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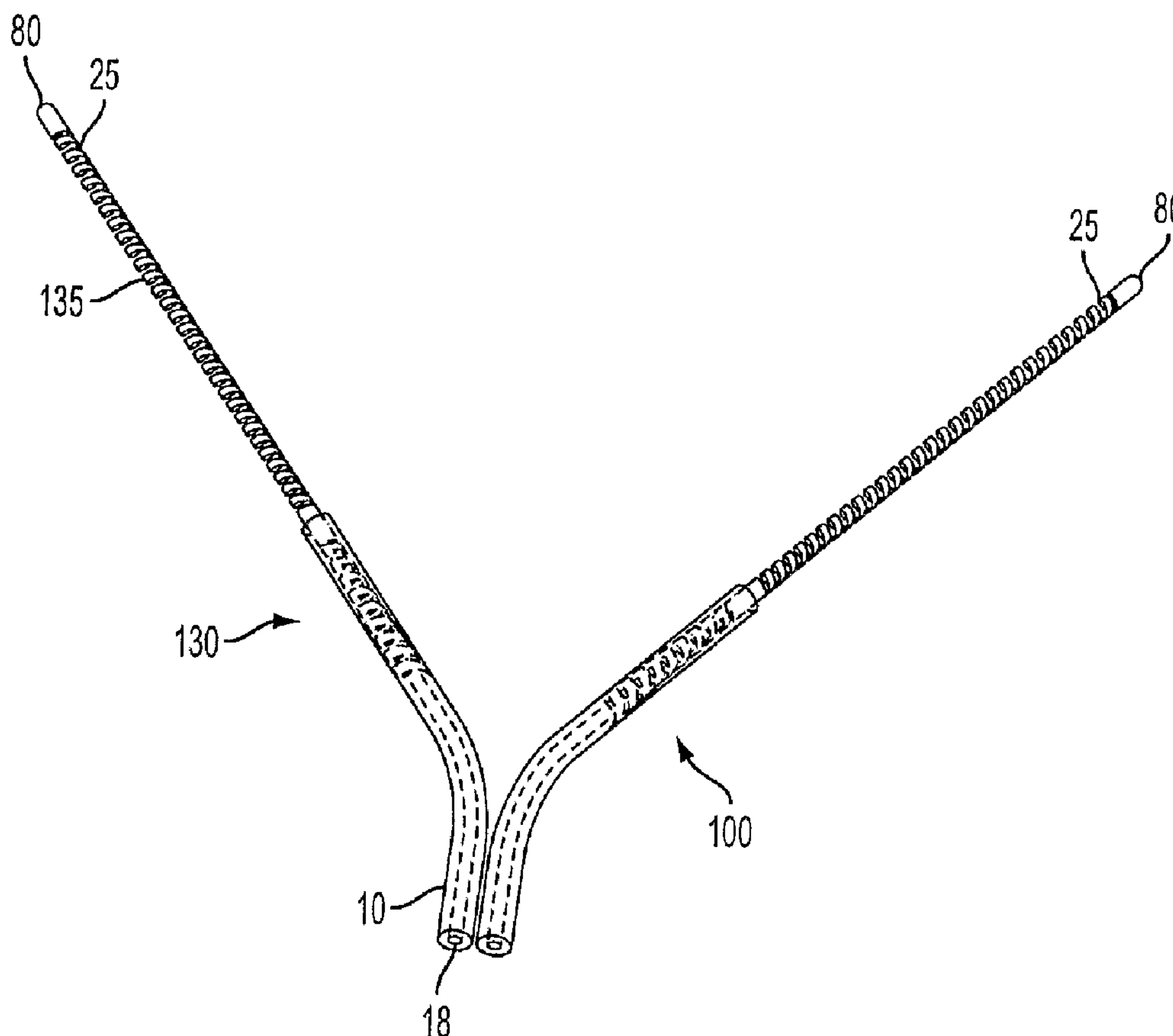
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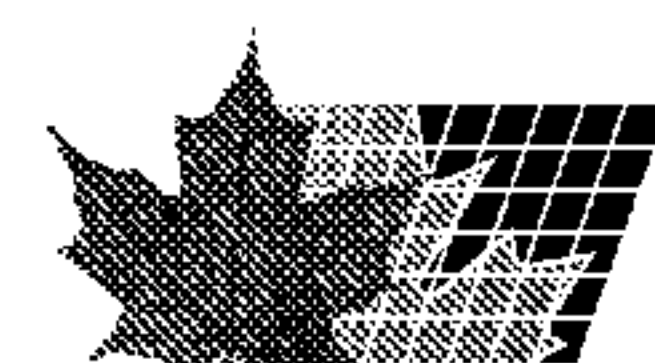
(54) Titre : DISPOSITIF DE DERIVATION A DEMEURE ET PROCEDES SERVANT A TRAITER LE GLAUCOME

(54) Title: INDWELLING SHUNT DEVICE AND METHODS FOR TREATING GLAUCOMA



(57) Abrégé/Abstract:

The present invention is directed to a novel indwelling shunt implant (100) and an associated surgical method for the treatment of glaucoma in which the implant device comprises at least one spiral body and/or grooved or corrugated body and is placed to divert



(57) Abrégé(suite)/Abstract(continued):

aqueous humor from the anterior chamber of the eye into Schlemm's canal, the collector channels, or the aqueous venous system or to distribute aqueous fluid within Schlemm's canal. The present invention is further directed to providing a permanent, indwelling shunt to provide increased egress of aqueous humor from the anterior chamber to Schlemm's canal, collector channels, or aqueous venous system for glaucoma management.

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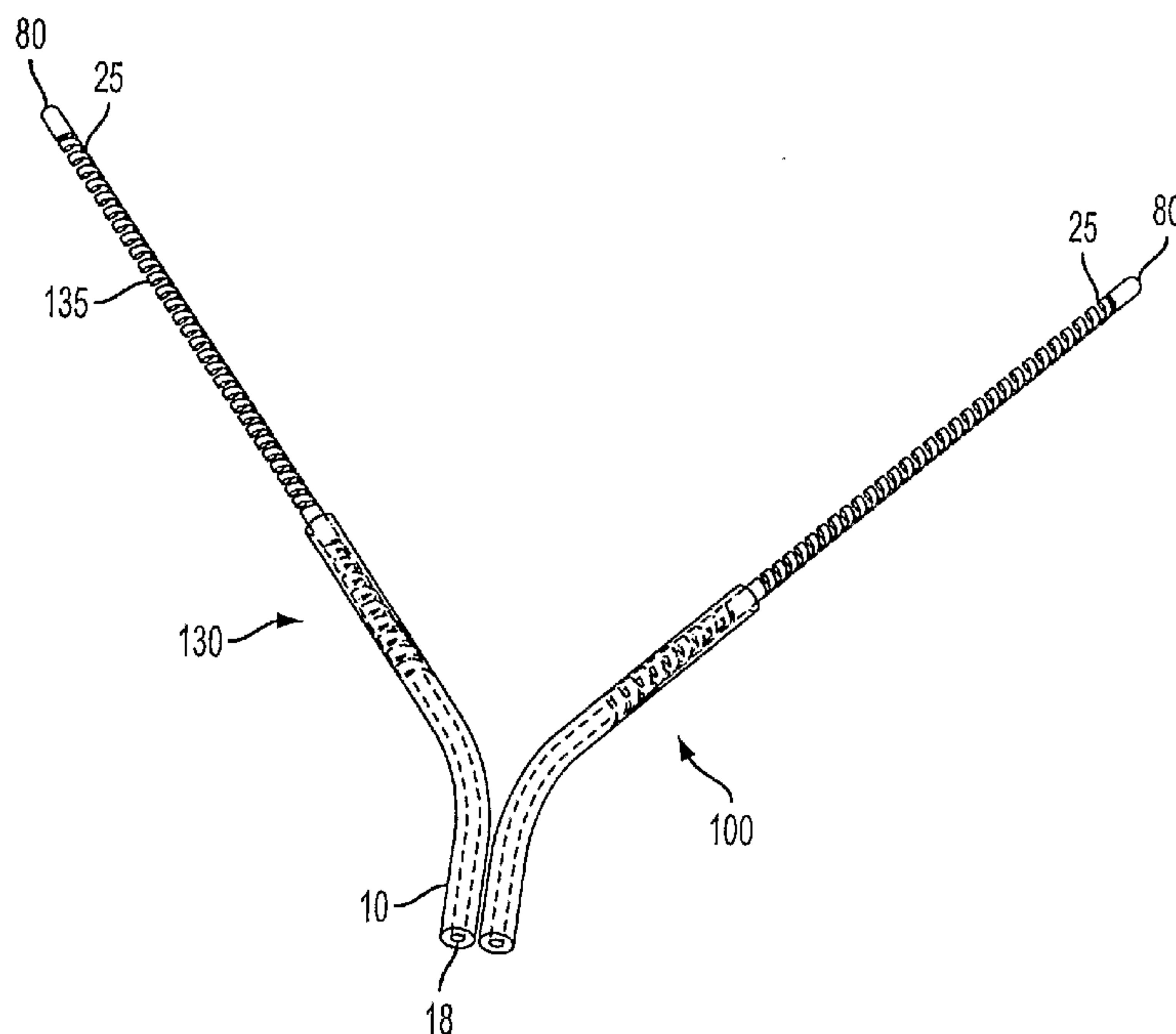
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INDWELLING SHUNT DEVICE AND METHODS FOR TREATING GLAUCOMA

TECHNICAL FIELD

The present invention is generally directed to a surgical treatment for
5 glaucoma, and relates more particularly to a device and method for continuously
decreasing elevated intraocular pressure in eyes affected by glaucoma by diverting
aqueous humor from the anterior chamber of the eye into Schlemm's canal, collector
channel, or aqueous venous system where post-operative patency of Schlemm's canal
can be maintained with an indwelling implant which can be surgically placed to
10 connect the canal with the anterior chamber.

BACKGROUND OF THE INVENTION

Glaucoma is a significant public health problem, because glaucoma is a major
cause of blindness. The blindness that results from glaucoma involves both central
15 and peripheral vision and has a major impact on an individual's ability to lead an
independent life.

Glaucoma is an optic neuropathy (a disorder of the optic nerve) that usually
occurs in the setting of an elevated intraocular pressure. The pressure within the eye
increases and this is associated with changes in the appearance ("cupping") and
20 function ("blind spots" in the visual field) of the optic nerve. If the pressure remains
high enough for a long enough period of time, total vision loss occurs. High pressure
develops in an eye because of an internal fluid imbalance.

The eye is a hollow structure that contains a clear fluid called "aqueous
humor." Aqueous humor is formed in the posterior chamber of the eye by the ciliary
25 body at a rate of about 2.5 microliters per minute. The fluid, which is made at a fairly

constant rate, then passes around the lens, through the pupillary opening in the iris and into the anterior chamber of the eye. Once in the anterior chamber, the fluid drains out of the eye through two different routes. In the "uveoscleral" route, the fluid percolates between muscle fibers of the ciliary body. This route accounts for
5 approximately 5-25 percent of the aqueous outflow in humans. The primary pathway for aqueous outflow in humans is through the "canalicular" route that involves the trabecular meshwork and Schlemm's canal.

The trabecular meshwork and Schlemm's canal are located at the junction between the iris and the sclera. This junction or corner is called "the angle." The
10 trabecular meshwork is a wedge-shaped structure that runs around the circumference of the eye. It is composed of collagen beams arranged in a three-dimensional sieve-like structure. The beams are lined with a monolayer of cells called trabecular cells. The spaces between the collagen beams are filled with an extracellular substance that is produced by the trabecular cells. These cells also produce enzymes that degrade
15 the extracellular material. Schlemm's canal is adjacent to the trabecular meshwork. The outer wall of the trabecular meshwork coincides with the inner wall of Schlemm's canal. Schlemm's canal is a tube-like structure that runs around the circumference of the cornea. In human adults, Schlemm's Canal is believed to be divided by septa into a series of autonomous, dead-end canals.

20 The aqueous fluid travels through the spaces between the trabecular beams, across the inner wall of Schlemm's canal into the canal, through a series of about 20-35 collecting channels that drain from Schlemm's canal and into the episcleral venous system. In a normal situation, aqueous production is equal to aqueous outflow and intraocular pressure remains fairly constant in the 15 to 21 mmHg range. In
25 glaucoma, the resistance through the canalicular outflow system is abnormally high.

In primary open angle glaucoma, which is the most common form of glaucoma, the abnormal resistance is believed to be along the outer aspect of trabecular meshwork and the inner wall of Schlemm's canal. It is believed that an abnormal metabolism of the trabecular cells leads to an excessive build up of extracellular materials or a build up of abnormally "stiff" materials in this area. Primary open angle glaucoma accounts for approximately eighty-five percent of all glaucoma. Other forms of glaucoma (such as angle closure glaucoma and secondary glaucomas) also involve decreased outflow through the canalicular pathway but the increased resistance is from other causes such as mechanical blockage, inflammatory debris, cellular blockage, etc.

With the increased resistance, the aqueous fluid builds up because it cannot exit fast enough. As the fluid builds up, the intraocular pressure (IOP) within the eye increases. The increased IOP compresses the axons in the optic nerve and also may compromise the vascular supply to the optic nerve. The optic nerve carries visual signals from the eye to the brain. Some optic nerves seem more susceptible to elevated IOP than other eyes. While research is investigating ways to protect the nerve from an elevated pressure, the only therapeutic approach currently available in glaucoma is to reduce the intraocular pressure.

The clinical treatment of glaucoma is currently approached in a step-wise fashion. Medication often is the first treatment option. Administered either topically or orally, these medications work to either reduce aqueous production or they act to increase outflow. Currently available medications may have a number of serious side effects including: congestive heart failure, respiratory distress, hypertension, depression, renal stones, aplastic anemia, sexual dysfunction and death. Compliance

with medication is a major problem, with estimates that over half of glaucoma patients do not follow their correct dosing schedules.

When medication fails to adequately reduce the pressure, laser trabeculoplasty often is performed. In laser trabeculoplasty, thermal energy from a laser is applied to a number of noncontiguous spots in the trabecular meshwork. It is believed that the laser energy stimulates the metabolism of the trabecular cells in some way, and changes the extracellular material in the trabecular meshwork. In approximately eighty percent of patients, aqueous outflow is enhanced and IOP decreases. However, the effect often is not long lasting and fifty percent of patients develop an elevated pressure within five years. The laser surgery is not usually repeatable. In addition, laser trabeculoplasty is not an effective treatment for primary open angle glaucoma in patients less than fifty years of age, nor is it effective for angle closure glaucoma and many secondary glaucomas.

If laser trabeculoplasty does not reduce the pressure enough, then filtering surgery is performed. With filtering surgery, a hole is made in the sclera and angle region. This hole allows the aqueous fluid to leave the eye externally through an alternate route.

The most commonly performed filtering procedure is a trabeculectomy. In a trabeculectomy, a posterior incision is made in the conjunctiva, the transparent tissue that covers the sclera. The conjunctiva is rolled forward, exposing the sclera at the limbus. A partial thickness scleral flap is made and dissected half-thickness into the cornea. The anterior chamber is entered beneath the scleral flap and a section of deep sclera and trabecular meshwork is excised. The scleral flap is loosely sewn back into place. The conjunctival incision is tightly closed. Post-operatively, the aqueous fluid passes through the hole, beneath the scleral flap and collects in an elevated space

beneath the conjunctiva. The fluid then is either absorbed through blood vessels in the conjunctiva or traverses across the conjunctiva into the tear film.

Trabeculectomy is associated with many problems. Fibroblasts that are present in the episclera proliferate and migrate and can scar down the scleral flap.

5 Failure from scarring may occur, particularly in children and young adults. Of eyes that have an initially successful trabeculectomy, eighty percent will fail from scarring within three to five years after surgery. To minimize fibrosis, surgeons now are applying antifibrotic agents such as mitomycin C (MMC) and 5-fluorouracil (5-FU) to the scleral flap at the time of surgery. The use of these agents has increased the
10 success rate of trabeculectomy but also has increased the prevalence of hypotony. Hypotony is a problem that develops when aqueous flows out of the eye too fast. The eye pressure drops too low (usually less than 6.0 mmHg); the structure of the eye collapses and vision decreases.

Trabeculectomy creates a pathway for aqueous fluid to escape to the surface of
15 the eye. At the same time, it creates a pathway for bacteria that normally live on the surface of the eye and eyelids to get into the eye. If this happens, an internal eye infection can occur called endophthalmitis. Endophthalmitis often leads to permanent and profound visual loss. Endophthalmitis can occur anytime after trabeculectomy. The risk increases with the thin blebs that develop after MMC and 5-FU. Another
20 factor that contributes to infection is the placement of a bleb. Eyes that have trabeculectomy performed inferiorly have about five times the risk of eye infection than eyes that have a superior bleb. Therefore, initial trabeculectomy is performed superiorly under the eyelid, in either the nasal or temporal quadrant.

In addition to scarring, hypotony and infection, there are other complications
25 of trabeculectomy. The bleb can tear and lead to profound hypotony. The bleb can be

irritating and can disrupt the normal tear film, leading to blurred vision. Patients with blebs generally cannot wear contact lenses. All of the complications from trabeculectomy stem from the fact that fluid is being diverted from inside the eye to the external surface of the eye.

5 When trabeculectomy doesn't successfully lower the eye pressure, the next surgical step often is an aqueous shunt device. An aqueous diversion device of the prior art is a silicone tube that is attached at one end to a plastic (polypropylene or other synthetic) plate. With an aqueous shunt device, an incision is made in the conjunctiva, exposing the sclera. The plastic plate is sewn to the surface of the eye
10 posteriorly, usually over the equator. A full thickness hole is made into the eye at the limbus, usually with a needle. The tube is inserted into the eye through this hole. The external portion of the tube is covered with either donor sclera or pericardium. The conjunctiva is replaced and the incision is closed tightly.

 With prior art aqueous diversion devices, aqueous drains out of the eye
15 through the silicone tube to the surface of the eye. Deeper orbital tissues then absorb the fluid. The outside end of the tube is protected from fibroblasts and scarring by the plastic plate. Many complications are associated with aqueous shunt devices. A thickened wall of scar tissue that develops around the plastic plate offers some resistance to outflow and in many eyes limits the reduction in eye pressure. In some
20 eyes, hypotony develops because the flow through the tube is not restricted. Many physicians tie an absorbable suture around the tube and wait for the suture to dissolve post-operatively at which time enough scar tissue has hopefully formed around the plate. Some devices contain a pressure-sensitive valve within the tube, although these valves may not function properly. The surgery involves operating in the posterior
25 orbit and many patients develop an eye muscle imbalance and double vision post-

operatively. With prior art aqueous shunt devices, a pathway is created for bacteria to get into the eye and endophthalmitis can potentially occur.

The prior art includes a number of such aqueous shunt devices, such as U.S. Pat. No. 4,936,825 (providing a tubular shunt from the anterior chamber to the corneal surface for the treatment of glaucoma), U.S. Pat. No. 5,127,901 (directed to a transscleral shunt from the anterior chamber to the subconjunctival space), U.S. Pat. No. 5,180,362 (teaching a helical steel implant that is placed to provide drainage from the anterior chamber to the subconjunctival space), and U.S. Pat. No. 5,433,701 (generally teaching shunting from the anterior chamber to the scleral or conjunctival spaces).

In addition to the prior art aqueous shunt devices described above, other prior art devices for glaucoma surgery have used setons, or other porous, wick-like components to divert and convey excess aqueous from the anterior chamber to the exterior ocular surface. Examples include U.S. Pat. Nos. 4,634,418 and 4,787,885 (teaching the surgical treatment of glaucoma using an implant that consists of a triangular seton (wick)), and U.S. Pat. No. 4,946,436, (teaching the use of a porous device to shunt anterior chamber to subscleral space). These patents do not teach placement in Schlemm's canal.

Some prior art references for glaucoma management have been directed at Schlemm's canal, but these have not involved the placement of long-term, indwelling shunts. U.S. Pat. No. 5,360,399 teaches the temporary placement of a plastic or steel tube with preformed curvature in Schlemm's canal with injection of a viscous material through the tube to hydraulically expand and hydrodissect the trabecular meshwork. The tube is removed from the canal following injection. Because the tube is directed outwardly from the eye for injection access, the intersection of the outflow element

with the preformed curved element within Schlemm's canal is at about a 90 degree angle relative to the plane of the curvature, and 180 degrees away from the anterior chamber. Therefore, at no time does any portion of the '399 device communicate with the anterior chamber. Furthermore, relative to that portion within Schlemm's canal, this tube has a larger diameter injection cuff element, which serves as an adapter for irrigation. Therefore, this device is not adapted for shunting aqueous between the anterior chamber and Schlemm's canal.

Most of the problems that have developed with current glaucoma treatment devices and procedures have occurred because aqueous fluid is drained from inside of the eye to the surface of the eye. A need exists, then, for a more physiologic system to enhance the drainage of aqueous fluid from the anterior chamber into Schlemm's canal. In the vast majority of glaucoma patients, the resistance problem lies between Schlemm's canal and the anterior chamber. The canal itself, the collecting channels and the episcleral venous system all are intact. Enhancing aqueous flow directly into Schlemm's canal would minimize the scarring that usually occurs with external filtration procedure since the internal angle region is populated with a single line of nonproliferating trabecular cells. Enhancing aqueous flow directly into Schlemm's canal would minimize hypotony since the canal is part of the normal outflow system and is biologically engineered to handle the normal volume of aqueous humor. Enhancing aqueous flow directly into Schlemm's canal would eliminate complications such as endophthalmitis and leaks.

Schlemm's canal may be collapsed in some patients. In those patients, a structure that maintains patency of the canal may improve drainage of aqueous flow.

The present invention is directed to a novel implant and an associated surgical method for the treatment of glaucoma in which the implant device comprises at least one spiral body and/or grooved body and is placed to divert aqueous humor from the anterior chamber of the eye into Schlemm's canal, the collector channels, or the aqueous venous system. The present invention is further directed to providing a permanent, indwelling shunt to provide increased egress of aqueous humor from the anterior chamber to Schlemm's canal, collector channels, or aqueous venous system for glaucoma management.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1A is an illustration showing an overhead perspective view of one embodiment of the present invention, in which the inventive shunt is comprised of tubular elements extending bi-directionally within Schlemm's canal.

