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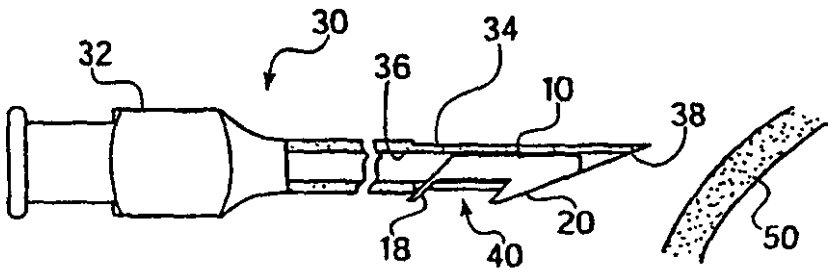

(57) Abstract: An implant having a tube for permitting fluid flow has an outer flange at the outlet end and a retention projection near the inlet end. The retention projection acts as a hook engaging the inside surface of the tissue, causing the implant to stay implanted in the tissue. An implant may also be provided with a methanism for temporary occlusion, in whole or in part, of the flow passage. Thus, the tube passage may be filled, partially or wholly, with absorbable material and/or a plurality of withdrawable or advanceable flow controlling strands.

WO 00/72788 A1

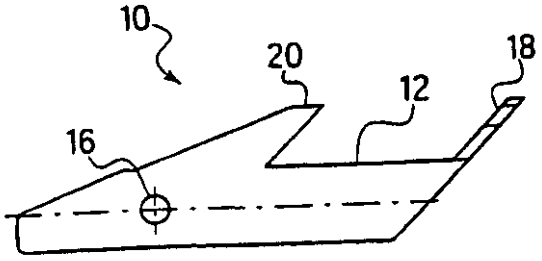

Fig. 1a

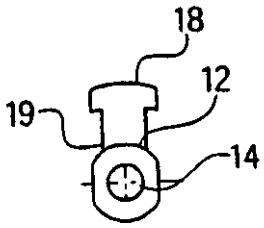

Fig. 1b

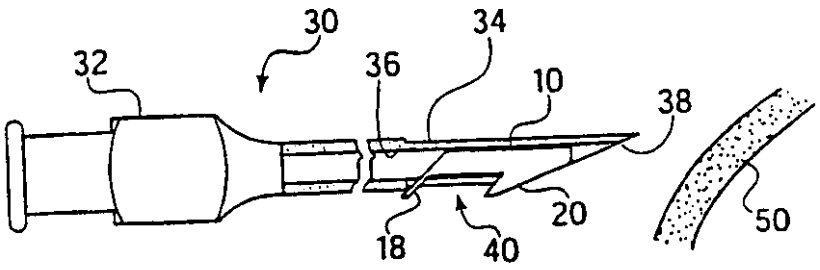

Fig. 2a

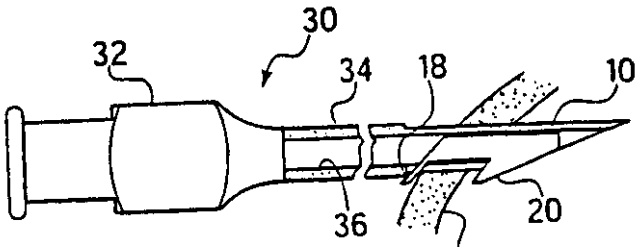

Fig. 2b

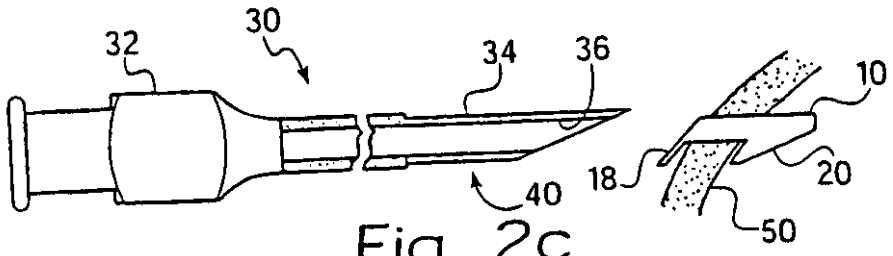

Fig. 2c

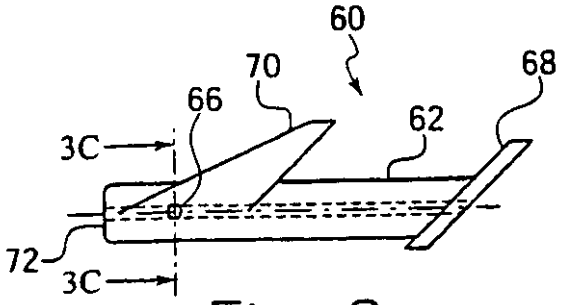

Fig. 3a

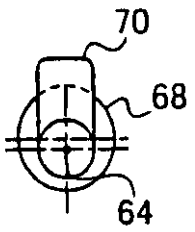

Fig. 3b

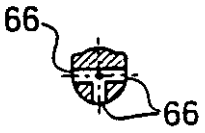

Fig. 3c

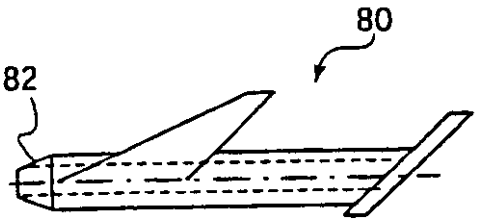

Fig. 4a

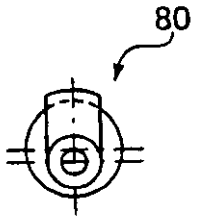

Fig. 4b

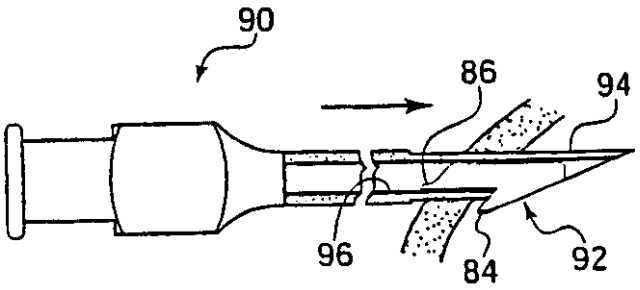

Fig. 5

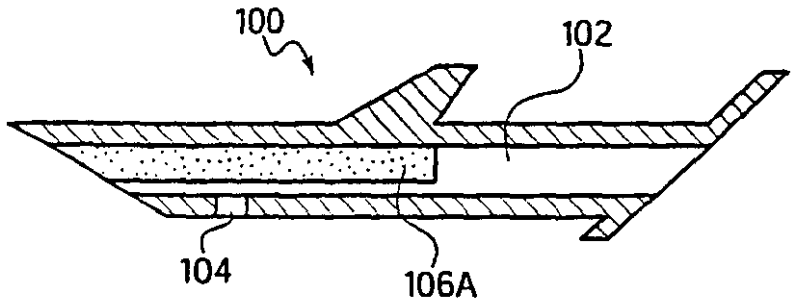

Fig. 6

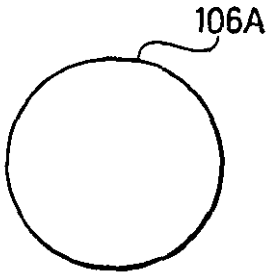

Fig. 7a

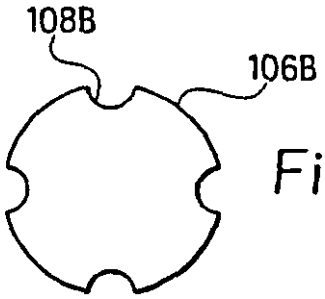

Fig. 7b

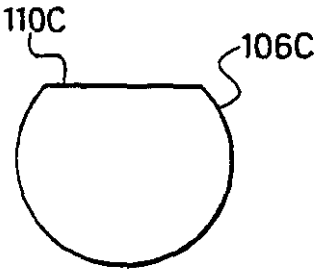

Fig. 7c

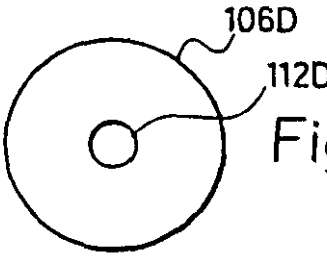

Fig. 7d

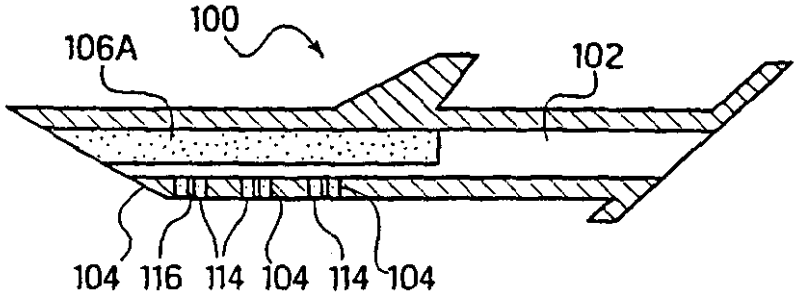

Fig. 8

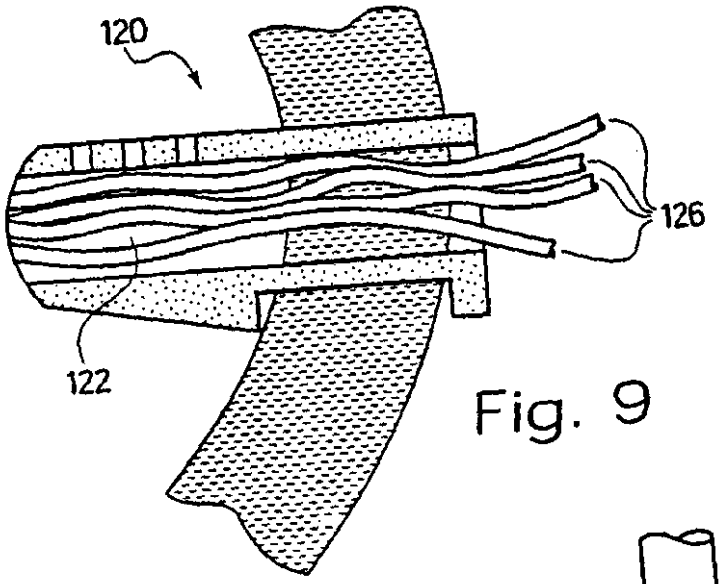

Fig. 9

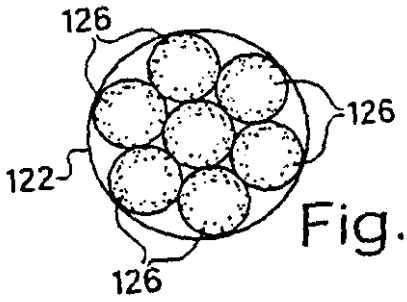

Fig. 10

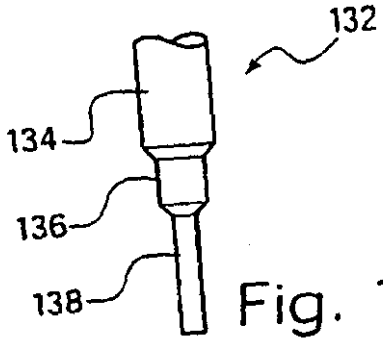

Fig. 12

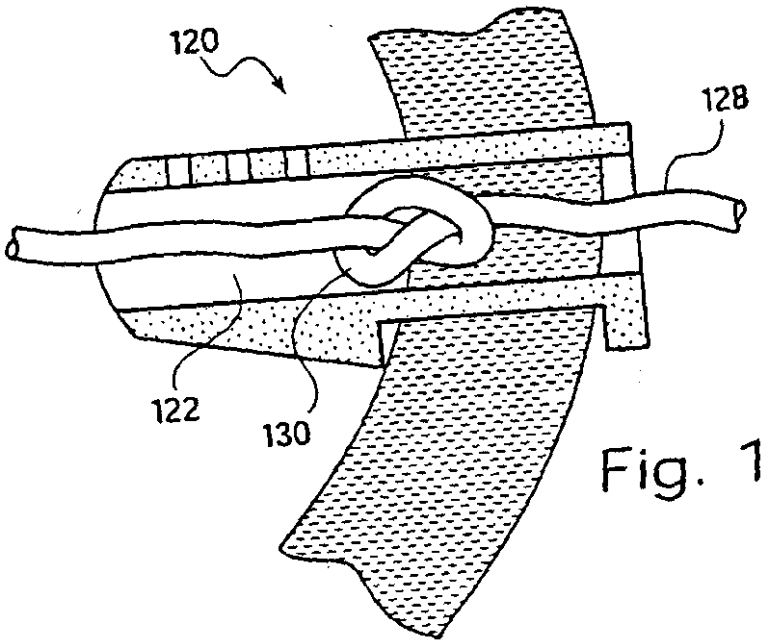

Fig. 11

FLOW CONTROL DEVICE, INTRODUCER AND METHOD OF IMPLANTING

FIELD OF THE INVENTION

The invention relates generally to medical implants used to regulate the flow of fluids within the body. The invention may be applied, for example, to ophthalmic implants for treatment of glaucoma. The invention also relates to delivery devices for implanting such implants, to methods of implanting such implants, and to methods of manufacturing such implants.

BACKGROUND OF THE INVENTION

Medical implants used to regulate the flow of fluids within the human body are known and used. One application for the use of such implants is in the treatment of glaucoma. Typical ophthalmic implants utilize drainage tubes for the release of aqueous humor from the eye to relieve the intraocular pressure (IOP).

Several disadvantages have at times been associated with prior implants. For example, implants using valve mechanisms to regulate fluid flow have risked malfunction due to defects in and/or failure of such valve mechanisms. Depending on such factors as the site of implantation, some implants have tended to clog while in use due to tissue covering the inlet end or the outlet end of the drainage tube. In addition, prior implants at times have required insertion operations that are complicated,

costly, and time-consuming, for example requiring suturing of the implant once it is in place.

PATENTS AND APPLICATIONS INCORPORATED BY REFERENCE

The assignee of this patent application is also the assignee of other patents and patent applications describing and illustrating implants directed at overcoming some of the drawbacks associated with prior implants, as well as delivery devices for such implants, methods of using such implants, and methods of manufacturing such implants.

For example, implants, delivery devices, methods of use, and methods of manufacturing are described and illustrated in United States Patent No. 5,868,697 and United States Patent No. 5,702,414, both of which are owned by the assignee of this application, and both of which are hereby expressly incorporated by reference into this application.

Further examples of such implants, delivery devices, methods of use, and methods of manufacturing are also described and illustrated in United States Patent Application No. 08/975,386, filed November 20, 1997, which is also owned by the assignee of this application, and which is also hereby expressly incorporated by reference into this application.

SUMMARY OF THE INVENTION

One object of the invention is to provide a flow regulating implant and an associated delivery device that enable the implant to be inserted in a relatively simple and efficient procedure.

In one embodiment in accordance with the invention, an implant having a tube for permitting fluid flow has an outer flange at the outlet end and one or more retention projections near the inlet end. An introducer or delivery device for implanting the implant has a central bore for accommodating the implant during the implantation procedure. The implant and delivery device are designed so that when the implant is loaded in the delivery device, the retention projection or projections of the implant protrude from the delivery device to act as a hook or hooks during the procedure.

In accordance with a method of using the implant and delivery device according to an embodiment of the invention, the implant is loaded in the delivery device with the retention projection protruding from the delivery device. The delivery device and implant then penetrate the tissue through which drainage is desired, for example, the sclera of an eye. Once the retention projection has fully penetrated through the tissue, the delivery device is withdrawn. The retention projection acts as a hook engaging the inside surface of the tissue, causing the implant to

stay implanted in the tissue when the delivery device is withdrawn.

The retention projection may be made, for example, of an elastic material, so that it is able to be flexed inward against the tube of the implant during penetration through the tissue. Alternatively, the retention projection may be designed to lie initially relatively flat against the tube for easier penetration and to prevent tearing of the tissue, with a mechanism for extending the retention projection outwardly when the implant is implanted.

Another object of the invention is to provide a simple and efficient method of manufacturing a flow regulating implant. In a method for manufacturing an implant according to an embodiment of the invention, the device may be molded out of a suitable material, for example, silicone. To provide the tube passage of the implant, a thin wire may be used during the molding process. The implant alternatively may be constructed out of stainless steel or any other suitable material.

A further object of the invention is to provide a flow regulating implant with beneficial flow characteristics. Thus, the implant may have various mechanisms for changing the configuration of the flow path. For example, a flow controlling rod or other obstruction may be placed in the tube passage for changing the dimensions within the tube passage. This rod or obstruction may be

