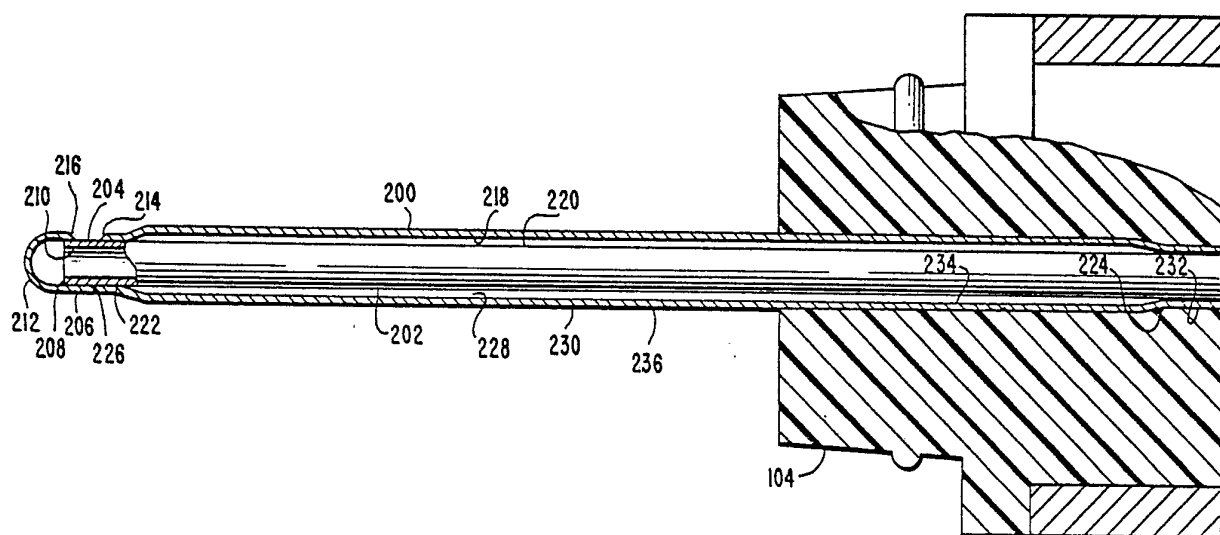




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(54) Title: INTRAOCULAR SURGICAL INSTRUMENT**(57) Abstract**

An intraocular surgical instrument includes an elongated inner tube (202) that is axially movably connected at a first end to a handpiece, and comprises a cutting edge (208) at a distal end. An elongated outer tube (200) is disposed coaxially with the inner tube (202), is connected at a first end to the handpiece, and includes a cutting edge (216) at a distal end. A first clearance (222) is provided between the inner tube and the outer tube at a first rearward region (224) and a second region (226) adjacent to the cutting edges, such that the cutting edges are maintained in a cutting relationship. A second clearance, larger than the first clearance, is provided at a third region (228) disposed between the first and second regions.

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INTRAOCULAR SURGICAL INSTRUMENTBACKGROUND OF THE INVENTION

This invention relates to intraocular surgical instruments and more particularly to instruments adapted
5 to vitrectomy surgery that incorporate reciprocating cutters.

It is sometimes necessary to surgically remove a portion of the vitreous body of the eye in order to eliminate opaque regions of the body, blood, retinal
10 tissue and the like. The vitreous body has a jelly-like consistency, requiring that portions to be excised be cleanly cut off from the remaining portion of the vitreous body. One method of severing vitreous portions involves the use of a surgical instrument that comprises
15 coaxial slender tubes and which is inserted into the region of the vitreous to be removed. The outer tube has an orifice with a sharp cutting edge on the internal surface of the tube, while the inner tube has a sharp cutting edge formed on its outer periphery. The portion
20 of the vitreous body to be excised is pulled into the orifice in the outer tube by suction applied to the inner tube, and the portion is severed by moving the cutting edge of the inner tube past the cutting edge of the outer tube in a reciprocating fashion.

25 It is important that the cutting edges of the reciprocating tubes of such instruments fit together closely in order to provide a good cutting action. If the cutting edges do not cooperate properly, there is a danger that a portion of the vitreous body might become
30 trapped between the outer wall of the inner tube and the inner wall of the outer tube. This is a serious problem because tissue that becomes trapped is difficult to cut cleanly away from the remaining vitreous body, and further movement of the instrument may cause tension on
35 the vitreous body that may damage the retina.

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Various means have been provided for effecting the proper orientation of the cutting edges of the inner and outer tubes in order to clearly sever the portion of vitreous body to be removed. In most of the prior art devices, this objective is addressed by providing minimal clearance between the internal wall of the outer cutter tube and the external wall of the inner cutter tube along the entire length of their adjacency. While this arrangement helps to ensure the proper orientation of the tubes at the point where the cutting edges meet, it has caused a considerable amount of friction between the two walls.

In an attempt to overcome the problem of friction while retaining a proper alignment at the cutting edges, a longitudinal portion of the outer tube has been cut away between its two ends, as disclosed in U.S. Patent 4,246,902, issued to Martinez. In this fashion, the friction that would have otherwise occurred between the cut-away portion and the inner tube is of course eliminated, but the amount of friction caused by movement of the remaining portions against the inner tube is maintained, and the lessened structural integrity caused by the removal may also be a source of problems. In particular, the cutting away of a large longitudinal portion of one of the cutting tubes may increase the flexibility of that tube to an extent that the precise orientation of the cutting edges is lost.

