(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
14 December 2006 (14.12.2006)

PCT

(10) International Publication Number
WO 2006/133066 A2

(51) International Patent Classification:
A61M 5/00 (2006.01) *A61F 11/00* (2006.01)

(21) International Application Number:
PCT/US2006/021692

(22) International Filing Date: 5 June 2006 (05.06.2006)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
11/145,847 6 June 2005 (06.06.2005) US

(63) Related by continuation (CON) or continuation-in-part (CIP) to earlier application:
US 11/145,847 (CIP)
Filed on 6 June 2006 (06.06.2006)

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(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, LY, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NG, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SM, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US (patent), UZ, VC, VN, YU, ZA, ZM, ZW.

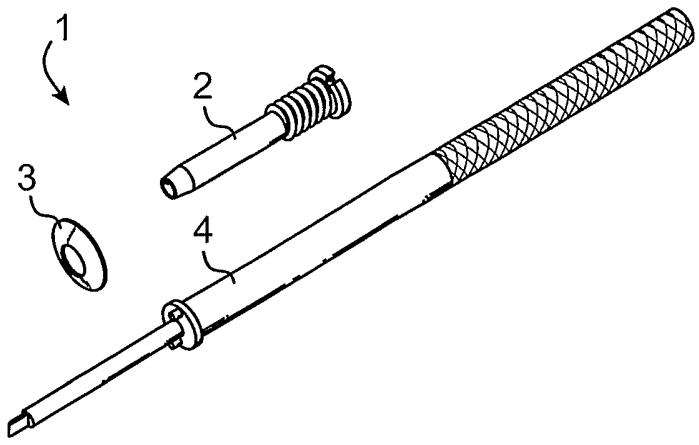
(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IS, IT, LT, LU, LV, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Declaration under Rule 4.17:
— *of inventorship (Rule 4.17(iv))*

Published:
— *without international search report and to be republished upon receipt of that report*

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) **Title:** LACRIMAL DRAINAGE DEVICE AND METHOD



(57) **Abstract:** A lacrimal bypass drainage device (1) uses a cannula or tube (2) having a flange on the ocular end and a threaded outer surface to provide for greater axial friction. The flange is keyed to allow engagement by a screwdriver type tool (4) having a correspondingly keyed trocar mounted to a manipulable handle. The trocar has a forward shaft portion for coaxially engaging the cylindrical lumen of the tube. The shaft portion has a front end formed into a blade and an opposite rear end formed into a radially widened haft. The haft carries two axially forward projecting prongs to engage correspondingly placed notches in the flange of the tube. The handle portion of the tool extends rearwardly from the haft. The blade can be formed into two frustoconical symmetric arcuate sections to enhance cutting during twisting manipulation of the tool. The trocar portion can be made to be replaceable for differently sized, shaped or bladed trocar portions. A removable biocompatible washer (3) is provided to discourage tissue overgrowth immediately after emplacement. One or more radial drainage holes can be formed near the distal end of the tube to overcome axial blockages. An alternate embodiment provides for a tube placed from the nasal side having nasal side radial protrusions and a removable eye side flange in the form of a keyed nut.

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Lacrimal Drainage Device and Method

Field of the Invention

This invention relates to devices and methods for correcting drainage in the lacrimal system, and more particularly to addressing canalicular stenosis or obstruction, and nasolacrimal duct obstruction that does not respond to dacryocystorhinostomy or dilation.

Background

The orbital portion of the lacrimal gland is located in the superotemporal orbit and the palpebral portion of the lacrimal gland is located on the posterior surface of the superotemporal upper lid. The lacrimal gland produces the aqueous portion of the tear film. Ductules from the orbital portion of the lacrimal gland pass through the adjacent palpebral lacrimal gland to empty into the superior conjunctival cul-de-sac. Smaller accessory lacrimal glands in the upper and lower lids also contribute to tear production. The tears bathe the surface of the eye and then drain into the puncta and canaliculi in the medial upper and lower lids. The superior and inferior canaliculi join as the short common canaliculus. The tears flow from the superior and inferior canaliculi through the common canaliculus, into the lacrimal sac, and down the nasolacrimal duct into the nose.

The canaliculi can become obstructed or stenotic on a congenital basis, from trauma such as lacerations, from inflammation, or the obstruction can be idiopathic. When the upper and lower canaliculi or the common canaliculus become obstructed, tears can no longer drain from the surface of the eye through the lacrimal system into the nose. The tears well up in the eye as a result, and run down the face. The excess tears blur the vision and the patient has to constantly dab the eye.

The nasolacrimal duct can also become obstructed leading to tearing. Tears stagnate in the lacrimal sac and bacteria multiply, causing infection which can lead to painful enlargement of the lacrimal sac filled with pus, and discharge over the eye.

Canalicular obstruction or stenosis is usually treated by forming a new passage through the obstruction with a probe, and dilation with probes or a balloon catheter. A silicone tube is often placed as a temporary stent. At times a dacryocystorhinostomy (DCR) is also performed. A DCR consists of surgically creating a new passage from the lacrimal sac into the nose. This can be performed with a balloon catheter as disclosed in my U.S. Patent Nos. 5,021,043 and 5,169,386, using an endoscope or externally through an incision.

Canalicular obstruction often recurs after dilation and silicone intubation. A new drainage system is then required to allow tears to drain from the conjunctival cul-de-sac into the nose. This necessitates placement of a permanent drainage tube, often called a canalicular bypass tube, which extends from the very medial conjunctiva into the nose. The tube is angled somewhat inferiorly to aid in tear drainage. A conjunctivodacryocystorhinstomy (CDCR), which is a DCR extending through the conjunctiva, is performed prior to or at the same time as tube emplacement.

A DCR for nasolacrimal duct obstruction without canalicular obstruction is usually successful. However, tearing persists in some patients in spite of a DCR that seems patent. The DCR cannot drain a large enough volume of tears in these patients, some of whom produce a larger volume of tears than normal. A canalicular bypass tube is often required in such patients.

The most commonly used canalicular bypass tube is a pyrex glass tube known as a "Jones tube" as described in Glatt, H.J. and Putterman, A. M., Conjunctivodacryocystorhinostomy in Mauriello, Jr., J.A. (Ed), Unfavorable Results of Eyelid and Lacrimal Surgery: Prevention and Management, Boston : Butterworth Heinemann, 2000; pp 577-582. It has a flange on the end that opens to the ocular surface. The end that is in the nasal cavity has no flange or a very minimal flange which is not adequate to discourage axial migration of the tube toward the eye. These tubes range from just over 2 millimeters ("mm") to 2.4 mm in outside diameter and 13 mm to 22 mm in length. A less commonly used tube is made of polyethylene and is not as rigid as glass. It is cut to the desired length during surgery.

The tube is placed in the following manner. The medial conjunctiva is excised with a small scissors. A large diameter needle is pushed through the conjunctival opening, angled about 25 degrees inferiorly, into the nasal cavity. The nasal end is visualized to be sure that the location and angle are proper. The needle is withdrawn and a two-sided knife blade is brought through the same tract. The knife blade is withdrawn and the tract is further dilated with dilators or balloon catheters. Next, a narrow diameter oblong rigid metal probe is placed through the lumen of the tube. The probe is placed in the tract to act as a guide. The tube is then slid along the probe and pushed into the tract so that it extends from just lateral to the conjunctiva through the tract into the nasal cavity.

Several problems may occur using the above method. Considerable force is often required to push the tube through the tract because the surrounding tissues tend to contract immediately after the dilator is removed. The pyrex tube can fracture and the broken glass may be difficult or impossible to retrieve from the deeper tissues. The softer polyethylene tube tends

to bend under the applied force and therefore may prevent the surgeon from being able to push the tube into place.

Other problems frequently occur early or late after surgery. The tube can migrate laterally or axially toward the eye as there is nothing to prevent this other than tissue contraction around the tube. This irritates the eye or the tube can completely extrude. The tube may also migrate medially in spite of the flange. It can then become covered with conjunctiva or other tissue, and be impossible to reposition or sometimes to even locate.

Another potential problem can occur when the distal end of the tube lies against the nasal septum or other nasal tissues which block the distal opening of the tube so that tears cannot freely drain out the end of the tube. This prevents tears from the surface of the eye draining through and out the distal tube opening into the nose. As a result tears well up in the eye and run down the face. The patient constantly has to dab the eye. Some or all of the following procedures are required if the distal end of the tube is blocked. The tube can be removed and replaced with a shorter tube. However, this can only be performed if there is adequate room between the nasal septum and lateral nasal wall. Otherwise the tube will be too short to allow the distal end of the tube to extend beyond the lateral nasal wall. An alternative is to reposition the tube at a different angle. Repositioning alone is usually not sufficient. Both tube exchange and tube repositioning must typically be performed in the operating room. The third treatment is a nasal septoplasty if the nasal septum is deviated to the side of the tube. Again, this requires surgery in the operating room.

The diameter of the flange of the tube is selected to be large enough to discourage axial migration and conjunctival overgrowth while not being so large as to be unduly uncomfortable or prevent the flow of tears. This has resulted in a trade-off where overgrowth still occurs in some patients.

A pyrex tube has been proposed having a second smaller flange that is 4 mm from the main flange on the ocular surface end. However, this second flange makes the tube difficult to push into position, and even more difficult to reposition or replace. Therefore, it has rarely been used.

A canalicular bypass tube having large flanges on both the nasal and ocular ends has not been constructed because there would be no practical way to push it into position, and no practical way to extract it.

A pyrex bypass tube has been made having a hole through the flange for passage of a suture to temporarily attach to the surrounding conjunctiva. This feature only enhances axial

stability while the suture is intact. Further, this approach also suffers from conjunctival overgrowth.

Therefore, a lacrimal bypass drainage device is needed which minimizes the above identified problems.

Summary

The instant embodiments provide a migration resistant lacrimal bypass drainage device. Some embodiments provide a lacrimal bypass drainage tube having an outer surface treated to provide for controlled axial friction and a flange on the ocular end. Axial friction is controlled by forming a helicoidal thread on the outer surface of the tube, thereby allowing the tube to be conveniently "screwed" into place, repositioned, or extracted. A removable biocompatible washer placed on the tube adjacent to the flange is provided to discourage tissue overgrowth immediately after emplacement. The flange is keyed to allow engagement by a tool having a correspondingly keyed surface to allow for the controlled application of torque.

In some embodiments, the preferred tool employs a keyed trocar portion secured to a manipulable handle. The trocar has a forward shaft portion for coaxially engaging the central cylindrical lumen of the drainage tube. In other embodiments, the shaft portion has a front end formed into a cutting bit and an opposite rear end formed into a radially widened haft. The haft carries two prongs which project axially forward to engage corresponding notches in the flange of the tube. The handle portion of the tool extends rearwardly from the haft. In one embodiment the cutting bit can be formed into two frustoconical symmetrically arcuate blades to enhance cutting during twisting manipulation of the tool. The keyed trocar can be made to be replaceable for differently sized, shaped or bladed trocars.

Some embodiments provide a drainage tube placed from the nasal side having a nasal side radial protrusions and a removable eye side flange in the form of a keyed nut. The nut is formed to have holes for engagement by temporary sutures immediately after emplacement. An overgrowth inhibiting biocompatible washer is provided to be placed on the tube adjacent to the nut.

