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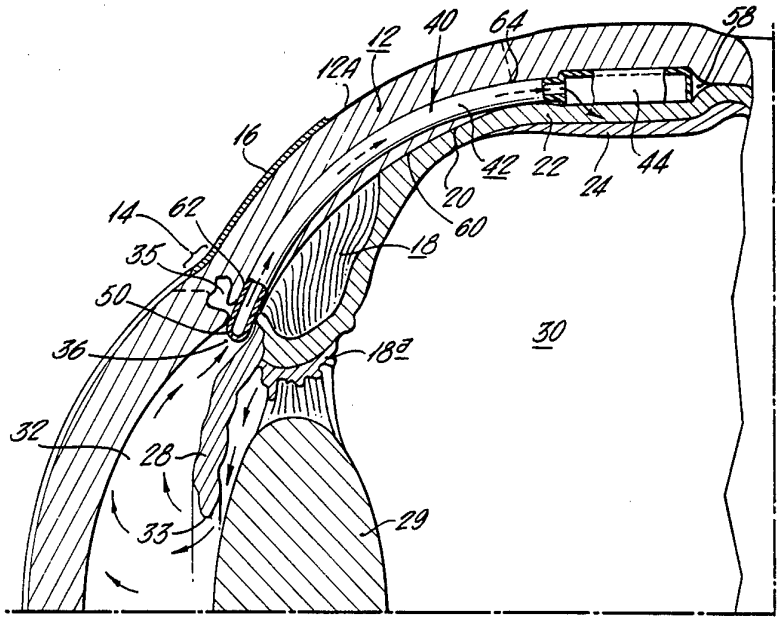

(57) Abstract

A tubular eye implant (40) and method are disclosed for posterior segment of the eye, to relieve glaucoma and/or to supply medicament to the posterior segment. The implant extends entirely within the eye, from within the limbal angle (36) to within the suprachoroidal space (58); the two end sections (44, 50) of the implant are apertured to permit flow of aqueous humor, but the sides of the central section (42) are closed to prevent leakage and resultant interference with fluid drainage due to overgrowth by adjacent tissue.

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EYE IMPLANT SUITABLE FOR RELIEF OF GLAUCOMA

Field of the Invention

This invention relates to a device and method for draining fluid from the limbal angle of the eye to the suprachoroidal space, for example to relieve glaucoma or to convey medicament from the anterior chamber to the posterior segment of the eye. The invention also relates to a method for installing such a device in the eye.

Background of the Invention

Glaucoma is a condition of the eye in which the normal body mechanisms for removing or draining off fluid generated in the eye do not operate effectively, with the result that the internal pressure of the eye rises excessively. With the passage of time, this excessively high internal pressure adversely affects the optic nerve, first causing a severe reduction in peripheral vision and finally complete blindness, unless the condition is successfully treated.

Various liquid medicaments are known which can be dropped periodically into the eye to limit the elevation of pressure. However, with many patients this procedure is not

effective because they do not properly follow the treatment prescribed, often due to negligence or to the relatively high cost of the medication. In other cases, the medicaments available may lose their effectiveness for that patient over long periods of treatment.

It has also been known to employ surgical procedures which, in effect, produce leaks in the eyeball through which the excess fluid can escape to the exterior. Surgical attempts have also been made to relieve the pressure by implanting wires, tubes or strips of various materials in the angle between the ciliary body and the sclera, where the absorption of excess fluid take place by natural means, or by implanting drains which extend directly through the frontal portion of the eyeball to the exterior. A procedure known as cyclodialysis is also known, in which a cut is made to separate opposed surfaces of the ciliary body and the adjacent sclera. However, difficulties have been encountered after such surgical procedures due to subsequent natural reapposition of sclera and ciliary body.

In any event, despite the existence of useful medicaments and the availability of various surgical and implant techniques, there still remain large numbers of patients who can no longer be helped by such procedures, and who become blind, or substantially so, as a result.

U.S. Patent No. 4,521,210 of Vernon G. Wong, issued June 4, 1985, describes and claims a surgically inserted implant for relieving the elevated eye pressure characteristic of glaucoma by providing a path along the surface of an implant for the flow of eye fluid from the limbal angle, through the sclera or between sclera and choroid, and thence to the suprachoroidal space, where it is absorbed. While quite effective in many cases in relieving internal eye pressure, it has been found that, over a substantial period of time, this implant tends to become clogged, and the desired flow is reduced or eventually cut off nearly completely, sometimes necessitating a surgical insertion of a new implant. The cause of this is believed

to be overgrowth of the exposed surfaces of the implant by ingrowth of connective tissue from Tenon's capsule and of connective tissue from the subconjunctiva as the result of the surgery. This previously-known type of implant contains surface channels extending along its length, from limbal angle to suprachoroidal space, and it is along at least a part of the central section of the implant extending between limbal angle and suprachoroid that the deleterious overgrowth tends to occur, blocking the desired fluid flow.

Further, in some cases it is desirable to be able to deliver medicament from the anterior chamber of the eye to the posterior segment of the eye. In the past this has been done by direct injection through the exterior wall of the posterior segment, with attendant difficulties and possible complications such as infection; frequent injections of this type over a long period of time are not considered to be feasible.

It is therefore an object of the present invention to provide a new and useful eye implant effective to deliver fluid from the limbal angle to the suprachoroidal space of the eye.

Another object is to provide such an eye implant suitable for use in relieving eye pressure due to glaucoma, or for delivering medication to the posterior segment, and which will remain effective over long periods of time.

A further object is to provide such an implant which will not be substantially degraded or blocked through overgrowth by surrounding tissue.

An additional object is to provide a method for inserting such an implant into the eye, and to provide a method for using the implant to supply medicament to the eye.

Summary of the Invention

These and other objects of this invention are achieved by the provision of an eye implant having a central section comprising a closed tube extending from the limbal

angle to the suprachoroidal space, along a path lying between the exterior of the choroid and the interior of the conjunctiva; in a preferred form, the implant lies entirely within the sclera, although in other embodiments it may extend along a path between sclera and conjunctiva or between sclera and choroid. One end section of the implant extends into the limbal angle, where it is provided with one or more apertures, and its other end extends into the suprachoroidal space, where it is also provided with one or more apertures, to permit fluid to flow from the limbal angle into the implant and thence to the suprachoroidal space in response to fluid pressure in the anterior chamber, without leakage of the fluid from the intervening central section, thereby preventing blockage of flow by tissue overgrowth.

As used to relieve glaucoma, the implant preferably presents a flow resistance which permits little or no flow when the eye pressure is in a normal range, but permits sufficient flow to relieve and hold down the eye pressure when it tends to rise above the normal range. This may be provided by selection of the diameter of the interior of the implant, by selection of the size of the openings at one or both ends of the implant, by using a flexible restrictor or valve in the implant which opens more widely when the eye pressure increases, or by any combination of these techniques which tends to present higher resistance to liquid flow at lower differential pressures than at higher differential pressures.

