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(71) Applicant *(for all designated States except US)*: **ALCON UNIVERSAL LTD.** [CH/CH]; Bösch 69, CH-6331 Hünenberg (CH).

(72) Inventor; and

(75) Inventor/Applicant *(for US only)*: **MAASKAMP, Armand** [US/US]; 22315 Clearbrook, Mission Viejo, CA 92692 (US).

(74) Agents: **LEE, W., David** et al.; Alcon Research Ltd., Mail Code: Q-148, 6201 South Freeway, Fort Worth, TX 76134 (US).

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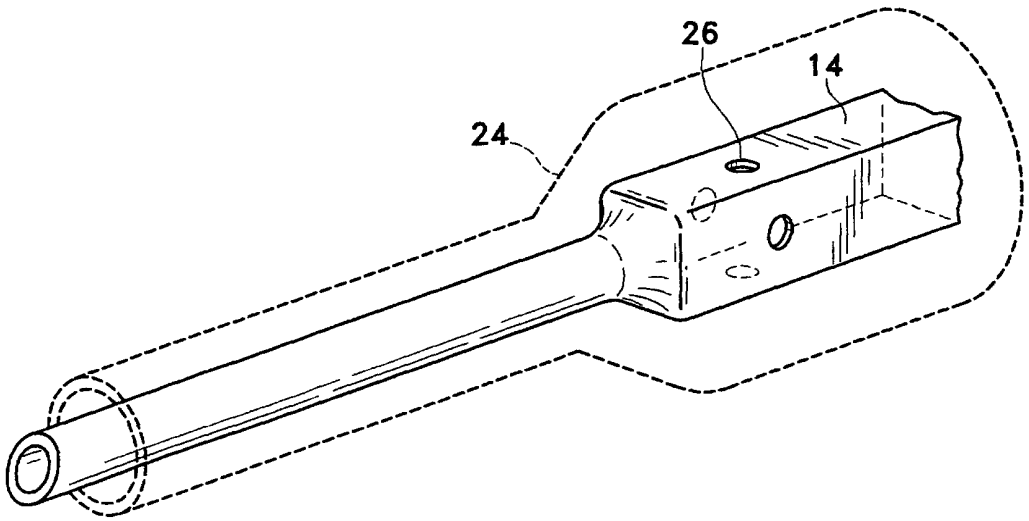
(54) Title: PHACO-EMULSIFICATION NEEDLE



(57) Abstract: A tip for a phaco-emulsification handpiece is disclosed. The geometry of the tip advantageously minimizes cavitation of the irrigation fluid supplied by the handpiece. The tip may be formed with shunt flow orifices that minimize the dangers of overpressure of the eye and eye chamber collapse when the tip of the needle becomes occluded. Various advantageous geometries and locations of the shunt flow orifices are disclosed.

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PHACO-EMULSIFICATION NEEDLE

FIELD OF THE INVENTION

This invention relates to irrigation/aspiration needle devices for the ophthalmic surgery field, and more particularly to ultrasonically energized needles used in phaco-emulsification procedures.

BACKGROUND OF THE INVENTION

Current ophthalmic surgery systems, such as are used for cataract removal, employ the phaco-emulsification procedure in which a needle, inserted through an incision in the eye, is ultrasonically agitated to break up capsular and tissue material. In the current state-of-the-art, the incision is very small, on the order of 2 mm. The needle is at the end of a handpiece held by the surgeon, which handpiece also generates the ultrasonic axial motion. The end of the handpiece mounts not only the needle but an encompassing infusion sleeve, since an infusion or irrigation liquid is to be passed into the eye chamber via the space between the needle and the sleeve. A hollow bore in the center of the needle is coupled to a suction source for aspiration of the matter that is being fragmented within the eye.

The flows of irrigation fluid into the eye chamber and aspirated material out of the eye chamber must be balanced adequately, if no exactly, since the eye cannot be allowed to collapse, which might cause irreparable harm. However, capsular material in the eye is drawn into the tip of the needle and clogs it, at least momentarily, before being broken down by the ultrasonic action. Intermittent clogging in this manner is not to be avoided, because it enables faster reduction of the capsular material under ultrasonic action, and thereby shortens the length of the surgical procedure. In conjunction with the very small incision in the eye, a reduction in duration of the procedure reduces the trauma and psychological problems associated with cataract removal and lens implantation. To this end, some workers in the art have increased the pressure differential, or suction level, sometimes to as much as 500 mm Hg or more, thus further reducing the time needed to complete extraction. This in turn requires a higher flow rate of irrigation fluid moving into the eye and makes the balance of flows more critical. It is readily understood that

higher suction increases the danger of eye collapse, and that any suction surge in the line can result in a dangerous momentary imbalance.