Some embodiments provide a lacrimal bypass drainage device which comprises an oblong hollow tube defining a central lumen, and having first and second ends, and an outer surface; wherein said tube has a major axis and an axial dimension selected to span between the conjunctival cul-de-sac and the nose; a flange extending radially outward from a portion of said outer surface proximate to said first end; and, wherein said outer surface is shaped to have a

threaded section. In some embodiments the threaded section is axially adjacent to said flange. In some embodiments the threaded section comprises a thread having a flattened crest-type shape. In some embodiments the flange is shaped to have a first angular bearing surface. In some embodiments the flange is shaped to have a first radial notch, thereby providing said first angular bearing surface. In some embodiments the flange is shaped to have a second radial notch diametrically opposite said first notch. In some embodiments the flange has a frustoconical outer surface and a substantially frusto conically shaped lumen entrance. In some embodiments a distal section of said outer surface tapers radially inwardly toward said second end. In some embodiments the tube is shaped to have at least one radial drainage opening spaced a distance from said second end. In some embodiments the tube is shaped to have at least one pair of radial drainage openings diametrically opposite from one another. In some embodiments the tube is shaped to have a plurality of radial drainage wherein a first of said plurality has a diameter greater than a diameter of a second of said plurality.

In some embodiments the device further comprises said threaded section being shaped to have a cross-section which exhibits defined mathematical derivatives at every concave part, and does not exhibit a defined mathematical derivative at a point in a convex part. In some embodiments the device is formed from a monolithic piece of material. In some embodiments the tube comprises PMMA. In some embodiments the tube has an axial length between said ends, said length being between about 5 millimeters and about 30 millimeters.

In some embodiments the device further comprises a washer having a central aperture sized and shaped to pass over said outer surface but not over said flange; and a peripheral edge portion sized to extend radially beyond a radial extent of said flange when said washer is mounted upon said tube. In some embodiments the washer has a non-planar shape. In some embodiments the washer has an outer diameter of between about 2.5 mm and about 15 mm.

In some embodiments, the device further comprises a keyed tool which comprises: a distal shaft sized to intimately penetrate said lumen; a proximal hand manipulable handle; and, a haft mounted between said shaft and said handle. In some embodiments the shaft terminates at a distal cutting bit. In some embodiments the device further comprises means for angularly securing said tube to said tool. In some embodiments the means comprise at least one prong extending axially from said haft. In some embodiments the flange is shaped to have a first angular bearing surface; and said haft is shaped to have a second angular bearing surface for bearing against said first angular bearing surface. In some embodiments the bit comprises a first blade. In some embodiments the blade has an arcuate cutting edge. In some embodiments the

blade is axially arcuate. In some embodiments the bit further comprises a second blade diametrically symmetrical with said first blade. In some embodiments the tool further comprises an angular orientation indicator. In some embodiments the shaft comprises axial gradation markings.

Some embodiments provide that in a lacrimal bypass drainage device comprising a tube having an outer diameter first and second ends, and a flange extending radially outward from said outer diameter proximate to said second end, there is an improvement which comprises a biocompatible washer shaped and dimensioned to have a through-hole sized to accommodate the outer diameter of said tube; and a peripheral edge portion sized to extend radially beyond a radial extent of said flange when said washer is mounted upon said tube. In some embodiments the flange is shaped to have an angular bearing surface. In some embodiments the improvement further comprises means for resisting inadvertent axial movement of said tube. In some embodiments the means comprise said tube being shaped to have a helicoidal thread extending radially outwardly from said outer diameter.

Some embodiments provide a threaded lacrimal bypass cannula.

Some embodiments provide a kit for installing a bypass drainage tube in the body of a patient, said kit comprises: a first threaded cannula having a radially extending flange at a first end; said flange having a first angular bearing surface; and, a trocar having a second surface shaped and dimensioned to intimately contact and bear against said first surface when said trocar matingly engages said cannula. In some embodiments the first angular bearing surface defines a given cross-sectional geometry; and wherein said second surface has a cross-sectional geometry substantially symmetrical with said given cross-sectional geometry. In some embodiments the first cannula has a first axial length, and said kit further comprises a second cannula having a second axial length greater than said first axial length. In some embodiments the kit comprises a plurality of differently sized cannulas.

Some embodiments provide a trocar comprising a keyed haft. In some embodiments the trocar further comprises a handle secured to said haft. In some embodiments the trocar further comprises an angular orientation indicator.

Some embodiments provide a method for forming a lacrimal bypass drain which comprises: forming a tract between the conjunctiva and the nasal cavity of a patient; selecting an open ended hollow tube having a keyed flange at a first end and an opposite second end, and a threaded outer surface; and, emplacing said tube into said tract. In some embodiments the emplacing comprises: securing said tube to a trocar having a cross-sectional geometry sized and

shaped to matingly engage said keyed flange; manipulating said trocar using said handle. In some embodiments the manipulating comprises: simultaneously axially pushing and angularly rotating said trocar. In some embodiments the method further comprises adjusting an axial position of said tube by rotating said tube.

Some embodiments provide that in a lacrimal bypass drainage device comprising a tube having an outer diameter, first and second ends, and a flange extending radially outward from said outer diameter proximate to said second end, an improvement which comprises said tube having an outer surface portion formed into a helicoidal thread.

Brief Description of the Drawings

Fig. 1 is a diagrammatic perspective view of the components of the lacrimal bypass drainage device.

Fig. 2 is a diagrammatic perspective view of the drainage cannula of Fig. 1.

Fig. 3 is a diagrammatic cross-sectional left side view of the cannula of Fig. 2 taken along line 3-3.

Fig. 4 is a diagrammatic cross-sectional side view of the cannula threads according to one embodiment of the invention.

Fig. 5 is a diagrammatic cross-sectional side view of buttress-shaped cannula threads according to an alternate embodiment.

Fig. 6 is a diagrammatic cross-sectional side view of hook-shaped cannula threads according to an alternate embodiment.

Fig. 7 is a diagrammatic ocular end view the cannula of Fig 2.

Fig. 8 is a diagrammatic perspective view of the emplacement tool component of Fig. 1.

Fig. 9 is a diagrammatic cross-sectional left side view of the tool of Fig. 8 taken along line 9-9.

Fig. 10 is a diagrammatic cross-sectional top view of the tool of Fig. 8 taken along line 10-10.

Fig. 11 is a diagrammatic perspective view of the washer component of Fig. 1.

Fig. 12 is a diagrammatic cross-sectional left side view of the washer of Fig. 11 taken along line 12-12.

Fig. 13 - Fig. 15 are diagrammatic views of the method steps for emplacing a lacrimal bypass drainage tube according to one embodiment of the invention.

Fig. 16 is a diagrammatic perspective view of the tube engaging portion of an adjustment tool according to an alternate embodiment.

Fig. 17 is a diagrammatic cross-sectional left side view of the tool of Fig. 16 taken along line 17-17.

Fig. 18 is a diagrammatic perspective view and zoomed view of the tube engaging trocar portion of an emplacement tool according to an alternate embodiment.

Fig. 19 is a diagrammatic left side elevational view of the cutting bit portion of the trocar of Fig 18.

Fig. 20 is a diagrammatic distal end elevational view of the cutting bit portion of the trocar of Fig 20.

Fig. 21 is a diagrammatic cross-sectional left side view of the cutting bit portion of a trocar according to an alternate embodiment.

Fig. 22a - Fig. 22k are diagrammatic ocular end views of various embodiments of a lacrimal bypass drainage tube providing angular bearing surfaces.

Fig. 23 is a diagrammatic perspective view of an alternate embodiment of a lacrimal drainage cannula having a conical flange and radial drainage opening.

Fig. 24 is a diagrammatic perspective view of an alternate embodiment of a lacrimal drainage cannula having a removable nut-type flange and dual opposite radial drainage openings.

Fig. 25 is a diagrammatic perspective view of an alternate embodiment of a lacrimal drainage cannula for emplacement from the nasal side.

Fig. 26a - Fig. 26h are diagrammatic views of the method steps for emplacing a lacrimal bypass drainage tube according to the cannula of Fig. 25.

Description of the Exemplary Embodiments

Referring now to the drawing, there is shown in Fig. 1, a first embodiment of the lacrimal bypass drainage device **1** according to the invention. The device includes a cannula or drainage tube **2**, an overgrowth inhibiting washer **3**, and a hand tool **4** for allowing emplacement and adjustment of the tube in a patient.

Referring now to Figs. 2-3, the tube **2** is preferably made from an integrated, monolithic piece of fracture resistant, biocompatible material such as polymethylmethacrylate (PMMA), titanium or other rigid or semi-rigid durable material. The tube is shaped to have a generally oblong cylindrical body **5** having a central major axis **6**, a cylindrical outer surface section **7** of a

given outside diameter $\mathbf{D_O}$ and a cylindrical central axial lumen **8** of a given inside diameter $\mathbf{D_L}$ which is less than the outside diameter and extends from a first opening at a distal, nasal end **9** to a second opening at an opposite proximal, ocular end **10**. The tube has a flange **13** located at the ocular end which extends circumferentially and radially outwardly beyond the outer surface of the body. The tube body has a medial section **19**, a threaded section **20**, and a distal tapered prow section **18** at the nasal end **9**.

The tube has a given axial length $\mathbf{L_C}$ which is selected according the anatomy of the patient. For most human patients the length is preferably between about 5 millimeters ("mm") and about 30 mm, and most typically between about 15 mm and about 22 mm. A number of specific length tubes can be made available as part of a kit so that the surgeon has a choice for a given situation. For example, a kit can contain six differently sized tubes ranging from 15 mm to 22 mm at 1 mm increments.

Similarly, the outside diameter $\mathbf{D_O}$ of the tube body in the medial section **19** is selected according to a patient's anatomy. A typical range in humans is between about 1 mm and 6 mm, and most typically is about 2.5 mm. The lumen diameter $\mathbf{D_L}$ is selected to provide adequate drainage throughput while maintaining structural soundness in the tube and is therefore dependent on the tube material as well as patient anatomy and condition. For a tube made from PMMA the inside diameter is selected so the thickness **T** of the tube wall in the median section is preferably at least 0.1 mm, more preferably at least 0.5 mm, and most preferably about 1.3 mm. Therefore, for most applications using a PMMA tube, the preferred range of the inside diameter is between about 0.25 mm and about 5 mm, and most typically is about 1.3 mm.

The distal prow section **18** of the tube has a given axial length and gradually tapers to form a generally frustoconical outer surface or otherwise tapered shape to facilitate emplacement. The axial length of the prow section preferably ranges between about 0.1 mm and about 2.5 mm, and most typically is about 2.2 mm. The outer diameter of the prow gradually tapers or decreases from the outside diameter $\mathbf{D_O}$ of the medial section to slightly greater than the lumen diameter $\mathbf{D_L}$ at the distal end **9** of the tube body so that a sharp edge is avoided at the distal end. Also, a rounded edge **21** is preferred to facilitate emplacement. For a tube having an outside diameter of 2.5 mm and a lumen diameter of 1.3 mm, the outer diameter of the prow goes from about 2.5 mm at its widest to about 1.4 mm at the nasal end. It should be noted that the outer diameter of the body may taper over part or all of the length of the tube.

