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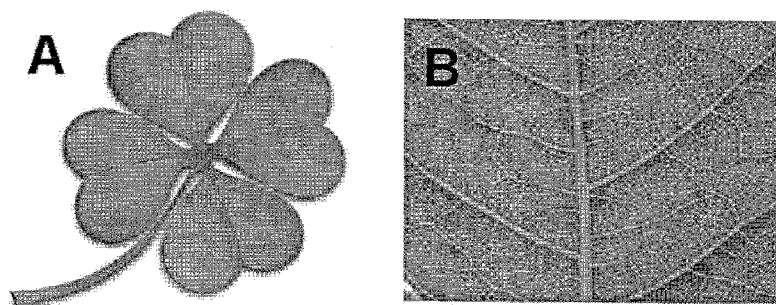
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(54) **Title:** DEVICES AND METHODS FOR CONTROLLING INTRAOCULAR PRESSURE WITH A MODULAR AQUEOUS DRAINAGE DEVICE SYSTEM

FIGURE 1



(57) **Abstract:** The present disclosure relates to modular ophthalmological aqueous drainage devices, systems and methods, and more particularly, to glaucoma treatment devices, systems and methods.

DEVICES AND METHODS FOR CONTROLLING INTRAOCULAR PRESSURE WITH A MODULAR AQUEOUS DRAINAGE DEVICE SYSTEM

CROSS-REFERENCE TO RELATED APPLICATIONS

5 The present application claims the benefit of U.S. Provisional Patent Application No. 61/900,771, filed on November 6, 2013, which is incorporated herein by reference.

FIELD OF THE INVENTION

10 The present disclosure relates to modular ophthalmological aqueous drainage devices, systems and methods, and more particularly, to glaucoma treatment devices, systems and methods.

BACKGROUND OF THE INVENTION

15 Glaucoma is a rapidly growing problem and represents a leading cause of vision loss and blindness globally. Currently, glaucoma is the second leading cause of irreversible blindness. Glaucoma prevalence is currently approximately 2.2 million people in the United States and over 60 million worldwide. Despite recent technological and pharmacologic advances in medicine, the number of people losing sight due to glaucoma continues to increase. What is needed is a device and method of treatment for glaucoma that enables fine adjustment of aqueous drainage
20 rates and may also connect to previously implanted devices to provide flexibility in the treatment of this disease.

SUMMARY OF THE INVENTION

The present disclosure relates to modular ophthalmological aqueous drainage devices, systems and methods, and more particularly, to glaucoma treatment devices, systems and methods. For example, the present invention relates to a modular aqueous drainage device and methods of
5 its use for treatment of various medical conditions including but not limited to eye diseases, such as glaucoma, using minimally invasive surgical techniques. Specifically, the device may be used in conjunction with an existing aqueous drainage device or independently as a sole aqueous drainage device.

In one embodiment, the invention relates to an ophthalmic aqueous drainage device,
10 comprising: a) a tube comprising an open lumen; and b) at least one or a plurality of plates in fluid communication with said open lumen, wherein said plate or plurality of plates comprise a tubular network terminating in openings. In one embodiment, said plates are made from silicone. In one embodiment, said plate or plurality of plates comprises a cloverleaf shape.

In one embodiment, the invention relates to a method, providing the device described
15 above and an existing implanted aqueous drainage tube; and a) attachment of said device onto said existing implanted aqueous drainage tube, b) suturing said plate or plurality of plates of the device described above to the sclera of the eye. In one embodiment, said method further comprises step c) modification of the tubular network so as to modify the aqueous drainage rate.

In one embodiment, one component of the device is implanted into the anterior chamber
20 and secured underneath a scleral flap 1-6 millimeters away from the limbus to allow for aqueous drainage. In one embodiment, the device does not require implantation under a scleral flap. In one embodiment, the initial implant would have a receiving end which allows for connection to a second component comprising a tubular network. In one embodiment, the initial implant may be connected to the second tubular network component if efficacy of the initial implant wanes.

In one embodiment, the proximal portion of the initial component contains features that allows for connection to the subsequently implanted tubular network in water tight fashion. In one embodiment, the connection system comprises at least one of the following: tabs, flaps, clips, self adhesives, or other methods of connecting two components to each other in water tight
5 fashion. In one embodiment, the initial implant may function as a drainage device independent of the tubular network when implanted alone, yet it is designed to allow for modulation of the drainage outflow when connected to the tubular network either at the time of the initial implantation of the first tube or at a later time. In one embodiment, the second component can function alone if connected directly to the anterior chamber of the eye.

10 The first implant can stand alone and allow for future connection to the second implant (tubular system). The second component can also stand alone as a functioning device directly connected to the anterior chamber of an eye. Many initial surgeries fail. This approach allows for modulation of an initial implant by augmenting outflow with use of the tubular system that is subsequently connected but bypasses the need to re-enter the anterior chamber with a new tube
15 since the tubular network can just be connected directly to the already existing tube.

In one embodiment, the invention relates to a method of treating a subject with glaucoma, providing the device described above and an existing implanted aqueous drainage tube; and a) attachment of said device onto said existing implanted aqueous drainage tube implanted in an eye with symptoms of glaucoma, b) suturing said plate or plurality of plates of the device
20 described above to the sclera of the eye, and c) treatment of glaucoma by reducing the pressure within the eye by means of drainage by said device. In one embodiment, said method further comprises step d) modification of the tubular network so as to modify the aqueous drainage rate. In one embodiment, said treating includes administration of therapeutic agents.

In one embodiment, the invention relates to an ophthalmic aqueous drainage device,

comprising: a) a first implant comprising a tube comprising an open lumen; and b) a second implant comprising a plate or plurality of plates in fluid communication with said open lumen, wherein said plate or plurality of plates comprise a tubular network terminating in openings. In one embodiment, said plates are made from silicone. In one embodiment, said plate or plurality
5 of plates comprises a cloverleaf shape. In one embodiment, said first implant further comprises receiving features. In one embodiment, said second implant further comprises docking features. In one embodiment, said receiving features are located the proximal portion of said first implant and enable a watertight connection to said second implant through docking features on said second implant.

10 In one embodiment, the invention relates to a method of treating a subject with glaucoma, providing the device described above an existing implanted aqueous drainage tube; and a) attachment of said device onto said existing implanted aqueous drainage tube, and b) suturing said plate or plurality of plates of second implant of the device to a sclera of the eye. In one embodiment, said method further comprises step c) modification of the tubular network so as to
15 modify the aqueous drainage rate.

In one embodiment, the invention relates to a method to allow for aqueous drainage, providing, a) a first implant comprising a tube comprising an open lumen and proximal end receiving features, and a subject comprising an eye, b) implantation of said first implant into the anterior chamber of said eye, and c) securing said first implant underneath a scleral flap of the
20 eye. In one embodiment, the invention relates to a method to allow for aqueous drainage, providing, a) a first implant comprising a tube comprising an open lumen and proximal end receiving features, and a subject comprising an eye, and b) implantation of said first implant into the anterior chamber of said eye, and c) securing said first implant. In one embodiment, securing further comprises affixing the first implant to the eye. In one embodiment, the first

tube does not need to be implanted under a flap if it has an inline fluid restriction mechanism negating the need for the flap which also provides restriction of flow. In one embodiment, method further comprises, providing a second implant comprising a plate or plurality of plates in fluid communication with a central lumen, wherein said plate or plurality of plates comprise a tubular network terminating in openings, and wherein said central lumen terminates with an opening containing docking features, and step d) connection of said first implant to said second implant, wherein said connection provides fluid communication with the central lumen of both implants and said connection is made by the interlocking of said receiving features and said docking features. In one embodiment, said method further comprises step e) suturing said plate or plurality of plates of the second implant to the sclera of the eye. In one embodiment, said method further comprises step f) modification of the tubular network of the second implant so as to modify the aqueous drainage rate. In one embodiment, said first implant is secured underneath a scleral flap between 1 to 6 millimeters away from the limbus to enable aqueous drainage. In one embodiment, said connection comprises at least one of the following: dovetail joints, tabs, flaps, slots, clips, tongue/groove, ball/receiver and self-adhesives. In one embodiment, said first implant functions as a drainage device when implanted alone. In one embodiment, the drainage rate may be further modulated by connected to said second implant. In one embodiment, said first implant comprises a short tube with or without a face-plate. In one embodiment, said short tube face-plate is attached to a standard silicone tube. In one embodiment, said tube is the same as that used for previously implanted glaucoma drainage devices with an outer diameter of 0.64 millimeters and inner diameter of 0.3 millimeters. In another embodiment, the tube is oval or flat in cross-section. In one embodiment, said short tube face-plate is sutured approximately 4 millimeters away from the limbus and said silicon tube enters the anterior chamber of the eye. In one embodiment, a sclera patch graft may be

used to cover said tube. In one embodiment, said sclera patch graft is comprised of collagen. In one embodiment, said collagen has a nominal thickness of 1 millimeter or less.

In one embodiment, said first implant may be implanted 1 to 6 millimeters posterior to the limbus. The first implant may be sutured in place or may be fixated underneath scleral to ensure immobility. In one embodiment, said first implant comprises a silicone material. In one embodiment, said first implant is injection molded. In one embodiment, said use of the first implant will eliminate the need for scleral flap creation due to flow restriction mechanisms already in place such as leaflet valves or constriction of the outflow channel to a cross section less than 50microns.