FIG. 1B is an overhead view of the embodiment of the present invention shown in FIG. 1A, with phantom lines detailing the internal communication between the lumens of the tubular elements comprising the inventive device.

FIG. 1C is an illustration showing an overhead perspective view of one embodiment of the present invention, in which the inventive shunt is comprised of mesh tubular elements extending bi-directionally within Schlemm's canal.

FIG. 1D is an illustration showing an overhead perspective view of one embodiment of the present invention, in which the inventive shunt is comprised of solid, porous elements extending bi-directionally within Schlemm's canal.

FIG. 1E is an overhead perspective view of another embodiment of the present invention, with phantom lines detailing the internal communication between the two proximal lumens and the single distal lumen of the inventive device.

FIG. 2 is an illustration showing another embodiment of the present invention, in which the inventive shunt is comprised of perforated tubular elements and with an angulated terminal aspect of the proximal portion.

FIG. 3A is an illustration showing a perspective of another embodiment of the present invention in which the inventive shunt is comprised of elements that are partially tubular and partially open in their configuration.

FIG. 3B is an illustration showing a top view of the embodiment of the present invention in FIG. 3A, with phantom lines detailing the internal communication of the device.

FIG. 3C is an illustration showing a side view from the proximal end of the embodiment of the present invention in FIG. 3A.

FIG. 3D is an illustration showing a perspective of another embodiment of the present invention in which the inventive shunt is comprised of elements that are partially open and trough-like in their configuration.

FIG. 4 is an illustration showing another embodiment of the present invention, in which the inventive shunt is comprised of distal elements having wicking extensions at their terminal ends, and in which the proximal portion has a sealed, blunted tip with a portal continuous with the lumen of the proximal portion, oriented to face away from the iris when the device is implanted in Schlemm's canal.

FIG. 5A is an illustration showing another embodiment of the inventive shunt in which a portion of the device enters Schlemm's canal in only one direction and shunts fluid in a non-linear path from the anterior chamber.

FIG. 5B is an illustration showing an alternative embodiment of the inventive shunt in which the entire shunt is placed within Schlemm's canal but contains a

fenestration to maintain fluid egress of aqueous humor from the anterior chamber to Schlemm's canal.

FIG. 5C is an illustration showing a side view of one embodiment of the present invention, in which the inventive shunt is comprised of tubular elements, with
5 a proximal portion extending towards the anterior chamber that is shorter relative to the distal portions which extend bi-directionally within Schlemm's canal.

FIG. 5D is an illustration showing an alternative embodiment of the inventive shunt comprised of a partially open trough-like element which is placed within Schlemm's canal but contains a portal to maintain fluid egress of aqueous humor from
10 the anterior chamber to Schlemm's canal.

FIG. 5E is an illustration showing an alternative embodiment of the inventive shunt comprised of a solid, but porous wick-like element which is placed within Schlemm's canal

FIG. 6A is an illustration showing certain anatomic details of the human eye.

15 FIG. 6B is a cross-sectional illustration showing the anatomic relationships of the surgical placement of an exemplary embodiment of the present invention.

FIG. 6C is a cross-sectional illustration showing the anatomic relationships of the surgical placement of another exemplary embodiment of the present invention in which the proximal portion has an angulated terminal aspect with a sealed, blunted tip
20 with a portal continuous with the lumen of the proximal portion, oriented to face away from the iris when the device is implanted in Schlemm's canal.

FIG. 7 is an illustrative example showing a spiral configuration body of one embodiment of the invention.

FIG. 8 is an illustrative example showing a spiral configuration body of one
25 embodiment of the invention.

FIG. 9 is is an illustrative example showing a spiral configuration body of one embodiment of the invention.

FIG 10. is an illustrative example showing a spiral configuration body of one embodiment of the invention.

5 FIG 11. is an illustrative example showing a grooved body of one embodiment of the invention.

FIG 12. is an illustrative example showing a spiral configuration body of one embodiment of the invention having an I beam cross section..

10 FIG 13. is an illustrative example showing a corkscrew configuration body of one embodiment of the invention.

FIG 14. is an illustrative example showing a bi-directional implant configuration of one embodiment of the invention.

FIG 15. is an illustrative example showing a bi-directional spiral configuration body within the exemplary eye of one embodiment of the invention.

15 FIG 16. is an illustrative example showing a ladder configuration of one embodiment of the invention.

FIG 17. is an illustrative example showing a corrugated configuration of one embodiment of the invention.

20 FIG 18. is an illustrative example showing another variation of a corrugated configuration of one embodiment of the invention.

DETAILED DESCRIPTION OF PRESENT INVENTION

25 The present invention provides an aqueous humor shunt device to divert aqueous humor in the eye from the anterior chamber into Schlemm's canal, a collector

channel, or an aqueous venous system in which the shunt device comprises a distal portion comprising at least one spiral body and/or grooved body having at least one terminal aspect sized and shaped to be circumferentially received within a portion of Schlemm's canal, collector channel, or aqueous venous system, and a proximal

5 portion having at least one terminal aspect sized and shaped to be received within the anterior chamber of the eye, wherein the device permits fluid communication between the proximal portion in the anterior chamber to the distal portion in Schlemm's canal, the collector channel, or the aqueous venous system. Fluid communication can be facilitated by an aqueous humor directing channel in either the proximal or distal

10 portions, as described below. Fluid communication can also be facilitated by a wicking function of the at least one spiral body and/or grooved body distal portion.

In some embodiments, the proximal portion also comprises at least one spiral body and/or grooved body. Therefore, in certain embodiments, the entire shunt implant device can comprise at least one spiral body. Alternatively, the spiral body

15 portions can be affected to or co-extensive with other solid, porous or fenestrated segments of the distal or proximal portions of the shunt.

The present invention also provides embodiments of an inventive shunt implant device comprising at least one spiral body and/or grooved body of biocompatible material of a size and shape adapted to be circumferentially received

20 within a portion of Schlemm's canal wherein the body facilitates the passage of aqueous humor into Schlemm's canal, the collector channel, or the aqueous venous system. This embodiment of the device of the present invention can be produced without the proximal portion of the previous embodiment extending into the anterior chamber. Certain embodiments of the spiral body or grooved body can have solid

25 porous or fenestrated encasings on either or both of the distal ends or on various

portions thereof. An aqueous humor directing channel within the spiral body or grooved body can facilitate the passage of aqueous humor from the anterior chamber into Schlemm's canal, the collector channel, or the aqueous venous system. Fluid communication can also be facilitated by a wicking function of the spiral body or
5 grooved body, for example.

The spiral body or grooved body can extend in a unidirectional or bi-directional orientation within Schlemm's canal. The spiral body can be tightly or loosely wound with a pitch of 1 to 20 turns per 1/1000 inch. Pitch is the measurement between peak to peak coils. For example, if the pitch is one wire width, the pitch is
10 closed and the wires will touch. The pitch of the body can also be adjusted by manual force depending upon the needs of the patient along any particular section of any length. The device can also comprise two or more parallel spiral bodies or grooved bodies for insertion into Schlemm's canal.

In certain embodiments, the spiral body can have a length of from 1.0 mm to
15 40.0 mm and an outer diameter of between about 0.1 to about 0.5 mm. The invention contemplates many different configurations for an aqueous humor directing channel, provided that each assists in channeling aqueous humor from the anterior chamber to Schlemm's canal, the collector channel, or the aqueous venous system, such as by providing a lumen, trough, wick or capillary action. For example, the aqueous humor
20 directing channel can be a fully enclosed lumen, a partially enclosed lumen, or a trough-like channel that is at least partially open.

In preferred embodiments of the present invention the aqueous directing channel is defined within the spiral body. Alternatively, the aqueous directing channel may be defined within the grooved body. Furthermore the gaps between the
25 coils, corkscrew, or spring of the spiral body serve to divert aqueous humor laterally

outside the directing channel, as a function of pitch. Alternatively, the indentation of the grooved body may also serve to divert aqueous humor laterally outside the directing channel.

In some embodiments, the distal portion and the spiral body can be co-extant,
5 such that the spiral body is partially mounted within the distal portion.

In some embodiments, the spiral body or the grooved body can be made of metal, such as stainless steel, nitinol, or titanium, and can be further coated in a polymer such as silicone or a fluorinated polymer (PTFE-FEP). Such materials of construction can be further treated with a drug or therapeutic agent, such as an
10 antibiotic, to elute therefrom.

In some embodiments, the spiral body or the grooved body may also comprise a cap on at least one longitudinal end thereof to facilitate insertion within Schlemm's canal. The cap is preferably a rounded and/or elongated, blunt tip element attached to the terminal aspect of the spiral body or the grooved body. The cap further provides
15 an endpoint for insertion of a guide wire through the length of the spiral for improved insertion into Schlemm's canal as described more fully below.

As used herein, the terms "shunt", "shunt device", and "device" are synonymous with the inventive indwelling shunt implant.

Therefore, in one embodiment of the present invention, a shunt implant device
20 with at least one spiral body and/or grooved body is provided. For example, the spiral body of the shunt may be coil, spring, corkscrew, patent or a combination thereof and may have a cross-section shape which includes but is not limited to round, oval, triangular, rectangular, square, polygonal, or oblong, which may be solid, hollow, porous, or a combination thereof. In another example, the entire shunt implant device
25 may be coil, spring, corkscrew or a combination thereof. In yet another example, the

shunt implant device, which comprises at least one spiral body and/or grooved body, may further comprise at least one solid, porous, or fenestrated portion. Alternatively the surface of the implant device may be grooved in any pattern or shape to channel the flow of fluid in the eye.

5 It is contemplated that one of ordinary skill in the art, may combine the spiral body or grooved body of the device in any manner available in the art such as welding, adhesives, molding, heating, bolting, screwing, stretching, indenting, or bending. It is also contemplated that any permutations of coil, spring, corkscrew, tubular, grooved, patent, hollow, solid, porous, curved, angular, or linear sections may
10 be employed to achieve the shunt implant device of the present invention.

 The invention contemplates that a solid monofilament or braided polymer, such as proline, can also be inserted into Schlemm's canal, the collector channel, or the aqueous venous system in association with the spiral body and/or grooved body to provide a wicking function to facilitate the passage of aqueous humor to Schlemm's
15 canal, the collector channel, or the aqueous venous system. Such a wicking extension can also be grooved or fluted along any portion of the length thereof, so as to be multi-angular or star-shaped in cross-section.

 In another embodiment, at least one retaining flap or any other design which allows for suture handling is provided on the shunt device. In another embodiment,
20 the invention contemplates at least one flap, arrowhead-like extension, grove, or hook design on the device which will retain, attach, or stabilize the device within the Schlemm's canal, collector channel, or aqueous venous system. The design may also be any combination of a flap, arrowhead-like extension, grove, or hook design. The placement of these designs may be on any location of the device which will stabilize
25 the device in the Schlemm's canal, collector channel, or aqueous venous system. For

example, the retaining, attaching, or stabilizing design may be placed at all ends of the device or one end of the device.

In another embodiment, the device may include a one-way valve for controlling the aqueous flow direction. For example, any one-way valve which
5 prevents blood reflux from the venous system into the eye may be used.

The present invention also provides methods of delivery and use of the shunt devices. One embodiment of the present invention is directed to a surgical method to divert aqueous humor from the anterior chamber of the eye into Schlemm's canal, the collector channel, or the aqueous venous system with a device that is implanted to
10 extend from within the anterior chamber to Schlemm's canal, the collector channel, or the aqueous venous system. The portion of the device extending into Schlemm's canal can be fashioned from a flexible material capable of being received within a portion of the radius, curvature, and diameter of Schlemm's canal, the collector channel, or the aqueous venous system.

15 In one embodiment of the present invention, the pitch of the spiral body is alterable at selected positions along the length thereof to provide sufficient egress of aqueous humor at desired positions depending upon the needs of the patient.

In one embodiment, the device and methods provided may be delivered in any known method to those skilled in the art. For example, non-limiting methods for
20 delivery includes, but are not limited to, manual insertion into Schlemm's canal or assistance with a guide wire, suture, or flexible rod. In one method of the invention a guide wire is inserted through the spiral body or grooved body and against the interior of a distal cap attached to the terminal aspect of the spiral body or grooved body. The guide wire and spiral body are then inserted into Schlemm's canal. After insertion,
25 the guide wire is withdrawn and the conjunctival flap is closed. It is apparent that

various embodiments of the present invention will be adapted for uni-direction or bi-directional flow of aqueous humor through Schlemm's canal.

In one embodiment, an implant device comprising a spring and coil portion, as defined by greater or lesser pitch of the spiral body, respectively, which is attached at
5 the coiled portion in parallel to another spring and coil portion at the coiled portion. This provides a flexible bi-directional shunt device. Again, the distal aspects of the spiral spring portions can comprise a ball or capped end which is atraumatic upon insertion into Schlemm's canal. In a sub-embodiment, the ball or capped end of the implant device may be pushed with a guidewire or rod into Schlemm's canal.

10 In another embodiment, an implant device comprising a tubular-spiral-tubular configuration, wherein the spiral body portion wraps substantially around the Schlemm's canal. In a sub-embodiment, this implant device may comprise a ball or capped end and can be delivered using a guide wire, suture, plastic rod, or a combination thereof.

15 One embodiment of the present invention is illustrated in FIG. 1A, in which the shunt device 100 is shown in a side view. The shunt device 100 of this embodiment is comprised of two portions, a proximal portion 10 which joins a distal portion 25. The proximal portion 10 and distal portion 25 shown create an enclosed tubular channeling structure. The total length of the distal portion 25 may be between
20 about 1 and 40 mm,

preferably about 6 mm. The same embodiment of the present invention is illustrated with phantom lines showing the internal fluid communication path in FIG.

1B. The lumen or channeling space defined by the walls of the proximal portion 10 and the distal portion(s) 25 are continuous at their junction at the distal portion portal
5 20. All or parts of the device may be solid, coiled, porous, hollow, corkscrewed, grooved, angular, patent, tubular, trough-like, fenestrated, curved or pre-curved.

An alternate embodiment of the present invention is shown in FIG. 1C, in which the shunt device 100 is comprised of two luminal mesh elements, with a proximal portion 10 which joins a distal portion 25. Yet another embodiment of the
10 present invention is shown in FIG. 1D, in which the shunt device 100 is comprised of two solid, porous elements which may provide wick-like fluid communication therethrough, with a proximal portion 10 which joins a distal portion 25.

An alternate embodiment of the present invention is shown in FIG. 1E, in which the shunt device 100 is comprised of a proximal portion 10 having two lumens
15 therein terminating in proximal portion portals 18. The distal portion 25 shaped and sized to be received within Schlemm's canal extends in either direction having separate lumens traversing therethrough from each of the distal portion portals 20.

Other examples of embodiments of the present invention are shown in FIGS. 2-5D. FIG. 2 shows an embodiment of the inventive shunt in which the device 100 is
20 tubular and fenestrated (15, 30) in its configuration, with an acute ($<90^\circ$) angle of junction between the proximal portion 10 and the plane defined by the distal portion 25. Such fenestrations (15, 30) may be placed along any portion of the device 100 to facilitate the passage of fluid therethrough, but are particularly directed towards the collecting channels of the eye. FIG. 2 further shows an alternate embodiment of the
25 present invention in which the terminal aspect 16 of the proximal portion is angulated

toward the iris 40 with respect to the main axis of the proximal portion 10, with the portal 18 of the proximal portion directed toward free the iris 40. In alternate embodiments as shown in FIG. 6C, the portal 18 of the proximal portion 16 is directed away from the iris 40.

5 FIG. 3A shows an embodiment of the inventive shunt in which a portion of the channeling device is enclosed and tubular in configuration at the junction of the proximal portion 10 and the distal portion 25, but where the distal portion 10 is a trough-like channel. The distal portion portal 20 is also shown. The invention contemplates that any portion of the device 100 can be semi-tubular, open and trough-
10 like, or a wick-like extension. Tubular channels can be round, coil, spring, ovoid, corkscrewed, grooved, patent, porous, triangular, rectangular, square, polygonal, or any other enclosed geometry. Preferably the non-tubular trough-like aspects are oriented posteriorly on the outer wall of the canal to facilitate aqueous humor drainage to the collecting channels of the eye, as shown in FIG. 3A.

15 FIG. 3B shows an overhead view of the embodiment of the inventive shunt of FIG. 3A, further detailing the relationship among the proximal portion 10 and the distal portion 25. The aqueous humor directing channel is shown in dashed lines. FIG. 3C shows a proximal view of the embodiment of the inventive shunt of FIG. 3A, further detailing the relationship among the proximal portion 10 and the distal portion
20 25.

 FIG. 3D shows another embodiment of the inventive shunt in which the structure of the device 100 comprises an aqueous humor directing channel that is both open and curved in a continuous trough-like configuration along the proximal portion 10 and the distal portion 25. The distal portion portal 20 is also an open trough-like
25 channel.

FIG. 4 shows another embodiment of the inventive shunt with the addition of aqueous humor-wicking extensions 32 which are either continuous with, or attached to the terminal aspects of the distal portion 25. The wicking extensions 32 can be fashioned from a monofilament or braided polymer, such as proline, and preferably have a length of 1.0 mm to 16.0 mm. Furthermore, the proximal portion 10 is curved with a sealed, blunted tip 16 and contains a portal 18 in fluid communication with the lumen of the proximal portion and oriented to face away from the iris when the shunt device 100 is implanted in its intended anatomic position. The shunt device 100 can also help to maintain the patency of Schlemm's canal in a stenting fashion.

FIG. 5A shows another embodiment of the inventive shunt in which the proximal portion 10 joins a single, curved distal portion 25 in a "V-shaped," tubular configuration. The embodiment shown in FIG. 5A can also have a portal (not shown) in the distal portion 25 adjacent to the junction with the proximal portion 10 in order to facilitate bi-directional flow of fluid within the canal. Fenestrations and non-tubular, trough-like terminal openings are contemplated in all embodiments of the invention, and these fenestrations and openings may be round, ovoid, or other shapes as needed for optimum aqueous humor channeling function within the anatomic spaces involved.

FIG. 5B shows another embodiment of the inventive shunt in which the body or device 100 comprises only a single, curved distal portion 25 which contains a distal portion portal 20 oriented towards the anterior chamber to allow egress of aqueous humor from the anterior chamber to Schlemm's canal. The body of this device can have a length of about 1.0 mm to 40 mm, preferably about 6 mm. The external diameter can be about 0.1 mm to 0.5 mm, or about 0.3 mm.

FIG. 5C shows another embodiment of the inventive shunt in which the device 100 comprises a bi-directional tubular distal portion 25 which is intersected by a proximal portion 10 which is short in length relative to the distal portion 25 and is directed towards the anterior chamber.

5 FIG. 5D shows still another embodiment of the inventive shunt in which the device 100 comprises a bi-directional, trough-like, curved distal portion 25 for insertion into Schlemm's canal, which contains a distal portion portal 20 oriented to allow egress of aqueous humor from the anterior chamber, wherein the trough-like distal portion 25 is oriented to open toward the collecting channels to facilitate the
10 egress of aqueous humor.

FIG. 5E shows another embodiment of the inventive shunt in which the device 100 comprises a bidirectional, solid distal portion 25 for insertion into Schlemm's canal to facilitate the egress of aqueous humor from the canal to the collecting channels in a wicking capacity. The solid distal portion 25 can be porous or non-
15 porous.

The present invention contemplates that the illustrative examples in Figs 1-5 may also include at least one spiral body and/or grooved body such as a coil, spring, corkscrew, patent or combination thereof configuration. The present invention also contemplates a device comprising at least one spiral body and/or grooved body in
20 linear, curved, Y-, L-, V-, or T-, shaped device. For example, the entire device may be a coil, spring, or combination thereof in a linear, curved, Y-, L-, V-, or T-, shaped device configuration. In another example, the device may comprise a coil section followed by a spiral body or grooved body.

As the inventive device is an implant, it can be fabricated from a material that
25 will be compatible with the tissues and fluids with which it is in contact. It is

preferable that the device not be absorbed, corroded, or otherwise structurally compromised during its in situ tenure. Moreover, it is equally important that the eye tissues and the aqueous remain non-detrimentally affected by the presence of the implanted device. A number of materials are available to meet the engineering and medical specifications for the shunts. In the exemplary embodiments of the present invention, the shunt device is constructed of a biologically inert, flexible material such as silicone or similar polymers. Alternate materials might include, but are not limited to, thin-walled Teflon, polypropylene, other polymers or plastics, metals, or some combination of these materials. The shunt device may be constructed as either porous or solid in alternate embodiments. The material can contain a therapeutic agent deliverable to the adjacent tissues.

In the embodiments shown in FIGS. 1-4, the proximal portion 10 joins the distal portion(s) 25 at an angle sufficient to allow the placement of the proximal portion 15 within the anterior chamber of the eye when the distal portion 25 is oriented in the plane of Schlemm's canal. The proximal portion 10 is preferably of sufficient length, about 0.1 to 3.0 mm or about 2.0 mm, to extend from its junction with the distal portion 25 in Schlemm's canal towards the adjacent space of the anterior chamber. While many geometries can be used for channeling aqueous humor, the diameter or width of the proximal portion 10 can be sized to yield an internal diameter of between about 0.1 and 0.5 mm, preferably 0.20 mm, for a tubular or curved shunt, or a comparable maximal width for a shunt with a multiangular configuration. In other embodiments, the proximal portion is a non-luminal, non-trough-like wicking, coiled, spring, patent, grooved, or corkscrewed extension that provides an aqueous humor directing channel along the length thereof.

Because the nature of the iris 40 is such that it tends to comprise a plurality of rather flaccid fimbriae of tissue, it is desirable to avoid said fimbriae from being drawn into the lumen of an implant, thus occluding the shunt device. Therefore, the proximal portion 10 may contain a plurality of fenestrations to allow fluid ingress, arranged to prevent occlusion by the adjacent iris. Alternately, the proximal portion 10 may comprise only a proximal portion portal 18 in the form of a fenestration oriented anteriorly to provide continuous fluid egress between the anterior chamber of the eye and the directing channel of the shunt. Said fenestrations may be any functional size, and circular or non-circular in various embodiments of the present invention. In addition, a porous structural material can assist in channeling aqueous humor, while minimizing the potential for intake of fimbriae.