temporary. For example, it may be made of absorbable (biodegradable) material that is eroded and absorbed. Alternatively, it may be constructed in such a way that it may be removed from the tube passage or advanced into the tube passage at a period of time after implantation. For example, one or more strands, such as sutures, may be placed in the tube passage and withdrawn or advanced by a physician as desired at a later time or times.

An implant according to the invention has other applications aside from the field of intraocular implants. For example, the implant may be used for drainage of a hydrocele sac, regulating flow between the hydrocele sac and the subcutaneous scrotum. Persons of ordinary skill in the art will appreciate that other applications of an implant in accordance with the invention are possible, as are various modifications of the embodiments described herein, without departing from the scope of the invention as defined in the claims.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1A is a side view of a first embodiment of a drainage implant;

Figure 1B is an end view of the drainage implant shown in Figure 1A;

Figures 2A through 2C illustrate a delivery device and insertion of the drainage implant of Figure 1A into desired tissue, with Figure 2A showing the delivery device and implant before insertion, Figure 2B showing the delivery device and implant being placed through the tissue, and Figure 2C showing the inserted implant after the delivery device has been withdrawn;

Figure 3A is a side view of a second embodiment of a drainage implant;

Figure 3B is an end view of the drainage implant shown in Figure 3A;

Figure 3C is a cross-sectional view taken along the plane identified by the line 3C--3C in Figure 3A;

Figure 4A is a side view of a third embodiment of a drainage implant;

Figure 4B is an end view of the drainage implant shown in Figure 4A;

Figure 5 illustrates a second embodiment of a delivery device with an implant inserted in the delivery

device and with the procedure at a stage corresponding to that in Figure 2B;

Figure 6 illustrates an intraocular implant according to the invention with a flow controlling plug made of absorbable material in the tube passage;

Figures 7A through 7D illustrate four variations of cross-sections for a flow controlling plug;

Figure 8 illustrates an intraocular implant according to the invention with a flow controlling plug made of absorbable material in the tube passage and with side holes partially occluded by plugs made of absorbable material;

Figure 9 illustrates an intraocular implant according to the invention with flow controlling strands in the tube passage;

Figure 10 illustrates an end view of an intraocular implant with flow controlling strands in the tube passage;

Figure 11 illustrates an intraocular implant according to the invention with a knotted flow controlling strand in the tube passage; and

Figure 12 illustrates an alternative construction of a flow controlling strand.

DETAILED DESCRIPTION OF EMBODIMENTS OF THE INVENTION

Figures 1A and 1B show a side view and end view, respectively, of a first embodiment of a drainage implant 10 in accordance with the invention. The implant 10 has a tube 12 having a tube passage 14 for permitting fluid flow between an inlet end of the implant and an outlet end of the implant. One or more side holes 16 may be provided around the circumference of the tube 12 near the inlet end, allowing access for fluid flow into the tube passage 14.

The implant 10 has an outer flange 18 at the outlet end and a retention projection 20 near the inlet end. The plane of the outer flange 18 may form an angle with the tube 12, with the angle selected to correspond to the angle between the surface of the tissue into which the implant 10 is to be inserted and the axis of insertion of the tube 12 of the implant 10.

Figures 2A through 2C illustrate an introducer or delivery device 30 for implanting the implant 10 and the method of implanting the implant 10 with that delivery device 30. The delivery device 30 has handle 32 and a tube 34 having a central bore 36 for accommodating the implant 10 during the implantation procedure. The delivery device 30 has a beveled tip 38 to allow penetration of the tissue 50

into which the implant is to be inserted. In an alternative embodiment, the implant itself penetrates the tissue by its beveled tip at the inlet end.

An opening 40 is provided in the wall of the tube 34 of the delivery device 30. In this illustrated embodiment, the opening 40 allows both the retention projection 20 and the outer flange 18 to protrude beyond the wall of the tube 34 when the implant 10 is loaded in the delivery device 30. Because it projects beyond the wall of the tube 34, the retention projection 20 of the implant 10 can act as a hook during the implantation procedure.

As can be seen in Figure 1B, the flange 18 of the implant 10 has notches or grooves 19 on either side. These notches or grooves 19 correspond approximately to the width of the wall of the tube 34 of the delivery device 30 and accommodate the wall of the tube 34 of the delivery device 30 when the implant 10 is loaded in the delivery device 30. The notches or grooves 19 may take any suitable shape. Alternatively, the flange 18 may have a continuous width, with no notches or grooves, with the width of the flange 18 being slightly narrower than the diameter of the tube 12 of the implant 10. Further variations of the configuration of the flange 18 are possible.

To use the implant 10 and delivery device 30, the implant 10 is loaded in the delivery device 30 with the retention projection 20 protruding from the delivery device,

as shown in Figure 2A. The delivery device 30, with the implant loaded inside, is then pressed through the tissue 50 through which drainage is desired, for example, the sclera of an eye. Figure 2B illustrates the delivery device 30 pressed through the tissue 50.

To facilitate introduction of the delivery device 30 and/or implant 10 into the tissue 50, the delivery device 30 may be oriented such that the beveled tip 38 forms a sharper angle with the tissue 50. Thus, for example, the delivery device as shown in Figure 2A may be rotated 180 degrees, i.e., with the retention projection 20 facing upward. In the case of an implant 10 being placed into the limbal sclera of an eye, this corresponds to the retention projection 20 being on the opposite side of the tube 12 from the iris. When the delivery device 30 and implant 10 are suitably through the tissue 50, they may be rotated to align the implant 10 properly in the tissue 50, with the flange 18 and retention projection 20 oriented as desired with respect to the tissue 50.