The suprachoroidal end section of the implant is preferably of larger cross-section than the closed central section and may be provided with apertures or, as in a presently-preferred embodiment, it may be entirely open along one side of the end section to facilitate dispensing of the effluent eye fluid over a large area of the suprachoroid, thereby to increase the rate of absorption of the fluid by the suprachoroid; use of a widened dimension, or flaring, of the suprachoroidal end section of the implant

also serves to enhance the positional stability of the drain when implanted.

The implant or drain is preferably made of a semi-rigid, plastic, biocompatible material, and may have a curvature corresponding generally to that of the choroid. To use the drain as a means for delivering medicament to the interior of the eye, the medicament is released into the anterior chamber of the eye, as by topical application of drops, and travels with the normal eye fluid (the aqueous humor) through the drain to the suprachoroidal space, where it suffuses the posterior segment of the eye sufficiently to exert a medicinal effect.

In the presently preferred embodiment, the implant is positioned with a first end section in the limbal angle, with the opposite end section in the suprachoroidal space, and with the intervening closed central section extending into the sclera and along the interior of the sclera, between adjacent layers thereof, before exiting into the suprachoroidal space. It has been found that fibrous connective tissue of Tenon's capsule and of the subconjunctiva tend to be stimulated into fibroblastic activity following surgery, and that the resultant scar tissue will tend to overgrow, and grow into, any adjacent openings in the tube, thereby tending to shut off the desired liquid flow. By assuring that the central section of the implant tube is closed, such interference with the desired flow of aqueous humor is obviated.

Brief Description of the Drawings

These and other objects and features of the invention will be more readily understood from a consideration of the following detailed description, taken with the accompanying drawings, in which:

Figure 1 is a diagrammatic front elevational view of a normal human eye, showing the major relevant parts and omitting irrelevant details;

Figure 2 is an enlarged fragmentary sectional view, taken along lines 2-2 of Fig. 1;

Figure 3 is a greatly enlarged fragmentary sectional view similar to Fig. 2, but showing only a quadrant of the eye, with a drain according to a preferred embodiment of the invention implanted in the eye in one preferred location;

Figure 4 is a side elevational view of an alternative form of drain, with parts broken away;

Figure 5 is a top plan view of the drain of Fig. 4;

Figure 6A is an enlarged fragmentary side elevational view, with parts broken away, of the limbal end section of the drain of Fig. 3;

Figure 6B is an enlarged fragmentary side elevational view of another form for the limbal end section of the drain;

Figure 6C is a view like Figs. 6A and 6B, but showing another limbal end arrangement using a plug to provide the fluid inlet aperture;

Figure 6D is a view like that of Fig. 6C, showing another form of plug providing the inlet aperture;

Figure 7 is a fragmentary side elevational view, and Figure 8 is a fragmentary top plan view, of another form of the suprachoroid end section of the drain which can be used in place of that shown in Fig. 3;

Figure 9 and 10 are fragmentary side elevation and top plan view of another form of suprachoroidal end section;

Figure 11 is a side elevation of still another form for the suprachoroidal end section of the drain of the invention, in this case comprising a simple open-ended tube;

Figures 12-20 are top plan views of an eye during successive steps of implanting into it a drain like that of Fig. 3; and

Figure 21 is a view similar to that of Fig. 3, but with a drain installed in it in a different location so as to lie partly between the conjunctiva and the sclera, and

using the simple type of tubular suprachoroidal end section shown in Fig. 11.

Detailed Description of Preferred Embodiments

Before describing the specific preferred embodiments of the invention shown in Figs. 3-21 by way of example only, Figs. 1 and 2 are presented to show schematically the relevant parts of a human eye, as an aid in understanding the anatomical terminology employed; it will be understood that many irrelevant anatomical details are omitted in the interest of clarity.

As shown, the transparent cornea 10 at the front of the eye merges into the generally spheroidal sclera 12 at an annular junction designated as the limbus 14. The sclera is covered with a very thin covering of fibrous connective tissue 12A called Tenon's capsule which is too thin to be shown in the drawings. The conjunctiva 16 extends posteriorly from the limbus over the front half of the eye and then projects in a forward direction, underlying the upper and lower eyelids. The interior side 16A of the conjunctiva is known as the subconjunctiva. In apposition with the interior side of the sclera, and beginning at the limbus, the ciliary body 18 extends posteriorly until at 20 it becomes the choroid 22, a layer containing many blood vessels. The choroid 22 extends further rearwardly around the back of the interior of the eye, and in turn is covered on its interior surface with the retina 24.

Near the forward end of the ciliary body 18, the diaphragm-like iris 28 extends radially inwardly of the eye to provide automatic control of the amount of light reaching the lens 29, which is positioned just behind the iris. The cavity positioned forward of the lens is called the anterior chamber. The posterior portion 30 of the eye rearward of the iris is designated as the vitreous cavity or posterior cavity, while the portion forward of the iris is designated as the anterior chamber 32, and contains the so-called

aqueous humor, a rather thin, watery, eye fluid.

Research in ophthalmology indicates that the aqueous humor is primarily generated rearward of the iris by the ciliary body 18, including the ciliary processes such as 18a, and reaches the anterior chamber 32 through the pupil 33, as indicated by the arrows in Fig. 2. Excess of the aqueous humor is believed normally to be removed through structures such as 35 located in the Canal of Schlemm, adjacent the peripheral limbal angle 36 of the anterior chamber. Purportedly, it is the failure of this drainage function which, in the glaucomatous eye, causes the internal pressure of the eye to rise excessively as new fluid is generated and delivered to the anterior chamber of the eye at a rate faster than it is removed by normal processes.

Figure 3 shows a vertical cross-section of a posterior quadrant of the eye of Figs. 1 and 2, but fitted with an implant or drain 40 constructed and positioned in accordance with one preferred embodiment of the invention. In this example, the drain 40 comprises a simple tubular central section 42 of uniform diameter, typically about 0.64 mm in outer diameter and about 0.3 mm in inner diameter, with a rectangular, open-bottomed end section 44 at one end, the overall length of the drain in this example being between about 5 and 10 mm. When the implant is used to deliver medication to the posterior eye, it may be somewhat longer,for example about 25 mm. It is preferably made of a biocompatible material wettable by aqueous humor, such as polymethyl methacrylate or silicone, and preferably has a curvature along its length substantially as shown, in this embodiment. This form of drain is preferred when a combination of simplicity of manufacture, low cost, and positional stability in the eye are primary considerations; other forms of the drain described hereinafter may be preferred where another set of considerations are of greater importance.

