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(54) **ADJUSTABLE FLOW GLAUCOMA SHUNTS  
AND METHODS FOR MAKING AND USING  
SAME**

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(57) **ABSTRACT**

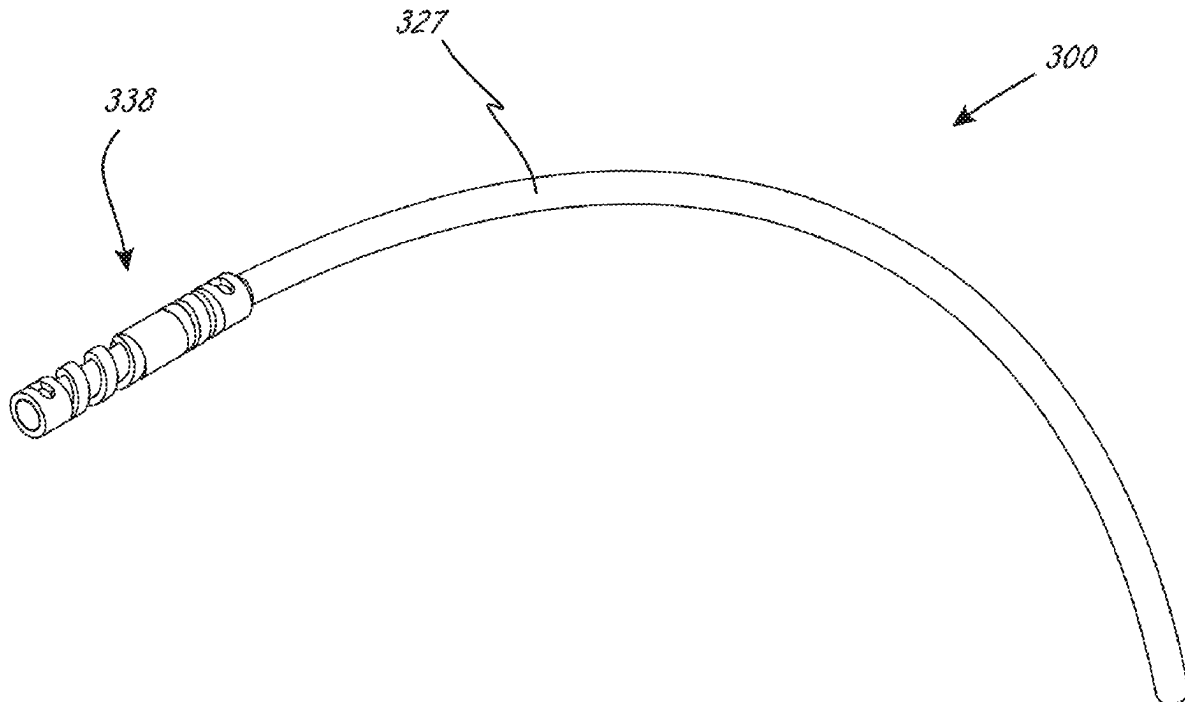
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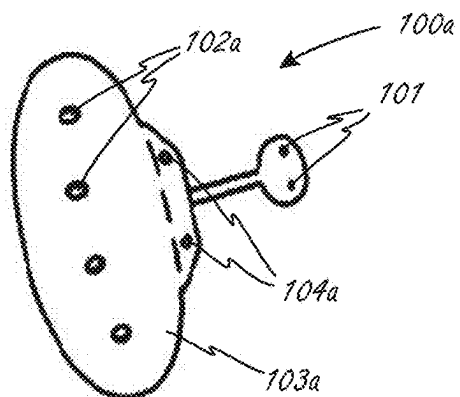
(63) Continuation of application No. 17/500,224, filed on  
Oct. 13, 2021, now Pat. No. 12,226,343, which is a  
continuation of application No. 16/840,137, filed on  
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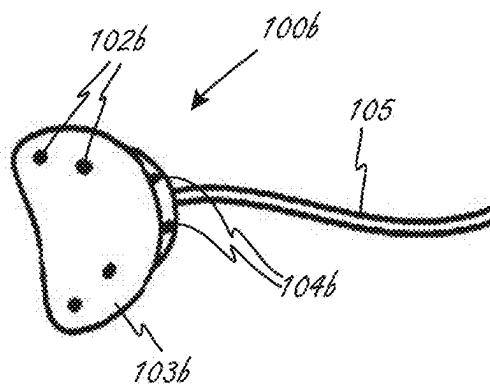
Systems and devices for facilitating the flow of fluid  
between a first body region and a second body region are  
disclosed herein. The devices generally include a drainage  
and/or shunting element having a lumen extending there-  
through for draining or otherwise shunting fluid between the  
first and second body regions. Further, devices configured in  
accordance with the present technology may be selectively  
adjustable to control the amount of fluid flowing between the  
first and second body regions. In some embodiments, for  
example, the devices comprise an actuation assembly that  
drives movement of a flow control element to modulate flow  
resistance through the lumen, thereby increasing or decreas-  
ing the relative drainage rate of fluid between the first body  
region and the second body region.



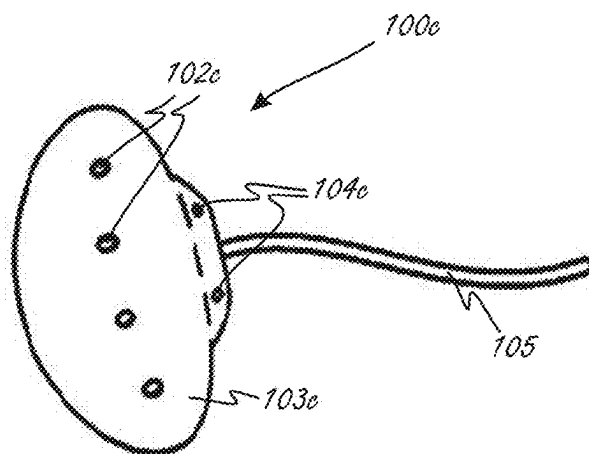
*Fig 1A*  
(PRIOR ART)



*Fig 1B*  
(PRIOR ART)



*Fig 1C*  
(PRIOR ART)



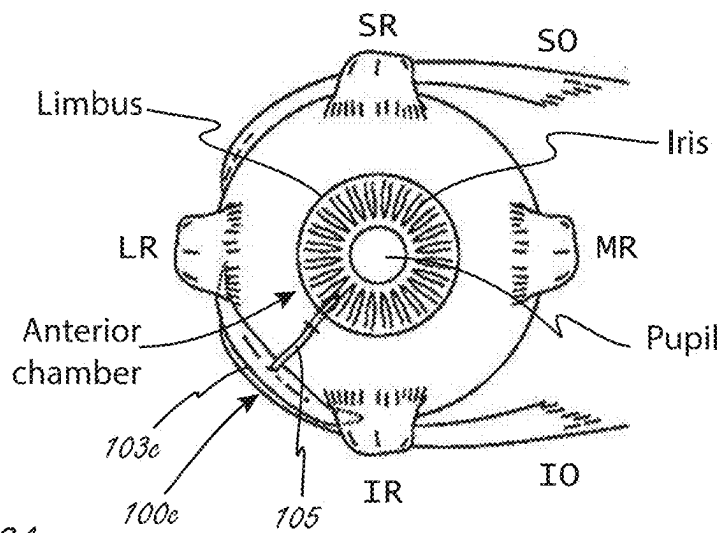


Fig. 2A

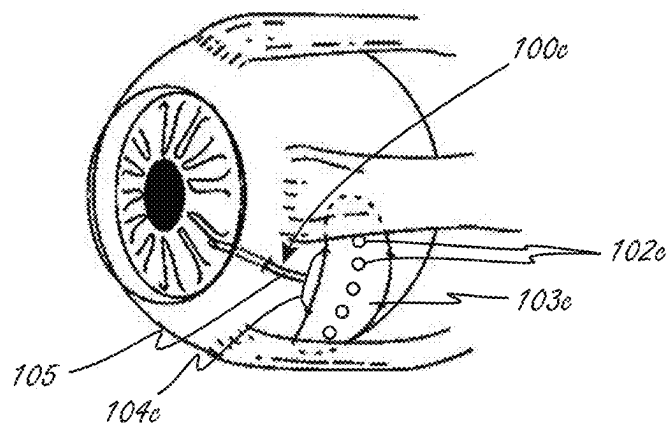
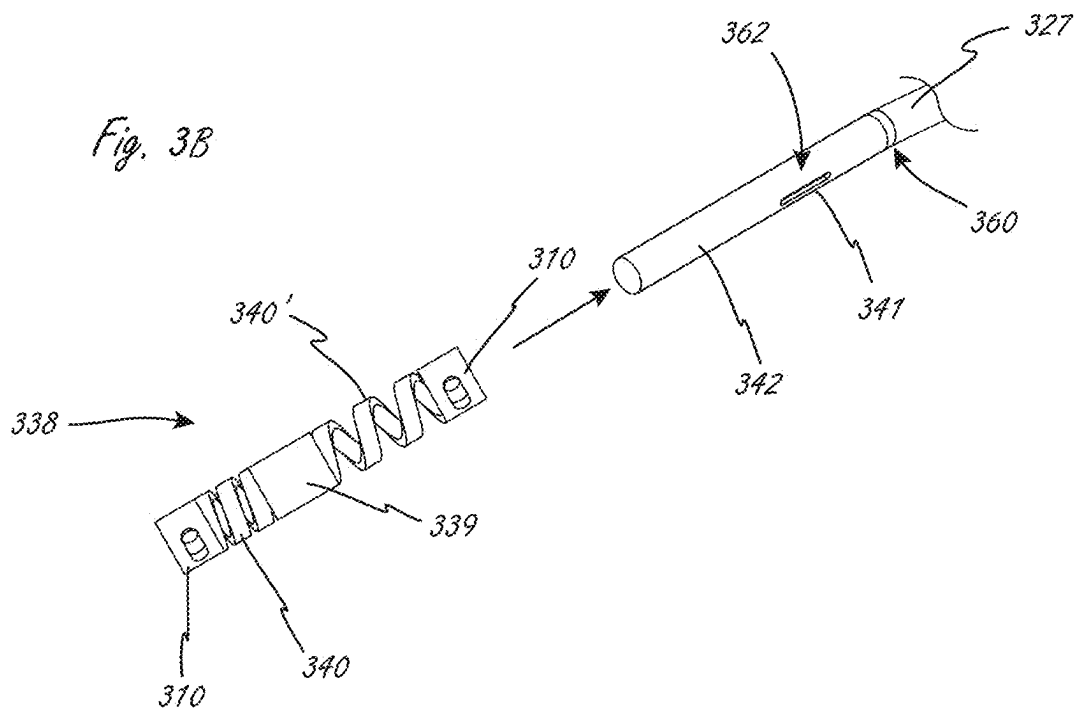
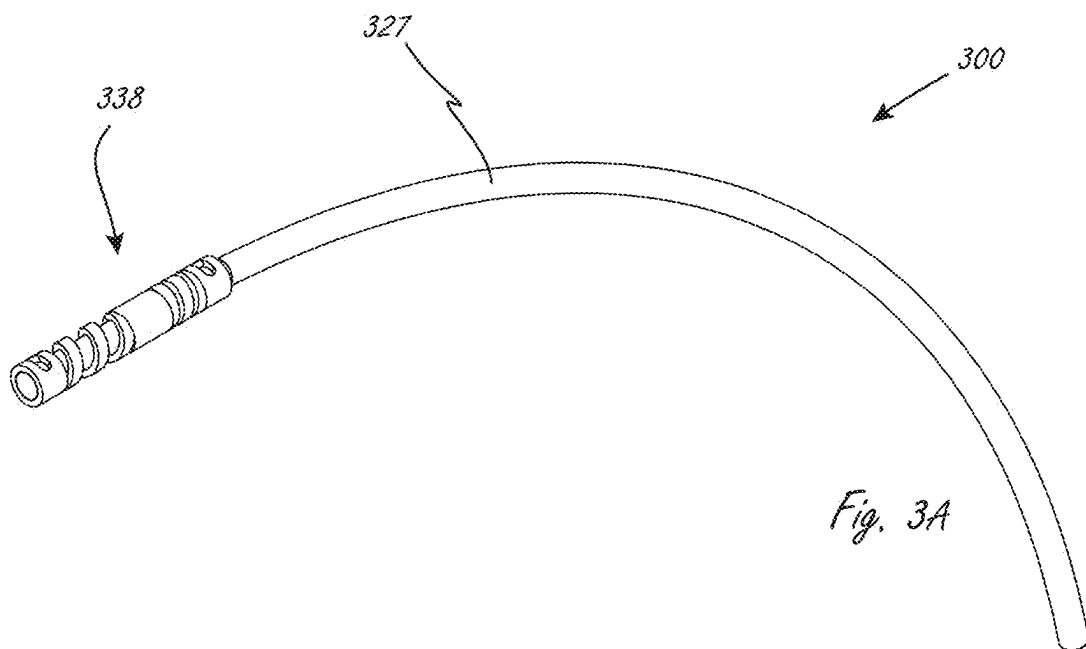