In one embodiment, said first implant has a 100 μ m lumen. In one embodiment, said second implant has a plate design with two halves divided by a ridge. In one embodiment, said second implant has an etched/micropatterned surface, which provides an anti-fibrosis effect. In one embodiment, the material is plasma coated to reduce tackiness and enhance biocompatibility. In one embodiment, said second implant has a double or triple inlet. In one embodiment, said second implant has fixation holes across the plate. In one embodiment, the long tube can enter the eye directly or attach to an initial short tube face plate/ first implant. In one embodiment, said second implant is 30 millimeters long and 12 millimeters wide. In another embodiment, the second implant is composed of multiple interconnected plates separated by more than 100 microns. In one embodiment, said second implant has eight fixation holes, four on each side. In one embodiment, said second implant has a double inlet, one inlet on each side.

It is not intended that embodiments of the invention be limited to any particular method, medical target, or device confirmation; however, it is believed that the device may be optimally designed to assist in aqueous drainage. It is not intended that embodiments of the invention be limited to any particular mechanism; however, it is believed that the modularity of the present

invention provides a device and method to more easily adjust the rate of aqueous drainage and may elongate the life of previously implanted aqueous drainage devices to which the present invention device may be connected.

5 **DEFINITIONS**

To facilitate the understanding of this invention, a number of terms are defined below. Terms defined herein have meanings as commonly understood by a person of ordinary skill in the areas relevant to the present invention. Terms such as “a”, “an” and “the” are not intended to refer to only a singular entity, but include the general class of which a specific example may
10 be used for illustration. The terminology herein is used to describe specific embodiments of the invention, but their usage does not delimit the invention, except as outlined in the claims.

As used herein, the term “patient” or “subject” refers to a living mammalian organism, such as a human, monkey, cow, sheep, goat, dog, cat, mouse, rat, guinea pig, or transgenic species thereof. In certain embodiments, the patient or subject is a primate. Non-limiting examples of
15 human subjects are adults, juveniles, infants and fetuses.

“Prevention” or “preventing” includes: (1) inhibiting the onset of a disease in a subject or patient which may be at risk and/or predisposed to the disease but does not yet experience or display any or all of the pathology or symptomatology of the disease, and/or (2) slowing the onset of the pathology or symptomatology of a disease in a subject or patient which may be at risk and/or
20 predisposed to the disease but does not yet experience or display any or all of the pathology or symptomatology of the disease.

As used herein, the terms “treat” and “treating” are not limited to the case where the subject (e.g. patient) is cured and the disease is eradicated. Rather, the present invention also

contemplates treatment that merely reduces symptoms, improves (to some degree) and/or delays disease progression. It is not intended that the present invention be limited to instances wherein a disease or affliction is cured. It is sufficient that symptoms are reduced.

As used herein “eye diseases” refers to various conditions of the eye including, but not limited to Glaucoma — optic neuropathy, Glaucoma suspect — ocular hypertension, Primary open-angle glaucoma, Primary angle-closure glaucoma, primary open angle glaucoma, normal or low tension glaucoma, pseudoexfoliation glaucoma, pigment dispersion glaucoma, angle closure glaucoma (acute, subacute, chronic), neovascular or inflammatory glaucoma, ocular hypertension, and other types of glaucoma that are related to dysregulation of intraocular pressure.

As used herein “hypotony” refers to reduced intraocular pressure. The statistical definition of hypotony is intraocular pressure (IOP) less than 6.5 mmHg, which is more than three standard deviations below the mean IOP. The clinical definition of hypotony is IOP low enough to result in pathology (vision loss). The vision loss from low IOP may be caused by corneal edema, astigmatism, cystoid macular edema, maculopathy, or other condition. Hypotony maculopathy is characterized by a low IOP associated with fundus abnormalities, including chorioretinal folds, optic nerve head edema in the acute setting, and vascular tortuosity.

The term “therapeutically effective amounts” or “pharmaceutically effective amounts”, as used herein means that amount which, when administered to a subject or patient for treating a disease, is sufficient to effect such treatment for the disease or to ameliorate one or more symptoms of a disease or condition (e.g. ameliorate pain).

The term “fascia bulbi” (also known as the capsule of Ténon, the bulbar sheath, or Tenon's capsule) as used herein refers to a thin membrane that envelops the eyeball from the optic nerve to the limbus, separating it from the orbital fat and forming a socket in which it moves.

The term “tubular network”, as used herein refers to a series of small tubes connected to a junction or main larger size tube. The tubular network contains egress pathways that change in caliber from large to small as the network moves away from the proximal inlet.

The term “plates”, as used herein refers to distinct areas with localized tubular networks contained within surfaces made of polymers or other materials.

The term “interlocking”, as used herein refers to connecting together (such as parts of a mechanism, for example) so that the individual parts affect each other in motion or operation, in particular to create a watertight connection. Examples of interlocking connects include, but are not limited to dovetail joints, tabs, flaps, slots, clips, tongue/groove, ball/receiver and/or self adhesive mechanisms and or agents.

The term “receiving features”, as used herein refers to structural features that enable an interlocking watertight connection when interfaced with structural “docking features.” Such connections may also be accompanied with chemical aids to enable the watertight aspect of the connection.

The term “docking features”, as used herein refers to structural features that enable an interlocking watertight connection when interfaced with structural “receiving features.” Such connections may also be accompanied with chemical aids to enable the watertight aspect of the connection.

BRIEF DESCRIPTION OF THE FIGURES

The accompanying figures, which are incorporated into and form a part of the specification, illustrate several embodiments of the present invention and, together with the description, serve to explain the principles of the invention. The figures are only for the purpose

of illustrating a preferred embodiment of the invention and are not to be construed as limiting the invention.

Figure 1A-B illustrates a useful parallel of the current device and the design of a cloverleaf. Figure 1A shows the design of the second implant that consists of plates that are shaped like a four leaf clover and contain veins comprising a tubular network. Figure 1B shows a close up of the veins of a cloverleaf's veins which comprise a tubular network.

Figure 2 shows the interaction of the first implant 1 with the eye. The first implant spans the layers of the eye connecting the anterior chamber 16 of the inside of the eye 15 and the outside of the eye 14. The inner end of the device may be open; the outer end of the first implant 1 may also comprise a faceplate.

Figure 3 shows one version of the device wherein both the first implant 1 and the second implant 6 are connected. The first implant 1 may function as a freestanding device or may be connected with a second implant 6 (such as the cloverleaf shown herein). In one embodiment, if the first implant fails or if a plate design is required, the first implant 1 can be directly connected with the second implant 6, such as the connected two sections in Figure 3. In one embodiment, said connection between the first implant 1 and the second implant 6 is by way of interlocking of the receiving features 5 of the first implant 1 and the docking features 12 of the second implant 6.

Figure 4 shows several regions of the second implant 6 of the current invention. The first part 8 is a junction where main tube connects with each leaf plate. Another part 7 is the main tube, which connects to first device or to inside of the eye. The main tube 7 also connects to a series of smaller tubes 10. Another part 9 is a leaf-like plate potentially made of silicone or other polymer and may be sutured to sclera. The leaf-like plate 9 contains the series of small tubes 10 that comprise a tubular network. In one embodiment, the first implant 1 and second

implant 6 may be connected by form fit without glue. The connection 13 between the first implant 1 and the second implant 6 may also be sutured to strengthen the connection. In one embodiment, said connection between the first implant 1 and the second implant 6 is by way of interlocking of the receiving features 5 of the first implant 1 and the docking features 12 of the second implant 6.

Figure 5 shows one embodiment of a prototype of the first implant 1.

Figure 6A&B show embodiments of the second implant 6 that attaches to the “ab externo shunt” or first implant 1. Figure 6A shows the series of smaller tubes 10 connecting to the main tube/lumen 7 when ends at the proximal part 11 of the second implant 6. The proximal part 11 of the second implant 6 is the implant what would contain the docking features 12 to interlock with the receiving features 5 of the first implant 1. Figure 6B shows an example of a series of smaller tubes 10 embedded in a secondary material which form to plates 9.

Figure 7 shows one embodiment of the Ab Externo (first implant 1) + Modular Plate (second implant 6) prior to attachment.

Figure 8 shows the attachment/connection 13 of the two implants.

Figure 9 shows one embodiment of the short tube faceplate of the first implant 1. The dimensions shown are in millimeters. This face plate is attached to a standard silicone tube 7. The tube is the same as that used for Baerveldt and Ahmed devices. The tube may be oval or flat in cross-section. The face plate may be sutured 4 millimeters away from the limbus and the tube enters the anterior chamber similar to how the tube enters on larger devices like the Ahmed. A sclera patch graft, such as Tutoplast®, may be used to cover the tube just like with an Ahmed. A sclera patch graft is comprised of high profile collagen with a nominal thickness of 1 millimeter. It is a multi-directional matrix for superior surgical handling and suture utility. The scleral graft is the industry standard for glaucoma implant/valve surgery.

This first implant 1 face plate may be implanted away from limbus. Compared to the ExPRESS device, this will allow for easier conjunctival closure and less rubbing against lid and other tissues. This first implant 1 face plate may be made of silicone, made by injection molding of parts, and will consequently be less expensive. The use of this device will eliminate the need for scleral flap creation due to inline flow restriction mechanisms. The tube may be tied off like a Baerveldt and opens on its own (or the suture is opened with a laser whenever the doctor needs or through biodegradation). This makes implantation easier for a wider range of doctors. The system using the first implant 1 is modular. Once the first implant 1 fails (as 50% do at 5 years), the larger plate (second implant 6) can be attached directly to the short tube 7 or the proximal thus mimicking the action of a Baerveldt or Ahmed without losing the quadrant where the short tube was implanted (which is the case with the ExPRESS shunt for example, due to scar tissue formation).

Figure 10 shows another angle of the first implant 1 face plate without the tube. The distal end of the device displays the 100 μ m lumen 20.

Figure 11 shows one embodiment of the second implant 6, which has a plate design with two halves divided by a ridge 23. The plate 6 has an etched/micropatterned surface 22, which provides an anti-fibrosis effect. The plate has a double inlet 24. The plate 6 has fixation holes 21 across plate. In one embodiment, the long tube 7 can enter eye directly or attach to an initial short tube face plate/ first implant 1.