A first radial drainage opening **11** is provided extending through from the outer surface of the tube body **5** to the lumen **8**. In this way, tears drain into the nose through the radial opening when the nasal septum or other nasal tissue blocks the distal, axial opening of the tube at the distal end **9**. The opening can be circular, elliptical, oval or other shape. Preferably the shape is rounded so that corners do not exist to trap fluid. The center of the opening is located proximate to but spaced apart a distance from the distal, nasal end **9** of the tube. This distance preferably ranges between about 1 mm and 15 mm and is typically about 2.5 mm. It is further preferable that the radial opening **11** does not extend axially into any tapered prow section **18** which could create surfaces impacting the insertability of the tube. The diameter of the radial opening preferably ranges between about 0.005 mm and 4 mm, and is typically about 0.5 mm, but will depend on the diameter of the tube, the tube material, its wall thickness, and the location of the radial opening or additional radial openings as described below. It should be noted that the tube can optionally be formed to have a rounded, closed distal end to allow easier insertion when no keyed trocar is used. In this case, one or more radial drainage openings would be required.

The tube **2** is formed to have a generally helicoidal threaded section **20** where at least one helicoidal thread **22** extends radially outwardly from the outside diameter $\mathbf{D_O}$ of the medial section to the outer diameter $\mathbf{D_T}$ at the thread crest. The threaded section allows the axial position of the tube to be adjusted by imparting a twisting motion upon the tube through application of sufficient torque to overcome the friction exerted by the surrounding tissue. The thread provides the tube with an angularly controlled radial prominence for discouraging inadvertent, unintended axial migration of the tube once it has been emplaced. The threaded section **20** preferably extends an axial length from a proximal part **15** adjacent to the flange **13** to a distal part **16** adjacent to the medial section **19** of the tube body **5**. It should be noted that the threaded section need not contact the flange, but should be located to engage the walls of the tract formed between the conjunctiva and the nasal cavity. The axial length of the threaded portion is preferably between about 10% and about 100% of the total axial length of the tube. In most instances, it is preferable to have the medial section **19** of the tube having a smooth outer surface to facilitate penetration through the tissues, particularly at a part which passes through the lateral nasal wall. In most instances, the axial length of the threaded section ranges between about 1 mm and about 30 mm, and most typically is about 5.5 mm. In most instances, the inside diameter of the thread troughs or roots ranges between about 0.005 inch and about 0.89 inch. It

should be noted that this diameter can be smaller than the outside diameter $\mathbf{D_O}$ of the tube body in the medial section but greater than the lumen diameter $\mathbf{D_L}$. In most instances, the outside diameter $\mathbf{D_T}$ of the thread crests ranges between about 0.01 inch and about 0.5 inch.

The threaded section is preferably shaped and dimensioned for the unique purpose of permanently or semi-permanently engaging the soft tissue in the lacrimal zone to a degree which discourages or prevents axial migration but without unduly creating structures which are too large to be accommodated by the surrounding anatomy, or can trap fluids and lead to infection. This is in marked contrast to other surgical devices which may use threaded tubes for the relatively short duration of the operative and/or post-operative periods and which do not have the anatomical restrictions imposed by the lacrimal area. It is preferred that in most cases the thread will act to discourage axial migration without the need for additional structures such as sutures, will help to partially cut the tract as the tube is emplaced, and will not unduly lacerate tissues during intentional or unintended extraction. Although many types of thread cross-sections may work adequately, preferred cross-sections will address the above requirements in a superior manner.

In Fig. 3 the cross-section of the threads shows a curved shape having rounded crests and rounded troughs. The cross-sectional plane includes the central axis **6** of the tube. These smooth and rounded features discourage fluid collection which can lead to infection and avoid laceration after emplacement or during removal. Unfortunately, such a shape is less resistant to axial migration than thread shapes having a larger diameter or having a sharper cross-section, and will tend not to cut a tract during emplacement.

Referring to Fig. 4, there is shown the threaded section **33** of a bypass tube having threads which have a Unified National Coarse ("UNC") or Unified National Fine ("UNF") shaped cross-section. This cross-sectional thread shape is characterized by a series of generally equilateral triangles forming the faces **34** and forming a thread angle $\mathbf{A_T}$ of typically 60 degrees. A crest portion **35** of the thread is flattened to form defined corners **36** between the crest portion and either face to facilitate the cutting or tapping of a threaded tract during emplacement, but is not so sharp as to lacerate after emplacement or during removal. The root or trough **37** of the thread is rounded or otherwise shaped to provide a smoothed, curved concave surface to avoid fluid stagnation. In most instances, the thread angle $\mathbf{A_T}$ ranges between about 45 degrees and about 75 degrees, and is most typically about 60 degrees. In most instances, a thread pitch is selected to provide between about 1 crest per inch and about 80 crests per inch. Although many

standard machine type threads having a flattened crest-type shape are acceptable, the preferred thread type is UNC 6-32 type threads. In most instances, other acceptable thread types vary from UNF 0-80 to UNC 5.875-16.

Referring to Fig. 5, there is shown an alternate embodiment wherein the threads have a Buttress-type cross-sectional shape to further discourage laceration during intended or unintended extraction. For this thread shape an angle $\mathbf{A_D}$ is formed between a distal face **38** and a plane perpendicular to the axis of the tube, and an angle $\mathbf{A_P}$ is formed between a proximal face **39** and a similar perpendicular plane. In most instances, angle $\mathbf{A_D}$ ranges between about 0 degrees and about70 degrees and is most typically is about 10 degrees to provide adequate dwell for manufacturing economy, and angle $\mathbf{A_P}$ ranges between about 10 degrees and about 70 degrees, and is most typically is about 45 degrees.

Referring to Fig. 6, there is shown a second alternate embodiment wherein the threads have a hook-type cross-sectional shape **40** wherein the distal face **41** has a convex shape to further discourage laceration during extraction. Further, the flattened portion **42** of the crest is angled toward distal end of the tube forming an angle $\mathbf{A_C}$ with a plane parallel to the tube axis. In most instances, angle $\mathbf{A_C}$ ranges between about 1 degree and about 120 degrees and is most typically is about 45 degrees to provide corners oriented to facilitate cutting or tapping of a tract during emplacement.

It is important to note that in the above embodiments relating to Figs. 4-6, the troughs are smooth and the crests have corners. In other words, the thread cross-section exhibits defined mathematical derivatives at every concave part of the curve, but does not exhibit a defined mathematical derivative at at least one point in the convex part of the curve.

Referring now to Figs. 2, 3 and 7, the flange **13** is generally circularly shaped and angularly extends 360 degrees circumferentially around the ocular end of the tube to provide an axial bearing surface **31** at the ocular end to bear an axial pushing force from the tool. The flange diameter is selected to be small enough for comfort and adequate drainage but large enough to discourage overgrowth. Because of the thread, the flange can have a smaller outside diameter while still allowing the tube to exhibit an adequate axial migration resistance. When used in combination with the temporary overgrowth inhibiting washer, the flange can have its radially largest portion be as small as 110% of the outside diameter $\mathbf{D_O}$ of the medial section. In most instances, the diameter of the flange preferably ranges between about 3 mm and about 8 mm, and most typically is about 4.5 mm. The axial length of the flange preferably ranges

between about 0.25 mm and about 3 mm, and most typically is about 1 mm. Although not shown, suture holes can be provided to extend axially through the flange.

Although during emplacement the surgeon can grasp the flange with a toothed forceps other tool to impart the twisting motion upon the tube to screw it into place or adjust its axial position, the present embodiment of the device provides at least one angular bearing surface on the tube sized, shaped and positioned to contact a corresponding surface on a torque inducing tool. In other words, the tube has a surface oriented to contact a corresponding surface on a twistingly manipulable tool such as a screwdriver to conveniently impart a twisting motion upon the tube.

Therefore, the tube is formed to have two diametrically opposite notches **25,26** extending radially inwardly from the circular outer periphery **27** of the flange **13** to provide the angular bearing surface **31** on any surfaces which are not tangent to any cylinder coaxial with the central axis **6** of the tube. In this embodiment, the notches are 180 degrees apart or diametrically opposite one another, sized shaped and located to be matingly engaged by corresponding prongs on the haft of the tool as described below. The notches are axially uniform having a generally bell-shaped contour and rounded edges to avoid sharp edges which could irritate surrounding tissues. Because the tube can be engaged by a finite number of angular orientations of the tool, the tube flange can said to be keyed. Furthermore, the tool would have a surface which is correspondingly keyed. In other words, the tool has a first cross-sectional geometry sized and shaped to matingly engage a second cross-sectional geometry of the keyed flange.

Referring now to Figs. 8-10, the emplacement or adjustment tool **4** has a generally oblong body **45** having a major axis **46** and a rear or proximal handle portion **48** and a forward or distal tube engaging portion **47**. The tool is preferably composed of a durable, easily sterilized material such as stainless steel. The tool has an axial length $\mathbf{L_T}$ which is preferably between about 25 mm and about 200 mm, and is typically about 127 mm. A knurled or otherwise roughened surface **49** is provided on the proximal 30 mm of the handle portion **48** to aid the surgeon in grasping and manipulating the tool. The roughened surface can extend the entire length of the handle portion. The handle portion has an outer diameter which preferably ranges between about 0.5 mm and about 10 mm, and is most typically 2.5 mm.

The tube engaging portion **47** has a substantially cylindrical oblong shaft **50** having a given outer diameter $\mathbf{D_S}$ sized to intimately engage the lumen of the tube. The rear or proximal end **51** of the shaft connects to a generally circularly shaped haft **52** which bonds to the handle

portion **48** of the tool. The forward or distal end **53** of the shaft can be formed to support a cutting bit **54** such that the tube engaging portion forms a trocar. In most instances, the shaft has an axial length of between about 15 mm and about 22 mm from the axially proximal end of the bit to the axially distal end of the haft. This distance preferably matches the length of the lacrimal drainage tube. As such, a kit having a plurality of tools can be provided having shaft portions of different lengths corresponding to the different lengths of the drainage tubes provided in the kit. Optionally, the shaft may have axial gradations or other markings **55** which allow it to act as an axial measuring trocar to help ascertain or verify patient anatomy.

In this embodiment the cutting bit **54** of the trocar is formed by a single blade having a substantially planar tongue **56** terminating in a sharpened distal cutting edge **57**. The blade has an axial length which is preferably between about 0.5 mm and about 10 mm, and most typically is about 2 mm. The distal cutting edge can be straight or curved, but typically is straight.

The haft **52** of the tube engaging portion is sized to matingly engage the flange **13** of the tube, and therefore extends radially beyond the outer diameter of the shaft and extends angularly 360 degrees circumferentially around the rear end of the shaft. This provides an axial bearing surface **59** for contacting the corresponding axial bearing surface **28** on the tube. The axial length of the haft preferably ranges between about 0.25 mm and about 5 mm, and most typically is about 1 mm. The diameter of the haft preferably ranges between about 3mm to about 8 mm, and most typically is about 4.5 mm, but should not be so wide as to interfere with patient tissues during emplacement.