Furthermore, the proximal portion 10 may be positioned sufficiently remote from the iris 40 to prevent interference therewith, such as by traversing a more anterior aspect of the trabecular meshwork into the peripheral corneal tissue. In yet another possible embodiment, as shown in FIG. 6C, the device 100 may comprise a proximal portion 10 in which the terminal aspect of said proximal portion 10 is curved or angled toward the iris 40, and with a blunted, sealed tip 16 and a portal 18 oriented anteriorly to face away from the underlying iris 40. Such a configuration would tend to decrease the possibility of occlusion of the shunt device by the iris 40.

The device 100 may contain one or more unidirectional valves to prevent backflow into the anterior chamber from Schlemm's canal. The internal lumen for an enclosed portion of the device or the internal channel defined by the edges of an open portion of the device communicates directly with the inner lumen or channel of the distal portion at the proximal portion portal 20.

The distal portion 25 may have a pre-formed curve to approximate the 6.0 mm radius of Schlemm's canal in a human eye. Such a pre-formed curvature is not required when flexible material is used to construct the shunt device 100. The distal portion 25 may be of sufficient length to extend from the junction with the proximal portion 10 through any length of the entire circumference of Schlemm's canal. Embodiments having a distal portion 25 that extends in either direction within Schlemm's canal can extend in each direction about 1.0 mm to 20 mm, or about 3.0 mm, to permit circumferential placement through Schlemm's canal. The diameter of width of the distal portion 25 can be sized to yield an outer diameter of between about 0.1 and 0.5 mm, or about 0.3 mm, for a tubular or curved shunt, or a comparable maximal width for a shunt with a multiangular configuration. The distal portion 25 may contain a plurality of fenestrations to allow fluid egress, arranged to prevent occlusion by the adjacent walls of Schlemm's canal. In other embodiments, the distal portion is a non-luminal, non-trough-like wicking extension that provides an aqueous humor directing channel along the length thereof.

In the exemplary embodiments of the present invention, the shunt device may be either bi-directional, with the distal portion of the implant intersecting with the proximal portion in a "T-shaped" junction as shown in FIGS. 1A-1E, 2, 3A-3D, 4 and 5C, or unidirectional, with a "V-shaped" junction of the proximal and distal shunt portions, as shown in FIG. 5A. A bi-directional shunt device can have a distal portion that is threaded into opposing directions within Schlemm's canal, the collector channel, or the aqueous venous system. In the case of the uni-directional shunt, only the distal shunt portion is placed within Schlemm's canal, the collector channel, or the aqueous venous system. In these exemplary embodiments, "non-linear fluid communication" means that at least some portion of the shunt through which fluid

passes is not in a straight line. Examples of non-linear shunts are the above described bi-directional "T" shapes, and the uni-directional "V" shapes, or shunts having two channel openings which are not in straight alignment with each other.

The surgical anatomy relevant to the present invention is illustrated in FIG.

5 6A. Generally, FIG. 6A shows the anterior chamber 35, Schlemm's canal 30, the iris 40, cornea 45, trabecular meshwork 50, collecting channels 55, episcleral veins 60, pupil 65, and lens 70. FIG. 6B illustrates the surgical placement of the exemplary embodiment of the present invention, with the relevant anatomic relationships. It should be noted that the inventive device is designed so that placement of the distal
10 portion 25 within Schlemm's canal 30 results in an orientation of the proximal portion 10 within the anterior chamber 35 within the angle defined by the iris 40 and the inner surface of the cornea 45. Therefore, if the plane defined by Schlemm's canal is defined as zero degrees, the proximal portion 10 can extend therefrom at an angle of between about +60 degrees towards the cornea 45 or -30 degrees toward the iris 40,
15 more preferably in the range of 0 to +45 degrees. This range may vary in individuals having a slightly different location of Schlemm's canal 30 relative to the limbal angle of the anterior chamber 35.

In another embodiment illustrated by FIG 7, the shunt device is configured as a linear spring having a proximal end 10 for insertion into the anterior chamber and a
20 distal end 25 which is placed in Schlemm's canal wherein at least some of the coils of the spring have an opening 20 between adjacent coils to permit fluid flow. The distal end may be terminated in a ball shape 80 or may be left an open lumen. The proximal end contains an open lumen 18. The coils 64 of the spring can themselves form the ball end 80 of the shunt by progressively tightening the coils as show in Figure 8. In

yet another embodiment, the devices of the present invention avoid blocking outflow to the collector channel is provided.

Figure 10 shows a bidirectional shunt embodiment employing a dual lumen coil spring. This embodiment would be wound from a continuous piece of suitable coil forming material such as nitinol or stainless steel wire or from suitable plastics or shape memory materials as are well known in the art. To form the ball the coils are wound progressively tighter and finished so that the coil material has reduced potential to snag tissue as it is inserted into Schlemm's canal.

In another embodiment as exemplified by FIG 11, the shunt is a solid body having transverse grooves 90 and/or ridges 75 on its external surface for channeling aqueous fluid. Alternatively, the grooves can be spiral in nature as shown in FIG 12. It preferred that these embodiments terminated in a rounded end 80 to reduce the potential for snagging tissues upon insertion.

In yet another embodiment as exemplified by FIG 13 the shunt can be a corkscrew or helical shape with ridges 75 defining a groove 90 through which fluid flows. The structure of the shunt in this embodiment can be constructed of material having any type of cross section, although an I beam cross section is most preferred because of the defined ridge 75 and subsequent groove 90 it creates.

A preferred embodiment is show in FIG 14. In this embodiment, the shunt device 100 is configured with one distal portion 10 which is tubular to provide a shunting functionality and at least two proximal portions 25 which provide an anchoring function to stabilize the overall implant device, in addition to providing fluid communication from the anterior chamber to Schlemm's Canal, collector channel, or aqueous venous system. In this embodiment it is most preferred that the proximal end 10 is a dual lumen silicone tube in which each lumen is joined to a

second open structured tube 135 either by friction fitting the open structured tube 135 into or around the lumen of the silicone tube or via bonding the two sections together. Alternatively, the device can be designed as three separate components comprising a shunt for bypassing fluid from the anterior chamber into Schlemm's canal and at least one stent section for maintaining the patency of Schlemm's canal. FIG 15 shows a plurality of devices 100 according to the present invention in place inside of Schlemm's Canal.

In yet another embodiment as exemplified by FIG 16, the shunt is constructed in a ladder configuration having side rails 115 and shaped transverse members 120 in which the transverse members extend above or below the side rails in an alternation fashion forming a lumen 110.

In another embodiment as exemplified by FIG 17, the shunt can be corrugated with a plurality of troughs and ridges having at least one aperture 110 through a side 111 of the corrugations. The corrugation can be either a squared form as shown or can be rounded or any other configuration which allows for creating of space for fluid flow.

In another embodiment as exemplified in Figure 18, the shunt can be created from a plurality of corrugated strips 107 having troughs 106 and ridges 109 which are offset from each other such that the ridge of one strip is positioned adjacent to the trough of the next corrugated strip thereby creating a plurality of openings 108 through which aqueous fluid can flow.

Devices of the present invention can readily be made by known extrusion, molding or coil forming processes. The devices can be made as one piece or in subcomponents and mechanically fastened or bonded during assembly or during the insertion.

In another embodiment, the devices of the present invention enhance the aqueous flow through the Schlemm's canal, the collector channel, or the aqueous venous system are provided. In yet another embodiment, the devices of the present invention prevents collapsing of the Schlemm's canal, collector channel, or aqueous
5 venous system.

In another embodiment of the present invention, the device provided may be used alone or in combination with available eye shunts. The present invention can be used in conjunction with a surgical implant device, such as a unidirectional or bi-directional shunt device described in U.S. Patent No. 6,450,984, incorporated by
10 reference herein in its entirety, used to divert aqueous humor in the eye from the anterior chamber into Schlemm's canal. Such a device comprises a distal portion having at least one terminal aspect sized and shaped to be circumferentially received within a portion of Schlemm's canal, and a proximal portion having at least one terminal aspect sized and shaped to be received within the anterior chamber of the
15 eye, wherein the device permits fluid communication between the proximal portion in the anterior chamber to the distal portion in Schlemm's canal. Such a device, for example, can have a distal portion of between about 1 mm and 40 mm in length. The diameter of the distal portion, for example, can be between about 0.1 mm to 0.5 mm.

In one embodiment of the present invention, the device may include porous
20 regions, so that new blood vessel growth occurs into pores, channels, or interstices of the porous material.

In another embodiment, the biocompatibility of the device may be improved (i.e., modified) with chemicals so that the subsequent healing response of tissue in association with the material forming the regions is altered once the glaucoma shunt is
25 implanted. The alteration in healing response can be a reduction in inflammatory

response typically seen with polymeric materials, and includes a reduced presence of macrophages and foreign body giant cells. The chemical modifications may include the covalent interaction of the chemical species with polymer. In addition, the chemical modifications include the absorption of the applied chemical species into the polymers. These chemical modifications include the use of proteins and peptides with known affects on cellular function, such as the reduction in inflammation, reduction in fibrous capsule formation by inhibiting the proliferation of cells found in developing fibrous capsules, or inhibition of extracellular matrix protein synthesis by cells in the fibrous capsule.

Further, a "denucleated" material reduces the inflammatory response of tissue surrounding the implant, and increases neovascularization (i.e., increase in new blood vessels) in tissue surrounding the material. That is, the glaucoma shunt may comprise a material selected from the group consisting of denucleated polytetrafluoroethylene (ePTFE), denucleated polyurethane, and denucleated elastomeric silicone, such that at least 60% of air trapped within the material is removed. Denucleation is a process which removes air trapped within the material.

Devices of the present invention may also be coated with a hydrophilic substance to ease insertion. Appropriate coatings include but are not limited to hydroxy-methyl acrylate, hydroxy-ethyl methacrylate or Poly Vinyl Alcohol (PVA). One of skill in the art will recognize that any hydrophilic coating suitable for use on an implanted medical device.

It is also appreciated that the devices and methods of the present invention may be carried out *ab externo* or *ab interno*.

In one embodiment, the device used comprises a metal wire such as stainless steel wire, e.g. 304 grade. In a sub-embodiment, the device comprises a rectangular

5 An exemplary surgical procedure to insert the device may require an approach through a conjunctival flap. A partial thickness scleral flap is then created and dissected half-thickness into clear cornea. The posterior aspect of Schlemm's canal is identified and the canal is entered posteriorly. The anterior chamber may be deepened with injection of a viscoelastic and a miotic agent. The proximal portion of the shunt is then inserted through the inner wall of Schlemm's canal and trabecular meshwork into the anterior chamber within the angle between the iris and the cornea. In some cases, an incision may be needed from Schlemm's canal through the trabecular meshwork into the anterior chamber to facilitate passage of the proximal portion therethrough. One arm of the distal portion of the shunt device is grasped and threaded into Schlemm's canal. In a similar fashion, the other arm of the distal portion of the shunt device (when present) is inserted into Schlemm's canal in the opposing direction from the first. The scleral flap and conjunctival wound are closed in a conventional manner.

25 Examples

Human cadaver eyes were used for Examples I-III. The shunt device used in Examples I-III comprised spiral body having a proximal end that starts with a closed-pitch coil. After 3 mm, the pitch is increased to get a traditional open-pitch spring configuration. The distal end has a ball end. The wire used for the spiral body was a stainless steel wire, 304 grade, with a rectangular cross section, 1.5 x 3 with a pitch of 0.006. The outer diameter was constant at 0.010 in. The total length of the device was 12 mm.

The surgical procedure of the following examples, to insert the device utilized an approach through a conjunctival flap. A partial thickness scleral flap is created and dissected half-thickness into clear cornea. The posterior aspect of Schlemm's canal is identified and the canal is entered posteriorly. The anterior chamber may be deepened with injection of a viscoelastic and a miotic agent. The proximal portion of the shunt is then inserted through the inner wall of Schlemm's canal and trabecular meshwork into the anterior chamber within the angle between the iris and the cornea. In some cases, as incision may be needed from Schlemm's canal through the trabecular meshwork into the anterior chamber to facilitate passage of the proximal portion therethrough. One arm of the distal portion of the shunt device is grasped and threaded into Schlemm's canal. In a similar fashion, the other arm of the distal portion of the shunt device (when present) is inserted into Schlemm's canal in the opposing direction from the first. The scleral flap and conjunctival wound are closed in a conventional manner.

Example I

Eye#1: The posterior aspect of Schlemm's canal was identified and the canal was entered posteriorly. After the proximal portion of the shunt is inserted through

the inner wall of Schlemm's canal and trabecular meshwork into the anterior chamber within the angle between the iris and the cornea, the ball end of the spring was introduced into the Schlemm's canal. The proximal end of the device was introduced into the anterior chamber. Finally, blue dye was introduced into the anterior chamber under a constant low pressure of approximately 16 mm Hg. After a few minutes, a blue coloration was observed along the entire length of the coil prototype. Schlemm's canal was unroofed on the other side of the surgical side, and no dye flow was observed. The canal was unroofed at the tip of the coil, and a blue coloration was present.

10

Example II

Eye#2: The ball end of the spring was introduced into Schlemm's canal, and the entire length of the device was fully pushed into one direction of the canal using a viscocannalastomy needle. A bi-directional shunt as described in U.S. Patent Nos. 6,450,984 was placed conventionally within the other side of Schlemm's canal of the implantation site; the other leg of the shunt was cut in order to be introduced into Schlemm's canal and to be "connected" to the proximal end of the spring. Finally, green dye was introduced into the anterior chamber under a constant low pressure of approximately 16 mm Hg. After a few minutes, a green coloration appeared on the coil side, throughout the entire length of the coil, and a limited coloration appears distally to the end of the device. At the location of implantation and the distal end of the traditional shunt, no coloration was present. The eye was then cut in half to expose the trabecular mesh: the spiral body did not "recoil" and the spring portion stayed "opened". The spiral body covered about a 120° portion of the Schlemm's

20

canal. Schlemm's canal outer diameter is about 12 mm, or 38 mm circumference, and the device was 12 mm long.

Example III

5 Eye #3: Once the canal was unroofed, the spiral body was set in place and the site of implantation closed. Dye was infused, but no coloration appeared in the venous outflow. Pressure measurement: An attempt was made to take pressure measurements using the WPI micropressure system. The system was initialized properly but the measurements seemed out-of-range once the sensor was placed into
10 the anterior chamber.

 Examples I-III resulted in IOP lowering. The devices of the present invention were easy to refine and implement. The devices has the ability to be used in conjunction with the '984 or '858 shunt to potentially improve the efficacy of '984 or '858 shunt or could be developed into a standalone '984 or '858 shunt type implant.

15 Thus, while there have been shown and described and pointed out fundamental novel features of the present invention as applied to preferred embodiments thereof, it will be understood that various omissions and substitutions and changes in the form and details of the devices illustrated, and in their operation, and in the method illustrated and described, may be made by those skilled in the art without departing
20 from the spirit of the invention as broadly disclosed herein.

We claim:

1. An aqueous humor shunt device to divert aqueous humor in an eye from the anterior chamber into Schlemm's canal, the shunt device comprising a distal portion having at least one terminal aspect sized and shaped to be received circumferentially within a portion of Schlemm's canal wherein the terminal aspect is an open coil and a proximal portion having at least one terminal aspect sized and shaped to be received within the anterior chamber of the eye, wherein device permits fluid communication from the proximal portion in the anterior chamber to the distal portion in Schlemm's canal.
2. The shunt device of claim 1 where in the distal end terminates in a ball shape.
3. The shunt device of claim 2 wherein the ball shape is an insert in the distal end.
4. The shunt device of claim 2 wherein the ball shape is formed from the coil of the distal end.
5. The shunt device of claim 1 wherein the proximal end of the shunt is a dual lumen spring
6. The shunt device of claim 1 wherein the shunt is made from shape memory materials.
7. The shunt device of claim 1 wherein the shunt is from 1.0 mm to 40.0 mm in length and an outer diameter of between about 0.1 to about 0.5 mm
8. An aqueous humor shunt device to divert aqueous humor in an eye from the anterior chamber into Schlemm's canal, the shunt device comprising a distal portion having at least one terminal aspect sized and shaped to be received circumferentially within a portion of Schlemm's canal wherein the terminal aspect comprises a flexible member having at least on conduit for fluid flow on the exterior of the flexible

member and a proximal portion having at least one terminal aspect sized and shaped to be received within the anterior chamber of the eye, wherein device permits fluid communication from the proximal portion in the anterior chamber to the distal portion in Schlemm's canal.

- 5 9. The shunt of claim 7 wherein the flexible member has spiral or helical ridges running from the proximal to the distal end which define the conduit for fluid flow.
10. The shunt of claim 7 wherein the flexible member has straight or undulating ridges running from the proximal to the distal end which define the conduit for fluid flow.
- 10 11. The shunt device of claim 7 wherein the shunt is from 1.0 mm to 40.0 mm in length and an outer diameter of between about 0.1 to about 0.5 mm
12. An aqueous humor shunt device to divert aqueous humor within Schlemm's canal, the shunt device comprising a distal portion having at least one terminal aspect sized and shaped to be received wholly within a portion of Schlemm's canal wherein
- 15 the terminal aspect comprises a flexible member having ridges that define at least one conduit for fluid flow on the exterior of the flexible member, wherein the device permits fluid communication along the shunt within Schlemm's canal.
13. The shunt of claim 12 wherein the flexible member has spiral or helical ridges running from the proximal to the distal end which define the conduit for fluid flow.
- 20 14. The shunt of claim 12 wherein the flexible member has straight or undulating ridges running from the proximal to the distal end which define the conduit for fluid flow.
15. The shunt device of claim 12 wherein the shunt is from 1.0 mm to 40.0 mm in length and an outer diameter of between about 0.1 to about 0.5 mm

16. An aqueous humor shunt device to divert aqueous humor within Schlemm's canal, the shunt device comprising a distal portion having at least one terminal aspect sized and shaped to be received wholly within a portion of Schlemm's canal wherein the terminal aspect comprises an open coil having a lumen there through wherein the device permits fluid communication along the shunt within Schlemm's canal.
17. The shunt device of claim 16 where in the distal end terminates in a ball shape.
18. The shunt device of claim 17 wherein the ball shape is an insert in the distal end.
19. The shunt device of claim 17 wherein the ball shape is formed from the coil of the distal end.
20. The shunt device of claim 16 wherein the shunt is made from shape memory materials.
21. The shunt device of claim 16 wherein the shunt is from 1.0 mm to 40.0 mm in length and an outer diameter of between about 0.1 to about 0.5 mm
22. An aqueous humor shunt device to divert aqueous humor within Schlemm's canal, the shunt device comprising a distal portion having at least one terminal aspect sized and shaped to be received wholly within a portion of Schlemm's canal wherein the terminal aspect comprises a corrugated member having at least one aperture in the corrugation that defines at least one conduit for fluid flow on the interior of the flexible member, wherein device permits fluid communication inside the shunt within Schlemm's canal.
23. The device according to claim 23 wherein the corrugations are formed by transverse members alternating above and below a pair of longitudinal rails.
24. The device according to claim 23 wherein the corrugations are sinusoidal.
25. The device according to claim 25 wherein the corrugations are squared off.

26. The device according to claim 23 wherein the shunt is from 1.0 mm to 40.0 mm in length and an outer diameter of between about 0.1 to about 0.5 mm.