In addition, prior art devices of this type are generally manufactured in a way that increases the cost of the devices and causes disposability after a single use to be impractical. For example, in U.S. Patent 4,246,902, the device is generally complex and requires a number of threaded parts.

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SUMMARY OF THE INVENTION

It is thus an object of the present invention to provide an intraocular surgical instrument adapted for vitrectomy surgery that incorporates a reciprocating cutter, wherein cutting edges of inner and outer tubes are precisely aligned in order to provide optimum cutting of a portion of the vitreous body.

It is a further object of the invention to reduce the amount of friction between the internal surface of the outer cutter tube and the external surface of the inner cutter tube of a reciprocating vitreous cutter.

It is a further object of the present invention to provide a vitrectomy instrument that is easily and inexpensively manufactured, such that the instrument is disposable after a single use.

In accordance with the present invention, these objects, and others that will become apparent from the following, are met by the provision of an intraocular surgical instrument that includes an elongated inner tube that is axially movably connected at a first end to a handpiece and that comprises a cutting edge at a distal end. An elongated outer tube is disposed coaxially with the inner tube, is connected at a first end to the handpiece, and includes a cutting edge at a distal end. A first clearance is provided between the inner tube and the outer tube at a first rearward region and a second region adjacent to the cutting edges, such that the cutting edges are maintained in a cutting relationship. A second clearance, larger than the first clearance, is provided at a third region disposed between the first and second regions.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is an elevational side view of the intraocular surgical instrument in accordance with the present invention, partially shown in section.

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Figure 2 is a detailed view of the cutter elements of the instrument of Figure 1, partially in section.

5 Figure 3 consists of detailed views of the front cap of the instrument of Figure 1, Figure 3(a) being a front view, Figure 3(b) being a side view, and Figure 3(c) being a rear view.

10 Figure 4 consists of detailed views of the barrel of the instrument of Figure 1, Figure 4(a) being a front view and Figure 4(b) being a side view, partially in section.

15 Figure 5 consists of detailed views of the rear cap of the instrument of Figure 1, Figure 5(a) being a front view and Figure 5(b) being a side view, partially in section.

Figure 6 consists of detailed views of a male part of the piston of the instrument of Figure 1, Figure 6(a) being a side view and Figure 6(b) being a front view.

20 Figure 7 consists of detailed views of a female part of the piston of the instrument of Figure 1, Figure 7(a) being a side view and Figure 7(b) being a front view.

Figure 8 consists of detailed views of a washer used in the piston of the instrument of Figure 1, Figure 8(a) being a top view and Figure 8(b) being a side view.

25 Figure 9 consists of detailed views of the tip cap and sleeve assembly of the instrument of Figure 1, Figure 9(a) being an end view, Figure 9(b) being a side view partially in section, Figure 9(c) being a front view and Figure 9(d) being a detail of a corner indicated by circular arrow d in Figure 9(b).

30 Figure 10 is an exploded side view of the handpiece with the tip cap and sleeve assembly removed.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

35 As depicted generally in Figure 1, the intraocular surgical instrument 100 of the present

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invention comprises a cylindrical barrel 102 that is enclosed at a front end with front cap 104 and at a rear end with rear cap 106. Piston 108 is disposed within the barrel between front cap 104 and rear cap 106 and a removable tip cap and sleeve assembly 110 is connected to a front surface of the front cap. Cutter assembly 112 is mounted onto a handpiece comprising barrel 102 and the parts that it holds. "Handpiece" as used herein generally refers to any apparatus onto which the cutter assembly is mounted.

The cutter assembly is detailed in Figure 2, wherein it is seen that it comprises an outer cutter tube 200 and an inner cutter tube 202. The inner cutter tube is coaxial with the outer cutter tube and is able to slide in a reciprocating fashion within the outer tube.

Both of the tubes are connected at one of their respective ends to the handpiece, and distal end 204 of the inner tube and distal end 206 of the outer tube are provided with respective cutting edges. Cutting edge 208 of the inner tube is disposed at a distal tip of the tube. It is annular in shape and defines an opening 210 through which suction is applied. In a typical embodiment, inner tube 202 is made from a 23-gauge stainless steel tube having an external diameter of 0.025 inches.

Distal end 206 of outer tube 200 is closed at distal tip 212, and cutting orifice 214 is defined within the distal end. The cutting orifice is circular and comprises cutting edge 216 which is typically ground at an angle of about 45°. As will be seen, inner tube 202 is caused to reciprocate in an axially directed fashion such that cutting edge 208 of the inner tube slides across cutting edge 216 of the outer tube. Outer tube

200 is typically made of stainless steel or the like, such as 20-gauge stainless steel tubing having an external diameter of 0.035 inches and an internal diameter of 0.027 inches.

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An important feature of the present invention involves the amount of clearance provided between internal wall 218 of the outer tube and external wall 220 of the inner tube. A first clearance 222 is provided between the two walls at a first rearward region 224 adjacent to the handpiece and a second region 226 that is adjacent to the cutting edges. A second clearance 228 is provided in a third region 230 that extends between first region 224 and second region 226.