The haft **52** supports a pair of peripheral substantially cylindrical prongs **60,61** projecting distally and substantially parallel to and spaced apart from the shaft. The prongs are sized, shaped and located to matingly engage the notches **25,26** in the flange of the tube. Therefore, in this embodiment, the prongs are each approximately 0.8 mm in diameter and 1 mm in axial length, and are angularly spaced 180 degrees apart. The length of the prongs may vary from 0.25 mm to 5 mm.

The prongs thus angularly fix the lacrimal drainage tube to the tool and allow the lacrimal drainage tube to screwed or unscrewed by the tool. It should be noted that angular location of the prongs can be selected as an indicator of the orientation of the blade. This can be helpful to the surgeon when the blade is hidden from view, particularly when in use. Alternately, the orientation indicator can be an indicia **62** formed onto an outer surface at a specific angular location on the tool.

Referring now to Figs. 11-12, a washer **3** is placed on the lacrimal drainage tube prior to screwing it into position. The washer prevents the lacrimal drainage tube from migrating medially and prevents overgrowth by the conjunctiva from covering the tube after surgery. The washer can be made from silicone, polyethylene, polyurethane, or other semi-rigid, resiliently flexible biocompatible materials. The washer is preferably disk shaped having a symmetrical axis **64** and a substantially circular outer circumferential edge **65** so that it will not appear to shift radially during axial rotation, having a preferred diameter $\mathbf{D_W}$ ranging between about 2.5 mm and 15 mm, and is typically about 7 mm. The washer has a substantially uniform thickness $\mathbf{T_W}$ which ranges from between about 0.005 inch and about 0.3 inch, and is typically about 0.02 inch thick. The thickness can also be selected to allow it to be easily cut and removed without repositioning the tube. The washer is shaped to have a central axial hole **66** having a diameter $\mathbf{D_H}$ commensurate with the outside diameter of the thread $\mathbf{D_T}$, or more preferably, the outside diameter $\mathbf{D_O}$ of the lacrimal drainage tube so that the washer can be fastened to the tube by screwing it on. Therefore, the preferred diameter ranges between about 1 mm and 6 mm, and is typically about 2.5 mm. The washer can also be shaped to be non-planar to help prevent portions of the outer circumferential edge jutting into the surrounding tissue. Therefore, for example, the washer can have an arcuate, dish or, as shown in the drawing, a shallow conical shape providing a conical surface at an angle **A** a plane perpendicular to the axis **64**.

Referring now to Figs. 13-15 the kit and device can be used as follows. Based on the patient anatomy, the surgeon selects the appropriate size of the lacrimal bypass drainage cannula or tube to be emplaced and a corresponding keyed trocar tool whether pointed, blunted, or bladed. As shown in Fig. 13, the trocar tool **80** (without the tube secured thereon) is pushed through the inferior caruncle **81** in the medial conjunctiva of the patient's eye area **82**, through the intervening tissues including the lateral nasal wall **83** into the nose **84**. The trocar alone is placed at this point to allow the formation of an initial tract, and to be sure that it is at the desired angle. The surgeon visualizes the distal tip of the trocar intranasally to confirm that it is properly angled. Optionally, the surgeon can use the trocar as a measuring device to determine or verify the optimal length of the tube. The trocar is then withdrawn. Optionally, the surgeon can first create a pilot hole using a needle prior to pushing the trocar through.

Referring now to Fig. 14, the washer **90** is placed over the lacrimal drainage tube **91** by inserting the distal end of the tube through the center hole of the washer until the washer is up against the flange **93**. The tube is then mounted coaxially onto the shaft **95** of the trocar portion

of the emplacement tool **80** so that the prongs on the haft **96** insert into the notches on the flange of the tube. Optionally, an amount of sterile, biocompatible lubricant such as MURILUBE brand mineral oil lubricant, commercially available from American Pharmaceutical Partners, Inc. of Schaumberg, Illinois can be used between the shaft and lumen to reduce friction and thus facilitate extraction of the trocar from the tube.

The trocar, with the mounted lacrimal drainage tube and washer, is then emplaced into the tract **97** that was previously created. This is done by first pushing the trocar with the lacrimal drainage tube and washer mounted thereon, medially **98** through the inferior caruncle in the medial conjunctiva until distal part of the threads **94** on the tube just contact the caruncle **81** in the medial conjunctiva. The surgeon now grasps the roughened proximal handle surface **99** of the tool and turns the tool clockwise **100** while gently pushing axially medially to screw the threaded end of the lacrimal drainage tube into the medial canthus. The lacrimal drainage tube is screwed in until the conjunctiva just touches the washer which is adjacent and medial to the flange of the lacrimal drainage tube.

Referring now to Fig. 15, the trocar tool **80** is removed. The lacrimal drainage tube **91** with the washer **90** is now emplaced. The washer can be trimmed with scissors if the surgeon deems this necessary. The tears can now freely drain through the lacrimal drainage tube into the nose. Later, the washer is incised with scissors and removed a few days to weeks after surgery. This is done after postoperative conjunctival edema and inflammation have resolved.

Referring to Figs. 16-17, a non-bladed version of the tool **101** is provided in the kit to be used an adjustment tool after the lacrimal bypass drainage tube has been emplaced. The tool has a tube engaging portion **102** similar to previous embodiments, however, it has a shaft portion **103** which terminates in a blunted distal end tip **104**. The adjustment tool can be used to screw or unscrew the lacrimal drainage tube and thereby adjust its axial positioning or remove it at any time during or after surgery.

Tube removal occurs as follows. The non-bladed version of the tool is inserted into the emplaced tube so that the keyed haft engages the correspondingly keyed flange on the tube. The surgeon then grasps the roughened handle surface of the tool and turns it counterclockwise while axially withdrawing the tool a corresponding amount. This unscrews the threaded end of the lacrimal drainage tube from the medial canthal tissues. When the threaded end of the tube has been entirely unscrewed from the medial canthal tissues, the surgeon removes the tool, and

grasps the lacrimal drainage tube with a forceps and pulls it entirely out of the medial canthus, thus completely removing the tube.

This embodiment also provides a tube engaging portion **102** which is interchangeable by being releasably secured to the handle portion **105** of the tool using releaseable fastening means such as cooperatively threaded matable post and pit **106,107**. It should be noted that this allows the kit to have a single handle onto which can be fastened a number of differently sized, shaped or bladed trocar-type tube engaging portions or non-bladed tube engaging portions.

Referring to Figs. 18-20, a differently bladed trocar version of the tool **110** is provided in the kit which can more conveniently and predictably form the tract from the inferior caruncle to the nose using a simple axial rotation of the tool while pushing axially medially. Specifically, the tube engaging trocar portion **111** has a shaft **112** which terminates at a cutting bit **113**. The cutting bit is formed to have a pair of blades **114,115** projecting distally from a distal end **116** of the shaft and diametrically separated from one another to define a central slot **121**. Each blade is shaped to be generally semi-cylindrical, semi-conical, or otherwise arcuate having an inner concave surface **117** and an outer convex surface **118**. The proximal end **119** bonds to the distal end of the shaft **112**, and the distal end is beveled from the concave surface distally outwardly to form a cutting edge **120** at the convex surface. Further, the cutting edge is shaped to have an axially arcuate concave shape. In other words, depending on the elevational location, the cutting edge will have a different axial terminus. This shape provides the edge with a pair of angularly spaced apart points **124,125** located axially distally from an elevationally medial portion **126** of the blade. The two blades are preferably diametrically symmetrical to one another. In some situations where only soft tissue exists between the inferior caruncle and nasal cavity such as after a dacryocystrhinostomy has already been performed, this cutting bit embodiment allows for a single step emplacement of the lacrimal bypass drainage tube where the tract is opened simultaneously as the tube is screwed into place.

Referring now to Fig. 21, there is shown an alternate embodiment of the bladed trocar portion of the tool is provided in the kit which can more conveniently push tissue aside during formation of the tract. The trocar portion is similar to the embodiment of Figs. 18-20 by providing a shaft **130** which terminates at a cutting bit **131** formed by a pair of arcuate blades (only one blade shown **132**) projecting distally from a distal end **133** of the shaft. The distal end is formed to have a radially symmetric, convex, coaxial point **134** which helps tissue escape from between the blades through the central slots. The point may be sharp or blunted.

Referring now to Figs 22a-22k, there are shown variations in the shape and dimensions of the flange of the lacrimal bypass drainage tube which all still provide an angular bearing surface on any surfaces which are not tangent to any cylinder coaxial with the central axis of the tube, for the keyed engagement by the correspondingly shaped and dimensioned emplacement tool. The shape, dimensions, location, and number of prongs or other surfaces on the haft of the emplacement and adjustment tool can vary to correspond to the characteristics of the surfaces of the flange of the lacrimal drainage tube.

For reference, Fig. 22a shows the proximal ocular end view of a tube **2** according to the embodiment shown in Figs. 1-3 having two notches **25,26** formed into the outer periphery **30** the flange **13** which are 180 degrees apart or diametrically opposite one another, sized shaped and located to be matingly engaged by the prongs on the haft of the tool. Each notch forms an angular bearing surface **31**.

Alternately, Fig. 22b shows a tube flange **139** having four notches **140**, and Fig.22c shows a tube flange **141** having three notches **142** angularly spaced evenly apart to provide a greater number of angular orientations for the tube to be engaged and angularly secured upon the tool. A greater number of orientations can be beneficial if one notch gets obstructed temporarily.

Alternately, Fig. 22d shows a tube flange **145** having at least one axial bore **146** radially and parallelly spaced apart from the lumen **147**, and providing an angular bearing surface **148**.

Alternately, Fig. 22e shows a tube flange **150** having a pair of flattened facets **151,152** formed into the outer periphery **153** which are 180 degrees apart or diametrically opposite one another, sized shaped and located to be matingly engaged by flattened prongs, or a correspondingly shaped and dimensioned socket on the haft of the tool. Each facet forms an angular bearing surface **154**.

Alternately, as shown in Figs. 22f, the tube flange **155** can be formed to have groove **156** extending axially into and diametrically across the proximal surface **157** of the flange, which is analogous to a standard slot-headed screw fastener keyed engagement. In this way, a standard slot-head-type screwdriver tool can be used to adjust the tube.

Alternately, Fig. 22g shows a tube flange **158** having a standard Phillips-type keyed engagement **159**. Those skilled in the art will readily appreciate other standard fastener keyed engagements such a hex or star-shaped engagement, for example.

Referring now to Fig. 22h, there is shown a tube flange **160** having an elliptically-shaped outer periphery **161** providing an angular bearing surface **162**. It should be noted that the shape

of the periphery can allow for some sections of it to have a smaller radial dimension than that of the crest of the thread **163**. The haft of the tool can be formed to have a correspondingly shaped and sized socket for matingly engaging the flange.

Alternately, Fig. 22i shows a tube flange **165** having at least one axial bump **166** radially and parallelly spaced apart from the lumen **167**, and providing an angular bearing surface **168**.

Alternately, Fig. 22j shows a tube flange **170** having a substantially uniformly circular periphery **171** and a coaxial elliptically conical indentation **172** which narrows as it extends distally from the proximal end to the central lumen **173** thereby providing an axial bearing surface **174**.