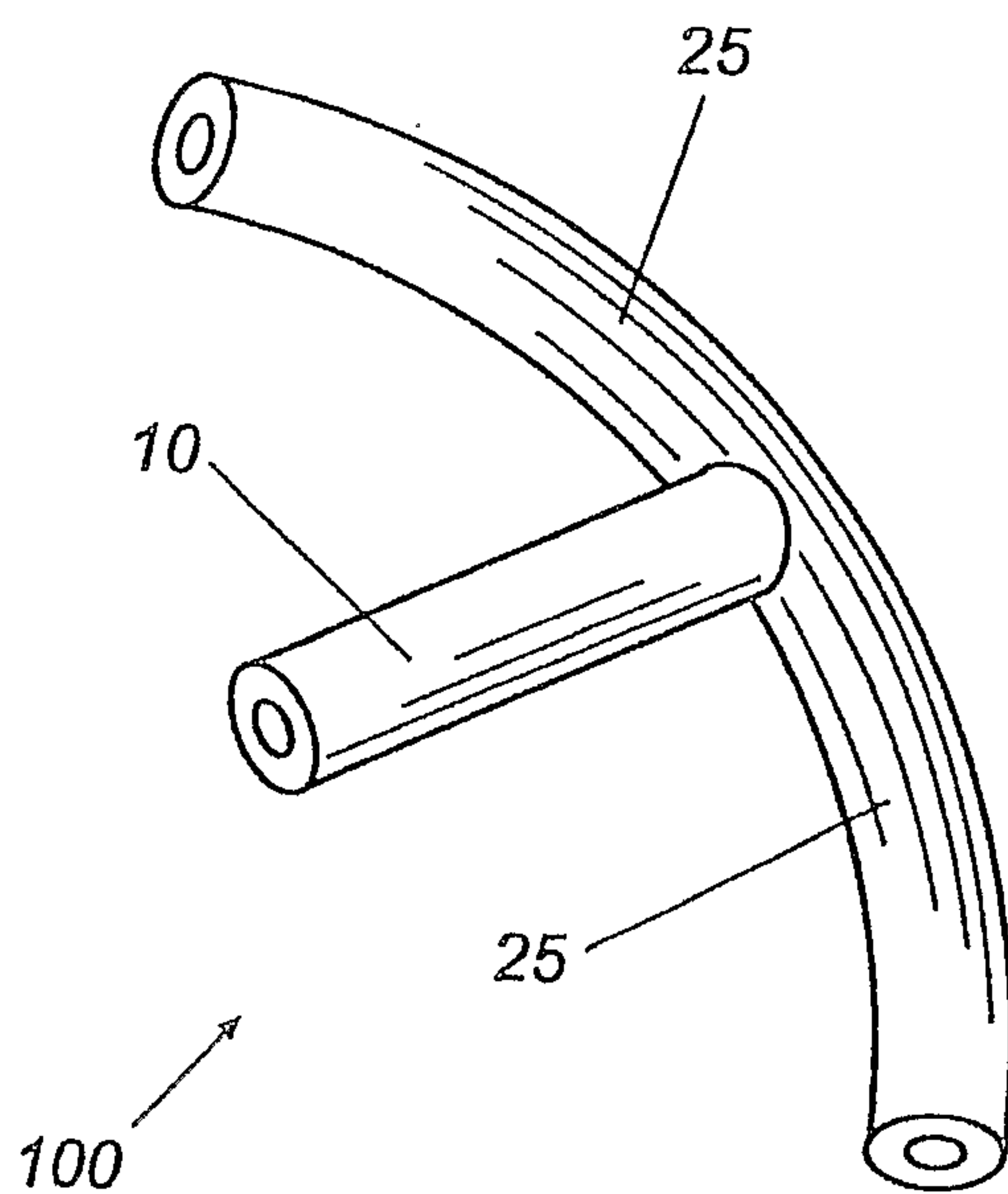
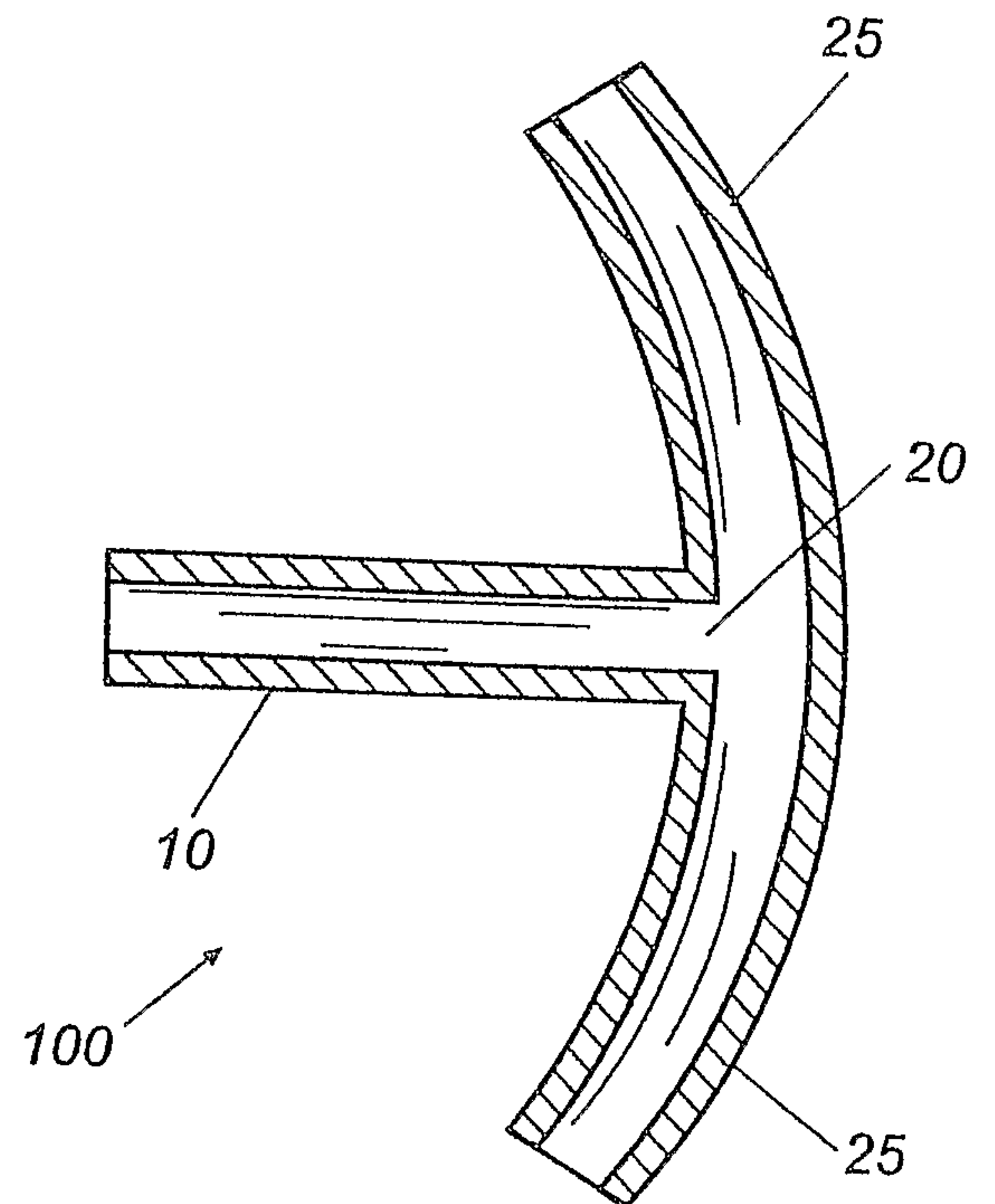
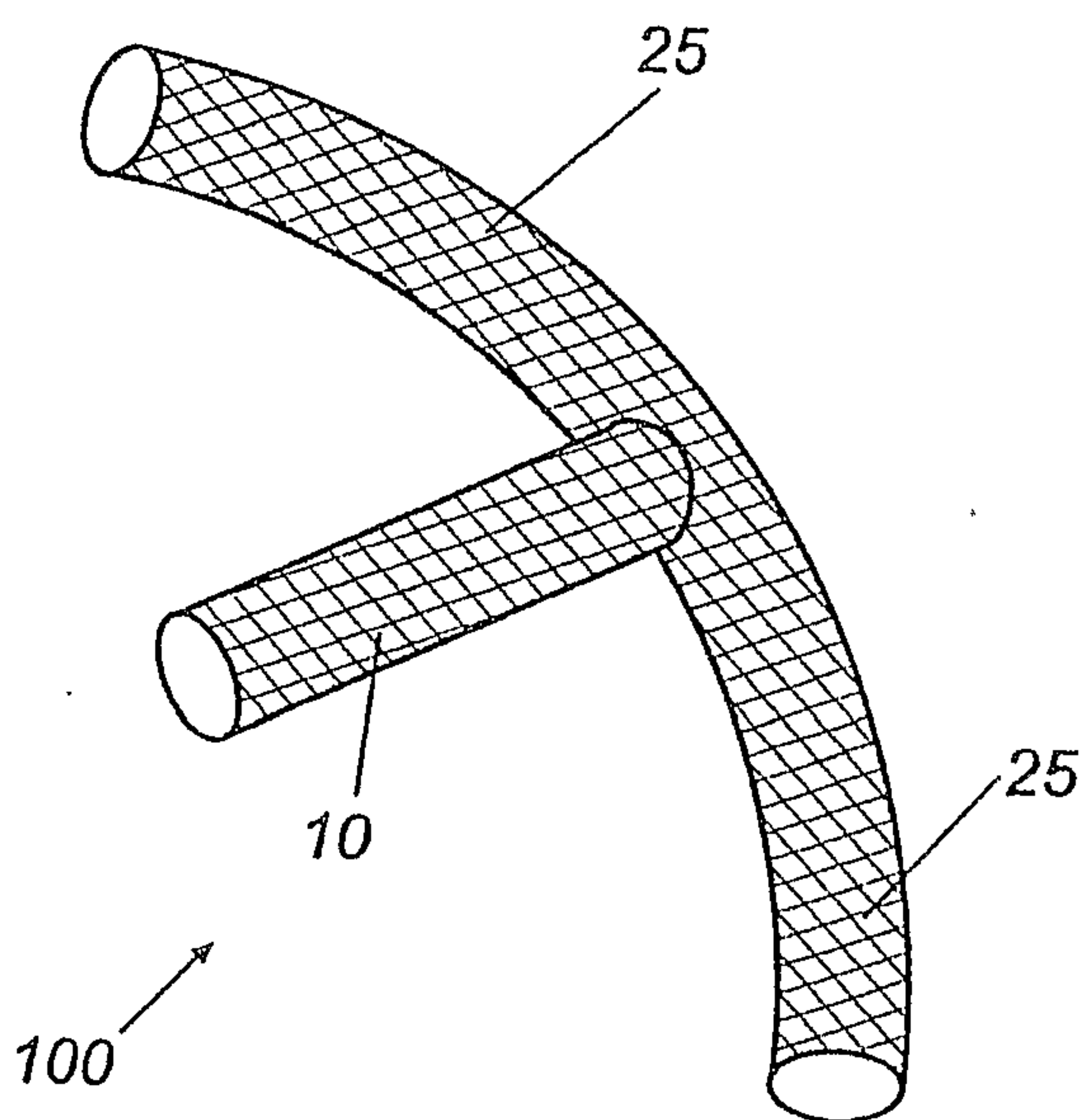
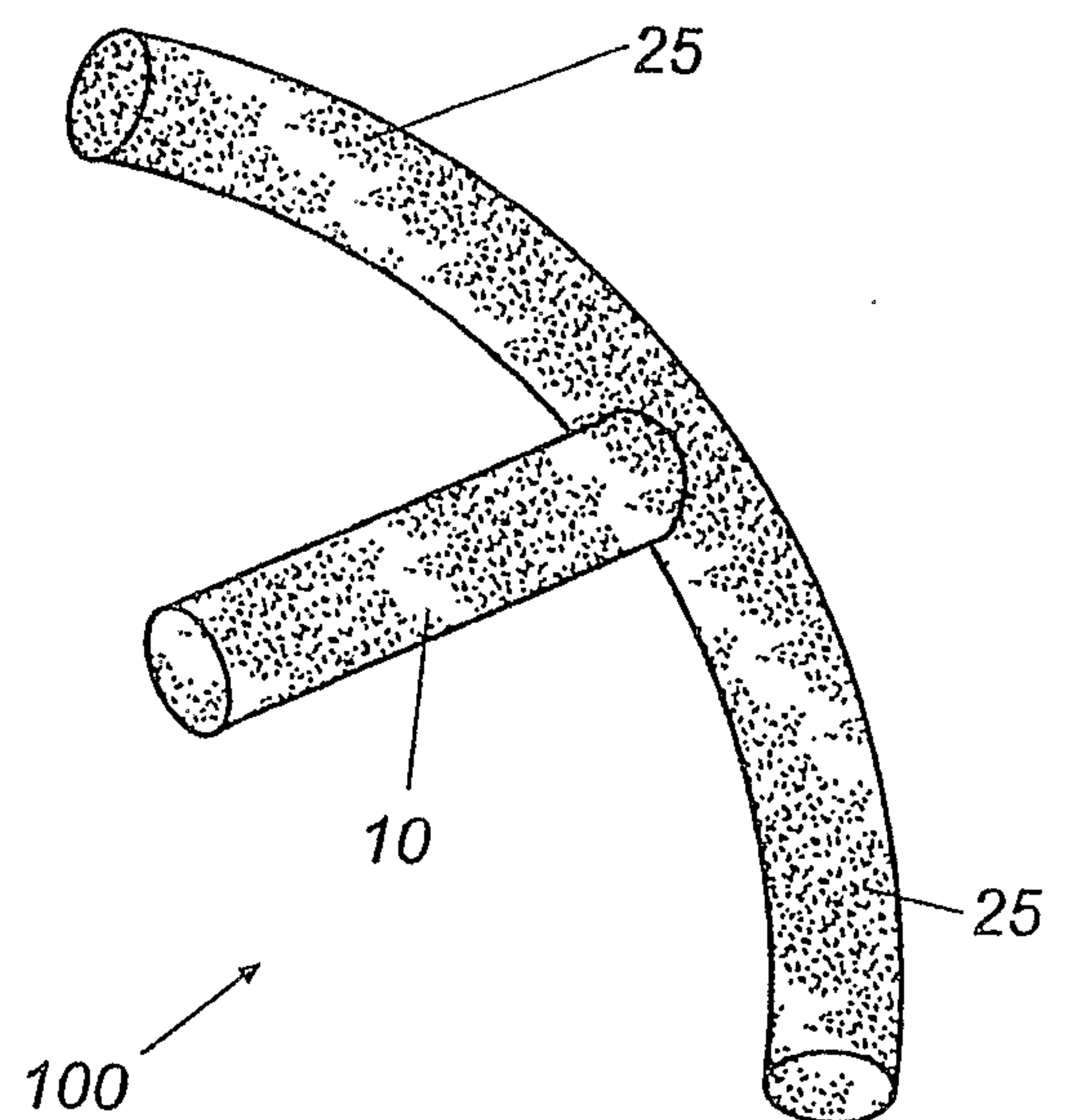
27. A method of treating glaucoma in a patient in need thereof comprising:

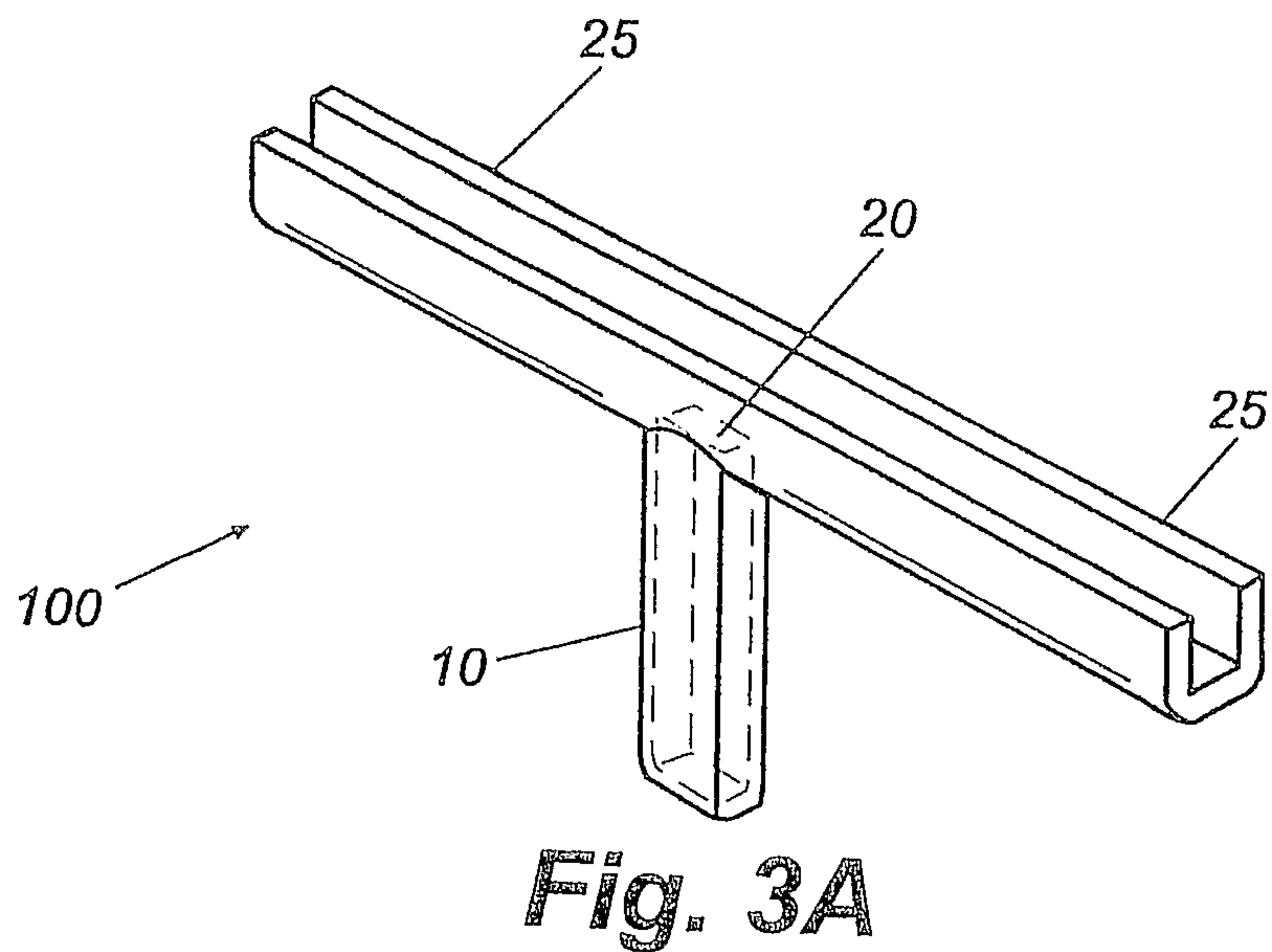
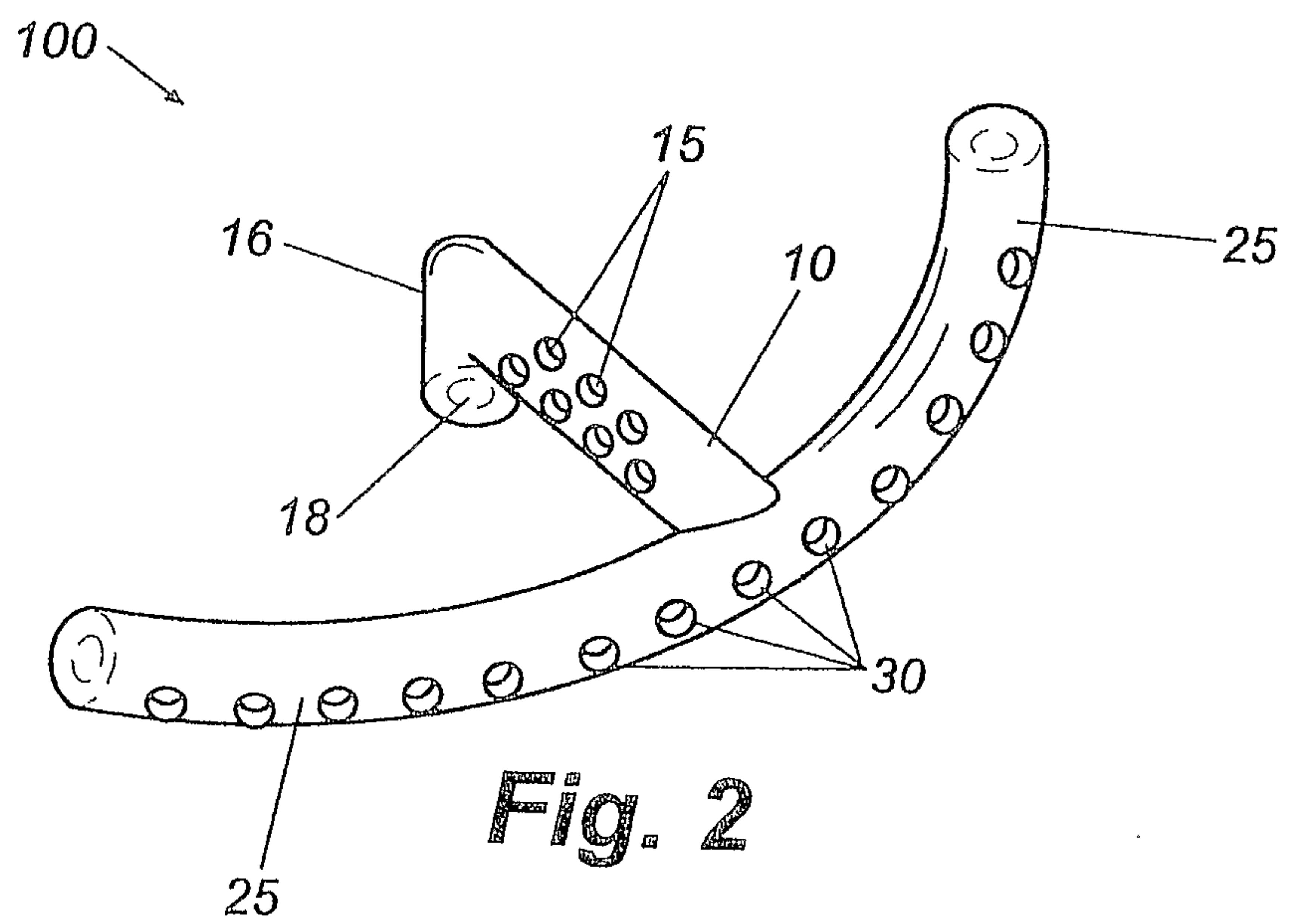
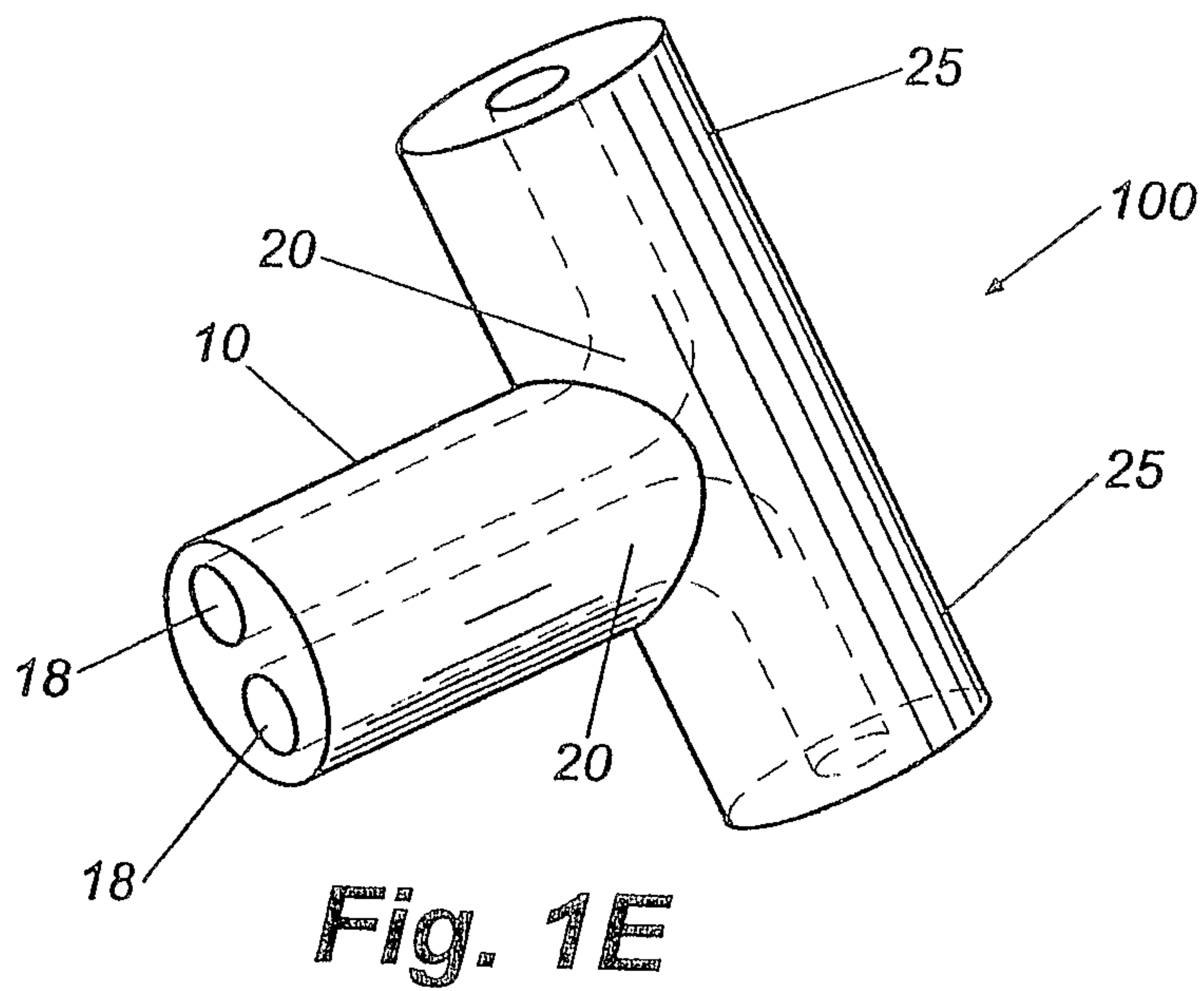
First introducing a second end into Schlemm's canal wherein the second end