Figure 12 shows dimensions of one version of the second implant 6. The dimensions shown are in millimeters. This embodiment of the device is 30 millimeters long and 12 millimeters wide. The device has two sides divided by a ridge 23. The device also has eight fixation holes 21, four on each side. The device has a double inlet 24, one inlet on each side.

Figure 13 shows a different angle view of the second implant 6.

Figure 14 shows a side view of the second implant 6. The dimensions shown are in millimeters.

LIST OF REFERENCE NUMERALS

5	1	the first implant
	2	the proximal part of the first implant 1
	3	the tapered shaped central part of the first implant 1
	4	the distal part of the first implant 1
	5	receiving features
10	6	the second implant
	7	the main tube
	8	a connector
	9	leaf-like plate
	10	a series of smaller tubes
15	11	the proximal part of the second implant 6
	12	docking features
	13	connection between first and second implant
	14	the outside of the eye
	15	the inside of the eye
20	16	the anterior chamber
	17	the limbus
	18	scleral flap made on the eye
	19	sclera and conjunctiva/Tenon's
	20	lumen of the first implant

- 21 fixation holes across plate
- 22 etched/micropatterned surface
- 23 ridge
- 24 double inlet into plate

5

DESCRIPTION OF THE PREFERRED EMBODIMENT

1. BACKGROUND:

10 In brief, glaucoma is characterized by high intraocular pressures, which over time cause damage to the optic nerve, resulting in loss of peripheral vision in early cases. Later stage disease can lead to loss of central vision and permanent blindness, treatment is aimed at lowering intraocular pressure.

The current standard of care for treating the blinding complications of glaucoma revolves
15 around topical medications, laser treatments, and surgery for the most advanced cases, all aimed at lowering intraocular pressure. For patients with advanced disease, filtering surgery (e.g., aqueous shunting or trabeculectomy) is often required to prevent vision loss.

With respect to aqueous shunting, implanted glaucoma drainage devices (GDDs) are typically used to create an alternate aqueous pathway from the anterior chamber by shunting
20 aqueous out of the eye through a tube to a subconjunctival bleb or reservoir, which is usually connected to a plate under the conjunctiva. A major disadvantage of this surgery is that the aqueous may tend to flow too rapidly out of the tube until a fibrous membrane has encapsulated the reservoir. To this end, medical practitioners may elect to tie off the external portion of the tube or block its lumen with suture or other material, such that once the reservoir has become

encapsulated, the suture can be removed. These represent an all-or nothing option concerning the amount of aqueous flow. Further, some GDDs have a valve that theoretically prevents flow below certain pressures, but cannot be titrated or adjusted by the medical practitioner.

As with conventional GDD implantation, current trabeculectomy surgeries are not
5 titratable by the medical practitioner post-operatively. During surgery, viscoelastic substances may be left in the anterior chamber to slow the rate of aqueous filtration for the first 24-48 hours, or contact lenses placed on the surface of the eye post-operatively to prevent low pressures. Alternatively, the medical practitioner may place sutures over the sclerostomy flap, and can open these with a laser or mechanically. Again, these allow the medical practitioner to either prevent
10 or allow flow, but without precision, often leading to gross under- or over-filtration. This problem contributes to the high rate of surgical failure with these surgeries long-term.

At least in part due to not being titratable, current surgical techniques are plagued by high rates of complications (such as over filtering and under filtering, hypotony, choroidal effusions/hemorrhages), with a failure rate of 50% at 5 years. To address this issue, there exist
15 prior art of using biodegradable implants, fibroblast inhibitors, antimetabolites, and other drugs over the surface of the scleral flap or stainless steel shunts under the scleral flap to encourage continued flow. For example, the Ex-Press Mini Glaucoma Shunt was originally developed by Optonol, Ltd. (Neve Ilan, Israel) for implantation under the conjunctiva for controlling intraocular pressure (IOP) [1, 2]. This biocompatible device is almost 3 millimeter long with an
20 external diameter of approximately 400 microns. The device is non-valved, MRI compatible, stainless steel device with a 50-micron lumen. The device has an external disc at one end and a spur-like extension on the other to prevent extrusion.

Other limitations of current GDDs: The single silicone tube that is inserted in the eye is large and not necessary. The outer diameter is over 600 microns and the inner diameter is over

300microns. The same silicone tube is used for all devices. The larger tube leads to erosion of tissue around it as well as trauma to the cornea after insertion. The single tube connects to a single plate, which means the pressure gradient across the tube is very large. There are no options for fluid flowing away from the single plate to relieve the buildup of pressure. This leads to plate
5 encapsulation (known as the hypertensive phase) and often leads to device failure.

Various aqueous/glaucoma drainage devices have been described. One device described by Cunningham Jr., in United States Patent Application Publication Number 2012-0089073 [3] is a potentially multi-lumen aqueous drainage device, but does not describe the multi plate or cloverleaf design as described in the present invention.

10 Another reference, Schmidt, W. *et al.* (2013) *Curr. Pharm. Biotechnol.* 14(1), 98-111 [4], describes various advances in controlling glaucoma pressure including several types of devices, some including plates. The devices described as having plates also were described as having valves. The present invention device does not utilize a valve. However, the reference does not describe the plurality of plates comprising a tubular network terminating in openings as
15 described in the present invention.

Another device is described in Agfid project team. (2001) *Br. J. Ophthalmol.* 85(10), 1231-1236 [5]. This reference describes an unconventional aqueous drainage device that has laser holes introduced into the body of the device to reduce the pressure gradient. However, the reference does not describe the plurality of plates comprising a tubular network terminating in
20 openings as described in the present invention.

Another device is described in Lim, *et al.* (1998) *Br. J. Ophthalmol.* 82(9), 1083-1089 [6]. This reference describes various aqueous drainage devices, including those that implement multiple “plates” in the device. These devices include those that employ plates for drainage, but do not describe the multi-lumen devices as described in the present invention.

Another device is described in Sarkisian, S. R. (2009) *Middle East Afr. J. Ophthalmol.* 16(3), 134-137 [2]. This reference describes the use of the Ex-Press shunt. The device shunts aqueous from the anterior chamber to a subconjunctival reservoir in a similar fashion as trabeculectomy, without removal of any sclera or iris. This reference does not describe the plurality of plates comprise a tubular network terminating in openings as described in the present invention.

Another device is described in Hendrick, A. M. and Kahook, M. Y. (2008) *Expert Rev. Med. Devices* 5(6), 673-677 [1]. This reference describes the use of the Ex-Press Mini glaucoma shunt in operation and use. This particular shunt does not directly involve plates for moderating the flow of aqueous. One of the authors of this article is the inventor of the present invention. In one embodiment, the inventor envisions an interaction of the Ex-Press Mini glaucoma shunt with the present device. This reference does not describe the plurality of plates comprise a tubular network terminating in openings as described in the present invention.

2. DEVICE DESCRIPTION

The current approach focuses upon a modular GDD that allows for a stepped approach to the surgical treatment of glaucoma once GDDs are needed. First step: Implant a small tube that is in the same arena of an ExPRESS mini-shunt with two important exceptions; (1) the tube can be inserted approximately 3 millimeter away from the limbus and (2) the tube can connect to another silicone tube in the future if needed.

Once a patient needs surgery, they will receive the first tube which often is sufficient to lower eye pressure for 5 years in 50% of patients. Once this device fails, as most do, instead of implanting another device in a separate location, the modular design will allow for connection of the already implanted tube to a second longer tube that has a plate associated with it (thus the

modular concept).

The second tube in the modular system consists of a silicone tube that can connect to the first already implanted tube. The second device also consists of a plate that is shaped like a four leaf clover (Clover Device, Figure 1A) and consists of four separate small plates each of which is
5 connected directly to the initial tube. The clover design works much like in nature, leaves contain veins (part of the tubular network) that allow for fluid to flow with lower pressure in each vein, as part of the tubular network, (spreading pressure across the surface) , see Figure 1B. The Clover Device can also connect directly to the inside of the eye without need to connect to an already implanted first stage device. Each leaf on the clover can be tied off by suture to limit
10 flow as needed. Each suture can then be lasered postoperatively to allow for egress of fluid and further lowering of eye pressure. In one embodiment, the clover device has a silicone tube (the stem) that has an outer diameter (OD) of 50 to 400 microns and an inner diameter (ID) of 10 to 380 microns. Each leaf is connected to the stem silicone tube independently.

In one embodiment, the first device: 3 to 6 millimeters in length ID/OD noted previously.
15 The side outside of the eye drains fluid out of eye. The other side connects to the inside of the eye 15. The side outside can connect with a future second device as noted previously (see Figure 2). In one embodiment, the device can function as a freestanding device or can be connected with a second device, such as in Figure 3. In one embodiment, if the first implant fails or if a plate design is required, the first device can be directly connected with the second implant 6, such as
20 in Figure 3.

In one embodiment, the clover device is shown in Figure 4. The first part 8 is a connector. In some embodiments, first part 8 is a connector, which in some circumstances comprises a junction where main tube connects with each leaf plate. Another part 7 is the main tube, which connects to first device or to inside of the eye. The main tube 7 also connects to a

series of smaller tubes 10. Another part 9 is a leaf-like plate potentially made of silicone or other polymer and may be sutured to sclera. The leaf-like plate 9 contains the series of small tubes 10, which comprise a tubular network. In one embodiment, the first implant 1 and second implant 6 can be connected by form fit without glue. The connection 13 between the first implant 1 and the second implant 6 may also be sutured to strengthen the connection.

