the depicted embodiment, radius 3264 is centered on axis 3201 such that body 3203 is symmetrical about axis 3201, but such centering and axial symmetry is not required in all embodiments. In some embodiments, radius 3264 is between about 5.0 mm and about 10.0 mm. In some embodiments, without limitation, radius 3264 is between about 3.0 mm and about 12.0 mm, or about 4.0 mm and about 11.0 mm, or about 6.0 mm and about 9.0 mm, or about 7.0 mm and about 8.0 mm.

Proximal end portion 3260 also includes radiused distal edges 3270a and 3270b. Radiused distal edges 3270a and 3270b can abut an outer surface of an eye when device 3200 is implanted in the eye. In some embodiments, radiused distal edges 3270a and 3270b have radii between about 5.0 mm and about 10.0 mm. In some embodiments, without limitation, radiused distal edges 3270a and 3270b have radii between about 3.0 mm and about 12.0 mm, or about 4.0 mm and about 11.0 mm, or about 6.0 mm and about 9.0 mm, or about 7.0 mm and about 8.0 mm.

In some embodiments, maximum longitudinal length L of body 3203 in comparison to a maximum lateral width (Wp in the depicted embodiment) of body 3203 is a ratio between about 1:1 to about 3:1. In some embodiments, without limitation, maximum longitudinal length L of body 3203 in comparison to a maximum lateral width of body 3203 is a ratio between about 1:1 to about 2.5:1, or about 1:1 to about 2:1, or about 1.3:1 to about 1.8:1, or about 1.6:1 to about 2.2:1.

Referring to **FIGS. 44 and 45**, another example device 3300 in accordance with some embodiments provided herein is illustrated. Device 3300 includes a body 3303 that defines a lumen 3305 and a longitudinal axis 3301. Body 3303 includes a distal end portion 3320, a mid-body portion 3340, and a proximal end portion 3360. Body 3303 includes a distal edge 3322 and a proximal edge 3362. Body 3303 has an external surface 3310 and a lumenal surface 3312.

Device 3300 is structurally configured essentially like device 3200. One difference between devices 3300 and 3200 is that device 3300 includes a surface portion 3318 that has been roughened by an oxygen plasma etching process. In the depicted embodiment, the roughened surface portion 3318 is on the mid-body portion 3340 only. In some embodiments, other portions of body 3303 may alternatively or additionally have roughened surface portions 3318 from an oxygen plasma etching process. Any of the device embodiments described herein can include one or more roughened surface portions that are created by any of the processes described herein, including, but not limited to, oxygen plasma etching.

Referring to **FIGS. 46 and 47**, another example device 3400 in accordance with some embodiments provided herein is illustrated. Device 3400 includes a body 3403 that defines a lumen 3405 and a longitudinal axis 3401. Body 3403 includes a distal end portion 3420, a mid-body portion 3440, and a proximal end portion 3460. Body 3403 includes a distal edge 3422 and a proximal edge 3462. Body 3403 has an external surface 3410, a lumenal surface 3412, and a surface portion 3418 that has been roughened, for example by an oxygen plasma etching process.

Device 3400 is structurally configured essentially like device 3200. One difference between devices 3400 and 3200 is that device 3400 includes suture attachment structures 3466a and 3466b that are defined in proximal end portion 3460. The suture attachment structures 3466a and 3466b are V-grooves in the depicted embodiment. In some embodiments, other types of suture attachment structures can be alternatively or additionally included (e.g., slots, eyelets, notches, etc.). While the depicted embodiment includes two suture attachment structures 3466a and 3466b, in some embodiments, zero, one, three, four, or more than four suture attachment structures are included.

Referring to **FIGS. 48 and 49**, another example device 3500 in accordance with some embodiments provided herein is illustrated. Device 3500 includes a body 3503 that defines a first lumen 3505, a second lumen 3506, and a longitudinal axis 3501. Body 3503 includes a distal end portion 3520, a mid-body portion 3540, and a proximal end portion 3560. Body 3503 includes a distal edge 3522 and a proximal edge 3462. Body 3503 has an external surface 3510, a first lumenal surface 3512, and a second lumenal surface 3513.

Body 3503 also defines an opening 3580. That is, mid-body portion 3540 comprises two longitudinal portions that are spaced apart from each other to thereby

define opening 3580 in between each other. The two longitudinal portions converge at the distal end of the mid-body portion 3540 to attach to the single distal end portion 3520. At the proximal end of the mid-body portion 3540, the two longitudinal branch portions attach to the proximal end portion 3560 at two distinct places, respectively. Opening 3580 can advantageously provide an opening space for tissue (e.g., sclera tissue) to grow into and through, so that body 3503 becomes encapsulated and secure as a result of the tissue ingrowth.

Device 3500 can also include one or more other features shown in the context of other device embodiments described herein. For example, without limitation, device 3500 can include features such as, but not limited to, suture attachment structures, roughened surface portions, and lateral protrusions.

Referring to **FIGS. 50 and 51**, another example device 3600 in accordance with some embodiments provided herein is illustrated. Device 3600 includes a body 3603 that defines a lumen 3605. Body 3603 includes a distal end portion 3620, a mid-body portion 3640, and a proximal end portion 3660. Body 3603 includes a distal edge 3622 and a proximal edge 3662. Body 3603 has an external surface 3610 and a surface portion 3618 that has been roughened, for example by an oxygen plasma etching process. Device 3600 includes suture attachment structures 3666a and 3666b that are defined in proximal end portion 3660. The suture attachment structures 3666a and 3666b are V-grooves in the depicted embodiment. In some embodiments, other types of suture attachment structures can be alternatively or additionally included (e.g., slots, eyelets, notches, etc.). While the depicted embodiment includes two suture attachment structures 3666a and 3666b, in some embodiments, zero, one, three, four, or more than four suture attachment structures are included.

Device 3600 is structurally configured essentially like device 3400. One difference between devices 3600 and 3400 is that device 3600 defines a first chamber 3624a and a second chamber 3624b. Chambers 3624a-b are sealed spaces that are located in distal end portion 3620 on opposite sides of lumen 3605. Each of the chambers 3624a-b is separated from lumen 3605 by a thin, deflectable polymer wall (e.g., made of anti-biofouling PEG). Chambers 3624a-b can be filled with a gas such as air, nitrogen, CO2, or another type of gas. Since gas-filled chambers 3624a-b can be considered to follow the ideal gas law (PV=nRT, where nRT is constant), the change in pressure within lumen 3605 is accompanied by a corresponding change in the volume of gas within chambers 3624a-b. For example, as depicted in FIG. 51 (in

comparison to FIG. 50), the thin membrane wall separating chambers 3624a-b from lumen 3605 will deflect into/towards lumen 3605 in response to a pressure decrease in lumen 3605. This partial occlusion of lumen 3605 results in an increased resistance to flow through lumen 3605 (e.g., preventing or inhibiting hypotony). Alternatively, with increasing IOP, lumen 3605 will become more opened as shown in FIG. 50 for example (compared to FIG. 51), allowing greater flow through lumen 3605 in patients with very high IOP.

Referring to **FIGS. 52 and 53**, in some cases an example insertion tool 3700 can be used to puncture a patient's sclera and to deploy an implant device 3750 in essentially a single step. A distal end portion of insertion tool 3700 is depicted (FIG. 52 is a plan view and FIG. 53 is a side view). A handle of any suitable style may be coupled to the depicted distal end portion of insertion tool 3700. Implant device 3750 is representative of any of the implant devices described herein.

Insertion tool 3700 includes a first, distal-most blade member 3710 and a second blade member 3720 that does not extend as far distally as distal-most blade member 3710. The blade members in some ways resemble keratome ophthalmic blades. The blade members 3710 and 3720 are coupled together such that a slot is defined between distal-most blade member 3710 and second blade member 3720. The slot is longer than the implant device 3750.

Implant device 3750 can be releasably received in the slot between blade members 3710 and 3720. Distal-most blade member 3710 extends farther distally than second blade member 3720. Accordingly, in use, as insertion tool 3700 is advanced toward an eye, distal-most blade member 3710 will be the first to pierce the tissue (e.g., scleral tissue). As insertion tool 3700 is advanced further distally, second blade member 3720 will subsequently pierce the tissue. As insertion tool 3700 is advanced still further distally, implant device 3750 will be positioned within the confines of the eye tissue until a proximal end portion 3752 of implant device 3750 abuts the outer surface of the eye. Then, insertion tool 3700 can be withdrawn (leaving implant device 3750 within the eye except for the protruding proximal end portion 3752). In some cases, another tool can be used to stabilize implant device 3720 as insertion tool 3700 is withdrawn. In some embodiments, insertion tool 3700 includes an implant device ejection actuator that can be actuated to press implant device 3750 out of the slot between blade members 3710 and 3720 while insertion tool 3700 is being withdrawn.

It should be understood that one or more features from one or more devices described herein can be combined with one or more features from one or more other devices described herein. All such combinations and permutations are within the scope of this disclosure.

While this specification contains many specific implementation details, these should not be construed as limitations on the scope of any invention or of what may be claimed, but rather as descriptions of features that may be specific to particular embodiments of particular inventions. Certain features that are described in this specification in the context of separate embodiments can also be implemented in combination in a single embodiment. Conversely, various features that are described in the context of a single embodiment can also be implemented in multiple embodiments separately or in any suitable subcombination. Moreover, although features may be described herein as acting in certain combinations and even initially claimed as such, one or more features from a claimed combination can in some cases be excised from the combination, and the claimed combination may be directed to a subcombination or variation of a subcombination.

Similarly, while operations are depicted in the drawings in a particular order, this should not be understood as requiring that such operations be performed in the particular order shown or in sequential order, or that all illustrated operations be performed, to achieve desirable results. In certain circumstances, multitasking and parallel processing may be advantageous. Moreover, the separation of various system modules and components in the embodiments described herein should not be understood as requiring such separation in all embodiments, and it should be understood that the described program components and systems can generally be integrated together in a single product or packaged into multiple products.

Particular embodiments of the subject matter have been described. Other embodiments are within the scope of the following claims. For example, the actions recited in the claims can be performed in a different order and still achieve desirable results. As one example, the processes depicted in the accompanying figures do not necessarily require the particular order shown, or sequential order, to achieve desirable results. In certain implementations, multitasking and parallel processing may be advantageous.

WHAT IS CLAIMED IS:

1. A device for treating an eye, the device comprising:

a body having a distal end portion and a proximal end portion, the body defining a lumen extending between the distal end portion and the proximal end portion, the body having external and lumenal surfaces, the body having a longitudinal length sufficient to provide fluid communication between an anterior chamber and a tear film of the eye through the lumen when the device is implanted in a sclera of the eye, a distal edge of the distal end portion having a radius.

2. The device of claim 1, wherein the radius of the distal edge is centered on a longitudinal axis of the device, and wherein the radius of the distal edge extends along an arc from a first lateral edge of the distal end portion to a second lateral edge of the distal end portion.

3. The device of claim 1, wherein the radius of the distal edge is between 0.2 mm to 0.8 mm.

4. A device for treating an eye, the device comprising:

a body having a distal end portion and a proximal end portion, the body defining a lumen extending along a longitudinal axis of the body between the distal end portion and the proximal end portion, the body having external and lumenal surfaces, the body having a longitudinal length sufficient to provide fluid communication between an anterior chamber and a tear film of the eye through the lumen when the device is implanted in a sclera of the eye, the distal end portion being laterally flared.

5. The device of claim 4, wherein a lateral width of the laterally flared distal end portion increases along the distal end portion toward the proximal end portion.

6. The device of claim 4, wherein a lateral width of the laterally flared distal end portion increases by a total of between 0.3 mm to 1.0 mm along the distal end portion toward the proximal end portion.

7. The device of claim 4, wherein the laterally flared distal end portion includes a first lateral edge and a second lateral edge, and wherein the first lateral edge and the second lateral edge are each nonparallel with the longitudinal axis.

8. The device of claim 7, wherein the first lateral edge and the second lateral edge each define angles in relation to the longitudinal axis between 5 degrees and 30 degrees.

9. A device for treating an eye, the device comprising:

a body having a distal end portion, a proximal end portion, and a mid-body portion extending between the distal end portion and the proximal end portion, the body defining a lumen extending along a longitudinal axis of the body between the distal end portion and the proximal end portion, the body having external and lumenal surfaces, the body having a longitudinal length sufficient to provide fluid communication between an anterior chamber and a tear film of the eye through the lumen when the device is implanted in a sclera of the eye, the mid-body portion being laterally narrower than some portions of each the distal end portion and the proximal end portion.

10. The device of claim 9, wherein a maximum total lateral width of the mid-body portion is at least 0.3 mm less than a maximum total lateral width of the distal end portion, and wherein the maximum total lateral width of the mid-body portion is at least 0.5 mm less than a maximum total lateral width of the proximal end portion.

11. The device of claim 9, wherein the mid-body portion includes a plurality of lateral protrusions.

12. The device of claim 11, wherein at least some edges of the lateral protrusions extend laterally along angles that are non-orthogonal in relation to the longitudinal axis.

13. A device for treating an eye, the device comprising:

a body having a distal end portion and a proximal end portion, the body

defining a lumen extending between the distal end portion and the proximal end portion, the body having external and lumenal surfaces, the body having a longitudinal length sufficient to provide fluid communication between an anterior chamber and a tear film of the eye through the lumen when the device is implanted in a sclera of the eye, a proximal edge of the proximal end portion having a radius.

14. The device of claim 13, wherein the radius of the proximal edge is centered on a longitudinal axis of the device, and wherein the radius of the proximal edge extends along an arc from a first lateral edge of the proximal end portion to a second lateral edge of the proximal end portion.

15. The device of claim 13, wherein the radius of the proximal edge is between 5.0 mm to 10.0 mm.

16. The device of claim 13, wherein the radius of the proximal edge is a first radius, and wherein a distal edge of the proximal end portion has a second radius.

17. The device of claim 16, wherein the distal edge of the proximal end portion abuts an outer surface of the eye when the device is implanted in the sclera of the eye.

18. The device of claim 16, wherein the second radius is between 5.0 mm to 10.0 mm.

19. The device of claim 18, wherein the first radius is between 5.0 mm to 10.0 mm.

20. A device for treating an eye, the device comprising:

a body having a distal end portion and a proximal end portion, the body defining a lumen extending along a longitudinal axis of the body between the distal end portion and the proximal end portion, the body having external and lumenal surfaces, the body having a longitudinal length sufficient to provide fluid communication between an anterior chamber and a tear film of the eye through the lumen when the device is implanted in a sclera of the eye, wherein a maximum longitudinal length of the body in comparison to a maximum lateral width of the body is a ratio between 1:1 to 3:1.

21. The device of any one of claims 1 through 20, wherein the proximal end portion includes at least one suture attachment feature configured for receiving a suture to attach the body to the eye.

22. The device of any one of claims 1 through 20, wherein the lumen is configured to maintain a desired intraocular pressure without having a porous element inside the lumen when the device is implanted in the sclera of the eye.

23. The device of any one of claims 1 through 20, wherein the body includes one or more ribs extending longitudinally through at least a portion of the lumen.

24. The device of any one of claims 1 through 20, wherein the lumenal surface of the device comprises a hydrophilic material.

25. The device of claim 24, wherein the hydrophilic material comprises polyethylene glycol.

26. The device of any one of claims 1 through 20, wherein the external surface of the device is coated with a hetero-bifunctional crosslinker.

27. The device of claim 26, wherein the hetero-bifunctional crosslinker is 5-azido-2-nitrobenzoic acid N-hydroxysuccinimide.

28. The device of any one of claims 1 through 20, wherein the external surface of the device includes one or more surface areas configured to provide increased friction with the sclera.

29. The device of claim 28, wherein the one or more surface areas configured to provide increased friction with the sclera includes an oxygen plasma etched surface area.

30. The device of any one of claims 1 through 20, wherein the proximal end portion includes one or more suture attachment features configured for receiving a suture to attach the body to the eye.

31. A method for treating glaucoma, the method comprising:

providing the device of any one of claims 1 through 30; and

implanting the device in the sclera of the eye such that aqueous humor flows from the anterior chamber to the tear film of the eye.

32. The method of claim 31, wherein, after implanting the device, the proximal end portion protrudes from the eye by a distance in the range from about 50 μm to about 500 μm.