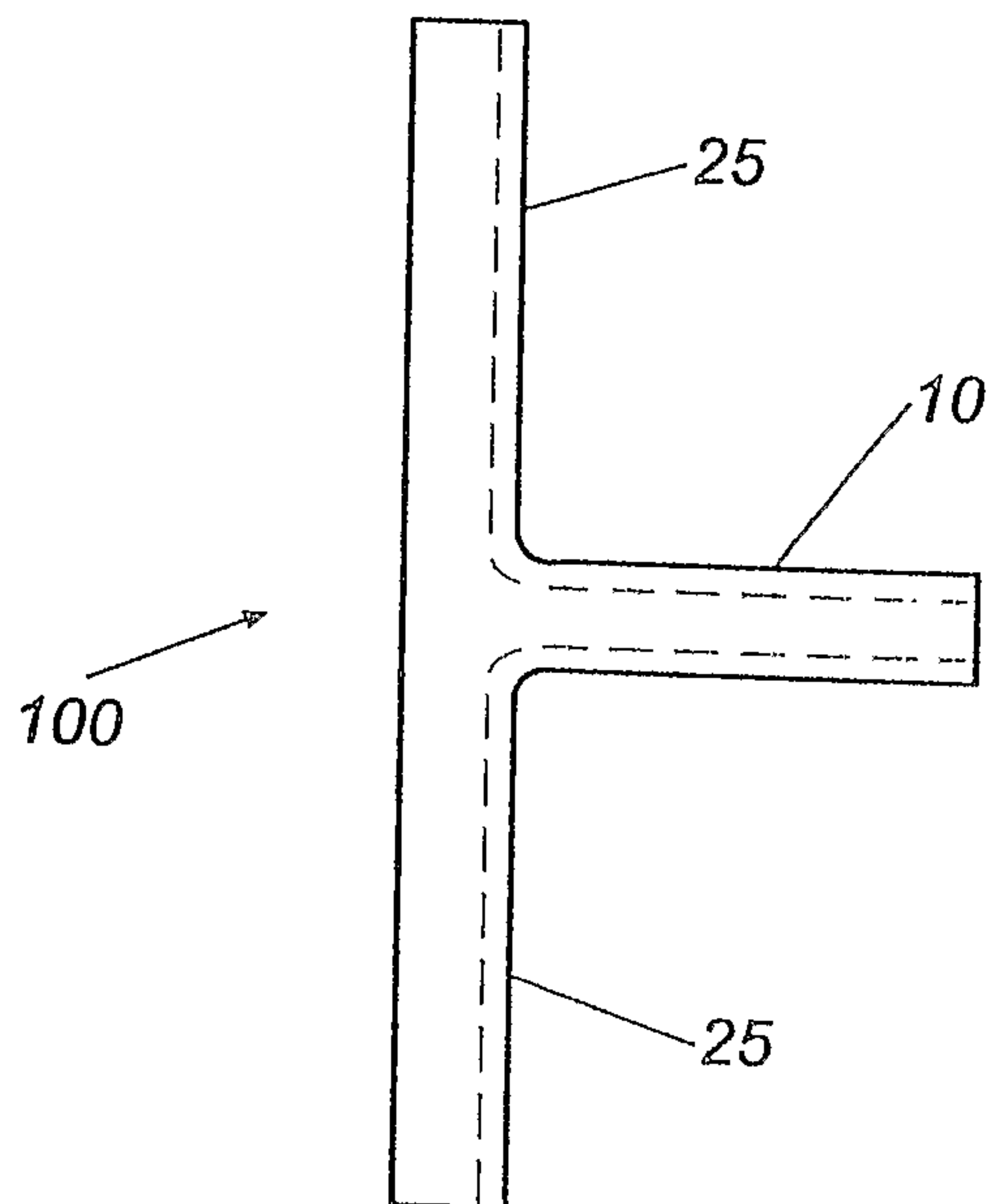
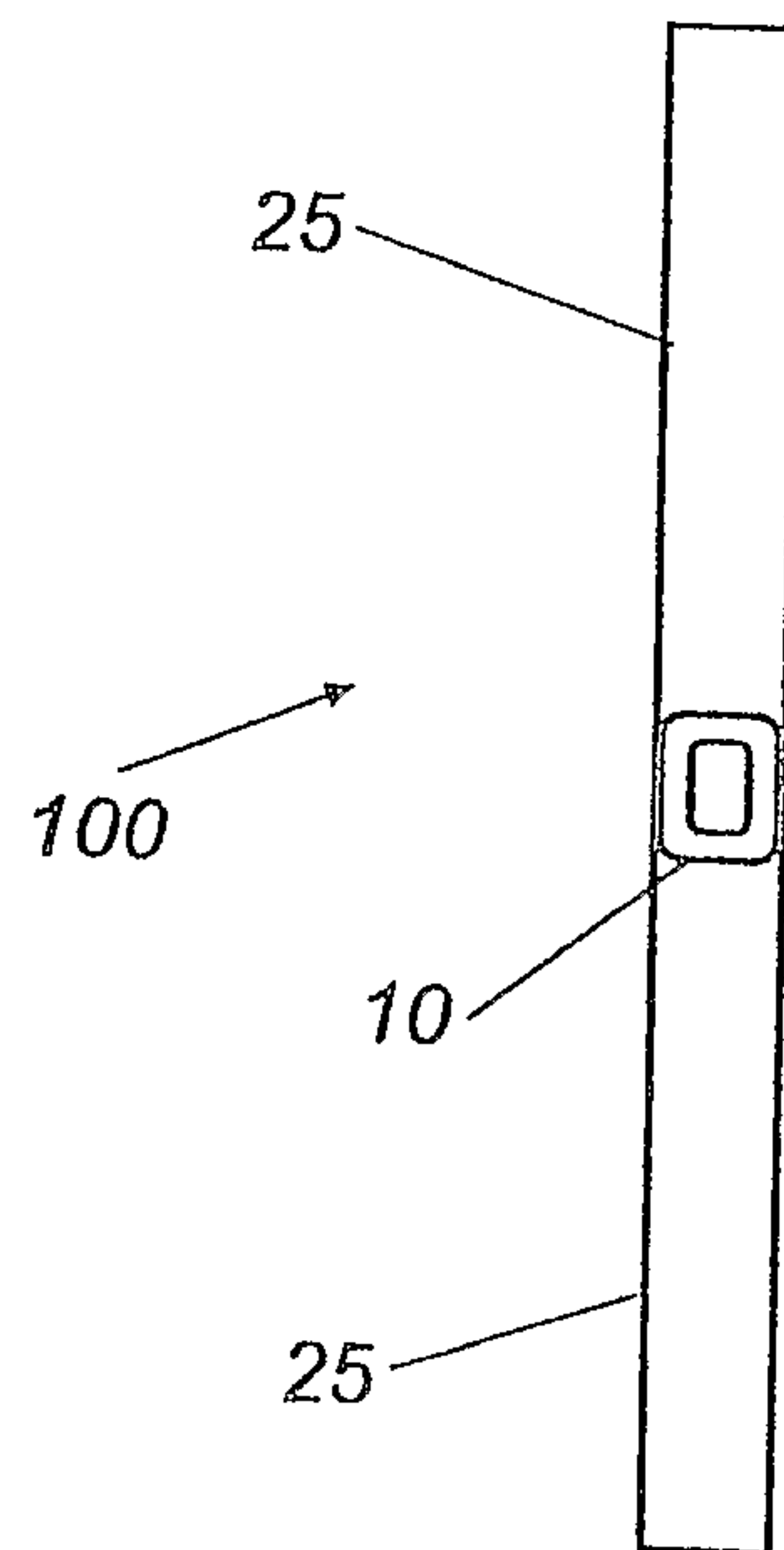
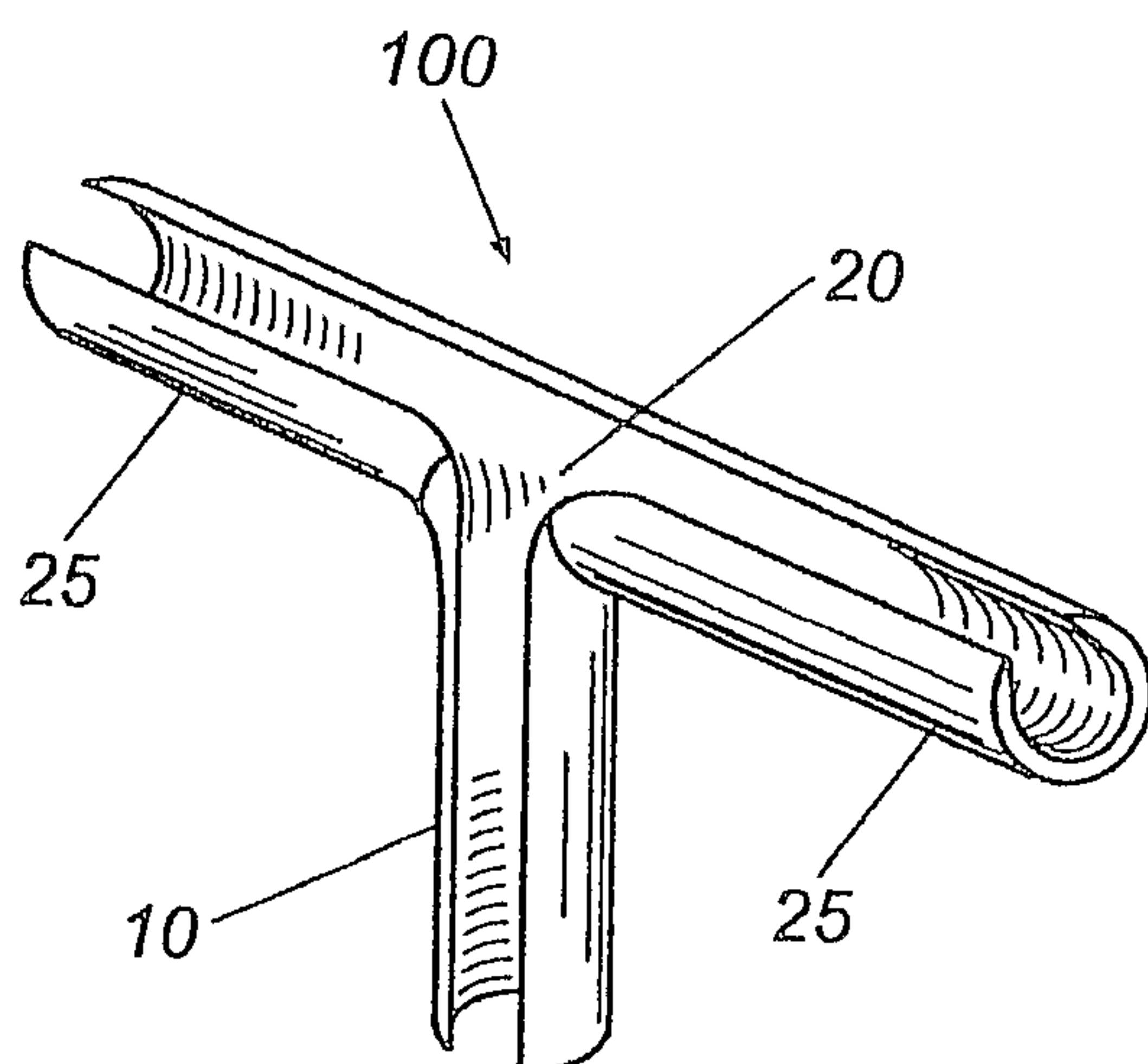
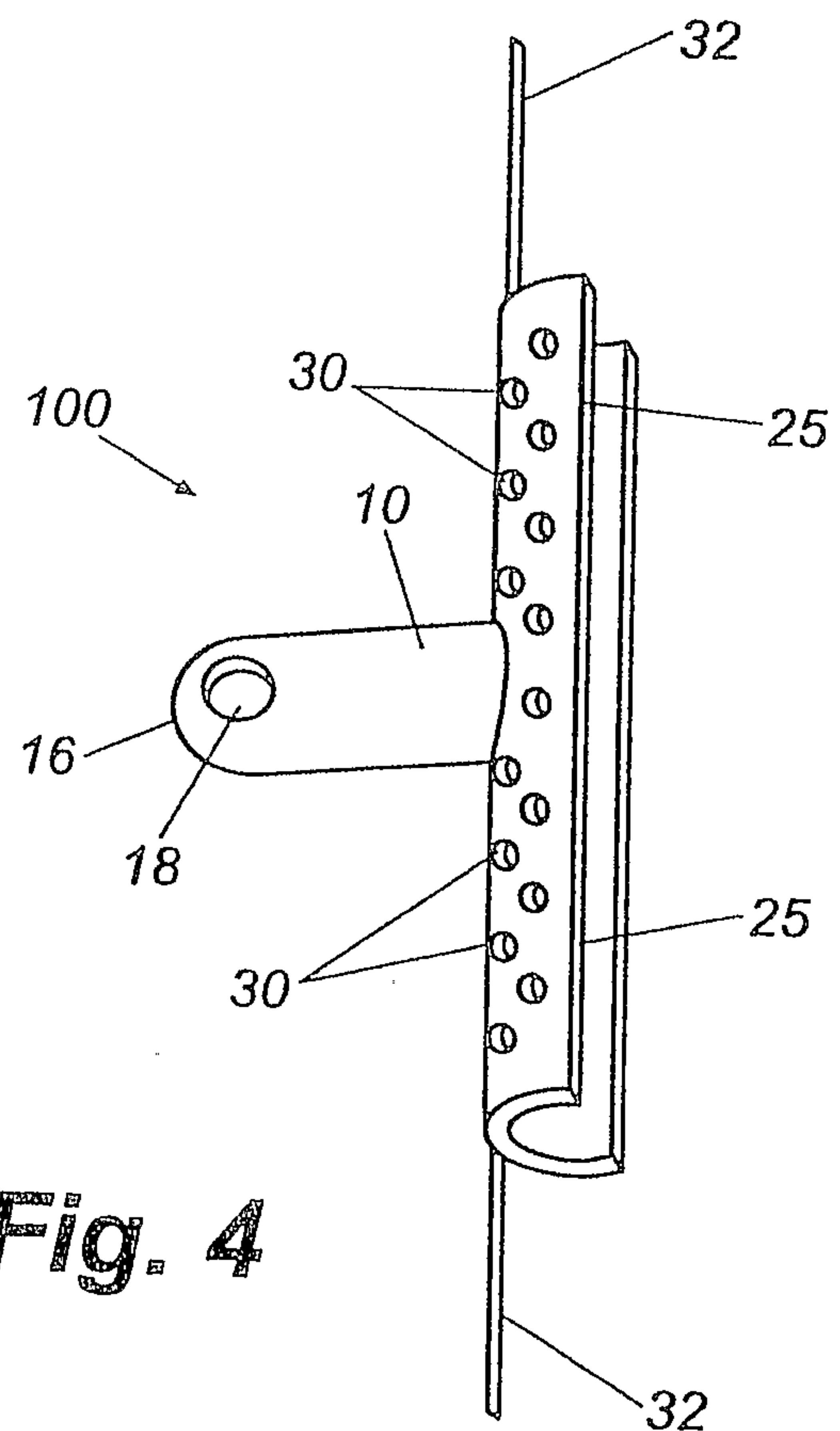
5 comprises an open coil or stent;