First clearance 222 is selected such that inner tube 202 is snugly retained within outer tube 200. The close fit in second region 226 provides a tight meshing of cutting edges 208 and 216, and the close fit in first region 224 further assures a proper alignment of the edges. The clearance in these regions is typically about 0.00025 inches. In the depicted preferred embodiment, first region 224 is disposed at one end 232 of the outer tube, but the positioning of the first region at other points rearward of third region 228 to achieve the beneficial results is within the scope of the invention.

At third region 228, the diameters of the interior wall 218 of the outer tube and exterior wall 220 of the inner tube are selected so that an increased clearance is achieved. The increased clearance is provided throughout most of the length of the outer tube and results in a relatively low friction between the walls of the tubes. The increased clearance is typically selected from the range of 0.002 to 0.003 inches. In a preferred embodiment, as depicted in Figure 2, the different clearances are provided by swaging outer tube 200 at regions 224 and 226, but other means for providing the first and second clearances, as for example by reducing the diameter of exterior wall 220 of the inner tube along the third region, are also within the scope of the invention.

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The instrument of the present invention is manufactured easily and inexpensively with press-fitting parts and is disposable after a single use. As depicted in Figure 2, outer tube 200 is retained within front cap 104 by press fitting. The front cap is molded from a synthetic resin such as acrylonitrile-butadiene-styrene resin (ABS) and defines a radially distensible axial bore 234 having a diameter slightly smaller than the diameter of outer wall 236 of outer tube 200. In this fashion, outer tube 200 is connected to front cap 104 by press fitting a portion of the tube into the cap, whereupon a slight pressure exerted by the axial bore against the outer tube retains the outer tube in position.

Front cap 104 is depicted in greater detail in Figure 3. The front cap is provided with a generally cylindrical wall 300, a collar 302 disposed forwardly of the wall, and a stem 304 disposed on a front surface 306 of the collar. Annular boss 308 is provided on stem 304 and spring chamber 310 is defined within rear surface 312. Exhaust ports 314 extend from surface 312 on either side of spring chamber 310, pass longitudinally along wall 300, and exit at an outer surface 316 of collar 302. Front surface 306 defines a recess 318 for engaging tip cap and sleeve assembly 110.

Wall 300 of the front cap is slightly tapered, having a lesser diameter at the region of rear surface 312 than at a forward region adjacent to collar 302. The diameter in the region adjacent to the collar is slightly larger than an interior diameter of barrel 102, and the diameter in the region of surface 312 is less than the internal diameter of the barrel. In this way, the angle of wall 300 facilitates the entry of the rear end of the front cap into the front end of the barrel, and the engagement of the front cap to the barrel is provided by an interference fit. Axial bore 234 is integrally molded

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within the cap and serves as a mounting and guiding means for the cutting elements as depicted in Figure 2.

Cylindrical barrel 102 is depicted in more detail in Figure 4. The barrel is made of metal and preferably from an extruded aluminum tube. Wall 402 is provided in one embodiment with a key 404 that protrudes interiorly. If desired, a bore 406 is provided for receiving end cap 106. Since the barrel serves as a handpiece, it is typically provided with a diamond knurl to facilitate gripping.

Rear cap 106 is, like front cap 104, molded from a synthetic resin such as ABS and is dimensioned to provide an interference fit within the rear end of barrel 102. In the embodiment illustrated in Figure 5, the end cap is thus provided with a wall 500 that is tapered toward its front surface 502. Because of a reduced dimension of wall 500 in the area of surface 502, the end cap is easily inserted within the barrel. A collar 504 is also provided, and when end cap 106 is inserted such that collar 504 abuts wall 402 of the barrel, an interference fit is achieved by virtue of the increased diameter of the rearward region of wall 500 adjacent to the collar.

The end cap defines three bores as depicted in Figure 5. Axial bore 506 is integrally molded within the cap and serves as a guiding means for inner tube 202. As depicted in Figure 1, rear end 118 of inner tube 202 extends through the rear cap and is attached to flexible tube 120, which is connected to a source of suction in order to remove severed portions of vitreous. A second bore 508 serves as an inlet that is connected through conduit 126 to a source of pressurized gas for driving the piston in a forward direction. Bore 510 includes threads 512 for receiving an adjustment screw 114 having a knurled end 116.

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Piston 108 in a preferred embodiment comprises three parts. Male part 600 is depicted in Figure 6, female part 700 is depicted in Figure 7, and washer 800 is depicted in Figure 8. Male part 600 is provided with a head 602 and stem 604. An outer wall 606 of head 602 defines longitudinally disposed groove 608, and axial bore 610 is molded into the part. The piston is composed of a suitable synthetic resin such as ABS such that axial bore 610 is radially distensible. The diameter of axial bore 610 is selected such that it is slightly smaller than an exterior diameter of inner tube 202, such that the inner tube is held by the piston by means of a press fit.

Female part 700 is generally cylindrical in shape and is also manufactured of a suitable synthetic resin such as ABS. The female part defines a bore 702 having a diameter slightly smaller than the diameter of stem 604 of the male part, such that the two parts are joined in a press fit. A bevelled edge 612 provided on stem 610 of the male part assists in the attachment.