While the surgeon has controls to regulate and terminate flow, it is not possible for the surgeon to respond reliably to suction surges that result from momentary needle clogging. An expedient that is used to avoid this problem is to provide a "lateral pre-aspiration orifice" in the needle, within the area covered by the infusion sleeve. This orifice ensures that there is some flow into the interior of the needle even if the tip of the needle is clogged, so that the tendency of a peristaltic pump, much used in modern systems, to cause a suction surge is counteracted to a degree at all times. The Wuchinich patent, U.S. Patent No. 4,493,694 for a "Surgical Pre-Aspirator" is illustrative of this approach.

There are also mechanical problems with these needle systems, resulting in some part from the tendency to make them smaller in size, more fragile, and thus more likely to be damaged and not reusable. The threaded male end of the needle must be mated into the threaded female end of the hub in the handpiece, in order to be secure under ultrasonic vibration. Often, the needle cannot be removed readily because the thread engagement tends to become more secure, and for this purpose flat surfaces, called wrench flats, are provided adjacent the threaded portion of the needle. Even with the wrench flats, an unacceptable percentage, often as high as 30%, of these needles are damaged during attempted removal.

The wrench flats are necessarily substantially bigger than the needle, so that a tapered merger region is disposed between the distal end of the needle and the wrench flats. The tapered region introduces another problem, for when the needle is ultrasonically vibrated, the tapered region presents a surface area nonparallel to the direction of the ultrasonic vibration which generates ultrasonic waves within the irrigation fluid. These waves are then reflected and re-reflected within the area between the needle and the infusion sleeve. At one or more points along the reflection path of these ultrasonic waves the fluid will begin to resonate and points of maximum and minimum pressure will be created, introducing cavitation and bubbles in the fluid which are deleterious to body tissue and must be avoided. Accordingly, to eliminate the cavitation, this type of design requires a "decoupler" to ensure that bubbles are not present in the irrigation fluid.

It is therefore desirable to provide a needle which not only functions to balance irrigation and aspiration flows and counteract suction surges, but is physically robust and at the same time avoids the cavitation problem.

SUMMARY OF THE INVENTION

These and other objectives are met by a phaco-emulsification needle in which a substantial proportion of a proximal end of the needle is threaded to engage into a handpiece and incorporates longitudinal wrench flats which extend for a substantial length inside an inner sleeve which forms a part of the distal end of the handpiece. One or more shunt flow orifices are formed in the needle walls in the distal end of the needle and/or the wrench flat area. The proximal end of the needle and the distal end of the handpiece are substantially encompassed by a flexible outer infusion sleeve which detachably engages the inner sleeve of the handpiece but stops short of covering the needle tip. The transition between the wrench flats and the distal end of the needle is curved but of short length and placed beyond the inner sleeve so that complex reflections and re-reflections are not transmitted via the irrigation fluid between the needle and the inner sleeve, and consequently cavitation is not introduced.

The extended length of wrench flat enables a much wider distribution of the torque that is generated when a wrench is turned, and therefore lower force loading on the wrench flat when it is time to disengage the needle from the handpiece, consequently reducing damage rates to a minimum. The shunt flow orifices in the distal end of the needle and/or the wrench flats divert increased fractions of irrigation fluid into the aspiration flow path during momentary clogging of the needle tip to prevent increased suction forces from the peristaltic pump and the resulting suction surge from affecting flow balance when the clogged matter breaks free. The reduced suction surge when occluded material breaks free minimizes momentary flow imbalances and improves fluid stability within the eye chamber.