Fig. 2B



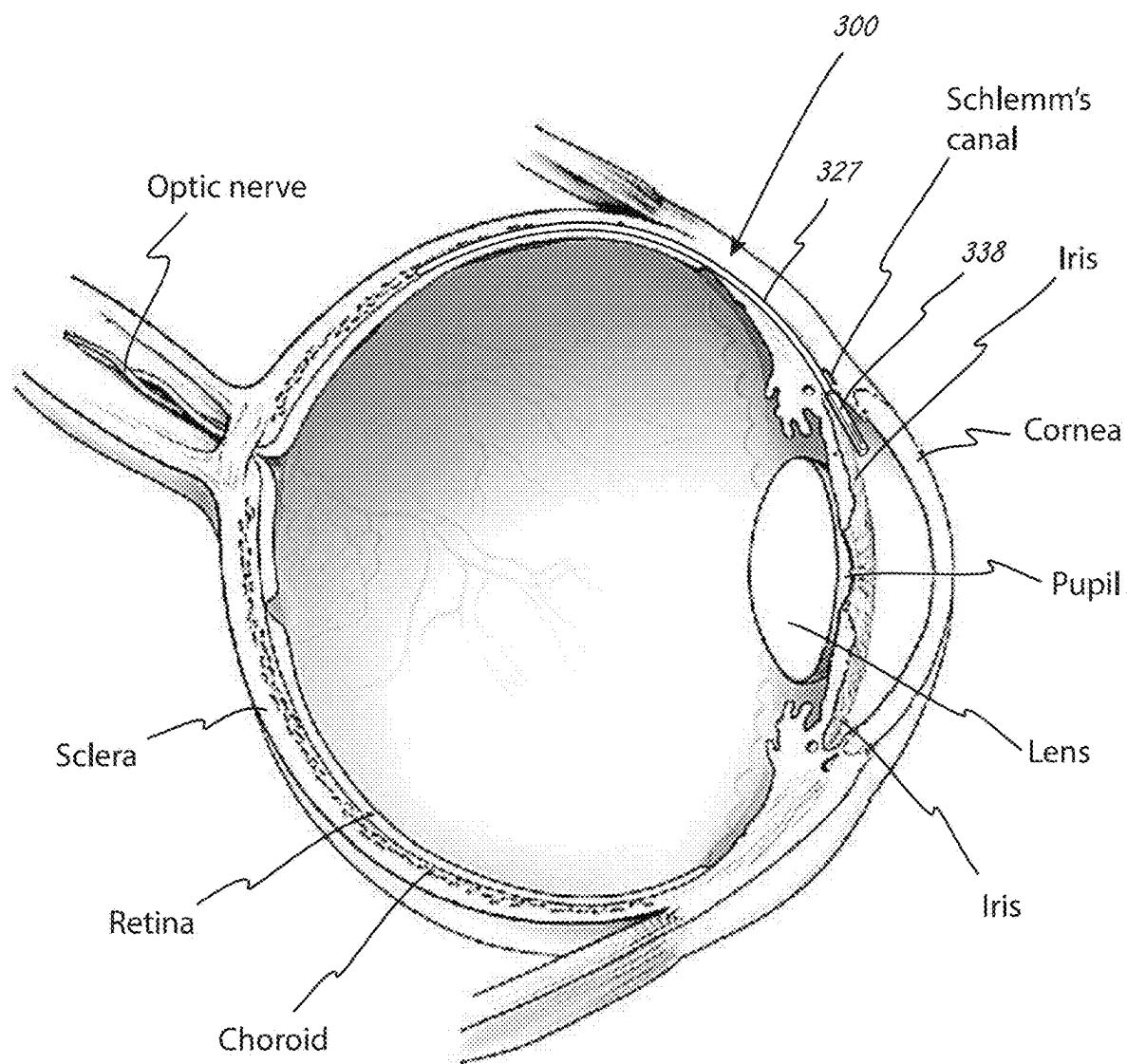


Fig. 3C

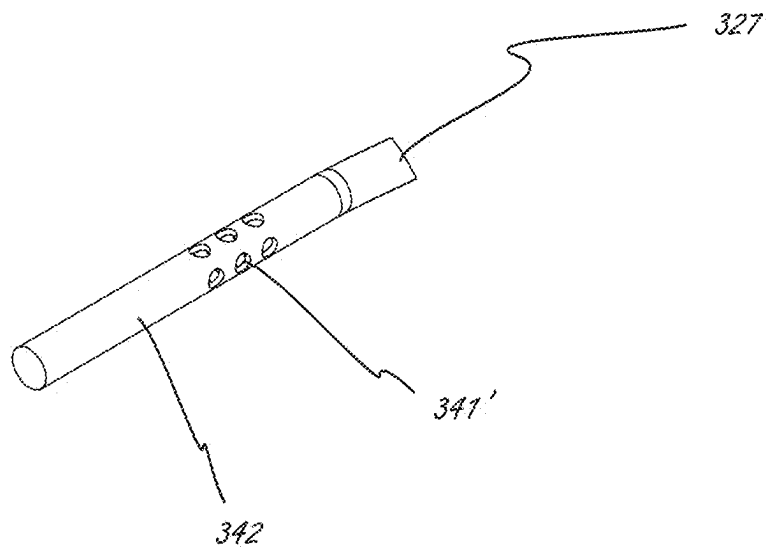


Fig. 3D

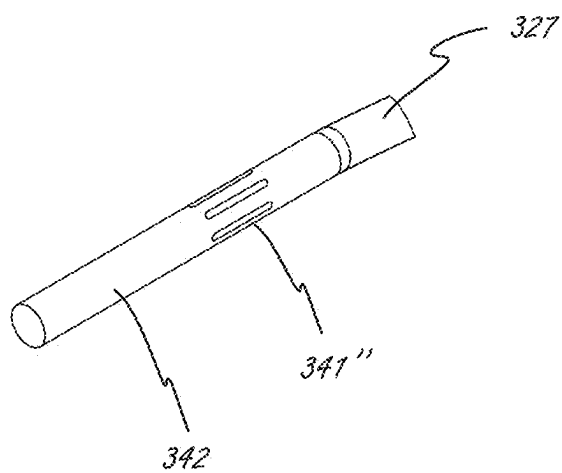
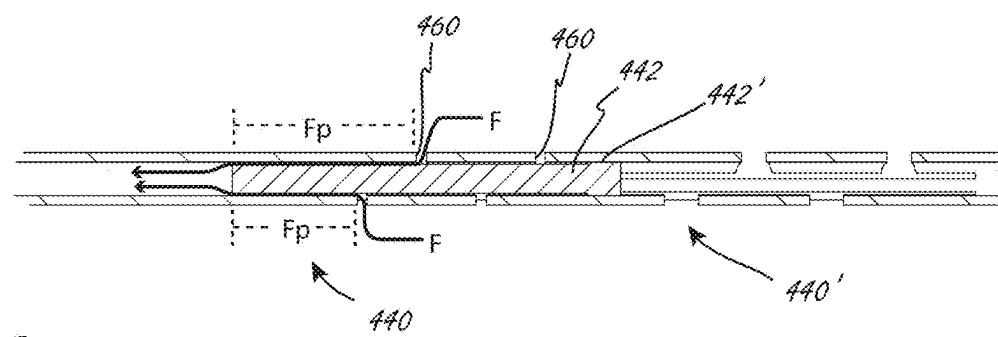
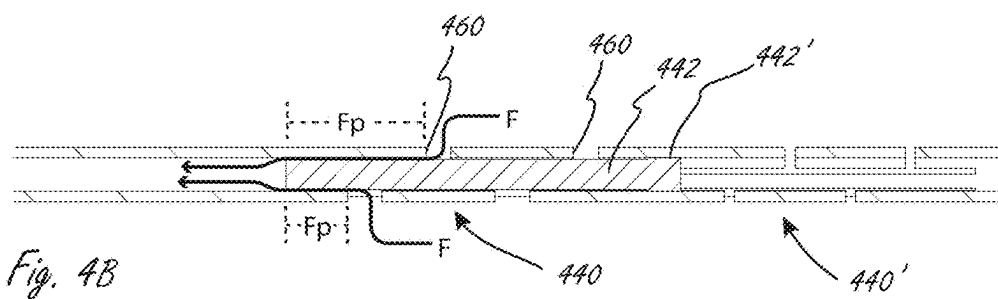
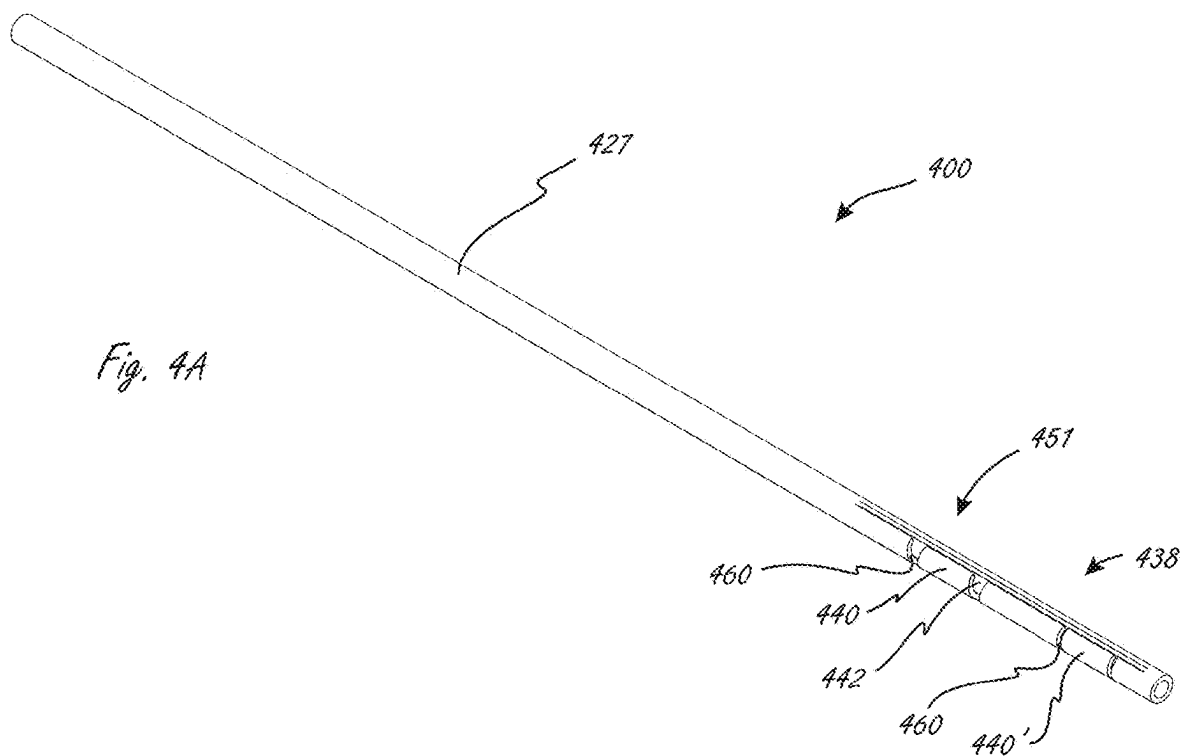
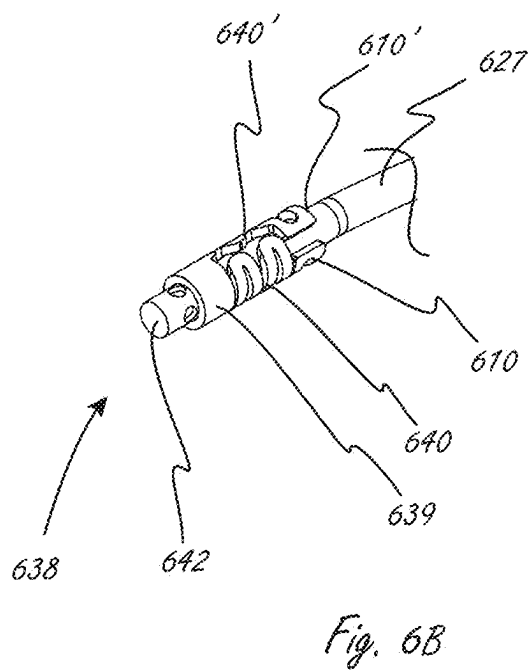
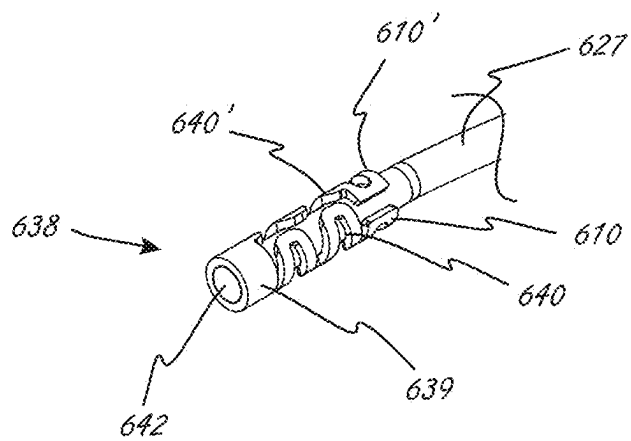
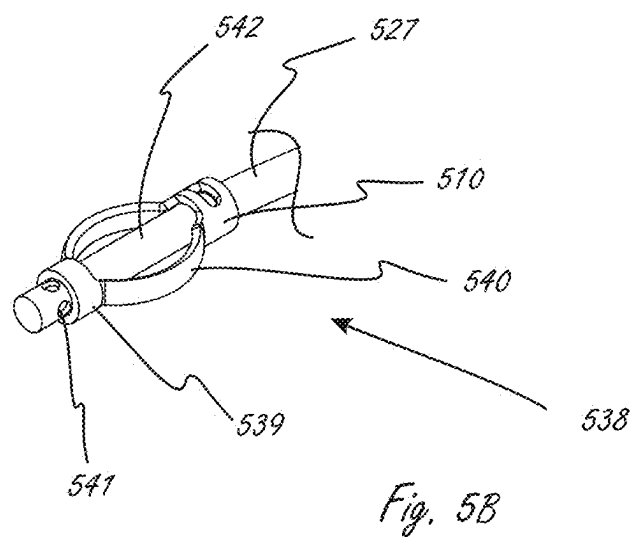
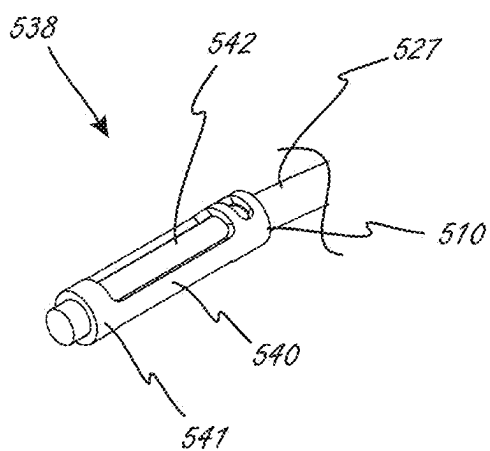
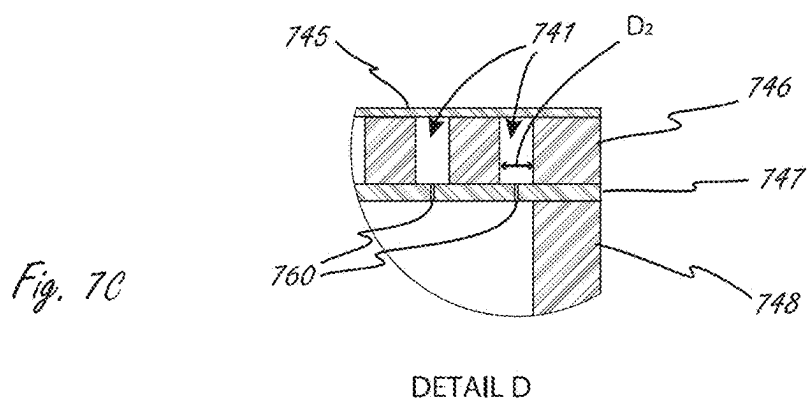
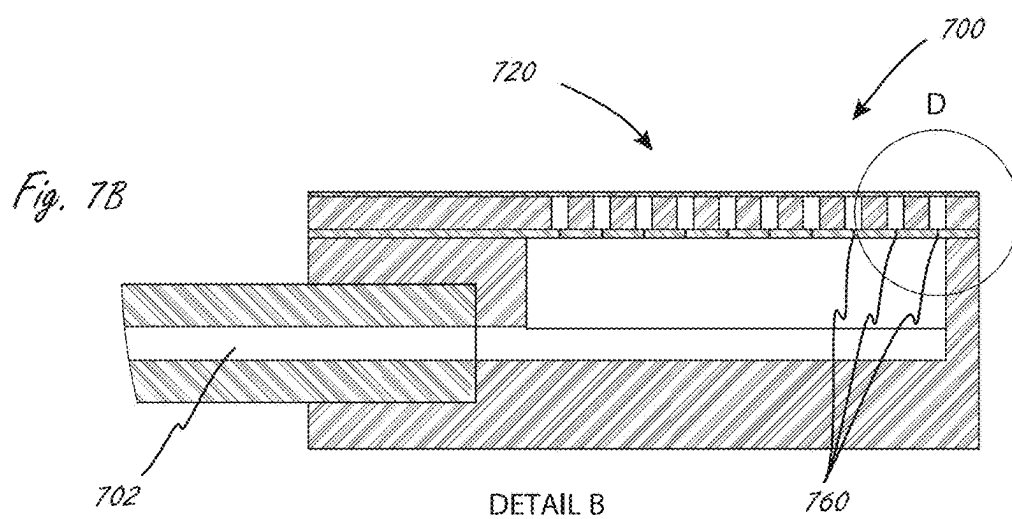
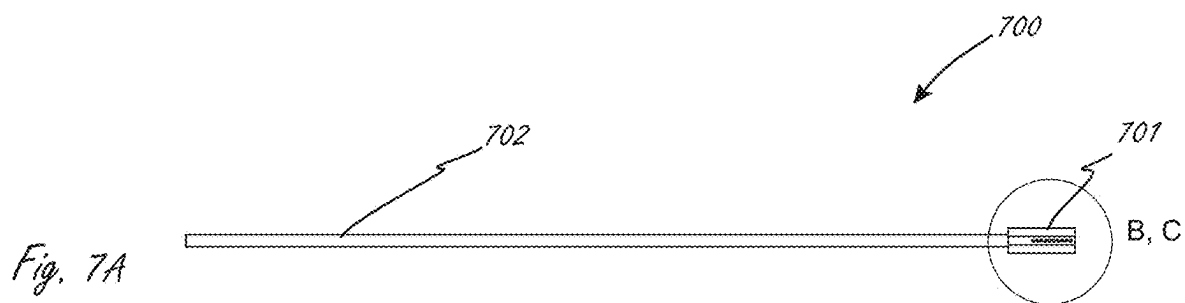


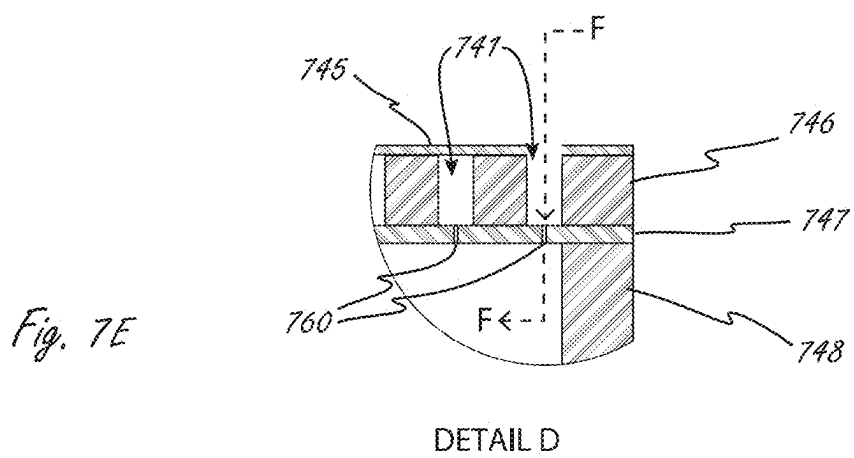
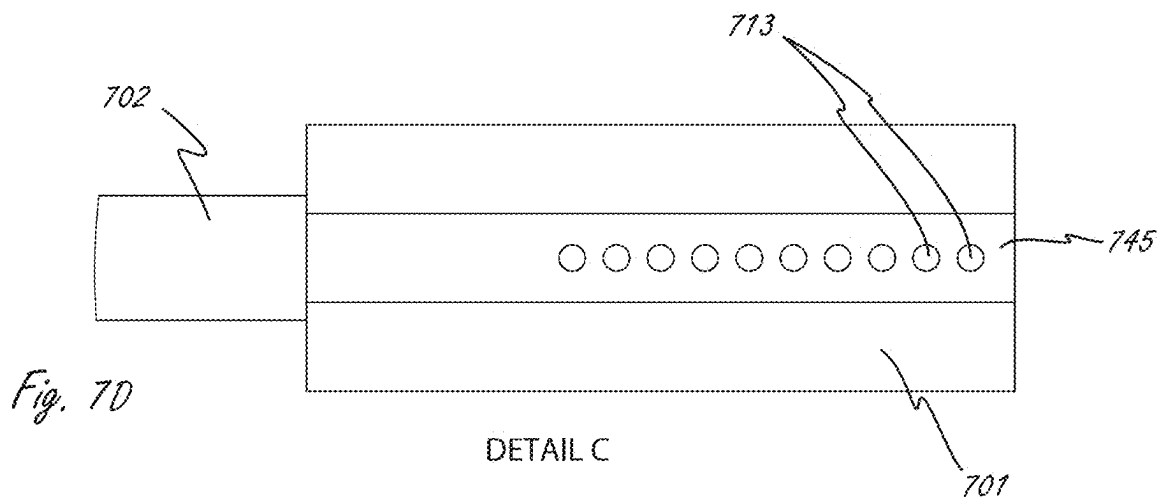
Fig. 3E