33. The method of claim 31, wherein the aqueous humor flowing from the anterior chamber to the tear film of the eye increases moisture and lubrication of a surface of the eye.

34. A system for treating an eye, the system comprising:

a deployment tool, the deployment tool including a distal end; and

the device of any one of claims 1 through 30,

wherein the distal end of the deployment tool is configured to be releasably engageable with the proximal end portion of the body.

35. The system of claim 34, wherein the distal end of the deployment tool is releasably engageable within the proximal end portion of the body using a dimensional interference fit therebetween.

36. The system of claim 34, further comprising a sterile package, and wherein the deployment tool and the device are engaged with each other and located within the sterile package.

37. A device for treating a dry eye condition in an eye, the device comprising:

a body having a distal end portion and a proximal end portion, the body defining a lumen extending between the distal end portion and the proximal end portion, the body having external and lumenal surfaces, the body having a longitudinal length sufficient to provide fluid communication between an anterior chamber and a tear film of the eye through the lumen when the device is implanted in

a sclera of the eye, a distal edge of the distal end portion having a radius.

38. A method for treating dry eye, the method comprising:

providing the device of any one of claims 1 through 30; and

implanting the device in the sclera of the eye such that aqueous humor flows from the anterior chamber to the tear film of the eye.

39. A method for treating an eye of a patient, the method comprising:

creating a bleb in a subconjunctiva of the eye; and

implanting a device in the eye, wherein the device comprises:

a body having a distal end portion and a proximal end portion, the body defining a lumen extending between the distal end portion and the proximal end portion,

wherein at least a portion of the proximal end portion is positioned within the bleb such that the lumen extends between an anterior chamber of the eye and the bleb.

40. A device for treating an eye, the device comprising:

a body having a distal end portion, a proximal end portion, and a mid-body portion extending between the distal end portion and the proximal end portion, the mid-body portion comprising two branch portions that are spaced apart from each other to define an open space in the mid-body portion between the two branch portions,

the body defining a first lumen extending between the distal end portion and the proximal end portion, the first lumen extending through a first branch portion of the two branch portions,

the body defining a second lumen extending between the distal end portion and the proximal end portion, the second lumen extending through a second branch portion of the two branch portions,

the body having a longitudinal length sufficient to provide fluid communication between an anterior chamber and a tear film of the eye through the first and second lumens when the device is implanted in a sclera of the eye.

41. A device for treating an eye, the device comprising:

a body having a distal end portion and a proximal end portion, the body

defining a lumen extending between the distal end portion and the proximal end portion, the body having a longitudinal length sufficient to provide fluid communication between an anterior chamber and a tear film of the eye through the lumen when the device is implanted in a sclera of the eye,

the distal end portion defining two gas-filled chambers that are separated from the lumen by thin, flexible walls, wherein the two gas-filled chamber are individually positioned on respective opposite sides of the lumen.

42. A device for treating glaucoma in an eye, the device comprising:

a body having a distal end portion, a proximal end portion, and a mid-body portion extending between the distal end portion and the proximal end portion, the body defining a lumen extending along a longitudinal axis of the body between the distal end portion and the proximal end portion, the body having external and lumenal surfaces, the body having a longitudinal length sufficient to provide fluid communication between an anterior chamber and a tear film of the eye through the lumen when the device is implanted in a sclera of the eye, the mid-body portion being laterally narrower than some portions of the distal end portion.

43. A device for treating glaucoma in an eye, the device comprising:

a body having a distal end portion, a proximal end portion, and a mid-body portion extending between the distal end portion and the proximal end portion, the body defining a lumen extending along a longitudinal axis of the body between the distal end portion and the proximal end portion, the body having external and lumenal surfaces, the body having a longitudinal length sufficient to provide fluid communication between an anterior chamber and a tear film of the eye through the lumen when the device is implanted in a sclera of the eye, the mid-body portion being laterally narrower than some portions of the proximal end portion.

44. A device for treating glaucoma in an eye, the device comprising:

a body having a distal end portion, a proximal end portion, and a mid-body portion extending between the distal end portion and the proximal end portion, the body defining a lumen extending along a longitudinal axis of the body between the distal end portion and the proximal end portion, the body having external and lumenal surfaces, the body having a longitudinal length sufficient to provide fluid

communication between an anterior chamber and a tear film of the eye through the lumen when the device is implanted in a sclera of the eye, wherein the lumenal surfaces comprise a hydrophilic or anti-biofouling material.

45. A system for treating an eye, the system comprising:

a deployment tool including a first distal-most blade and a second blade, wherein a slot is defined between the first distal-most blade and the second blade; and

the device of any one of claims 1 through 30 and 40 through 44, wherein the device is releasably engageable within the slot.