BRIEF DESCRIPTION OF THE DRAWINGS

For a more complete understanding of the present invention, and for further objects and advantages thereof, reference is made to the following description taken in conjunction with the accompanying drawings in which:

Fig. 1 is a side sectional view of an example of a needle coupled to a handpiece (shown partially) and having shunt flow orifices and substantially encompassed by a

flexible outer infusion sleeve in a device in accordance with the invention;

Fig. 2 is a more detailed side sectional view of the Fig. 1 example of the wrench flat area of a needled coupled to a handpiece (shown partially);

Fig. 3 is an enlarged side sectional view of an example of a distal end of a needle with shunt flow orifices substantially encompassed by a flexible outer infusion sleeve in accordance with the invention;

Fig. 4 is a perspective view of an example of a needle with shunt flow orifices in the wrench flat area, providing an alternative example in accordance with the invention;

Fig. 5 is a perspective view of the distal end of a curved needle with shunt flow orifices in accordance with the invention;

Fig. 6 is a side sectional view of an example of a shunt flow orifice in the wall of a needle in accordance with the invention;

Fig. 7 is a side sectional view of another example of a shunt flow orifice in the wall of a needle in accordance with the invention;

Fig. 8 is a side sectional view of another example of a shunt flow orifice in the wall of a needle in accordance with the invention; and

Fig. 9 is a side sectional view of another example of a shunt flow orifice in the wall of a needle in accordance with the invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

Figs. 1 and 2 are side sectional views of an advantageous version of a phaco-emulsification needle coupled to a handpiece (shown partially) and substantially encompassed by a flexible outer infusion sleeve. The needle is specifically designed for phaco-emulsification procedures for ophthalmic surgery. Referring to Figs. 1 and 2, the invention comprises a hollow needle 10 of small outer diameter (e.g. about 0.0365 inches or less) at its tip, to be inserted into an eye chamber through a small incision. In a representative embodiment, the distal end of the needle is a thin, hollow, elongated cylinder for emulsifying and withdrawing body material through an open end 12 and into a hollow central bore 18. Towards the proximal end, the needle exterior curves in a transition region 13 to a second, elongated, thicker area that is no longer cylindrical, but faceted with flat surfaces or "wrench flats" 14 for engagement by a special wrench. At the extreme proximal end of the needle the wrench flats merge into a threaded length 16 which engages a mating thread on the handpiece 20.

The handpiece may include an inner sleeve 22 which surrounds a part of the wrench flats 14 but stops short of covering the entire wrench flat area. The extending wrench flat areas may be more readily engaged by a special wrench 34 (shown in dotted line form in Fig. 2 only) used to couple and decouple the needle to the handpiece. The proximal end of the needle and the distal end of the handpiece are substantially encompassed by a flexible outer infusion sleeve 24, which detachably engages the inner sleeve of the handpiece but stops short of covering the needle tip. However, the outer infusion sleeve extends far enough distally to cover one or more lateral shunt flow orifices 26 formed in the walls of the needle near (less than about 0.5 inches from) the tip, as shown in Fig. 3. In one example embodiment of the present invention, the outer infusion sleeve leaves approximately 1.0 to 2.0 mm of exposed tip.

Fig. 5 illustrates another variant of the present invention wherein the needle tip is bent to improve emulsification and the reach of the needle within the eye cavity. If a plurality of shunt flow orifices are employed as illustrated in Fig. 5, the orifices may be provided at different longitudinal positions to minimize the chance of needle breakage during ultrasonic vibration.

Alternatively, the shunt flow orifices can be placed in other regions of the needle, including the wrench flat segments as shown in Fig. 4. Such a placement enables the use of more or larger shunt flow orifices, as required, because of the increased structural integrity of the needle in the wrench flat areas. In addition, because of the lower flow rate of irrigation fluid in the wrench flat area, as compared to the flow rate near the distal end of the needle, shunt flow orifices in the wrench flats may able to shunt the irrigation fluid more efficiently than orifices near the needle tip.

In operation, the distal end of the needle is inserted into the surgical site and ultrasonically vibrated as irrigation fluid flows around it and aspirated material is withdrawn through it, being drawn by a peristaltic pump. When the ultrasonically vibrated needle tip contacts tissue such as a formed cataract in some stage of solidification, the material is emulsified and is then aspirated (suctioned) into the hollow bore of the needle and transported to a collection area.

As illustrated in Fig. 1, throughout the phaco-emulsification process the irrigation fluid 28 is fed into the eye chamber from along a gap 30 between the infusion sleeve and the wrench flats leading into the smaller gap 32 between the infusion sleeve and the

needle at the distal end. Because the wrench flats encompassed by the inner sleeve present a parallel face to the direction of ultrasonic vibration, ultrasonic waves are not readily formed in the irrigation fluid between the needle and infusion sleeve, and the formation of cavitation bubbles is minimized.