Figure 5 shows one embodiment of a prototype of the first implant 1. This is an ab externo shunt implanted through the sclera and into the anterior chamber 16. The proximal part 2 may be sutured to the sclera or held in place at the sclera by virtue of its tapered shaped 3. The distal part 4 is in contact with aqueous humor in the anterior chamber and fluid is shunted from the distal part 4 to the proximal part 2. The proximal part 2 can be implanted under a scleral flap 18 to further control egress of fluid from the distal part 4 to the proximal part 2. The material is typically silicone, PTFE, or other biocompatible materials. The tube can be sutured closed and the suture lasered at a later time to allow for fluid egress when the physician desires. This device functions much like the current Ex-PRESS shunt that is made of stainless steel but is considerably longer (2-3x longer) and can be implanted further away from the limbus. The design is also unique in that the area at the proximal part 2 can accommodate a secondary device, which is explained in the next figures and paragraphs.

Figure 6A&B show embodiments of the second implant which attaches to the “ab externo shunt” or first implant 1. This device may be made of silicon, PTFE, Polyimide or other biocompatible materials. Figure 6A shows the device attaches to the proximal point 2 of the ab externo device. The modular plate (second implant 6) may be used after the “ab externo shunt” has failed due to scar formation around the proximal part of the “ab externo shunt”. The procedure for implanting the modular plate containing second implant 6 would involve incising the conjunctiva over the ab externo device and dissecting away the scleral flap 18 if one were

created during the initial procedure. The modular plate containing second implant 6 is then sutured to the sclera at a site more posterior on the globe to where the scar tissue formed around the ab externo device. The modular plate is then attached to the ab externo device or first implant 1 and fluid can once again flow away from the anterior chamber to decrease eye pressure. The modular plate containing second implant 6 consists of a main tube 7 that connects distally to a series of smaller tubes 10 that decrease in diameter as they move further away from the main tube 7. The series of smaller tubes 10 might have multiple branches and may or may not be embedded in a silicone (or other biocompatible material) plate 9. Figure 6A also shows the series of smaller tubes 10 connecting to the main tube/lumen 7 when it ends at the proximal part 11 of the second implant 6. The proximal part 11 of the second implant 6 is the implant that would contain the docking features 12 to interlock with the receiving features 5 of the first implant 1. Figure 6B shows an example of a series of smaller tubes 10 embedded in a secondary material which form plates 9. The plates 9 act to create a space between the sclera and conjunctiva/ Tenon's capsule 19 for fluid to flow into.

Figure 7 shows one embodiment of the Ab Externo (first implant 1) + Modular Plate (second implant 6) prior to attachment. Figure 8 shows the attachment/connection 13 of the two implants. In one embodiment, the attachment mechanism is unique between the first implant 1 and the second implant 6 (implant comprising a tubular network/Modular plate). In other words, the modular plate attachment (second implant 6) is specifically designed to attach to the ab externo device (first implant 1) and not to any other device on the market. It is a preferred embodiment, that the connection 13 between the first implant 1 and the second implant 6 is a watertight connection. It is a preferred embodiment, that the connection 13 between the first implant 1 and the second implant 6 comprises a connection system that employs at least one connection feature such as tabs, flaps, clips, and/or self-adhesives. In some embodiments, said

connection 13 may comprise a fitted connection.

3. DIMENSIONS OF SOME EMBODIMENTS OF THE DEVICE

Ab externo: this first implant 1 is a tube with outer diameter of approximately 10 microns
5 to 1 millimeter and an inner diameter of 10 microns to 400 microns. Modular Plate: this second
implant 6 includes tubes that taper from approximately 300 microns to 10 microns. Some tubes
do not taper down, others taper over 1 millimeter while others taper gradually over a distance of
approximately 15 millimeters. The tubes 10 in the modular plate 9 can be sutured closed and
opened using a laser during the postoperative period to increase flow of aqueous out of the eye
10 across a wider area posteriorly. This is similar to the veins on a leaf that taper as they move away
from the leaf stem. Such veins comprise a tubular network.

Procedures. Once glaucoma surgery is needed, the patient is taken to the Operating
room and prepped for surgery. For Ab Externo (first implant 1): A conjunctival peritomy may be
created followed by creation of a scleral flap 18 approximately 1-4 millimeters away from the
15 limbus. A 23-27 gauge needle may be used to create a pilot incision and the device is inserted
into the incision and threaded into the anterior chamber. The device may or may not be sutured to
the sclera. The scleral flap 18 is then sutured and flow is checked. The peritomy is then sutured
closed.

Once glaucoma surgery is needed, the patient is taken to the Operating room and prepped
20 for surgery. If Ab Externo fails due to scar tissue: A peritomy is created and the old scleral flap
site is located and lifted off of the scleral bed and proximal end of ab externo (first implant 1).
The conjunctiva is then dissected posteriorly to make room for the modular plate (second implant
6). The plate 9 is sutured to the sclera and connected to the ab externo device 1 so that aqueous
flows from the anterior chamber to the veins (part of the tubular network) in the modular plate

(second implant 6). The modular plate veins (part of the tubular network) may or may not be sutured to control flow during the postoperative phase.

4. DETAILED DESCRIPTION OF THE INVENTION

5 The following detailed description, and the drawings to which it refers, are provided for the purpose of describing and illustrating certain preferred embodiments or examples of the invention only, and no attempt has been made to exhaustively describe all possible embodiments or examples of the invention. Thus, the following detailed description and the accompanying drawings shall not be construed to limit, in any way, the scope of the claims recited in this patent
10 application and any patent(s) issuing there from.

 This invention is in the field of surgical medicinal intervention. For example, the present invention relates to a device and methods of its use for treatment of various medical conditions including but not limited to eye diseases, such as glaucoma, using minimally invasive surgical techniques. Specifically, the device may be a glaucoma aqueous drainage device in the eye or be
15 connected to previously implanted glaucoma aqueous drainage devices.

 Specific advantages of some embodiments described herein as compared to other conventional devices include but are not limited to:

1. No mechanically moving parts
2. Device may connect to an already existing GDD implant or other device (modular
20 concept)
3. The tubular network allows for a post implantation variable adjustment of drainage rate
4. The receiving features of the first implant and the docking features of the second implant that enable the specific interlocking connection to enable a watertight fit.

5. The first and second implants can be connected by form fit without glue. They might also be sutured to strengthen the connection.

In one embodiment, the invention relates to a device that may be used as an ophthalmological aqueous drainage device. In one embodiment, the device comprises two implants. In one embodiment, the first implant 1 comprises an ab externo device section comprising a channel or lumen. In one embodiment, the proximal part of the first implant 2 is sutured to the sclera or held in place at the sclera by virtue of the tapered shaped 3 of the center part of the first implant 1. In one embodiment, as shown in Figure 5, shows a prototype of the first implant 1. This is an ab externo shunt implanted through the sclera and into the anterior chamber 16. The proximal part 2 is sutured to the sclera or held in place at the sclera by virtue of its tapered shaped 3. The distal part 4 is in contact with aqueous humor in the anterior chamber and fluid is shunted from the distal part 4 to the proximal part 2. The proximal part 2 can be implanted under a scleral flap 18 to further control egress of fluid from the distal part 4 to the proximal part 2. In one embodiment, the device comprises a second implant 6. In one embodiment, the second implant 6 comprises a main tube 7 that connects to a connector/junction 8 where main tube connects with each leaf-plate 9. In one embodiment, connector/junction 8 connects to a series of smaller tubes 10 that are contained within the leaf-like plates 9. In one embodiment, the series of smaller tubes 10 branch within said leaf-like plates 9 in a similar fashion to veins in a plant's leaf. In one embodiment, the series of smaller tubes 10 branch into tubes of decreasing size. In one embodiment, the series of smaller tubes 10 taper from 300 microns to 10 microns. In some embodiments, the series of smaller tubes 10 do not taper down, may taper over 1 millimeter, or may taper gradually over a distance of 15 millimeters. In some embodiments, the tubes 10 in the modular plate 9 can be sutured closed and opened using a laser during the postoperative period to increase flow of aqueous out of the eye across a wider

area posteriorly. This is similar to the veins on a leaf that taper as they move away from the leaf stem. In some embodiments, such series of smaller tubes **10** or veins comprise a tubular network. In some embodiments, said series of smaller tubes **10** are contained within the larger structure of said plates **9**. In one embodiment, said plates **9** comprise a polymeric layer containing said series of smaller tubes **10**. The present invention should not be limited by the number of plates **9** contained within said second implant **6**. In one embodiment, said second implant **6** contains between 1 and 10 plates **9**. In some embodiments, the first implant **1** and second implant **6** may be linked through a connection **13**. In some embodiments, said connection **13** may comprise a fitted connection. In some embodiments, said connection **13** comprises interlocking connection. In some embodiments, said connection **13** may connect the first implant **1** and second implant **6** with the help of an adhesive agent, such as glue or other physical agent. In some embodiments, said second implant **6** may be housed within a scleral flap made on the eye **18**.

Figure 9 shows one embodiment of the short tube faceplate of the first implant **1**. The dimensions shown are in millimeters. This face plate is attached to a standard silicone tube **7**. The tube is the same as that used for Baerveldt and Ahmed devices. The tube may be oval or flat in cross-section. The face plate may be sutured 4 millimeters away from the limbus and the tube enters the anterior chamber similar to how the tube enters on larger devices like the Ahmed. A sclera patch graft, such as Tutoplast®, may be used to cover the tube just like with an Ahmed. A sclera patch graft is comprised of high profile collagen with a nominal thickness of 1 millimeter. It is a multi-directional matrix for superior surgical handling and suture utility. The scleral graft is the industry standard for glaucoma implant/valve surgery.