Once the retention projection 20 has fully penetrated through the tissue 50, the delivery device 30 is withdrawn. The retention projection 20 acts as a hook engaging the inside surface of the tissue 50, causing the implant 10 to stay implanted in the tissue 50 when the delivery device 30 is withdrawn. Figure 2C illustrates the implant 10 implanted in the tissue 50, with the delivery

device 30 withdrawn.

Since the tube 34 of the delivery device 30 is hollow, it may be used to inject fluid or viscoelastic material. Thus, fluid may be injected into the anterior chamber of an eye upon implantation to reduce the risk of hypotony. Similarly, a viscoelastic material may be injected under the conjunctiva to help fill the bleb that exists after implantation.

The implant 10 may be molded out of a suitable material, for example, silicone. To provide the tube passage 14 of the implant 10, a thin wire may be used during the molding process. More than one wire may be used, in order to have more than one tube passage in the implant. The implant alternatively may be constructed out of stainless steel or another suitable material. It may be coated with a suitable anti-fibrosis material, such as heparin.

The retention projection 20 may be formed of the same material as the rest of the implant 10. Alternatively, it may be made of a more flexible material to allow it to be flexed inward against the tube 12 of the implant 10 during penetration through the tissue 50. Alternatively, the retention projection 20 may be designed to lie initially relatively flat against the tube 12 for easier penetration and to prevent tearing of the tissue 50, to be extended outwardly by an expansion mechanism, for example a balloon,

when the implant 10 is implanted.

Figures 3A, 3B and 3C show a side view, end view, and cross-section, respectively, of a second embodiment of a drainage implant 60 in accordance with the invention. Like the implant 10 shown in Figures 1A and 1B, the implant 60 in Figures 3A, 3B, and 3C has a tube 62 having a tube passage 64 and side holes 66 opening into the tube passage 64. The implant 60 also has an outer flange 68 at the outlet end and a retention projection 70 near the inlet end. In this case, the outer flange 68 projects beyond the outer surface of the tube 62 in all directions around the circumference of the tube 62.

Figures 4A and 4B show a side view and end view, respectively, of a third embodiment of a drainage implant 80, similar to the implant 60 shown in Figures 3A, 3B, and 3C. The tip 82 of the implant 80 is conical, in contrast to the blunt tip 72 of the implant 60.

In an alternative construction, the implant may be made with a closed end with a slit in it. Fluid can only pass through the device when the pressure rises sufficiently to open the slit. Alternatively, a different portion along the length of the tube passage may be provided with such a construction.

Figure 5 illustrates an alternative embodiment of a delivery device 90 in accordance with the invention. In this embodiment, the opening 92 allows only the retention

projection 84 of the implant to protrude beyond the wall of the tube 94 of the delivery device. The outer flange 86 is accommodated within the central bore 96 of the delivery device 90. In this embodiment, the outer flange 86 must be folded or bent to be accommodated within the central bore 96 of the delivery device 90. The outer flange 86 is resilient, so that when the implant is removed from the delivery device, the outer flange 86 extends to a position relatively coplanar with the outer surface of the tissue into which the implant is inserted.

Similarly, the retention projection 84 may also be constructed to be sufficiently resilient to allow it to be compressed and completely accommodated within the central bore 96 of the delivery device 90. In addition, the delivery device 90 may be constructed with the tube 94 having a continuous outer wall, with no opening 92. To facilitate removal of the implant from the delivery device, a pusher rod or wire may be located within the bore of the delivery device. By advancing the pusher rod or wire within the delivery device against the implant, the physician can force the implant out of the delivery device, thereby allowing the retention projection to expand outwardly to its initial, relaxed position, enabling it to engage the inside surface of the tissue.

Various mechanisms may be used, if desired, for giving different flow characteristics to the implant. It

may be desirable to use implants with different flow characteristics for different patients and/or to have an implant in which the flow characteristics may be changed after implantation in a particular patient.

U.S. Patent Application No. 08/975,386, filed November 20, 1997 and incorporated by reference herein, describes and illustrates various mechanisms for assisting in controlling the flow of fluid, e.g. aqueous humor, through an implant. It describes and illustrates the use of a flow controlling wire or rod in the tube passage of an implant.

The effect of the flow controlling rod or wire is to reduce the cross-sectional area through which the fluid flows for a particular length inside the tube passage of the implant. Because the flow is a function of the cross-section and length of the lumen through which it passes, the interposition of the flow controlling rod or wire serves to increase the resistance to flow. In an intraocular implant, for example, this assists in reducing the risk of hypotony.

The configuration and dimensions of the flow controlling rod or wire may be selected in accordance with the flow characteristics that are desired. It may have one or more internal bores or external grooves, any of which may be helically arranged to increase its length. It may be adjustable, by moving it axially or rotating it, to modify

the flow characteristics. Persons skilled in the art will appreciate that numerous other variations are possible for the configuration of the flow controlling rod or wire.

The flow controlling rod or wire may have its axis aligned parallel with the axis of the tube passage, but other orientations are possible. For example, a flow controlling rod or wire having a diameter slightly smaller that the tube passage may be oriented transverse to the tube passage. The transversely oriented rod or wire will have a short length, corresponding approximately to the diameter of the tube or tube passage. It serves as an obstruction to the flow through the tube passage, altering the flow characteristics. Other obstruction may be placed in the tube passage for achieving similar results.

Another mechanism described and illustrated in U.S. Patent Application No. 08/975,386 for assisting in controlling the flow of fluid through an implant is the use of temporary occlusion. By occluding the flow passage of the implant with an absorbable material or with a material that may be removed after implantation, for example by a tool or laser probe, the resistance to flow can be reduced after implantation.

The use of temporary occlusion is advantageous in situations in which flow through the implant is desired to be kept low at implantation, and possibly also for a period of time after implantation. For example, when an implant is

implanted in the eye, the incision in the conjunctiva and/or possible tearing of the sclera around the implant provide potential flow passages for aqueous humor. Thus, to reduce the risk of hypotony, it may be desirable to prevent or reduce flow through the implant upon implantation and for a period thereafter. Once the conjunctiva and/or sclera have healed, the flow through the implant can be increased.

The temporary occlusion need not be limited to any particular part of the flow passage. For example, the side holes and/or the tube passage of the implant may be filled, partially or wholly, with absorbable material. Thus, for example, as shown in Figure 6, a plug 106A of absorbable material may be placed in the tube passage 102 of the implant 100. With an absorbable material that biodegrades by surface erosion, as fluid contacts and flows adjacent to the plug 106A, the material of the plug 106A is absorbed into the fluid, thereby reducing the dimensions of the plug 106A. As the dimensions of the plug 106A are reduced, the resistance to flow through the implant is similarly reduced. Alternatively, an absorbable material that biodegrades by bulk erosion may be used. Absorbable (biodegradable) materials are known and used, and such materials are described, for example, in Middleton & Tipton, "Synthetic Biodegradable Polymers as Medical Devices," Medical Products and Biomaterials, March 1998.

Figure 6 shows the plug 106A only partially

filling the tube passage 102, but it will be appreciated that the plug 106A may completely fill the tube passage 106A. In that case, fluid flow would initially be completely obstructed. Fluid flow begins only after the plug 106A has been sufficiently absorbed to provide a path for fluid to flow out of the implant.

An absorbable plug may be used with any suitable configuration of implant, including implants with flow controlling rods or other flow controlling obstructions. Similarly, an absorbable plug may have any suitable configuration and dimensions, selected in accordance with the flow characteristics that are desired. If desired, more than one absorbable plug may be used.

Some possible cross-sectional shapes for alternative absorbable plugs are shown in Figures 7A through 7D. Absorbable plug 106A has a circular cross-section. Absorbable plug 106B is similar to absorbable plug 106A with the addition of external grooves 108B. Absorbable plug 106C has a flat surface 110C. Absorbable plug 106D has a longitudinal bore 112D. Alternative constructions include combining external grooves and internal bores, changing the number of them, and/or arranging them helically or in any other suitable configuration. The absorbable plug may be in a tapered or other suitable shape. It will be appreciated that the configuration of the absorbable plug will affect the absorption of the absorbable plug, with the areas in

contact with the fluid being absorbed first.

Figure 8 shows the use of an absorbable plug 106A in conjunction with partially occluded side holes 104. Each of the side holes 104 is partially occluded by absorbable plugs 114, each of which has a central bore 116. As with the absorbable plug 106A in the tube passage 102, the absorbable plugs 114 in the side holes 104 may have any suitable configuration, and may be used in conjunction with any configuration of absorbable plug in the tube passage or with no absorbable plug in the tube passage.

Figures 9 through 11 show alternative mechanisms for partial and/or temporary occlusion of the flow passage. In Figure 9, the intraocular implant 120 has a number of flow controlling strands 126 in the tube passage 122. The flow controlling strands 126 serve to alter the flow characteristics through the implant, either partially or wholly obstructing flow through the implant. The number and/or size of the strands may be varied as desired, and the strands may be of any suitable material. For example, ordinary sutures, such as polypropylene sutures, may be used.

At a period of time after implantation, one or more of the flow controlling strands 126 may be withdrawn from the implant (or advanced into the implant). Further strands may be withdrawn (or advanced) at later times. In this manner, the obstruction to flow through the implant can

be altered, at once or over a period of time, after the implantation procedure has taken place.

It will be appreciated that the ability to withdraw or advance one or more strands over time allows the physician to alter the flow characteristics of the implant in accordance with the needs of the patient. For example, at a certain period of time after the implant has been implanted in a patient's eye, the physician can check the intraocular pressure of the eye and determine whether one or more strands should be withdrawn or advanced to increase or reduce flow through the implant. The patient can be checked periodically, and the strands can be left in place, withdrawn or advanced as appropriate over a period of time.

The ability to withdraw strands is useful in the event the implant should become clogged. In such a case, the physician can withdraw one or more strands in order to restore proper flow through the implant.

Figure 10 shows an end view of an implant with a plurality of flow controlling strands 126 in the tube passage 122. It will be appreciated that the strands 126 may be arranged within the tube passage 122 in any suitable manner, and the shape and configuration of the strands 126 are not limited to that shown. For example, the strands may have different cross-sections (e.g., oval, semi-circular, irregular, hollow, etc.) and different sizes. The cross-sectional shapes and dimensions may vary along the length of

a single strand. Each of the strands in a single implant may have different configurations, e.g., different cross-sectional shapes and/or dimensions. With different strands in the implant, the physician can selectively withdraw (or advance) the appropriate strand or strands in accordance with the desired flow characteristics. For example, if a small increase in flow is desired, a strand with a small cross-section can be withdrawn, and if a larger increase in flow is desired, a strand with a larger cross-section can be withdrawn.