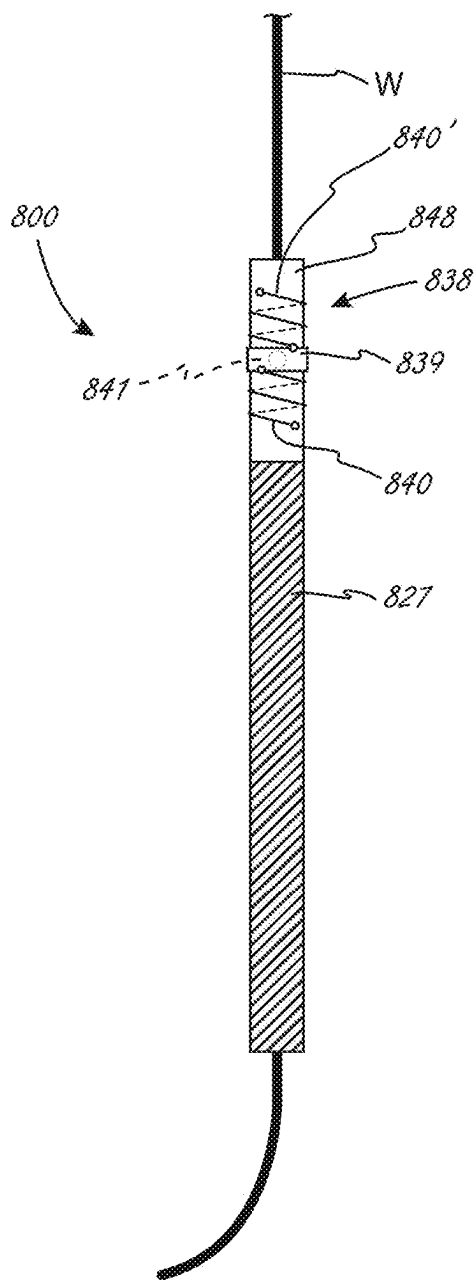


Fig. 8A

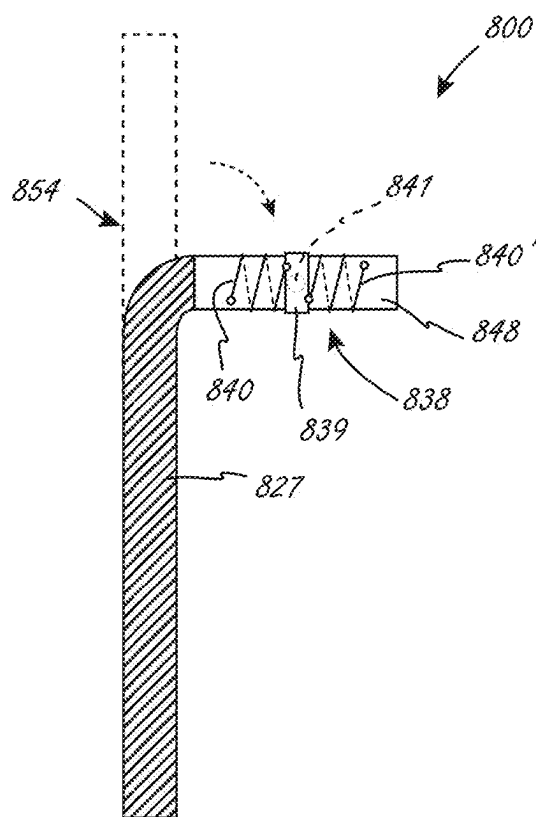


Fig. 8B

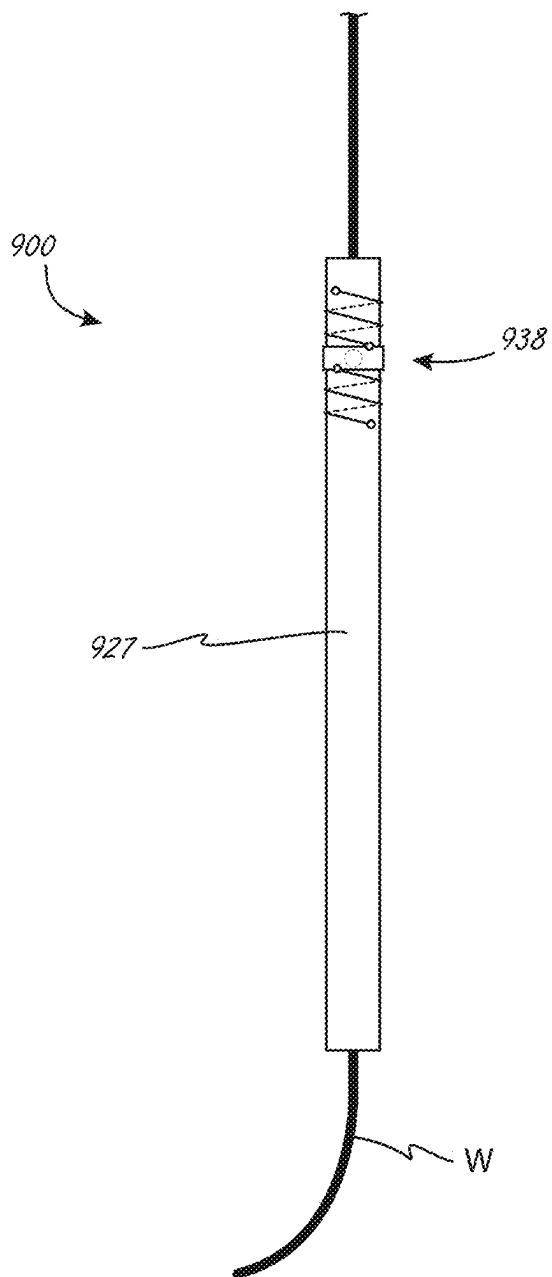


Fig. 9A

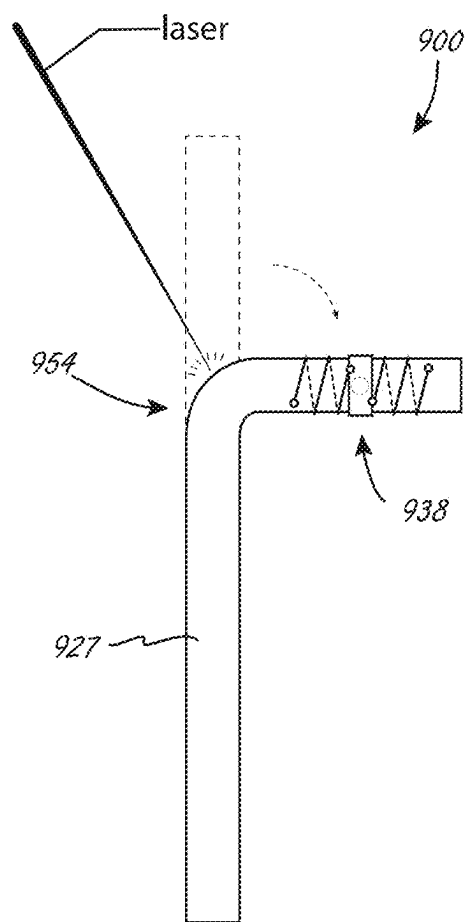
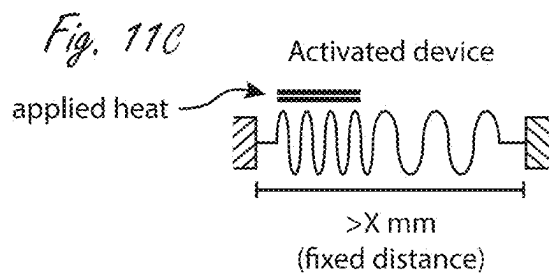
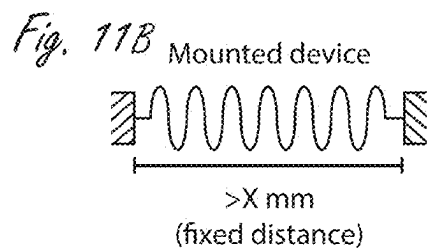
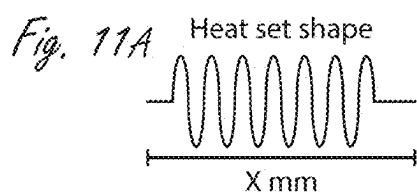
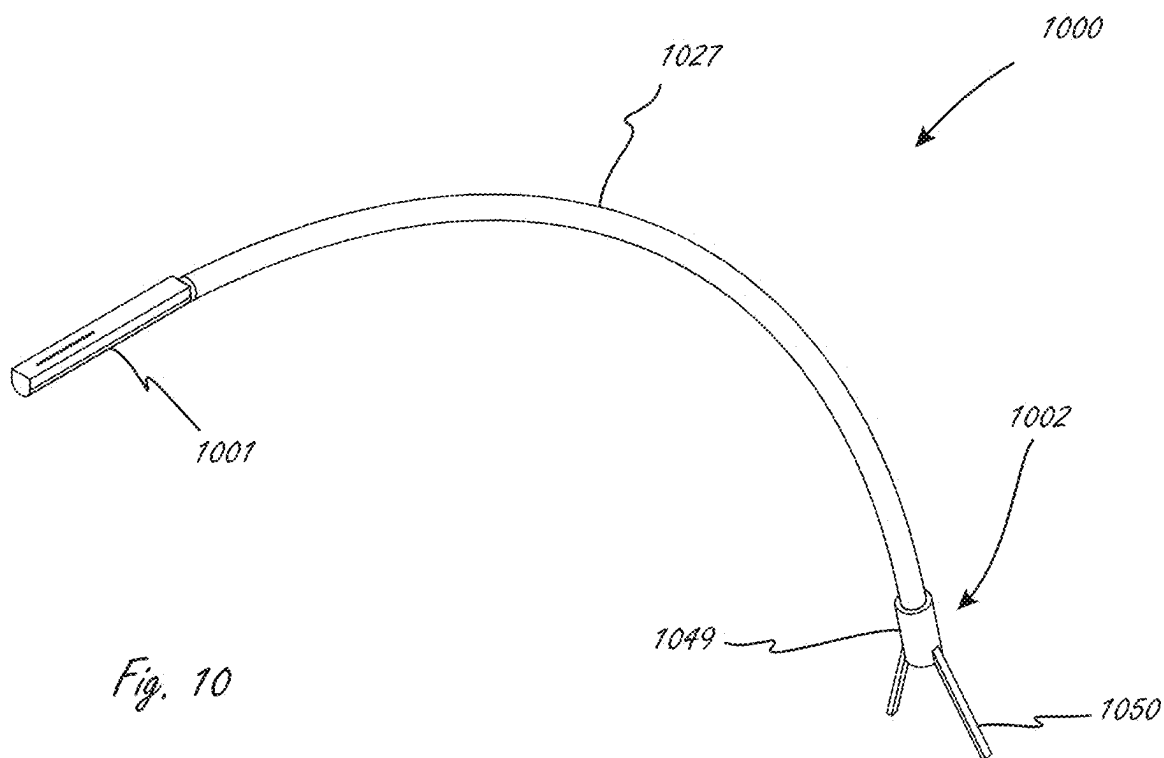


Fig. 9B



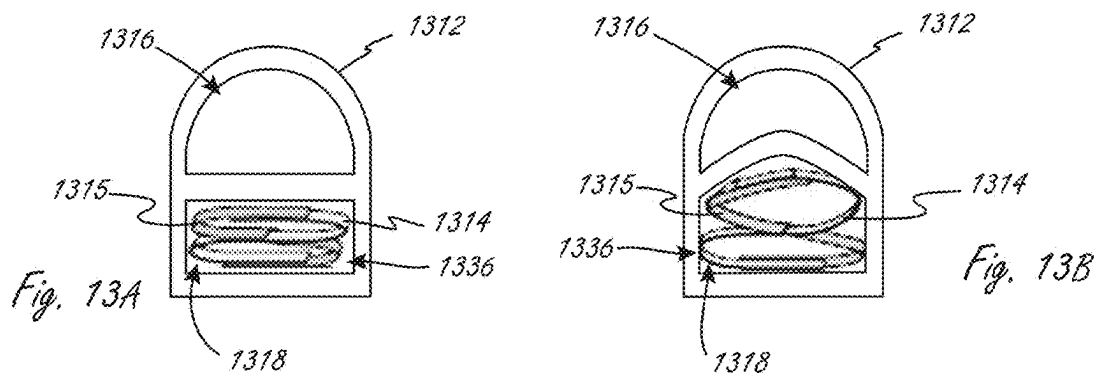
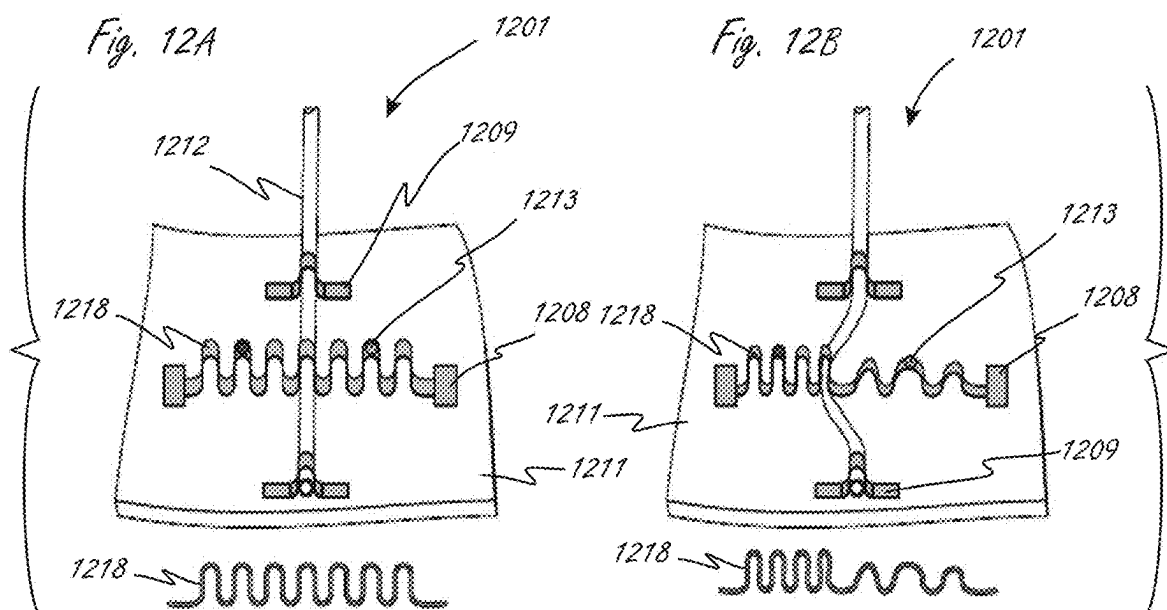


Fig. 13C

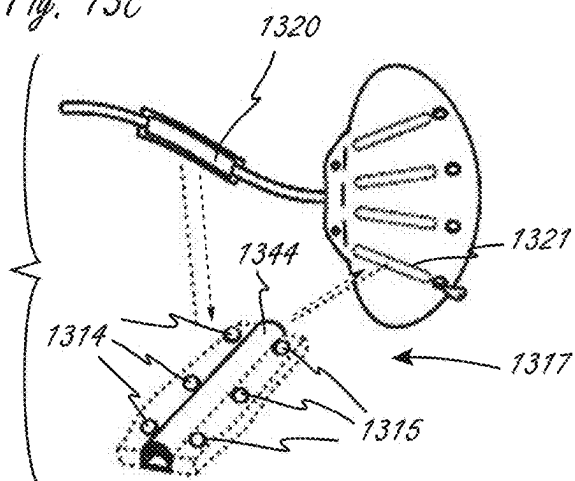


Fig. 13D

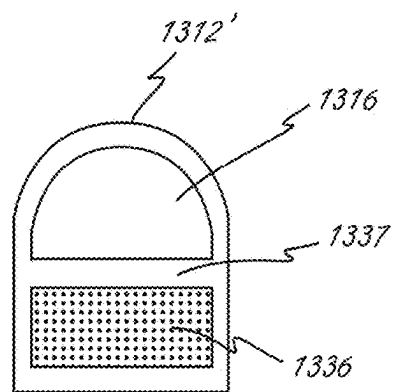
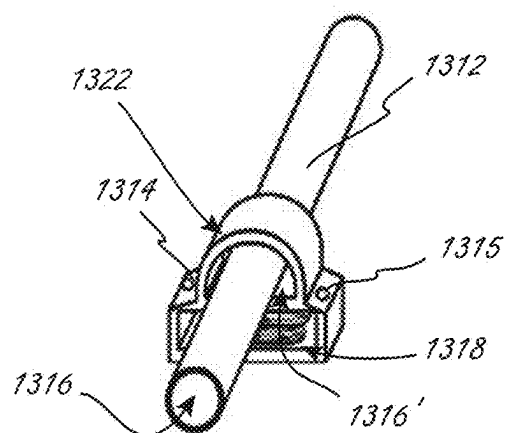


Fig. 13E

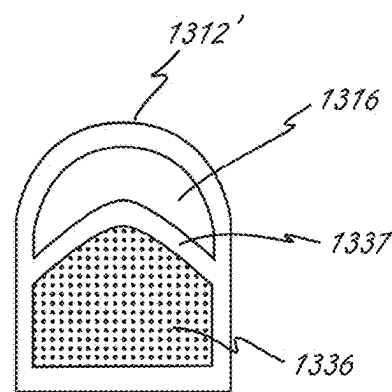


Fig. 13F

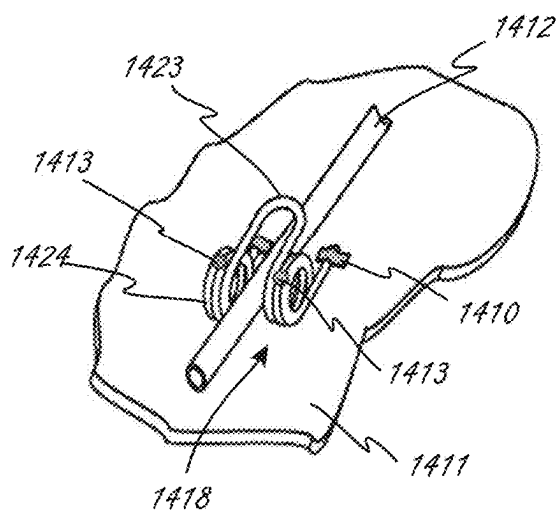


Fig. 14A

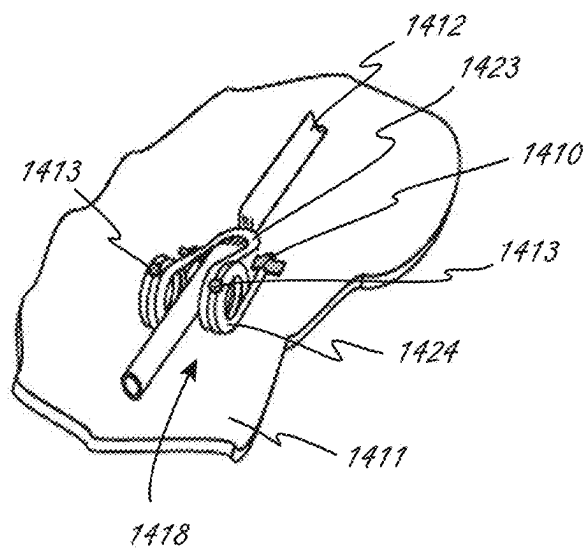
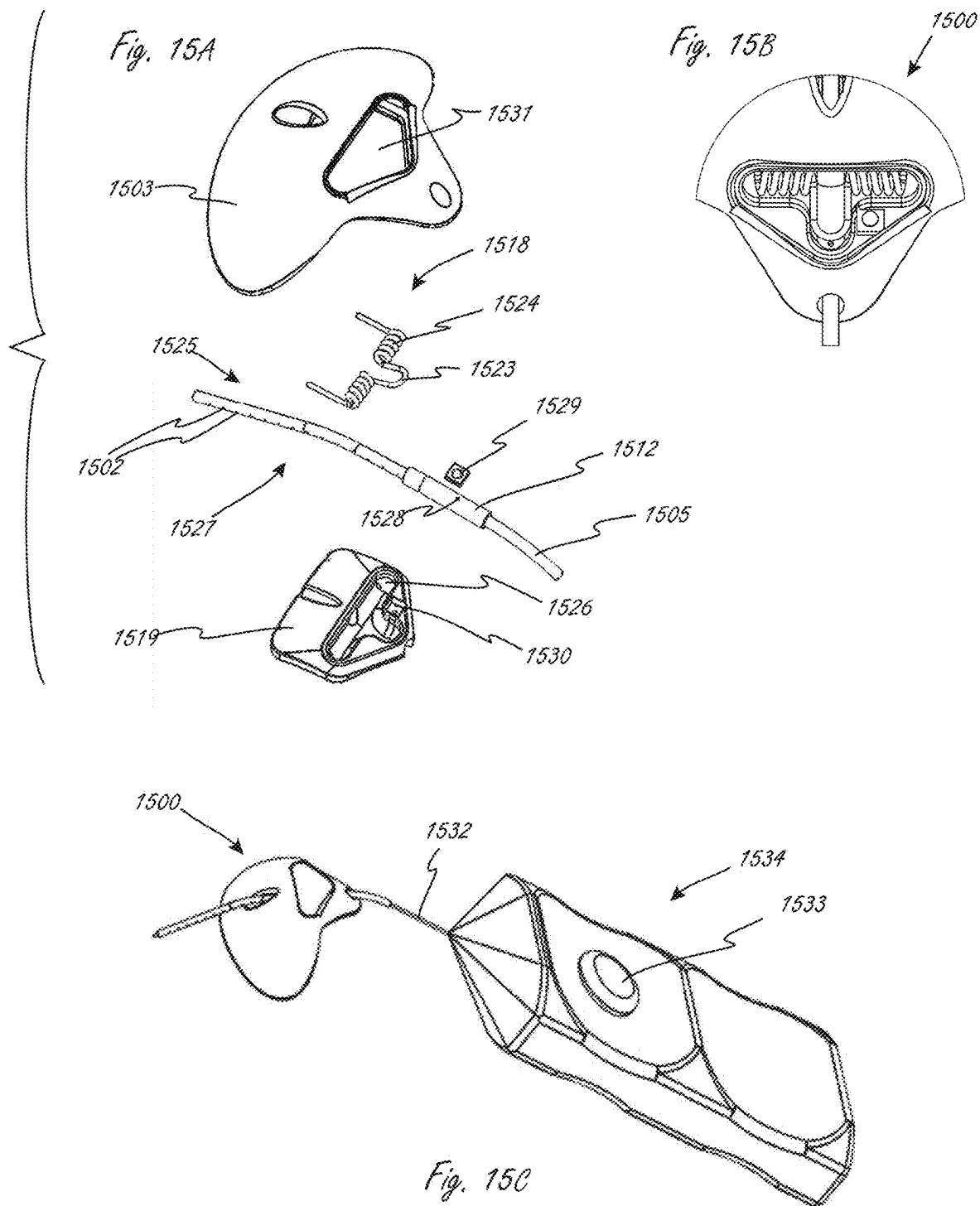