This first implant **1** face plate may be implanted away from limbus. Compared to the EXPRESS device, this will allow for easier conjunctival closure and less rubbing against lid and

other tissues. This first implant 1 face plate may be made of silicone, made by injection molding of parts, and will consequently be less expensive. The use of this device will eliminate the need for scleral flap creation due to inline flow restriction mechanisms. The tube may be tied off like a Baerveldt and opens on its own (or the suture is opened with a laser whenever the doctor needs or through biodegradation). This makes implantation easier for a wider range of doctors. The system using the first implant 1 is modular. Once the first implant 1 fails (as 50% do at 5 years), the larger plate (second implant 6) can be attached directly to the short tube 7 or the proximal thus mimicking the action of a Baerveldt or Ahmed without losing the quadrant where the short tube was implanted (which is the case with the EXPRESS shunt for example, due to scar tissue formation).

Figure 10 shows another angle of the first implant 1 face plate without the tube. The distal end of the device displays the 100 μ m lumen 20.

Figure 11 shows one embodiment of the second implant 6, which has a plate design with two halves divided by a ridge 23. The plate 6 has an etched/micropatterned surface 22, which provides an anti-fibrosis effect. The plate has a double inlet 24. The plate 6 has fixation holes 21 across plate. In one embodiment the long tube 7 can enter eye directly or attach to an initial short tube face plate/ first implant 1.

Figure 12 shows dimensions of one version of the second implant 6. The dimensions shown are in millimeters. This embodiment of the device is 30 millimeters long and 12 millimeters wide. The device has two sides divided by a ridge 23. The device also has eight fixation holes 21, four on each side. The device has a double inlet 24, one inlet on each side.

Figure 13 shows a different angle view of the second implant 6.

Figure 14 shows a side view of the second implant 6. The dimensions shown are in millimeters.

It is not intended that embodiments of the invention be limited to any particular construction material; however, it is believed that preferred materials include silicon, PTFE, polyimide, polymers or other biocompatible materials, all herein incorporated by reference. In some embodiments, the device of the current invention is rigid at room temperature, but is more flexible at body temperature. In some embodiments, the portions of the device of the current invention are rigid at room temperature, but are more flexible at body temperature. In some embodiments, portions of the device are made from different materials. In some embodiments, portions of the device are made from materials of various rigidity.

Thus, specific compositions and configurations of devices and methods for controlling intraocular pressure with a modular aqueous drainage device system have been disclosed. It should be apparent, however, to those skilled in the art that many more modifications besides those already described are possible without departing from the inventive concepts herein. The inventive subject matter, therefore, is not to be restricted except in the spirit of the disclosure. Moreover, in interpreting the disclosure, all terms should be interpreted in the broadest possible manner consistent with the context. In particular, the terms “comprises” and “comprising” should be interpreted as referring to elements, components, or steps in a non-exclusive manner, indicating that the referenced elements, components, or steps may be present, or utilized, or combined with other elements, components, or steps that are not expressly referenced.

All publications mentioned herein are incorporated herein by reference to disclose and describe the methods and/or materials in connection with which the publications are cited. The publications discussed herein are provided solely for their disclosure prior to the filing date of the present application. Nothing herein is to be construed as an admission that the present invention is not entitled to antedate such publication by virtue of prior invention. Further, the dates of publication provided may be different from the actual publication dates, which may need

to be independently confirmed.

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CLAIMS:

We claim:

1. An ophthalmic aqueous drainage device, comprising:
 - 5 a) a first implant comprising a tube comprising an open lumen; and
 - b) a second implant comprising a plurality of plates in fluid communication with said open lumen, wherein said plurality of plates comprise a tubular network terminating in openings.
- 10 2. The device of claim 1, wherein said plates are made from silicone.
3. The device of claim 1, wherein said plurality of plates comprise a cloverleaf shape.
4. The device of claim 1, wherein said first implant further comprises receiving features.
- 15 5. The device of claim 1, wherein said second implant further comprises docking features.
6. The device of claim 4, wherein said receiving features are located the proximal portion of said first implant and enable a watertight connection to said second implant through
20 docking features on said second implant.
7. A method, providing
 - the device of claim 1 and an existing implanted aqueous drainage tube; and
 - a) attachment of said device onto said existing implanted aqueous drainage tube,

b) suturing said plurality of plates of second implant of the device of claim 1 to the sclera of the eye.

8. The method of claim 7, wherein said method further comprises step c) modification of the tubular network so as to modify the aqueous drainage rate.

9. A method to allow for aqueous drainage providing

a) a first implant comprising a tube comprising an open lumen and proximal end receiving features, and a subject comprising an eye,

b) implantation of said first implant into the anterior chamber of said eye, and

c) securing said first implant underneath a scleral flap of the eye.

10. The method of claim 9, wherein said method further comprises, providing a second implant comprising a plurality of plates in fluid communication with a central lumen, wherein said plurality of plates comprise a tubular network terminating in openings, and wherein said central lumen terminates with an opening containing docking features,

d) connection of said first implant to said second implant, wherein said connection provides fluid communication with the central lumen of both implants and said connection is made by the interlocking of said receiving features and said docking features.

11. The method of claim 10, wherein said method further comprises step e) suturing said plurality of plates of the second implant to the sclera of the eye.

12. The method of claim 11, wherein said method further comprises step f) modification of the tubular network of the second implant so as to modify the aqueous drainage rate.
13. The method of claim 11, wherein said first implant is secured underneath a scleral flap
5 between 1 to 6 millimeters away from the limbus to enable aqueous drainage.
14. The method of claim 10, wherein said connection comprises at least one of the following: dovetail joints, tabs, flaps, slots, clips, tongue/groove, ball/receiver and self-adhesives.
- 10 15. The method of claim 9, wherein said first implant functions as a drainage device when implanted alone.
16. The method of claim 10, wherein the drainage rate may be further modulated by connected to said second implant.