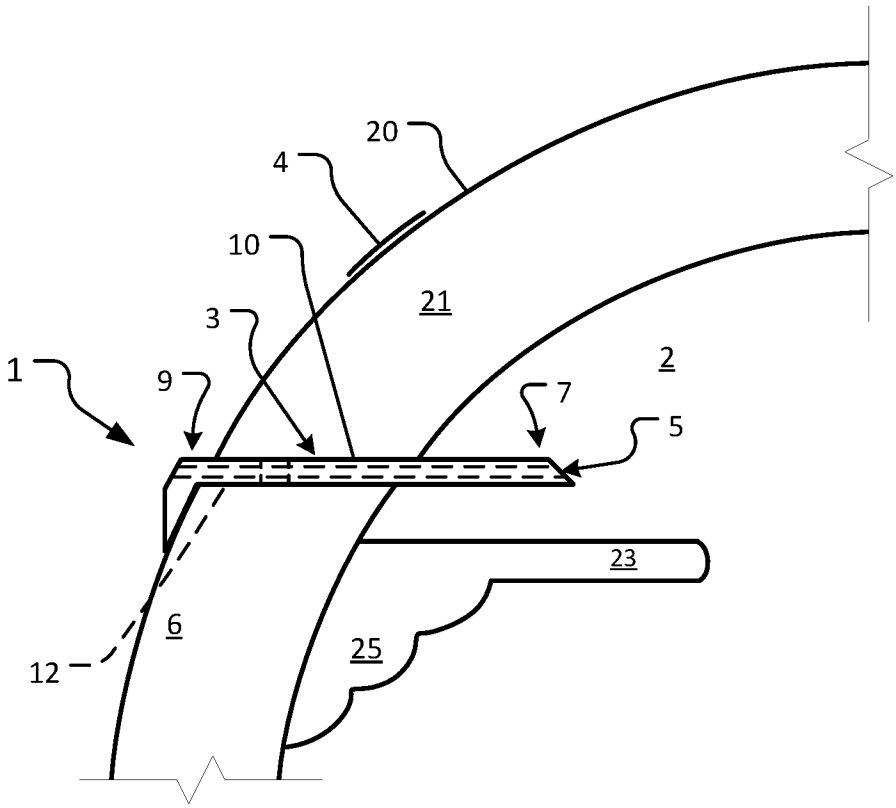


FIG. 1

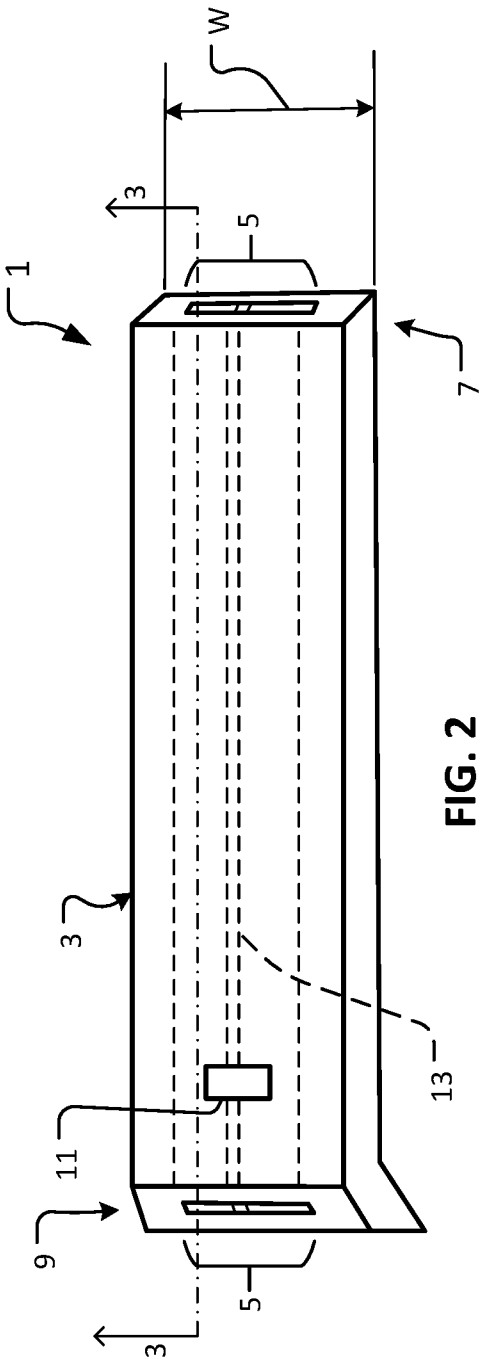


FIG. 2

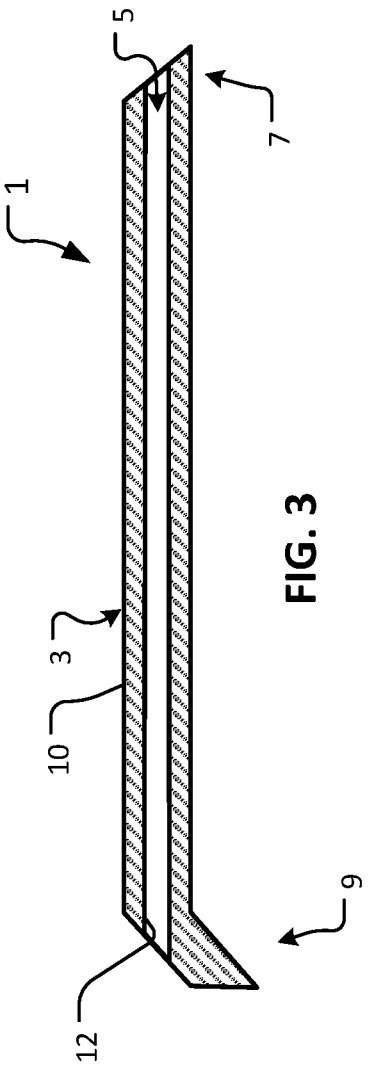


FIG. 3

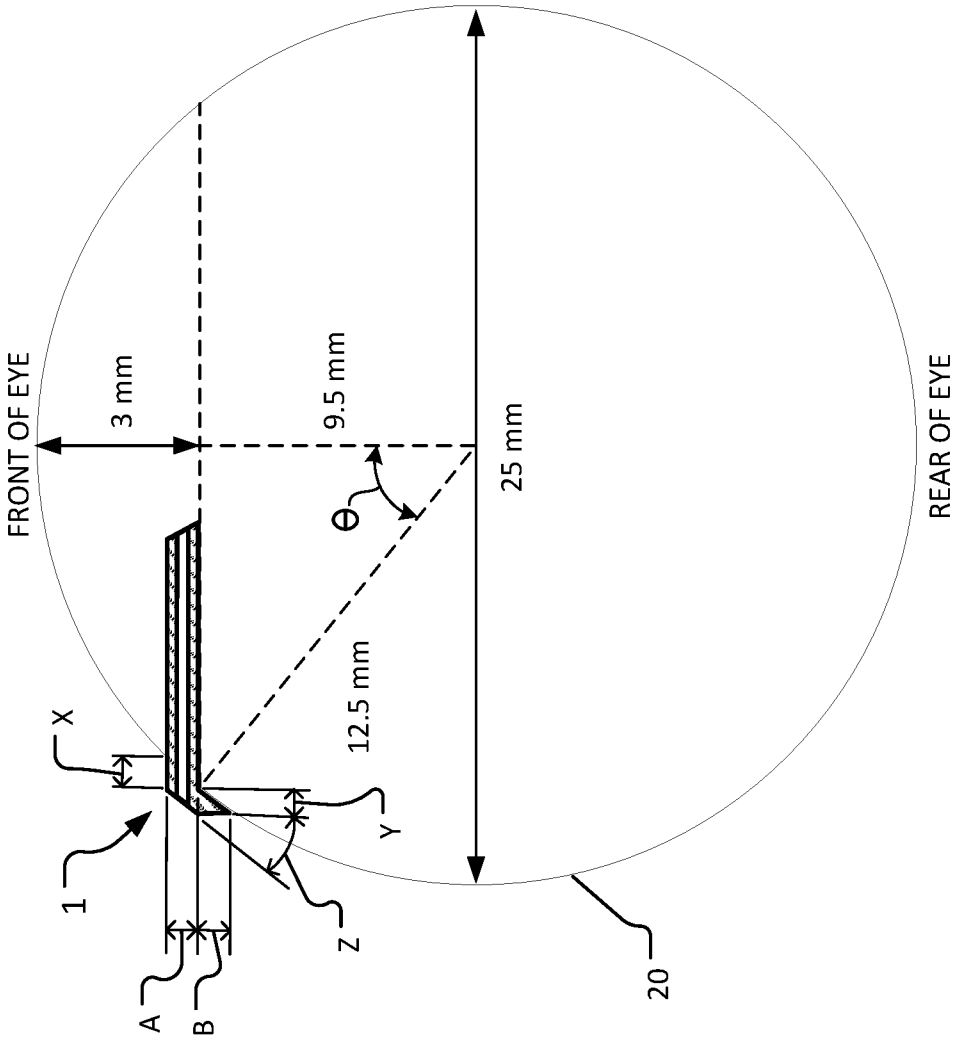


FIG. 4

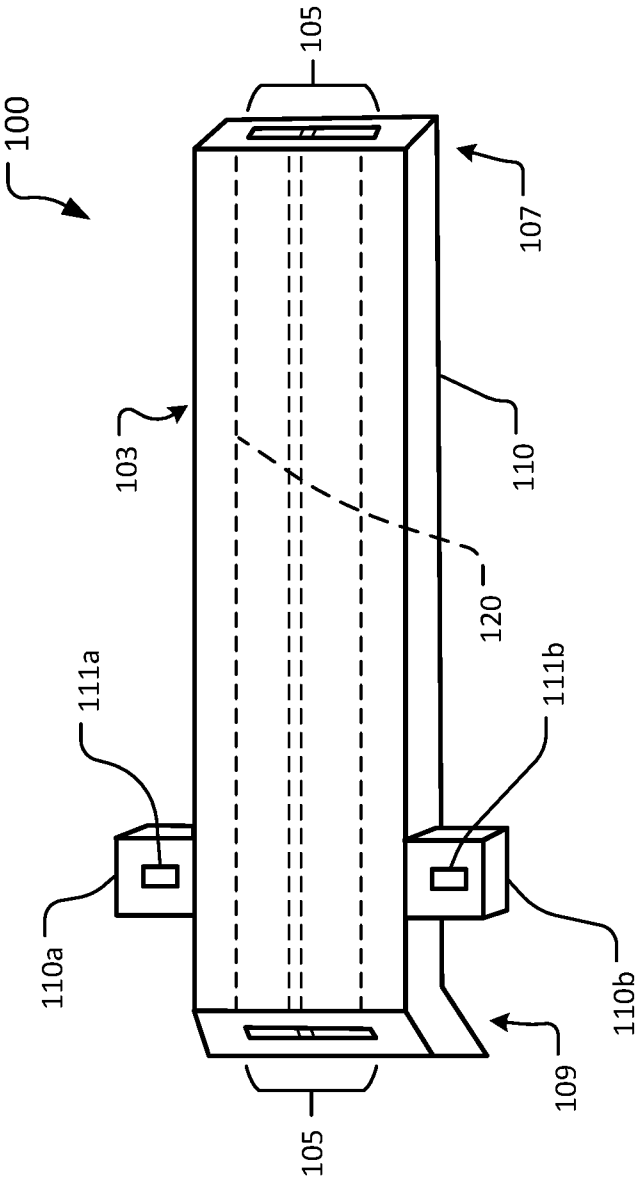


FIG. 5

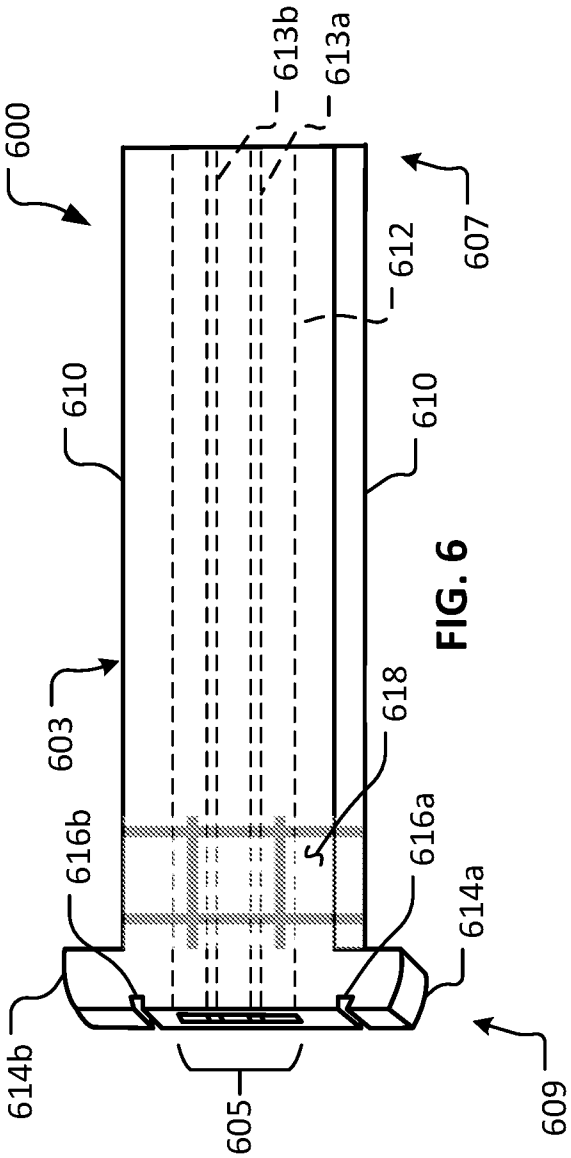

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FIG. 6

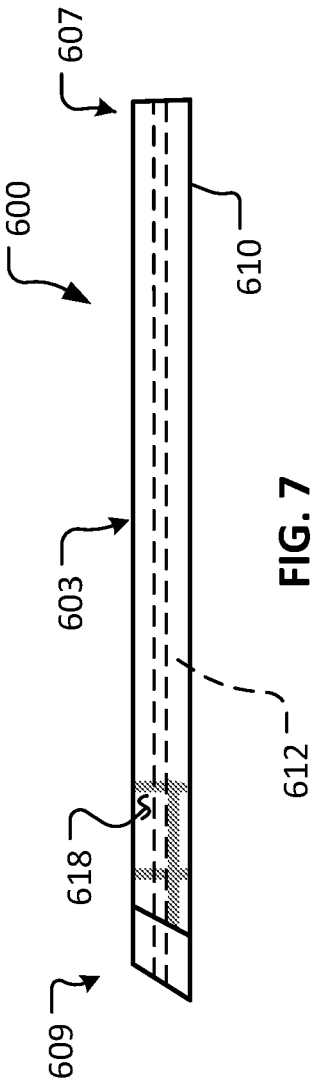

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FIG. 7

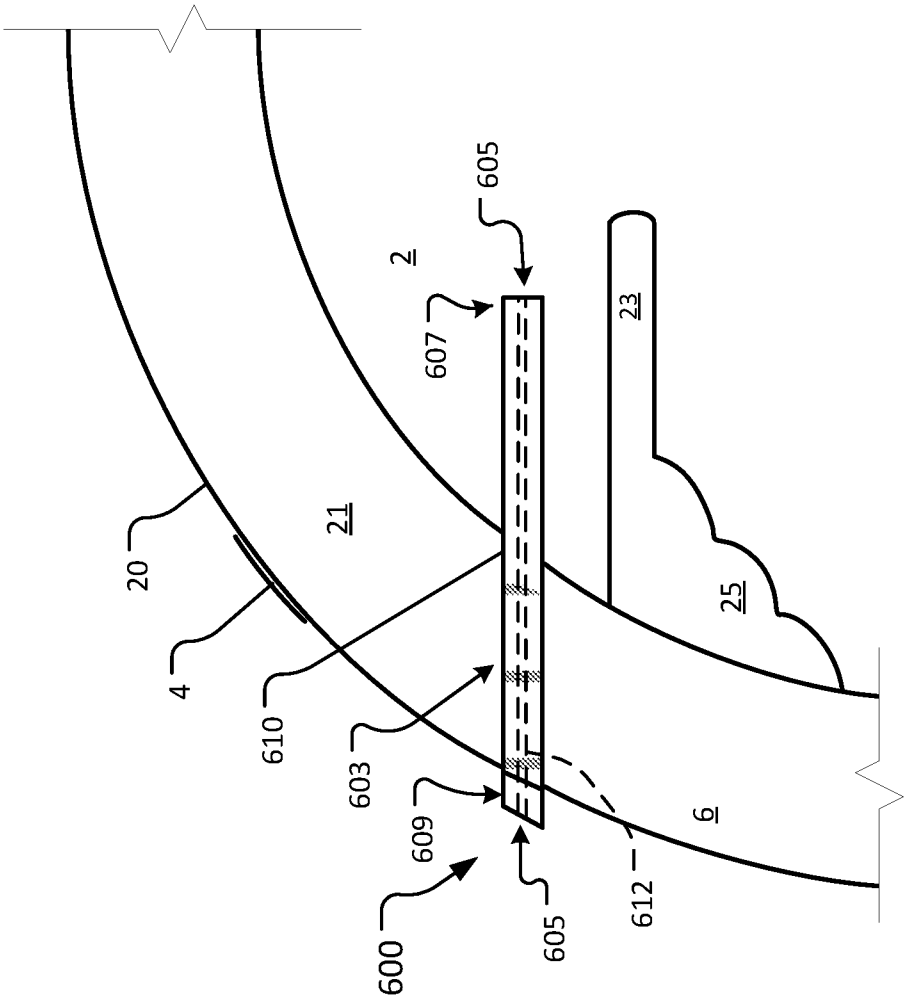


FIG. 8

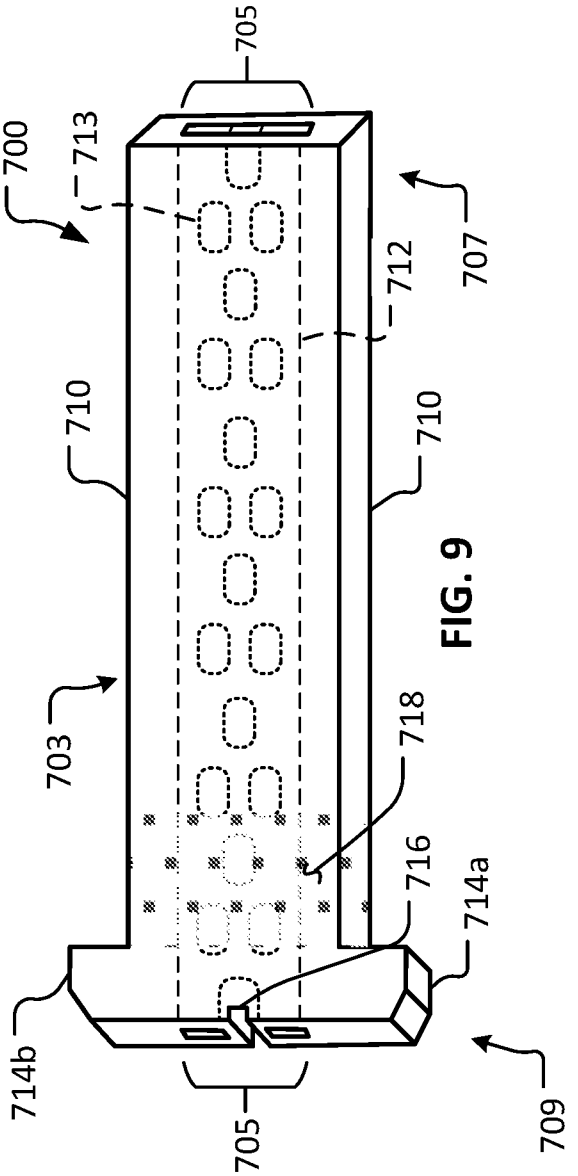

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FIG. 9

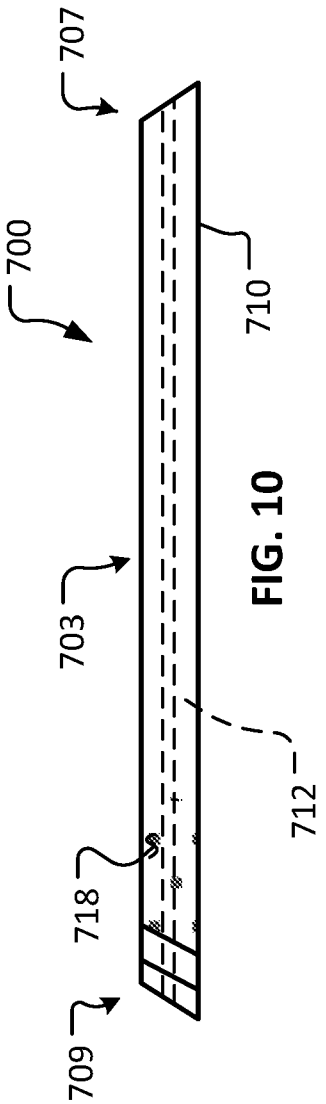

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FIG. 10