Fig. 14B





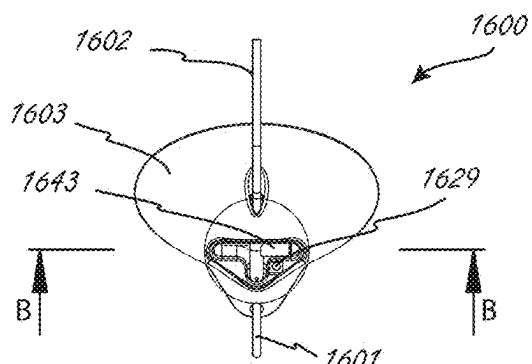


Fig. 16A

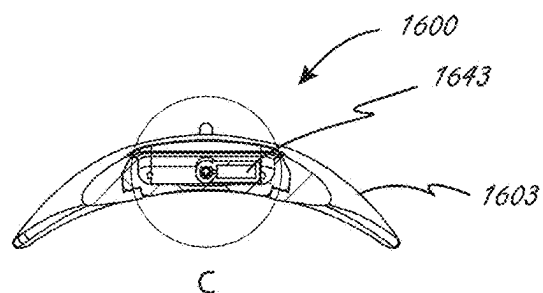


Fig. 16B

Fig. 16C

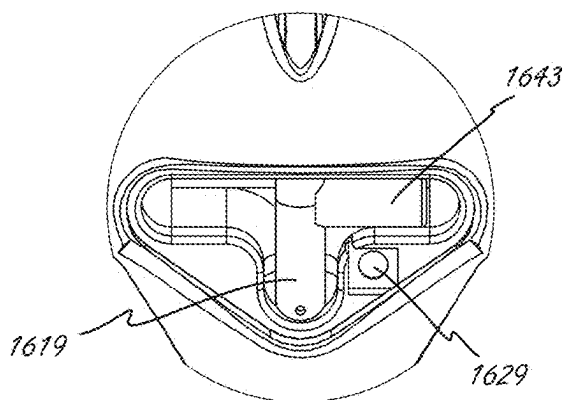
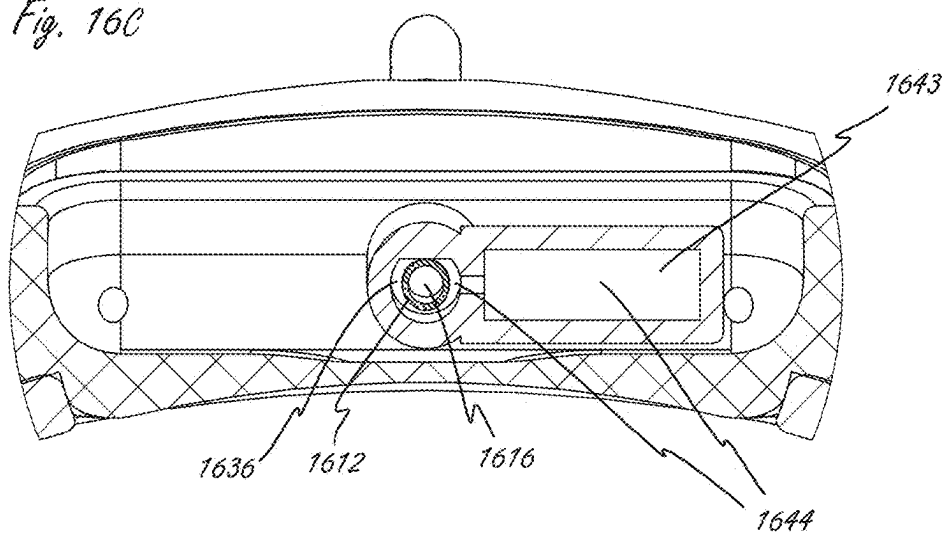


Fig. 16D

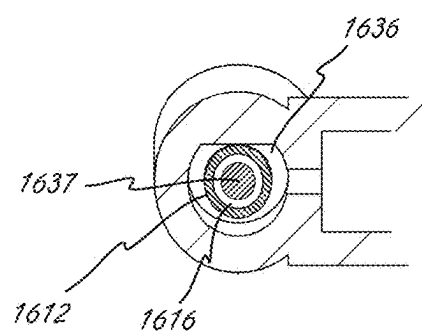
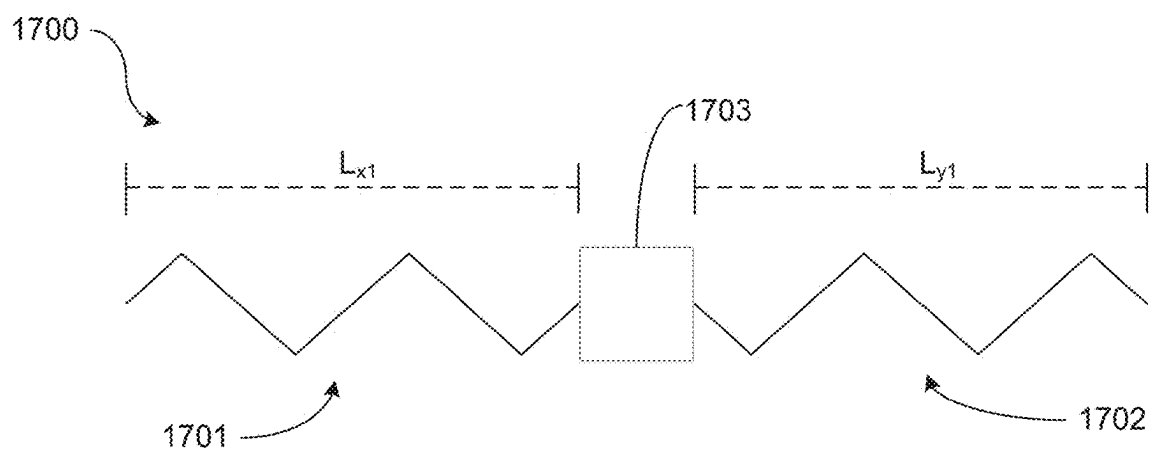
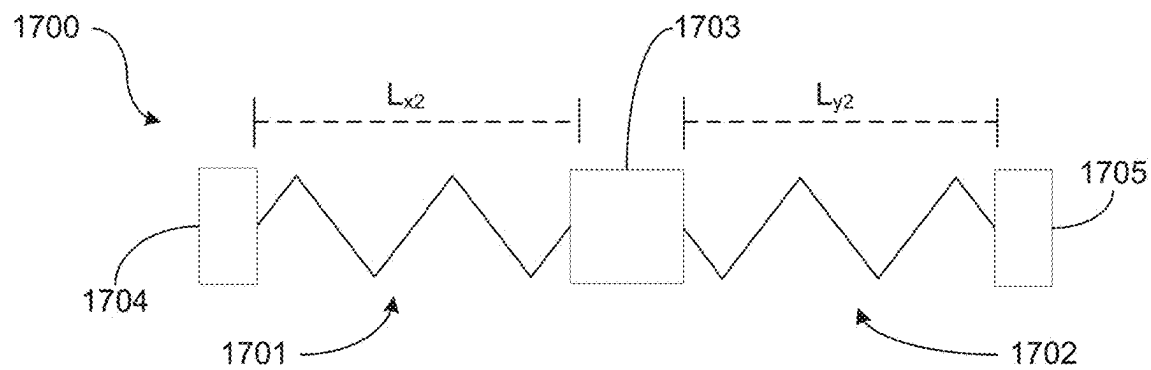


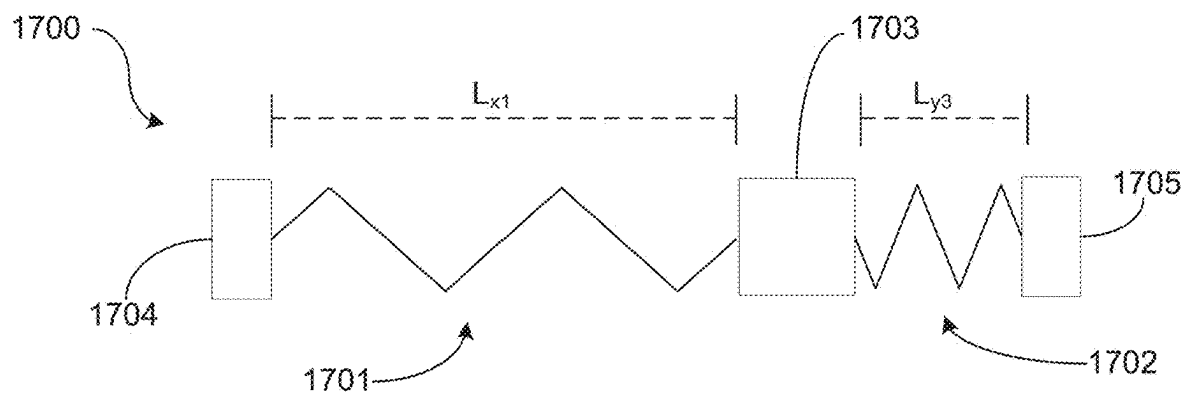
Fig. 16E



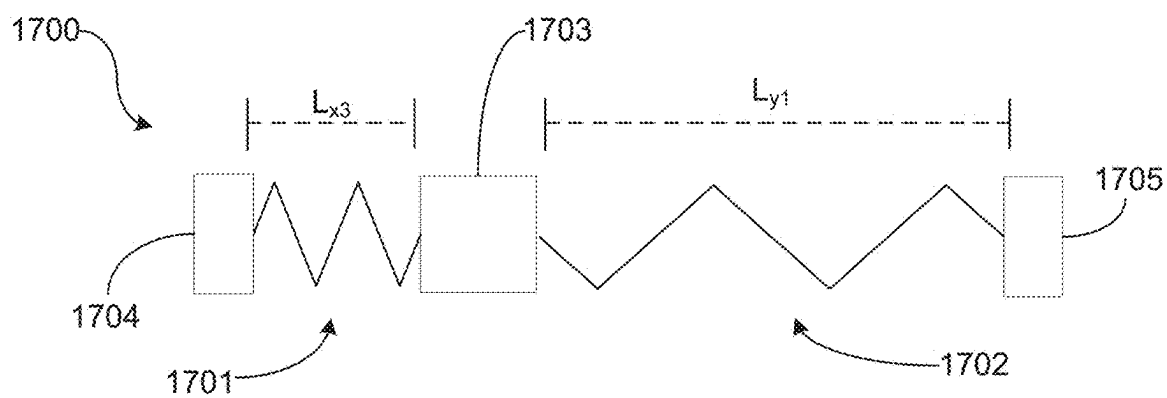
**FIG. 17A**



**FIG. 17B**



**FIG. 17C**



**FIG. 17D**

# ADJUSTABLE FLOW GLAUCOMA SHUNTS AND METHODS FOR MAKING AND USING SAME

## CROSS-REFERENCE TO RELATED APPLICATION(S)

**[0001]** This application is a continuation of U.S. Ser. No. 17/500,224, filed on Oct. 13, 2021, which is a continuation of Patent Application No. U.S. patent application Ser. No. 16/840,137, filed Apr. 3, 2020, now issued as U.S. Pat. No. 11,166,849, which is a continuation-in-part of U.S. patent application Ser. No. 16/632,008, filed Jan. 17, 2020, now issued as U.S. Pat. No. 11,058,581, which is a 35 U.S.C. § 371 U.S. National Phase application of International Patent Application No. PCT/US2018/043158, filed Jul. 20, 2018, which claims priority to U.S. Provisional Patent Application No. 62/643,125, filed Mar. 14, 2018, Provisional Patent Application No. 62/626,615, filed Feb. 5, 2018, and Provisional Patent Application No. 62/535,125, filed Jul. 20, 2017, the contents of which are all incorporated herein by reference in their entireties.

## TECHNICAL FIELD

**[0002]** The present technology relates to adjustable flow glaucoma shunts and methods for making and using such devices.

## BACKGROUND

**[0003]** Glaucoma, ocular hypertension, is a disease associated with an increase in pressure within the eye resultant from an increase in production of aqueous humor (aqueous) within the eye and/or a decrease in the rate of outflow of aqueous from within the eye into the blood stream. Aqueous is produced in the ciliary body at the boundary of the posterior and anterior chambers of the eye. It flows into the anterior chamber and eventually into the capillary bed in the sclera of the eye. Glaucoma typically results from a failure in mechanisms that transport aqueous out of the eye and into the blood stream.

**[0004]** Normal aqueous production, for example, is around 2.5 uL/min, and if it is assumed the lowest pressure that can exist in the capillary bed into which the aqueous drains is 0 torr, then maximum outflow resistance in a normal eye at the maximum of normal pressure is expected to be approximately 9 torr/(uL/min). Normal pressure within the eye ranges between 12 torr and 22 torr. As noted above, glaucoma is usually associated with high pressure inside the eye that can damage eye tissues and result in vision loss. The condition where pressures are significantly below this range is called hypotany or ocular hypotension. In some patients, hypotany can be just as damaging (if not more) than glaucoma.

**[0005]** The early stages of glaucoma are typically treated with drugs. When drug treatments no longer suffice, however, surgical approaches are used. Surgical or minimally invasive approaches primarily attempt to lower the outflow resistance of aqueous from the anterior chamber to the blood stream either by the creation of alternative fluid paths or the augmentation of the natural paths for aqueous outflow.

**[0006]** Devices used to lower outflow resistance are generally referred to as “glaucoma shunts” or “shunts.” FIGS. 1A-1C, for example, illustrate several different traditional glaucoma plate shunts **100** (identified individually as **100a-**

**c**) configured to provide constant resistance to flow. The shunt **100a** of FIG. 1A, for example, includes a plate **103a**, a plurality of outflow ports **102a**, one or more inflow ports **101**, and tie-downs or engagement features **104a**. The shunts **100b** and **100c** shown in FIGS. 1B and 1C, respectively, include several features similar to the features of shunt **100a**. For example, these shunts **100b-c** include plates **103b-c**, outflow ports **102b-c**, and tie-downs or engagement features **104b-c**. The shunts **100b-c**, however, include an inflow tube **105** instead of the inflow ports **101** of the shunt **100a**.

**[0007]** FIGS. 2A and 2B illustrate a human eye E and suitable location(s) in which shunts **100a-c** may be implanted within the eye. More specifically, FIG. 2A is a simplified front view of the eye E, and FIG. 2B is an isometric view of the eye capsule of FIG. 2A. Referring first to FIG. 2A, the eye E includes a number of muscles to control its movement, including a superior rectus SR, inferior rectus IR, lateral rectus LR, medial rectus MR, superior oblique SO, and inferior oblique IO. The eye E also includes an iris, pupil, and limbus.

**[0008]** Referring to FIGS. 2A and 2B together, shunt **100c** is positioned such that inflow tube **105** is positioned in an anterior chamber of the eye, and outflow ports **102c** are positioned at a different location within the eye. Depending upon the design of the device, the outflow ports **102c** may be placed in a number of different suitable outflow locations (e.g., between the choroid and the sclera, between the conjunctiva and the sclera). For purposes of illustration, only shunt **100c** is shown implanted in the eye E. It will be appreciated, however, that shunts **100a-b** may be similarly implanted within the eye E.

**[0009]** Outflow resistance typically depends on the outflow location. Additionally, outflow resistance changes over time as the outflow location goes through its healing process after surgical implantation of the device. Because the outflow resistance changes over time, in many procedures the shunt **100a-c** is modified at implantation to temporarily increase its outflow resistance. After a period of time deemed sufficient to allow for healing of the tissues and stabilization of the outflow resistance, the modification to the shunt **100a-c** is reversed, thereby decreasing the outflow resistance. Such modifications can be invasive, time-consuming, and expensive for patients. If such a procedure is not followed, however, the likelihood of creating hypotany and its resultant problems is high.

## BRIEF DESCRIPTION OF THE DRAWINGS

**[0010]** Many aspects of the present technology can be better understood with reference to the following drawings. The components in the drawings are not necessarily drawn to scale. Instead, emphasis is placed on illustrating clearly the principles of the present technology. Furthermore, components can be shown as transparent in certain views for clarity of illustration only and not to indicate that the component is necessarily transparent. Components may also be shown schematically.

**[0011]** FIGS. 1A-1C illustrate traditional glaucoma plate shunts configured to provide constant resistance to flow.

**[0012]** FIG. 2A is a simplified front view of an eye E with an implanted shunt, and FIG. 2B is an isometric view of the eye capsule of FIG. 2A.

**[0013]** FIGS. 3A and 3B illustrate an adjustable flow glaucoma shunt configured in accordance with an embodiment of the present technology.

[0014] FIG. 3C is a partially schematic illustration of an eye capsule of a human patient showing the adjustable flow glaucoma shunt of FIGS. 3A and 3B implanted within the eye capsule.

[0015] FIGS. 3D and 3E illustrate inflow regions configured in accordance with additional embodiments of the present technology.

[0016] FIGS. 4A-4C illustrate an adjustable flow glaucoma shunt configured in accordance with another embodiment of the present technology.

[0017] FIGS. 5A-6B illustrate inflow control assemblies configured in accordance with embodiments of the present technology.

[0018] FIGS. 7A-7E illustrate a variable flow shunt configured in accordance with an embodiment of the present technology.

[0019] FIGS. 8A-9B illustrate additional embodiments of variable flow glaucoma shunt devices configured in accordance with the present technology.

[0020] FIG. 10 illustrates a variable flow shunt device including an actuatable member at an outflow end of the device in accordance with an embodiment of the present technology.

[0021] FIGS. 11A-11C illustrate a ribbon or wire composed of shape memory material and configured in accordance with an embodiment of the present technology.

[0022] FIGS. 12A and 12B illustrate a fluid control element including variable fluid resistors composed of shape memory materials in accordance with an embodiment of the present technology.

[0023] FIGS. 13A and 13B are partially schematic, cross-sectional views of a variable fluid resistor comprising a dual lumen elastomeric tube configured in accordance with an embodiment of the present technology.

[0024] FIGS. 13C-13F illustrate additional embodiments of variable fluid resistor devices configured in accordance with the present technology.

[0025] FIGS. 14A and 14B illustrate a fluid control element including variable fluid resistors composed of shape memory materials in accordance with additional embodiments of the present technology.

[0026] FIGS. 15A-15C illustrate an adjustable flow glaucoma shunt configured in accordance with another embodiment of the present technology.

[0027] FIGS. 16A-16E illustrate an adjustable flow glaucoma shunt configured in accordance with still another embodiment of the present technology.

[0028] FIGS. 17A-17D illustrate an actuation assembly configured in accordance with embodiments of the present technology.

#### DETAILED DESCRIPTION

[0029] The present technology is directed to adjustable flow glaucoma shunts and methods for making and using such devices. In many of the embodiments disclosed herein, the adjustable flow glaucoma shunts comprise an adjustable fluid resistor ("resistor" within the context of this document refers to a fluid resistor), actuator, and/or actuation mechanism. Additionally, in certain embodiments, the shunts may also include an adjustable opening pressure control mechanism. These mechanisms can be selectively adjusted or modulated to increase or decrease the outflow resistance and/or opening pressure of the shunt in response to changes in any (or any combination of) intraocular pressure (IOP),

aqueous production rate, native aqueous outflow resistance, and/or native aqueous outflow rate.

[0030] In one embodiment, for example, an adjustable flow shunt for treating glaucoma in a human patient comprises an elongated outflow drainage tube having a proximal inflow region and a distal outflow region. The proximal inflow region can include one or more apertures defining a fluid inlet area positioned to allow fluid to flow therethrough and into the outflow drainage tube. The adjustable flow shunt further comprises an inflow control assembly at the proximal inflow region. The inflow control assembly can include a control element sized and shaped to slidably engage the proximal inflow region and a spring element operably coupled between the control element and an anchor element engaged with the proximal inflow region. The spring element is configured to be activated by a non-invasive energy and, upon activation, slidably move the control element along the proximal inflow region such that (a) the one or more apertures are accessible and have a first fluid flow cross-section or (b) the one or more apertures are at least partially covered by the control element and have a second fluid-flow cross-section less than the first fluid flow cross-section.

[0031] In another embodiment of the present technology, an adjustable flow shunt for treatment of glaucoma may comprise an elongated outflow tube having (a) a proximal inflow portion configured for placement within an anterior chamber in a region outside of an optical field of view of an eye of the patient, and (b) a distal outflow portion at a different location of the eye. The adjustable flow shunt also includes an actuator positioned along the outflow tube between the inflow portion and the outflow portion. The actuator is transformable between an open position that allows fluid to flow through the outflow tube and resistance positions that partially obstruct fluid flow through the outflow tube. During operation, the actuator is movable between positions in response to non-invasive energy.