Alternately, Fig. 22k shows a tube flange **175** having an elliptically-shaped outer periphery **176** and an elliptically conical indentation **177** similar to that shown in Fig. 22j.

Referring now to Fig. 23, there is shown an alternate embodiment of the lacrimal bypass drainage tube **178** having a generally oblong cylindrical body **179** defining an axial lumen and terminating at a tapered distal, nasal end **180** and an opposite, proximal ocular end **181**. A helicoidal thread having a flattened crest **182** is formed onto the outer surface of the body. A flange **183** extends radially outwardly and axially proximally from the ocular end and has a substantially frustoconical outer surface **184** and a substantially frustoconically shaped indentation or pit as an entrance **185** leading to the central lumen. An inwardly extending bump **186** provides an angular bearing surface to contacted by an emplacement tool. In some instances this type of flange can provide improved drainage by locating the edge of the indentation **185** within a closer distance $\mathbf{D_I}$ of the flange periphery **187** around the entire circumference of the flange to provide the same drainage capability regardless of angular orientation. First and second radial drainage openings **188,189** having different locations and diameters are shown to circumvent blockage of the axial opening at the distal end **180**.

Referring now to Fig. 24, there is shown an alternate embodiment of the lacrimal bypass drainage tube **190** where the thread **191** extends to the ocular end **192** of the tube. A flange structure **195** is provided as a removable nut **196** which has an inner thread matingly corresponding to the thread of the tube. The nut has a rounded distal circumferential edge **194** for comfort and tissue irritation avoidance. The tube has a pair of radial openings **197** proximate to the distal, nasal end **198** of the tube and are diametrically opposite one another. In this way this insures that the surgeon, with slight rotation of the tube , can always be sure that at least one hole is oriented inferiorly to allow the best use of gravity to assist in tear drainage. Alternately,

there can be a plurality of radial openings, which are particularly indicated in larger tubes or in situations where the location of potentially blocking radial tissues is uncertain.

Typically, the diameter of each opening $\mathbf{D_{RO}}$ would not be larger than the diameter of the tube's axial lumen $\mathbf{D_L}$. Given these parameter ranges, the ratio between the diameters $\mathbf{D_{RO}/D_L}$ range from about 2% to about 80%, and more typically fall in the range of about 20% to 40% when a single pair of radial openings are used. When a plurality of openings are used such as five or more, the openings will obviously not all be opposite one another. In tubes having multiple radial openings, such as shown in the embodiment of Fig. 23, the diameters of the openings can be different depending on their distance from the distal end.

Referring now to Fig. 25, here is shown a further alternate embodiment of a surgically implantable lacrimal bypass drainage device providing a cannula or drainage tube **200** having axial migration inhibiting structures on both ends when emplaced. The device has an oblong tubular body **201** having a rounded cornered quadrangular end stop **202** spaced a distance **203** from a first nasal end **204** and an opposite ocular end **205** having a threaded section **206** sized to be engaged by a nut **210** having a substantially toroidal shape, defining an internally threaded axial hole **211**, and having top and bottom flat surfaces or facets **212** provide an angular bearing surface for engagement by a hemostat or other implement which causes twisting of the nut onto, or off of the body. Two parallelly spaced axial suture holes **215,216** are formed through the nut and angularly spaced apart by an angle of about 45 degrees. The end stop structure **202** on the nasal end is a pair of radial protrusions **220,221**or "wings" and is integral with the tube. The migration inhibiting structure on the ocular end is the threaded nut **210** which extends circumferentially 360 degrees around the end of the tube when fastened thereon. The body and nut are each preferably made from an integrated, monolithic piece of fracture resistant, biocompatible material such as polymethylmethacrylate (PMMA), titanium or other rigid or semi-rigid durable material. A washer **224** is also provided and made of a semi-rigid or resiliently flexible biocompatible material such as silicone.

Referring now to Fig. 26a-26h, a surgical method for placement of the drainage tube of the embodiment shown in Fig. 25 is envisioned. In Fig. 26a, an initial opening is created by pushing a 16 gauge metal needle **231** from the conjunctiva of the medial canthus into the nasal cavity **230**. This allows the surgeon to visualize the needle intranasally to be sure that the tract is properly angled. The needle is then withdrawn.

In Fig. 26b, and a steel trocar **235** is placed through the same tract from the conjunctiva through the intervening tissues into the nasal cavity **230**. The trocar **235** has a substantially nail-shaped pin **236** and an outer metal sheath **237** having a flange on its proximal ocular end **238**.

In Fig. 26c, the pin is removed leaving the outer sheath **237** in place.

In Fig. 26d, a hollow flexible positioning cable **240** made from sterile silicone rubber and having an internally threaded distal end **241** is inserted into the central axial lumen of the sheath **237** at its ocular end and through to the nasal cavity **230**. The surgeon reaches up the nose and grasps the cable's distal end **241** with a hemostat and pulls it down the nose and out the naris. The cable now extends from the ocular surface through the trocar sheath down the nose and out the naris. In Fig. 26e, the proximal threaded end **205** of the drainage tube body **201** is then threaded into the distal end **241** of the cable **240**.

In Fig. 26f, the cable **240** is slowly withdrawn, causing the body **201** of the drainage tube to be drawn up into the sheath **237**. Care is taken to properly orient the drainage tube as it is being drawn through the nasal cavity **230** into the sheath. As the tube reaches the sheath, the end stop **202** bears against the distal end of the sheath. Further withdrawing of the cable causes the sheath to move laterally until the end stop bears against the lateral nasal wall **242**.

In Fig. 26g, the sheath has been removed off the proximal end of the flexible positioning cable **240** leaving the body **201** of the drainage tube in the tract. The cable **240** itself is then detached from the body **201** of the drainage tube.

In Fig. 26h, the washer **224** and nut **210** are placed onto the thread of the drainage tube body **201** to emplace the drainage tube. The nut is manipulated using a hemostat or other tool. The drainage tube may then be further secured in place during the immediate postoperative period by the placement of sutures through the holes in the nut. This also allows the tube to be pulled proximally if needed.

While the preferred embodiments of the invention have been described, modifications can be made and other embodiments may be devised without departing from the spirit of the invention and the scope of the appended claims.

What is claimed is:

CLAIMS

1. A lacrimal bypass drainage device comprises:

an oblong hollow tube defining a central lumen, and having first and second ends, and an outer surface;

wherein said tube has a major axis and an axial dimension selected to span between the conjunctival cul-de-sac and the nose;

a flange extending radially outward from a portion of said outer surface proximate to said first end; and,

wherein said outer surface is shaped to have a threaded section.

2. The device of Claim 1, wherein said threaded section is axially adjacent to said flange.

3. The device of Claim 1, wherein said threaded section comprises a thread having a flattened crest-type shape.

4. The device of Claim 1, wherein said flange is shaped to have a first angular bearing surface.

5. The device of Claim 4, wherein said flange is shaped to have a first radial notch, thereby providing said first angular bearing surface.

6. The device of Claim 5, wherein said flange is shaped to have a second radial notch diametrically opposite said first notch.

7. The device of Claim 1, wherein a distal section of said outer surface tapers radially inwardly toward said second end.

8. The device of Claim 3, which further comprises said threaded section being shaped to have a cross-section which exhibits defined mathematical derivatives at every concave part, and does not exhibit a defined mathematical derivative at a point in a convex part.

9. The device of Claim 1, wherein said device is formed from a monolithic piece of material.

10. The device of Claim 1, wherein said tube is shaped to have at least one radial drainage opening spaced a distance from said second end.

11. The device of Claim 1, wherein said tube is shaped to have at least one pair of radial drainage openings diametrically opposite from one another.

12. The device of Claim 1, wherein said tube is shaped to have a plurality of radial drainage wherein a first of said plurality has a diameter greater than a diameter of a second of said plurality.

13. The device of Claim 1, wherein said tube comprises PMMA.

14. The device of Claim 1, wherein said tube has an axial length between said ends, said length being between about 5 millimeters and about 30 millimeters.

15. The device of Claim 1, which further comprises a washer having a central aperture sized and shaped to pass over said outer surface but not over said flange; and a peripheral edge portion sized to extend radially beyond a radial extent of said flange when said washer is mounted upon said tube.

16. The device of Claim 15, wherein said washer has a non-planar shape.

17. The device of Claim 15, wherein said washer has an outer diameter of between about 2.5 mm and about 15 mm.

18. The device of Claim 1, which further comprises a keyed tool which comprises:
a distal shaft sized to intimately penetrate said lumen;
a proximal hand manipulable handle; and,
a haft mounted between said shaft and said handle.

19. The device of Claim 18, wherein said shaft terminates at a distal cutting bit.

20. The device of Claim 18, wherein said device further comprises means for angularly securing said tube to said tool.

21. The device of Claim 20, wherein said means comprise at least one prong extending axially from said haft.

22. The device of Claim 18, wherein said flange is shaped to have a first angular bearing surface; and said haft is shaped to have a second angular bearing surface for bearing against said first angular bearing surface.

23. A method for forming a lacrimal bypass drain comprises:

forming a tract between the conjunctiva and the nasal cavity of a patient;

selecting an open ended hollow tube having a keyed flange at a first end and an opposite second end, and a threaded outer surface; and,

emplacing said tube into said tract.

24. The method of Claim 23, wherein said emplacing comprises:

securing said tube to a trocar having a cross-sectional geometry sized and shaped to matingly engage said keyed flange;

manipulating said trocar using said handle.

25. The method of Claim 24, wherein said manipulating comprises:

simultaneously axially pushing and angularly rotating said trocar.

26. The method of Claim 23, which further comprises:

adjusting an axial position of said tube by rotating said tube.

27. In a lacrimal bypass drainage device comprising a tube having an outer diameter, first and second ends, and a flange extending radially outward from said outer diameter proximate to said second end, an improvement which comprises said tube having an outer surface portion formed into a helicoidal thread.