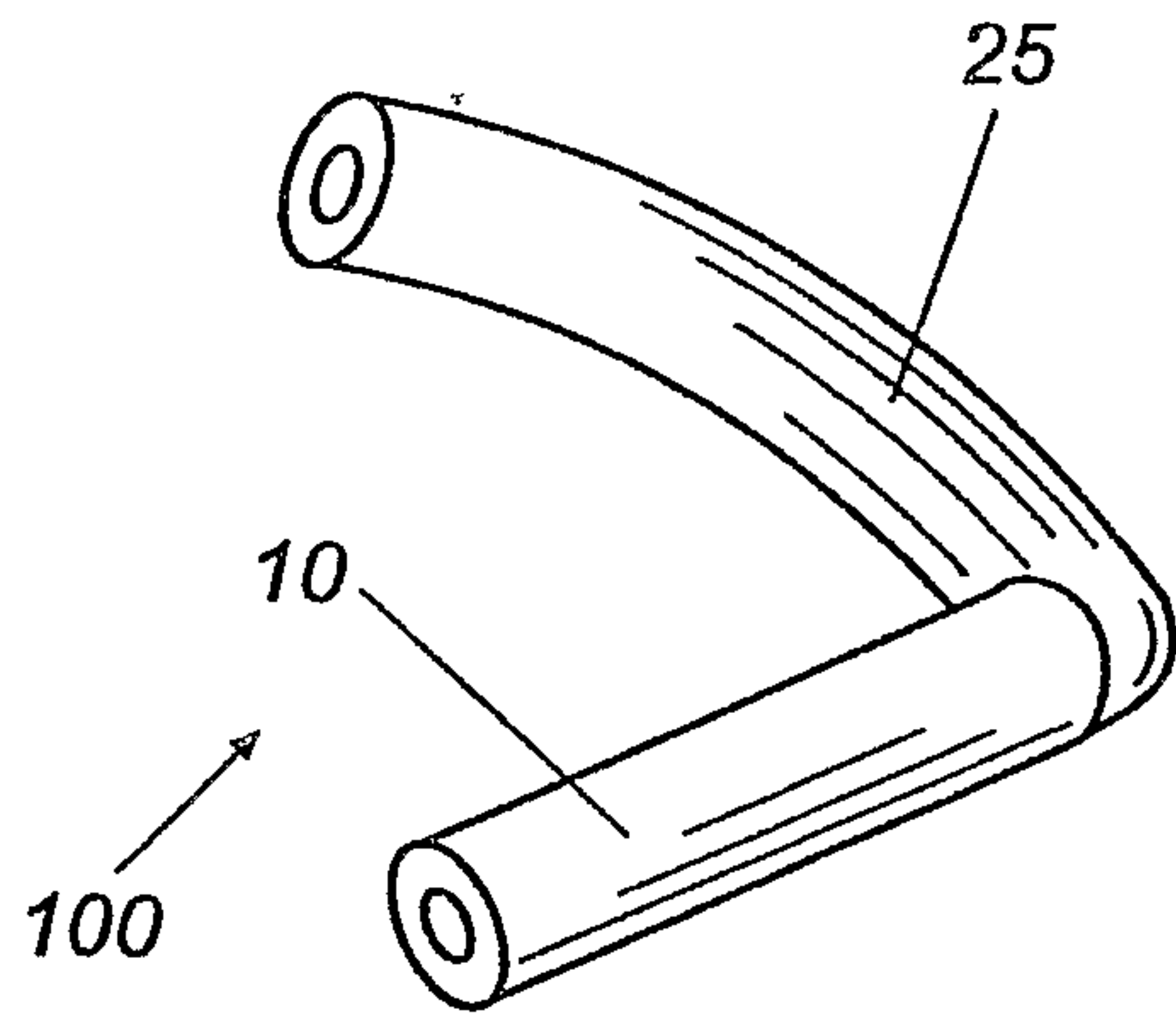
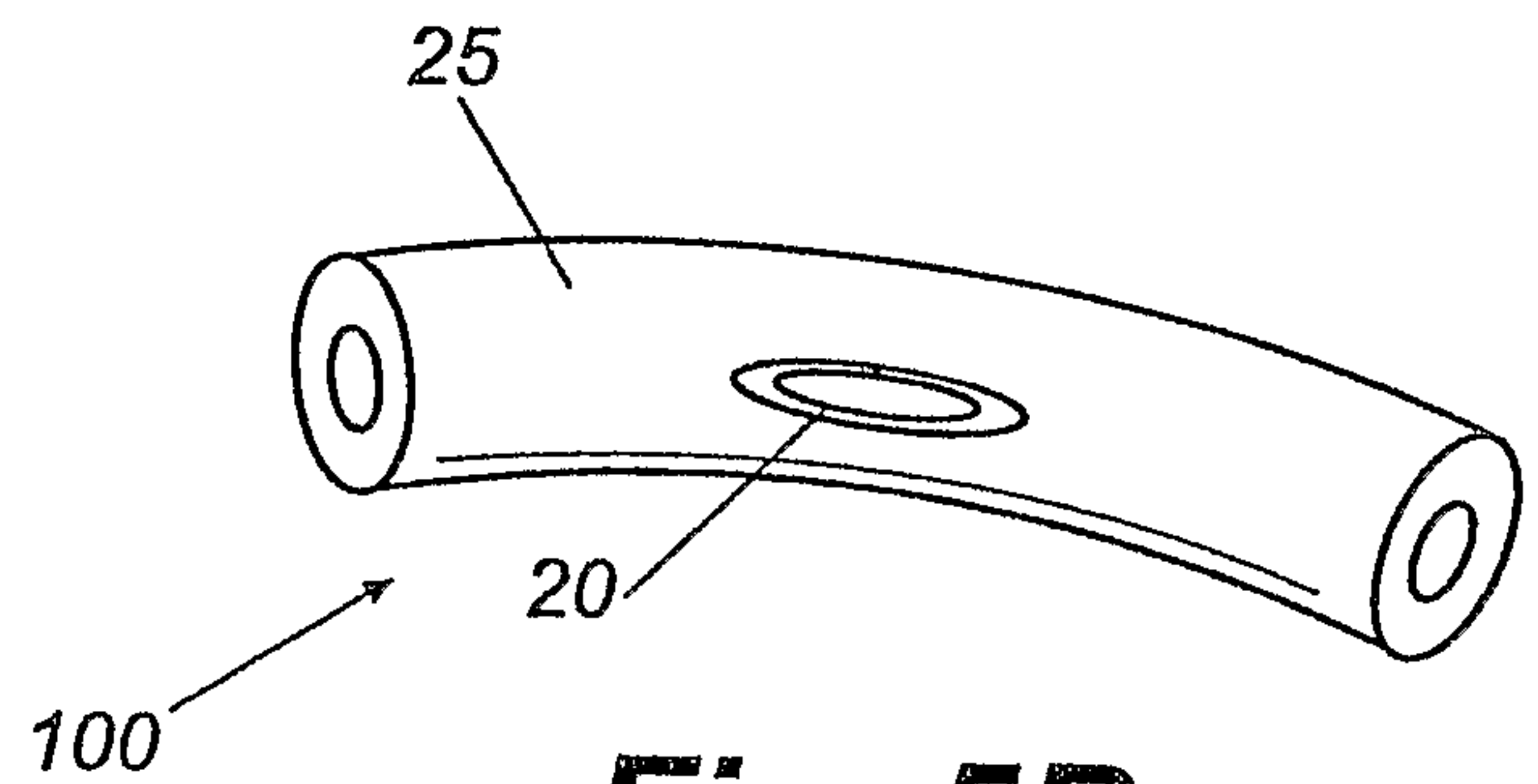
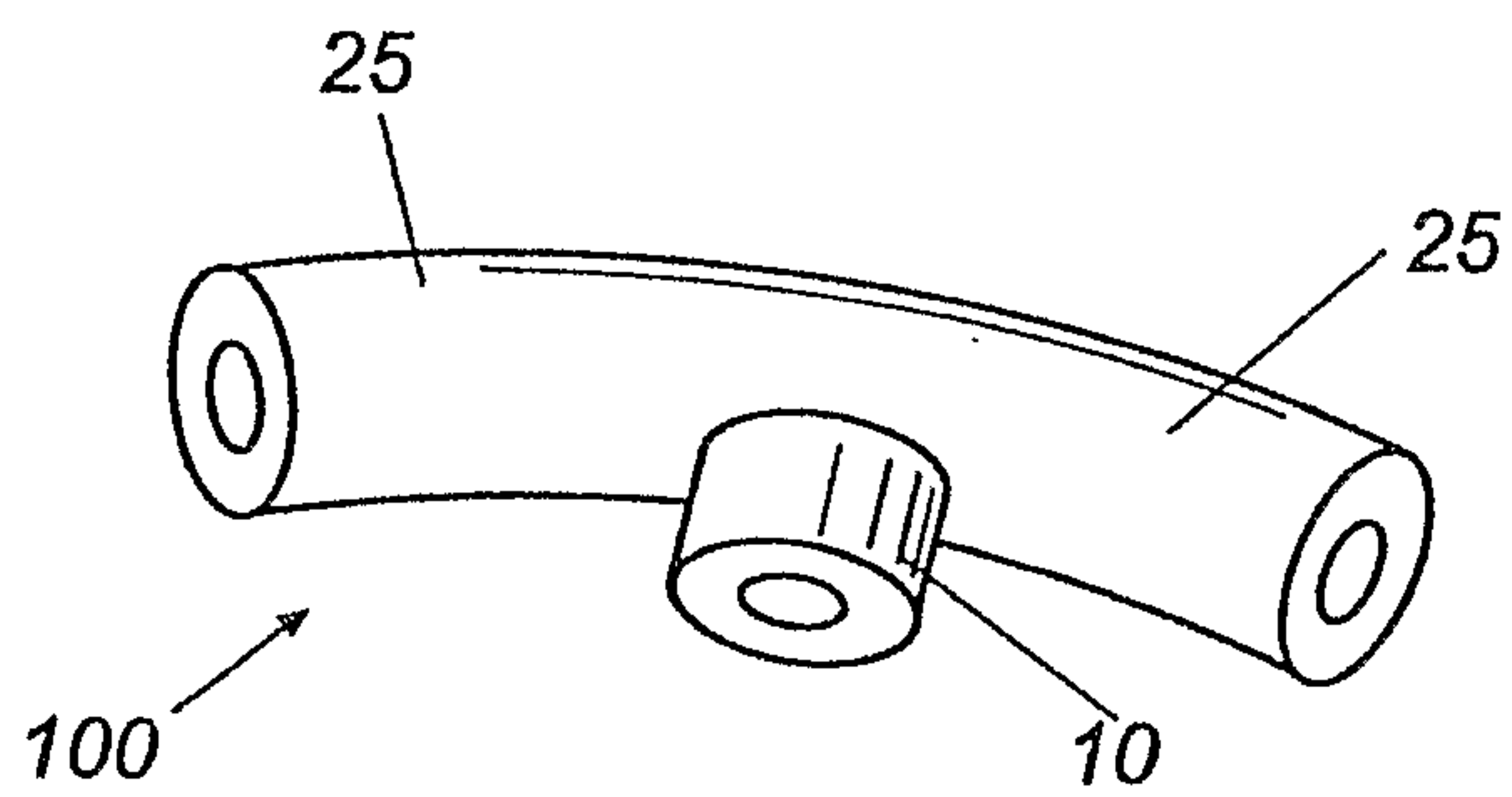
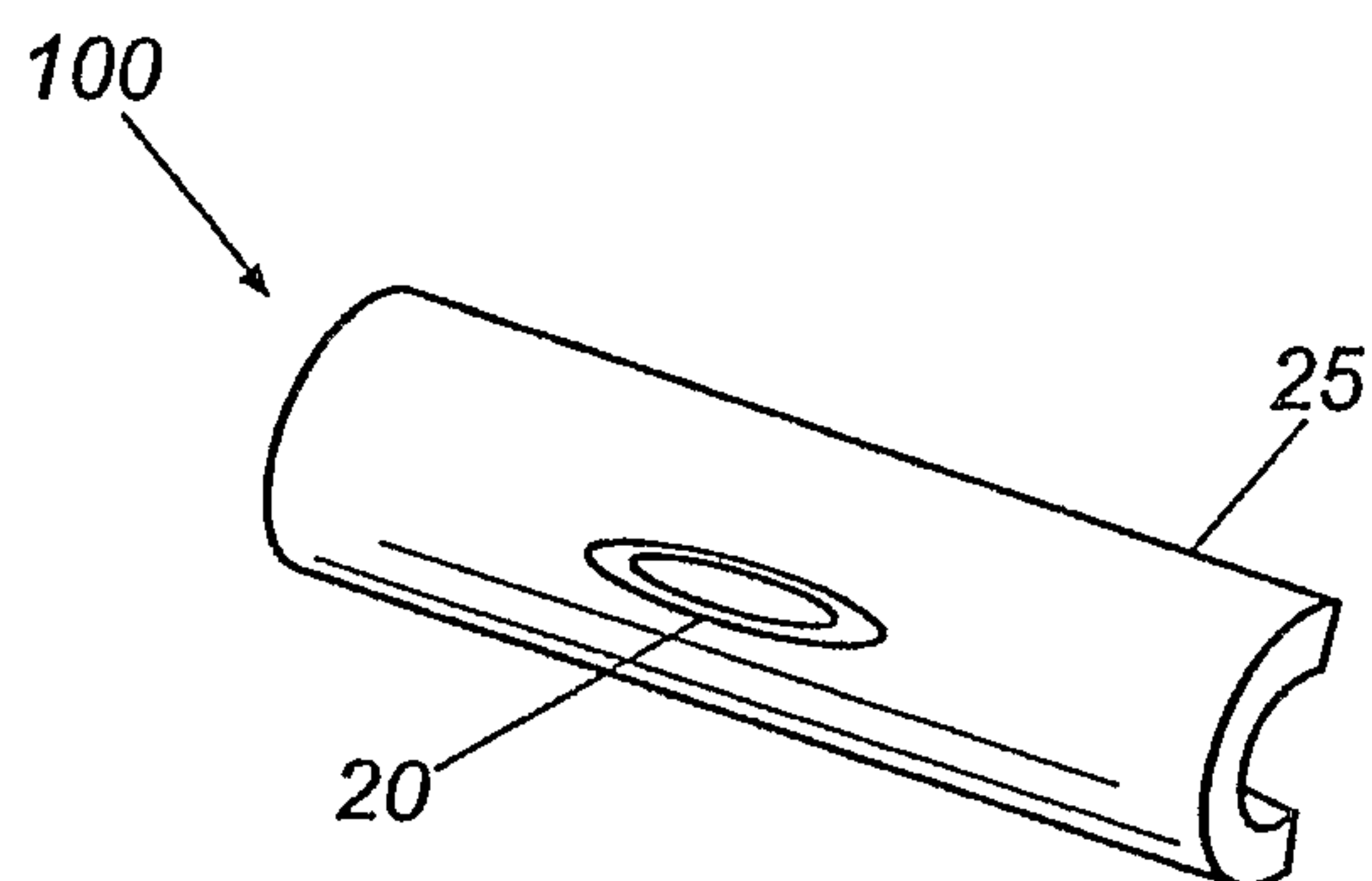
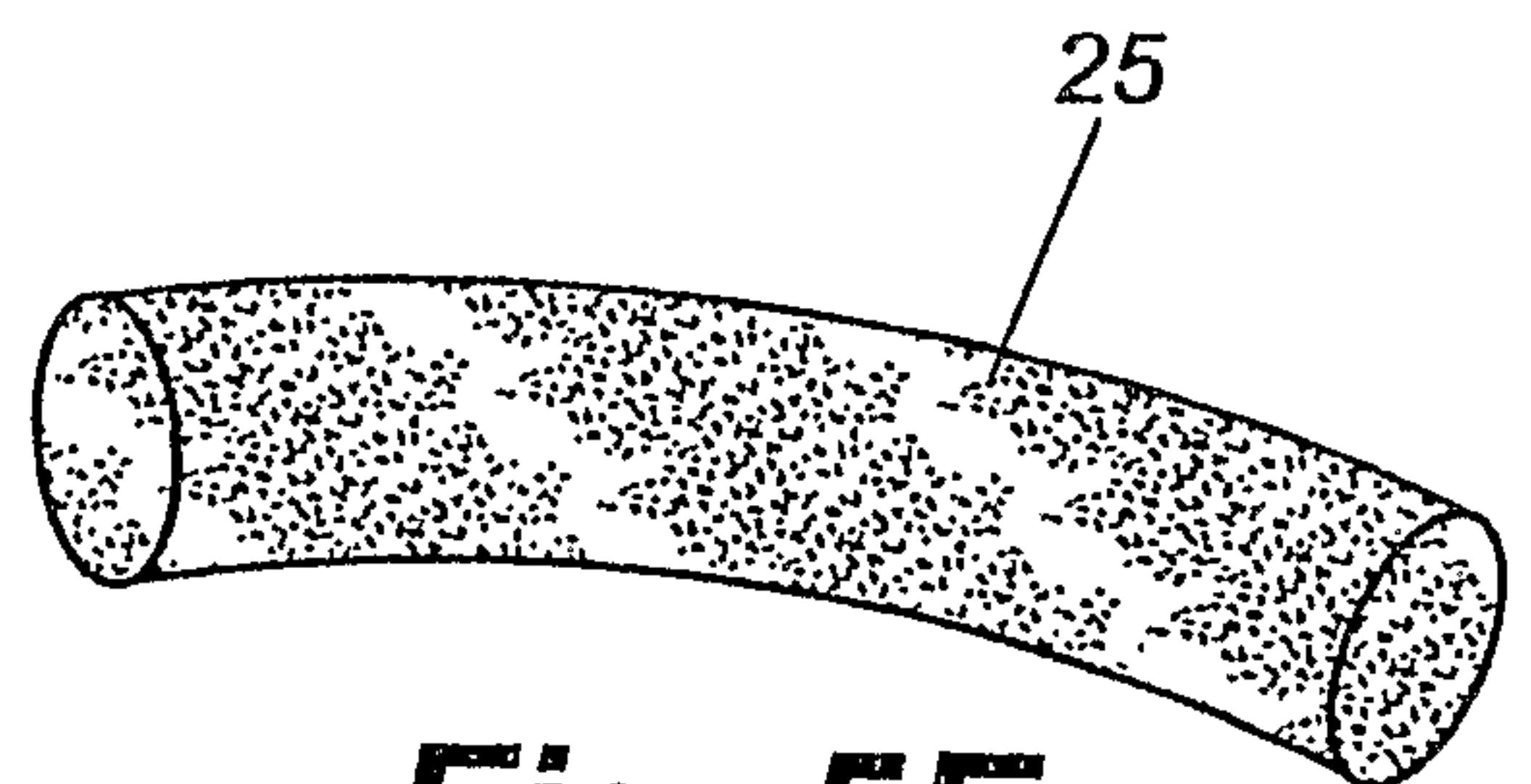
Second introducing a first end of a shunt device into the anterior chamber of the eye, wherein the first end comprises a silicone tube, thereby allowing aqueous fluid to flow from the anterior chamber into Schlemm's canal.

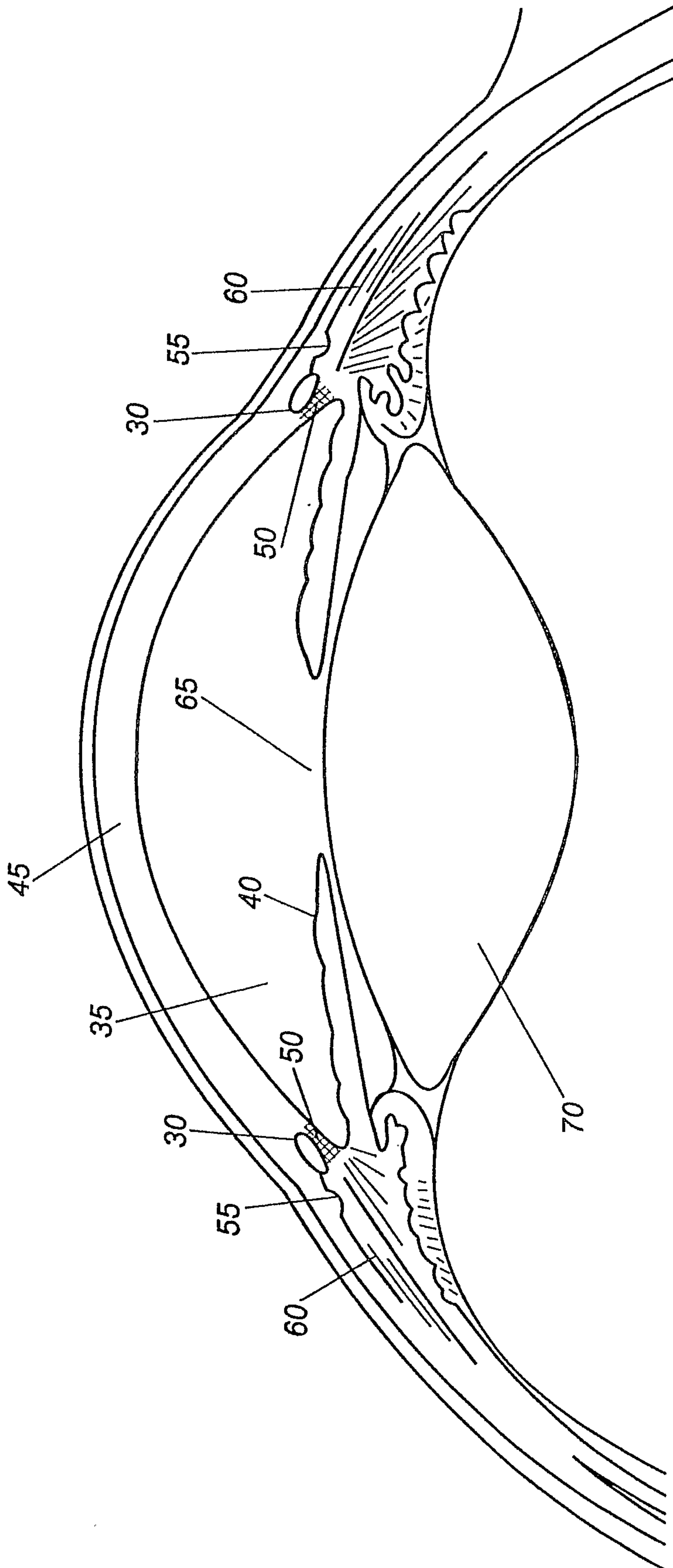
10

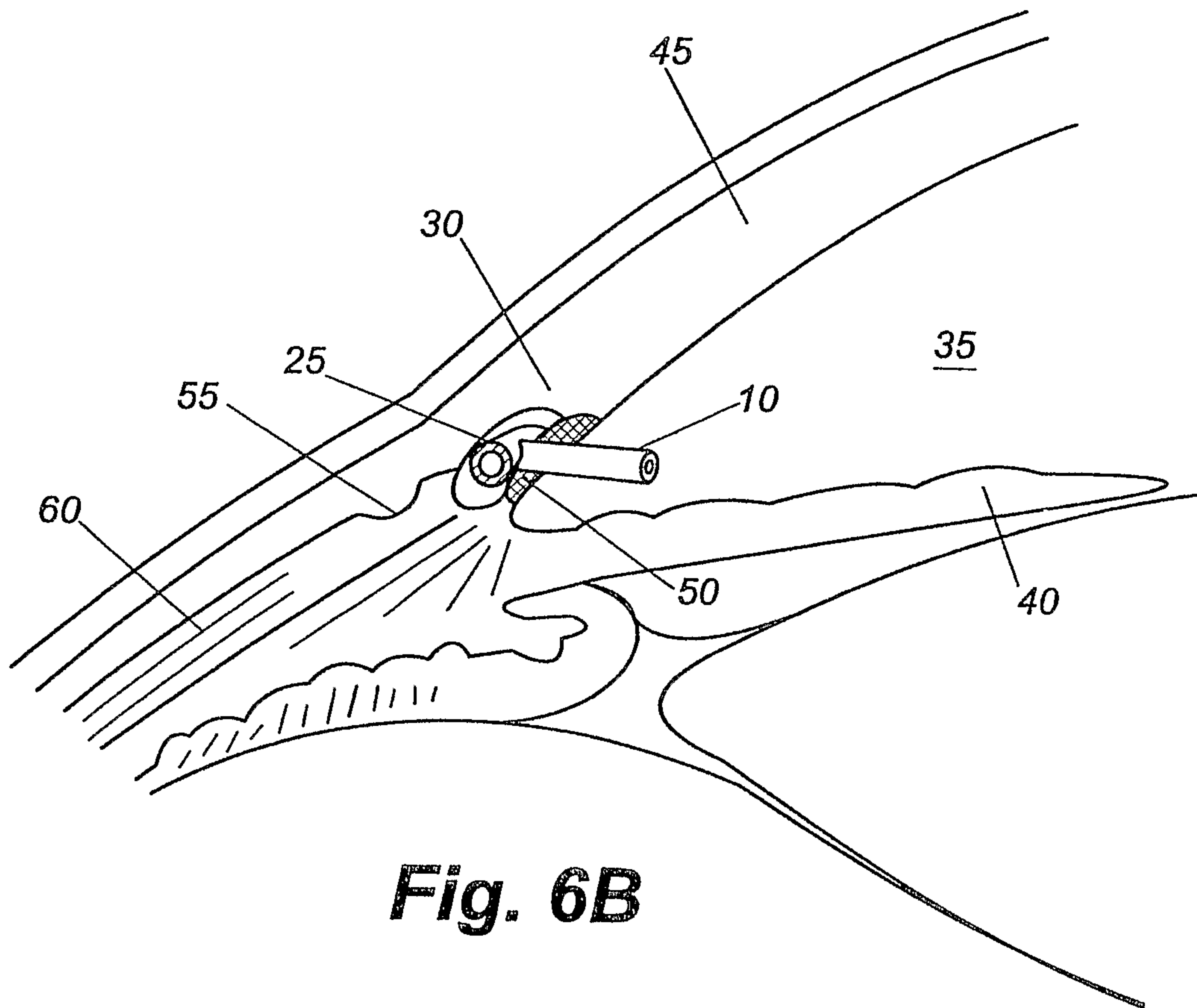
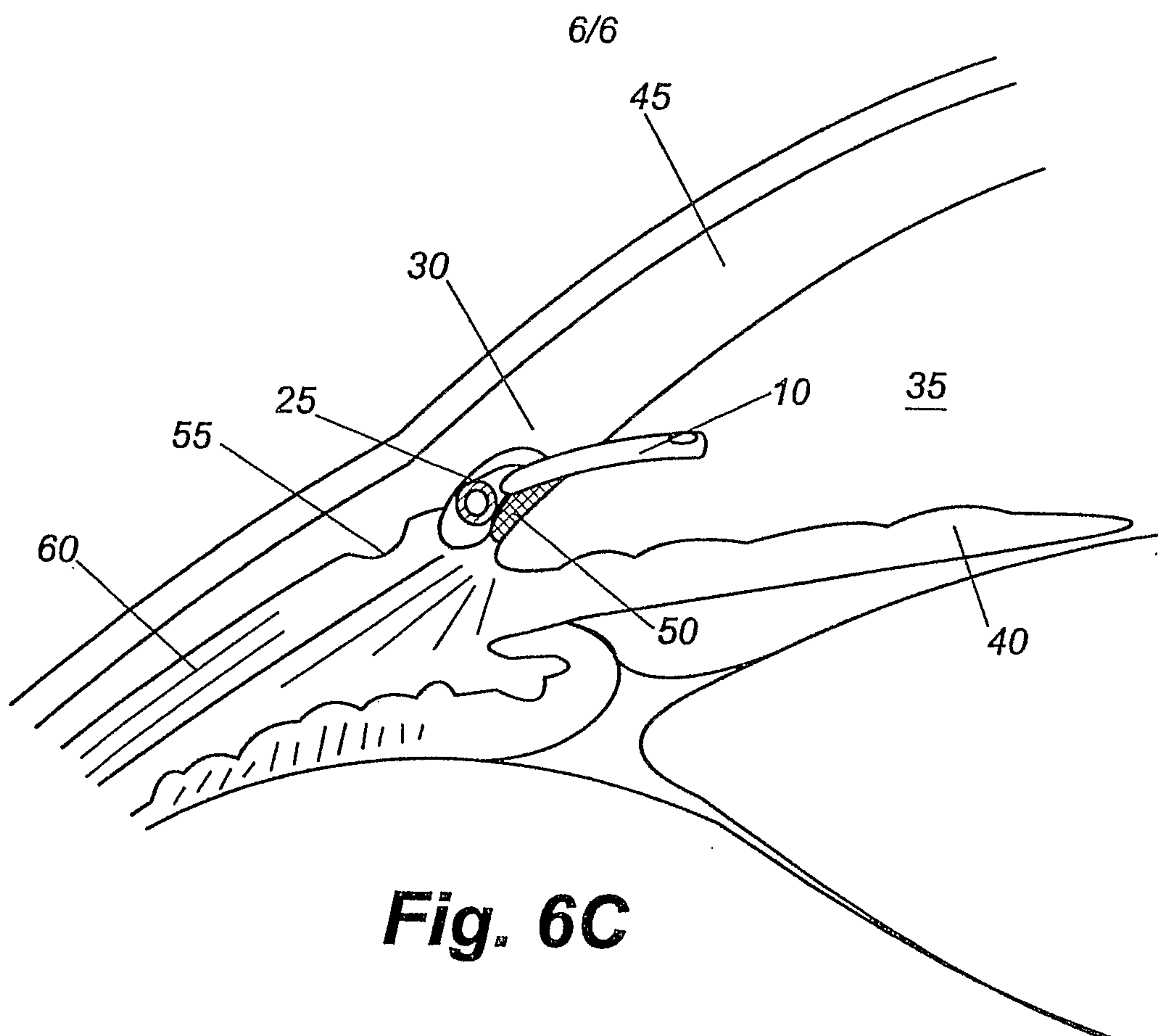
**Fig. 1A****Fig. 1B****Fig. 1C****Fig. 1D**