[0032] An adjustable flow shunt assembly configured in accordance with still another embodiment of the present technology can include an elongated drainage tube having a proximal portion and a distal portion. The proximal portion includes an inflow port configured to be in fluid communication with a fluid chamber in an eye of the patient. The adjustable flow shunt can also include a variable resistor assembly configured to selectively control flow of fluid into the inflow port. The variable resistor assembly in this embodiment comprises a base portion and an aperture plate carried by the base portion. The aperture plate comprises a plurality of first apertures extending therethrough. The variable resistor assembly also comprises a standoff plate carried by and extending away from the aperture plate. The standoff plate comprises a plurality of second apertures extending therethrough, with the second apertures aligned with corresponding first apertures of the aperture plate. The variable resistor assembly further comprises a membrane disposed on and carried by the standoff plate. The membrane is positioned to sealably cover an open end of each of the second apertures. During operation of the shunt assembly, a portion of the membrane over one or more second apertures of the standoff plate is configured to be selectively targeted and removed via non-invasive energy, thereby creating a fluid path from the site of fluid in the patient through the accessible open ends of the targeted second apertures, the corresponding first apertures, and into the drainage tube.

[0033] Specific details of various embodiments of the present technology are described below with reference to FIGS. 3A-16E. Although many of the embodiments are described below with respect to adjustable flow glaucoma shunts and associated methods, other embodiments are within the scope of the present technology. Additionally, other embodiments of the present technology can have different configurations, components, and/or procedures than those described herein. For instance, shunts configured in accordance with the present technology may include additional elements and features beyond those described herein, or other embodiments may not include several of the elements and features shown and described herein.

[0034] For ease of reference, throughout this disclosure identical reference numbers are used to identify similar or analogous components or features, but the use of the same reference number does not imply that the parts should be construed to be identical. Indeed, in many examples described herein, the identically numbered parts are distinct in structure and/or function.

#### Selected Embodiments of Variable Flow Glaucoma Shunts

[0035] FIGS. 3A-16E illustrate a number of different embodiments for variable flow glaucoma shunt devices, along with particular components and features associated with such devices. FIG. 3A, for example, illustrates a variable flow glaucoma shunt 300 (“shunt 300”) configured in accordance with an embodiment of the present technology. The shunt 300 includes an inflow control assembly 338 and an outflow drainage tube or outflow assembly 327. The inflow control assembly 338 of the shunt 300 is configured for placement within an anterior chamber in a region outside of the optical field of view of the eye, but within a region visible through the cornea (as described below with reference to FIG. 3C). The outflow drainage tube 327 comprises tubing (e.g., a fine bore length of thin walled tubing) sized and shaped to span the region between the anterior chamber and a desired outflow location. As described in greater detail below, the inflow control assembly 338 comprises a control mechanism configured to act as a variable resistor during operation.

[0036] FIG. 3B is a partially exploded view of the shunt 300 with a portion of the inflow control assembly 338 removed from the outflow drainage tube 327 for purposes of illustration. As best seen in FIG. 3B, a proximal end 360 of the outflow drainage tube 327 comprises a proximal inflow region defined by a core element or core feature 342 extending therefrom. The core element 342 may be composed of a relatively stiff material or a combination of stiff materials including, but not limited to, polyether ether ketone (PEEK), acrylic, polycarbonate, metal, ceramic, quartz, and/or sapphire. The portion of the outflow drainage tube 327 not comprised in the core element 342 may be composed of a relatively flexible material (e.g., silicone, urethane, or another suitable material). The core element 342 includes one or more apertures or openings 341 (only one is shown in the illustrated embodiment) that define a fluid inlet area 362. The fluid inlet area 362 is in fluid communication with a lumen of the outflow drainage tube 327. In other embodiments, the aperture(s) 341 may have a different arrangement and/or there may be a different number of apertures 341. For example, in another embodiment the aperture 341 may extend helically about the core element

342. The aperture(s) 341 are positioned to allow fluid to flow therethrough during operation of the shunt 300.

[0037] Referring to FIGS. 3A and 3B together, for example, the inflow control assembly 338 in the illustrated embodiment includes a control element 339 configured to be positioned on or around an external surface of the core element 342 (as shown by the arrow in FIG. 3B). During operation, the control element 339 may be adjusted to cover more or less of the fluid inlet area 362. For example, in some embodiments, the control element 339 may be adjusted to increase or decrease the length of a fluid path between an edge of the control section 339 and the aperture(s) 341 (FIG. 3B). In some embodiments, a hydrogel coating may be applied to an inside surface of the control element 339 to further enhance the ability of the control element 339 to slide relative to the core element 342 and enhance sealing of the components during operation. In additional embodiments, the hydrogel coating may also be applied to the core element 342 (in addition to, or in lieu of, application of the coating on the control element 339). Further details regarding adjusting/manipulating the control element 339 are described below.

[0038] The inflow control assembly 338 in the illustrated embodiment can also include an adjustable spring element (shown as first and second spring elements 340 and 340') arranged on opposite sides of the control element 339. Each spring element 340 and 340' may further comprise a corresponding anchor element 310.

[0039] In the embodiment illustrated in FIGS. 3A and 3B, the control element 339 is composed of a single material. For example, the control element 339 may be fabricated from materials such as (but not limited to) ceramics, alumina oxide, silica oxide, sapphire, and/or quartz. Such materials, for example, may be ground to very high tolerances/precise dimensions. In other embodiments, however, the control element 339 may have different portions/regions composed of different materials. The first and second spring elements 340 and 340' may be composed of a shape memory material (e.g., nitinol or another suitable shape memory material) capable of activation via non-invasive energy, such as light (and/or heat). The anchor elements 310 may be fabricated from similar material(s) or other suitable materials.

[0040] In operation, first and second spring elements 340 and 340' are configured to be selectively activated by non-invasive energy and, upon activation, slidably move the control element 339 along the proximal inflow region in a first direction or a second direction, respectively, such that (a) the aperture(s) 341 have a first fluid flow cross-section (e.g., completely open and accessible), or (b) the aperture(s) are at least partially covered by the control element 339 and have a second fluid-flow cross-section less than the first fluid flow cross-section (e.g., partially open/accessible). Further, in some instances the control element 339 may be slidably adjusted such that the aperture(s) 341 are fully covered and inaccessible. One feature of the arrangement shown in FIGS. 3A and 3B is that the inflow control assembly 338 can be selectively adjusted after placement within the eye (e.g., via non-invasive energy) to provide a variety of different outflow resistance levels by incrementally adjusting the control element 339 relative to the aperture(s) 341.

[0041] FIG. 3C is a partially schematic illustration of an eye capsule of a human patient showing the adjustable flow glaucoma shunt 300 of FIGS. 3A and 3B implanted within the eye capsule. In particular, a typical surgery for implant-

tation of the shunt **100** in the eye capsule comprises the following: (a) a portion of conjunctiva is peeled back; (b) a portion of sclera is removed to create a pocket where the plate is to be placed; (c) the inflow control assembly **338** is routed into the anterior chamber of the eye capsule; (d) the outflow drainage tube **327** is extended through the tissue and into a desired pocket; and (e) the outflow drainage tube **327** and any other portions of the shunt **300** not otherwise buried in the other tissues are covered with conjunctiva. In the embodiment illustrated in FIG. 3C, for example, the shunt **300** is configured for placement traversing a region in the anterior chamber to a region in a suprachoroidal location of the eye. In other embodiments, however, the shunt **300** may be adapted for placement within different portions of the eye. In one embodiment, for example, shunts configured in accordance with the present technology may be positioned at a subconjunctival region within the eye.

**[0042]** FIGS. 3D and 3E illustrate core elements configured in accordance with different embodiments of the present technology. Referring first to FIG. 3D, for example, core element **342** comprises a plurality of apertures or openings **341'** extending therethrough and defining, at least in part, a fluid path in communication with a lumen of the corresponding outflow drainage tube **327**. The apertures **341'** in the illustrated embodiment have a different arrangement/configuration than the aperture **341** described above with reference to FIGS. 3A and 3B. It will be appreciated that while six apertures **341'** are shown in FIG. 3D, the core element **342** may include a different number of apertures **341'** in other embodiments. Moreover, the apertures **341'** may have a different arrangement relative to each other. FIG. 3E illustrates yet another embodiment of core element **342** having apertures

**341''** configured in accordance with still yet another arrangement of the present technology. In this embodiment, the apertures **341''** comprise a plurality of elongated slots arranged about the core element **342**. In other embodiments, the apertures **341'/341''** may have a variety of other suitable shapes/sizes.

**[0043]** FIGS. 4A-4C illustrate a variable flow glaucoma shunt **400** ("shunt **400**") configured in accordance with yet another embodiment of the present technology. The shunt **400** includes an inflow control assembly **438** and an outflow drainage tube or outflow assembly **427**. The inflow control assembly **438** includes several features similar to the inflow control assembly **338** of the shunt **300** described above with reference to FIGS. 3A and 3B. For example, inflow control assembly **438** includes a first or proximal spring element **440'** and a second or distal spring element **440** arranged adjacent each other. The inflow control assembly **438** further includes a core element or feature **442** coupled to an inner portion of the inflow control assembly at anchor point **442'** (as best seen in FIGS. 4B and 4C) between the spring elements **440** and **440'**. A fixation spine **451** extends between and is operably coupled to the spring elements **440** and **440'**. Although only one fixation spine **451** is shown in the illustrated embodiment, in other embodiments the shunt **400** may include one or more additional fixation spines. In the illustrated embodiment, the fixation spine **451** and first and second spring elements **440** and **440'** are all integrally formed from the same tube using a laser cutting process. In other embodiments, however, the spring elements **440** and **440'** and/or fixation spine **451** may be separate, discrete components formed from different materials.

**[0044]** In operation, the shunt **400** is configured to operate in an analogous fashion to the shunt **300** described above with respect to FIGS. 3A-3C. In particular, the first and second spring elements **440** and **440'** are configured to be selectively activated by non-invasive energy and, upon activation, slidably move the core element **442** to change the length of a flow path through openings or slits **460** of the inflow control assembly **438**. Referring to FIG. 4B, for example, when the distal spring **440** is expanded/actuated, the core element **442** moves proximally and the length of the core portion **442** inside an uncut portion of the shunt **400** (and the corresponding flow **F** through openings **460** and along flow path **FP** in the inflow control assembly **438**) is at a minimum.

**[0045]** Referring to FIG. 4C, however, when the distal spring **440** is compressed and the proximal spring **440'** is expanded/actuated, the length of the core portion **442** inside the uncut portion (and the corresponding flow **F** along flow path **FP**) is maximized. The disclosed arrangement is expected to provide an effective and predictable way to incrementally increase/decrease flow resistance in a linear fashion via the shunt **400**. In other embodiments, rather than the incremental adjustments in flow rate provided by the shunt **400** shown in FIGS. 4A-4C, the shunt **400** may be configured to provide a binary on/off arrangement via selective actuation of the first and second spring elements **440** and **440'**. Further, in some embodiments, the width and/or shape of the openings/slits **460** can be modified to allow for further control of the flow resistance of the shunt **400**. In yet another embodiment the core pin may be affixed to the proximal end of spring element **440'** and not extend into a flow path. In such an embodiment, the flow path is altered by expanding or compressing the space between the elements of the spring **440** and **440'**. In other embodiments, the shape of the pin and/or the inner lumen can be modified to change allow for a nonlinear control of flow as a function of core travel.

**[0046]** FIGS. 5A-6B illustrate inflow control assemblies configured in accordance with further embodiments of the present technology. Referring first to FIGS. 5A and 5B, for example, inflow control assembly **538** is positioned on or around an external surface of core element **542** at the inflow or inlet region of the drainage tube **527**. Inflow control assembly **538** comprises control element **539** and spring elements **540** fixed thereto and extending in a proximal direction toward the drainage tube **527**. The inflow control assembly **538** further includes an anchor element **510** operably coupled to the spring elements **540** at a proximal region of the inflow control assembly **538**. FIG. 5A illustrates the inflow control assembly **538** in a low or minimum flow configuration in which control element **539** is positioned entirely over or approximately entirely over apertures **541** (FIG. 5B) in the core element **542**. FIG. 5B illustrates the inflow control assembly **538** in a maximum flow configuration in which the spring elements **540** have been actuated. In some embodiments, for example, the spring element **540** may be heated via non-invasive energy (e.g., laser energy), thereby causing the spring elements **540** to bow outwardly and slidably move control element **539** in a proximal direction such that apertures **541** are exposed and fluid can flow therethrough into drainage tube **527**.

**[0047]** FIGS. 6A and 6B illustrate another embodiment of an inflow control assembly **638** configured in accordance with the present technology. In this embodiment, the inflow control assembly **638** includes a control element **639** and

first and second spring elements **640** and **640'** fixed thereto and extending in a proximal direction toward the drainage tube **627**. The first and second spring elements **640** and **640'** have a different configuration than spring elements **540** and **540'** described above with reference to FIGS. **5A** and **5B**. Further, each spring element **640** and **640'** is operably coupled to a corresponding anchor element **610** and **610'**. Because the individual spring elements **640** and **640'** have their own anchor elements **610** and **610'**, respectively, the spring elements **640** and **640'** can be independently set in an initial configuration and independently controlled during operation. As shown in FIG. **6B**, for example, the individual spring elements **640** and **640'** can be actuated (e.g., via heat), thereby causing the spring elements **640** and **640'** to coil more tightly and slidably move control element **639** in a proximal direction along core element **642** and create an open fluid path (to a lumen of drainage tube **627**) via exposed apertures **641**.

**[0048]** In the embodiments shown in in FIGS. **3A-6B**, the inflow ends of the various illustrated shunts are sealed. Such shunts may be delivered via a needle (not shown) traversing a desired flow path (as described above with reference to FIG. **3C**). In other embodiments, however, the inflow end of a shunt may be initially open (such that the shunt can be delivered over a guide wire) and then sealed after delivery and placement.

#### Additional Embodiments of Adjustable Flow Glaucoma Shunts

**[0049]** A collection of additional embodiments of adjustable flow and/or adjustable pressure regulated glaucoma shunts comprising plates are described below with reference to FIGS. **7A-16E**. Such shunts may be implanted as described above and illustrated in FIG. **3C**, or the shunt(s) may be implanted using other suitable techniques and in other suitable locations within the eye. In some of these embodiments, traditional outflow ports are augmented with additional tubes to distribute the aqueous over larger regions of tissue. Outflow tube(s) are covered by at least the conjunctiva. Many of the embodiments of the present technology additionally comprise an adjustable fluid resistor, some of which may additionally comprise an adjustable opening pressure control mechanism. These mechanisms can be adjusted to increase or decrease the outflow resistance and/or opening pressure of the shunt in response to changes in the following: IOP, aqueous production rate, native aqueous outflow resistance, native aqueous outflow rate, and combinations thereof.

**[0050]** FIGS. **7A-7E** illustrate another embodiment of a variable flow shunt **700** configured in accordance with the present technology. FIG. **7A**, for example, is a schematic top view of the shunt **700**, which is configured for minimally invasive placement (like the shunts described above with reference to FIGS. **3A-6B**). The shunt **700** includes an elongated drainage tube **702** having a proximal portion with an inflow port **701** and a distal portion opposite the proximal portion. The shunt **700** differs from the shunts describe above in that fluid resistance of the shunt **700** is selectively controlled by modifying the number of apertures that allow fluid to flow through the inflow port **701**. In some embodiments, for example, the shunt **700** can be configured to allow only for sequential decreases in outflow resistance. In other embodiments, however, the shunt **700** may be configured to selectively allow for both finite decreases and increases in

outflow resistance. Further details regarding the shunt **700** and its operation are described below.

**[0051]** FIG. **7B** is an enlarged, partially schematic cross-sectional view of the shunt **700** taken along line B-B of FIG. **7A**, and FIG. **7C** is an enlarged view of the region C identified in FIG. **7B**. Referring to FIGS. **7B** and **7C** together, the inflow port **701** of the shunt **700** further comprises a variable resistor assembly **720** configured to selectively control flow of fluid into the inflow port (and the outflow port **702**). The variable resistor assembly **720** comprises a membrane **745** disposed on and carried by a standoff plate **746**. The standoff plate **746** is operably coupled to and extends from aperture plate **747**. The aperture plate **747** is carried by a base portion or housing **748** of the shunt **700**.

**[0052]** The aperture plate **747** comprises a plurality of first apertures or first openings **760** extending therethrough. The first apertures **760** have a first cross-sectional dimension  $D_1$  (not shown). The first apertures **760** can be precisely formed so that each opening is identical or nearly identical and all of the first apertures **760** are a predetermined size. The standoff plate **746** comprises a plurality of second apertures or second openings **741** extending therethrough. The second apertures **741** have a second cross-sectional dimension  $D_2$  larger than the first cross-sectional dimension  $D_1$ . As will be described in greater detail below, the second apertures **741** do not need to be as precisely formed as the first apertures **760**. As shown in FIG. **7C**, the membrane **745** completely covers one end (an upper or first end) of each of the second apertures **741**. The opposite end of each second aperture **741** (a second or lower end) is aligned with a corresponding first aperture or first opening **760** extending through the aperture plate **747**.

**[0053]** FIG. **7D** is a top view of the variable resistor assembly **720**. As best seen in FIG. **7D**, the variable resistor assembly **720** further comprises a plurality of target indicia or markers **713** ("targets **713**"). The individual targets **713** correspond to and are aligned with each first aperture **741** (FIG. **7B**). Referring next to FIG. **7E**, after the shunt **700** is implanted within a patient and it is desired to reduce the fluid resistance of the shunt **700**, non-invasive energy (e.g., a surgical laser) can be directed at a selected target **713** on membrane **745**. In embodiments using laser energy, for example, the laser can be activated or fired to selectively ablate the targeted material of the membrane **745**, thereby removing such membrane material and exposing the open end of the corresponding second aperture **741**. Without the membrane blocking the targeted second aperture **741**, fluid can flow therethrough (as shown by the arrow F), and subsequently through the corresponding first aperture **760** and into the outflow drainage tube **702**. If a further reduction in fluid resistance is desired, one or more additional targets **713** on membrane **745** may be ablated to expose additional second apertures **741** and allow additional fluid to flow therethrough to outflow drainage tube **702**.

**[0054]** In the illustrated embodiment, outflow resistance can only be lowered as there is no means of sealing the second apertures **741** of the implanted shunt **700** once the corresponding targeted portions of the membrane **745** are removed to open the second aperture(s) **741** to aqueous flow. In other embodiments, however, there may be techniques to later impede or stop fluid flow by blocking one or more open second apertures **741**. For example, referring to FIGS. **7B** and **7C**, in some embodiments the membrane **745** and standoff plate **746** may be composed, at least in part, from



a hydrophobic material (e.g., a low melting point wax) adapted to be melted by the surgical laser (not shown) at temperatures that will not cause particular harm to the aqueous. In such embodiments, a relatively small, fine beam from the laser source can be used to melt the wax material of the target membrane **754** and open the corresponding second aperture **741**. At a later point in time, if it is desired to slow or limit flow of aqueous, a larger beam from the laser source can be used to melt the wax material of the standoff plate **746**, thereby causing the material to “puddle” or accumulate over the corresponding second aperture **760** within the previously opened second aperture **741** and close or block fluid flow through the first aperture **760**.