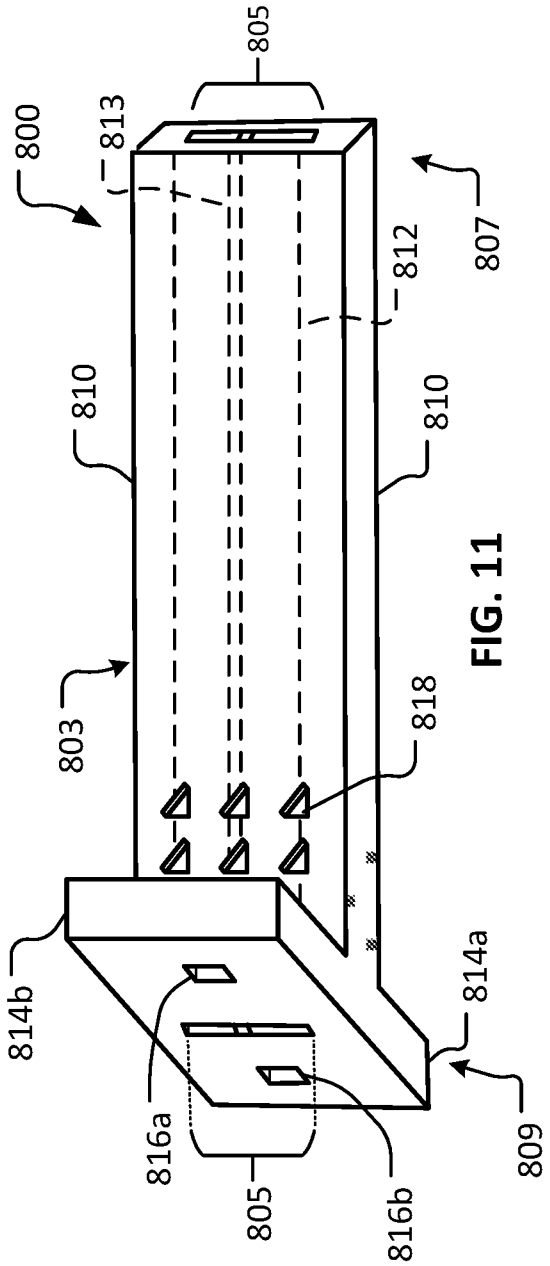

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FIG. 11

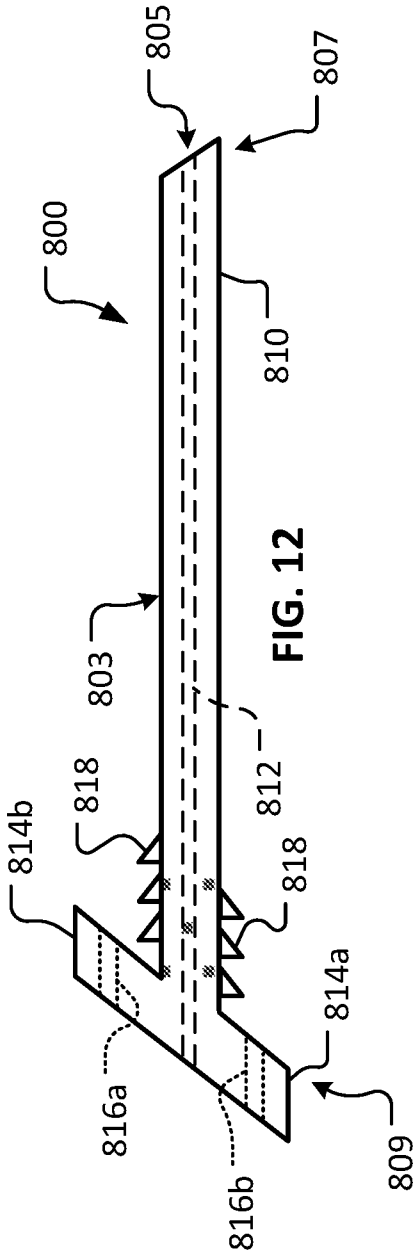

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FIG. 12

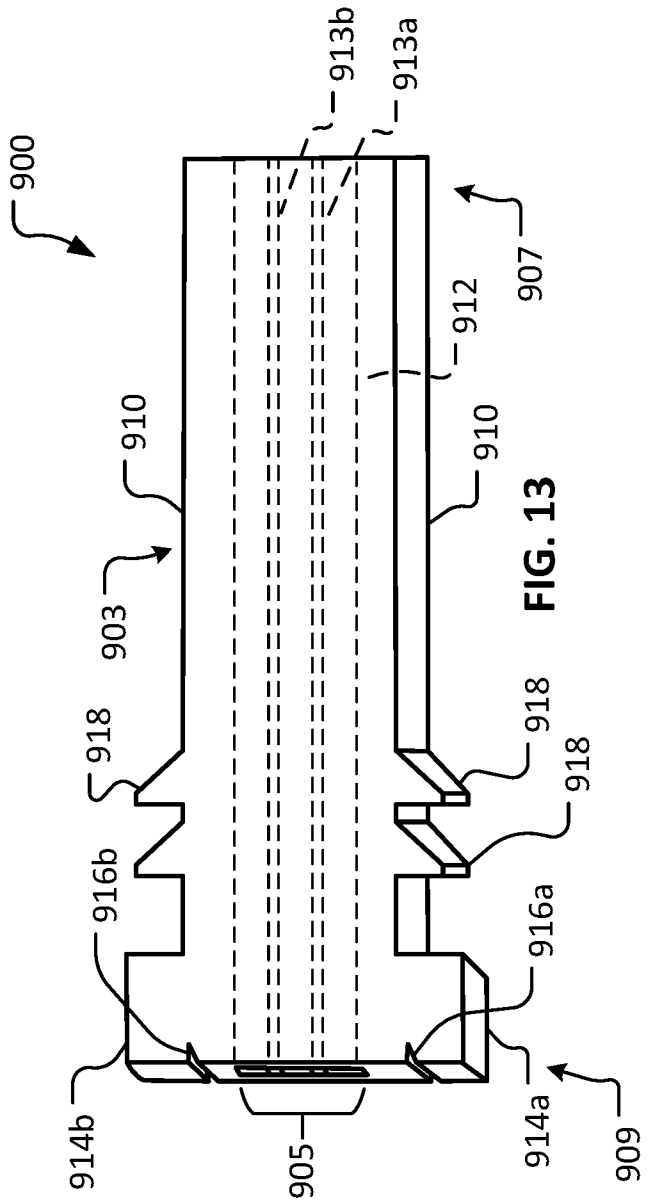

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FIG. 13

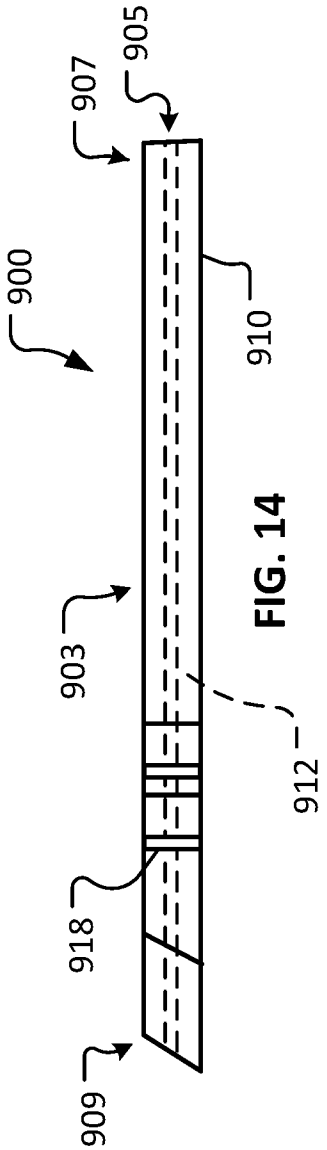

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FIG. 14

FIG. 15

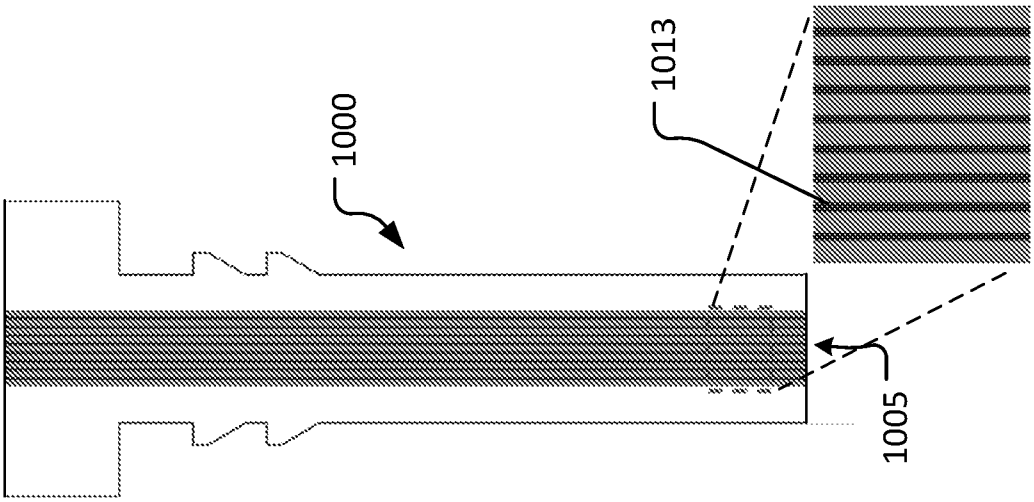


FIG. 16

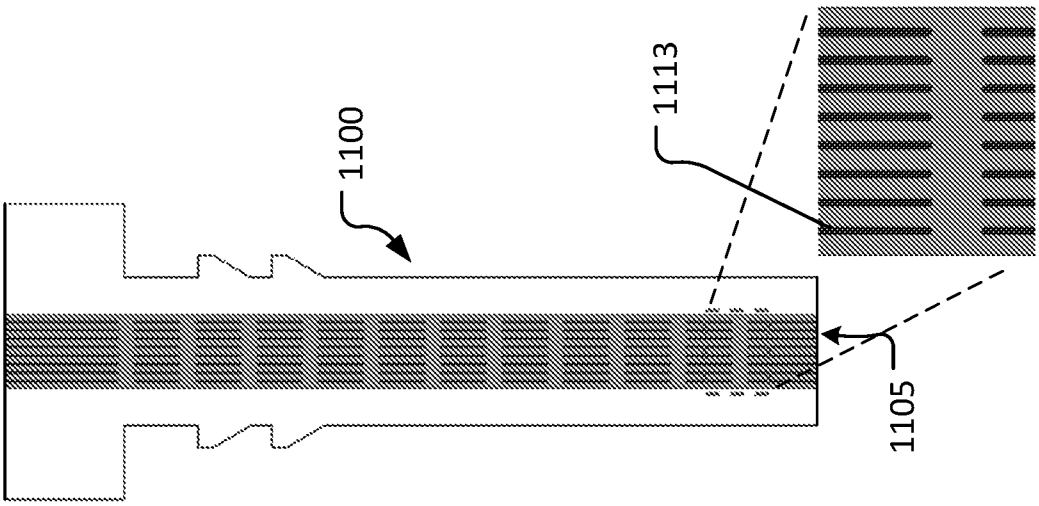
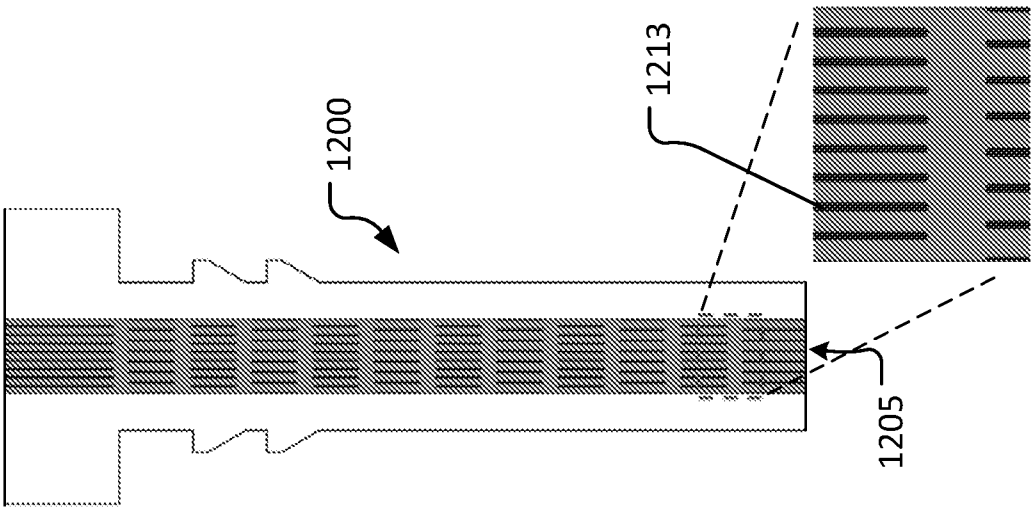
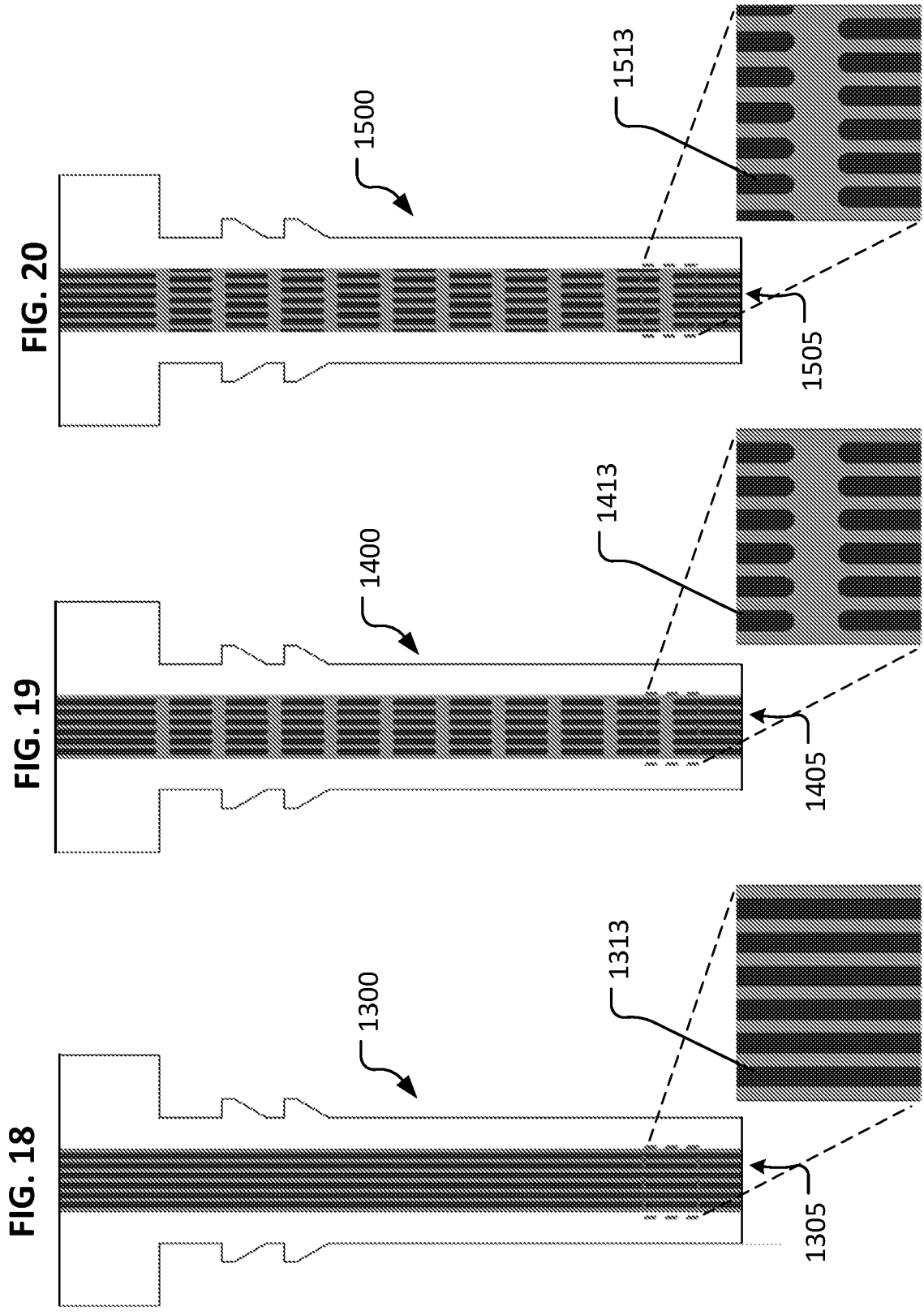
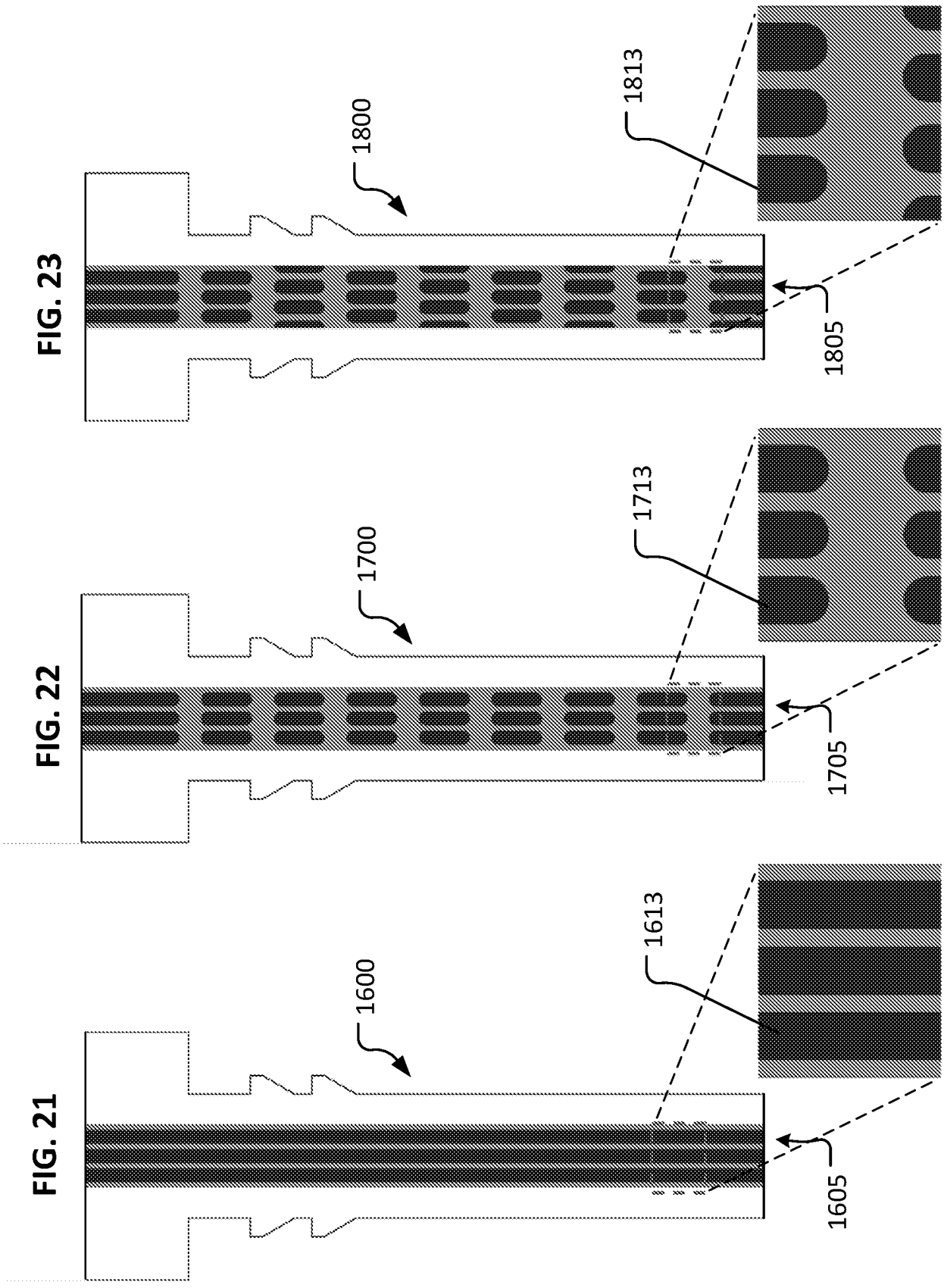
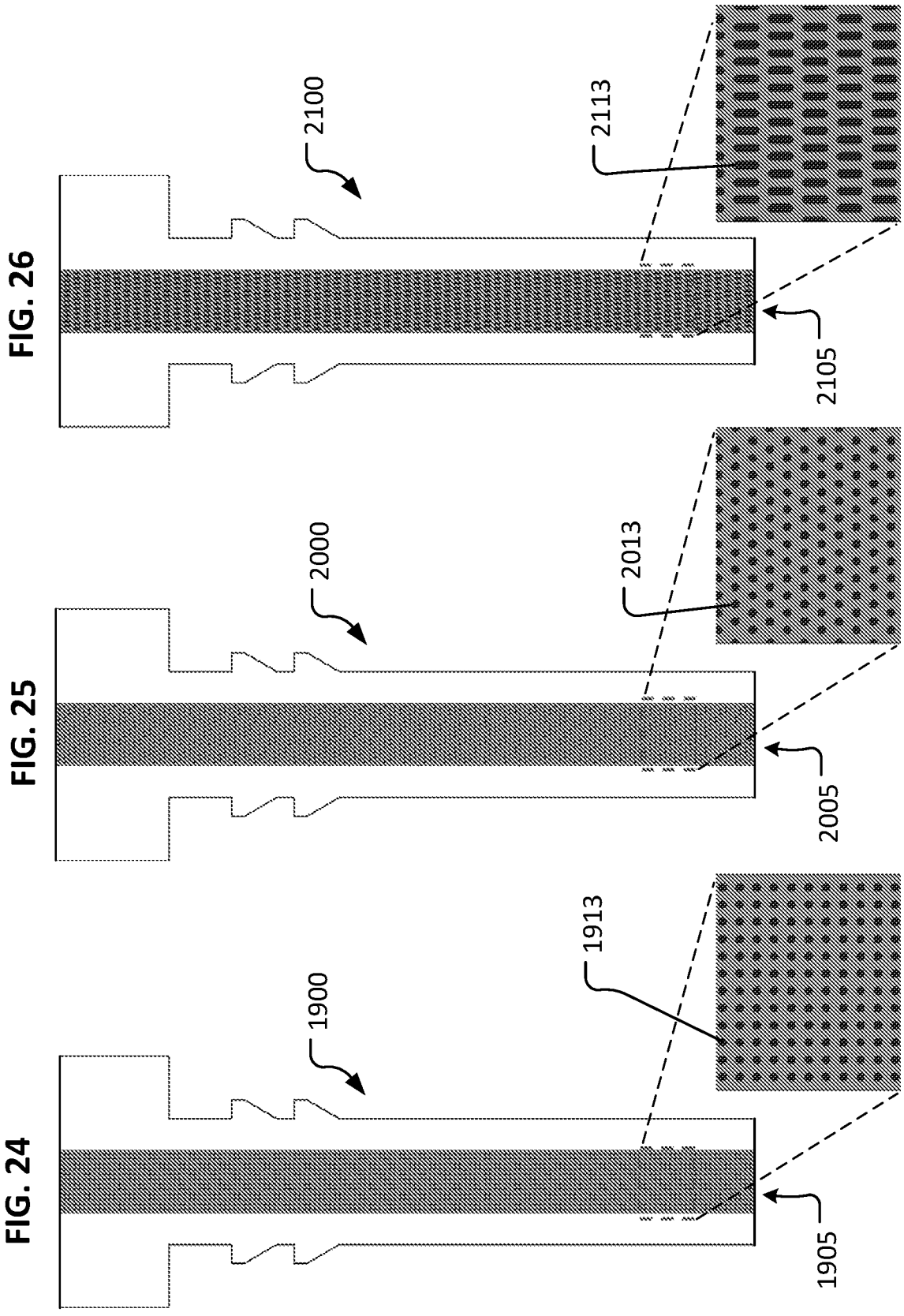