Figure 11 shows an implant in which a single flow controlling strand 128 having a knot 130 is placed within the tube passage 122. The knot 130 serves to increase the flow obstruction. Alternatively, a plug or other obstruction may be attached to the strand 128, and more than one strand 128 with a knot, plug or other attached obstruction may be used. Similar to the use of strands of different shapes and/or sizes, strands may be used having knots or plugs of different shapes and/or sizes, allowing selective withdrawal or advancement of the appropriate strand or strands in accordance with the desired flow characteristics.

Figure 12 shows an alternate construction of a flow controlling strand 132 in which the cross-sectional size of the strand varies along its length. The illustrated strand 132 has three different sections. Section 138 on the

end of the strand has the smallest diameter, the adjacent section 136 has a slightly larger diameter, and the remainder 134 of the strand has an even larger diameter. The remainder 134 of the strand may be sized to correspond to the diameter of the tube passage, with the sections 136 and 138 being incrementally smaller. Thus, with a tube passage having a diameter, for example, of 100 microns, the strand may also have a diameter of 100 microns, with incremental steps down to, for example, 20 microns. Of course, other dimensions may be used, and the remainder 134 of the strand need not have the same size as the tube passage. In the initial positioning, the strand 132 is located in the tube passage of the implant with the section 138 near the inlet end and with part of the section 134 located within the tube passage near the outlet end. When it is desired to increase the flow in the implant, the strand 132 may be partially withdrawn such that only section 134 comes out of the tube passage. Thus, the obstruction within the tube passage is decreased, thereby increasing the flow. Later, if desired, the other sections may be successively withdrawn. Alternatively, the strand may be further advanced into the tube passage to further constrict flow.

Variations of the strand shown in Figure 12 are possible, with the sections being aligned along the strand in any desired pattern. The concept of a single strand

which may be partially withdrawn or advanced in successive increments to vary the flow in steps may additionally or alternatively be achieved by using knots or plugs of different shapes and/or sizes along the length of a strand.

A flow controlling strand in accordance with the invention may be completely separate from the implant and inserted into the implant some period of time after implantation, or the strand may be partially in the implant upon implantation, with the option of advancing it further into the implant at a later time.

An implant having withdrawable (and/or advanceable) flow controlling strands may be implanted using a delivery device 30 as shown in Figure 2A. In such a case, the strands that extend out of the outlet end of the implant may be accommodated in the central bore 36 of the delivery device 30. Alternatively, with a suitably sized opening 40 in the wall of the tube 34 of the delivery device 30, the strands may pass outside of the delivery device 30.

When the implant is implanted in an eye, the flow controlling strands can be oriented to extend under the conjunctiva away from the implant. The strands used may be long enough to extend out of the implant beyond the slit made in the conjunctiva for inserting the implant. In this case, after implanting the implant, the physician can tuck the loose ends of the strands under the conjunctiva to extend away from the slit. When it is desired to withdraw

one or more of the strands, a small slit can be made in the conjunctiva near the ends of the strands, and the strands can be pulled through that slit. Because these ends are remote from the implant and the prior slit made in the conjunctiva, the potential trauma to the eye is reduced.

To fix the strands in place and facilitate later access to them, the loose ends may be sutured to the adjacent tissue, e.g., the sclera. This may be done either with additional sutures or with the strands themselves. In the latter case, suturing needles may be attached to the loose ends of the strands to facilitate suturing of the strands after implantation of the implant.

It will be appreciated that various features of the above-described embodiments may be combined as desired. For example, the flow controlling strands may be made of absorbable material, leaving the option of having a physician physically withdraw the strands or allowing them to be absorbed. Additionally or alternatively, plugs or other obstructions secured to the strands may be made of absorbable material. Different strands, plugs or obstructions may be made from materials with different rates of absorption, and/or they may be made from a combination of materials with different rates of absorption.

As will also be appreciated by persons having ordinary skill in the art, the various embodiments of implants, methods of manufacture, delivery devices, and

methods for implantation described hereinabove are given by way of example only. Various changes, modifications and variations may be applied to the described embodiments without departing from the scope of the invention, defined by the appended claims.

What is Claimed is:

1. An implant in combination with a delivery device for implanting the implant, wherein the implant comprises a tube and an outwardly extending retention projection, wherein the delivery device comprises a tube having an outside surface and a central bore for accommodating the implant, and wherein the delivery device has an opening in the side of the tube allowing the retention projection to project beyond the outside surface of the tube of the delivery device.

2. An implant and delivery device according to claim 1, wherein the implant is formed of plastic.

3. An implant and delivery device according to claim 1, wherein the retention projection is located at an inlet end of the implant, and wherein the implant further comprises an outer flange located at an outlet end of the implant.

4. An implant and delivery device according to claim 3, wherein the opening in the side of the tube of the delivery device also allows the outer flange of the implant to project beyond the outside surface of the tube of the delivery device.

5. An implant and delivery device according to claim 3, wherein the outer flange of the implant is resilient so that it may be accommodated within the central bore of the tube of the delivery device.

6. An implant in combination with a delivery device for implanting the implant, wherein the implant comprises a tube having an inlet end and an outlet end and an outwardly extending retention projection, wherein the delivery device comprises a tube having an outside surface, a central bore for accommodating the implant and an opening at one end for allowing the implant to exit the central bore, and wherein the implant is accommodated within the central bore with its inlet end closer to the opening than its outlet end so that the inlet end of the implant exits the central bore of the delivery device before the outlet end.

7. An implant and delivery device according to claim 6, wherein the implant is formed of plastic.

8. An implant and delivery device according to claim 6, wherein the retention projection is located proximate the inlet end of the implant, and wherein the implant further comprises an outer flange located proximate the outlet end of the implant.

9. An implant and delivery device according to claim 8, wherein the outer flange of the implant is resilient so that it may be accommodated within the central bore of the tube of the delivery device.

10. An implant and delivery device according to claim 6, wherein the retention projection of the implant is resilient so that it may be accommodated within the central bore of the tube of the delivery device.

11. A delivery device for use in implanting an implant, wherein the delivery device comprises a tube having an outside surface and a central bore for accommodating the implant, and wherein the delivery device has an opening in the side of the tube allowing a retention projection of the implant to project beyond the outside surface of the tube of the delivery device.

12. A delivery device according to claim 11, wherein the opening in the side of the tube of the delivery device also allows an outer flange of the implant to project beyond the outside surface of the tube of the delivery device.

13. A method of implanting an implant, comprising the steps of:

placing the implant in a central bore of a delivery device, said placing step including allowing a retention projection of the implant to project beyond an outer surface of a tube of the delivery device;

inserting the delivery device with the implant placed in the delivery device through tissue into which the implant is to be implanted; and

withdrawing the delivery device, leaving the implant implanted in the tissue.

14. A method of implanting an implant, comprising the steps of:

placing the implant in a central bore of a delivery device, said placing step including positioning the implant so that the implant is accommodated within the central bore with an inlet end of the implant closer to an opening in the delivery device than an outlet end of the implant;

inserting the delivery device with the implant placed in the delivery device through tissue into which the implant is to be implanted; and

withdrawing the delivery device, leaving the implant implanted in the tissue.

15. A method of manufacturing a flow control device comprising the steps of:

providing a mold having a cavity with a generally tubular shape;

positioning a wire within the mold such that the wire is suspended to extend along a longitudinal axis of the generally tubular shaped cavity;

putting a moldable material into the mold; and

allowing the moldable material to harden such that it hardens in the generally tubular shape of the mold, with a longitudinal tube passage formed in the hardened material on account of the wire positioned in the mold.

16. An implant for regulating fluid flow comprising:

a tube comprising an inlet end, an outlet end, and a tube passage extending between the inlet end and the outlet end for permitting fluid to flow through the tube passage; and

absorbable material located within the tube passage, wherein initially the absorbable material serves to partially or wholly obstruct flow through the tube passage and wherein the absorbable material erodes as it contacts fluid such that the obstruction of flow through the tube passage is reduced over time.

17. An implant according to claim 16, wherein initially the absorbable material substantially fills the tube passage so as to prevent flow through the tube passage.

18. An implant according to claim 16, wherein initially the absorbable material partially fills the tube passage so as to allow partial flow through the tube passage.

19. An implant for regulating fluid flow comprising:

a tube comprising an inlet end, an outlet end, and a tube passage extending between the inlet end and the outlet end for permitting fluid to flow through the tube passage; and

one or more flow controlling strands located within the tube passage, wherein initially the one or more flow controlling strands serve to partially or wholly obstruct flow through the tube passage and wherein at least one flow controlling strand may be displaced with respect to the tube passage to change the obstruction of flow through the tube passage.

20. An implant according to claim 19, wherein initially the one or more flow controlling strands substantially fill the tube passage so as to prevent flow through the tube passage.

21. An implant according to claim 19, wherein initially the one or more flow controlling strands partially fill the tube passage so as to allow partial flow through the tube passage.

22. An implant according to claim 19 further comprising a plug attached to one or more of said flow controlling strands.

23. An implant according to claim 19 wherein one or more of said flow controlling strands has a knot in it.

24. An implant according to claim 19, wherein at least one flow controlling strand may be withdrawn from the tube passage to reduce the obstruction of flow through the tube passage.

25. An implant according to claim 24, wherein at least one flow controlling strand may be completely withdrawn from the tube passage to reduce the obstruction of flow through the tube passage.

26. An implant according to claim 24, wherein at least one flow controlling strand may be partially withdrawn from the tube passage to reduce the obstruction of flow through the tube passage.

27. An implant according to claim 19, wherein at least one flow controlling strand may be advanced within the tube passage to increase the obstruction of flow through the tube passage.

28. An implant according to claim 19 comprising at least two strands.

29. An implant according to claim 28, wherein two of the strands have different cross-sectional dimensions.

30. An implant according to claim 28, wherein each of at least two strands has a plug attached to it, with the plugs on the at least two strands having different cross-sectional dimensions.

31. An implant according to claim 28, wherein each of at least two strands has a knot in it, with the knots in the at least two strands having different dimensions.

32. An implant according to claim 19 wherein at least one flow controlling strand has different areas along its length with different cross-sectional dimensions.

33. An implant according to claim 19 wherein at least one flow controlling strand is made of absorbable material.

34. An implant for regulating fluid flow comprising:

a tube comprising an inlet end, an outlet end, and a tube passage extending between the inlet end and the outlet end for permitting fluid to flow through the

tube passage; and

means for temporarily obstructing, in whole or in part, fluid flow through the tube passage.

35. An implant according to claim 34 wherein the means for temporarily obstructing, in whole or in part, fluid flow through the tube passage comprises absorbable material located in the tube passage.

36. An implant according to claim 34 wherein the means for temporarily obstructing, in whole or in part, fluid flow through the tube passage comprises at least one flow controlling strand located in the tube passage.