**[0055]** In the embodiment illustrated in FIGS. 7A-7E, the components of the variable resistor assembly **720** are separate, discrete components that are operably coupled together before implantation of the shunt **700**. The components may be composed of similar materials, or one or more different materials. In other embodiments, however, the membrane **745** and standoff plate **746** may be fabricated as a single unitary component composed of the same material, such as the example described above in which the membrane **745** and standoff plate **746** comprise a unitary component composed of a hydrophobic material. In other embodiments, however, the integral membrane **745**/standoff plate **746** may be composed of other suitable materials. In still other embodiments, the standoff plate **746** and aperture plate **747** may be fabricated of a single unitary component composed of the same material with the first and second apertures **741** and **760** formed therein. In yet additional embodiments, the aperture plate **747** may be integrally formed with the base portion **748** of the shunt **700**.

**[0056]** FIGS. 8A-9B illustrate additional embodiments of variable flow glaucoma shunt devices configured in accordance with the present technology. In these embodiments, the shunts are configured to be delivered to a target location within an eye capsule of the patient via a guidewire, and then transformed between a delivery configuration and a deployed configuration upon removal of the guidewire. FIG. 8A, for example, illustrates shunt **800** in a delivery configuration on guidewire **W**. The shunt **800** includes an inflow control assembly **838** and an outflow tube or outflow assembly **827**. The inflow control assembly **838** can include several features generally similar to the shunts described above with reference to FIGS. 3A-6B. For example, the shunt **800** includes a control element **839** positioned over one or more apertures or openings **841** (shown in broken lines) extending through a body portion **848** of the inflow control assembly **838**. The aperture(s) **841**, when at least partially exposed, are configured to allow aqueous to flow therethrough and into the outflow tube **827**. The shunt **800** also comprises a pair of adjustable spring elements **840** and **840'** arranged on opposite sides of the control element **839**. The spring elements **840** and **840'** are coupled between the body portion **848** and the control element **839**. In some embodiments, the spring elements **840** and **840'** are composed of a shape memory material (e.g., nitinol) and adapted to expand/contract when heat is applied. For example, applying heat to the first spring element **840** can induce this spring element to coil more tightly, thereby moving the control element **839** toward the first spring element **840** and stretching or expanding the second spring element **840'**. Moving the control element **839** also at least partially

exposes the aperture(s) **841** to allow aqueous to flow there-through similar to the techniques described above with reference to FIGS. 3A-6B.

**[0057]** In the illustrated embodiment, the inflow control assembly **838** is composed of a first material having a first rigidity and the outflow tube **827** is composed of a second material having a second rigidity less than the first rigidity. Referring to FIGS. 8A and 8B together, the shunt **800** may be preshaped prior to implantation such that the shunt **800** includes one or more bends along its length. In the illustrated embodiment, for example, the shunt **800** comprises a generally “L” shaped arrangement and includes a bend or elbow **854** at or near a distal region of the outflow tube **827**.

**[0058]** When the shunt **800** is positioned on guidewire **W** for delivery, the shunt **800** assumes a generally linear, straight delivery configuration. As shown in FIG. 8B, however, when the guidewire **W** is removed, the shunt **800** transforms between its delivery configuration and an expanded/deployed configuration in which the shunt **800** assumes its predetermined “L” shaped arrangement including elbow **865**. This configuration is expected to allow for rapid and reliable delivery of the shunt **800** via guidewire **W**, and enable precise placement of the inflow control assembly **838** within the eye capsule of the patient once the guidewire is removed and the shunt **800** assumes its predetermined shape.

**[0059]** FIGS. 9A and 9B illustrate a shunt **900** configured in accordance with still another embodiment of the present technology. The shunt **900** includes a number of features generally similar to the features of shunt **800**. The shunt **900** differs from shunt **800** in that the shunt **900** is not composed of different materials having different rigidities. Rather, the shunt **900** comprises an inflow portion or region **938** and an outflow portion or outflow tube **927** composed of a single material (e.g., a shape memory material such as nitinol). The shunt **900**, like shunt **800** described above, also includes a preset, generally “L” shaped arrangement and includes a bend or elbow **954**. In this embodiment, however, removing the guidewire **W** does not transform the shunt **900** between its delivery configuration (FIG. 9A) and its deployed/expanded configuration (FIG. 9B). Instead, as best seen in FIG. 9B, once guidewire **W** is removed and the shunt **900** is at a desired location within the patient, a laser source (e.g., an ophthalmic laser—not shown) can be used to direct a laser beam to selectively heat a portion of the shunt **900** and induce the shunt **900** to bend about elbow **954** and return to its preset shape (the generally “L” shaped arrangement).

**[0060]** FIG. 10 illustrates a variable flow shunt device **1000** configured in accordance with yet another embodiment of the present technology. The shunt **1000** comprises an inflow assembly **1001** and an outflow drainage tube **1027** with an outflow port **1002**. The shunt **1000** further comprises an actuatable member **1049** at the outflow end of the outflow port **1002** (opposite the inflow assembly **1001**). The actuatable member **1049** comprises one or more tissue disruption members **1050** (e.g., barbs or other suitable types of devices) to disrupt/disturb tissue at or proximate the outflow end of the outflow port **1001** after the shunt **1000** is implanted within the patient. In one embodiment, the barbs **1050** of the actuatable member **1049** can be moved and actuated by an operator via an externally applied magnetic field to disrupt target tissue adjacent the outflow end of the shunt **1000**. In other embodiments, however, the barbs **1050** may be moved/actuated using other suitable techniques, such as thermally

induced shape changes. Further, it will be appreciated that a different number of barbs **1050** may be used and/or the barbs **1050** may have a different arrangement relative to each other and the actuatable member **1049**.

**[0061]** Many of the embodiments disclosed herein make use of a shape memory material (SMM), such as nitinol, shape memory polymers, and the like, as a control in an adjustable fluid resistor. As noted previously, such fluid resistors allow controlled flow of aqueous from within the anterior chamber of the eye to a location into which the aqueous can diffuse. One such location is within or on top of the sclera posterior to the cornea. In general, SMM elements utilized in the various devices disclosed herein can be repeatedly activated in one direction to increase fluid resistance and in another direction to decrease fluid resistance. In some embodiments, for example, each of multiple activations on targets in one section of the actuation element will incrementally increase the resistance, while multiple activations on targets in another section of the actuation element will incrementally decrease the resistance. When a target is heated above its transition temperature, such as by heating via non-invasive laser energy, the SMM shifts from its larger volume, lower stiffness, low temperature martensite (Mar) form to its high temperature, smaller volume, stiffer austenite form (Aus).

**[0062]** Aus (austenite) 75-83 GPa, smaller volume, high temperature

**[0063]** Mar (martensite) 28-40 GPa, larger volume, low temperature

**[0064]** One such configuration is illustrated in FIGS. 11A-11C, which represents a side view of a ribbon or wire configured in accordance with embodiments of the present technology. Referring first to FIG. 11A, the ribbon has been shape-set in a form comprising multiple uniform folds. As illustrated, there are six folds, but it will be appreciated that in other embodiments ribbons with more or less folds can be used depending on the desired amount of resolution and displacement. Referring next to FIG. 11B, the ribbon can then be mounted between two anchors such that the constrained length is larger than the heat set length. Referring now to FIG. 11C, applying heat to the fold(s) in the portion of SMM heated above its Aus, shifts it from its less stiff, higher volume Mar form to its stiffer and lower volume Aus form. In the illustrated embodiment, the entire SMM component is not allowed to return to its heat set shape even if the entire portion of SMM is heated above the transformation temperature. The unheated portion can expand further to compensate. In addition, heating previously unheated sections is expected to stretch previously unheated and heated sections reversing the mechanism.

**[0065]** FIGS. 12A and 12B illustrate a fluid control element **1201** configured in accordance with another embodiment of the present disclosure. The fluid control element **1201** may be used with any of the variable flow shunts described herein or other suitable shunts. In this embodiment, the fluid control element **1201** comprises variable fluid resistors actuated by SMM elements (like those described above with reference to FIGS. 11A-11C). Referring first to FIG. 12A, fluid control element **1201** comprises a base **1211** and a flow-through drainage tube **1212** carried by and operably coupled to the base **1211**. For example, the flow-through tube **1212** can be fixed to the base **1211** via flow-through anchors **1209**. In other embodiments, however, other suitable techniques may be used to secure the flow-

through tube **1212** to the base **1211**. The flow-through tube **1212** is also operably engaged with an actuator **1218**. In the illustrated embodiment, the actuator **1218** comprises a ribbon or wire composed of SMM and including a plurality of folds. The actuator **1218** has a fixed length and each end of the actuator **1218** is anchored to the base **1211**.

**[0066]** The actuator **1218** may be actuated using techniques similar to those described above with reference to FIGS. 11A-11C. During operation, for example, the tops of the folds along the actuator **518** may be used as target regions to be selectively heated via non-invasive energy (e.g., laser energy) to locally heat such regions along the actuator **518**. As discussed previously with respect to FIGS. 11A-11C, heating folds on one side relative to the other side will allow incremental shifting of resistance (up or down) to modify the state of the actuator **1218**, and thereby change fluid resistance through the flow-through tube **1212**. FIG. 12A, for example, illustrates a low-resistance state of the fluid control element **1201** in which the actuator **1218** is fairly uniform along its length and provides minimal resistance or interference with fluid flow through the flow-through tube **1212**. FIG. 12B illustrates a high resistance state of the fluid control element **1201**. The high resistance state or high resistance position is a result, for example, of multiple actuations via the actuation element **1218** to the flow-through tube **1212**. In particular, heating each of the folds of the actuation element **1218** on the left side of the flow-through tube **1212** above the actuation temperature causes the actuation element **1218** in this region to shrink, thereby “pinching” and compressing the flow-through tube **1212** in this direction and increasing fluid resistance therethrough. When desired, fluid control element **1201** can be transformed again to additional resistance positions or orientations than that shown in FIG. 12B (e.g., back to the state shown in FIG. 12A or a different state) via further manipulation/modulation (e.g., heating selected regions) of actuation element **1218**.

**[0067]** FIGS. 13A and 13B are partially schematic, cross-sectional views of a variable fluid resistor comprising a dual lumen elastomeric tube **1312** configured in accordance with still another embodiment of the present technology. More specifically, FIG. 13A illustrates the elastomeric tube **1312** in an initial or low-resistance state before modulation. The elastomeric tube **1312** comprises a first lumen or a fluid flow-through lumen **1316** having an initial cross-sectional shape (e.g., a “D” shaped lumen). The elastomeric tube **1312** further comprises a second lumen or a control lumen **1336** adjacent the first lumen **1316** and a diaphragm therebetween. The control lumen **1336** contains one or more actuation elements **1318**. In the illustrated embodiment, for example, the actuation element **1318** is composed of SMM and includes a first or expansion portion **1314** and a second or shrinkage portion **1315**. Although only a single actuation element **1318** is shown in the cross-sectional views of FIGS. 13A and 13B, it will be appreciated that in further embodiments multiple actuation elements **618** can be arrayed serially along a length of the elastomeric tube **1312**.

**[0068]** FIG. 13B illustrates the elastomeric tube **1312** in an increased or higher resistance state after activation of the actuation element **1318**. More specifically, non-invasive energy (e.g., heating via laser energy) has been used on expansion portion **1314** of the actuation element **1318**, thereby causing the actuation element **1318** to expand. Such expansion pushes the diaphragm toward the flow-through

lumen 1316 and decreases the cross-sectional dimension of the flow-through lumen 1316. This decrease in size of the flow-through lumen 1316 accordingly increases the fluid resistance through the lumen 1316. The cross-sectional dimension of the flow-through lumen 1316 can be further modified via additional modulation of the actuation element 1318. For example, fluid resistance through the flow-through lumen 1316 can be further decreased by additional heating of the expansion portion 1314 or returned to a lower resistance state via heating of the shrinkage portion 1315.

[0069] In some FIG. 13C illustrates another embodiment of an inflow mounted variable resistor 1320 in accordance with the present technology. In this embodiment, multiple actuation elements 618 can be arrayed serially along a length of control lumen 636 (FIG. 13A). As the expansion portion 1314 of each target actuation element 1318 is actuated, the length of the restricted area is increased thereby increasing the fluid resistance linearly. Likewise, actuating shrinkage portion(s) 1315 of target actuation element(s) 1318 can decrease fluid resistance. As shown in FIG. 13C, such fluid controls can be incorporated into a shunt plate 1303, inflow tube 1305, an outflow mounted variable resistor 1321, and/or the outflow tube (not shown).

[0070] FIG. 13D illustrates a variable fluid resistor configured in accordance with still another embodiment of the present technology. The embodiment shown in FIG. 13D can include a number of features similar to those of the variable fluid resistors described above with reference to FIGS. 13A and 13B. In this embodiment, however, the elastomeric tube 1312 comprises a single fluid flow-through lumen 1316, while an actuation assembly 1322 positioned along the elastomeric tube 1312 comprises a dual-lumen arrangement similar to that described above. In particular, the actuation assembly 1322 comprises a first lumen 1316' having a predetermined cross-sectional shape (e.g., a "D" shaped lumen). The elastomeric tube 1312 is positioned within and extends through the first lumen 1316' of the actuation assembly 1322. The actuation assembly 1322 further comprises a second lumen or a control lumen 1336' adjacent the first lumen 1316'. The control lumen 1336' contains one or more actuation elements 1318 similar to the actuation elements described previously. In this embodiment, for example, the actuation element 1318 is composed of SMM and includes a first or expansion portion 1314 and a second or shrinkage portion 1315.

[0071] Selectively heating the expansion portion 1314 can cause the actuation element 1318 to expand. Like the arrangement described above with reference to FIGS. 13A and 13B, such expansion decreases the cross-sectional dimension of the elastomeric tube 1312 by driving the elastomeric tube 1312 away from the control lumen 1336' and toward fixed inner walls of the first lumen 1316'. By decreasing the cross-sectional dimension of the elastomeric tube 1312, fluid resistance through the tube 1312 is accordingly increased. The fluid resistance through elastomeric tube 1312 can be further decreased by additional heating of the expansion portion 1314, or the elastomeric tube 1312 can be returned to a lower resistance state via heating of the shrinkage portion 1315 of actuation element 1318. Although only a single actuation assembly 1322 is shown, it will be appreciated that in further embodiments multiple actuation assemblies 1322 can be positioned along a length of elastomeric tube 1312.

[0072] FIGS. 13E and 13F are partially schematic, cross-sectional views of a fluid resistor comprising a dual lumen elastomeric tube 1312' configured in accordance with yet another embodiment of the present technology. The fluid resistor in the embodiment illustrated in FIGS. 13E and 13F operates using a similar principle to that described above with reference to FIGS. 13A and 13B. For example, FIG. 13E illustrates the elastomeric tube 1312' in an initial or low-resistance state before modulation. The elastomeric tube 1312' comprises a first lumen or a fluid flow-through lumen 1316' having an initial cross-sectional shape (e.g., a "D" shaped lumen). The elastomeric tube 1312' further comprises a second lumen or a control lumen 1336' adjacent the first lumen 1316'. The control lumen 1336' is filled with a control fluid. Referring next to FIG. 13F, when a volume of control fluid is increased, the cross-sectional dimension of the flow-through lumen 1316' is decreased as an elastomeric diaphragm 1337 expands into the flow-through lumen 1316', thereby increasing fluid resistance and decreasing flow through the lumen 1316'. Likewise, when control fluid is removed from the control lumen 1336', the elastomeric diaphragm 1337 retracts and the cross-sectional dimension of the flow-through channel 1316' is increased, thereby reducing fluid resistance and increasing outflow through the lumen 1316'. Control fluid can be removed or added to the control lumen 1336', for example, using a syringe. In some embodiments, one or more reservoirs (not shown) may be fluidly interfaced with the control lumen 1336' and fluid volume of the control lumen 1336' can be adjusted by adding or removing fluid from the reservoir(s). Further, it will be appreciated that in some embodiments fluid control systems configured in accordance with the present technology may comprise multiple fluid control sealed lumens serially distributed along the length of the control system.

[0073] FIGS. 14A and 14B illustrate yet another embodiment of a SMM-based actuator 1418 configured in accordance with the present technology and adapted for use in an adjustable flow glaucoma shunt. In this embodiment, the actuator 1418 comprises one or more coils 1424 arranged about a periphery of clamping arm 1423. The coil(s) 1424 and clamping arm 1423 may both be composed of SMM. Anchors 1410 are positioned to fixedly hold the actuator 1418 in position on base 1411 such that the clamping arm 1423 is pressed against elastomeric flow-through tube 1412. The elastomeric flow-through tube 1412 can have a stiffness that maintains the outer coils 1424 in a state comparable to the mounted state for the ribbon/wire actuators 1318 described above with reference to FIGS. 12A-13B.

[0074] In operation, sections of the coil(s) 1424 can be selectively actuated to adjust the clamping pressure of the clamping arm 1423 against flow-through tube 1412, and thereby the fluid resistance. Referring to FIG. 14B, for example, coils 1424 on one side (e.g., the right side) of clamping arm 1423 can be heated via laser energy applied at target site 1413. Such heating actuates the selected coils 1424 and causes them to coil more tightly, thereby actuating the clamping arm 1423 to increase pressure and increase resistance on the flow-through tube 1412. Actuation of the coils 1424 on the other side of the clamping arm 1423 (the left side coils) relaxes the clamping arm 1423 and thereby decreases pressure and resistance on the flow-through tube 1412.

[0075] In alternate embodiments, the actuator 1418 can be set in a rest or initial position such that the clamping arm

**1423** completely occludes the flow-through **1412** and the coils **1424** can be selectively adjusted to increase or decrease the tension of the clamping arm **1423** against the base **1411**. The base **1411** accordingly acts as an anvil as the clamping arm **1423** drives the flow-through tube **1412** against it during operation. In some embodiments, such an arrangement may be used to operate an adjustable opening pressure valve (not shown), which is set to selectively control the desired control Intraocular Pressure (IOP). In other embodiments, however, the actuator **1418** may have a different arrangement and/or include different features.

[0076] FIGS. 15A-15C illustrate an adjustable glaucoma shunt **1500** configured in accordance with another embodiment of the present technology and include fluid resistor elements such as those described above with reference to FIGS. 14A and 14B. FIG. 15A, for example, is an exploded view of the shunt **1500**, and FIG. 15B is a top view of the assembled shunt **800**. Referring to FIGS. 15A and 15B together, the shunt **1500** comprises an elastomeric flow-through tube **1512** carried by and operably coupled with control assembly **1519**. The flow-through tube **1512** comprises an inflow region or inflow portion **1505** at one end of the flow-through tube **1512**, and an outflow assembly **1527** including one or more outflow ports **1502** at or near an opposite end of the flow-through tube **1512**.

[0077] The shunt **1500** also includes an actuator **1518** carried by and operably coupled to control assembly **1519**. The actuator **1518** can be similar to the actuator **1418** described above with reference to FIGS. 14A and 14B. In the illustrated embodiment, for example, actuator **1518** includes a clamping arm **1523** operably coupled to and positioned between a plurality of coils **1524**. The coils **1524** (like the coils **1424** described above) can be composed of SMM and adapted to selectively modulate the flow-through tube **1512** to increase/decrease pressure therethrough as described previously.

[0078] In the illustrated embodiment, the shunt **1500** includes a pressure port **1528** and corresponding pressure transducer **1529** configured to be positioned within a pressure transducer housing **1530** on the control assembly **1519**. The pressure port **1528**/pressure transducer **1529** are configured to provide pressure information to a clinician/operator during operation of the shunt **1500**. In other embodiments, the pressure port and/or pressure transducer **1529** may have a different arrangement relative to each other and the other components of the shunt **1500**. Further, the pressure port **1528**/pressure transducer **1529** are optional components that may not be included in some embodiments. In some embodiments, the shunt **1500** may also optionally include a differential port **1526** in the control assembly **1519**.