As illustrated in Fig. 3, when the open end 12 of the needle 10 is unoccluded, the aspiration flow 36 from within the eye chamber is free-flowing and predominantly through the hollow bore 18 of the needle, although a minor proportion of irrigation fluid 28 within the gap 32 may be diverted into the bore though the shunt flow orifices 26. Pressure differentials and the cross sectional area of the orifices determine the proportion of diverted flow under nominal conditions.

In ophthalmic surgery, it has long been recognized that a balance between the flow of irrigation fluid into the eye chamber and the flow of eye material and irrigation fluid out of the eye chamber is essential to prevent collapse of the eye chamber. This is described, for example, in U.S. Patent No. 3,589,363 (1971) and U.S. Patent No. 3,693,613 (1972), which are early examples of phaco-emulsification devices. During the phaco-emulsification process, some of the emulsified material drawn to the needle tip may momentarily clog the needle tip. This is desirable to a limited extent, because the contact between the ultrasonically vibrated needle tip and solidifying lens material enables quick emulsification, shortening the time required for the surgical procedure. However, momentary clogging of the needle tip causes a temporary increase in the suction force generated by the peristaltic pump. When the clogged matter breaks free, the momentary surge in the suction level may create a dangerous temporary increase in the aspiration flow rate, tending to evacuate the eye chamber. This is especially true in modern phaco-emulsification systems, which are now employing increasingly higher suction levels to shorten the ophthalmic surgical procedure. This momentary partial evacuation of the eye chamber also causes fluidic and particulate movement within the eye chamber, which is often undesirable to a surgeon. This movement within the eye chamber will continue until the eye chamber is replenished with aspiration fluid.

To counteract this effect, the shunt flow orifices of the present invention allow irrigation fluid to flow directly into the hollow bore during moments of clogging at the tip. As the hollow bore begins to occlude, aspiration flow through the needle tip begins to decrease, while correspondingly increasing amounts of irrigation fluid are drawn through

the shunt flow orifice. The flow of irrigation fluid through the shunt flow orifice reduces the pressure differential between the outside and the inside of the needle, and a vacuum effect builds more slowly than without a shunt flow orifice. In addition, the reduced pressure differential counteracts aspiration flow surges by reducing the likelihood of total occlusion at the hollow bore. The shunting of irrigation fluid through the shunt flow orifice also lowers irrigation fluid flow rates into the eye until the clogging material clears. The dangers of overpressure in the eye, on the one hand, and eye chamber collapse, on the other, are thus reduced.

Because the shunt flow orifice reduces the pressure differential and minimizes the likelihood of total occlusion, the flow within the hollow bore between the tip of the needle and the shunt flow orifice usually remains dynamic as some amount of aspiration occurs through the only partially occluded tip. This aspiration flow allows material within the hollow bore near the tip to be evacuated even during moments of partial tip occlusion, which reduces the time it takes to return the hollow bore to its unclogged state once the occlusion breaks free.

In the present invention, the dimensions of the needle, bore and shunt flow orifices are selected with respect to the operating parameters of the handpiece, and infusion sleeve, as well as the pressure of the irrigation fluid and the suction within the hollow needle, to ensure the proper balance of flows into and out of the eye chamber, as well as modified response to surge conditions. Many combinations of the above parameters may be combined with varying effect. For example, for needles with a diameter of 0.9 mm operating with a vacuum of 50 mm Hg, a shunt flow orifice may be designed to produce a shunt flow rate of 4 cc/min at full occlusion. Alternatively, the same needle operating with a vacuum of 400 mm Hg may employ a shunt flow orifice designed to produce a shunt flow rate of 11 cc/min at full occlusion. For needles with a diameter of 1.1 mm operating with a vacuum of 50 mm Hg, shunt flow orifice may be designed to produce a shunt flow rate 6 cc/min at full occlusion. Alternatively, the same needle operating with a vacuum of 400 mm Hg may employ a shunt flow orifice designed to produce a shunt flow rate of 15 cc/min.

The shunt flow rate at full occlusion has a direct correlation to the response of the needle to surge conditions. For example, if the needle design and suction force from the peristaltic pump results in an unoccluded aspiration rate through the hollow bore of 45

cc/min, and the shunt flow orifice is designed such that 11 cc/min of irrigation fluid is drawn through the orifice during total tip occlusion, the flow into the hollow bore will be reduced by approximately 11 cc/min at occlusion break.