The piston comprises washer 800 in order to sealingly engage an annular inner surface 122 of barrel 102. In a preferred embodiment, the seal is a washer made of a highly fluorinated synthetic resin such as a polytetrafluoroethylene. Outer periphery 802 has a diameter selected to sealingly engage inner surface 122, and inner periphery 804 is selected to fit around stem 604 of the male part. As illustrated in Figure 1, washer 800 is positioned between the male and female parts before they are press fit together. In another embodiment, the piston is integrally formed with an annular groove into which an O-ring is fitted. By virtue of the sealing engagement of washer 800 and rear cap 106 with the inner surface of barrel 102 a chamber 124 is defined between the washer and the rear cap.

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In a preferred embodiment, inner tube 202 is slightly bent in a direction toward cutting orifice 214 of the outer tube, typically at an angle of about 2 to 3 degrees, at a region adjacent to the inner tube's distal end 204. By bending the inner tube in this fashion, additional pressure is applied in order to further assist in maintaining a proper meshing between cutting edges 208 and 216. The additional pressure also assists in providing a self-sharpening action of the cutting edges. In this embodiment, it is necessary to provide a suitable guide means in order to keep inner tube 202 from rotating with respect to outer tube 200. This is accomplished by virtue of the fact that inner tube 202 is held by piston 108, and piston 108 is restrained from rotational movement by virtue of the cooperation between longitudinal groove 608 of the piston and key 404 of the barrel. As can best be appreciated in Figure 1, key 404 moves within, groove 608 as piston 108 moves axially within barrel 102.

Before pressurized gas is introduced through inlet 508, into chamber 124, piston 108 is urged rearwardly by spring 126 which is disposed about inner tube 202 in spring chamber 310. The extent to which the piston is moved by the rearward urging is controlled by adjustment screw 114 which, at its tip 128, abuts a rear surface of the piston. By adjusting screw 114, the rearward extent of the reciprocating axial movement of the piston and inner tube 202 is varied.

When pressurized gas is admitted through inlet 508 into chamber 124, the pressurized gas exerts a forwardly directed force on the piston that is greater than the competing rearward force exerted by the spring causing the piston and inner tube to move forward. The piston and inner tube are caused to move axially forward and backward in a reciprocating fashion by intermittently applying pressurized gas.

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As depicted in Figure 1, a second chamber 130 is defined within barrel 102 between front cap 104 and piston 108. As described hereinabove, front cap 104 defines exhaust ports that extend from a surface in contact with the second chamber to an exterior surface of the front cap. Air that is in chamber 130 when pressurized air is supplied to chamber 124 is allowed to escape to the exterior environment through the exhaust ports.

When it is desired to provide a source of irrigation fluid to the interior of the eye, as for example in order to prevent collapse of the anterior chamber of the eye when the instrument is used therein, tip cap and sleeve assembly 110 is fitted over the outer tube. The tip cap and sleeve assembly is depicted in, detail in Figure 9. The assembly comprises tip cap 900 which is molded from a synthetic resin, for example a silicone resin, and in which is embedded sleeve 902. The internal diameter of sleeve 902 is selected such that it fits over outer tube 200. The tip cap defines an inlet 904 which is connected to a source of irrigation fluid, and the sleeve defines at least one laterally directed irrigation outlet 906 from which irrigation fluid flows into the surgical site. Annular opening 908 is provided at the rear of the cap and annular flange 910 defines a groove 912 adjacent to the annular opening.

The arrangement of flange 910 and groove 912 allows tip cap and sleeve assembly 110 to be press fitted onto front surface 306 of front cap 104. In this way, boss 308 disposed on stem 304 of the front cap is received within groove 912 after it passes through flange 910. When attached, distal tip 914 of the sleeve extends to a point adjacent to and rearward of second cutting edge 216. Irrigation outlet 906, being disposed adjacent to distal tip 914, is similarly situated adjacent to and rearward of the cutting edge.

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Preferably, there are two diametrically opposite irrigation outlets and each are maintained in a 90° alignment with cutting orifice 214 by virtue of the provision of key 916 which is provided on a rear surface of tip cap 900. When assembled, key 916 is received within recess 318 defined within front cap 104, such that rotational movement of the tip cap and sleeve assembly with respect to the cutting orifice is prevented.

By selecting appropriate interior dimensions of the cap and sleeve, an annular channel is provided for conducting the irrigation fluid from inlet 904 to outlet 906. In the depicted embodiment, the interior dimensions of the cap allow for the flow of irrigation fluid over stem 304 of front cap 104. The internal diameter of sleeve 902 is greater than an external diameter of outer tube 200 in order to allow fluid to pass between the outer tube and the inner surface of the sleeve. At distal end 914, the diameter of the sleeve is reduced so that irrigation fluid passes through irrigation outlets 906 rather than the distal end.

Figure 10 shows the tip cap and sleeve assembly 110 disengaged from the front cap 104 and removed from the handpiece. The dashed lines show how the tip cap and sleeve assembly 110 is fitted over the outer cutter tube 112 and onto the front cap 104 of the handpiece.