FIG. 17




FIG. 18
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FIG. 19
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FIG. 20
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FIG. 23
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FIG. 22
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FIG. 21
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FIG. 26
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FIG. 25
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FIG. 24
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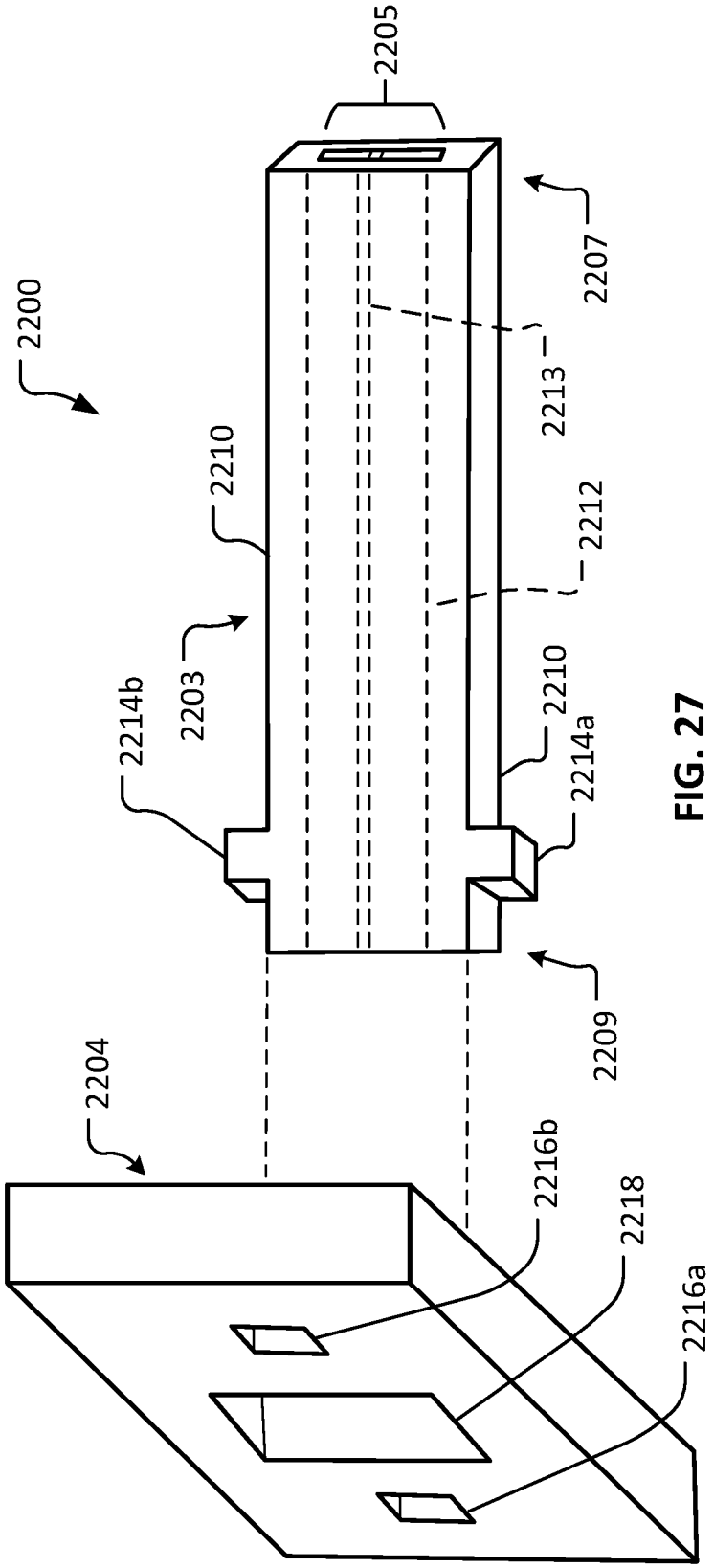