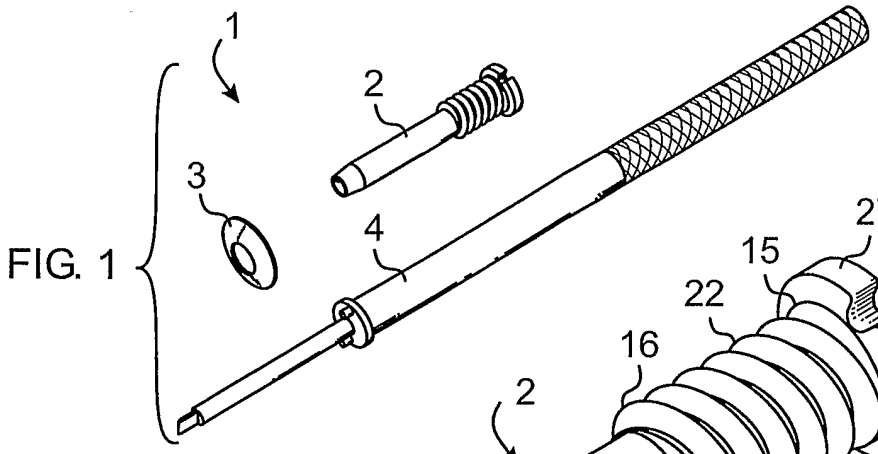

FIG. 1

FIG. 2

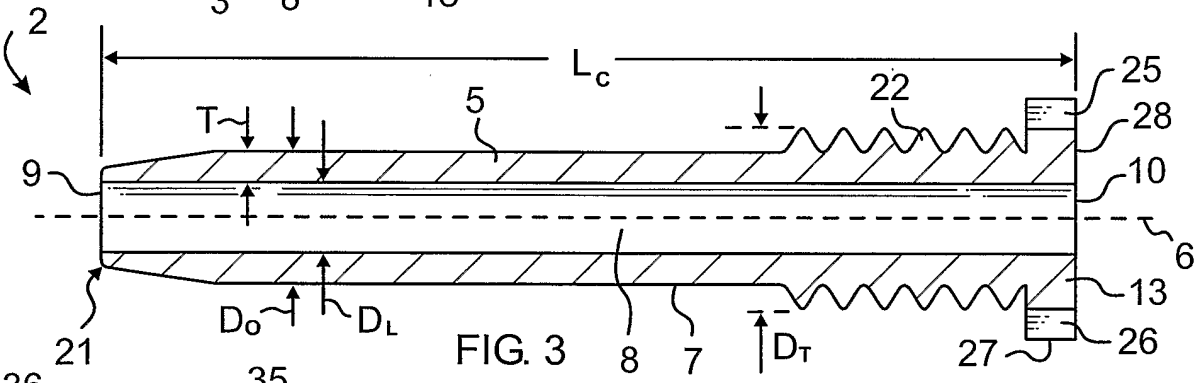

FIG. 3

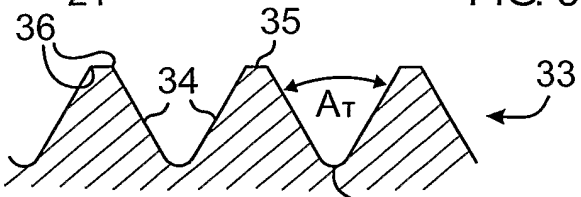

FIG. 4

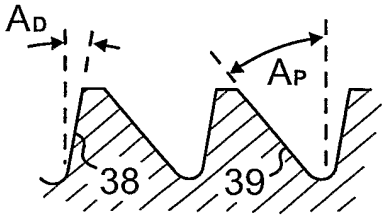

FIG. 5

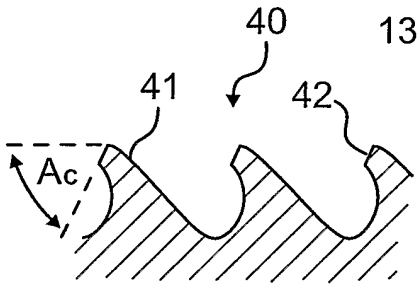

FIG. 6

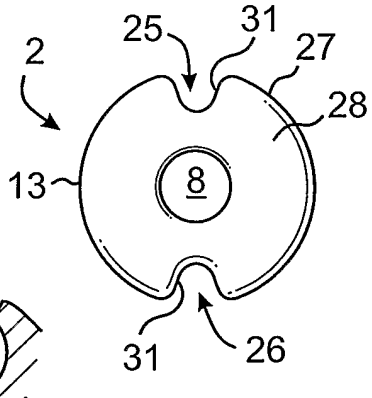

FIG. 7

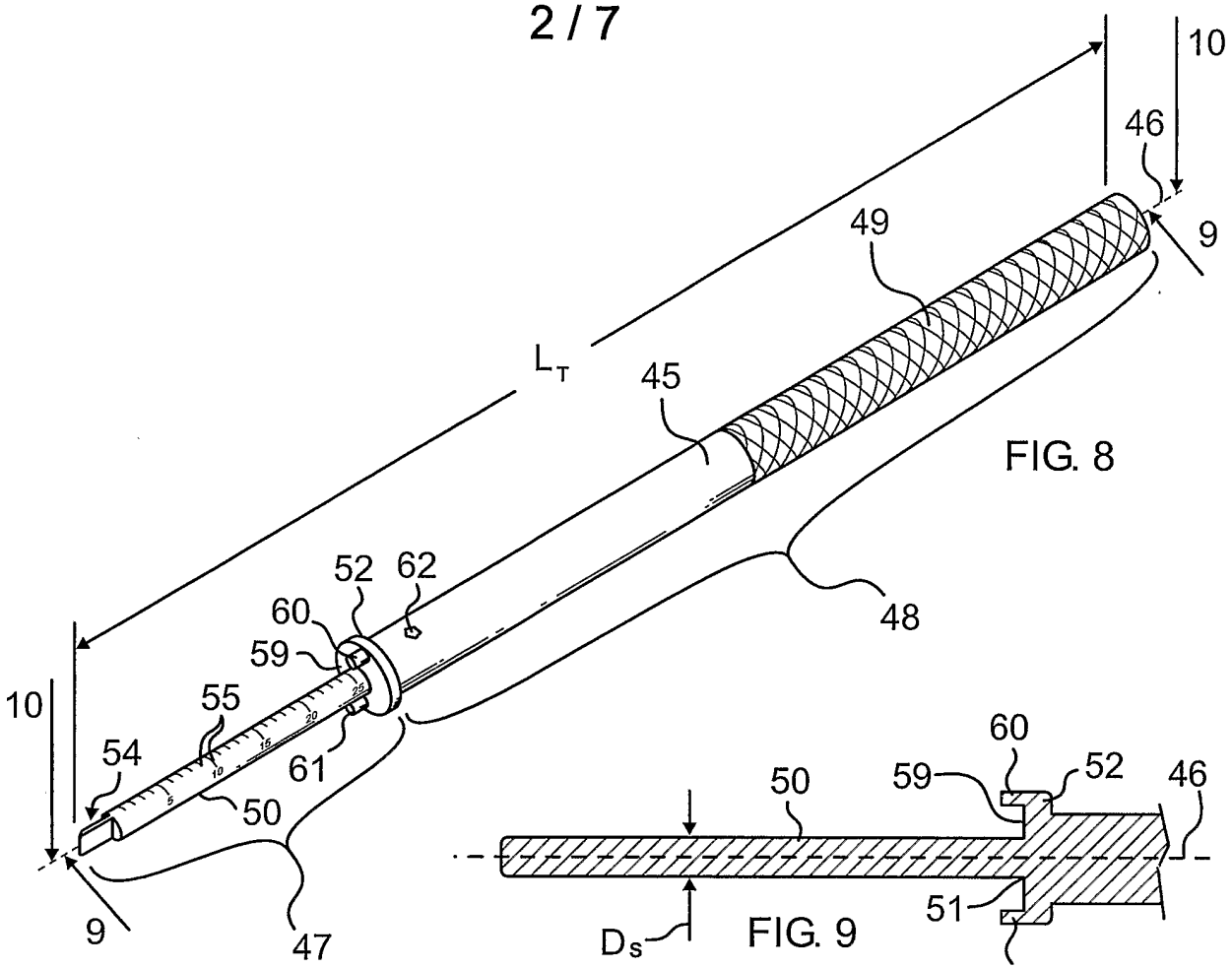

FIG. 8

FIG. 9

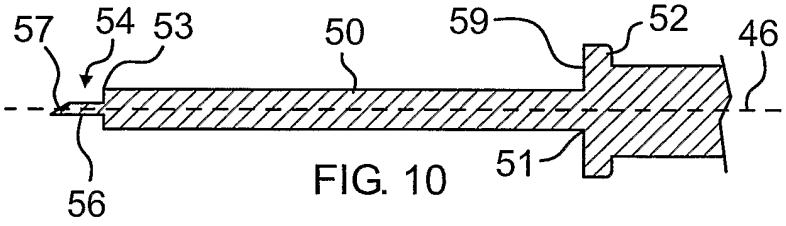

FIG. 10

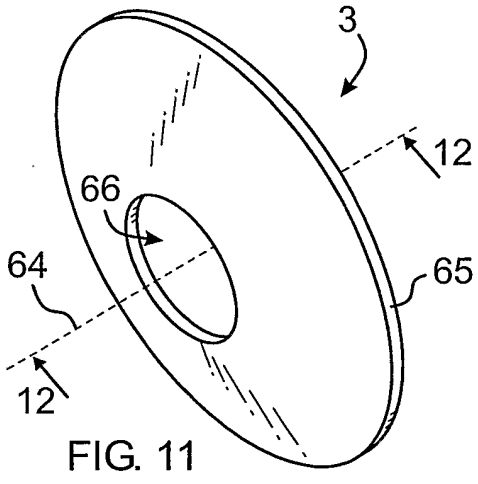

FIG. 11

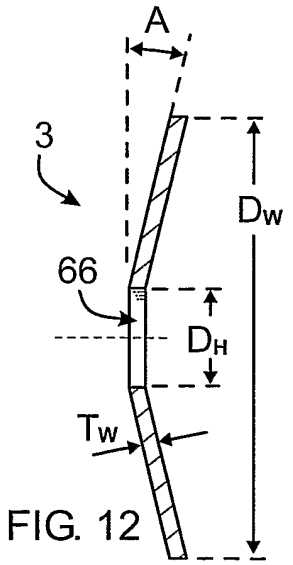

FIG. 12

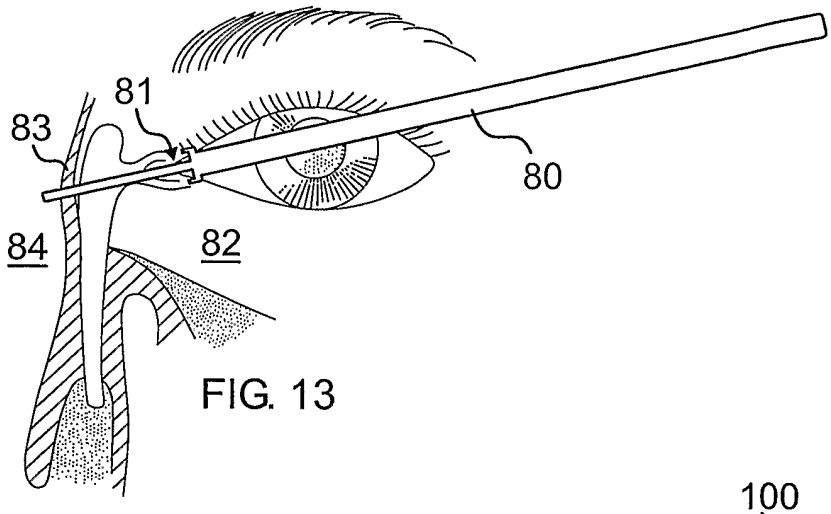

FIG. 13

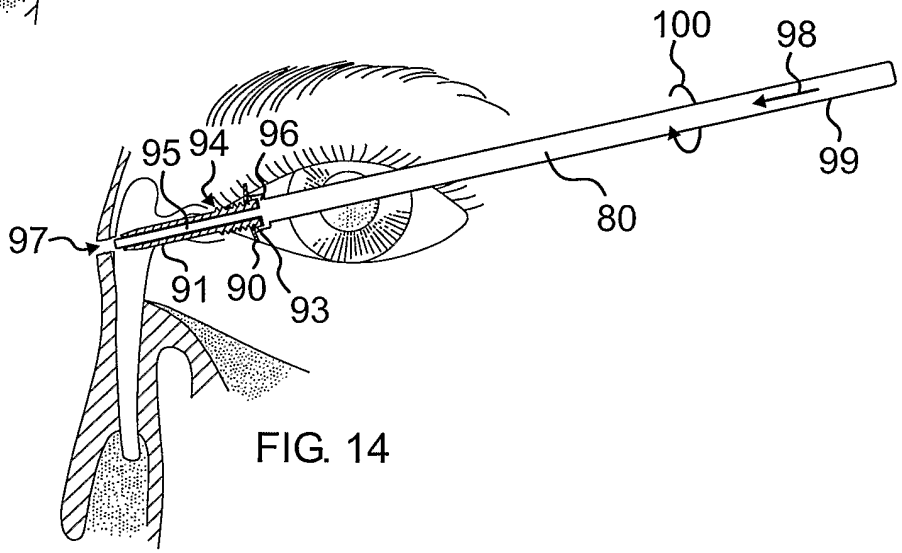

FIG. 14

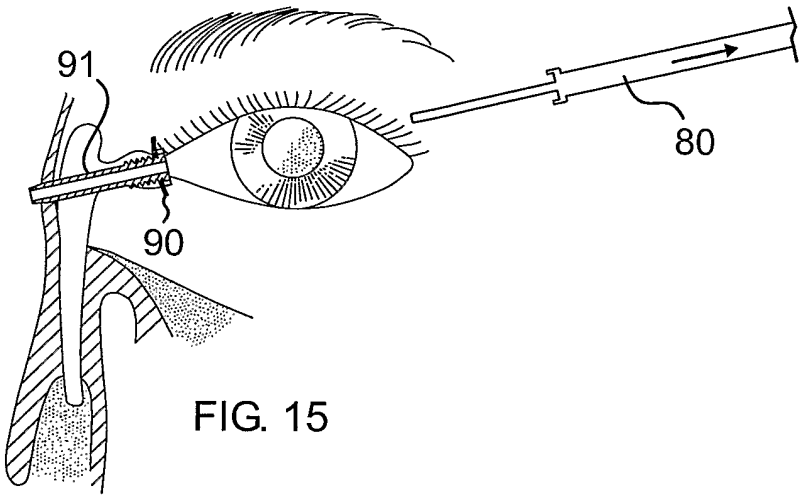

FIG. 15

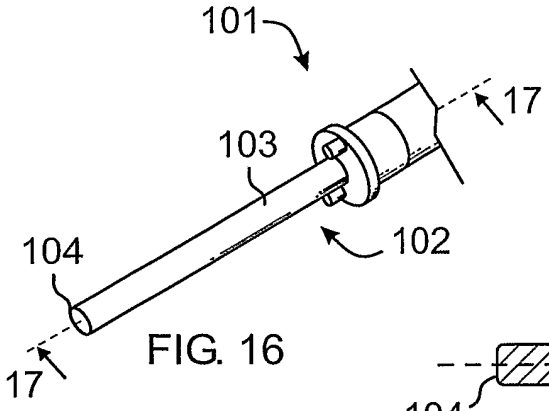