Figs. 6-9 illustrate possible variants of the shunt flow orifice in the wall of the distal end of the needle or the wrench flats. Fig. 6 illustrates the basic approach where the orifice side walls are perpendicular to the direction of irrigation and aspiration flows. This approach is also easiest from a manufacturing standpoint, using precision lasers to drill the orifices. Figs. 7-9 illustrate variants which increase the shunt flow of irrigation fluid through an orifice of given cross-sectional area. Fig. 7 illustrates an orifice angled in the direction of irrigation flow. Fig. 8 illustrates an orifice with a larger opening on the irrigation flow side. Fig. 9 illustrates a perpendicularly formed orifice with protrusions 38 located in the distal side of the orifices. These protrusions create an area of increased fluid pressure 40 in the irrigation flow stream, and an area of decreased fluid pressure 42 in the aspiration flow stream. The resulting pressure differential increases the shunt flow of irrigation fluid through the orifice.

It is believed that the operation and construction of the present invention will be apparent from the foregoing description. While the apparatus and methods shown or described above have been characterized as being preferred, various changes and modifications may be made therein without departing from the spirit and scope of the invention as defined in the following claims.

WHAT IS CLAIMED IS:

1. A tip for a phaco-emulsification handpiece, comprising:

a hollow needle having a first portion with a distal, open end, a second portion for removably coupling to a phaco-emulsification handpiece and having an outer surface with wrench flats, and a transition region disposed between said first portion and said second portion;

wherein said transition region has a length shorter than a length of said first portion or a length of said second portion.

2. The tip of claim 1 wherein, when said second portion is coupled to a phaco-emulsification handpiece having an inner sleeve, said transition region is located beyond a distal end of said inner sleeve.

3. A tip for a phaco-emulsification handpiece comprising a hollow needle having a plurality of orifices passing from an outer surface to an inner bore of said hollow needle, each of said orifices disposed at a different position along a longitudinal axis of said hollow needle.

4. The tip of claim 3 wherein, when said tip is coupled to a phaco-emulsification handpiece having a flexible outer sleeve, at least one of said plurality of orifices is angled in a direction of a flow of irrigation fluid between said flexible outer sleeve and said hollow needle.

5. The tip of claim 3 wherein at least one of said plurality of orifices has a diameter on an outer surface of said hollow needle larger than a diameter on an inner surface of said hollow needle.

6. The tip of claim 3 wherein at least one of said plurality of orifices has

a generally annular protrusion disposed on a distal side of said one of said plurality of orifices.

7. A tip for a phaco-emulsification handpiece, comprising:

a hollow needle having a first portion with a distal, open end, a second portion for removably coupling to a phaco-emulsification handpiece and having an outer surface with wrench flats, and a transition region disposed between said first portion and said second portion;

wherein said second portion has an orifice passing from said outer surface to an inner bore of said second portion.

8. The tip of claim 7 wherein said second portion has a plurality of orifices passing from said outer surface to said inner bore of said second portion.

9. The tip of claim 7 wherein, when said tip is coupled to a phaco-emulsification handpiece having a flexible outer sleeve, said orifice is angled in a direction of a flow of irrigation fluid between said flexible outer sleeve and said hollow needle.

10. The tip of claim 7 wherein said orifice has a diameter on an outer surface of said second portion larger than a diameter on an inner surface of said second portion.

11. The tip of claim 7 wherein said orifice has a generally annular protrusion disposed on a distal side of said orifice.