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FIG. 27

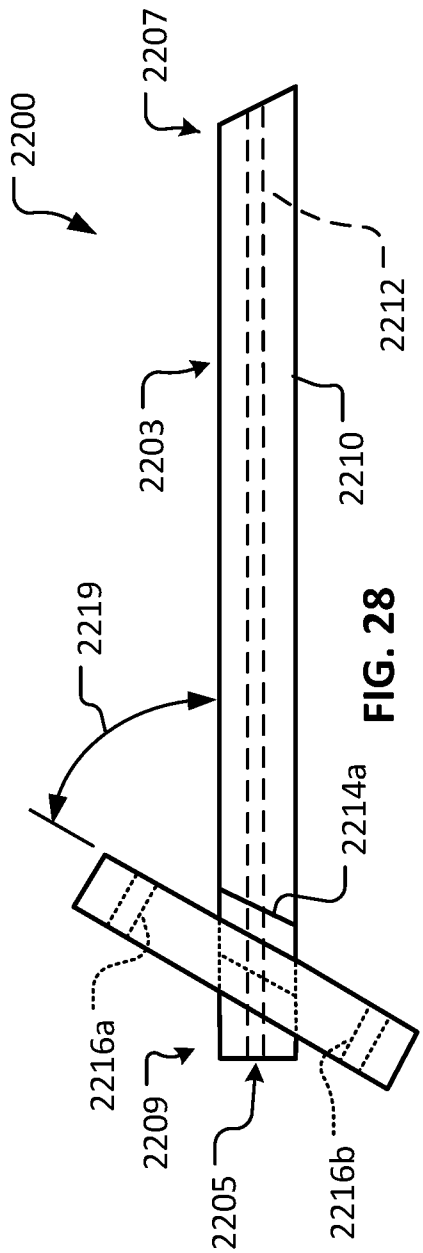

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FIG. 28

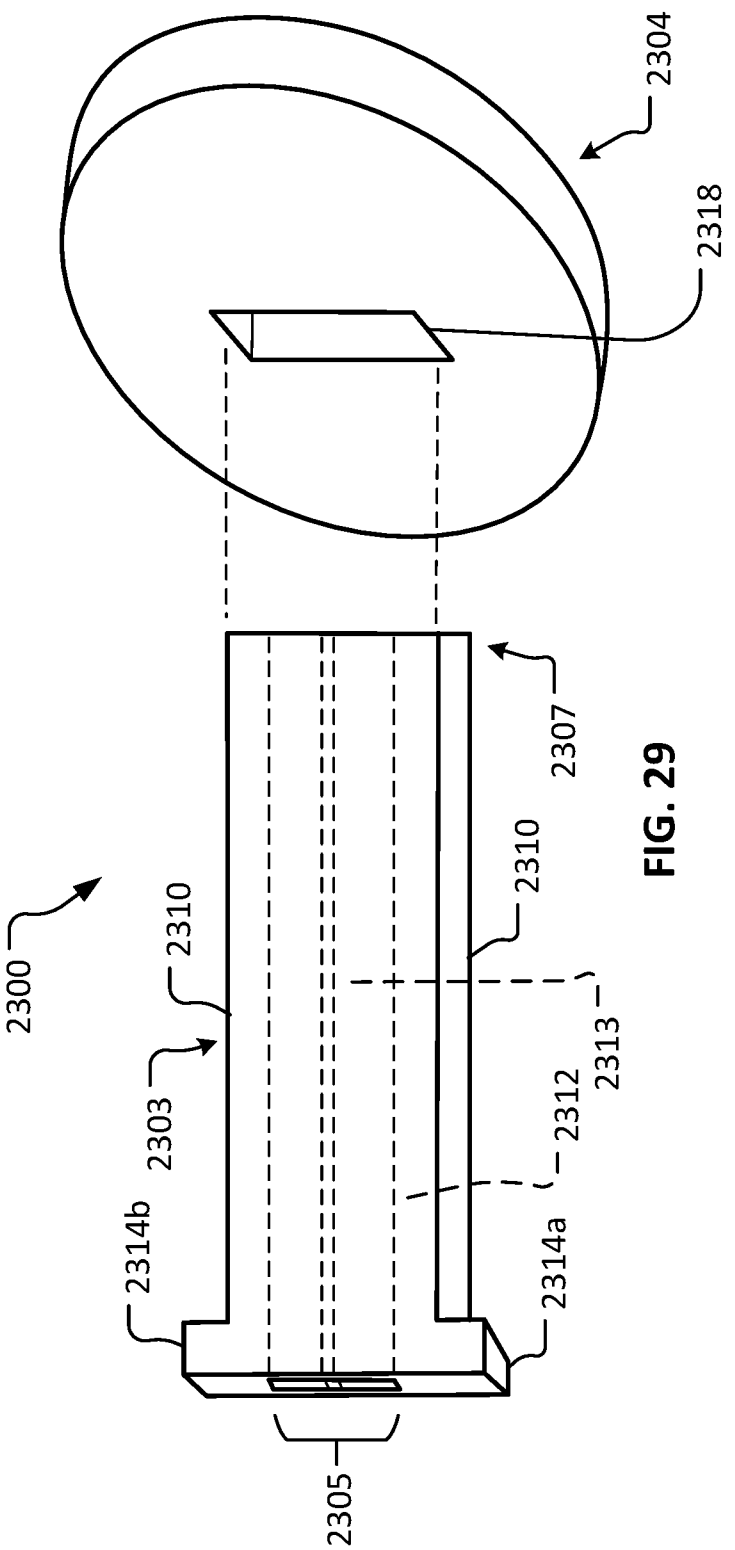

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FIG. 29

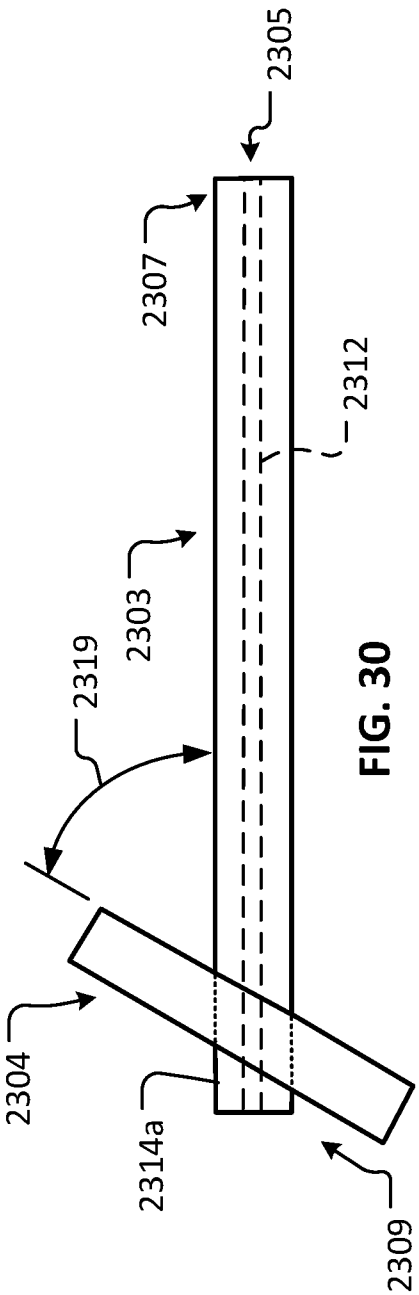

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FIG. 30

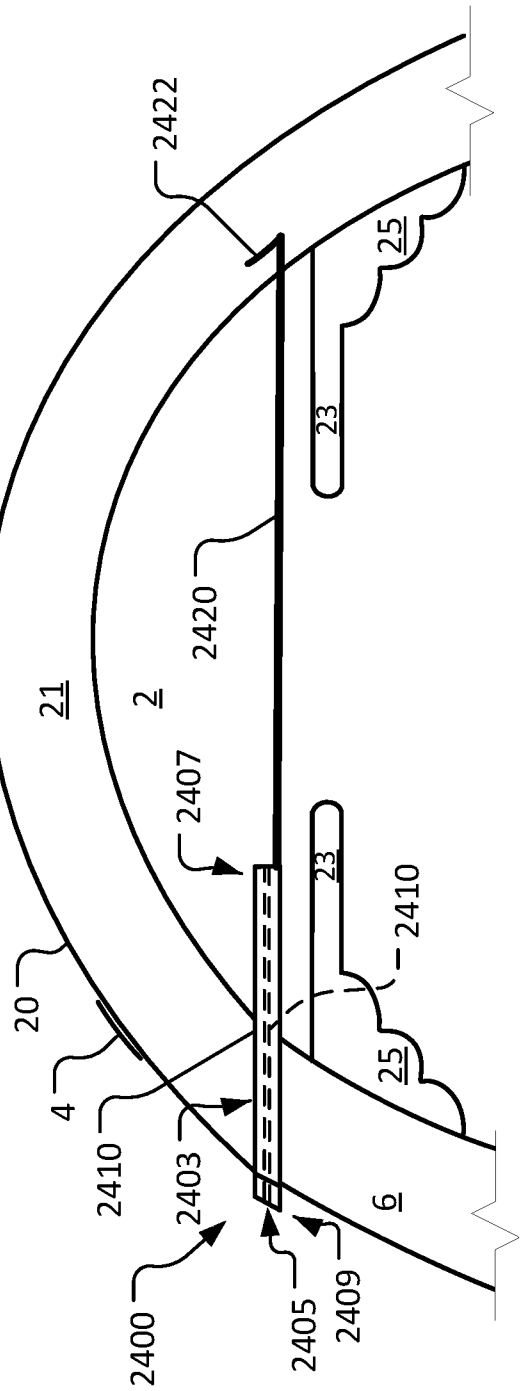

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FIG. 31

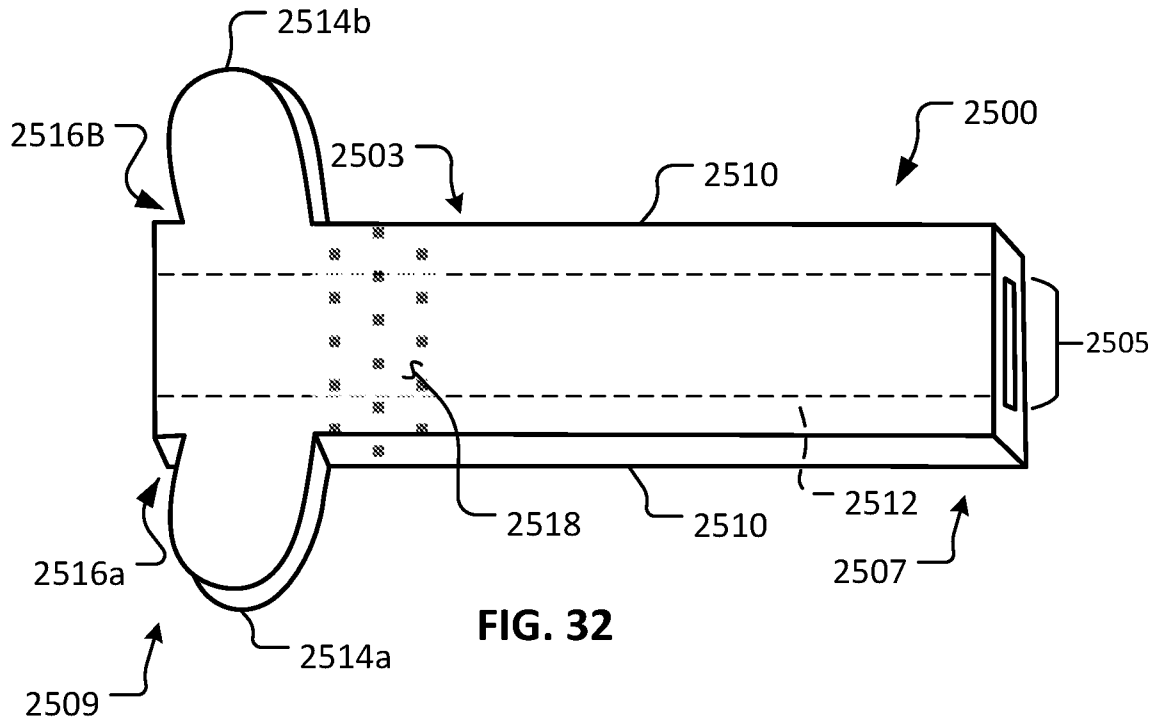

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FIG. 32

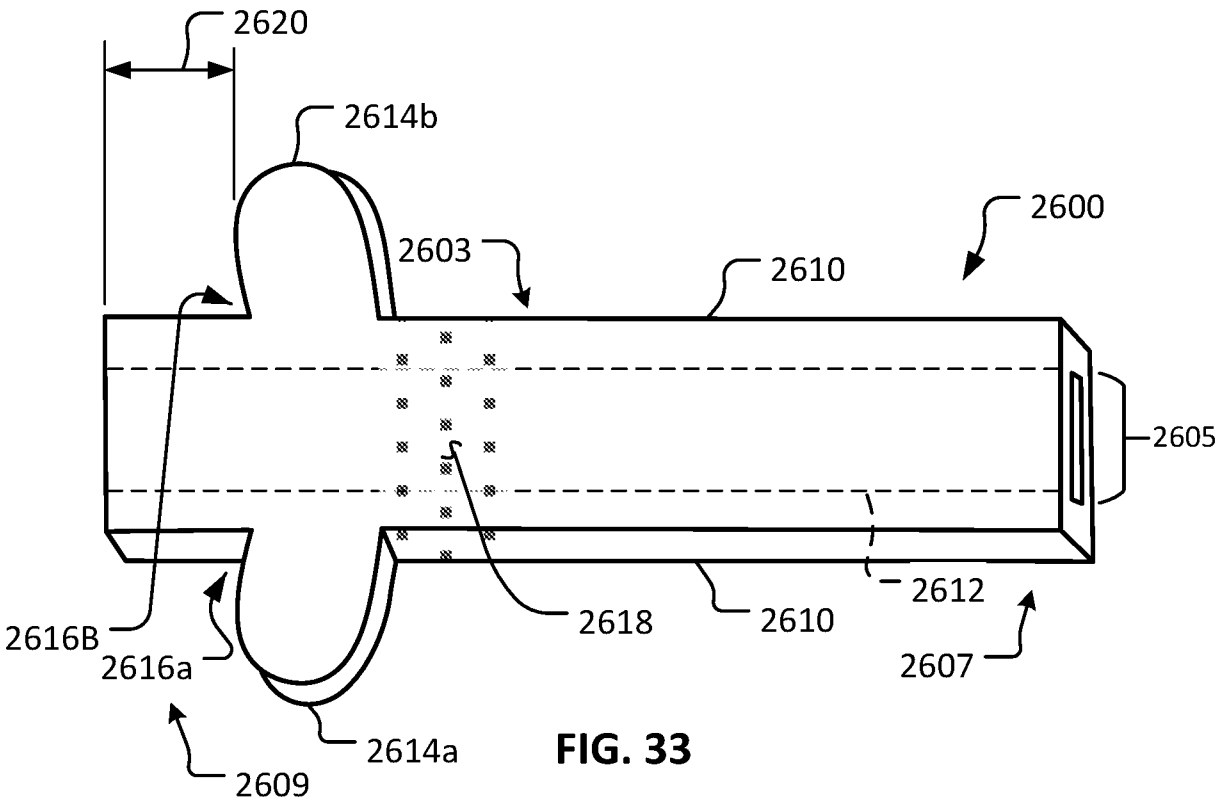

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FIG. 33

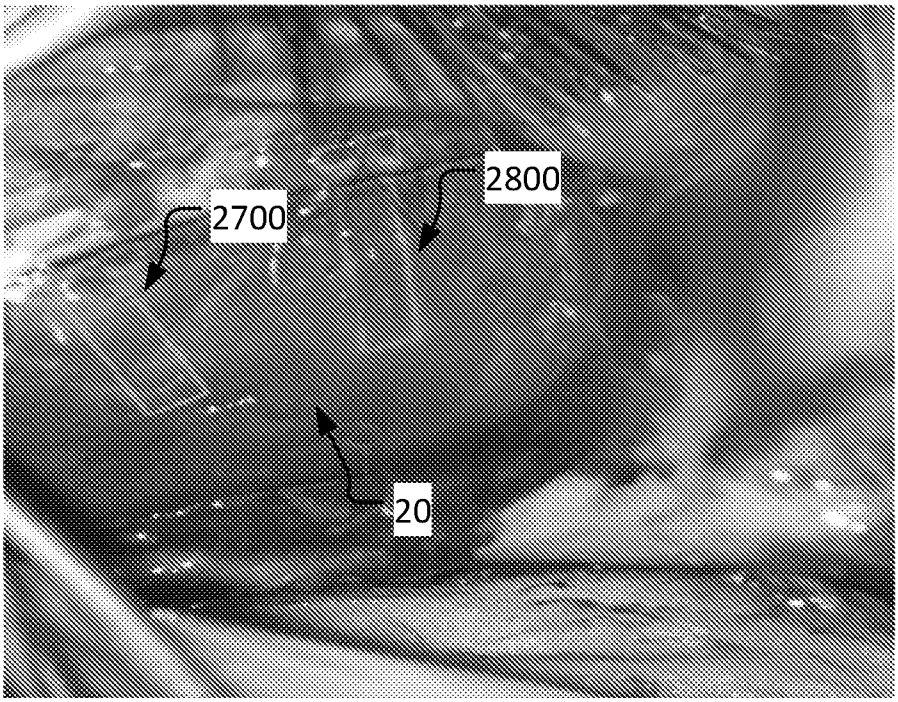


FIG. 34

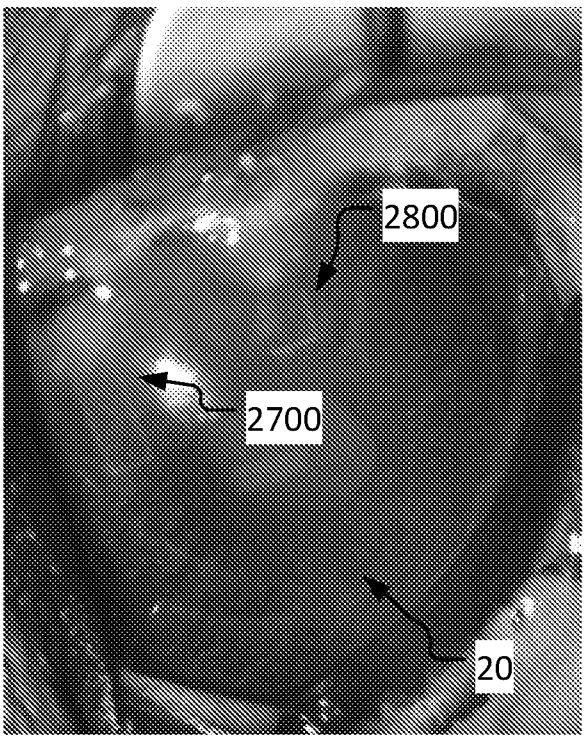


FIG. 35

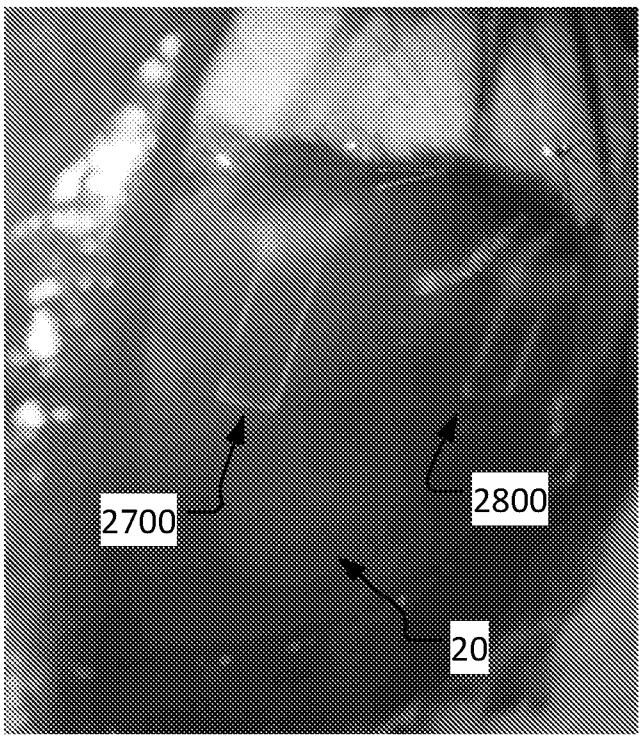


FIG. 36

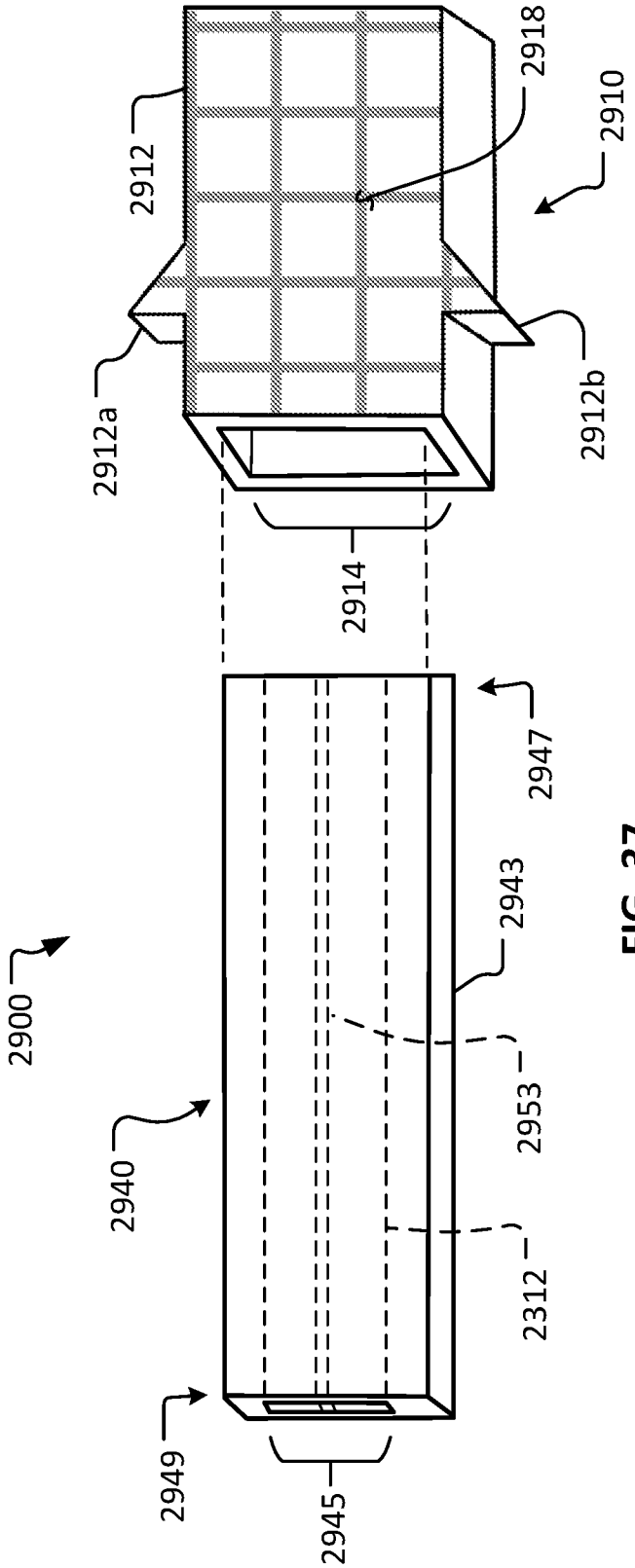

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FIG. 37

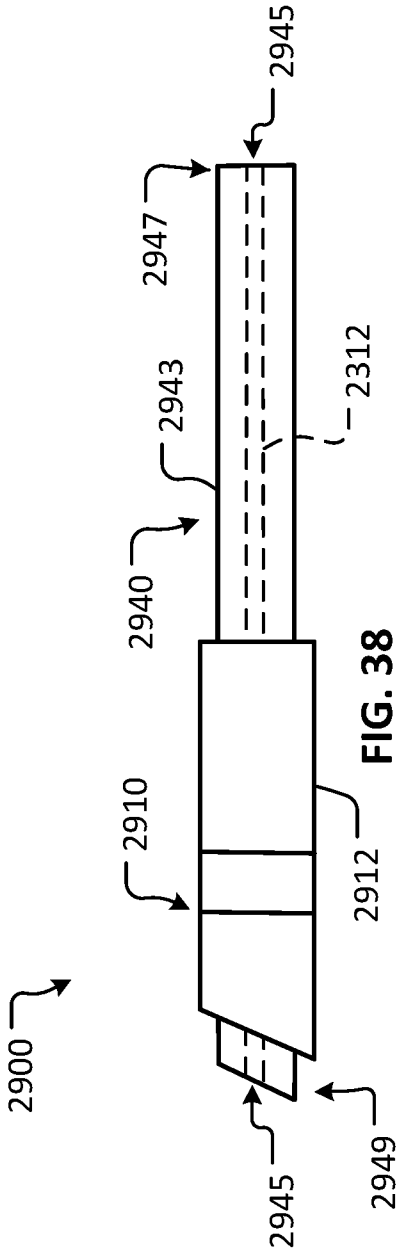

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FIG. 38

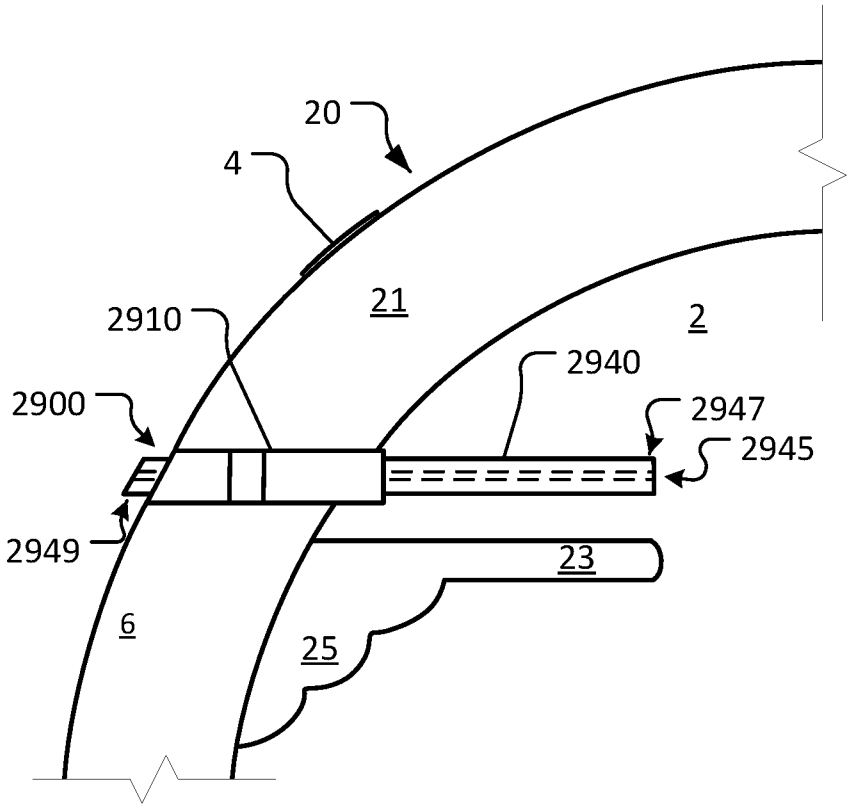


FIG. 39

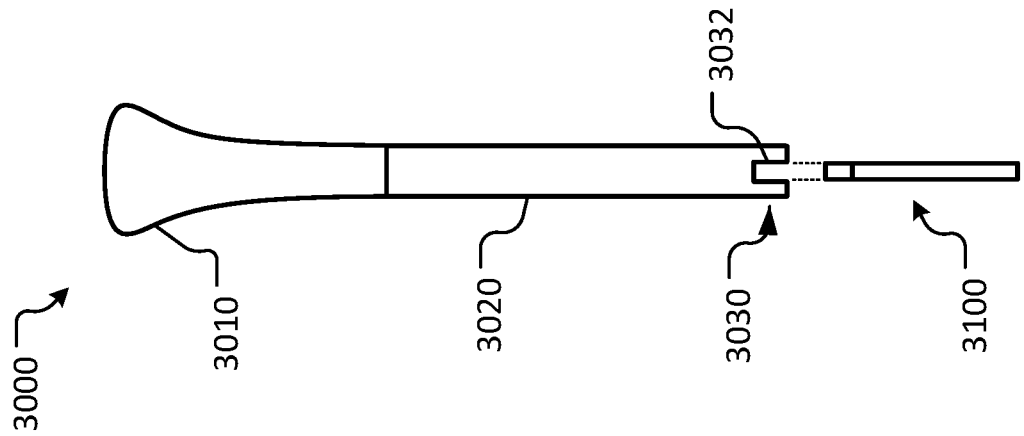


FIG. 41

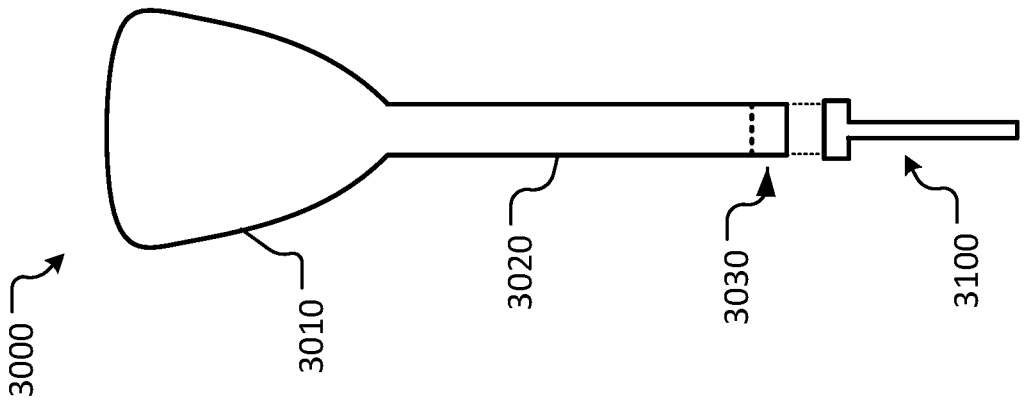


FIG. 40

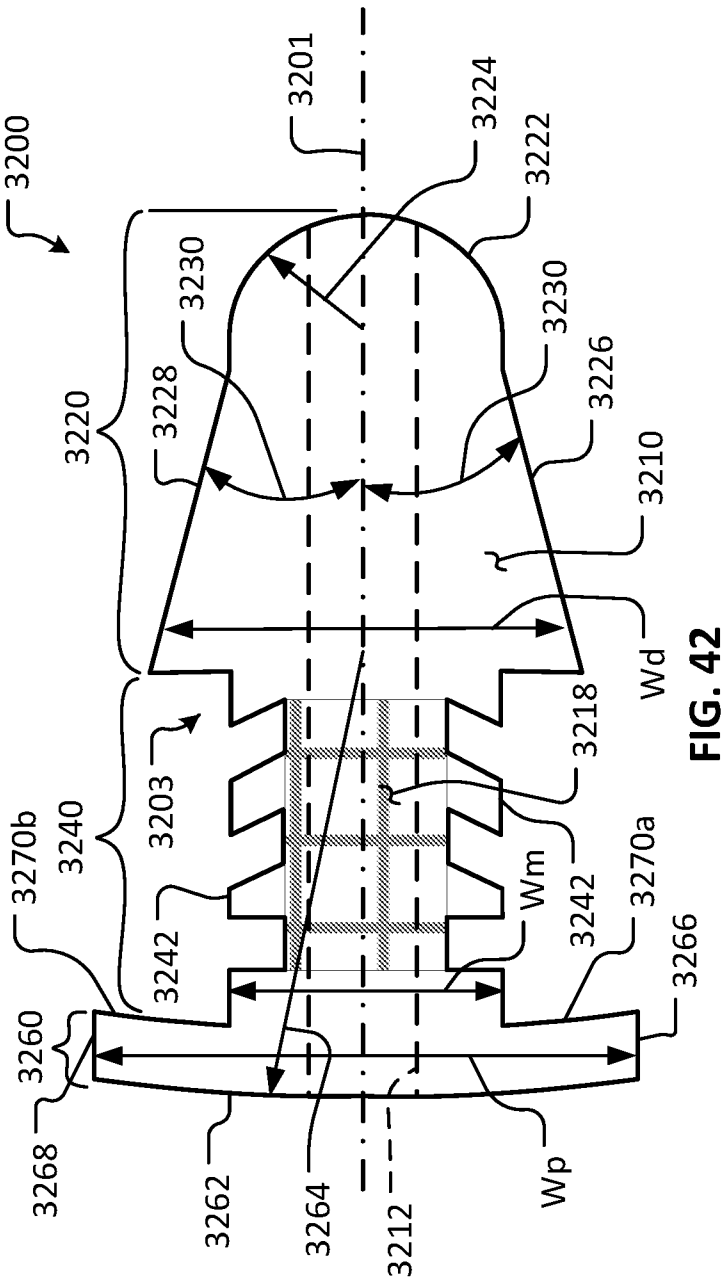

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3264
3212
Wp

FIG. 42

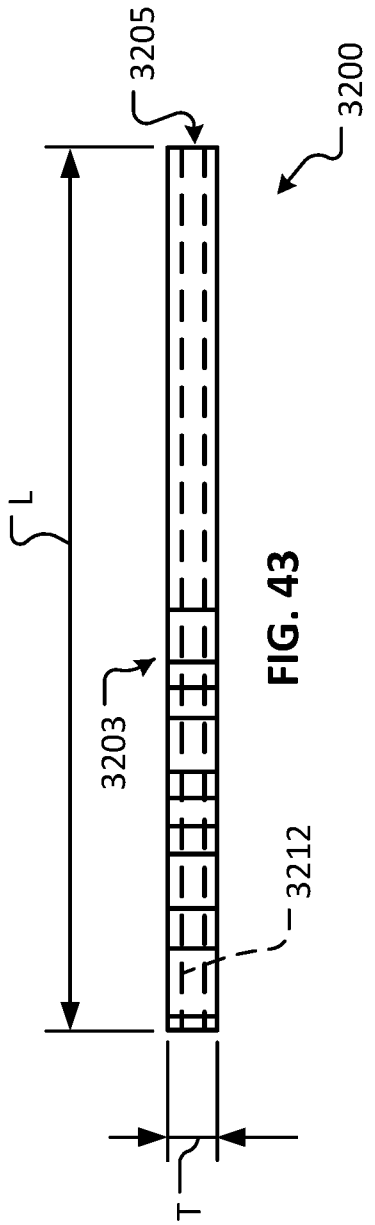

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FIG. 43

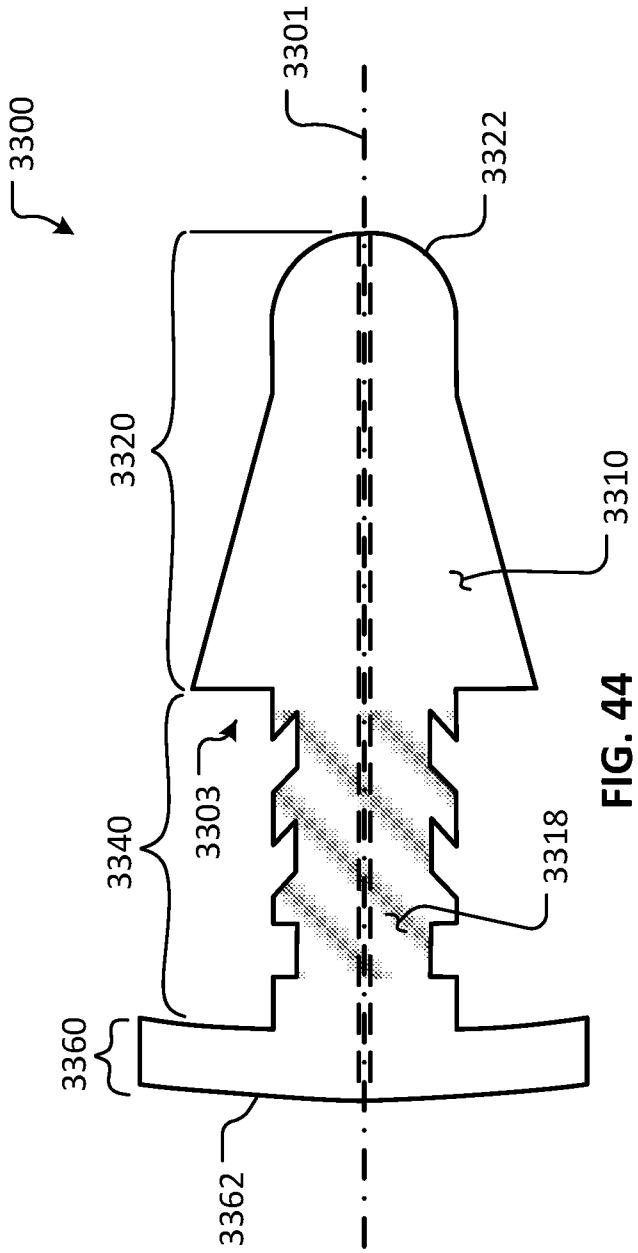

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FIG. 44

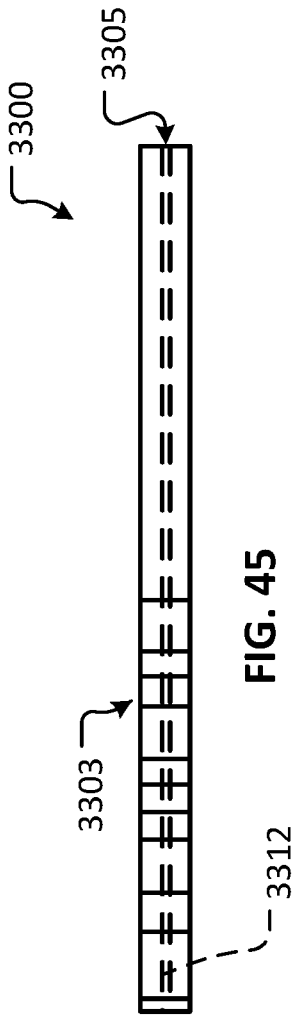

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FIG. 45

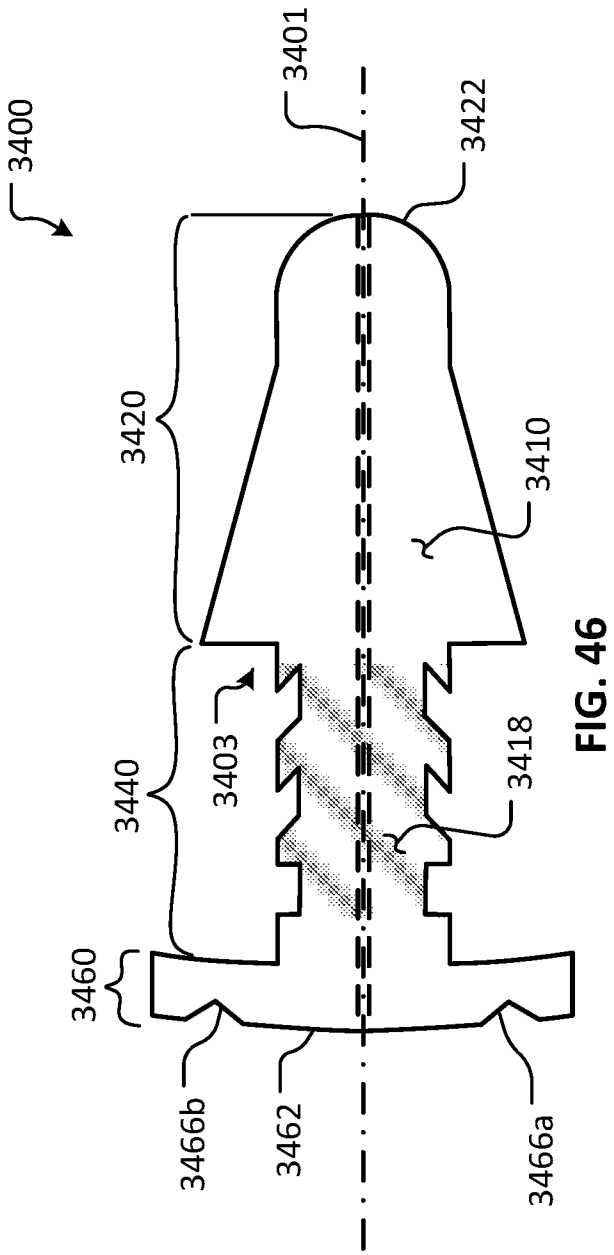

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FIG. 46

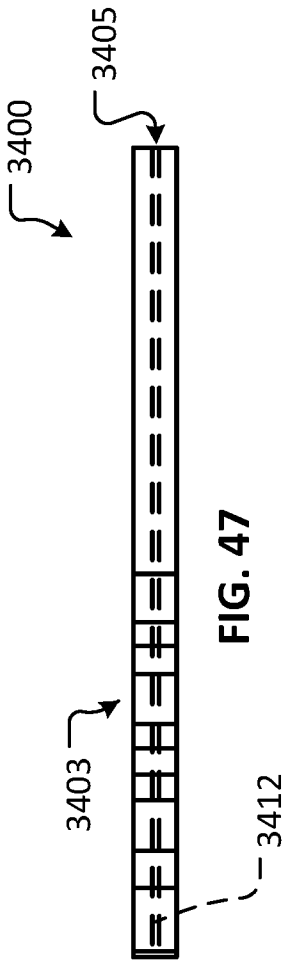

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FIG. 47

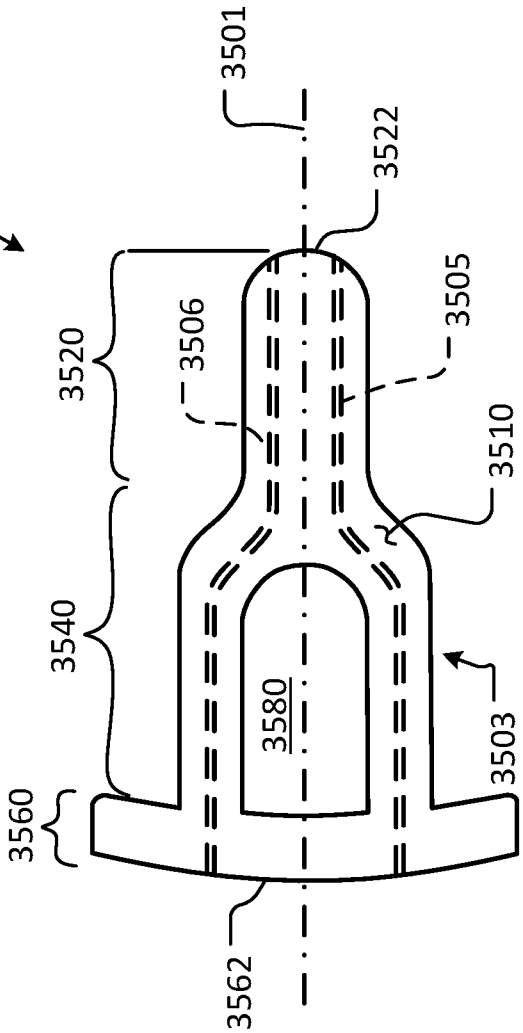

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3562

FIG. 48

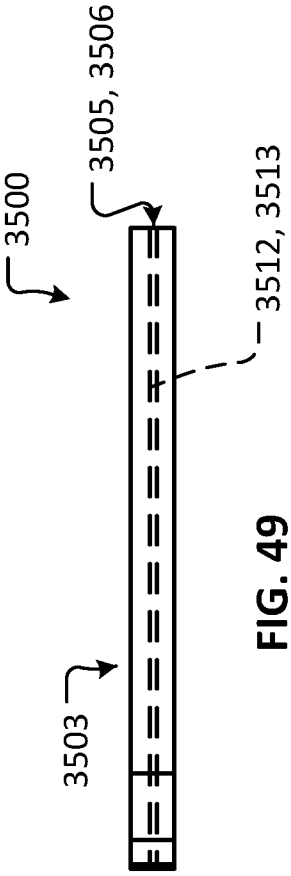

3500
3505, 3506
3512, 3513
3503

FIG. 49

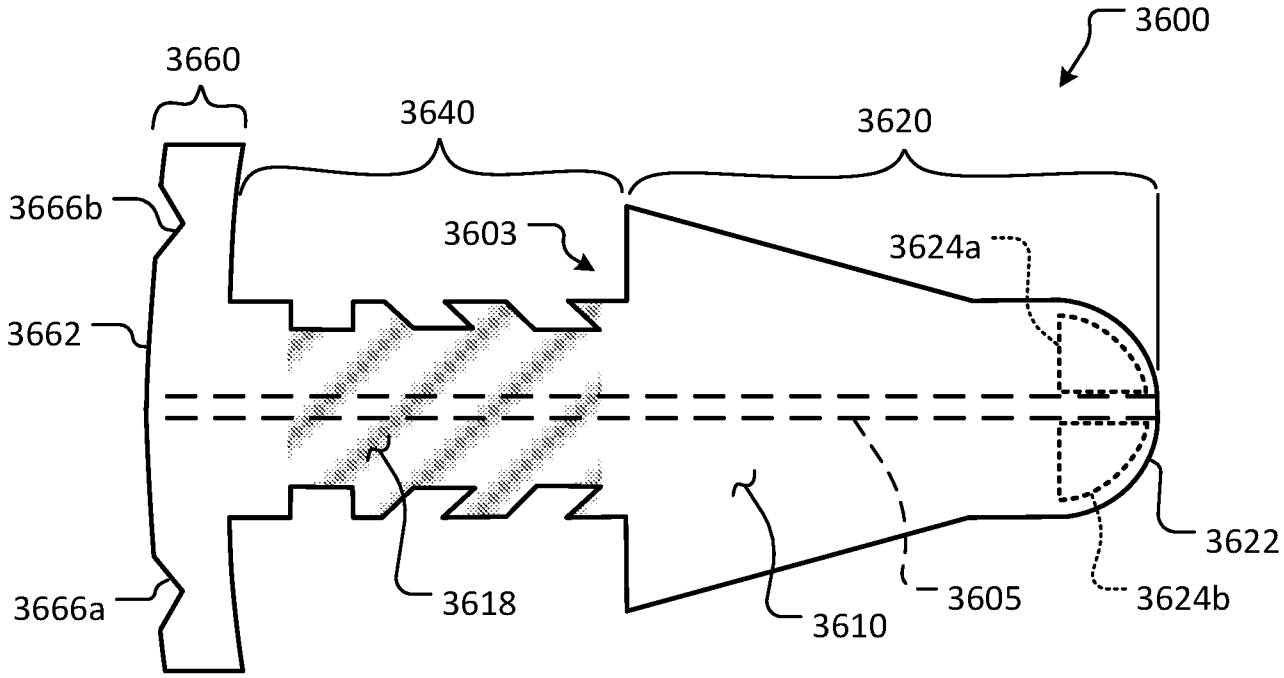

3600
3660
3640
3620
3666b
3603
3624a
3662
3622
3618
3605
3624b
3666a
3610

FIG. 50

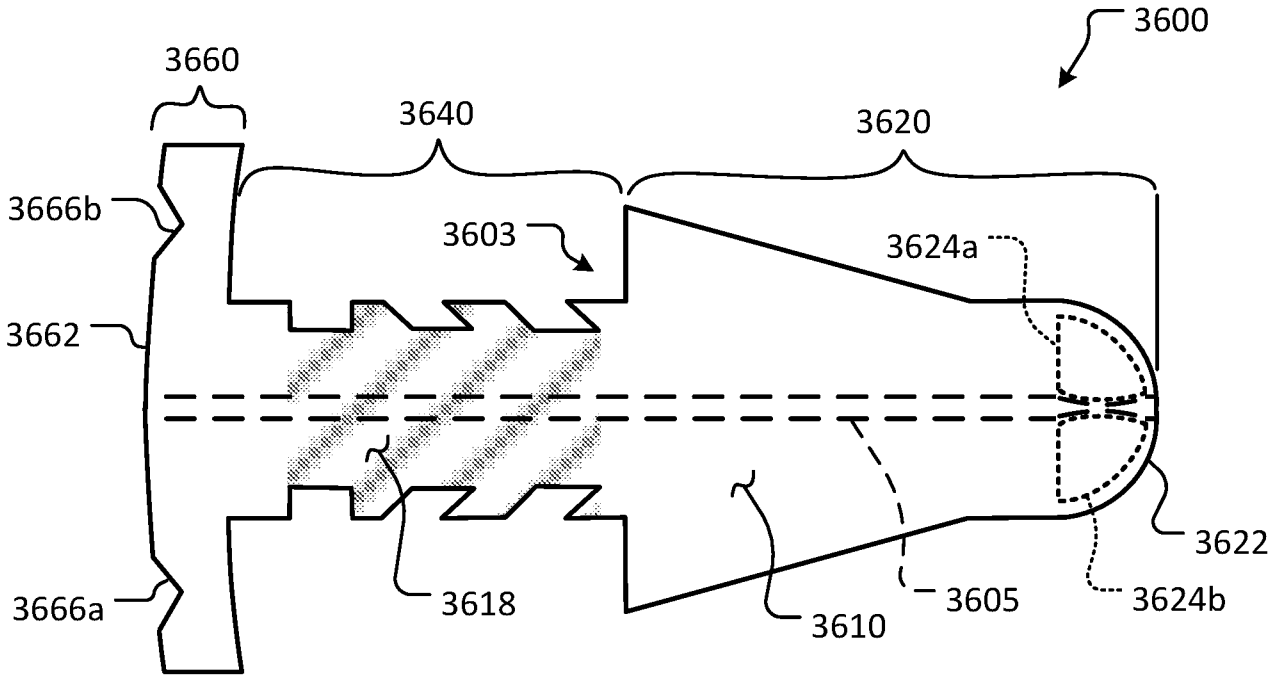

3600
3660
3640
3620
3666b
3603
3624a
3662
3622
3618
3605
3624b
3666a
3610

FIG. 51

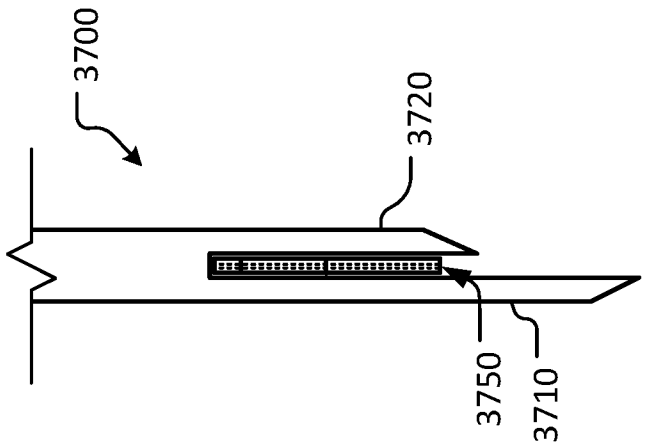


FIG. 53

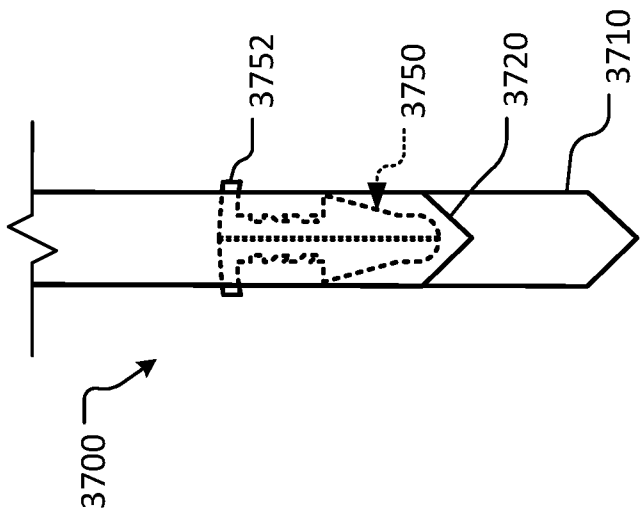


FIG. 52

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US17/40738

A. CLASSIFICATION OF SUBJECT MATTER
IPC - A61M 1/00, A61F 9/00 (2017.01)
CPC - A61M 1/00; A61F 9/00, 9/00781

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)
See Search History document

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

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X --- Y	US 2008/0161741 A1 (BENE, Eet al.) July 3, 2008, figures 15, 16; paragraphs [0030], [0033], [0049], [0057], [0060], [0061], [0064], [0072], [0083]	1,13, 37 3, 15-19
X	US 2010/0056977 A1 (WANDEL, T) March 4, 2010, figure 2a; paragraph [0017]	1-2, 13-14
Y	US 2004/0260227 A1 (LISK JR, J, et al.) December 23, 2004, figure 1; paragraph [0034]	15, 18-19
Y	US 2014/0350103 A1 (MATI THERAPEUTICS, INC) November 27, 2014, paragraph [0113]	3
Y	US 2015/0018746 A1 (GEUDER AG) January 15, 2015, figure 1; paragraphs [0021], [0029]	16-19
P,X	WO 2017/059272 A1 (MICROOPTX INC.) April 6, 2017, the entire document	1-3, 13-19, 37
A	US 5,127,901 A (ODRICH, R) July 7, 1992, the entire document	1-3, 13-19, 37
A	US 2006/0241749 A1 (TU, H et al.) October 26, 2006, the entire document	1-3, 13-19, 37
A	US 5,807,302 A (WANDEL, T) September 15, 1998, the entire document	1-3, 13-19, 37

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

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

Date of the actual completion of the international search	Date of mailing of the international search report