More particularly, the drain 40 has a first end section 50 which when installed lies entirely within the

limbal angle 36; an opposite, second end section 44 lies entirely within the suprachoroidal space 58, and an intervening central section 42 extends through the sclera 12 and pierces the interior surface 60 of the sclera at 62 and 64. The only openings in the tubular drain 40 in this example are in its end sections 50 and 44, which lie, respectively, entirely within the limbal angle 36 and within the suprachoroidal space 58. Accordingly, the only openings in the drain are not exposed to the possibility of overgrowth by episcleral or subconjunctival tissue, which in the past has produced substantial overgrowth problems.

Figures 4 and 5 show an alternative form of the implant of the invention, in which the suprachoroidal end section 44' is in the form of a box-like, right parallelopiped having four holes such as 67 extending through each of its major faces.

As shown in Fig. 6A, the inlet aperture 70 in the limbal end section of the drain of either Fig. 3 or Fig. 4 is provided by a closure 72, axially perforated at its center; the aperture has a diameter suited for the patient. A diameter of about 0.1 mm is typical for an average glaucomatous patient, using a tube the remainder of which has an inner diameter of about 0.3 mm.

Other embodiments of the drain of the invention are illustrated by Figs. 6B to 11 and in Fig. 21. Figs. 6B through 6D illustrate possible variations in the limbal end section of the drain, and Figs. 7 through 11 illustrate possible variations of the suprachoroidal end section of the drain. Any of the types of limbal end section shown may be used with any of the suprachoroidal end sections, but the sizes and numbers of the apertures in the drain should be selected to provide the desired total flow resistance desired for the specific application. Thus, larger limbal-end apertures may require smaller suprachoroidal apertures, and vice versa; similarly, if a valve-type of flow restrictor is used, the outlet aperture(s) may be relatively

large, with flow controlled primarily by the valve structure.

Thus Fig. 6B shows an end section comprising an axially apertured plug 76, the aperture 78 being of small diameter compared with that of the inner diameter of the end section tube 42'. Such an inlet construction is preferably employed with a suprachoroidal end section having substantially less total resistance to fluid flow, so that the axial aperture 78 primarily determines the total rate of flow of eye fluid.

Fig. 6C shows a limbal end section using another type of plug 80 acting more like a flapper valve in that it is preferably elastomeric and is provided with a constricted portion 82 of small axial length which will "give" slightly when the eye pressure is elevated, to provide a higher flow rate per mm of eye pressure than when the eye pressure is lower, thereby providing a greater ability to hold the eye pressure near a fixed, desired value.

Fig. 6D shows a limbal end section using a flow-control plug 86 somewhat similar to that of Fig. 6C in that it is elastomeric and has a restriction at 88 which is of short axial length, again serving to present lower resistance to flow for higher eye pressure.

Figs. 7 and 8 show a suprachoroidal end section comprising a reservoir 100 in the shape of a circular pill box, ie. having two opposed circular major faces 102 and 104, through each of which apertures such as 106 extend.

Figs. 9 and 10 show another form of suprachoroidal end section comprising a reservoir 110 having opposed major faces 112 and 114 of triangular form through which apertures such as 120 for discharging eye fluid extend.

At present, applicant's preferred embodiment uses a combination of a simple cylindrical tube 42 as central section with a simple axially-perforated tubular limbal end section 72, and with the type of suprachoroidal end section 44 shown in Fig. 3 to provide a simple, inexpensive drain with good positional stability.

Any of the drains shown or described may be molded by conventional techniques, with apertures drilled out if appropriate. To implant them, conventional surgical techniques analogous to those described in the above-identified patent of Wong may be used. For example, the presently preferred embodiment using the limbal end section 50 of Fig. 6A with the suprachoroidal end section 44 of Fig. 3 may be made by molding the drain, using removable plugs where the limbal and suprachoroidal apertures are to be formed, or by molding the drain without apertures and drilling-out one or more of the apertures, if this is more convenient. For increased positional stability of the implant, it may be provided with laterally extending stabilizing portions, such as the wing-like cross-arm used in the implant of my 4,521,210 patent, for example.

To install such a drain in the eye, a surgical limbal-based conjunctival flap 200 is first formed surgically and folded forwardly, as shown in Figs. 12 and 13. A split-thickness scleral flap 202 measuring about 2x5 to 5x5 mm is made and reflected forwardly toward the limbus as shown in Figs. 14 and 15 to form a rectangular "trap door" 210. An anterior incision 220, typically 1 to 3 mm in length, is made at the surgical limbus into the anterior chamber of the eye to accommodate passage of the limbal end section of the implant, and another parallel posterior incision 222 just wide enough to pass the rectangular suprachoroidal end section 44 is made posteriorly of the anterior incision, to expose the choroid. The anterior tip 230 of the drain 40 is urged through the anterior incision 220 and about 2-3 mm into the anterior chamber as shown in Fig. 18. The suprachoroidal end section is then slid through posterior incision 222 into the suprachoroidal space 58 by about 5 mm as shown in Fig. 19, and the anterior and posterior incisions closed tightly with sutures; the scleral flap and the conjunctival flap are then closed with interrupted or running sutures (see Fig. 20).

There is thereby provided an eye implant in the form of a drain which transfers eye fluid, with or without medicament therein, from the limbal angle to the suprachoroidal space for absorption therein, to relieve eye pressure and/or to transfer medicament into the posterior segment of the eye, and which is capable of continuing such transfer of fluid over long periods of time. Where appropriate, the drain may readily be provided with at least one pressure-sensitive aperture which provides higher resistance to flow for lower pressures, thereby minimizing excessive lowering of internal eye pressure which might otherwise be encountered in some cases. Preferably the aperture system is such that a pressure head (excess of pressure in anterior chamber over that in the suprachoroidal space) of at least about 15 mm of mercury must be achieved before appreciable flow occurs through the drain. In some cases a simple tube 44" of uniform inner diameter throughout may be used, as shown in Fig. 11.

The drain 40' may be placed so that its central section 42" extends between layers in the sclera as shown in Fig. 3; or, it may extend in part between conjunctiva 16 and sclera 12 as shown in Fig. 21, in which this simple form of tubular drain is used. Alternatively, it may extend between the inner side of the sclera and the ciliary body 18 and the choroid 58 as illustrated in Fig. 4 of the above-cited Wong patent.

In all cases, the drain is entirely closed in the region between limbal angle 36 and suprachoroidal space 58, to minimize or eliminate problems due to tissue overgrowth. There is then no leakage of anterior chamber fluid from the central section of the implant, which might otherwise find its way (through the incisions, for example) to Tenon's capsule and/or the subconjunctival region, and no opportunity for scar tissue or the like to be stimulated into growth and enter the implant so as to interfere with liquid flow.

While the invention has been described with particular reference to specific embodiments in the interest of complete definiteness, it will be understood that it may be embodied in a variety of forms diverse from those specifically shown and described, without departing from the spirit and scope of the invention.