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 00/15200

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61F9/007

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61F A61M

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 practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 300 020 A (L ESPERANCE JR FRANCIS A) 5 April 1994 (1994-04-05) figures 1-4 column 3, line 3 - line 48 column 3, line 64 -column 4, line 9 column 7, line 41 - line 68 claims 1-3,8-11	15-18, 34-36
A		1,6,11, 19

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[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
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European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Mary, C

INTERNATIONAL SEARCH REPORT

Int itional Application No
PCT/US 00/15200

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication,where appropriate, of the relevant passages	Relevant to claim No.
P,X	WO 99 26567 A (OPTONOL LTD ;YARDEN ORIT (IL); YARON IRA (IL); WERNER MARY C (US)) 3 June 1999 (1999-06-03) cited in the application figures 1,5-10,18-29 page 18, line 25 -page 19, line 18 page 21, line 12 - line 24 page 24, line 13 - line 19 page 28, line 4 - line 21 page 31, line 15 - line 28	15-22, 24-27, 32-36
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A	US 5 800 376 A (VASKELIS PAUL S ET AL) 1 September 1998 (1998-09-01) figure 2 claims 1-4	1,6,11, 15,16, 19,34

INTERNATIONAL SEARCH REPORT

Information on patent family members

Int ational Application No
PCT/US 00/15200

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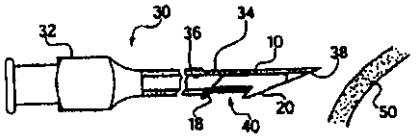
权利要求书4页 说明书11页 附图页数4页

[54]发明名称 用于植入的流动控制装置、导引器和方法

[57]摘要

一种具有用于允许流体流动的管的植入物,该植入物在出口端处 具有外部凸缘,在入口端的附近具有一个或多个固位突出部。该固位 突出部起着接附于组织内表面上的钩子的作用,使得该植入物保持植 入在该组织内。该植入物也提供了用于整体地或部分地临时性地堵塞 该流动通道的机构。因此,该管通道可以部分地或整体地用可被吸收 的材料和/或多个可抽出的或可插入的流动控制线填充。



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权　利　要　求　书

1. 一种植入物和用于植入该植入物的输送装置，其中，该植入物包括一管和一向外延伸的固位突出部，其中，该输送装置包括具有外表面的管和用于容纳该植入物的中心孔，其中，该输送装置在该管的该侧边上具有开口，以便使该固位突出部突出于该输送装置的该管的该外表面之外。

2. 如权利要求 1 所述的植入物和输送装置，其特征在于：该植入物用塑料制成。

3. 如权利要求 1 所述的植入物和输送装置，其特征在于：该固位突出部位于该植入物的入口端，其中该植入物还包括一位于该植入物出口端的外部凸缘；

4. 如权利要求 3 所述的植入物和输送装置，其特征在于：该输送装置的该管的该侧边上的该开口也使得该植入物的该外部凸缘突出于该输送装置的该管的该外表面之外。

5. 如权利要求 3 所述的植入物和输送装置，其特征在于：该植入物的外部凸缘是有弹性的，以便它可被容纳于输送装置的管的中心孔内。

6. 一种植入物和用于植入该植入物的输送装置，其中，该植入物包括具有入口端和出口端的管以及向外延伸的固位突出部，其中，该输送装置包括具有外表面的管、容纳该植入物的中心孔以及在一端上的用于使得该植入物退出该中心孔的开口，其中，该植入物被容纳于该中心孔内，其入口端比其出口端更靠近该开口，以便该植入物的该入口端在该出口端之前退出该输送装置的该中心孔。

7. 如权利要求 6 所述的植入物和输送装置，其特征在于：该植入物用塑料制成。

8. 如权利要求 6 所述的植入物和输送装置，其特征在于：该固位突出部位于靠近该植入物的入口端，并且该植入物还包括位于靠近该植入物的该出口端的外部凸缘。

9. 如权利要求 8 所述的植入物和输送装置，其特征在于：该植入物的该外部凸缘是有弹性的，使得它可以被容纳于该输送装置的该管的该中心孔内。

10. 如权利要求 6 所述的植入物和输送装置，其特征在于：该植

入物的该固位突出部是有弹性的，使得它可以被容纳于该输送装置的该管的该中心孔内。

11. 一种用于植入植入物的输送装置，其中，该输送装置包括具有外表面的管和用于容纳该植入物的中心孔，其中，该输送装置具有在该管的该侧边上的开口，以使该植入物的固位突出部突出于该输送装置的该管的该外表面之外。

12. 如权利要求 11 所述的输送装置，其特征在于：该输送装置的该管的该侧边上的该开口还使该植入物的外部凸缘突出于该输送装置的该管的该外表面之外。

13. 一种植入植入物的方法，其包括以下步骤：

将该植入物放置在输送装置的中心孔内，上述放置步骤包括使该植入物的固位突出部突出于该输送装置的管的外表面；

将在该输送装置中放置有该植入物的该输送装置置入要植入该植入物的组织；以及

抽出该输送装置，使该植入物植入于该组织中。

14. 一种植入植入物的方法，其包括以下步骤：

将该植入物放置在输送装置的中心孔内，上述放置步骤包括定位植入物，使得植入物被容纳于该中心孔内，其中该植入物的入口端与植入物的出口端相比更靠近该输送装置的开口；

将在该输送装置中放置有该植入物的该输送装置置入要植入该植入物的组织；以及

抽出该输送装置，使该植入物植入于该组织中。

15. 一种制造流动控制装置的方法，其包括以下步骤：

提供一种具有通常为管形空腔的模具；

在该模具内放置金属丝，使得该金属丝悬挂成沿通常为管形空腔的纵轴线延伸；

将可模制的材料放入该模具内；以及

使可模制的材料硬化，使得它硬化成该模具的通常的管形状，由于该金属丝放置在该模具中，在硬化的材料中形成一纵向的管通道。

16. 一种调节流体流动的植入物，其包括：

一包括入口端、出口端和在该入口端和该出口端之间延伸的管通道的管，以便使流体流过该管通道；

位于在该管通道内的可被吸收的材料，其中，该可被吸收的材料在开始时部分地或整体地阻塞通过该管通道的流动，并且其中该可被吸收材料在接触流体时被侵蚀，以至于随着时间推移通过该管通道的该阻塞被减小。

17. 如权利要求 16 所述的植入物，其特征在于：该可被吸收的材料在开始时大体上填充该管通道，以便阻止通过该管通道的流动。

18. 如权利要求 16 所述的植入物，其特征在于：该可被吸收的材料在开始时部分地填充该管通道，以便允许部分地通过该管通道的流动。

19. 一种调节流体流动的植入物，其包括：

一包括入口端、出口端和在该入口端和该出口端之间延伸的管通道的管，以便使流体流过该管通道；

位于该管通道内的一根或多根流动控制线，其中，该一根或多根流动控制线在开始时部分地或整体地阻塞通过该管通道的流动，其中，至少一根流动控制线可以相对于该管通道移置，以改变通过该管通道的流动阻塞。

20. 如权利要求 19 所述的植入物，其特征在于：该一根或多根流动控制线在开始时大体上填充该管通道，以便阻止通过该管通道的流动。

21. 如权利要求 19 所述的植入物，其特征在于：该一根或多根流动控制线在开始时部分地填充该管通道，以便允许部分地通过管通道的流动。

22. 如权利要求 19 所述的植入物，还包括接附于一根或多根上述流动控制线上的塞子。

23. 如权利要求 19 所述的植入物，其特征在于：该一根或多根上述流动控制线上具有结。

24. 如权利要求 19 所述的植入物，其特征在于：可以从管通道中抽出至少一根流动控制线，以减少通过该管通道的流动阻塞。

25. 如权利要求 24 所述的植入物，其特征在于：可以从该管通道中完全抽出至少一根流动控制线，以减少通过该管通道的流动阻塞。

26. 如权利要求 24 所述的植入物，其特征在于，可以从该管通

道中部分抽出至少一根流动控制线，以减少通过该管通道的流动阻塞。

27. 如权利要求 19 所述的植入物，其特征在于，可以将至少一根流动控制线插入到该管通道内，以增加流过管通道的阻力。

28. 如权利要求 19 所述的植入物，其包括至少两根线。

29. 如权利要求 28 所述的植入物，其特征在于：两根该线具有不同的横截面尺寸。

30. 如权利要求 28 所述的植入物，其特征在于：至少两根线中的每根线上具有接附于其上的的塞子，在至少两根该线上的该塞子具有不同的横截面尺寸。

31. 如权利要求 28 所述的植入物，其特征在于：至少两根线中的每根线上具有结，该至少两个线上的结具有不同的尺寸。

32. 如权利要求 19 所述的植入物，其特征在于：至少一个流动控制线沿其长度的不同横截面尺寸具有不同区域。

33. 如权利要求 19 所述的植入物，其特征在于：至少一个流动控制线用可被吸收的材料制成。

34. 一种调节流体流动的植入物，其包括：

一包括入口端、出口端和在该入口端和该出口端之间延伸的管通道的管，以便使流体流过该管通道；

用于整体地或部分地临时性地阻塞流体流过该管通道的装置。

35. 如权利要求 34 所述的植入物，其特征在于：用于整体地或部分地临时性地阻塞流体流过该管通道的装置包括位于在管通道内的可被吸收的材料。

36. 如权利要求 34 所述的植入物，其特征在于：用于整体地或部分地临时性地阻塞流体流过该管通道的装置包括至少一根位于管通道内的流动控制线。

02.01.30

说　明　书

用于植入的流动控制装置、导引器和方法

技术领域

本发明一般涉及用于调节体内的流体流动的医疗用植入物。例如本发明可应用于治疗青光眼的眼用植入物。本发明也涉及植入这种植入物的输送装置，和植入这种植入物的方法以及制造这种植入物的方法。

背景技术

应用调节人体内流体流动的医疗用植入物为已知的和已经使用的。使用这样的植入物的一个应用是治疗青光眼。典型的眼用植入物利用引流管来释放眼睛中的眼房水，从而缓解眼内压力（IOP）。

先有技术的植入物时常具有一些相关的缺点。例如，应用阀门机构调节流体流动的植入物容易出现由于这种阀门机构有缺陷和/或失效所导致的故障的危险。取决于诸如植入位置这样的因素，有些植入物在使用期间由于组织覆盖引流管的入口端和出口端而容易堵塞。另外，先有的植入物有时需要复杂的、昂贵的和费时间的植入手术，例如一旦植入物就位时需要缝合植入物。

作为参考文献引入的专利和申请

本专利申请的受让人也是其它相关专利和专利申请的受让人，这些相关专利和专利申请说明和示出了一些植入物旨在克服先有与植入物相关的一些缺陷以及这种先有植入物的输送装置、应用这种植入物的方法和制造这种植入物的方法等有关的一些缺陷。

例如，在美国专利 No. 5,868,697 以及美国专利 No. 5,702,414 中说明和示出了植入物、输送装置、使用方法以及制造方法，这两个专利由本申请的受让人拥有，因此这两个专利特别作为参考文献包含在本申请中。

在 1997 年 11 月 21 日提交的美国专利申请 No. 08/975,386 中也说明和示出了这种植入物、输送装置、应用方法以及制造方法的另外的例子，此专利也由本申请的受让人拥有，因此本专利也特别作为参考文献包含在本申请中。