12. A tip for a phaco-emulsification handpiece, comprising:

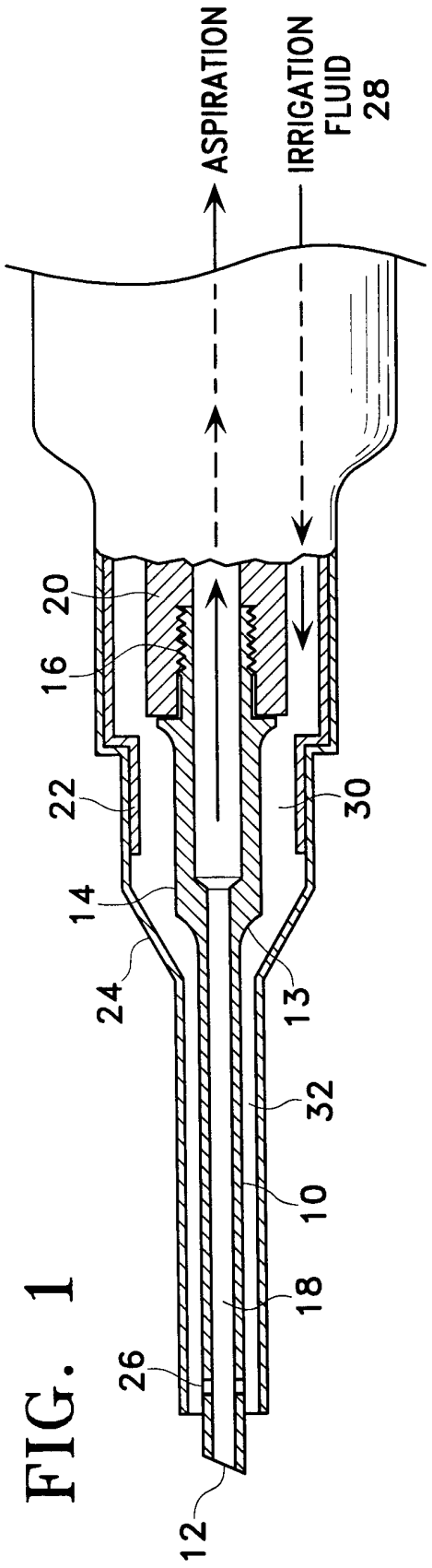
a hollow needle having a distal, open end, a proximal end for removably coupling to a phaco-emulsification handpiece, and a plurality of wrench flats disposed between said distal and proximal ends;

wherein when said needle is ultrasonically vibrated by said handpiece, each of said wrench flats presents a generally parallel surface to a direction of said ultrasonic vibration.

13. The tip of claim 12 wherein:

said handpiece comprises an inner sleeve; and

wherein said wrench flats are at least partially surrounded by said inner sleeve when said needle is coupled to said handpiece.


ASPIRATION
IRRIGATION FLUID 28
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12

FIG. 1

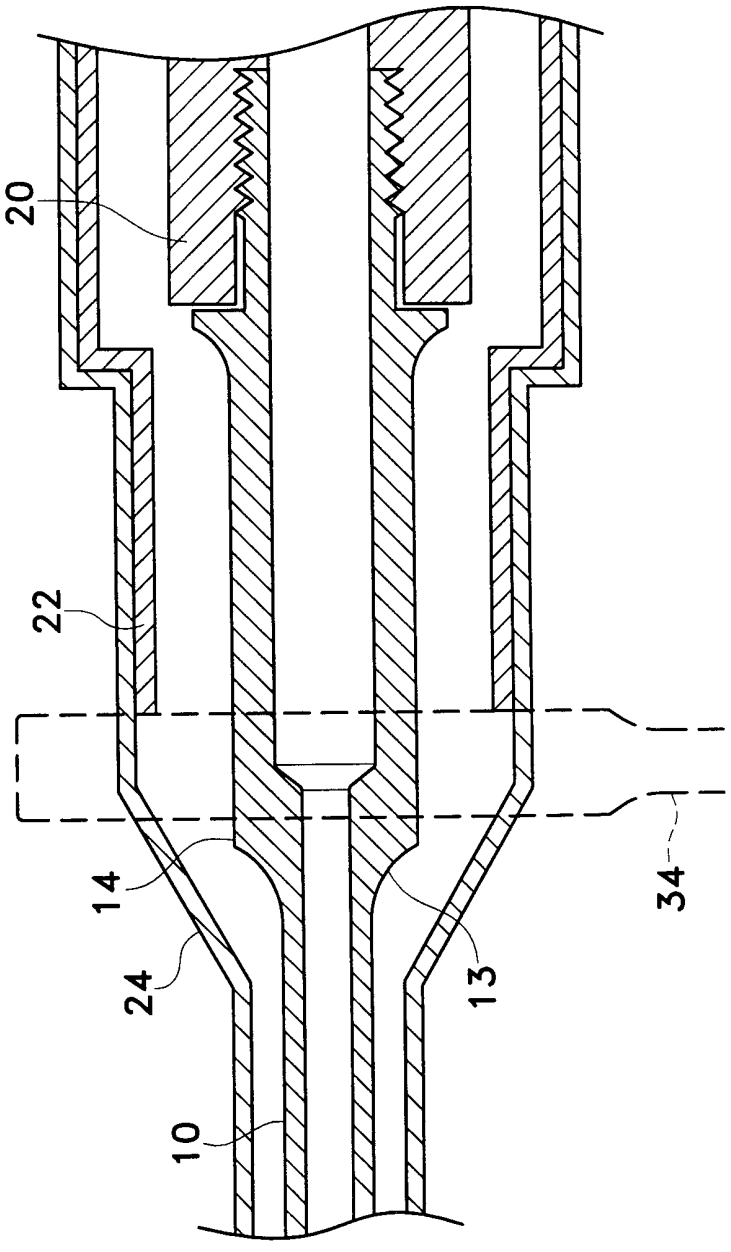
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FIG. 2