**Fig. 3B****Fig. 3C****Fig. 3D****Fig. 4**

**Fig. 5A****Fig. 5B****Fig. 5C****Fig. 5D****Fig. 5E**

**Fig. 6A**

**Fig. 6B****Fig. 6C**

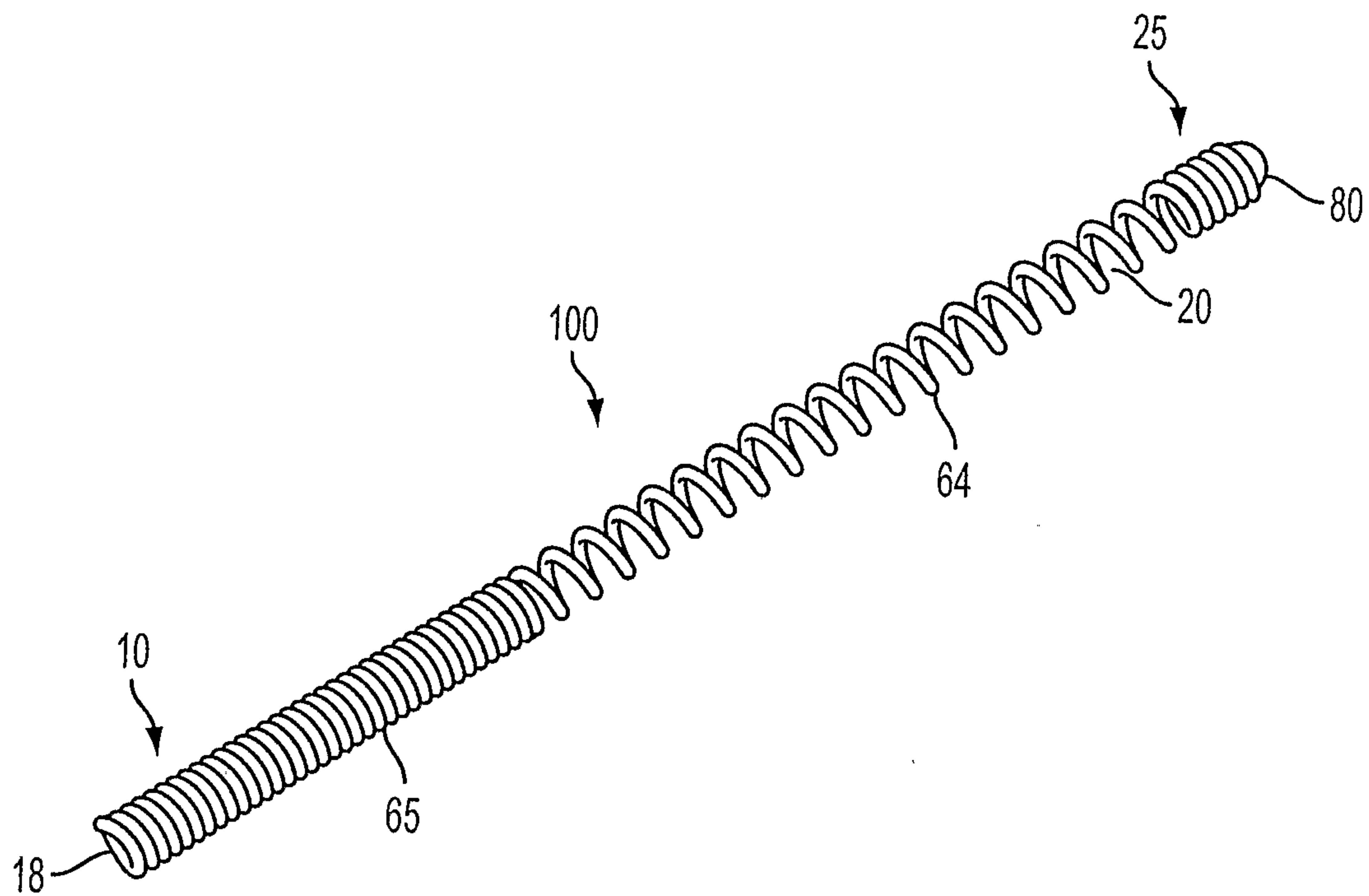


FIG. 7

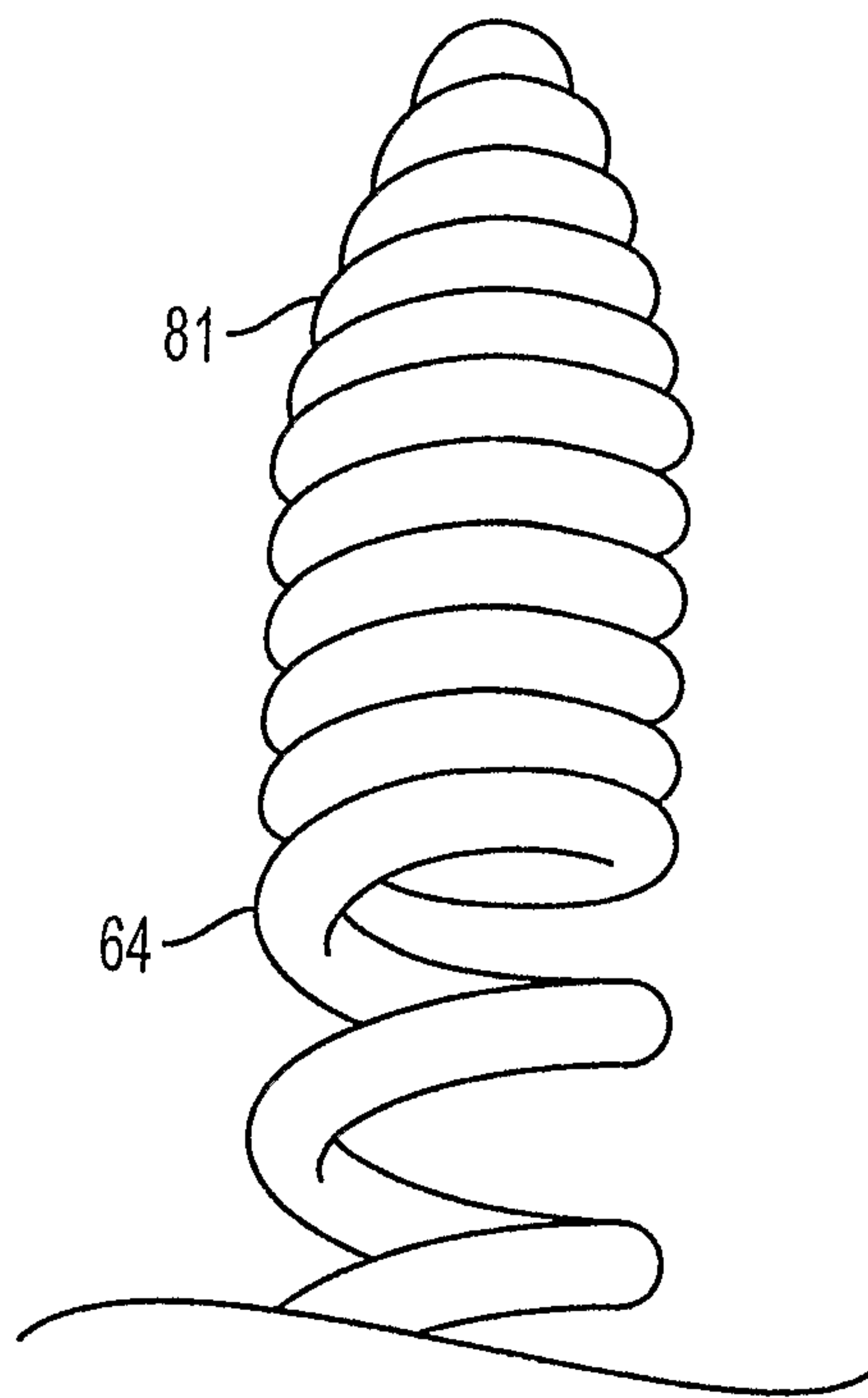


FIG. 8

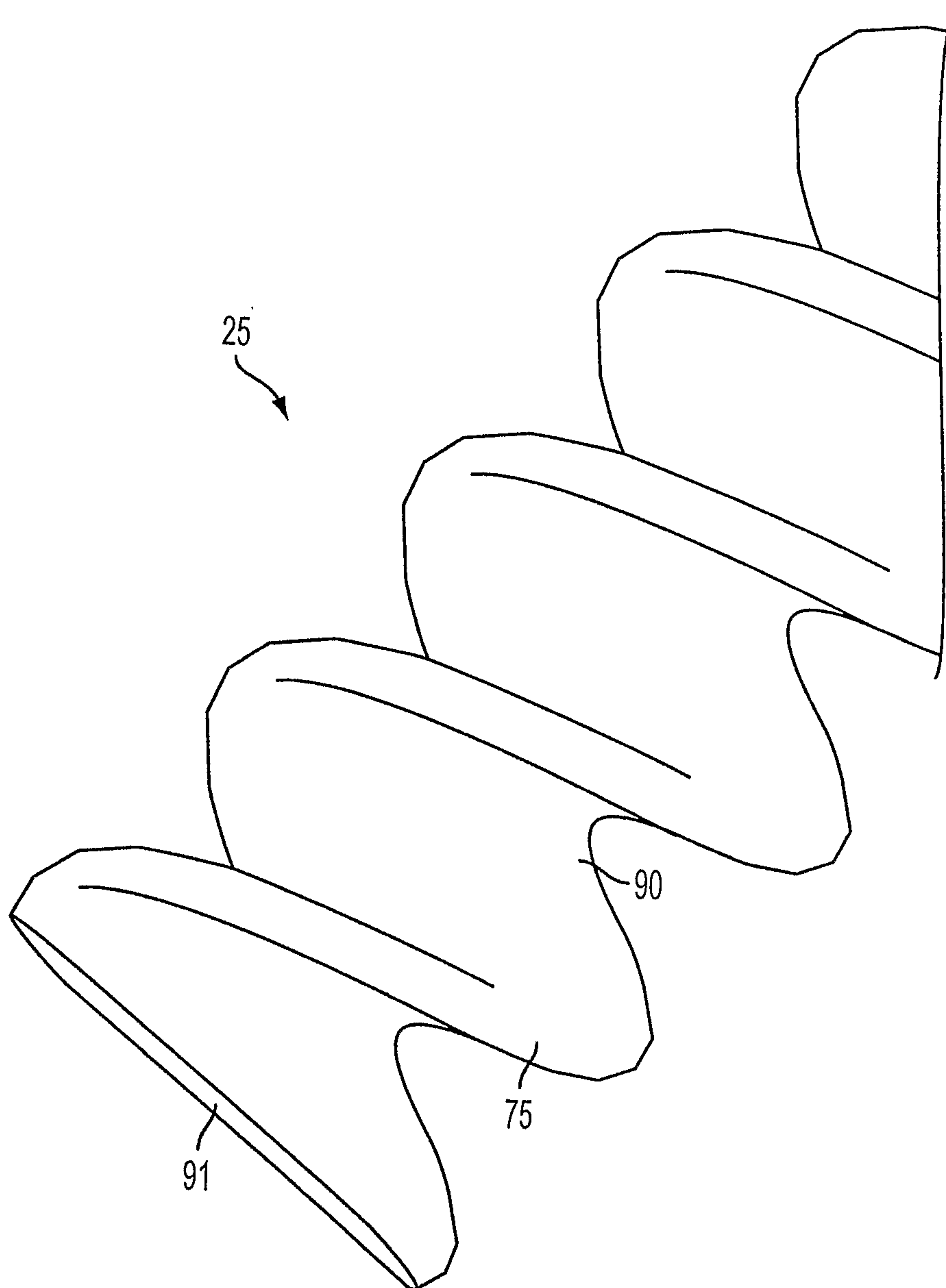


FIG. 9

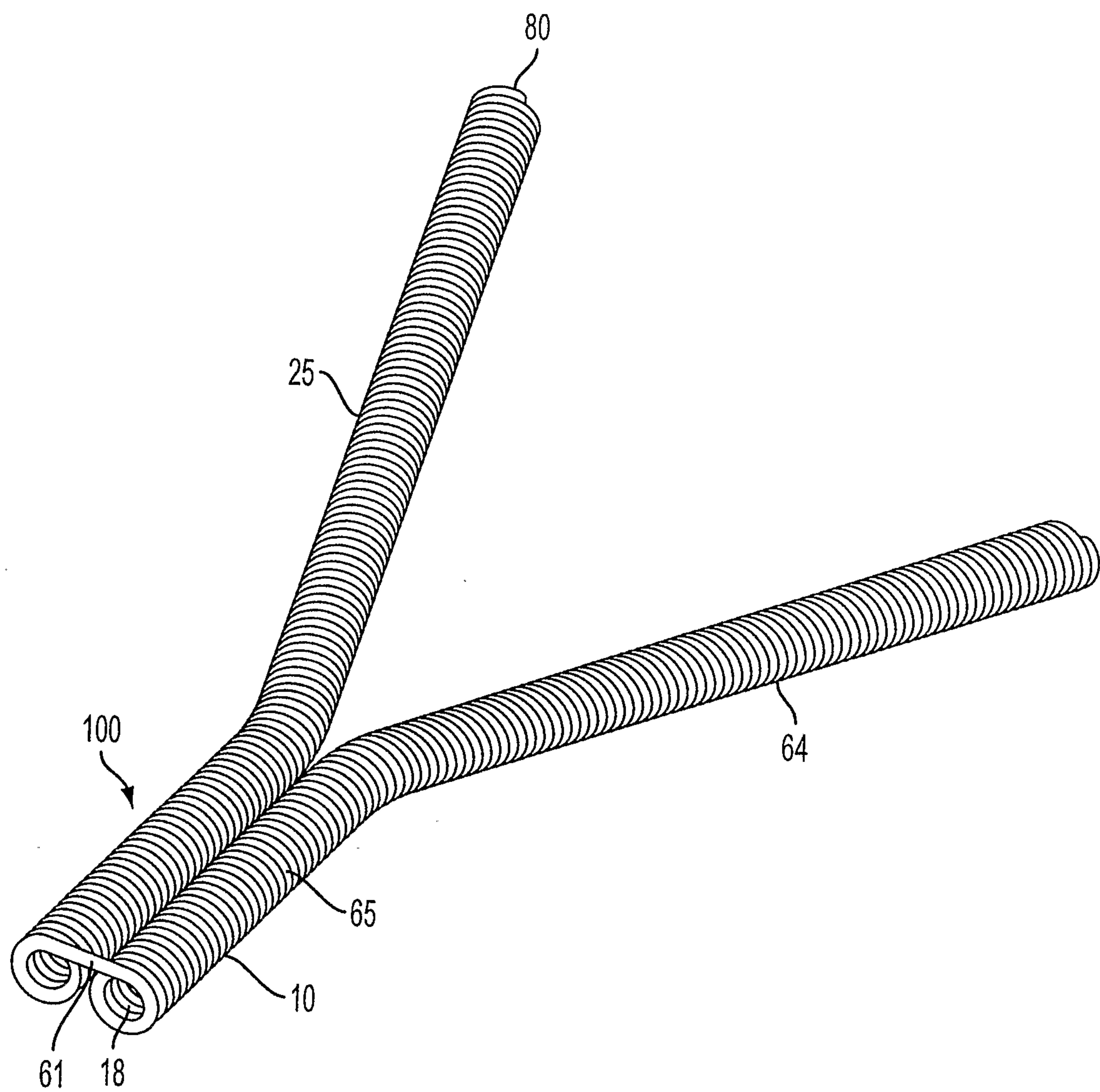


FIG. 10