CLAIMS

What is claimed is:

1. An eye implant for transferring fluid from the limbal angle of the eye to the suprachoroidal space, comprising:

an elongated body of biocompatible material having a length to extend from within the limbal angle of the anterior chamber of the eye to within the suprachoroidal space, along a path extending entirely within the eye;

said body having a first end section adapted to be located entirely within said limbal angle and a second end section adapted simultaneously to be located entirely within said suprachoroidal space;

said body also having a hollow central section extending between and connecting said first and second end sections, the sides of which central section are closed to the exterior to prevent tissue growth into it, said central section having a length at least as great as the distance along said body between the angle of the eye and the suprachoroidal space;

said first end section being apertured to receive eye fluid present in said limbal angle and deliver it to said central section, and said second end section being apertured to deliver eye fluid from said central section to said suprachoroidal space.

2. The implant of claim 1, wherein said body is a tube, the opposite ends of which are open.

3. The implant of claim 1, wherein said second end section has a greater cross-sectional area than said central section, to provide a reservoir therein for said fluid and to stabilize said implant in position in said suprachoroidal space.

4. The implant of claim 2, wherein said second end section is provided with openings through its side surfaces for afflux of said eye fluid therefrom into said suprachoroidal space.

5. The implant of claim 1, wherein said first end section comprises an aperture structure presenting a lowered resistance to liquid flow for higher pressures applied to it.

6. The implant of claim 1, wherein said first end section comprises a tube and a plug within said tube, said plug having an axial opening through it.

7. The implant of claim 5, wherein said aperture structure comprises a plug of an elastomeric material.

8. The method of providing for transfer of liquid from the limbal angle of the eye to the suprachoroidal space, comprising:

inserting into said eye a tubular drain with one end section lying entirely within said angle and the opposite end section thereof lying entirely within said suprachoroidal space, said drain being closed throughout the central section thereof extending between said first and second end sections.

9. The method of supplying medicament to the posterior segment of the eye, comprising:

implanting in said eye an implant having a closed central section adapted to extend from the limbal angle to the suprachoroidal space, and having a first end section adapted to be placed in said suprachoroidal space, to provide fluid communication between the interior of said central section and said limbal angle and said suprachoroidal space, respectively; and

administering medicament to the anterior chamber

of said eye, whereby it is carried to said posterior segment by flow through said implant in response to the fluid pressure in said anterior chamber.

FIG. 1.

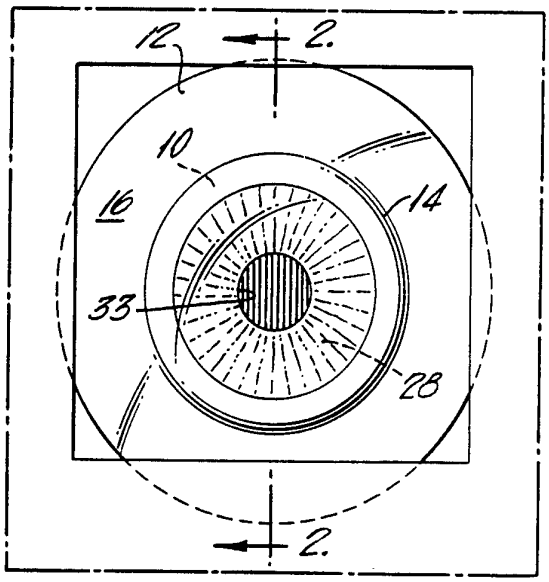
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FIG. 2.

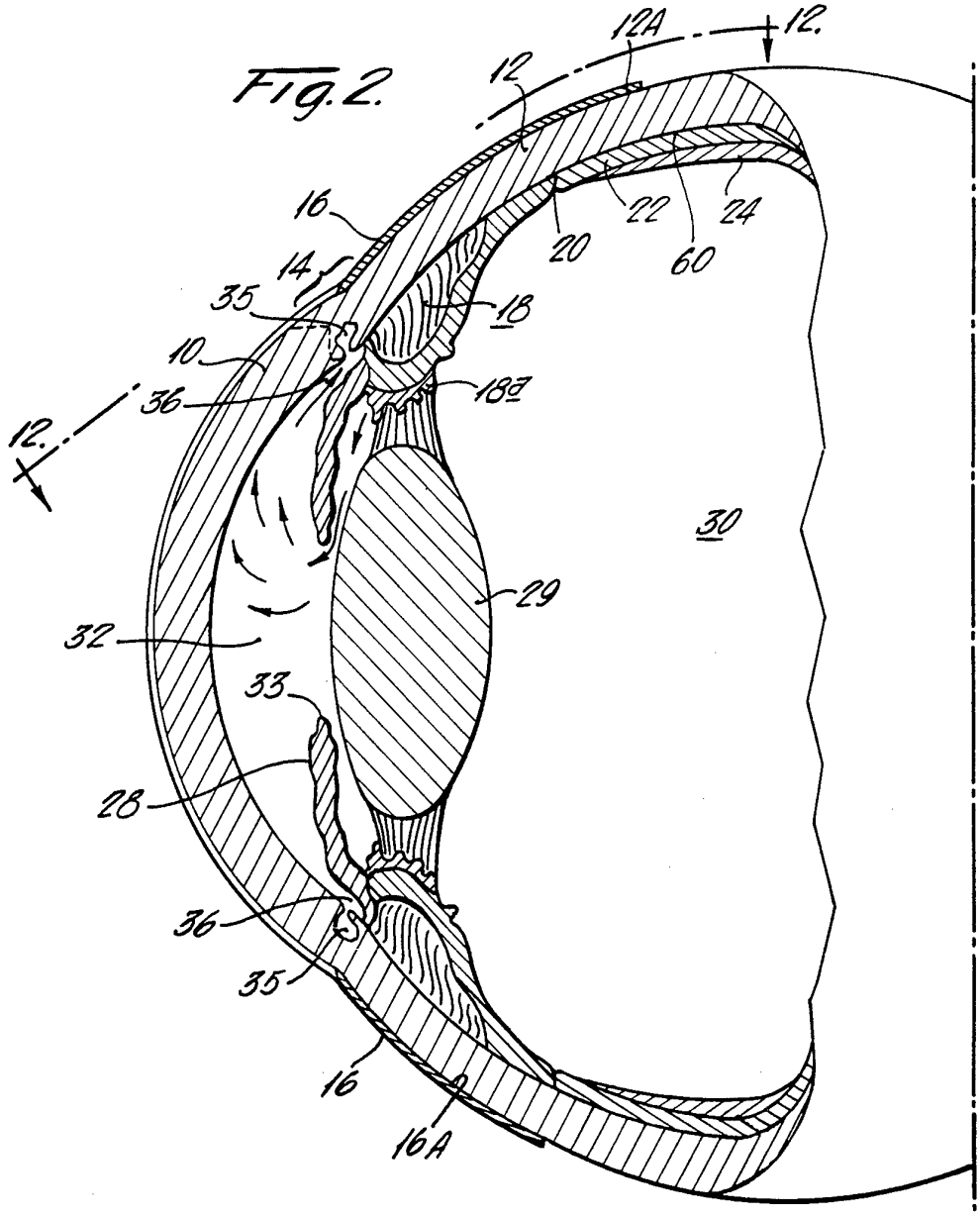
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Fig. 3.