25 August 2017 (25.08.2017)	02 NOV 2017
Name and mailing address of the ISA/ Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-8300	Authorized officer Shane Thomas PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

Form PCT/ISA/210 (second sheet) (January 2015)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US17/40738

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☒ Claims Nos.: 31-36, 38, 45
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

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

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

-***-Continued Within the Next Supplemental Box-***-

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

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

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

4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:
1-3, 13-19, 37

Remark on Protest

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

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

☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT
Information on patent family members

International application No.
PCT/US17/40738

-***-Continued from Box No. III Observations where unity of invention is lacking-***-

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In order for all inventions to be examined, the appropriate additional examination fees must be paid.

Group I: Claims 1-3, 13-19, 37 are directed toward a device for treating an eye, the device comprising: a distal or proximal edge of the distal or proximal end portion having a radius

Group II: Claims 4-8 are directed toward a device for treating an eye, the device comprising: the distal end portion being laterally flared

Group III: Claims 9-13, 42-43 are directed toward a device for treating an eye, the device comprising: the mid-body portion being laterally narrower than some portions of each the distal end portion and the proximal end portion

Group IV: Claims 20-30 are directed toward a device for treating an eye, the device comprising: wherein a maximum longitudinal length of the body in comparison to a maximum lateral width of the body is a ratio between 1: 1 to 3: 1.

Group V: Claim 39 is directed toward a method for treating an eye of a patient, the method comprising: creating a bleb in a subconjunctiva of the eye; and implanting a device in the eye, wherein the device comprises: a body having a distal end portion and a proximal end portion, the body defining a lumen extending between the distal end portion and the proximal end portion, wherein at least a portion of the proximal end portion is positioned within the bleb such that the lumen extends between an anterior chamber of the eye and the bleb.

Group VI: Claim 40 is directed toward a device for treating an eye, the device comprising: the mid-body portion comprising two branch portions, a first branch portion, a second lumen, a second branch portion

Group VII: Claim 41 is directed toward a body having a distal end portion, a proximal end portion, and a mid-body portion, the body defining a lumen, the distal end portion defining two gas-filled chambers individually positioned on respective opposite sides of the lumen of the body of the device.

Group VIII: Claim 44 is directed toward a body having a distal end portion, a proximal end portion, and a mid-body portion, the body defining a lumen, wherein the luminal surfaces of the lumen comprise a hydrophilic or anti-biofouling material.

The inventions listed as Groups I-VIII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons.

The special technical features of Group I include a distal or proximal edge of the distal or proximal end portion having a radius (which is not present in Groups II-VIII)