Having thus described the invention in terms of a detailed embodiment, it will be readily apparent to those skilled in the art that many modifications and variations may be introduced without departing from the inventive scope of the present teachings.

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CLAIMS

2 1. An intraocular surgical instrument
3 comprising:

4 a handpiece;

5 an elongated inner tube axially movably
6 connected at a first end to said handpiece and comprising
7 a first cutting edge at a second end; and

8 an elongated outer tube disposed coaxially about
9 said inner tube, connected at a first end to said
10 handpiece, and comprising a second cutting edge at a
11 second end.

12 wherein a first clearance is provided between
13 said inner tube and said outer tube at a first rearward
14 region and a second region adjacent to said cutting edges,
15 such that said cutting edges are maintained in a cutting
16 relationship, and wherein a second clearance, larger than
17 said first clearance, is provided at a third region
18 disposed between said first and second regions.

20 2. The instrument of claim 1, wherein said
21 first region is disposed adjacent to said first end of
22 said outer tube.

24 3. The instrument of claim 1, wherein said
25 first clearance is about 0.00025 inches.

27 4. The instrument of claim 1, wherein said
28 second clearance is about 0.002 to 0.003 inches.

30 5. The instrument of claim 1, wherein said
31 first clearance is provided by a reduced internal diameter
32 of said outer tube in said first and second regions.

34 6. The instrument of claim 1, wherein said
35 first cutting edge is disposed about an annular tip of

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1 said inner tube and wherein said second cutting edge is
2 disposed on an edge of a cutting orifice defined within
3 said second end of said outer tube, such that said first
4 cutting edge slides across said second cutting edge when
5 said inner tube is axially moved.

6
7 7. The instrument of claim 6, wherein a distal
8 tip of said outer tube is closed, said inner tube is
9 hollow and comprises an opening defined by said first
10 cutting edge, and a suction is provided through said inner
11 tube such that severed material is sucked through said
12 cutting orifice and said inner tube.

13
14 8. The instrument of claim 6, wherein said
15 second end of said inner tube is bent in a direction of
16 said cutting orifice of said outer tube and said
17 instrument is provided with a guide means to prevent a
18 rotational movement of said inner tube.

19
20 9. The instrument of claim 8, wherein said
21 guide means comprises a key disposed on an interior wall
22 of said handpiece and a piston having a wall that defines
23 a longitudinally disposed groove, said piston being
24 connected to said inner tube, wherein said piston is
25 contained within said handpiece and is adapted to move
26 axially such that said key moves within said groove.

27
28
29 10. The instrument of claim 1, wherein said
30 hand piece comprises:

31 a barrel open at both ends;

32 a front cap defining an axial bore adapted to
33 hold said outer tube and through which said inner tube
34 passes, said axial bore having a diameter slightly smaller
35 than an outer diameter of said outer tube such that said

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1 outer tube is press fitted into said axial bore, said
2 front cap further comprising a tapered outer wall having a
3 diameter at a forward end that is slightly larger than an
4 interior diameter of said barrel such that said front cap
5 is press fitted into said barrel; and

6 a rear cap defining an axial bore through which
7 said inner tube passes, said rear cap further comprising a
8 tapered outer wall having a diameter at a rearward end
9 that is slightly larger than an interior diameter of said
10 barrel, such that said rear cap is press fitted into said
11 barrel.

12

13 11. The instrument of claim 10, wherein said
14 handpiece further comprises:

15 a piston disposed between said front and rear
16 caps, said piston defining an axial bore through which
17 said inner tube passes, said bore of said piston having a
18 diameter slightly smaller than an exterior diameter of
19 said inner tube such that said inner tube is press fit
20 within said bore, said piston further comprising a member
21 that sealingly engages an annular inner surface of said
22 barrel such that a chamber is defined between said member
23 and said rear cap;

24 a biasing means adapted to rearwardly urge said
25 piston; and

26 an inlet to said chamber connected to a source
27 of pressurized gas, wherein a forwardly directed force
28 exerted on said piston by said pressurized gas when said
29 gas is caused to enter said chamber is greater than a
30 competing force of said biasing means such that said
31 piston moves forward when said gas enters said chamber.

32

33 12. The instrument of claim 11, wherein said
34 piston comprises a male and a female part, said female
35 part having an interior diameter slightly smaller than an

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1 exterior diameter of said male part such that said parts
2 are press fitted together and said member is retained
3 between said press fitted parts.

4
5 13. The instrument of claim 11, wherein said
6 front cap defines at least one exhaust port extending from
7 a surface in contact with a second chamber, defined in
8 part by said piston, to an exterior surface of said front
9 cap such that air passes through said port between said
10 second chamber and an exterior environment when said
11 piston is axially moved.

12
13 14. The instrument of claim 11, wherein said
14 rear cap further defines a threaded bore and comprises an
15 adjustment screw, said screw having an end that extends a
16 variable amount into said chamber and abuts a rear surface
17 of said piston when said piston is rearwardly urged.