FIG. 3

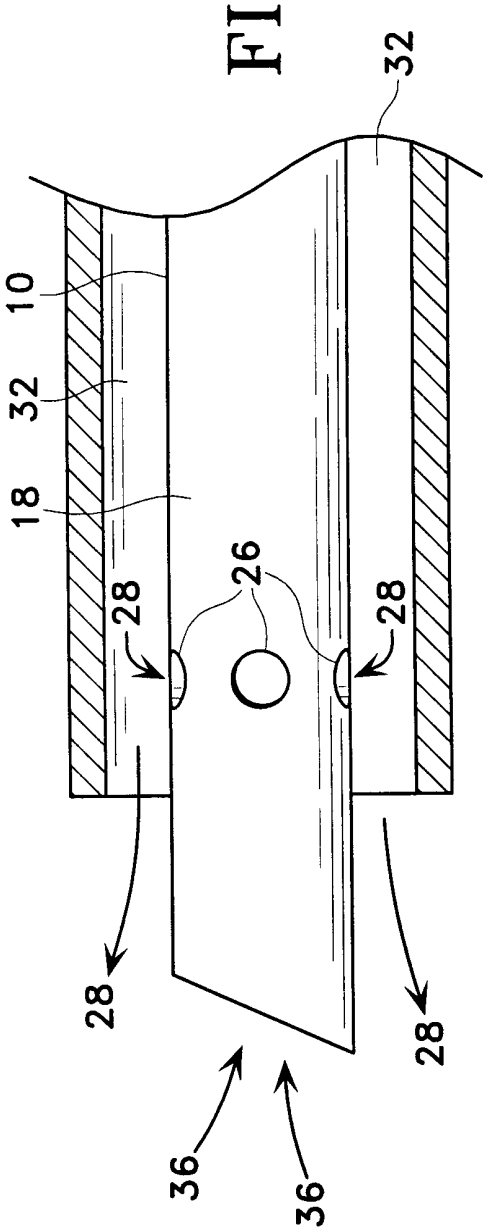


FIG. 4

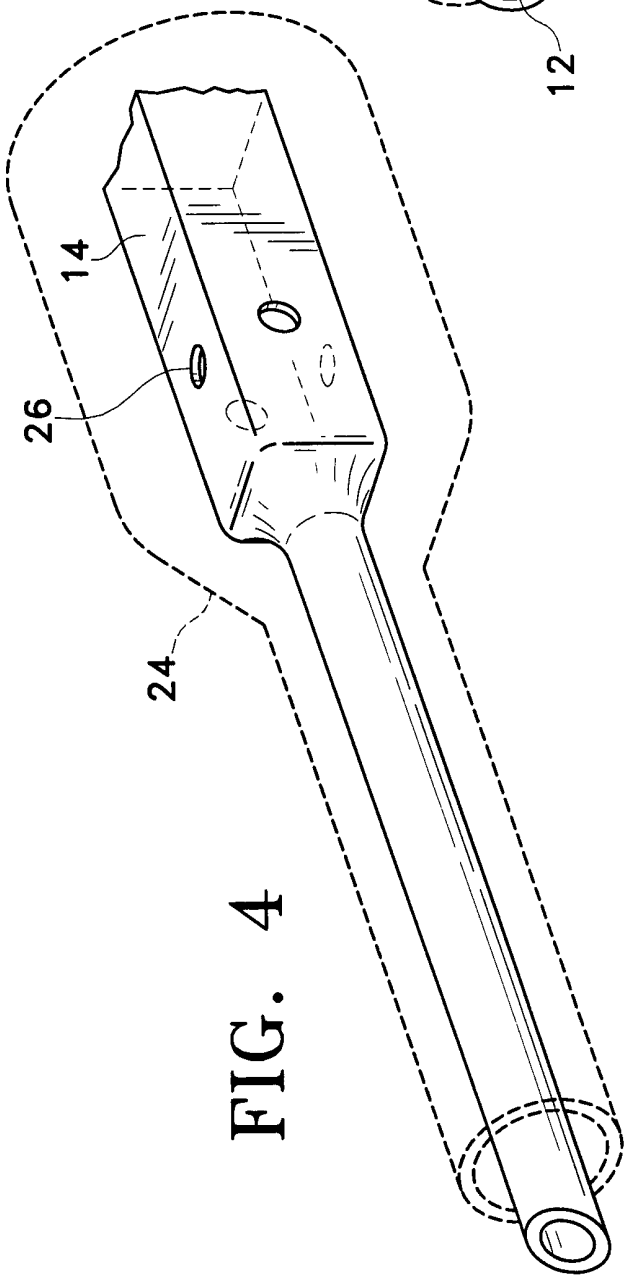
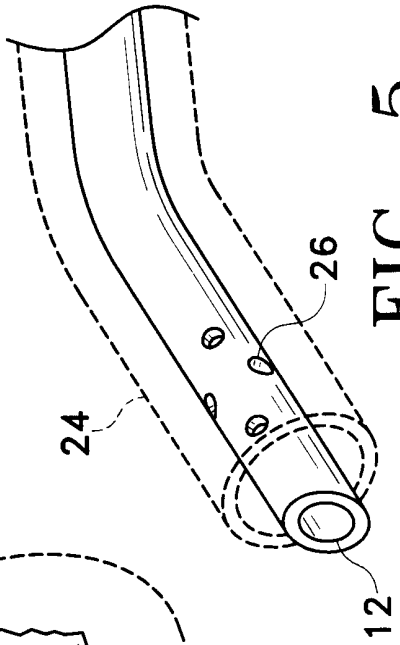


FIG. 5



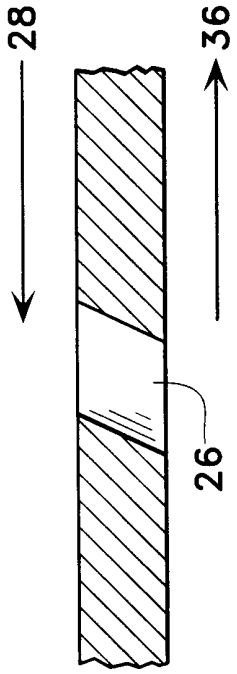