FIG. 16

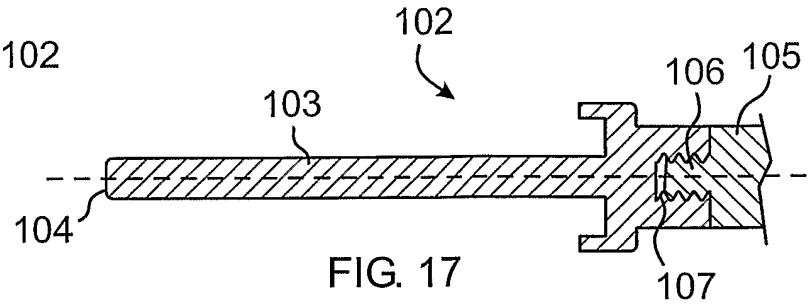

FIG. 17

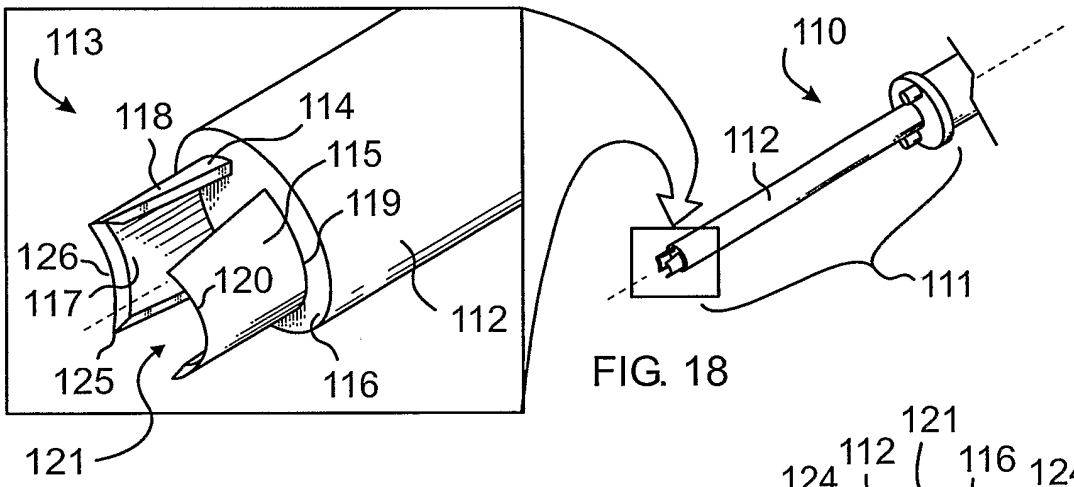

FIG. 18

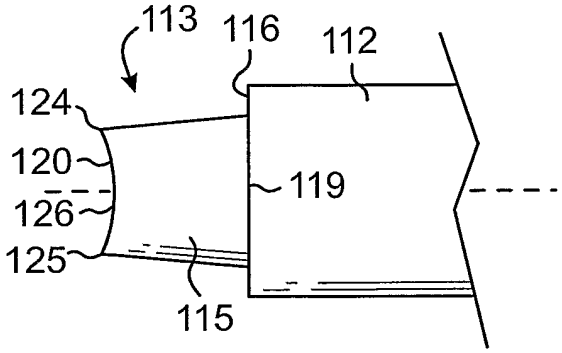

FIG. 19

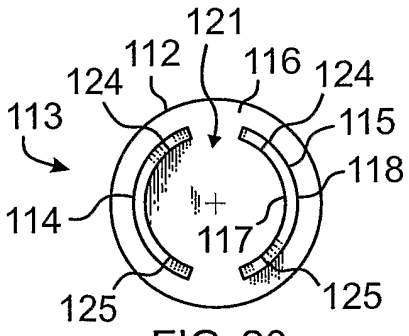

FIG. 20

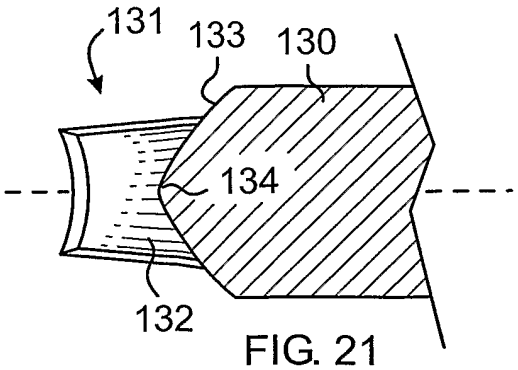

FIG. 21

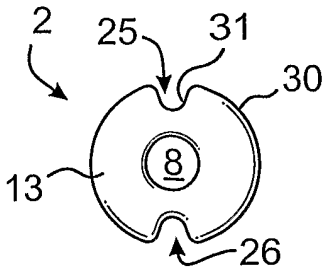

FIG. 22a

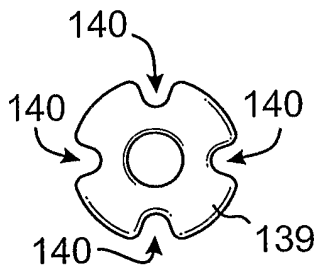

FIG. 22b

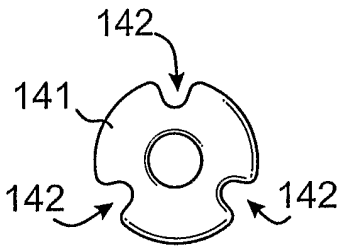

FIG. 22c

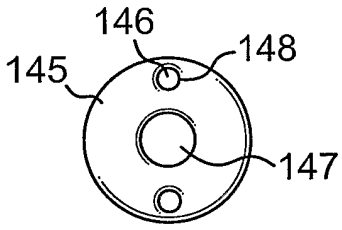

FIG. 22d

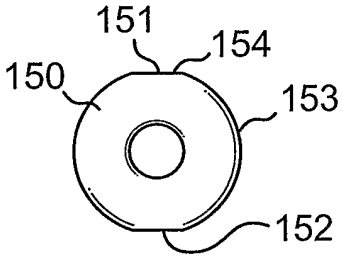

FIG. 22e

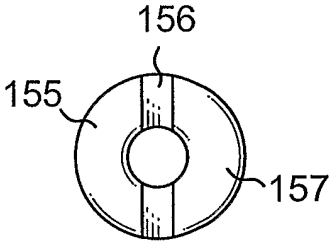

FIG. 22f

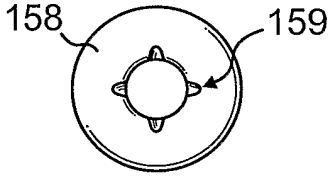

FIG. 22g

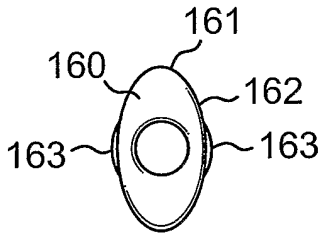

FIG. 22h