18
19 15. The instrument of claim 10, further
20 comprising a tip cap and sleeve assembly defining an inlet
21 for an irrigation fluid, at least one irrigation outlet
22 disposed adjacent to a distal end of said sleeve, said
23 distal end being disposed adjacent to and rearward of said
24 second cutting edge, and a channel connecting said inlet
25 to said irrigation outlet, said assembly further defining
26 an annular opening and comprising an annular flange that
27 defines a groove adjacent said annular opening, wherein a
28 front surface of said front cap comprises a stem having an
29 annular boss adapted to fit within said annular groove to
30 thus retain said assembly on said front cap.

31
32 16. The instrument of claim 15, further
33 comprising a key and defining a recess, one of said notch
34 and recess being disposed on a rear surface of said tip
35 cap and the other being disposed on a surface of said

- 17 -

- 1 front cap that is adjacent said rear surface, such that
- 2 said at least one irrigation outlet is positioned at 90°
- 3 to said second cutting edge.

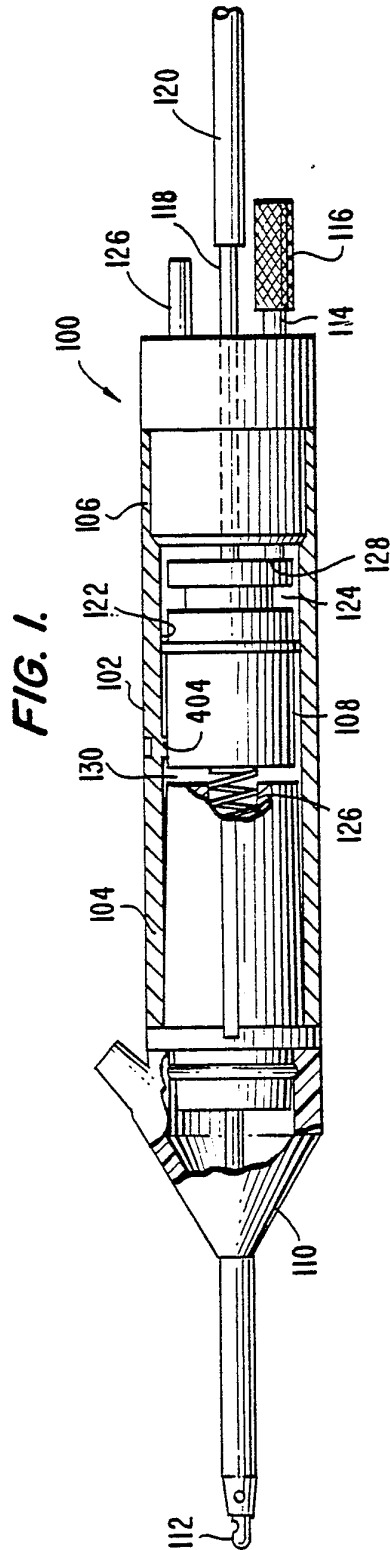


FIG. 3(c).

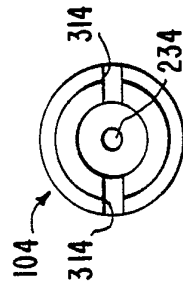


FIG. 3(b).

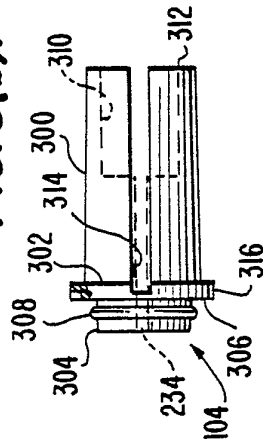


FIG. 3(a).

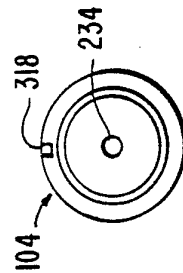


FIG. 4(b).

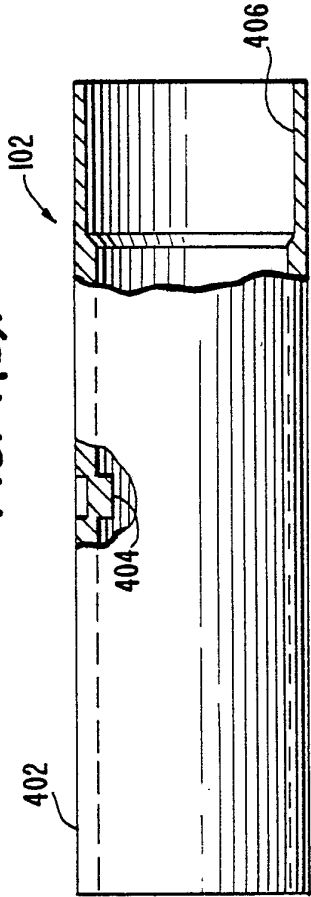


FIG. 4(a).

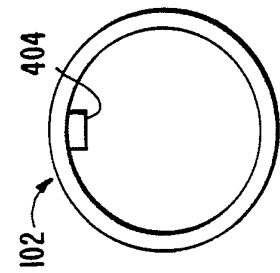


FIG. 2.