发明内容

本发明的一个目的是提供调节流动的植入物以及相关的输送装置，该输送装置能使植入物以相对简单的和有效的操作被插入。

在根据本发明的一个实施例中，一具有允许流体流动的管的植入物在出口端具有外部凸缘，在入口端的附近具有一个或多个固位突出部。用于植入该植入物的导引器或输送装置具有中心孔，以便在植入操作期间容纳植入物。该植入物和输送装置被设计成使得当植入物装在输送装置上时，该植入物的一个或多个固位突出部突出于输送装置，以便在植入操作期间作为一个或多个钩子。

按照本发明一个实施例的植入物和输送装置的使用方法，植入物装在输送装置上时该固位突出部突出于该输送装置。然后输送装置和植入物穿透需要引流的组织，例如穿过眼睛的巩膜。一旦固位突出部完全穿透组织时便可抽出输送装置。固位突出部作为接附于组织内表面的钩子，使得抽出输送装置时植入物可以保持植入在组织中。

固位突出部可以用例如塑料制作，使得在穿透植入物期间它可以向内弯曲靠在植入物的管上。或者，固位突出部可以设计成起初相对平顺地靠着管以便容易穿透和防止组织的撕裂，并具有在植入植入物后使固位突出部向外伸开的机构。

本发明的另一目的是提供一种简单和有效的方法来制造流动可调的植入物。在制造本发明一个实施例植入物的方法中，该植入物可以用适当的材料例如硅酮进行模制。为了提供植入物的管通道，在模制操作期间可以应用一细金属丝。植入物或者可以用不锈钢或其它任何合适的材料制作。

本发明的再一目的是提供一种具有有益的流动特性的流动可调的植入物。因此植入物可以具有各种各样的用于改变流动通道的形状的机构。例如可以在管通道内放置控制流动的杆或其它的阻塞物，用于改变管通道内的尺寸。此种杆或阻塞物可以是临时性的，例如它们可以用可被侵蚀的和被吸收的可被吸收（可生物降解）材料制作，或者此种杆或阻塞物可以在植入后的一定时间内从管通道中取出或插入。例如可以在管通道内放入一根或多根诸如缝合线之类的线，医生可以按需要在以后一次或多次地抽出或插入这些线。

除眼内植入物方面之外，本发明的植入物还可以应用在其他方面。例如植入物可以用来引流阴囊积水肿囊，控制阴囊积水肿囊和皮

下阴囊之间的流量。本专业的普通技术人员将会认识到本发明的植入物也可应用在其它方面，作为本文说明的实施例的各种变型，而不超出如权利要求书确定的本发明的范围。

附图说明

图 1A 是引流植入物的第一实施例的侧视图；

图 1B 是图 1A 所示引流植入物的端视图；

图 2A～2C 示出了输送装置以及将图 1A 所示的引流植入物插入所需的组织，其中图 2A 示出了植入前的输送装置和植入物，图 2B 示出了输送装置和正在置入组织的植入物，而图 2C 示出了抽出输送装置之后的已插入的植入物；

图 3A 是引流植入物第二实施例的侧视图；

图 3B 是图 3A 所示引流植入物的端视图；

图 3C 是沿图 3A 中的线 3C-3C 确定的平面所截取的横截面图；

图 4A 是引流植入物第三实施例的侧视图；

图 4B 是图 4A 所示引流植入物的端视图；

图 5 示出输送装置的第二实施例，其中植入物已插入到输送装置中，并且其操作的阶段对应于图 2B 所示的阶段；

图 6 示出了本发明的在管通道内具有由可被吸收材料制作的流动控制塞的眼内植入物；

图 7A～7D 示出流动控制塞的横截面的四种变型；

图 8 示出了本发明的眼内植入物，该植入物在管通道内具有由可被吸收材料制作的流动控制塞和被由可被吸收材料作的塞子部分地阻塞的侧孔；

图 9 示出了本发明的在管通道内具有流动控制线的眼内植入物；

图 10 是具有在管通道内具有流动控制线的眼内植入物的端视图；

图 11 示出了本发明的在管通道内具有打结的流动控制线的眼内植入物；

图 12 示出了流动控制线的另一种结构。

具体实施方式

图 1A 和图 1B 分别示出本发明的引流植入物 10 的第一实施例的侧视图和端视图。该植入物 10 具有管 12，该管具有可使流体在植入

物入口端和植入物出口端之间流动的管通道 14. 在靠近入口端的管 12 的圆周上设置了一个或多个侧孔 16，从而可使流体流入管通道 14.

植入物 10 具有在出口端的外部凸缘 18 和靠近入口端的固位突出部 20. 外部凸缘 18 的平面与管 12 形成一定角度，选定该角度使其等于插入植入物 10 的组织表面和植入物 10 的管 12 的插入轴线之间的角度.

图 2A～2C 示出了用于植入植入物 10 的导引器或输送装置 30 以及用该输送装置 30 植入植入物 10 的方法. 该输送装置 30 具有手柄 32 和管 34，该管具有在植入操作期间容纳植入物 10 的中心孔 36. 输送装置 30 具有斜面尖头 38，以便可以穿透将要植入植入物的组织 50. 在另一实施例中，植入物本身可以用其入口端的斜面尖头穿透组织.

在输送装置 30 的管 34 的壁上设有开口 40. 在此例示的实施例中，该开口 40 在将植入物 10 装在输送装置 30 上时，使得固位突出部 20 和外部凸缘 18 两者均可突出于管 34 的壁之外. 在植入操作期间，因为固位突出部突出于管 34 的壁之外，所以植入物 10 的固位突出部 20 可以起钩子的作用.

如图 1B 所示，植入物 10 的凸缘 18 的两侧具有凹槽或者沟槽 19，这些凹槽或者沟槽 19 近似等于输送装置 30 的管 34 壁的宽度，并能在植入物 10 装在输送装置 30 上时容纳输送装置 30 的管 34 的壁. 该凹槽或者沟槽 19 可以为任何的形状. 或者，凸缘 18 具有连续的宽度而没有凹槽或沟槽，且凸缘 18 的宽度稍小于植入物 10 的管 12 的直径. 凸缘 18 还可能具有另外的结构变型.

如图 2A 所示，为了使用植入物 10 和输送装置 30，需将植入物 10 装在输送装置 30 上，其中固位突出部 20 突出于输送装置. 然后将内部装有植入物的输送装置 30 压入需要引流的组织 50，例如刺穿眼睛的巩膜. 图 2B 示出了压入组织 50 的输送装置 30.

为便于将输送装置 30 和/或植入物 10 引入组织 50，可以这样定向输送装置 30，使得斜面尖头 38 与组织 50 形成一个更小的锐角. 因此，例如如图 2A 所示的输送装置可以转动 180 度，即固位突出部面 20 朝上. 在植入物 10 进入眼睛边缘巩膜的情况下，这相当于使固

位突出部 20 位于管 12 的相对侧，离开虹膜。当输送装置 30 和植入物 10 适当地穿过组织 50 时，它们可以转动，使得可以将植入物 10 在组织 50 内正确的定位，并按要求使凸缘 18 和固位突出部 20 相对于组织 50 进行定向。

一旦固位突出部 20 已完全穿透组织 50 时，便可抽出输送装置 30。固位突出部 20 起着接附于组织 50 内表面的钩子的作用，使得在抽出输送装置 30 时植入物 10 可以保持植入在该组织 50 内。图 2C 示出了已植入组织 50 的植入物 10，图中输送装置 30 已被抽出。

因为输送装置 30 的管 34 是空心的，所以可以用它来注射流体或者黏弹材料。因此在植入时可以将流体注射到眼球前房内以减少张力过低的危险。同样可以在结膜下注入粘弹材料，以便充满植入后存在的气泡。

植入物 10 可以用适当的材料例如硅酮进行模制。为了在植入物 10 上形成管通道 14 可以在模制操作期间加入细的金属丝。可以应用一根以上的金属丝，以便在植入物上形成一个以上的管通道。或者该植入物可以用不锈钢或者用其它的适当的材料制作。该植入物上可以涂上一层适当的抗纤维化的材料，例如肝磷脂。

固位突出部 20 所用的材料与植入物 10 的其余部分材料相同。或者，该突出部可以用更柔性的材料制作，以便可以在穿透组织 50 时可以向内靠在植入物 10 的管 12 上。或者，将固位突出部 20 设计成起始时相对平顺地靠在管 12 上，以便容易穿透和防止组织 50 的撕裂，然后在植入植入物 10 后利用例如气囊之类的膨胀机构使其向外伸开。

图 3A、3B 和 3C 分别是本发明的引流植入物 60 的第二实施例的侧视图、端视图和横截面图。与图 1A 和图 1B 所示的植入物 10 一样，在图 3A、3B 和 3C 中所示的植入物 60 具有管 62，该管具有管通道 64 和通向管通道 64 的侧孔 66。该植入物 60 也具有在出口端的外部凸缘 68 和靠近出口端的固位突出部 70。在这种情况下，外部凸缘 68 在围绕管 62 圆周的所有方向突出于过管 62 的外表面之外。

图 4A 和 4B 分别是引流植入物 80 的第三实施例的侧视图和端视图，该植入物和图 3A、3B 和 3C 中所示的植入物 60 相似。植入物 80 的尖头 82 是圆锥形的，与植入物 60 的钝头 72 相反。

在另外的结构中，该植入物可以制成其中具有狭缝的封闭端部。当流体压力升高到冲开该狭缝时，流体才能流过该装置。或者，可以在管通道长度的不同位置设置这种结构。

图 5 示出本发明输送装置 90 的另一实施例。在此实施例中开孔 92 只允许植入物的固位突出部 84 突出于输送装置的管 94 的壁之外。外部凸缘 86 被容纳于在输送装置 90 的中心孔 96 内。在此实施例中必须折叠或弯曲外部凸缘 86，使其能够容纳于输送装置 90 的中心孔 96 内。外部凸缘 86 是有弹性的，使得当植入物脱离输送装置时，外部凸缘 86 便可伸开到与插入入植入物的组织的外表面相对共面的位置。

同样，固位突出部 84 也可以制成具有足够的弹性，以便使它能够被压缩和完全地容纳于输送装置 90 的中心孔 96 内。另外，输送装置 90 可以制成具有连续外壁的管 94。为了便于植入物脱离输送装置，可以在输送装置的中心孔内设置推杆或金属丝。医生通过顶着植入物推动输送装置内的推杆或金属丝可迫使植入物脱离输送装置，由此可使固位突出部向外伸开到其初始的放松的位置，使它接附于组织的内表面。

如果需要，可以利用各种机构使得植入物具有不同的流动特性。所要求的是对于不同的病人使用具有不同流动特性的植入物和/或在植入个别病人后其流动特性可以改变的植入物。

于 1997 年 11 月 20 日提交申请的美国专利申请 No. 08/975,386 作为参考在此引入，并说明和例示了有助于控制例如眼房水的流体流过植入物的流动的各种机构。它说明和例示了在植入物的管通道内控制金属丝或杆的应用。