15

FIGURE 1

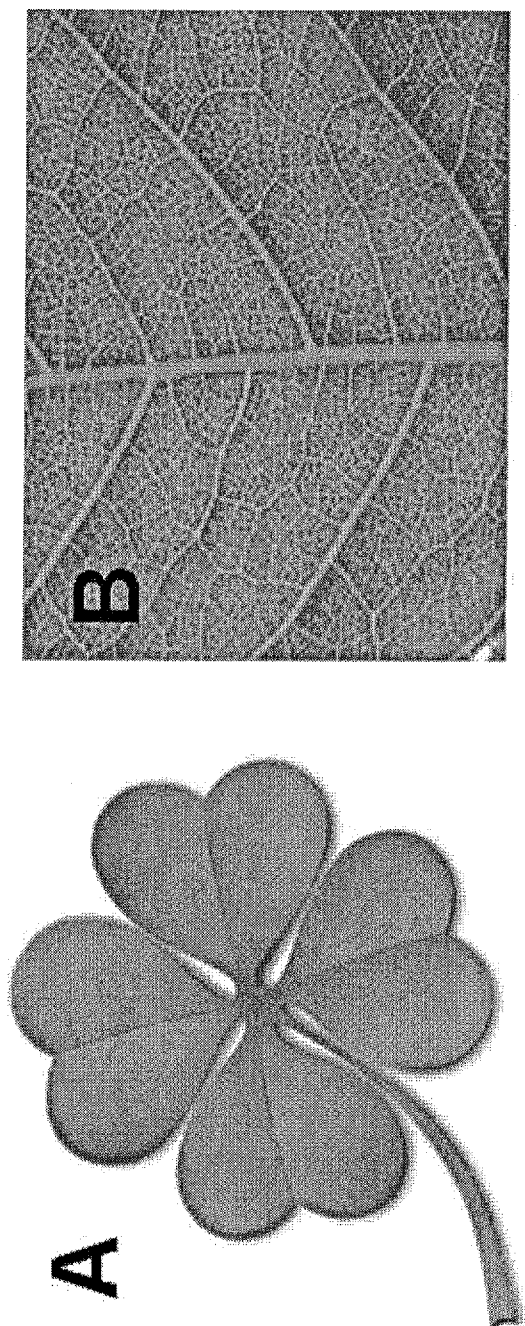


FIGURE 2

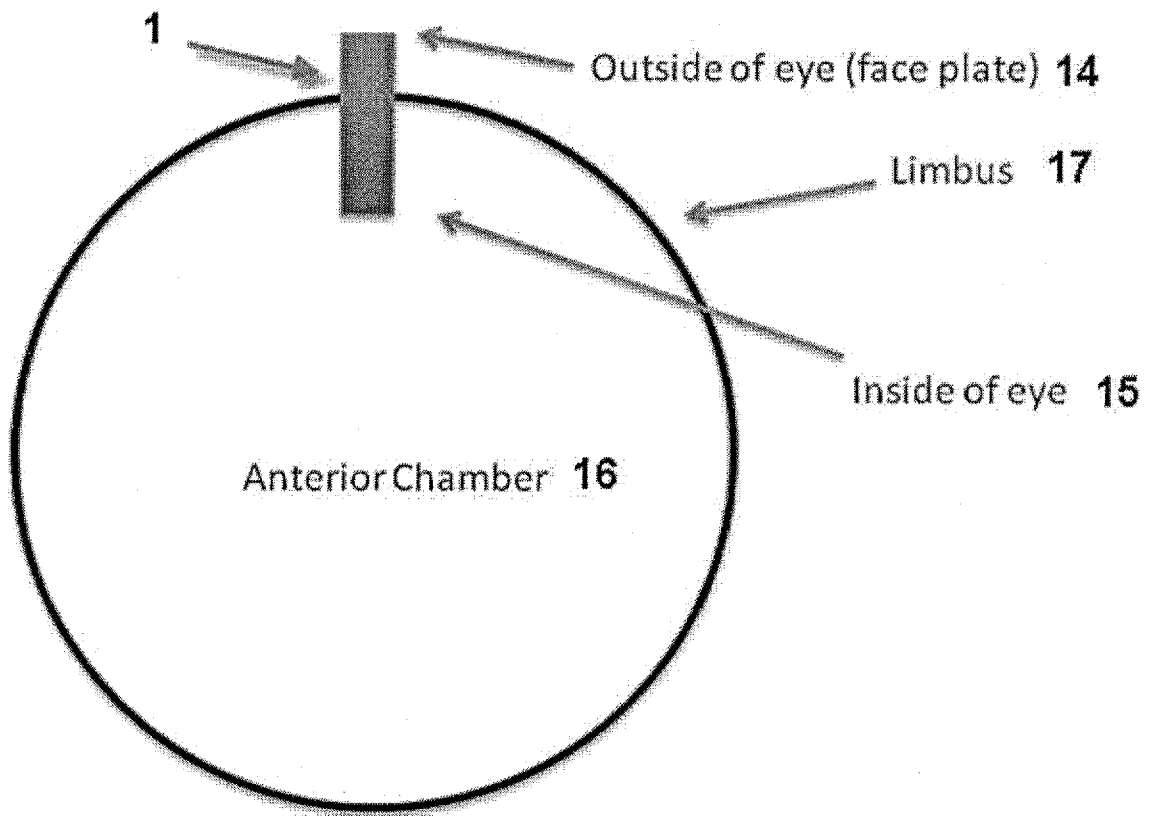


FIGURE 3

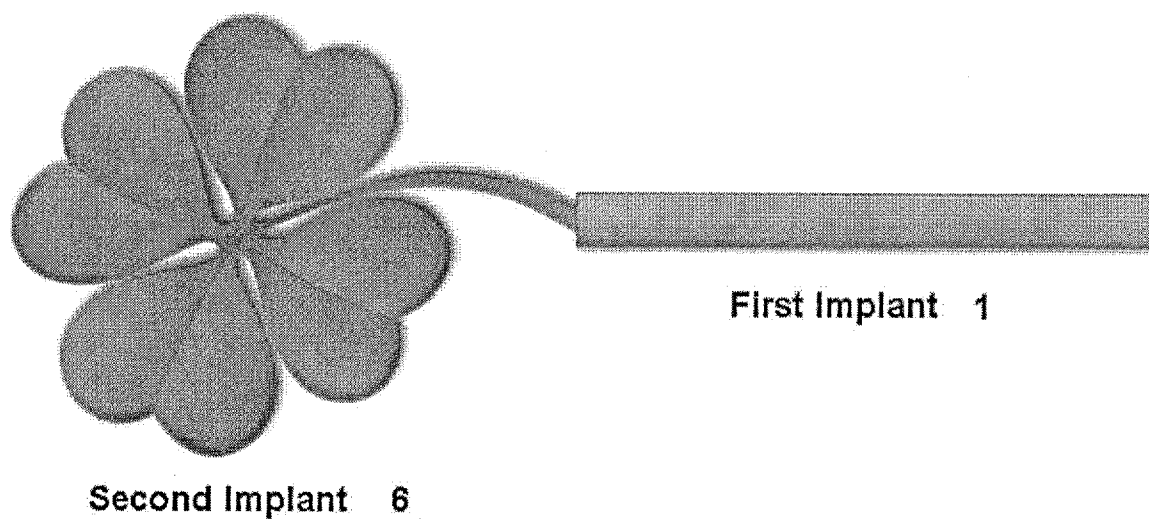


FIGURE 4

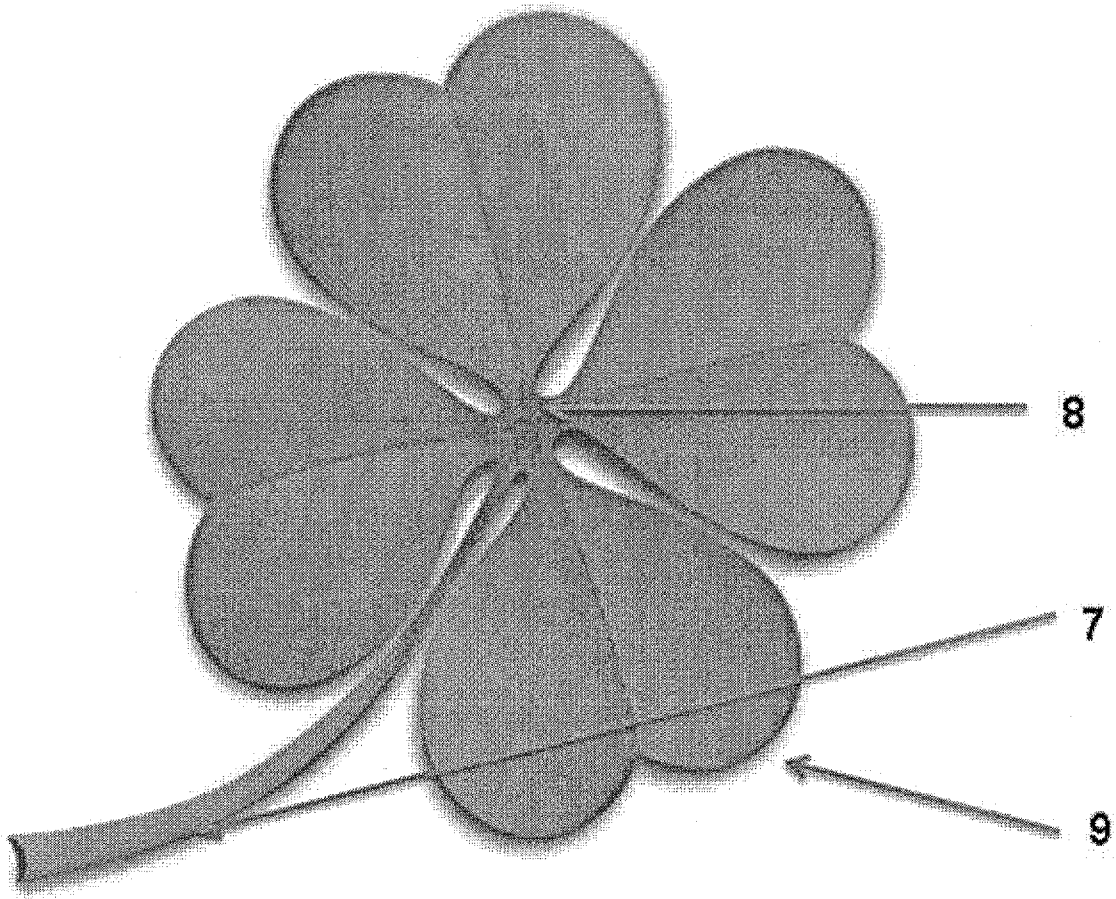


FIGURE 5

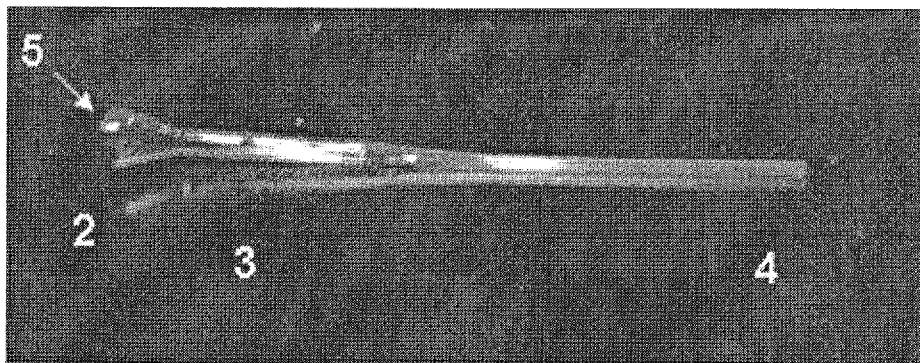


FIGURE 6

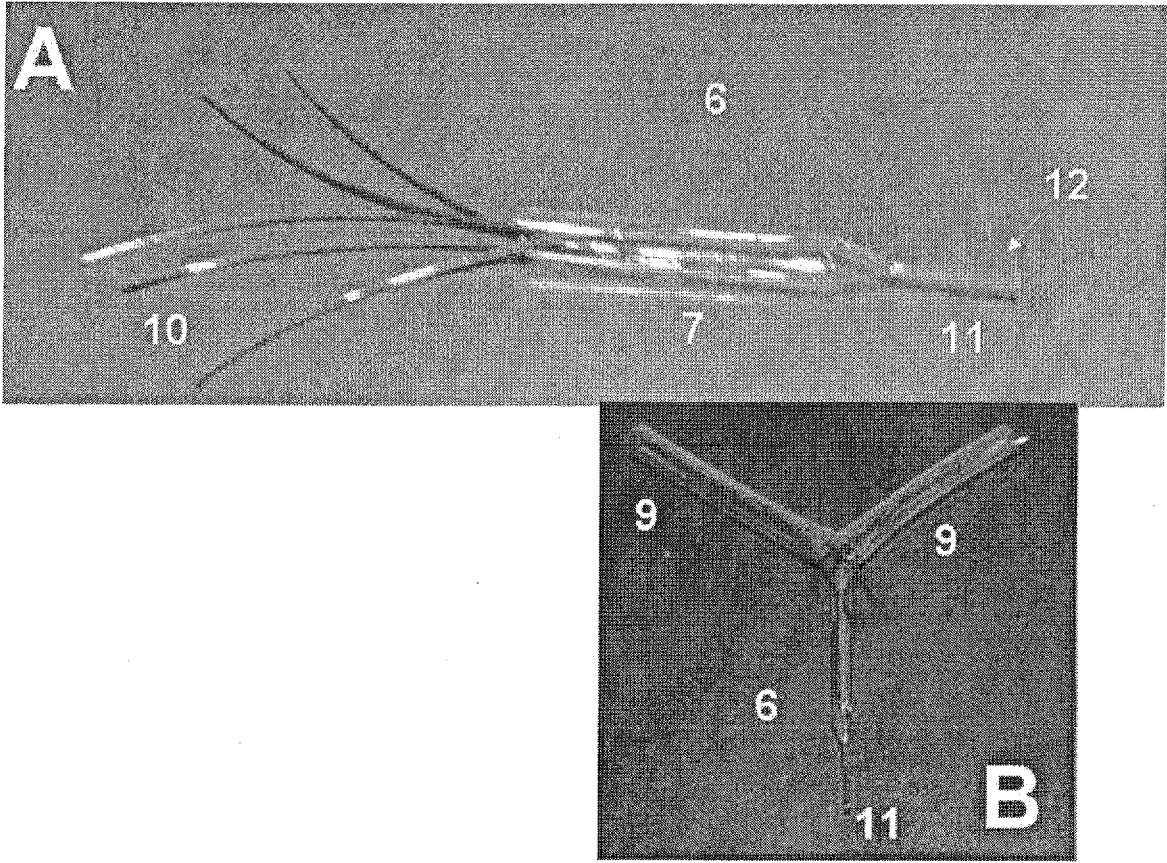


FIGURE 7

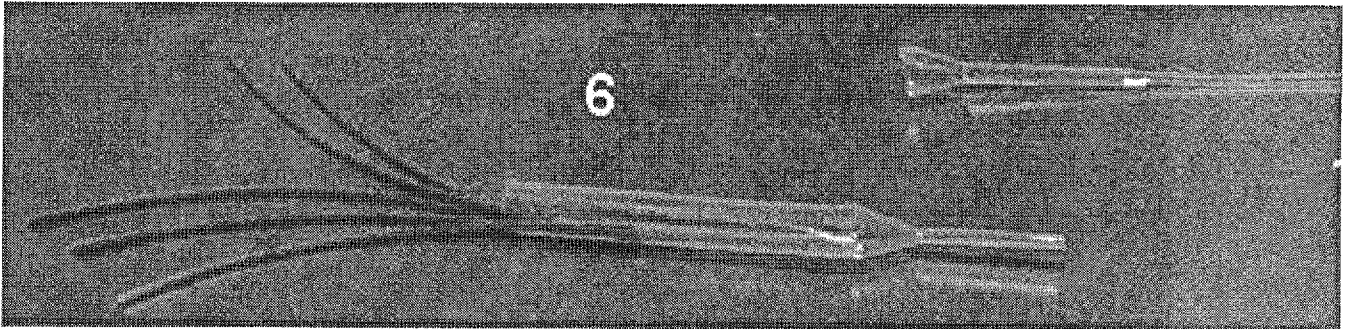


FIGURE 8

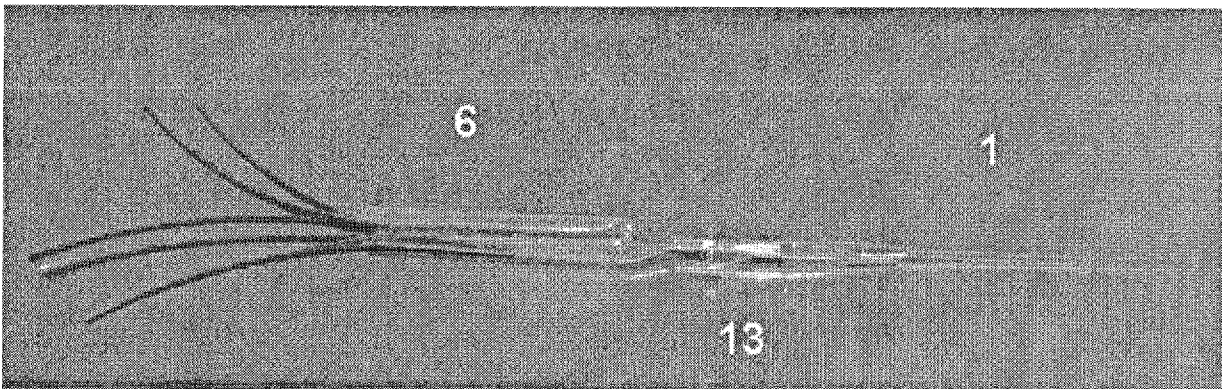


FIGURE 9

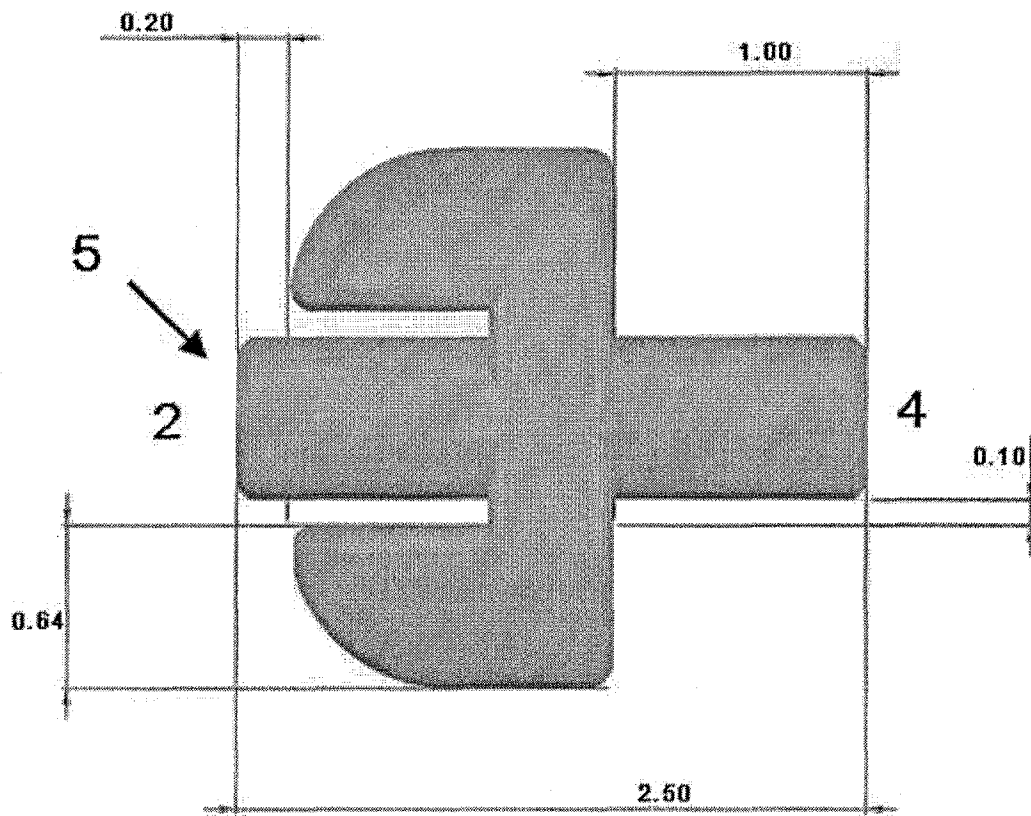


FIGURE 10

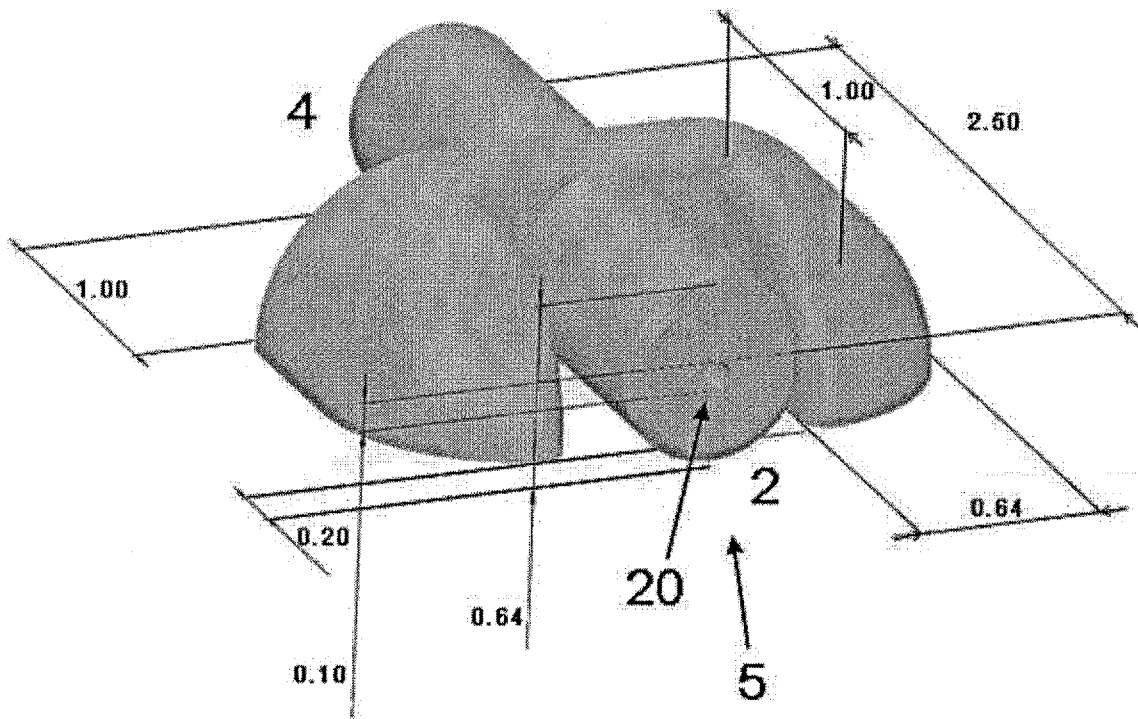


FIGURE 11

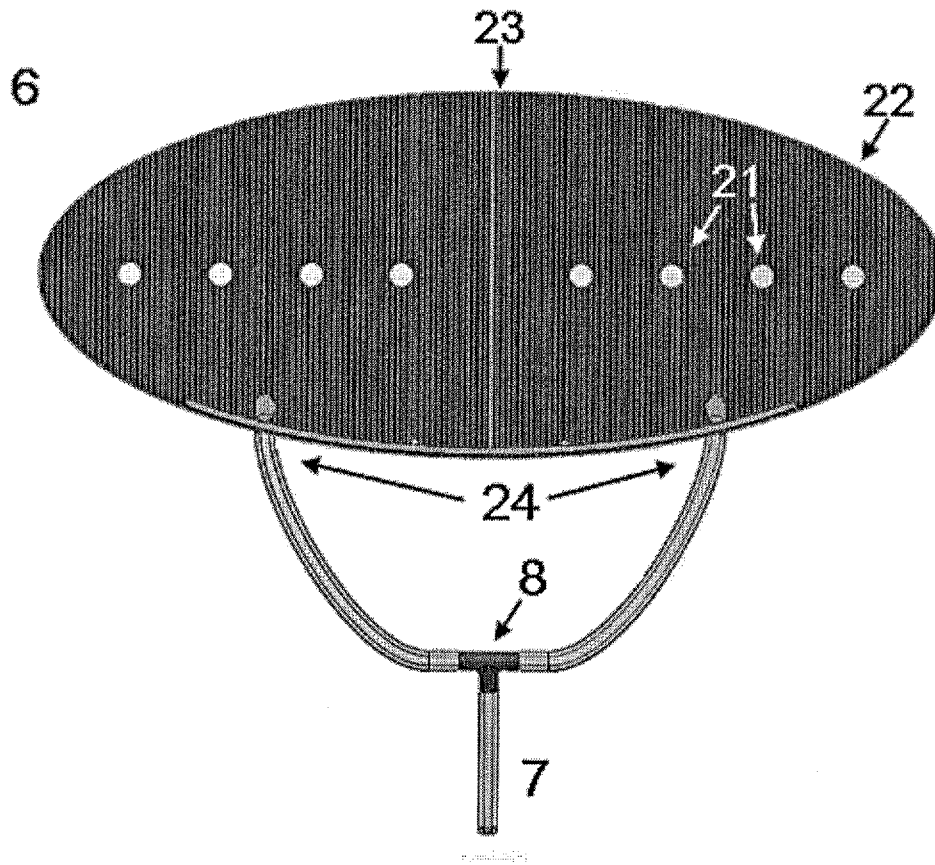


FIGURE 12

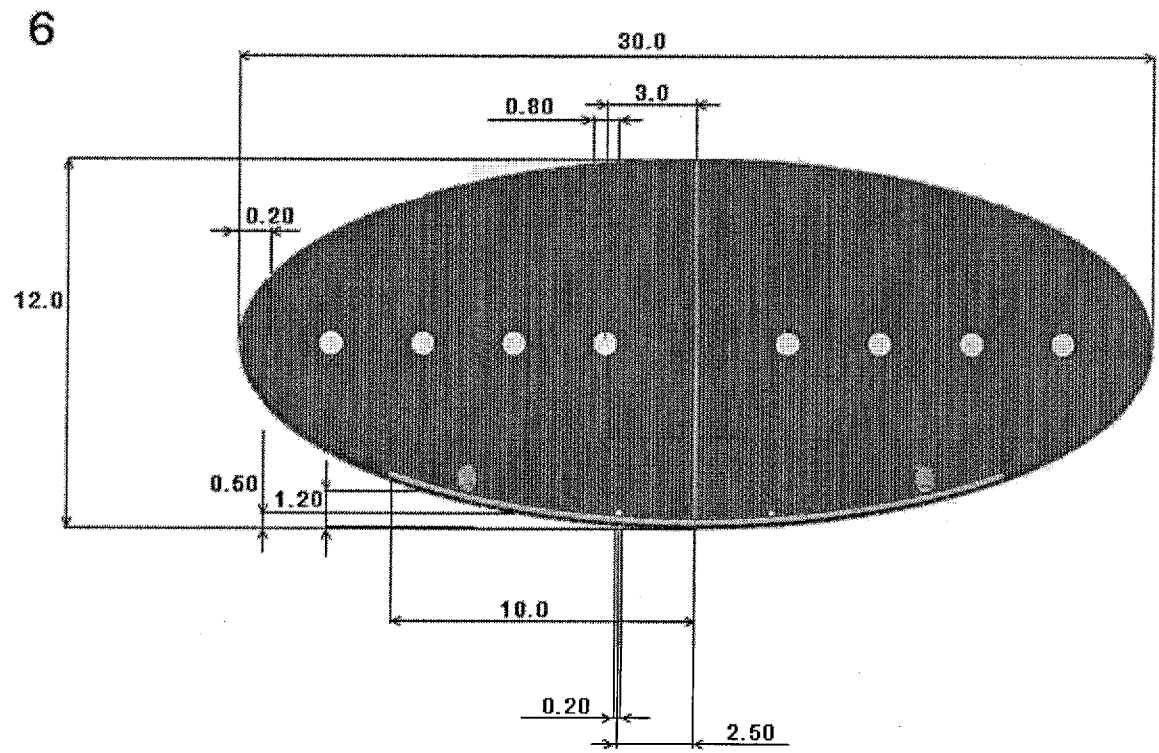


FIGURE 13

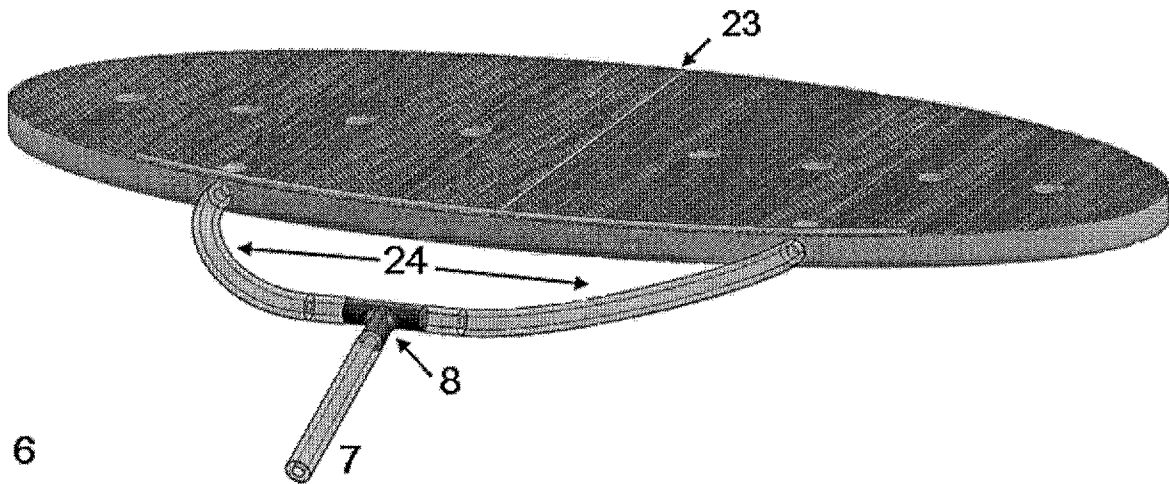
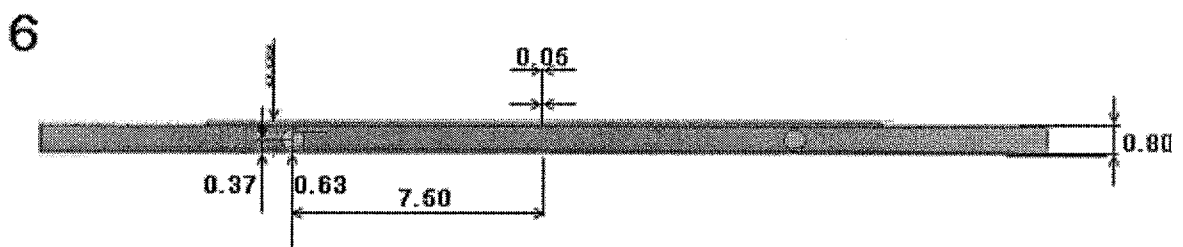


FIGURE 14



INTERNATIONAL SEARCH REPORT

International application No.

PCT/US2014/064129