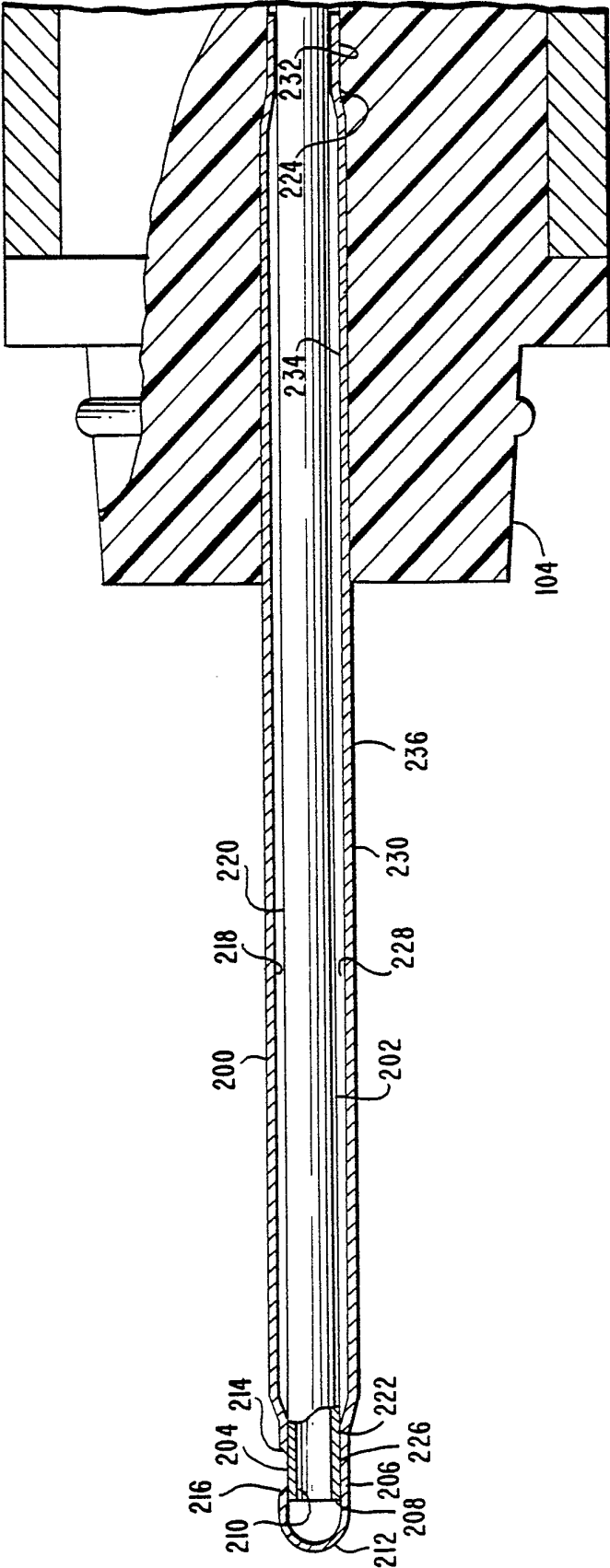


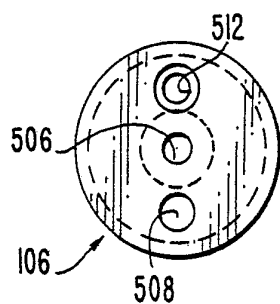
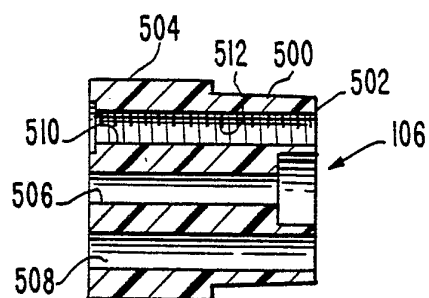
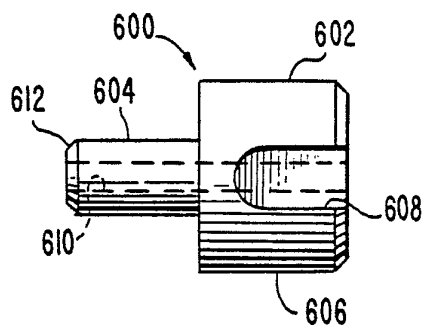
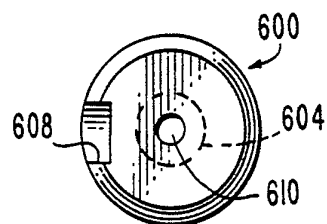
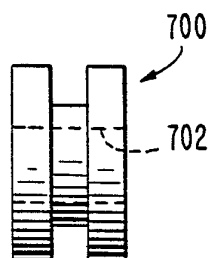
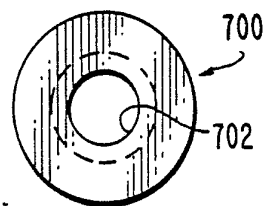
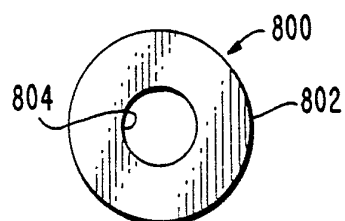
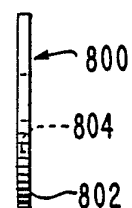
FIG. 5(a).**FIG. 5(b).****FIG. 6(a).****FIG. 6(b).****FIG. 7(a).****FIG. 7(b).****FIG. 8(a).****FIG. 8(b).**

FIG. 9(a).