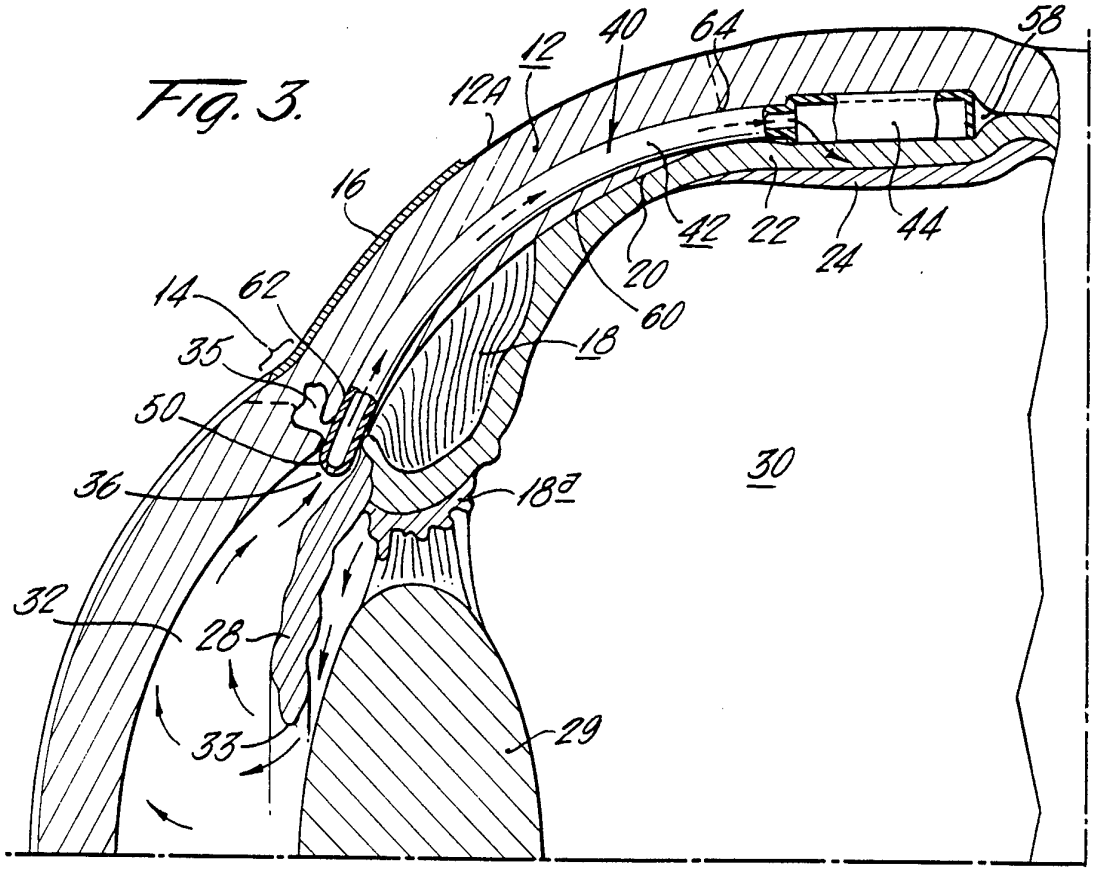


Fig. 5.

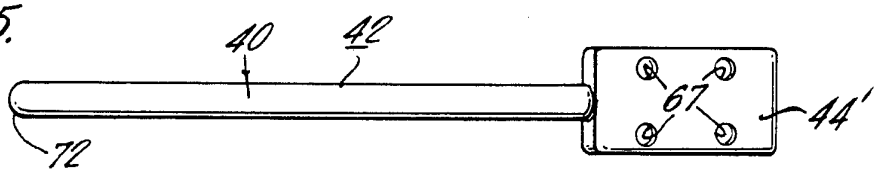


Fig. 4.

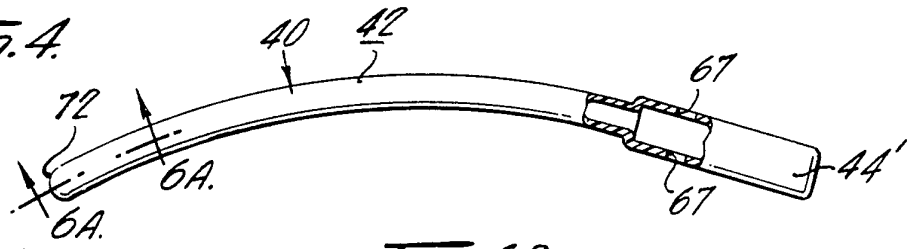


Fig. 6A.

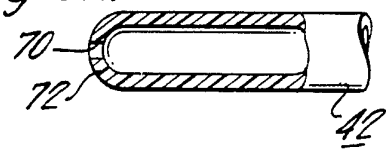


Fig. 6B.

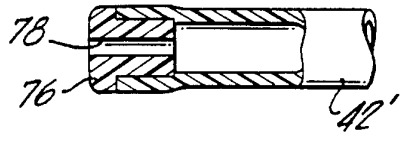


Fig. 6C.

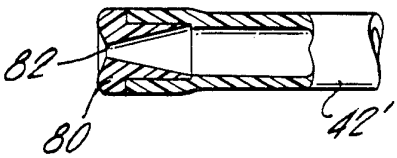


Fig. 6D.

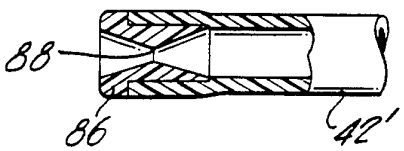


Fig. 8.

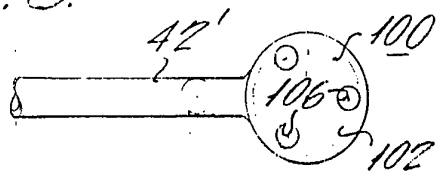
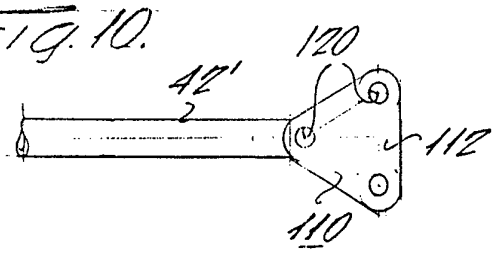


Fig. 10.