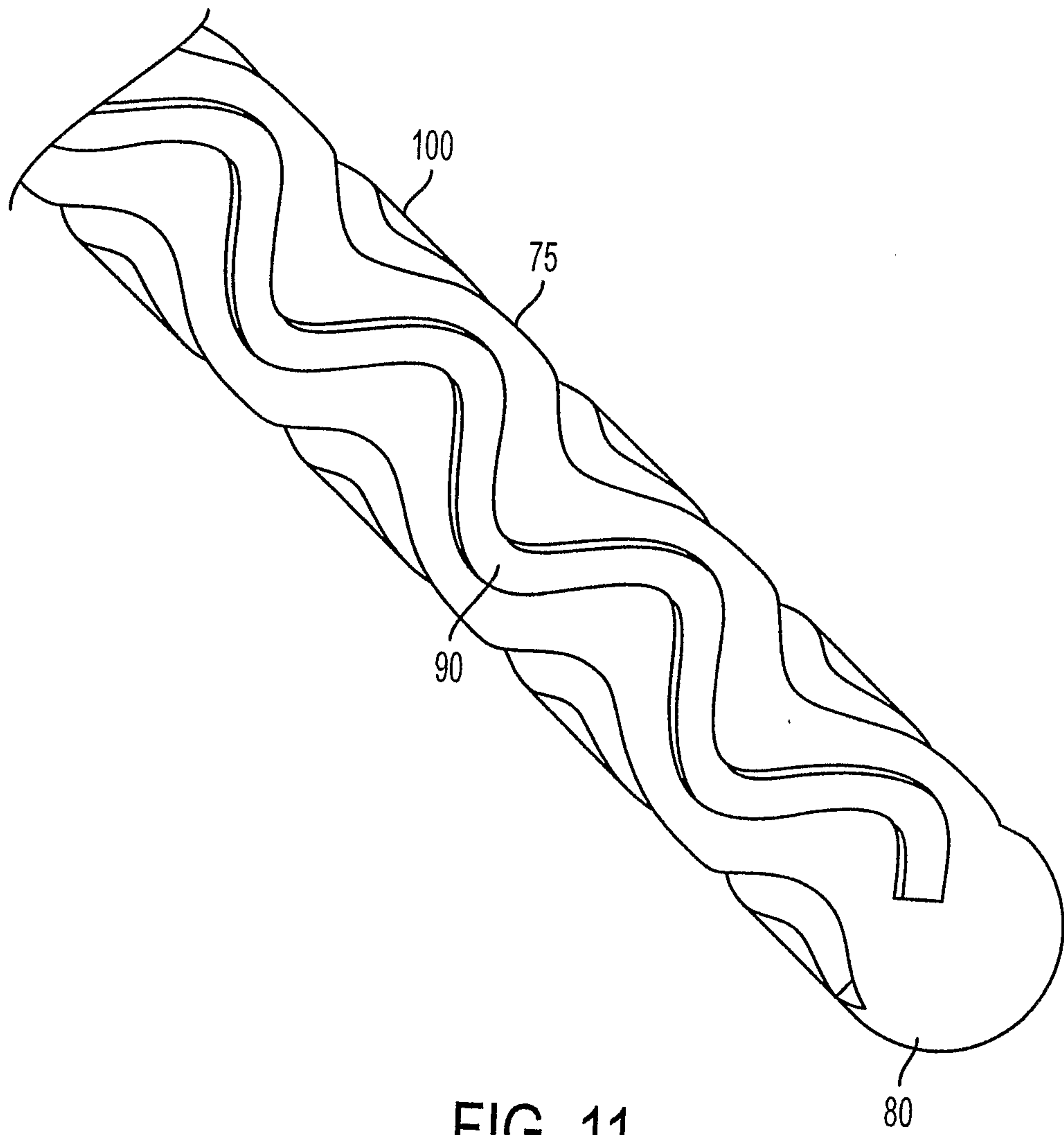


FIG. 11

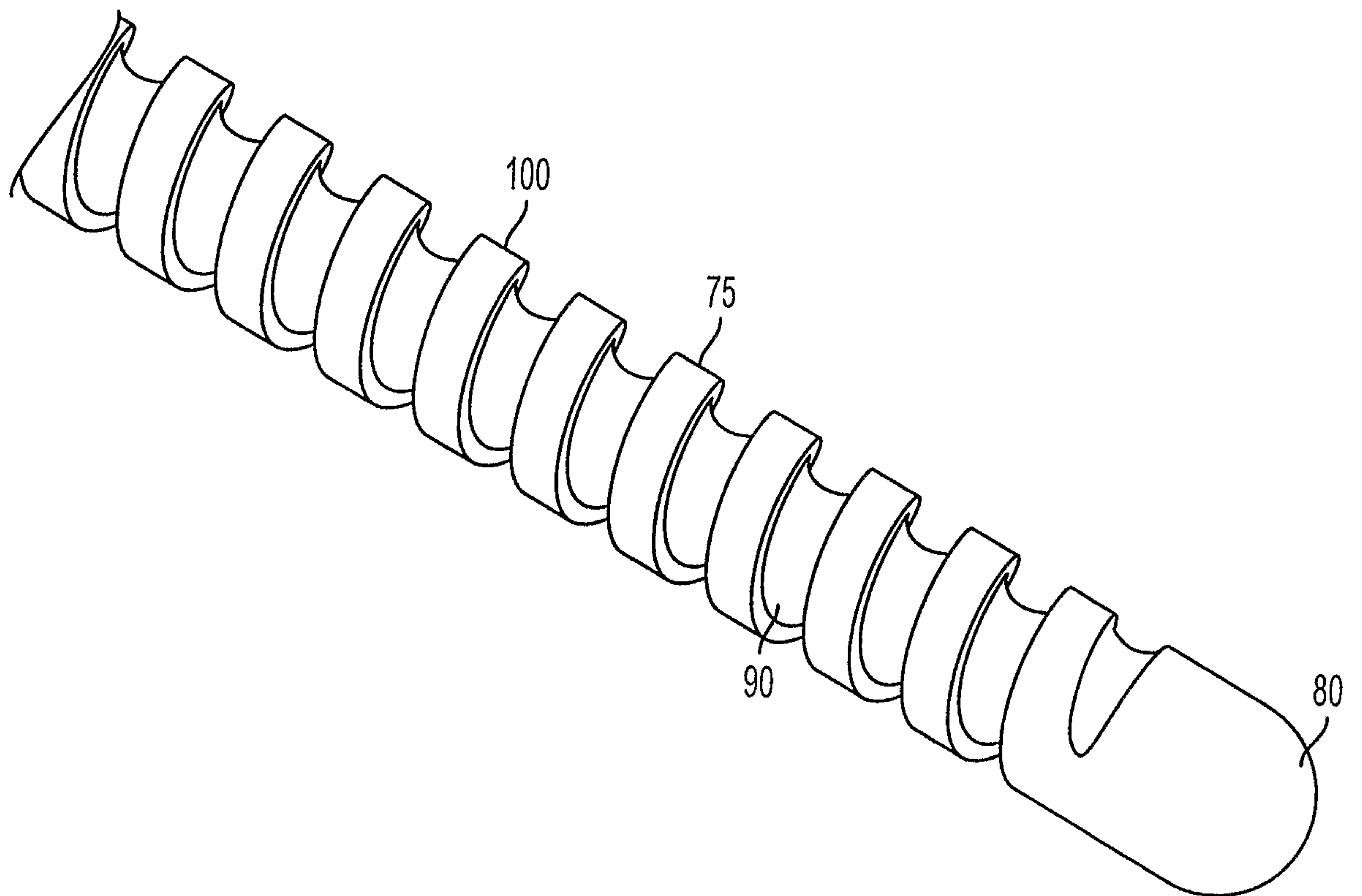


FIG. 12

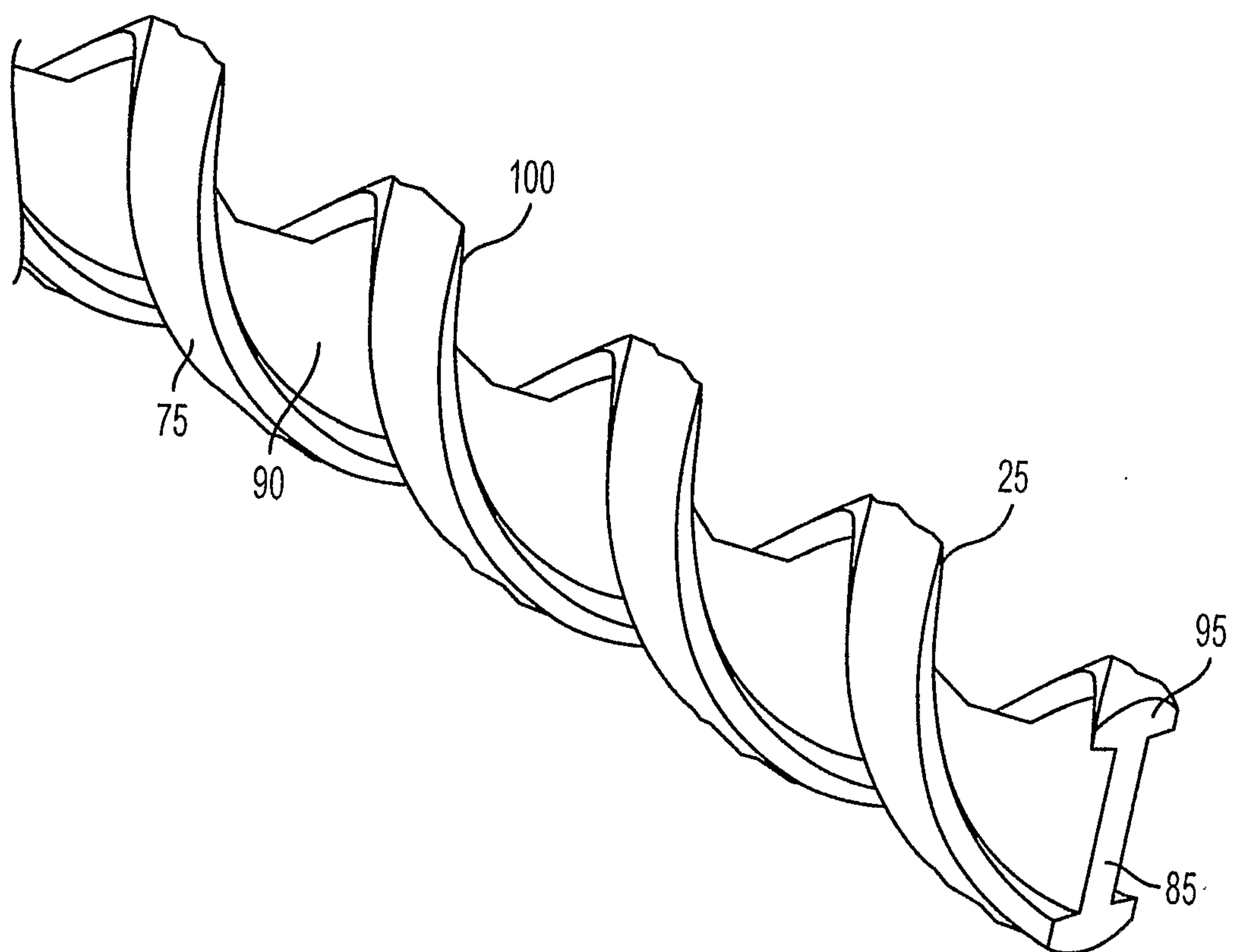


FIG. 13

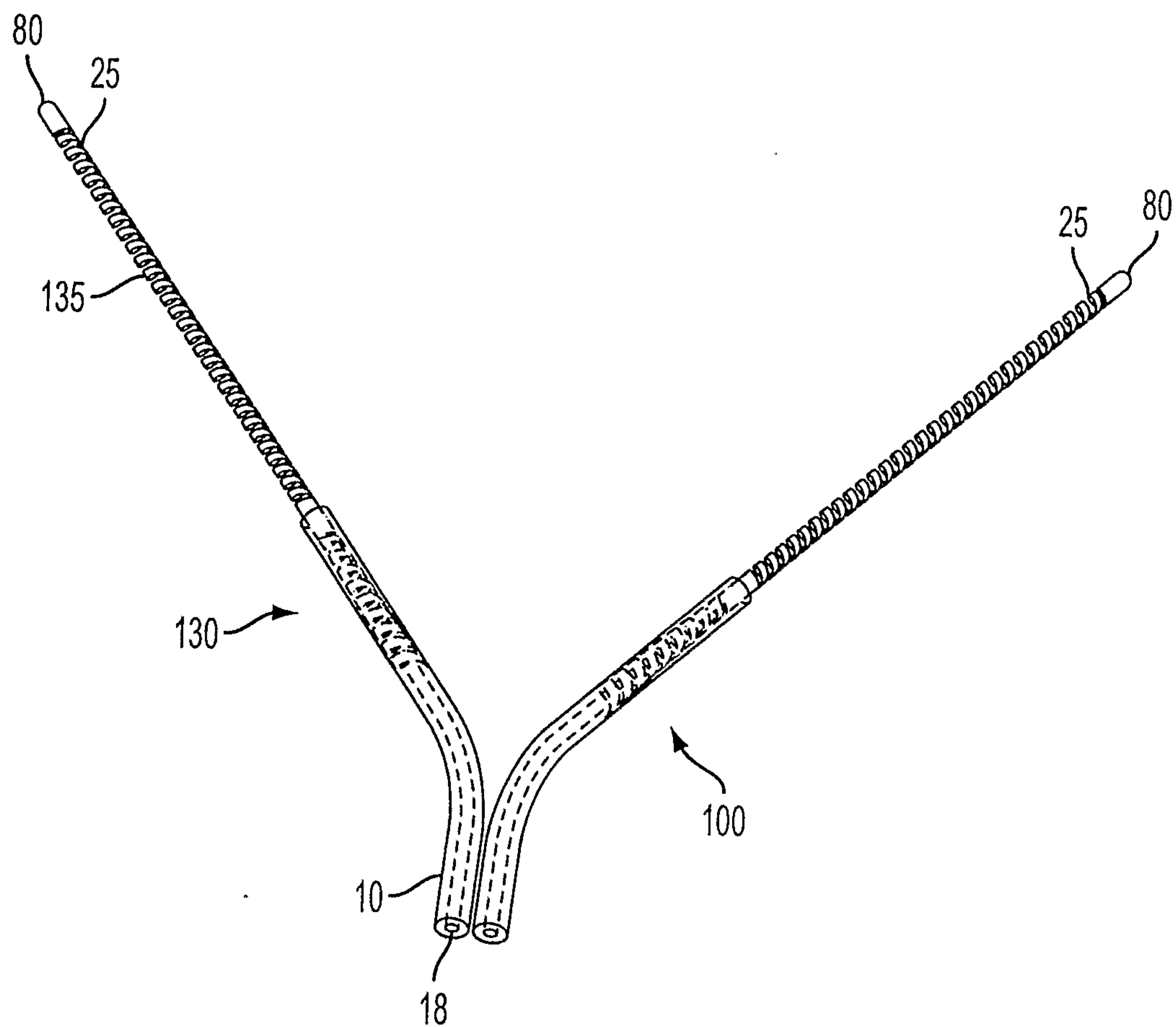


FIG. 14

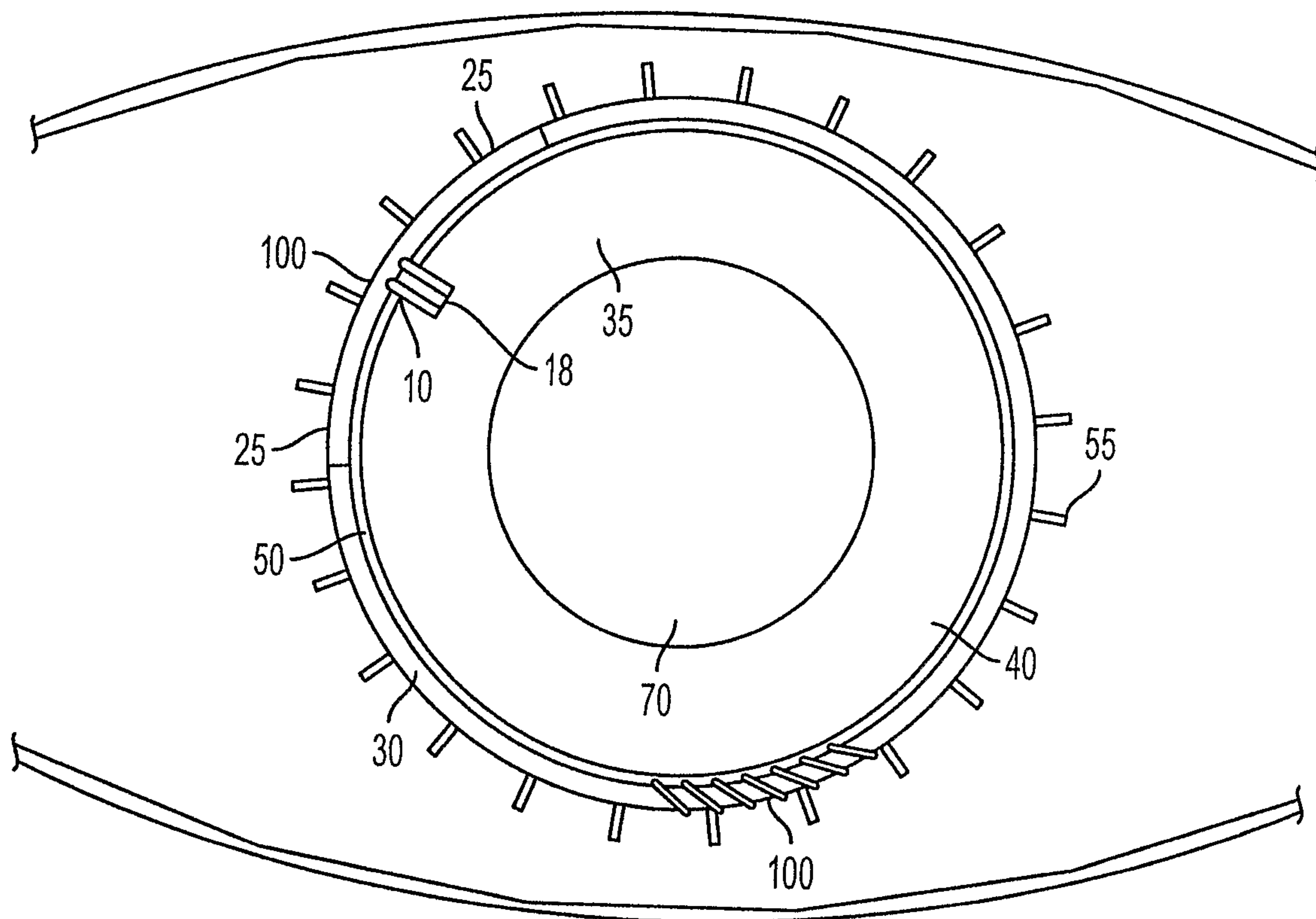


FIG. 15

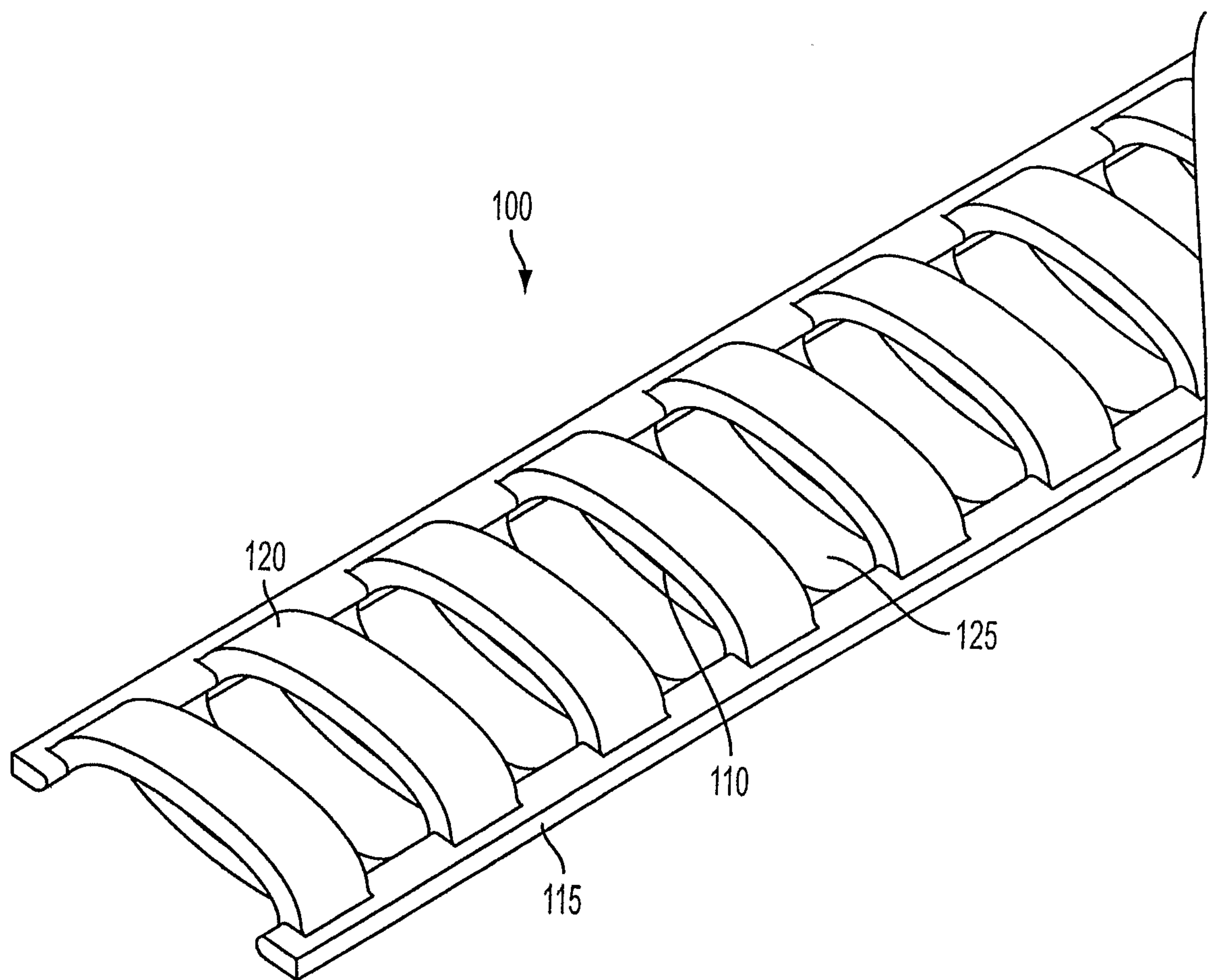


FIG. 16

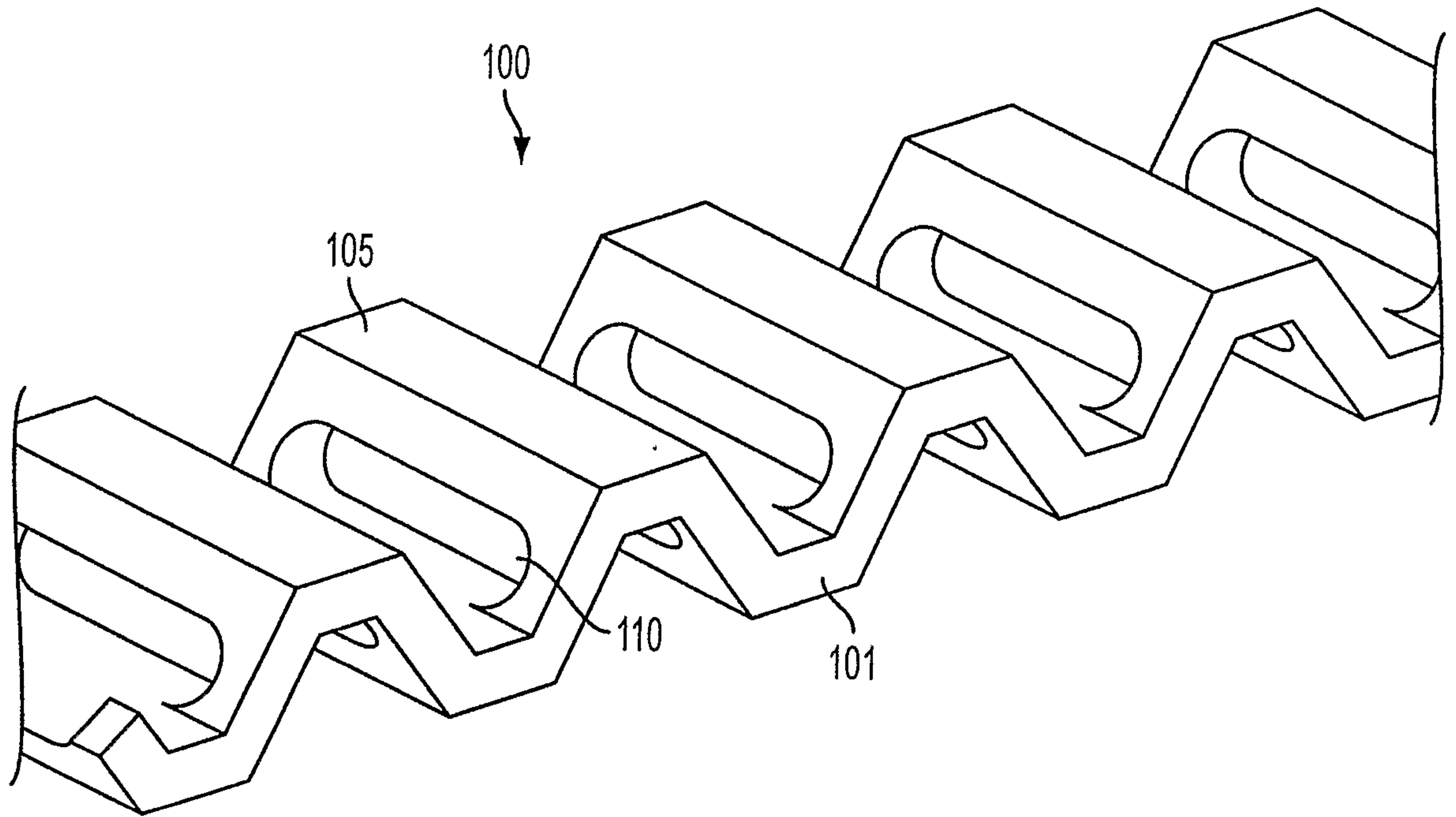


FIG. 17