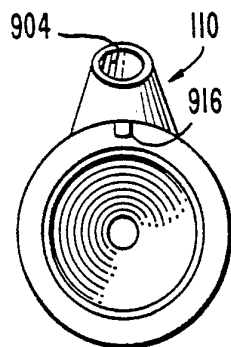


FIG. 9(b).

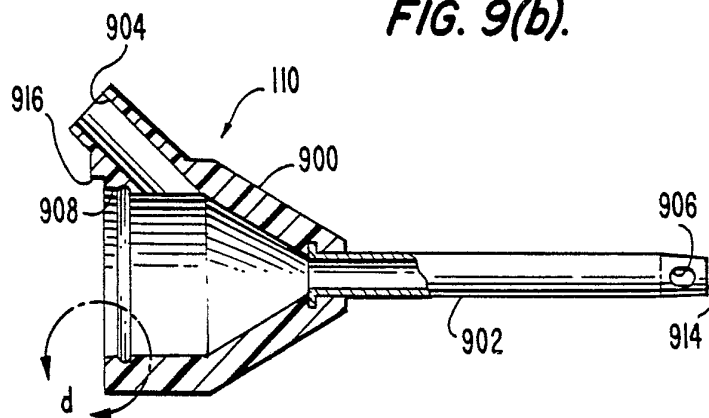


FIG. 9(c).

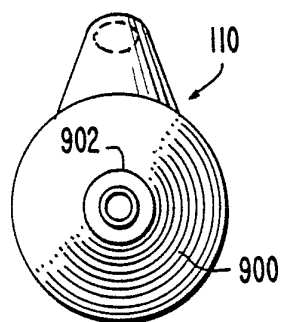


FIG. 9(d).

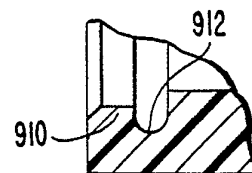
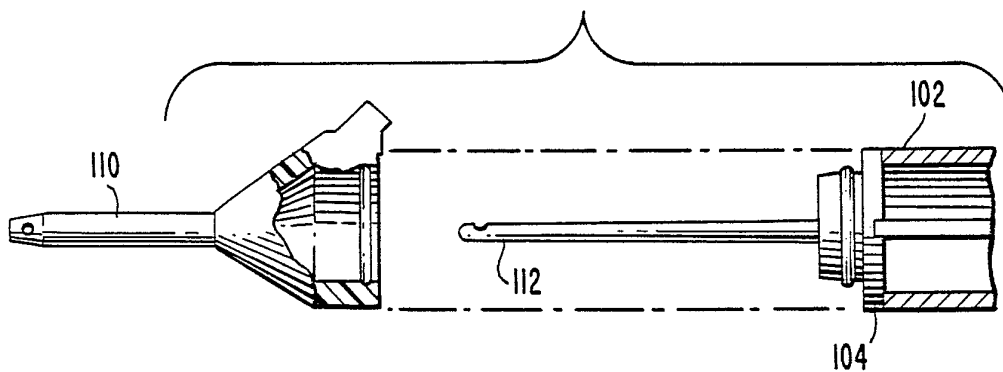
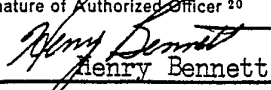


FIG. 10.



INTERNATIONAL SEARCH REPORT

International Application No PCT/US 86/01530

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) ³ According to International Patent Classification (IPC) or to both National Classification and IPC IPC(4) A 61B 17/32; A 61B 17/16; A 61B 17/20 U.S. CL. 128/305, 310; 604/22		
II. FIELDS SEARCHED		
Minimum Documentation Searched ⁴		
Classification System	Classification Symbols	
U.S.	128/305, 310 604/22	
Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched ⁵		
III. DOCUMENTS CONSIDERED TO BE RELEVANT ¹⁴		
Category *	Citation of Document, ¹⁶ with indication, where appropriate, of the relevant passages ¹⁷	Relevant to Claim No. ¹⁸
Y	US, A, 4,577,629 (Martinez) 25 March 1986 See Fig 1, See column 1 lines 56-60, see column 2 lines 61-68, see column 5 lines 9- 15.	1,6,7,11,12, 13
Y	US, A, 4,200,106 (Douvas et al) 29 April 1980 See Fig 1, see column 2 lines 41-44,56-68, see column 3 lines 21-24, see column 4 lines 53-63.	1-5,10,15,16
Y	WO, N, 01363 (Unisearch Limited) 28 May 1981 See page 2 lines 17-23, see page 3, lines 8-14, see page 5 lines 8-12.	10
* Special categories of cited documents: ¹⁵ "A" document defining the general state of the art which is not considered to be of particular relevance "E" earlier document but published on or after the international filing date "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) "O" document referring to an oral disclosure, use, exhibition or other means "P" document published prior to the international filing date but later than the priority date claimed "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art. "&" document member of the same patent family		
IV. CERTIFICATION		
Date of the Actual Completion of the International Search ²		Date of Mailing of this International Search Report ³
September 15, 1986		26 SEP 1986
International Searching Authority ¹		Signature of Authorized Officer ²⁰
US		 Henry Bennett