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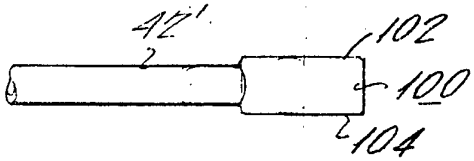

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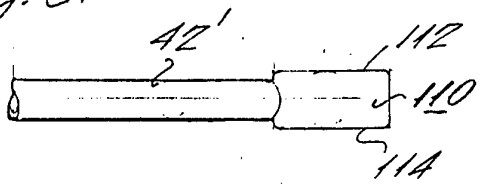

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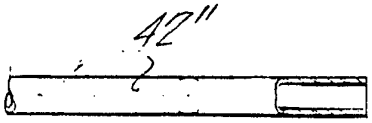

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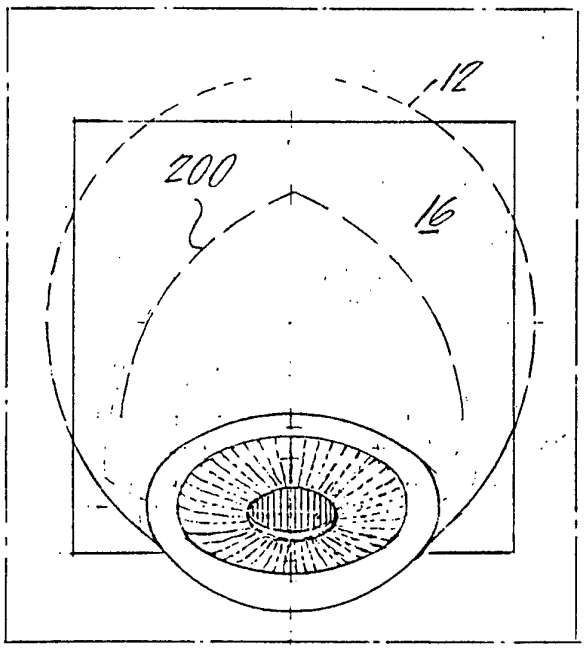

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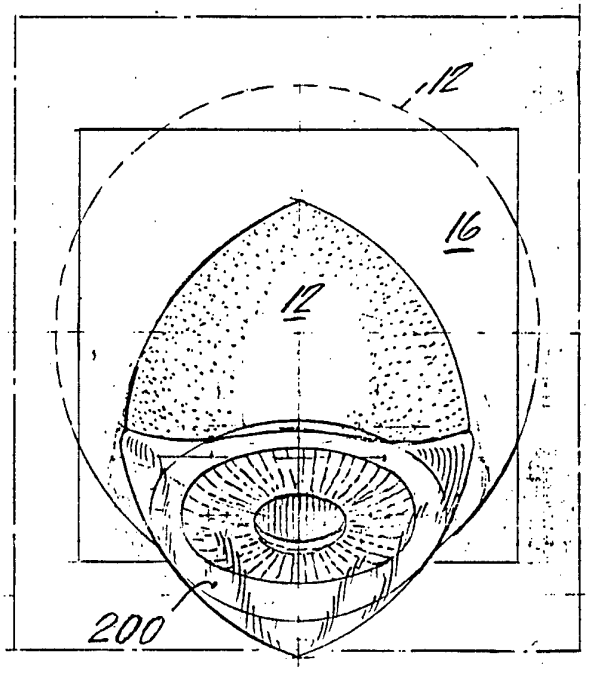

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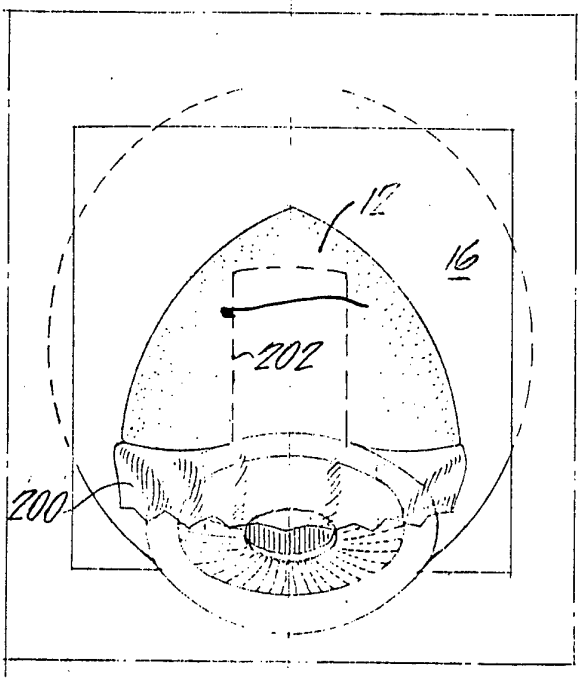

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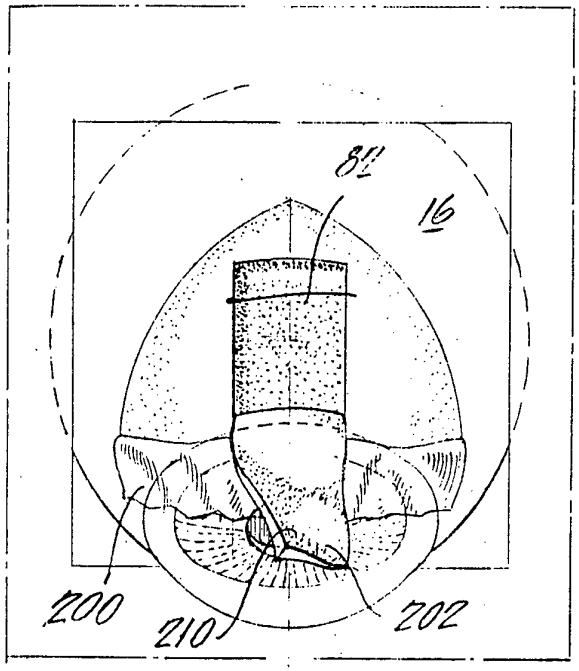

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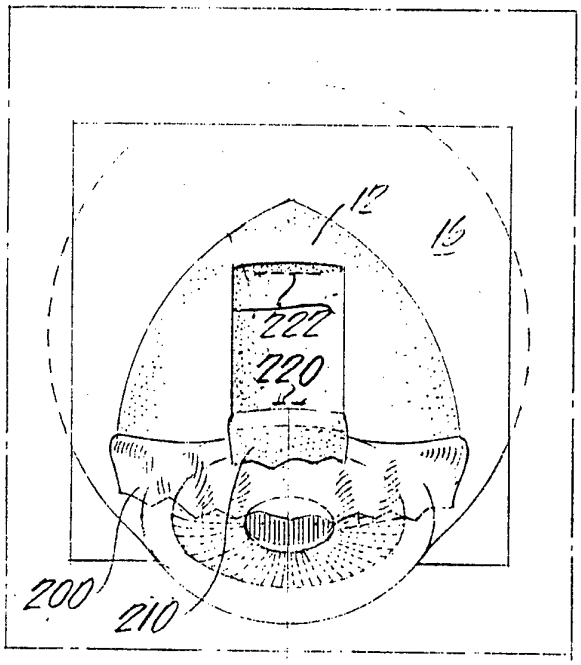


Fig. 17.