The special technical features of Group II include the distal end portion being laterally flared (which is not present in Groups I, III-VIII)

The special technical features of Group III include the mid-body portion being laterally narrower than some portions of each the distal end portion and the proximal end portion (which is not present in Groups I-II, IV-VIII)

The special technical features of Group IV include wherein a maximum longitudinal length of the body in comparison to a maximum lateral width of the body is a ratio between 1: 1 to 3: 1 (which is not present in Groups I - III, V-VIII)

The special technical features of Group V include a method for treating an eye of a patient, the method comprising: creating a bleb in a subconjunctiva of the eye; and implanting a device in the eye, wherein at least a portion of the proximal end portion is positioned within the bleb such that the lumen extends between an anterior chamber of the eye and the bleb (which is not present in Groups I - IV, VI-VIII)

The special technical features of Group VI include the mid-body portion comprising two branch portions, a first branch portion, a second lumen, a second branch portion (which is not present in Groups I - V, VII-VIII)

The special technical features of Group VII include the distal end portion defining two gas-filled chambers individually positioned on respective opposite sides of the lumen of the body of the device (which is not present in Groups I - VI, VIII)

The special technical features of Group VIII include wherein the luminal surfaces of the lumen comprise a hydrophilic or anti-biofouling material. (which is not present in Groups I - VII)

The common technical features of Groups I – VIII include a body having a distal end portion, a proximal end portion, and a mid-body portion extending between the distal end portion and the proximal end portion, the body defining a lumen extending along a longitudinal axis of the body between the distal end portion and the proximal end portion, the body having external and luminal surfaces, the body having a longitudinal length sufficient to provide fluid communication between an anterior chamber and a tear film of the eye through the lumen when the device is implanted in a sclera of the eye.

-***-Continued Within the Next Supplemental Box-***-

-***-Continued from Previous Supplemental Box -***-

These common technical features are disclosed by 2008/0161741 A1 to Eric A. Bene et al. (hereinafter "BENE"): a body having a distal end portion, a proximal end portion (shunt 210 (body) has two ends; figure 15; paragraph [0049]), and a mid-body portion extending between the distal end portion and the proximal end portion (as shown in figure 15), the body defining a lumen extending along a longitudinal axis of the body between the distal end portion and the proximal end portion (a shunt body comprising a channel (lumen) between the distal and proximal ends; figure 15; paragraphs [0033], [0049], [0072]), the body having external and luminal surfaces (a shunt body comprising an outer (external) surface and inner surface 212 (luminal); paragraph [0061]), the body having a longitudinal length sufficient to provide fluid communication between an anterior chamber and a tear film of the eye through the lumen when the device is implanted in a sclera of the eye (the device shunts aqueous humor (provide fluid communication) from the anterior chamber to the tear film through the opening of capillary members having an expanded portion along a longitudinal axis (sufficient length) when implanted through the sclera; paragraphs [0060], [0064], [0083]).

Because the common technical features are disclosed by BENE, the inventions are not so linked as to form a single general inventive concept. Therefore, Groups I-VIII lack unity.