流动控制杆或金属丝的作用是减少沿植入物管通道内特定长度部分流过流体的横截面积。因为流量是流体流过的内腔的横截面和腔长度的函数，所以插入流动控制杆或者金属丝可以用来增加流体流动的阻力。例如在眼内植入物中这有助于减少张力过低的危险。

根据所需的流动特性来选择流动控制杆或者金属丝的构形和尺寸。其可以具有一个或多个内孔或者多个外部槽，任何一个内孔或者外部槽可以配置成螺旋形以增加其长度。这种控制杆或金属丝是可调的，通过使它轴向移动或转动便可改变其流动特性。本技术领域的技

术人员应当认识到，对于流动控制杆或者金属丝的构形可以有许多其它的变形。

流动控制杆或金属丝其轴线可定位使得其平行于管通道的轴线，但是也可以采取其它的定向。例如其直径稍小于管通道的流动控制杆或者金属丝可以定向为横向于管通道。横向定向的杆和金属丝具有较小的长度，近似等于管或者管通道的直径。它对流体流过管通道起一种阻塞物的作用，从而改变流动特性。也可以在管通道内放置其他的阻挡物，以便获得类似的效果。

在美国专利申请 No. 08/975,386 中说明和例示的另一机构是应用了有助于控制流体流过植入物的流动的临时性的堵塞。由于采用可被吸收的材料或者在植入后可用例如工具或者激光探针除去的材料来堵塞植入物的流体通道，所以在植入后可以减小流动阻力。

使用临时性的堵塞在以下情况有优点，即在植入时以及在植入后一段时间内需要使流过植入物的流量保持在低流量。例如当植入物被植入到眼内时，在结膜上的切口和/或围绕植入物的可能的巩膜的撕裂将会形成眼房水的潜在的流体通道。因此，为了减少张力过低的危险，需要防止或减少在植入时或植入后一段时间内流过植入物的流动。一旦结膜和/或巩膜已经愈合后便可增加流过植入物的流动。

临时性的堵塞不一定限制在流体通道的任何特定的部分。例如可以用可被吸收材料部分或者整体地填充植入物的侧孔和/或管通道。因此，如图 6 所示，例如可将可被吸收材料做的塞子 106A 安放在植入物 100 的管通道 102 内。可被吸收材料可通过表面侵蚀而生物降解，所以当流体接触塞子 106A 和流到该塞子时，该塞子 106A 的材料便被流体吸收，由此减少了塞子 106A 的尺寸。当塞子 106A 的尺寸减小时，流过植入物的阻力便同样减少。或者，可以应用通过整体腐蚀而生物降解的可被吸收材料。可被吸收的（可生物降解的）材料已为大家所知并得到应用，例如在 Middleton & Tipton 中，在 1998 年 3 月的 Medical Products and Biomaterials 中的“作为医疗装置的人工合成的生物降解聚合物”（Synthetic Biodegradable Polymer as Medical Devices）说明了这种材料。

图 6 示出塞子 106A 只部分地填充管通道 102，但是应当知道，塞子 106A 可以整体地填满管通道 106A。在这种情况下，开始时完全阻

塞了流体的流动．只是在塞子 106A 已经被足够地吸收以后流体才开始流动，形成流体从植入物中流出的流道．

可被吸收的塞子可以与任何适当构形的植入物联用，包括具有流动控制杆或其它流动控制阻塞物的植入物。同样，可被吸收的塞子可以具有按所需流动特性选出的任何适当的构形和尺寸．如果需要，可以使用一个以上的可被吸收的塞子．

图 7A～7D 示出了可被吸收塞子另外的一些可能的横截面形状．可被吸收的塞子 106A 具有圆形横截面．可被吸收的塞子 106B 类似于可被吸收的塞子 106A，但具有附加的外部槽 108B．可被吸收的塞子 106C 具有一平表面 110C．可吸收的塞子 106D 具有纵向孔 112D．另外的结构包含外部槽加内孔以及这些槽和内孔数目的变化，和/或将这些外部槽和内孔配置成螺旋形，或者配置在其它任何的适合结构上．可被吸收的塞子可以是圆锥形的或其它适合的形状．但是应当知道，可被吸收的塞子的形状将影响可被吸收的塞子的吸收，即影响与流体接触的首先被吸收的接触面积。

图 8 示出了可被吸收的塞子 106A 和被部分堵塞侧孔 104．各个侧孔 104 部分地由可被吸收的塞子 114 堵塞，各个可被吸收的塞子 114 具有中心孔 116．如管通道 102 中的可被吸收的塞子 106A 一样，侧孔 104 中的可被吸收的塞子 114 可以具有任何适当的构形，并且该塞子可以与在管通道内的任何形状的可被吸收的塞子或无可被吸收的塞子联用．

图 9～11 示出了用于部分和/或临时性地阻塞流体通道的另外结构．图 9 中，眼内植入物 120 具有许多放在流体通道 122 内的流动控制线 126．该流动控制线 126 用于改变流体流过植入物的流动特性，或部分或整体地阻塞流体流过植入物．线的数目和尺寸可以根据需要改变，线可以用任何适当的材料制作．例如可采用诸如聚丙烯缝合线之类的普通缝合线．

在植入后的一定时间，可以从植入物中抽出（或插入植入物）一根或多根流动控制线 126．可以在更后的时间中抽出（或插入）其它的线．采用这种方式，便可在进行植入操作之后马上或经过一定时间以后改变流体流过植入物的阻塞状况．

应当知道，随着时间的推移能够抽出或插入一根或多根线，使得

医生可以根据病人的需要改变植入物的流动特性。例如，在将植入物植入病人眼中的一定时间后，医生可以检查眼内压力，以确定是否需要抽出或插入一根或多根线，以增加或减少流体流过植入物的流量。可以定期检查病人，并在适当的经过一段时间后留置、抽出或插入线。

在植入物万一发生堵塞时能够抽出线是特别有用的。在这种情况下，医生可以抽出一根或多根线以恢复流体流过植入物的适当的流量。

图 10 示出管通道 122 内装有多个流动控制线 126 的植入物的端视图。应当知道，线 126 可以以任何适当的方式配置在管通道 122 内，线 126 的形状和构形不限于图中所示。例如线可以具有不同的横截面（例如椭圆形、半圆形、不规则的形状以及空心的截面等）和不同的尺寸大小。沿着一根线的长度该线的横截面形状和尺寸可能改变。在单一植入物中的各个线可以具有不同的构形如不同的横截面形状和/或尺寸。当植入物中装有不同的线，医生可以按照要求的流动特性选择地抽出（或插入）一根或多根适当的线。例如，如果希望少量增加流量，则抽出横截面小的线，而如果需要较大增加流量，则可抽出横截面较大的线。

图 11 示出了一种植入物，在这种植入物中，在管通道 122 内只放置单根具有线结 130 的流动控制线 128。该线结 130 用于增加流动的阻塞。或者，可以在线 128 上接附上塞子或其它的阻塞物，并可以应用多根具有线结、塞子或其它接附阻挡物的线 128。类似于应用不同形状和/或不同尺寸的线一样，可以采用具有不同形状和/或不同尺寸的线结或塞子的线，使得可以根据要求的流动特性选择性地抽出或插入一根或多根适当的线。

图 12 示出流动控制线 132 的其它结构，在这种结构中沿线的长度其横截面是变化的。图示的线 132 具有三种不同的部段。在线端部的部段 138 具有最小的直径，相邻部段 136 具有稍大的直径，而线的剩余部段 134 具有更大的直径。线的剩余部段 134 的尺寸可以定为等于该管通道的直径，而部段 136 和 138 则逐级的减少。因此，在管通道的直径为 100 微米时，线的直径也可以为 100 微米，而递减的级差可以降为例如 20 微米。当然可以采用其它的尺寸，而且线的剩余部

段 134 的尺寸不一定要与管通道的尺寸相同。在开始定位时，线 132 可以放在植入物的管通道内，使部段 138 靠近入口端，而使部段 134 中的一部分位于靠近出口端的管通道内。当需要增加植入物中的流量时，可以部分地抽出线 132，使得只有部段 134 抽出管通道。这样便减少了管通道内的阻塞，由此增加了流量。如果需要可以在随后连续地抽出其它部段。或者，可以将线再插入到管通道内，以便再限制流量。

图 12 示出线的可能的变型，这些变型还可具有沿线长度配置的包含任何所需样式的横截面。以连续增加的方式部分地抽出或插入单根线来逐步地改变流量的这种概念可以按另外的或按替换的方式通过沿线的长度应用多个不同形状和/或尺寸的塞子或结而实现。

本发明的流动控制线可以完全与植入物分开，并可以在植入后的一定时间再插入到植入物中，或者可使线在植入时部分地装在植入物内。然后在随后的时间可选择地将线再推入到植入物中。

可以利用输送装置 30 植入具有可抽出（和/或插入）的流动控制线的植入物，如图 2A 所示。在这种情况下，伸出植入物出口端的线可以容纳于输送装置 30 的中心孔 36 内。或者，使用输送装置 30 的管 34 的壁上形成具有适当尺寸的开口 40，使线伸到输送装置 30 的外面。

当植入物植入眼内时，流动控制线可以定向为在结膜的下面延伸，并远离植入物。所用的线可以长到足以伸出植入物，越过为植入植入物在结膜上形成的缝。在这种情况下，在植入植入物之后，医生可以将线的松开端部塞到结膜的下面，使其伸离狭缝。当需要抽出一根或多根线时，可以在靠近线端部的结膜上形成小狭缝，并通过该狭缝抽出该线。因为这些端部远离植入物，而且在结膜上预先形成狭缝，所以可以减少对眼睛的潜在创伤。

为了使线固定就位并有利于随后使用它们，可以将松开的端部缝合在邻接的组织上，例如缝合在巩膜上。这种缝合可以用额外的缝合线或用线本身的线进行缝合。在后一种情况下，缝针可以系在线的松开端部以利于在植入植入物后用线缝合。

应当知道，可以根据需要联合应用上述实施例的各种特征。例如可以用可被吸收的材料制作流动控制线，医生可选择用手术抽出线或

使线被吸收。另外的或替代方式为，固定于线的塞子或其它阻塞物可以用可被吸收的材料制作。不同的线、塞子或阻塞物可以用具有不同吸收率的材料制作，和/或它们可以混用具有不同吸收率的材料制作。

本技术领域的普通技术人员还可以看出，上述植入物、制造方法、输送装置和植入方法的各种实施例仅仅是作为例子给出。上述实施例可以进行各种改变、变型和变化而不超出所附权利要求书确定的本发明的范围。