A. CLASSIFICATION OF SUBJECT MATTER IPC(8) - A61F 9/007 (2014.01) CPC - A61F 9/00781 (2014.11) According to International Patent Classification (IPC) or to both national classification and IPC		
B. FIELDS SEARCHED Minimum documentation searched (classification system followed by classification symbols) IPC(8) - A61F 9/007; A61M 5/00 (2014.01) CPC - A61F 9/00781 (2014.12) Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched USPC - 604/8, 294 (keyword delimited) Electronic data base consulted during the international search (name of data base and, where practicable, search terms used) Orbit, Google Patents, Google Scholar, Google. Search terms used: detachable shunt controllable ophthalmic aqueous drainage device silicone tubes multiple plates clover		
C. DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 5,681,275 A (AHMED) 28 October 1997 (28.10.1997) entire document	1-6, 9-16
Y	US 2006/0235367 A1 (TAKASHIMA et al) 19 October 2006 (19.10.2006) entire document	1-6, 9-16
Y	US 2010/0249691 A1 (VAN DER MOOREN et al) 30 September 2010 (30.09.2010) entire document	9-16
A	US 7,850,637 B2 (LYNCH et al) 14 December 2010 (14.12.2010) entire document	1-16
A	US 2010/0274259 A1 (YARON et al) 29 October 2010 (28.10.2010) entire document	1-16
A	US 2007/0293872 A1 (PEYMAN) 20 December 2007 (20.12.2007) entire document	1-16
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Date of the actual completion of the international search 12 January 2015		Date of mailing of the international search report 03 MAR 2015
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201		Authorized officer: Blaine R. Copenheaver PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774