[0079] The shunt **1500** can further include a plate **1503** configured to be positioned over at least a portion of the control assembly **1518**, flow-through tube **1512**, and actuator **1518**. The plate **1503** can include a window **1531** such that when the shunt **1500** is assembled (as shown in FIG. 15B), the window **1531** provides access to the actuator **1518** and other components carried by the control assembly **1519**.

[0080] FIG. 15C illustrates an implant tool **1534** configured to deliver and position shunt **1500** within an eye capsule of a patient (not shown) in accordance with an embodiment of the present technology. The implant tool **1534** can include, for example, a guide needle **1532** configured to carry the shunt **1500** for delivery, and a guide needle release **1533** that an operator can actuate to release the shunt

**1500** once at a desired position/orientation within the patient. In other embodiments, however, the implant tool **1534** may have a different configuration and/or the shunt **1500** may be delivered using other suitable devices/techniques.

[0081] FIGS. 16A-16E illustrate various features of an adjustable glaucoma shunt **1600** configured in accordance with yet another embodiment of the present technology. The shunt **1600** can include a number of features similar to the shunt **1500** described above with reference to FIGS. 15A-15C. For example, as best seen in FIG. 16A, the shunt **1600** comprises a flow-through tube **1612** having an inflow port or inflow region **1601** at one end, and an outflow port **1602** at an opposite end of the flow-through tube **1612**. The shunt **1600** further comprises a control assembly **1619** configured to modulate flow through the flow-through tube **1612**. The flow-through tube **1612**, control assembly **1619**, and a number of other components of the shunt are carried by plate **1603**.

[0082] The shunt **1600** differs from the shunt **1500**, however, in that the shunt **1600** includes a different system for modulating fluid flow along the flow-through tube **1612**. In particular, rather than the actuator **1518** including the clamping arm **1523**/coils **1524** described previously, the shunt **1600** in the present embodiment comprises an arrangement similar to that described above with reference to FIGS. 13E and 13F. Referring to FIGS. 16B-16D, for example, the control assembly **1629** of shunt **1600** comprises a control fluid **1644** contained within a control fluid chamber **1636** comprising an annular region around a thin walled tubular flow-through channel of tube **1612**. The control fluid chamber **1636** is fluidly isolated from the flow-through channel. A reservoir **1643** is interfaced with and in fluid communication with the control fluid chamber. The reservoir **1643** is configured to provide a larger target for conveniently injecting or removing control fluid **1636** from the system. In operation, control fluid **1644** may be added/removed from the control fluid chamber **1636** to increase/decrease a fluid cross-sectional dimension of an aqueous flow path **1616** through flow-through channel **1612**, thereby decreasing/increasing the corresponding fluid flow therethrough.

[0083] In some embodiments, a solid core may optionally be introduced into flow path **1616** to initially reduce the fluid cross-sectional dimension even further and thereby make the flow path more sensitive to small changes in the diameter of flow-through channel **1612**. In FIG. 16E, for example, optional solid core pin or element **1637** has been introduced into the flow-through channel **1612** and flow path **1616** now has an annular cross-sectional profile.

[0084] In the illustrated embodiment, the shunt **1600** further comprises a pressure transducer **1629**. The pressure transducer **1629** is an optional component that may not be included in some embodiments. Further, it will be appreciated that shunt **1600** may include features other than those described herein and/or the features of shunt **1600** may have a different arrangement relative to each other.

[0085] In many of the embodiments described herein, the actuators or fluid resistors are configured to compress or “pinch” the drainage tube during operation. In this way, the actuators/fluid resistors can incrementally or continuously change the flow resistance through the drainage tube to selectively regulate pressure/flow. The actuators and fluid resistors configured in accordance with the present technology can accordingly adjust the level of resistance or com-

pression between a number of different positions, and accommodate a multitude of variables (e.g., IOP, aqueous production rate, native aqueous outflow resistance, and/or native aqueous outflow rate) to precisely regulate flow rate through the drainage tube.

**[0086]** The disclosed actuators and fluid resistors can all be operated using non-invasive energy. This feature allows such devices to be implanted in the patient and then modified/adjusted over time without further invasive surgeries or procedures for the patient. Further, because the devices disclosed herein may be actuated via non-invasive energy, such devices do not require any additional power to maintain a desired orientation or position. Rather, the actuators/fluid resistors disclosed herein can maintain a desired position/orientation without power. This can significantly increase the usable lifetime of such devices and enable such devices to be effective long after the initial implantation procedure.

#### Operation of Actuation Elements

**[0087]** As described above, the present technology is generally directed to implantable systems and devices for facilitating the flow of fluid between a first body region and a second body region. The devices generally include a drainage and/or shunting element having a lumen extending therethrough for draining or otherwise shunting fluid between the first and second body regions. Further, devices configured in accordance with the present technology may be selectively adjustable to control the amount of fluid flowing between the first and second body regions. In some embodiments, for example, the devices comprise an actuation assembly that drives movement of a flow control element to modulate flow resistance through the lumen, thereby increasing or decreasing the relative drainage rate of fluid between the first body region and the second body region.

**[0088]** In some embodiments of the present technology, the actuation assemblies (e.g., flow control assemblies, flow control mechanisms, fluid resistors, etc.) comprise at least two actuation elements coupled to a moveable element (e.g., an arm, a spring element, etc.). The moveable element can be formed to interface with (e.g., at least partially block) a corresponding port. The port can be an inflow port or an outflow port. In other embodiments, the moveable element can be an intermediate element between the actuation element and a flow control element that interfaces with or otherwise engages a shunt lumen or orifice. In such embodiments, movement of the moveable element can adjust a geometry of the flow control element, which in turn adjusts a size, shape, or other dimension of a shunt lumen or orifice. Movement of the actuation elements generates (e.g., translational and/or rotational) movement of the moveable element.

**[0089]** The actuation element(s) can include a shape memory material (e.g., a shape memory alloy, or a shape memory polymer), and movement of the actuation element(s) can be generated through applied stress and/or use of a shape memory effect (e.g., as driven by a change in temperature). The shape memory effect enables deformations that have altered an element from its shape-set geometric configuration to be largely or entirely reversed during operation of the actuation assembly. For example, thermal actuation (heating) can reverse deformation(s) by inducing a change in state (e.g., phase change) in the actuator material, inducing a temporary elevated internal stress that promotes

a shape change toward the original shape-set geometric configuration. For a shape memory alloy, the change in state can be from a martensitic phase (alternatively, R-phase) to an austenitic phase. For a shape memory polymer, the change in state can be via a glass transition temperature or a melting temperature. The change in state can reverse deformation(s) of the material—for example, deformation with respect to its original geometric configuration—without any (e.g., externally) applied stress to the actuation element. That is, a deformation that is present in the material at a first temperature (e.g., body temperature) can be (e.g., thermally) recovered and/or altered by raising the material to a second (e.g., higher) temperature. Upon cooling (and changing state, e.g., back to martensitic phase), the actuation element retains its shape-set geometric configuration. With the material in this relatively cooler-temperature condition it may require a lower force or stress to thermoelastically deform the material, and any subsequently applied external stress can cause the actuation element to once again deform away from the original geometric configuration.

**[0090]** The actuation element(s) can be processed such that a transition temperature at which the change in state occurs (e.g., the austenite start temperature, the austenite final temperature, etc.) is above a threshold temperature (e.g., body temperature). For example, the transition temperature can be set to be about 45 deg. C., about 50 deg. C., about 55 deg. C., or about 60 deg. C. In some embodiments, the actuator material is heated from body temperature to a temperature above the austenite start temperature (or alternatively above the R-phase start temperature) such that an upper plateau stress (e.g., “UPS\_body temperature”) of the material in a first state (e.g., thermoelastic martensitic phase, or thermoelastic R-phase at body temperature) is lower than an upper plateau stress (e.g., “UPS\_actuated temperature”) of the material in a heated state (e.g., superelastic state), which achieves partial or full free recovery. For example, the actuator material can be heated such that UPS\_actuated temperature > UPS\_body temperature. In some embodiments, the actuator material is heated from body temperature to a temperature above the austenite start temperature (or alternatively above the R-phase start temperature) such that an upper plateau stress of the material in a first state (e.g., “thermoelastic martensite or thermoelastic R-phase at body temperature”) is lower than a lower plateau stress (e.g., “LPS”) of the material in a heated state (e.g., superelastic state), which achieves partial or full free recovery. For example, the actuator material can be aged such that LPS\_activated temperature > UPS\_body temperature. In some embodiments, the actuator material is heated from body temperature to a temperature above the austenite start temperature (or alternatively above the R-phase start temperature) such that an upper plateau stress of the material in a first state (e.g., thermoelastic martensite or thermoelastic R-phase) is higher than a lower plateau stress of the material in a heated state, which achieves partial free recovery. For example, the actuator material can be aged such that LPS\_activated temperature < UPS\_body temperature.

**[0091]** The actuation assembly can be formed such that the actuation elements have substantially the same heat set shape (e.g., memory shape, or length,  $L_0$ ). The actuation assembly can be assembled such that, upon introduction into a patient (e.g., implantation), at least one (e.g., a first) actuation element/shape memory element has been deformed with respect to its memory shape (e.g., to have

$L_1 \neq L_0$ ), while at least one other opposing (e.g., a second) actuation element/shape memory element positioned adjacent to the first actuation element is substantially at its memory shape (e.g.,  $L_0$ ). In other embodiments, however, both the first and second actuation elements may be deformed with respect to their corresponding memory shapes upon introduction into the patient (e.g., the first actuation element is contracted relative to its memory shape and the second actuation element is expanded).

[0092] In some embodiments of the present technology,  $L_1 > L_0$ —for example, the deformed first actuation element is elongated with respect to its shape memory length. In some embodiments,  $L_1 < L_0$ —for example, the deformed first actuation element is compressed with respect to its shape memory length. The actuation assembly can be formed such that, in operation, its overall dimension (e.g., overall length) is substantially fixed (e.g.,  $L_0 + L_1 = \text{a constant}$ ). For example, (e.g., outermost) ends of the actuation elements can be fixed, such that movement of the actuation elements occurs between the points of fixation. The overall geometry of the actuation elements, along with the lengths, can be selected such that, in operation, deformation within the actuation elements remains below about 10%, about 9%, about 8%, about 7%, or about 6%.

[0093] The (e.g., first and second) actuation elements are arranged such that a movement (e.g., deflection or deformation) of the first actuation element/first shape memory element is accompanied by (e.g., causes) an opposing movement of the second actuation element/second shape memory element. The movement can be a deflection or a deformation. In operation, selective heating of the first actuation element of the actuation assembly causes it to resume its memory shape (e.g., revert from  $L_1$  to  $L_0$ ), moving the coupled moveable element. At the same time, the elongation of the first actuation element is accompanied by (e.g., causes) a compression of the second actuation element (e.g., from  $L_0$  to  $L_1$ ). The second actuation element is not heated (e.g., remains at body temperature), and therefore the second actuation element deforms (e.g., remains martensitic and compresses) without (e.g., superelastic) recovery. The first actuation element cools following heating, and returns to a state in which it can be plastically deformed. To reverse the configuration of the actuation assembly (e.g., the position of the moveable element), the second actuation element is heated to return to its memory shape (e.g., from  $L_1$  to  $L_0$ ). The return of the second actuation element to its memory shape causes the moveable element to move back to its prior position, and compresses the first actuation element (e.g., from  $L_0$  to  $L_1$ ). The position of the moveable element for the actuation assembly can be repeatably toggled (e.g., between open and closed) by repeating the foregoing operations. The heating of an actuation element can be accomplished via application of incident energy (e.g., via a laser or inductive coupling). Further, as mentioned above, the source of the incident energy may be external to the patient (e.g., non-invasive).

[0094] FIGS. 17A-17D illustrate an embodiment of an actuation assembly 1700 configured in accordance with select embodiments of the present technology. The actuation assembly 1700 is configured for use with a system or device for shunting, draining, or otherwise moving fluid from a first body region or chamber to a second body region or chamber. Referring collectively to FIGS. 17A-17D, the actuation assembly 1700 can include a first actuation element 1701

and a second actuation element 1702. The first actuation element 1701 can extend between a moveable element 1703 and a first anchoring element 1704. The second actuation element 1702 can extend between the moveable element 1703 and a second anchoring element 1704. The first anchoring element 1704 and the second anchoring element 1705 can be secured to a generally static component of the system or device for shunting fluid (not shown). In other embodiments, the first anchoring element 1704 and/or the second anchoring element 1705 can be omitted and the first actuation element 1701 and/or the second actuation element 1702 can be secured directly to a portion of the device or system for shunting fluid (not shown). As provided above, the moveable element 1703 can be formed to interface with (e.g., at least partially block) a corresponding port on the system or device (not shown). In other embodiments, the moveable element 1703 can be an intermediate element to drive a flow control element (not shown) that interfaces with or otherwise engages a lumen or orifice of the device or system for shunting fluid (not shown). In any of these embodiments, selectively modifying fluid flow through the shunt occurs without damaging or otherwise negatively affecting tissue of the patient.

[0095] The first actuation element 1701 and the second actuation element 1702 can be composed of a shape memory material, such as a shape memory alloy (e.g., nitinol). Accordingly, the first actuation element 1701 and the second actuation element 1702 can be transitionable between a first state (e.g., a martensitic state, a R-phase, etc.) and a second state (e.g., a shape memory state, an austenitic state, etc.). In the first state, the first actuation element 1701 and the second actuation element 1702 may be deformable (e.g., plastic, malleable, compressible, expandable, etc.). In the second state, the first actuation element 1701 and the second actuation element 1702 may have a preference toward a specific original shape (e.g., geometry, length, and/or dimension). The first actuation element 1701 and the second actuation element 1702 can be transitioned between the first state and the second state by applying energy (e.g., heat) to the actuation elements to heat the actuation elements above a transition temperature. In some embodiments, the transition temperature for both the first actuation element 1701 and the second actuation element 1702 is above an average body temperature. Accordingly, both the first actuation element 1701 and the second actuation element 1702 are typically in the deformable first state when the device 1700 is implanted in the body until they are heated (e.g., actuated).

[0096] If an actuation element (e.g., the first actuation element 1701) is deformed relative to its original shape while in the first state, heating the actuation element (e.g., the first actuation element 1701) above its transition temperature causes the actuation element to transition to the second state and therefore transition from the deformed shape to the original shape. Heat can be applied to the actuation elements via an energy source positioned external to the body (e.g., a laser), RF heating, resistive heating, or the like. In some embodiments, the first actuation element 1701 can be selectively heated independently of the second actuation element 1702, and the second actuation element 1702 can be selectively heated independently of the first actuation element 1701.

[0097] Referring to FIG. 17A, the first actuation element 1701 and the second actuation element 1702 are shown in a state before being secured to the first and second anchoring

elements. In particular, the first actuation element **1701** and the second actuation **1702** are in their unbiased original shapes (e.g., memory shape, heat set shape, etc.). In the illustrated embodiment, the first actuation element **1701** has an original shape having a length  $L_{x1}$ , and the second actuation element **1702** has an original shape having a length  $L_{y1}$ . In some embodiments,  $L_{x1}$  is equal to  $L_{y1}$ . In other embodiments,  $L_{x1}$  is less than or greater than (i.e., not equal to)  $L_{y1}$ .

[0098] FIG. 17B illustrates the device **1700** in a first (e.g., composite) configuration after the first actuation element **1701** has been secured to the first anchoring element **1704**, and the second actuation element **1702** has been secured to the second anchoring element **1705**. In the first configuration, both the first actuation element **1701** and the second actuation element **1702** are at least partially deformed relative to their original shape. For example, the first actuation element **1701** is compressed (e.g., shortened) relative to its original shape (FIG. 17A) such that it assumes a second length  $L_{x2}$  that is less than the first length  $L_{x1}$ . Likewise, the second actuation element **1702** is also compressed (e.g., shortened) relative to its original shape (FIG. 17A) such that it assumes a second length  $L_{y2}$  that is less than the first length  $L_{y1}$ . In the illustrated embodiment,  $L_{x1}$  is equal to  $L_{y1}$ , although in other embodiments  $L_{x1}$  can be less than or greater than (i.e., not equal to)  $L_{y1}$ . In other embodiments, the first actuation element **1701** and/or the second actuation element **1702** are stretched (e.g., lengthened) relative to their original shape before being secured to the anchoring elements. For example, in some embodiments, the first actuation element **1701** is compressed (e.g., shortened) relative to its original shape and the second actuation element **1702** is stretched (e.g., lengthened) relative to its original shape. In some embodiments, only one of the actuation elements (e.g., the first actuation element **1701**) is deformed relative to its original shape, and the other actuation element (e.g., the second actuation element **1702**) retains its original shape.

[0099] FIG. 17C illustrates the device **1700** in a second configuration different than the first configuration. In particular, in the second configuration, the device **1700** has been actuated relative to the first configuration shown in FIG. 17B to transition the first actuation element **1701** from the first (e.g., martensitic) state to the second (e.g., austenitic) state. Because the first actuation element **1701** was deformed (e.g., compressed) relative to its original shape while in the first configuration, heating the first actuation element **1701** above its transition temperature causes the first actuation element **1701** to assume its original shape having a length  $L_{x1}$  (FIG. 17A). As described above, the first anchoring element **1704** and the second anchoring element **1705** are fixedly secured to a generally static structure (e.g., such that a distance between the first anchoring element **1704** and the second anchoring element **1705** does not change during actuation of the first actuation element **1701**). Accordingly, as the first actuation element **1701** increases in length toward its original shape, the second actuation element **1702**, which is unheated and therefore remains in the generally deformable (e.g., martensitic) state, is further compressed to a length  $L_{y3}$  that is less than  $L_{y1}$  and  $L_{y2}$ . In the illustrated embodiment, this moves the moveable element away from the first anchoring element **1704** and towards the second anchoring element **1705**.

[0100] FIG. 17D illustrates the device **1700** in a third configuration different than the first configuration and the

second configuration. In particular, in the third configuration the device **1700** has been actuated relative to the second configuration shown in FIG. 17C to transition the second actuation element **1702** from the first (e.g., martensitic) state to the second (e.g., austenitic) state. Because the second actuation element **1702** was deformed (e.g., compressed) relative to its original shape while in the second configuration, heating the second actuation element **1702** above its transition temperature causes the second actuation element **1702** to assume its original shape having a length  $L_{y1}$  (FIG. 17A). As described above, the first anchoring element **1704** and the second anchoring element **1705** are fixedly secured to a generally static structure (e.g., such that the distance between the first anchoring element **1704** and the second anchoring element **1705** does not change during actuation of the second actuation element **1702**). Accordingly, as the second actuation element **1702** increases in length toward its original shape, the first actuation element **1701**, which is unheated and therefore remains in the generally deformable (e.g., martensitic) state, is further deformed (e.g., compressed) relative to its original shape to a length  $L_{x3}$  that is less than  $L_{x1}$  and  $L_{x2}$ . In the illustrated embodiment, this moves the moveable element **1703** away from the second anchoring element **1705** and towards the first anchoring element **1704** (e.g., generally opposite the direction the moveable element **1703** moves when the first actuation element **1701** is actuated).