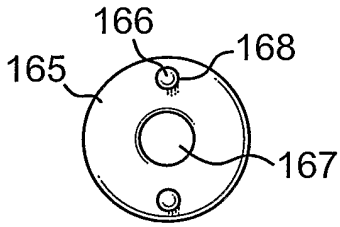

FIG. 22i

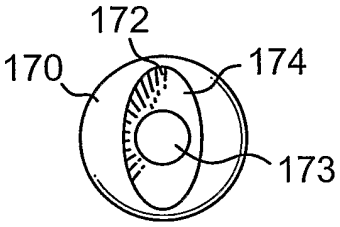

FIG. 22j

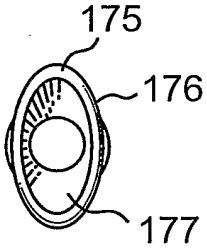

FIG. 22k

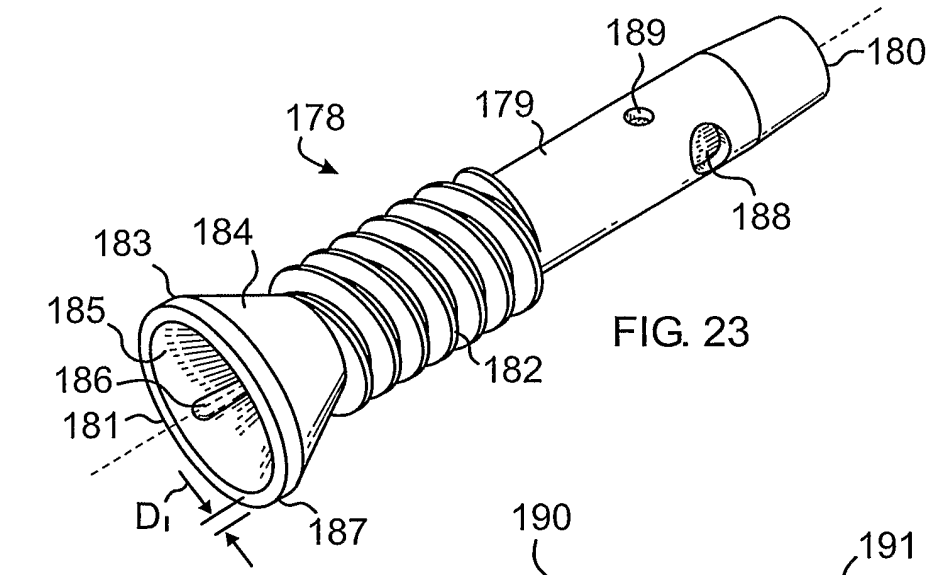

FIG. 23

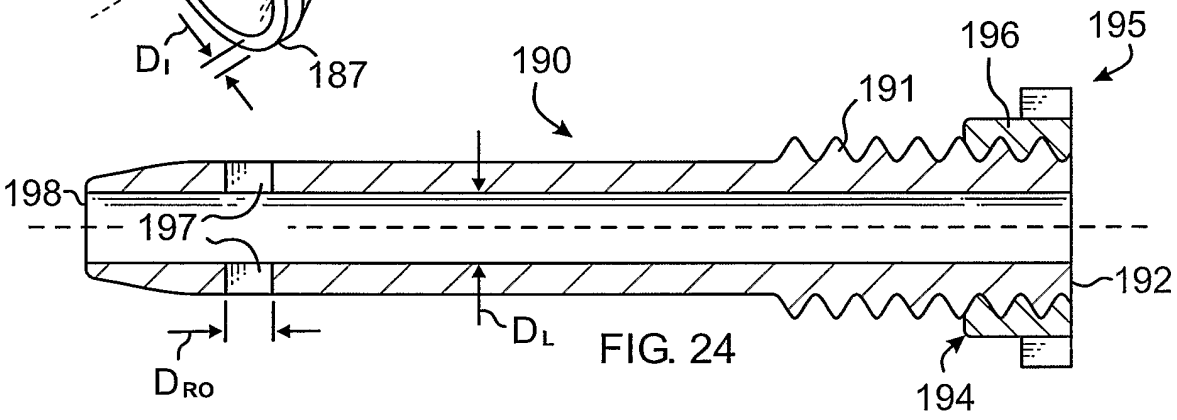

FIG. 24

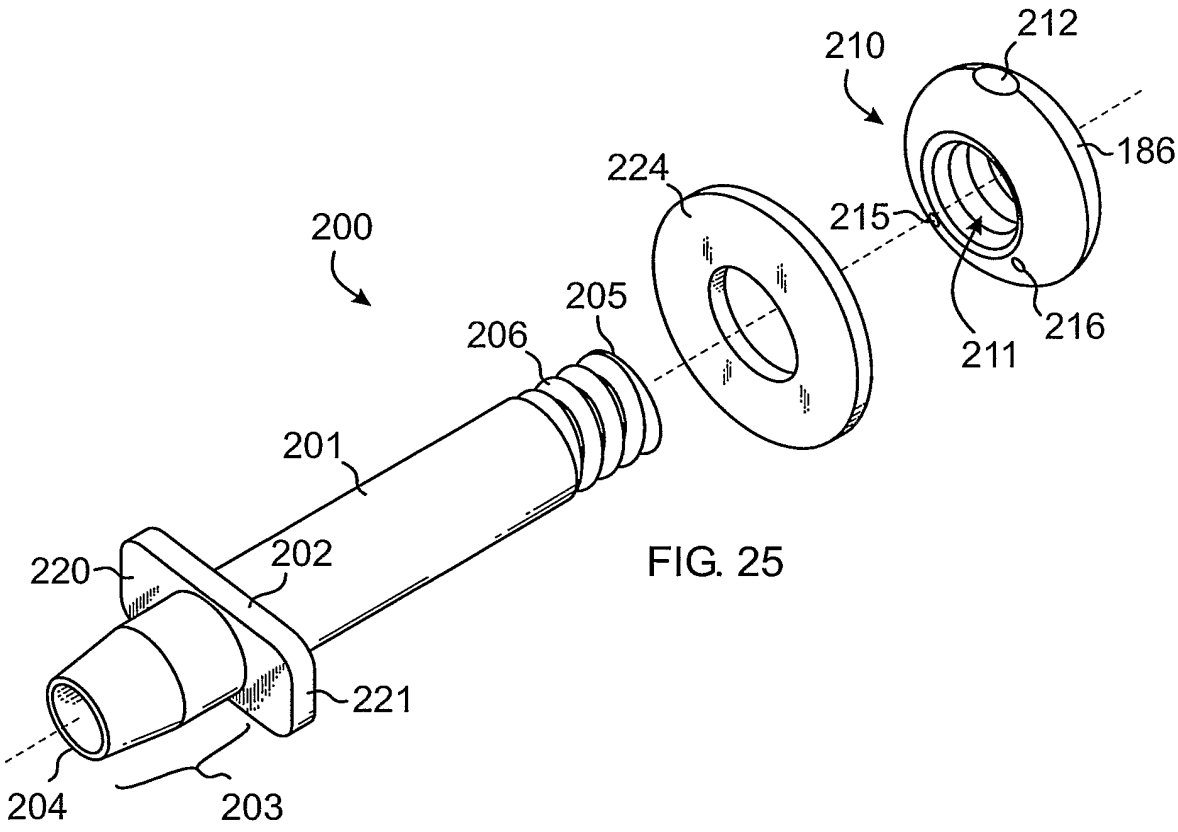

FIG. 25

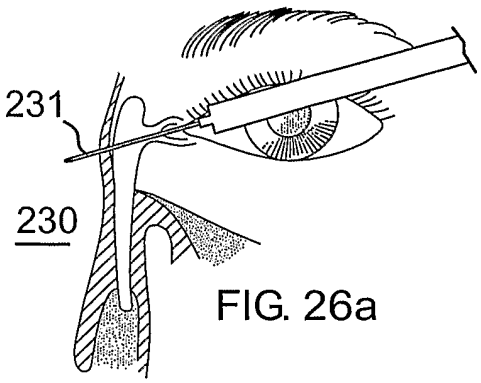

FIG. 26a

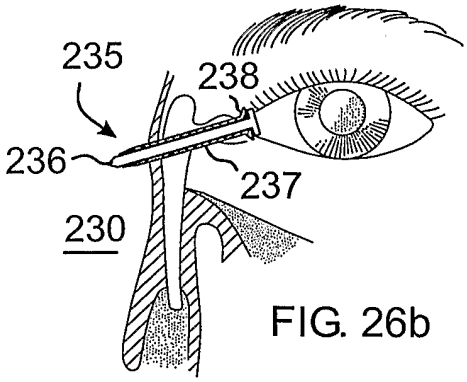

FIG. 26b

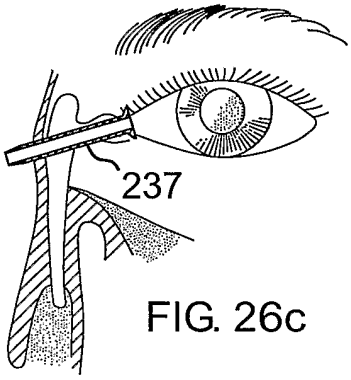

FIG. 26c

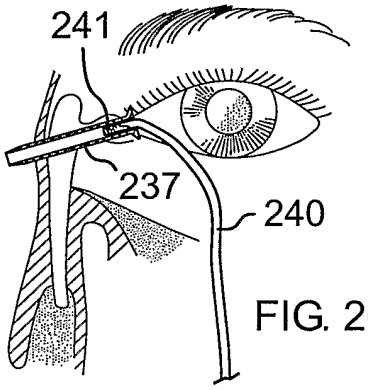

FIG. 26d

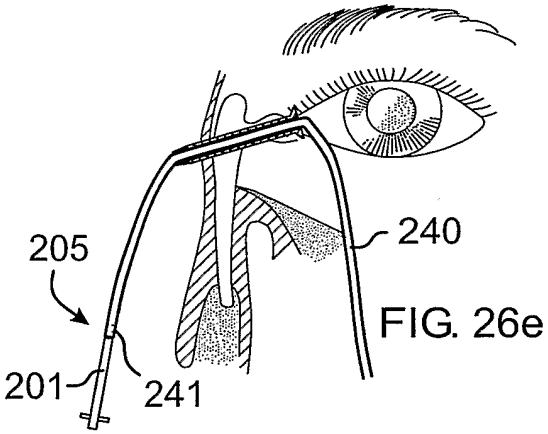

FIG. 26e

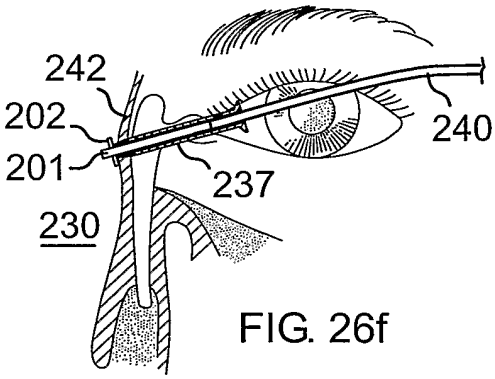

FIG. 26f

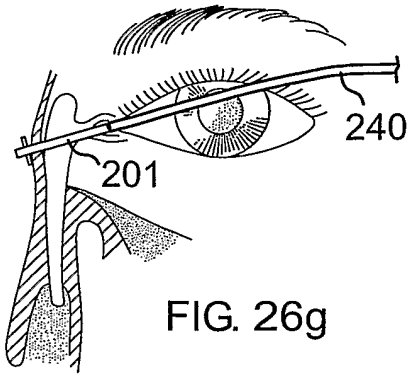

FIG. 26g

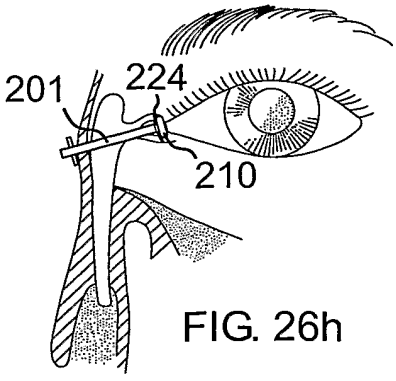

FIG. 26h