FIG. 7

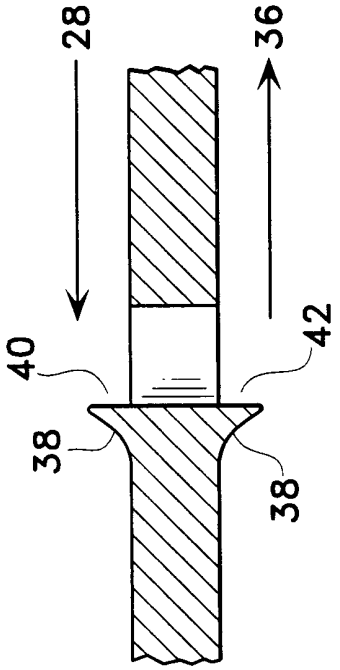


FIG. 9

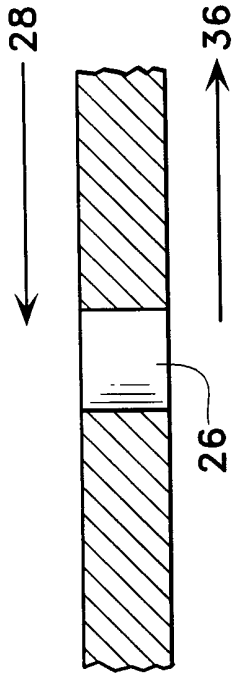


FIG. 6

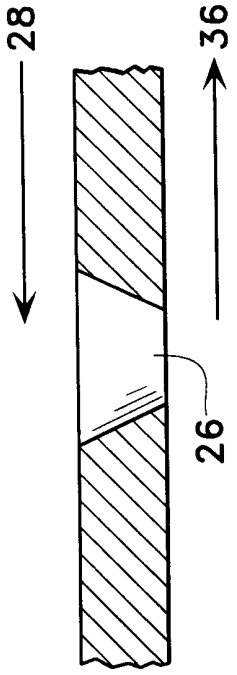


FIG. 8