[0101] The device **1700** can be repeatedly transitioned between the second configuration and the third configuration. For example, the device **1700** can be returned to the second configuration from the third configuration by heating the first actuation element **1701** above its transition temperature once the second actuation element **1702** has returned to the deformable first state (e.g., by allowing the second actuation element **1702** to cool below the transition temperature). Heating the first actuation element **1701** above its transition temperature causes the first actuation element **1701** to assume its original shape, which in turn pushes the moveable element **1703** back towards the second anchoring element **1705** and transitions the device **1700** to the second configuration (FIG. 17C). Accordingly, the device **1700** can be selectively transitioned between a variety of configurations by selectively actuating either the first actuation element **1701** or the second actuation element **1702**. After actuation, the device **1700** can be configured to substantially retain the given configuration until further actuation of the opposing actuation element. In some embodiments, the device **1700** can be transitioned to intermediate configurations between the second configuration and the third configuration (e.g., the first configuration) by heating a portion of the first actuation element **1701** or the second actuation element **1702**.

[0102] As provided above, heat can be applied to the actuation elements via an energy source positioned external to the body (e.g., a laser), RF heating, resistive heating, or the like. In some embodiments, the first actuation element **1701** can be selectively heated independently of the second actuation element **1702**, and the second actuation element **1702** can be selectively heated independently of the first actuation element **1701**. For example, in some embodiments, the first actuation element **1701** is on a first electrical circuit and/or responds to a first frequency range for selectively and resistively heating the first actuation element **1701** and the second actuation element **1702** is on a second

electrical circuit and/or responds to a second frequency range for selectively and resistively heating the second actuation element **1702**. As described in detail above, selectively heating the first actuation element **1701** moves the moveable element **1703** in a first direction and selectively heating the second actuation element **1702** moves the moveable element **1703** in a second direction generally opposite the first direction.

#### EXAMPLES

**[0103]** Several aspects of the present technology are set forth in the following examples.

**[0104]** 1. An adjustable flow shunt for treating glaucoma in a human patient, the shunt comprising:

**[0105]** an elongated outflow drainage tube having a proximal inflow region and a distal outflow region; and

**[0106]** an inflow control assembly at the proximal inflow region, wherein the inflow control assembly comprises—

**[0107]** a control element sized and shaped to slidably engage the proximal inflow region; and

**[0108]** a spring element operably coupled between the control element and an anchor element engaged with the proximal inflow region;

**[0109]** wherein the proximal inflow region comprises one or more apertures defining a fluid inlet area positioned to allow fluid to flow therethrough and into the outflow drainage tube,

**[0110]** wherein the spring element is configured to be activated by a non-invasive energy and, upon activation, slidably actuate the control element along the proximal inflow region such that (a) the one or more apertures are accessible and have a first fluid flow cross-section or (b) the one or more apertures are at least partially covered by the control element and have a second fluid-flow cross-section less than the first fluid flow cross-section.

**[0111]** 2. The adjustable flow shunt of example 1 wherein the proximal inflow region comprises a core element operably coupled to and extending from a proximal end of the outflow drainage tube, and wherein the one or more apertures extend through a sidewall of the core element to define the fluid inlet area.

**[0112]** 3. The adjustable flow shunt of example 2 wherein the core element is composed of a different material than the outflow drainage tube.

**[0113]** 4. The adjustable flow shunt of example 2 wherein the core element is composed of a first material having a first rigidity, and wherein the outflow drainage tube is composed of a second material having a second rigidity less than the first rigidity.

**[0114]** 5. The adjustable flow shunt of example 2 wherein the core element is composed of polyether ether ketone (PEEK), acrylic, polycarbonate, metal, ceramic, quartz, and/or sapphire.

**[0115]** 6. The adjustable flow shunt of any one of examples 1-5 wherein the elongated outflow drainage tube is composed of silicone and/or urethane.

**[0116]** 7. The adjustable flow shunt of any one of examples 1-6 wherein the spring element is composed of a shape memory material.

**[0117]** 8. The adjustable flow shunt of any one of examples 1-6 wherein the spring element is composed of nitinol.

**[0118]** 9. The adjustable flow shunt of any one of examples 1-8 wherein the inflow control assembly is configured for placement within an anterior chamber in a region outside of the optical field of view of the eye.

**[0119]** 10. The adjustable flow shunt of example 9 wherein the outflow drainage tube is sized and shaped to traverse a region between the anterior chamber to a region in a suprachoroidal location of the eye.

**[0120]** 11. The adjustable flow shunt of example 9 wherein the outflow drainage tube is sized and shaped to traverse a region between the anterior chamber to a region in a subconjunctival location of the eye.

**[0121]** 12. The adjustable flow shunt of any one of examples 1-11 wherein the one or more apertures comprises a single elongated slot extending axially along the proximal inflow region.

**[0122]** 13. The adjustable flow shunt of any one of examples 1-11 wherein the one or more apertures comprises a plurality of apertures extending radially about the proximal inflow region.

**[0123]** 14. The adjustable flow shunt of any one of examples 1-11 wherein the one or more apertures comprises a plurality of apertures extending helically about the proximal inflow region.

**[0124]** 15. The adjustable flow shunt of any one of examples 1-14 wherein the spring element is configured to be activated via laser energy.

**[0125]** 16. The adjustable flow shunt of any one of examples 1-15 wherein the spring element comprises a first spring and the anchor comprises a first anchor, and wherein the first spring and first anchor are positioned on a first side of the control element, and wherein the inflow control assembly further comprises:

**[0126]** a second spring and a corresponding second anchor on a second, opposite side of the control element;

**[0127]** wherein the first and second spring elements are configured to be selectively activated by non-invasive energy and, upon activation, slidably move the control element along the proximal inflow region in a first direction or a second direction, respectively, such that (a) the one or more apertures have the first fluid flow cross-section, or (b) the one or more apertures are at least partially covered by the control element and have the second fluid-flow cross-section less than the first fluid flow cross-section.

**[0128]** 17. The adjustable flow shunt of example 16 wherein the first and second spring elements are configured such that, upon activation, the control element slidably moves the control element along the proximal inflow region such that the one or more apertures are fully covered and inaccessible.

**[0129]** 18. The adjustable flow shunt of any one of examples 1-15 wherein the spring element and corresponding anchor element are positioned on a proximal end of the control element between the control element and the outflow drainage tube.

**[0130]** 19. The adjustable flow shunt of any one of examples 1-15 wherein the spring element comprises one or more coil springs extending about the proximal inflow region.

**[0131]** 20. The adjustable flow shunt of any one of examples 1-15 wherein the spring element comprises one or



more elongated bow springs extending between the control element and the anchor element.

[0132] 21. An adjustable flow shunt assembly for treatment of glaucoma, the shunt assembly comprising:

[0133] an elongated drainage tube having a proximal portion and a distal portion, wherein the proximal portion includes an inflow port configured to be in fluid communication with a fluid chamber in an eye of the patient;

[0134] a variable resistor assembly configured to selectively control flow of fluid into the inflow port, wherein the variable resistor assembly comprises a base portion;

[0135] an aperture plate carried by the base portion, wherein the aperture plate comprises a plurality of first apertures extending therethrough;

[0136] a standoff plate carried by and extending away from the aperture plate, wherein the standoff plate comprises a plurality of second apertures extending therethrough, and wherein the second apertures are aligned with corresponding first apertures of the aperture plate; and

[0137] a membrane disposed on a carried by the standoff plate, wherein the membrane is positioned to sealably cover an open end of each of the second apertures;

[0138] wherein, during operation, a portion of the membrane over one or more second apertures of the standoff plate is configured to be selectively targeted and removed via non-invasive energy, thereby creating a fluid path from the site of fluid in the patient through the accessible open ends of the targeted second apertures, the corresponding first apertures, and into the drainage tube.

[0139] 22. The adjustable flow shunt assembly of example 21 wherein:

[0140] the first apertures have a first cross-sectional dimension; and

[0141] the second apertures have a second cross-sectional dimension greater than the first cross-sectional dimension.

[0142] 23. The adjustable flow shunt assembly of example 21 wherein the first apertures have identical cross-sectional dimensions.

[0143] 24. The adjustable flow shunt assembly of any one of examples 21-23 wherein the standoff plate is composed, at least in part, of a hydrophobic material configured to be at least partially melted via non-invasive energy.

[0144] 25. The adjustable flow shunt assembly of any one of examples 21-23 wherein the standoff plate is composed, at least in part, of a wax material configured to be at least partially melted via non-invasive energy.

[0145] 26. The adjustable flow shunt assembly of any one of examples 21-23 wherein the base portion, aperture plate, and standoff plate of the variable resistor assembly are separate, discrete components operably coupled together.

[0146] 27. The adjustable flow shunt assembly of any one of examples 21-23 wherein the standoff plate and membrane are fabricated as a single, unitary component composed of the same material.

[0147] 28. The adjustable flow shunt assembly of any one of examples 21-23 wherein the aperture plate and standoff plate are fabricated as a single, unitary component composed of the same material.

[0148] 29. The adjustable flow shunt assembly of any one of examples 21-28 wherein:

[0149] the membrane further comprises a plurality of target indicia aligned with and corresponding with individual second apertures; and

[0150] during operation, the non-invasive energy is delivered to corresponding target indicia of the membrane to selectively remove membrane material at the targeted location.

[0151] 30. An adjustable flow shunt for treatment of glaucoma in a human patient, the adjustable flow shunt comprising:

[0152] an elongated outflow tube having (a) a proximal inflow portion configured for placement within an anterior chamber in a region outside of an optical field of view of an eye of the patient, and (b) a distal outflow portion at a different location of the eye; and

[0153] an actuator positioned along the outflow tube between the inflow portion and the outflow portion, wherein the actuator is transformable between an open position that allows fluid to flow through the outflow tube and resistance positions that partially obstruct fluid flow through the outflow tube,

[0154] wherein during operation, the actuator is movable between positions in response to non-invasive energy.

[0155] 31. The adjustable flow shunt of example 30 wherein the actuator is configured to partially obstruct fluid flow through the outflow tube in the resistance positions by engaging the outflow tube and changing a diameter and/or a cross-sectional shape of the outflow tube.

[0156] 32. The adjustable flow shunt of example 30 or example 31 wherein the actuator is movable between positions in response to laser energy.

[0157] 33. The adjustable flow shunt of example 30 wherein:

[0158] the outflow tube comprises a dual lumen tube having a first lumen for carrying fluid therethrough and a second lumen adjacent to the first lumen and separated by the first lumen by a diaphragm;

[0159] the actuator is positioned within the second lumen, and wherein the actuator comprises one or more actuation elements configured to transform between an expanded state and an initial state in response to the non-invasive energy,

[0160] in the expanded state, actuation elements engage and push the diaphragm toward the first lumen and decrease a cross-sectional dimension thereof.

[0161] 34. The adjustable flow shunt of any one of examples 30-33 wherein the actuator is configured to hold the open position or one of the resistance positions without power.

[0162] 35. An adjustable flow shunt, comprising:

[0163] an elongated outflow tube having a proximal inflow portion configured for placement at a first location within an eye of the patient, and a distal outflow portion at a second location of the eye spaced apart from the first location,

[0164] wherein the outflow tube comprises a dual lumen tube having a first lumen for carrying fluid therethrough and a second lumen adjacent to the first lumen and fluidly isolated from the first lumen; and

[0165] a control fluid disposed within the second lumen,

[0166] and wherein, during operation—

- [0167] increasing a volume of control fluid within the second lumen decreases a cross-sectional dimension of the first lumen, thereby partially obstructing fluid flow through the first lumen, and
- [0168] decreasing a volume of control fluid within the second lumen increases a cross-sectional dimension of the first lumen, thereby increasing fluid flow through the first lumen.
- [0169] 36. The adjustable flow shunt of example 35 wherein the elongated outflow tube comprises an elastomeric tube.
- [0170] 37. The adjustable flow shunt of example 35 or example 36, further comprising a reservoir in fluid communication with the second lumen, and wherein the volume of control fluid within the second lumen is changed by transferring control fluid to and/or from the reservoir.
- [0171] 38. The adjustable flow shunt of any one of examples 35-37 wherein the volume of control fluid within the second lumen is changed by transferring control fluid to and/or from the second lumen via a syringe.
- [0172] 39. The adjustable flow shunt of any one of examples 35-38 wherein the first lumen is separated from the second lumen by a diaphragm, and wherein:
- [0173] increasing a volume of control fluid within the second lumen moves the diaphragm toward the first lumen and decreases a cross-sectional dimension thereof; and
- [0174] decreasing a volume of control fluid within the second lumen moves the diaphragm away from the first lumen and increases a cross-sectional dimension thereof.
- [0175] 40. A shunt for treatment of glaucoma in a human patient, the shunt comprising:
- [0176] an elongated outflow drainage tube having a proximal inflow region and a distal outflow region;
- [0177] an inflow control assembly at the proximal inflow region; and
- [0178] a transition region along the outflow tube between the inflow region and the outflow region, wherein, during operation, the transition region is transformable between a first generally linear delivery shape and a second shape different than the first shape to anchor the shunt at a desired location of the eye.
- [0179] 41. The shunt of example 40 wherein the outflow drainage tube is configured to be delivered via guidewire, and wherein the transition region is configured to transform between the first delivery shape and the second shape upon removal of the guidewire.
- [0180] 42. The shunt of example 40 or example 41 wherein the transition region is configured to transform between the first delivery shape and the second shape upon application of non-invasive energy to one or more selected areas of the transition region.
- [0181] 43. The shunt of example 40 or example 41 wherein the transition region is configured to transform between the first delivery shape and the second shape in response to application of non-invasive laser energy to one or more selected areas of the transition region.
- [0182] 44. The shunt of any one of examples 40-43 wherein the second shape comprises a generally "L" shaped configuration.

## CONCLUSION

[0183] The above detailed description of embodiments of the technology are not intended to be exhaustive or to limit the technology to the precise form disclosed above. Although specific embodiments of, and examples for, the technology are described above for illustrative purposes, various equivalent modifications are possible within the scope of the technology as those skilled in the relevant art will recognize. For example, any of the features of the variable flow shunts described herein may be combined with any of the features of the other variable flow shunts described herein and vice versa. Moreover, although steps are presented in a given order, alternative embodiments may perform steps in a different order. The various embodiments described herein may also be combined to provide further embodiments.

[0184] From the foregoing, it will be appreciated that specific embodiments of the technology have been described herein for purposes of illustration, but well-known structures and functions associated with variable flow shunts have not been shown or described in detail to avoid unnecessarily obscuring the description of the embodiments of the technology. Where the context permits, singular or plural terms may also include the plural or singular term, respectively.

[0185] Moreover, unless the word "or" is expressly limited to mean only a single item exclusive from the other items in reference to a list of two or more items, then the use of "or" in such a list is to be interpreted as including (a) any single item in the list, (b) all of the items in the list, or (c) any combination of the items in the list. Additionally, the term "comprising" is used throughout to mean including at least the recited feature(s) such that any greater number of the same feature and/or additional types of other features are not precluded. It will also be appreciated that specific embodiments have been described herein for purposes of illustration, but that various modifications may be made without deviating from the technology. Further, while advantages associated with some embodiments of the technology have been described in the context of those embodiments, other embodiments may also exhibit such advantages, and not all embodiments need necessarily exhibit such advantages to fall within the scope of the technology. Accordingly, the disclosure and associated technology can encompass other embodiments not expressly shown or described herein.

1-39. (canceled)

40. An actuator assembly for selectively modifying fluid flow through a shunt configured to be implanted in a human patient, the actuator assembly comprising:

- a first actuation element selectively transitionable between a first material state and a second material state, wherein in the second material state the first actuation element has a preference toward a first shape set geometry;
- a second actuation element operably coupled to the first actuation element and selectively transitionable between a third material state and a fourth material state, wherein in the fourth material state the second actuation element has a preference toward a second shape set geometry,

wherein, when the first actuation element is deformed relative to the first shape set geometry, transitioning the first actuation element from the first material state to the second material state moves the first actuation element toward the first shape set geometry and at least

partially deforms the second actuation element relative to the second shape set geometry, and wherein, when the second actuation element is deformed relative to the second shape set geometry, transitioning the second actuation element from the third material state to the fourth material state moves the second actuation element toward the second shape set geometry and at least partially deforms the first actuation element relative to the first shape set geometry.

41. The actuator assembly of claim 40 wherein the first actuation element and the second actuation element are composed of a shape memory material.

42. The actuator assembly of claim 40 wherein the first material state comprises a martensitic phase or an R-phase.

43. The actuator assembly of claim 40 wherein the second material state comprises an R-phase or an austenitic phase.

44. The actuator assembly of claim 40 wherein the actuator assembly comprises a unitary structure.

45. The actuator assembly of claim 40 wherein the actuator assembly is configured such that a combined length of the first actuation element and the second actuation element remains the same or about the same (a) in response to the first actuation element transitioning from the first material state to the second material state, and (b) in response to the second actuation element transitioning from the third material state to the fourth material state.

46. The actuator assembly of claim 40 wherein the actuator assembly is sized and shaped for use within an intraocular shunt configured to be implanted within a patient's eye.

47. An actuator assembly for selectively modifying fluid flow through a shunt configured to be implanted in a human patient, the actuator assembly comprising:

- a first actuation element selectively transitionable between a first material state and a second material state, wherein in the second material state the first actuation element has a preference toward a first shape set geometry;

- a second actuation element operably coupled to the first actuation element and selectively transitionable between a third material state and a fourth material state, wherein in the fourth material state the second actuation element has a preference toward a second shape set geometry,

wherein, when the first actuation element is deformed relative to the first shape set geometry, transitioning the first actuation element from the first material state to the second material state moves the first actuation element toward the first shape set geometry, and

wherein, when the second actuation element is deformed relative to the second shape set geometry, transitioning the second actuation element from the third material state to the fourth material state moves the second actuation element toward the second shape set geometry.

48. The actuator assembly of claim 47 wherein the first actuation element and the second actuation element are composed of a shape memory material.

49. The actuator assembly of claim 47 wherein the first material state comprises a martensitic phase or an R-phase, and wherein the second material state comprises an R-phase or an austenitic phase

50. The actuator assembly of claim 47 wherein the actuator assembly comprises a unitary structure composed of the same material.

51. The actuator assembly of claim 50 wherein the unitary structure is composed of Nitinol.

52. The actuator assembly of claim 46 wherein the actuator assembly is sized and shaped for use within an intraocular shunt configured to be implanted within a patient's eye.

53. An actuator assembly for selectively modifying fluid flow through a shunt configured to be implanted in a human patient, the actuator assembly comprising:

- a control element;

- a first actuation element coupled to the control element and selectively transitionable between a first material state and a second material state, wherein in the second material state the first actuation element has a preference toward a first shape set geometry;

- a second actuation element coupled to the control element and selectively transitionable between a third material state and a fourth material state, wherein in the fourth material state the second actuation element has a preference toward a second shape set geometry,

wherein, when the first actuation element is deformed relative to the first shape set geometry, transitioning the first actuation element from the first material state to the second material state moves the first actuation element toward the first shape set geometry and moves the control element in a first direction, and

wherein, when the second actuation element is deformed relative to the second shape set geometry, transitioning the second actuation element from the third material state to the fourth material state moves the second actuation element toward the second shape set geometry and moves the control element in a second direction, different than the first direction.

54. The actuator assembly of claim 53 wherein:

- the first actuation element comprises a first fixed end and a second end disposed from the first fixed end and coupled to the control element; and

- the second actuation element comprises a first fixed end and a second end disposed from the first fixed end and coupled to the control element.

55. The actuator assembly of claim 53 wherein the first actuation element and the second actuation element are composed of a shape memory material.

56. The actuator assembly of claim 53 wherein the first material state comprises a martensitic phase or an R-phase, and wherein the second material state comprises an R-phase or an austenitic phase.

57. The actuator assembly of claim 53 wherein the actuator assembly comprises a unitary structure.

58. The actuator assembly of claim 57 wherein the unitary structure is composed of Nitinol.

59. The actuator assembly of claim 57 wherein the actuator assembly is sized and shaped for use within an intraocular shunt configured to be implanted within a patient's eye.

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