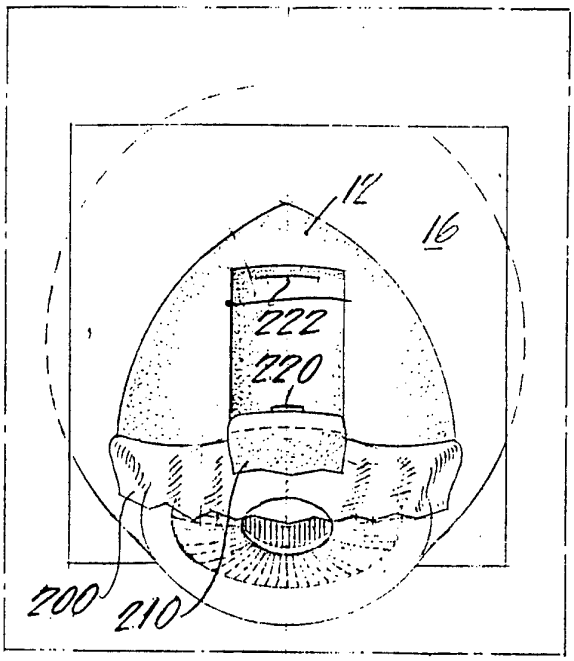


Fig. 18.

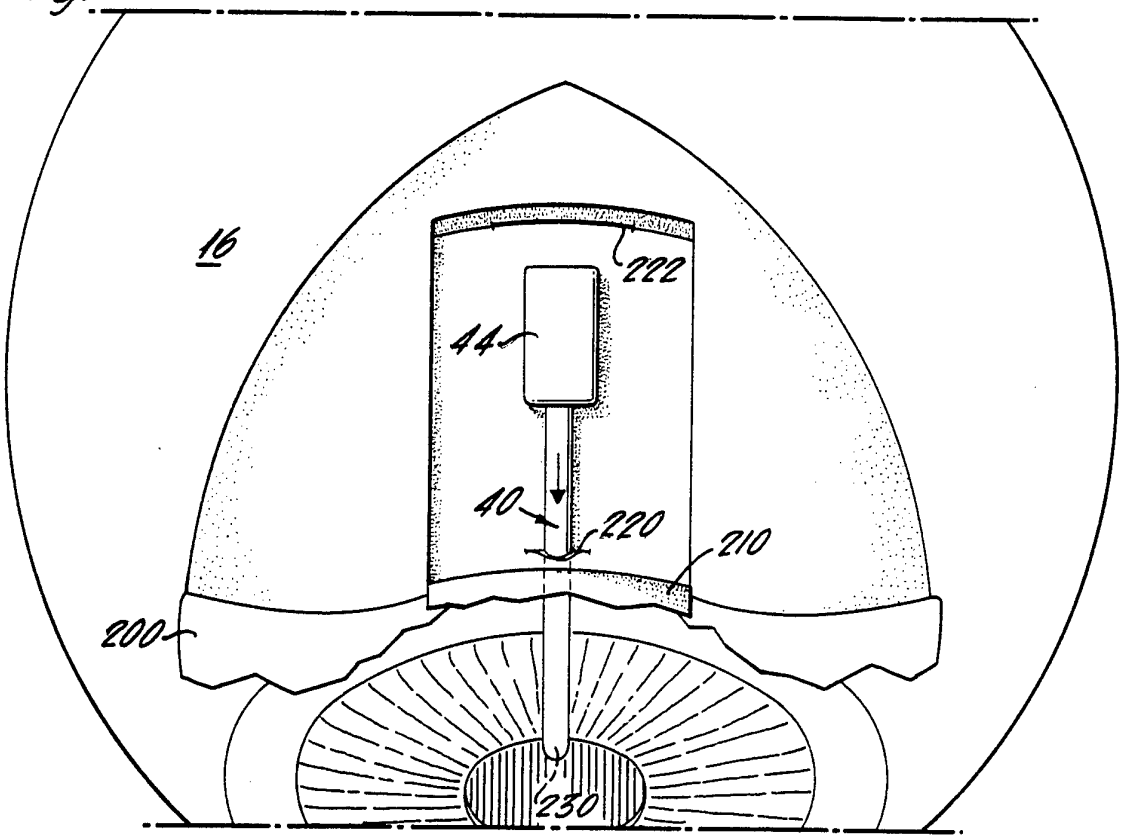
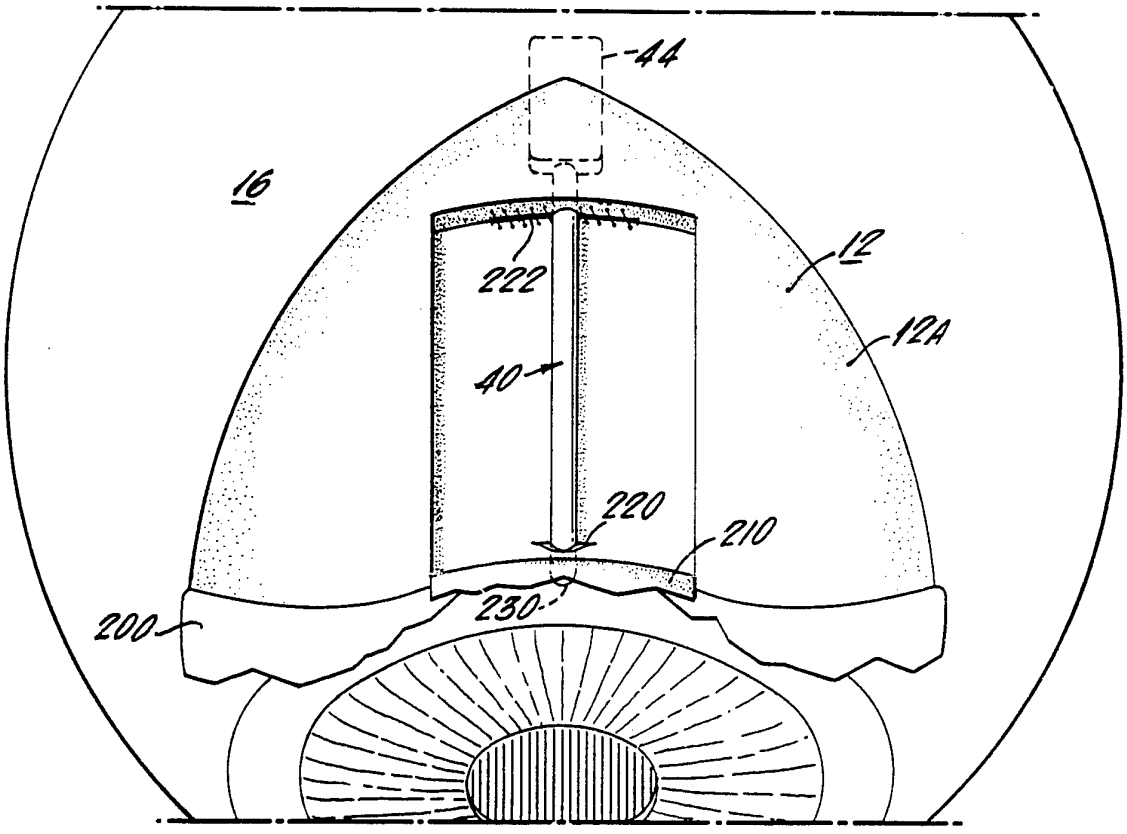


Fig. 19.