说 明 书 附 图

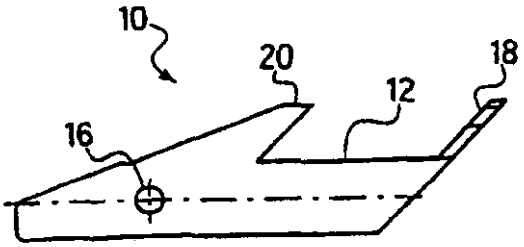

图 1a

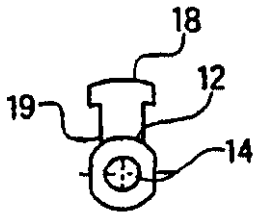

图 1b

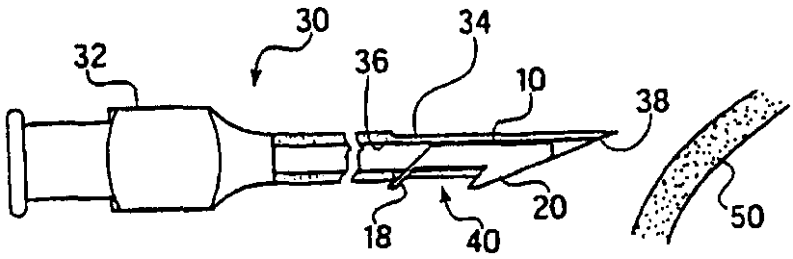

图 2a

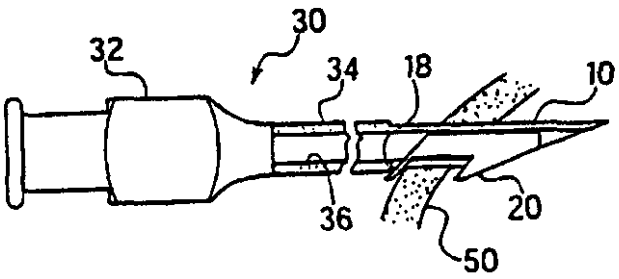

图 2b

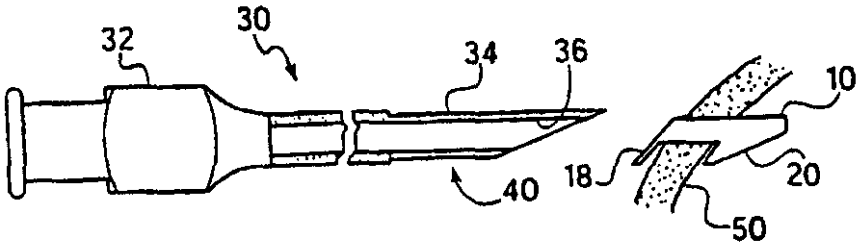

图 2c

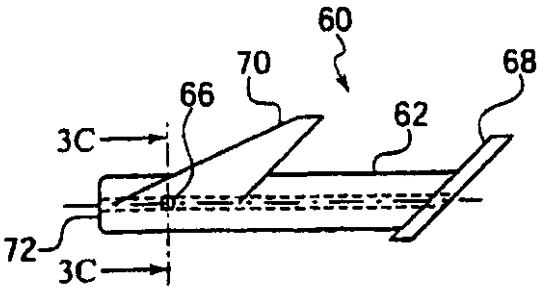

图 3a

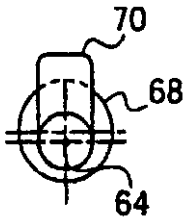

图 3b

图 3c

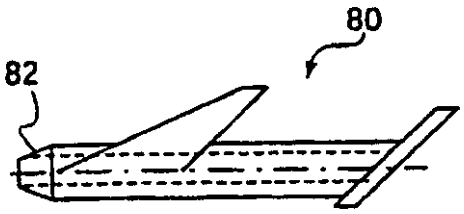

图 4a

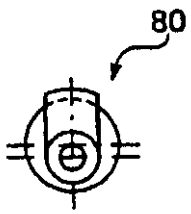

图 4b

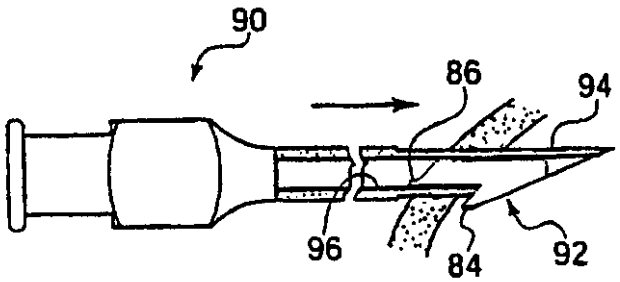

图 5

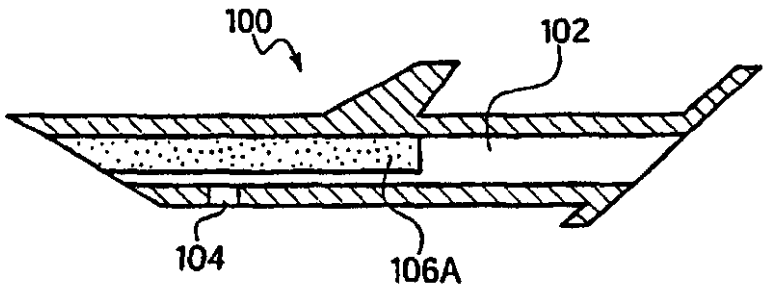

图 6

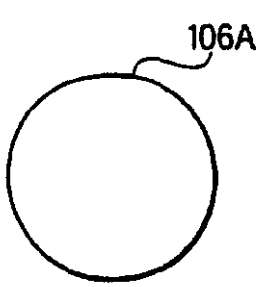

图 7a

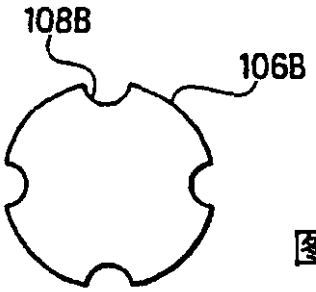

图 7b

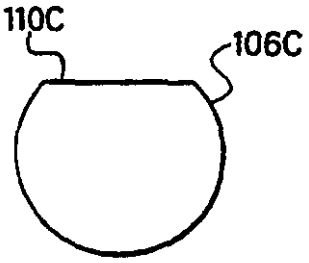

图 7c

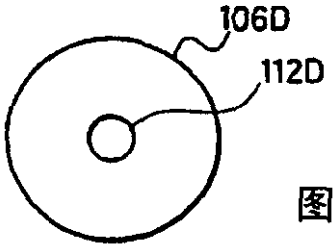

图 7d

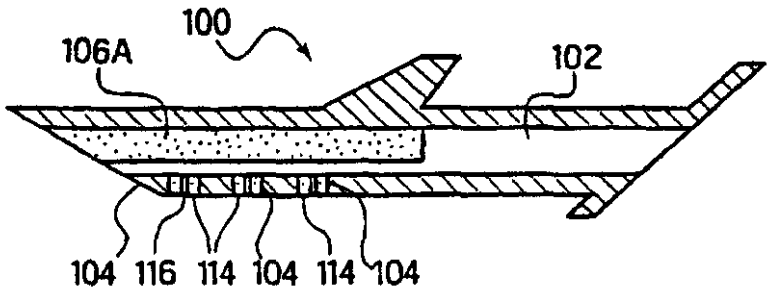

图 8

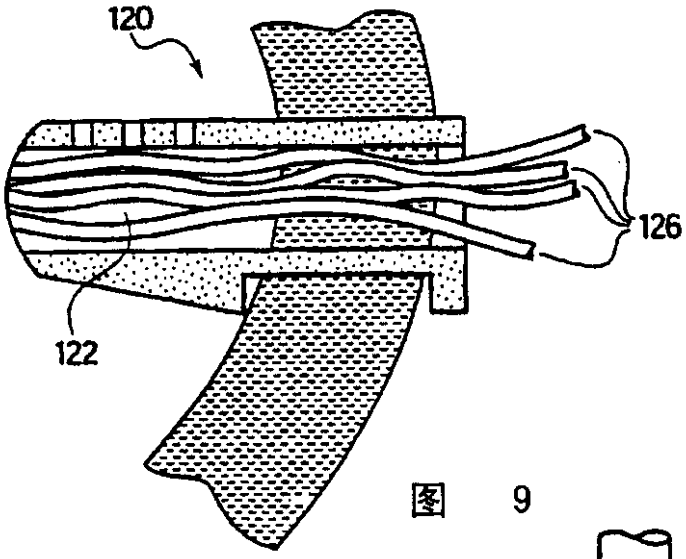

图 9

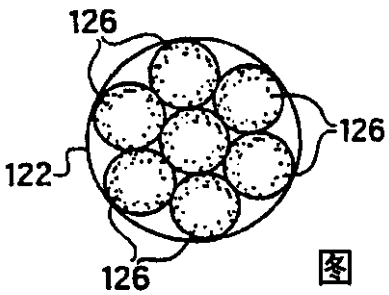

图 10

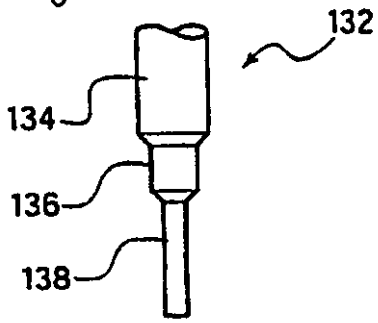

图 12

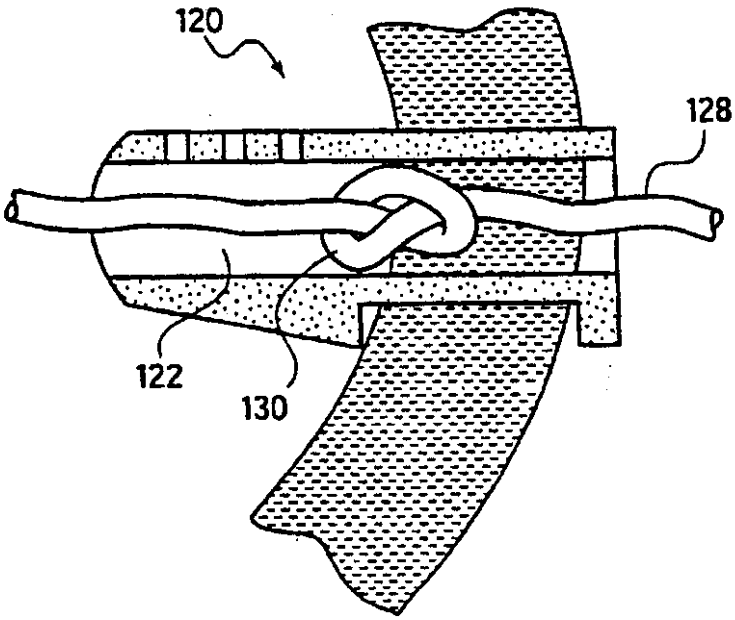

图 11

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FLOW CONTROL DEVICE, INTRODUCER AND METHOD OF IMPLANTING

An implant having a tube for permitting fluid flow has an outer flange at the outlet end and a retention projection near the inlet end. The retention projection acts as a hook engaging the inside surface of the tissue, causing the implant to stay implanted in the tissue. An implant may also be provided with a methanism for temporary occlusion, in whole or in part, of the flow passage. Thus, the tube passage may be filled, partially or wholly, with absorbable material and/or a plurality of withdrawable or advanceable flow controlling strands.