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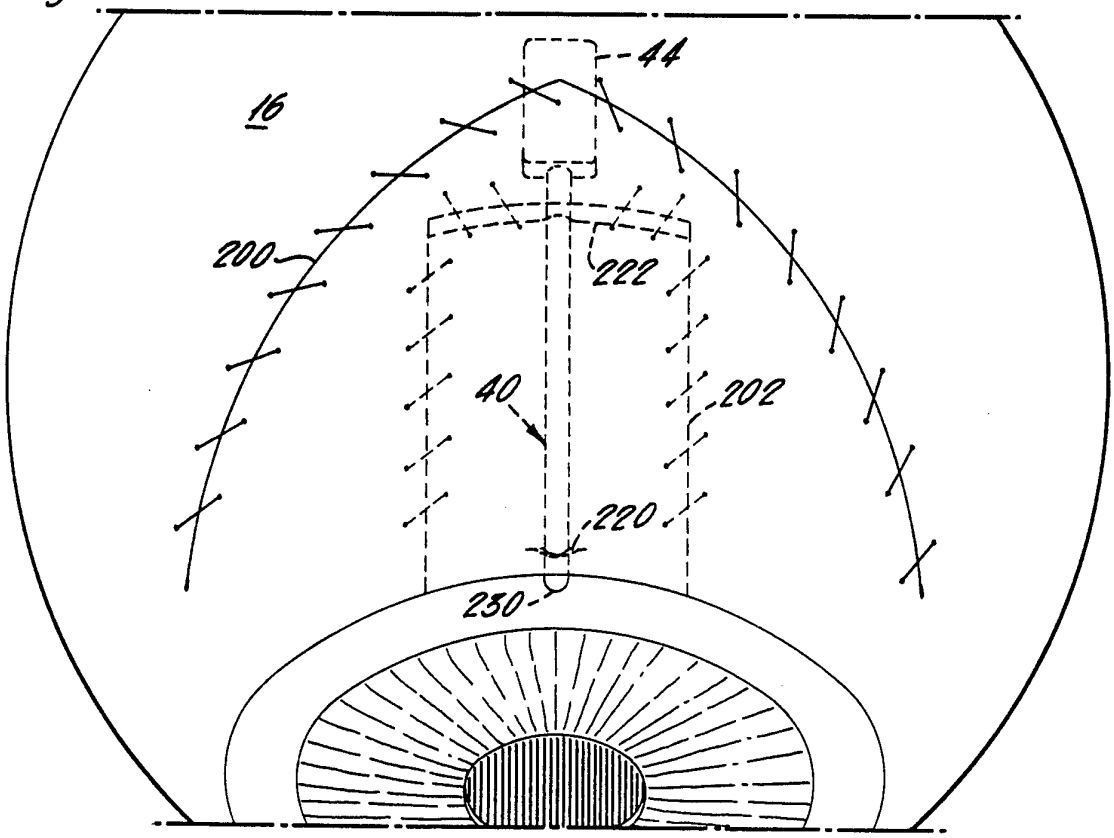
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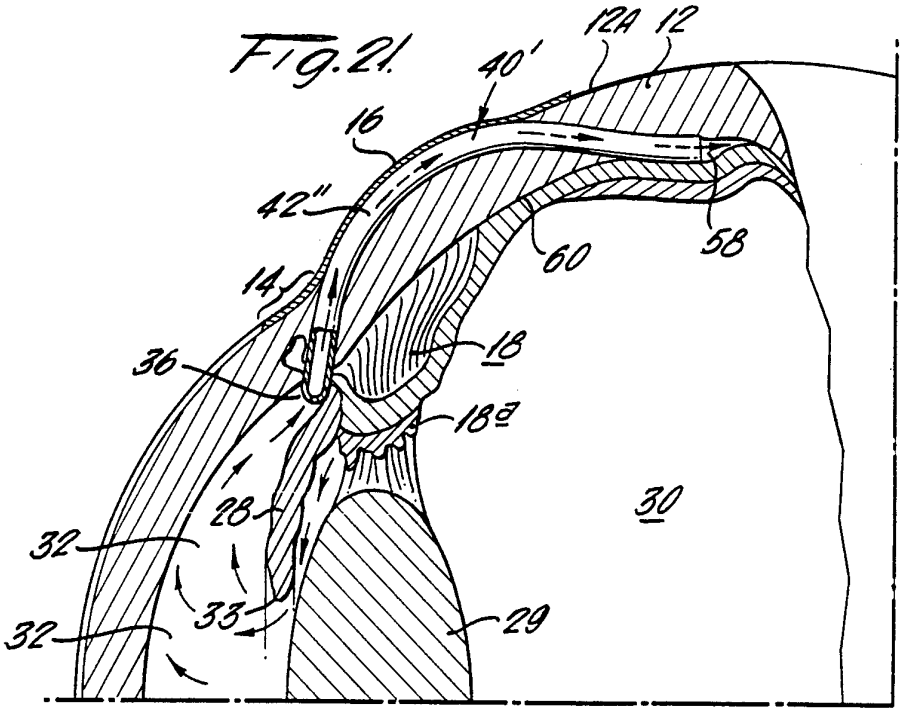
Fig. 21.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INTERNATIONAL SEARCH REPORT

International application No.
PCT/US93/06374

A. CLASSIFICATION OF SUBJECT MATTER
IPC(5) : IPC(5) A 61M 5/00
US CL :US Cl: 604/9
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)

U.S. : US Cl: 623/4; 604/8-10, 175, 247, 294, 264

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

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US, A, 4,729,761 (White) 08 March 1988, see Figures 1-7.	1-9
Y	US, A, 4,554,918 (White) 26 November 1985, see Figures 1-3.	1, 2, 5-9
Y	US, A, 5,073,163 (Lippman) 17 December 1991, see Figures 4 and 6.	5-7
Y	US, A, 4,521,210 (Wong) 04 June 1985, see column 2, lines 16-21.	1-9

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

* Special categories of cited documents:
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Date of the actual completion of the international search
16 July 1992

Date of mailing of the international search report
11 JAN 1994

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