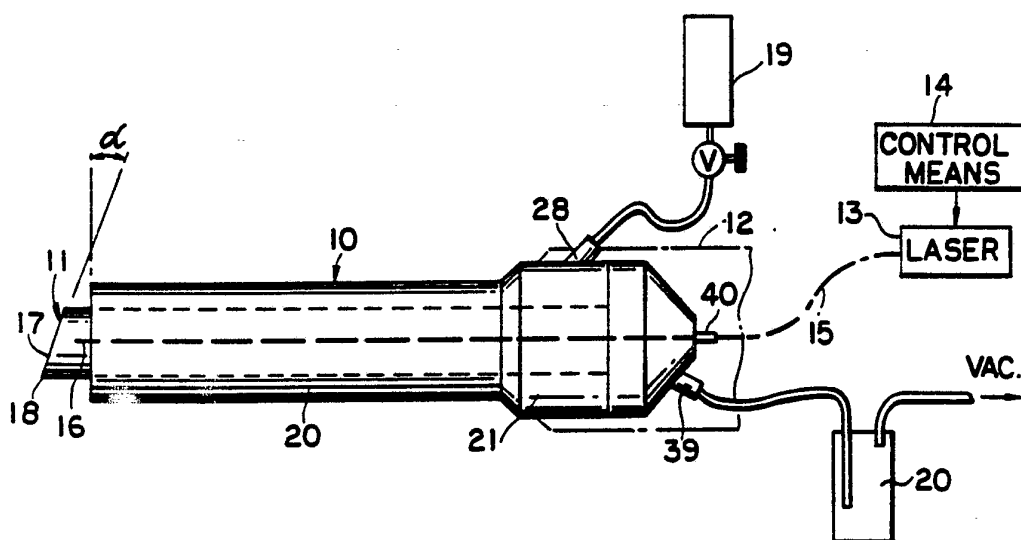




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<p>(21) International Application Number: PCT/US92/05636</p> <p>(22) International Filing Date: 6 July 1992 (06.07.92)</p> <p>(30) Priority data: 734,940 24 July 1991 (24.07.91) US</p> <p>(71) Applicant: L'ESPERANCE MEDICAL TECHNOLOGIES, INC. [US/US]; 1 East 71st Street, New York, NY 10021 (US).</p> <p>(72) Inventor: L'ESPERANCE, Francis, A. ; 255 Oakwood Road, Englewood, NJ 07631 (US).</p> <p>(74) Agent: HOPGOOD, Roy, C.; Hopgood, Calimafde, Kalil, Blaustein & Judlowe, Lincoln Building, 60 East 42nd Street, New York, NY 10165 (US).</p>		<p>(81) Designated States: CA, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IT, LU, MC, NL, SE).</p> <p>Published <i>With international search report.</i></p>

(54) Title: APPARATUS FOR REMOVING CATARACTOUS-LENS TISSUE



(57) Abstract

A hand-held phaco-extractor instrument (10) comprises an elongate tubular irrigation/aspiration system (28/39) for a distal or operating end (11), wherein a fiber-optic cable (15, 16) delivers laser-irradiation of wavelength which is so substantially coincident with the known high absorptivity in water that laser-energy penetration is essentially limited to the region of cataractous-lens tissue to be fragmented and extracted. In other words, for the aqueous environment in which the particular laser radiation is to do its fragmentation, there is no possibility of damaging radiation penetration to the retina or to other regions of the eye which are irrelevant to the involved cataract-removal surgery.

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APPARATUS FOR REMOVING CATARACTOUS-LENS TISSUEBACKGROUND OF THE INVENTION

The present invention relates to surgically
5 invasive apparatus for accessing a cataracted natural
lens via the anterior chamber and a dilated iris, and for
removing cataractous material from the lens.

Within the last ten years, there have been important
advances in instrumentation and techniques for removal of
10 cataractous-lens material. What has been termed
phacoemulsification is perhaps the most important of
these advances, and it should be noted that this term has
applied to the use of ultrasonic energy, delivered at the
small tip of a piezoelectric or magnetostrictive device;
15 this is the currently favored means of locally fragmenting
cataractous tissue, for extraction via a continuous flow
of benign liquid. But use of such phacoemulsification
devices calls for great skill, in that excessive delivery
or misdirected delivery of ultrasonic energy can result in
20 irreparable damage to the capsular bag, the retina and/or
other parts of the eye.

It has also been proposed, but not generally
accepted, to use local delivery of laser radiation to
fragment cataractous material, to an extent permitting
25 extraction in a continuous flow of irrigating liquid. But
again, there is the prospect of irreversible damage to
other parts of the eye, and great surgical skill is
required.

To simplify the problem of surgical skill and to
30 reduce the potential for damage through posterior escape

of laser radiation, a recently published article mentions the work of Dr. Patricia E. Bath with her "laserphaco" apparatus, which is said to involve phacoablation, and irrigation and aspiration (I/A). Her apparatus is said to
5 utilize a neodymium-YAG laser (presumably frequency-quadrupled, for ultraviolet-wavelength radiation) or an exciter laser, a laser-phaco probe, a laser-synchronized computer, and a laser interface. The computer is said to sense the high ultraviolet absorbance of the cataracted
10 lens, and the computer selects the correct wavelength; the computer is also said to distinguish between the different refractive indices of the nucleus and the cortex, and to adjust the laser's energy density, thus minimizing the possibility of radiation outside the desired zone. Dr.
15 Bath is quoted as stating that "the computer aims the beam, focuses the beam, tests the beam, and executes ablation of the foci with no escape of radiation posteriorly... So what you have coming through a single probe is mapping, focusing, ablation and I/A".

20 Throughout this case, the terms phacoemulsification, phacoablation, and tissue-fragmentation are deemed to be synonymous, in the sense that they apply to the use of externally supplied and locally delivered energy, whether ultrasonically applied or laser radiation, to break up and
25 reduce cataractous material to a particle size small enough for external removal by the flow of an irrigating liquid in an I/A system.

BRIEF STATEMENT OF THE INVENTION

30 It is an object of the invention to provide an improved laser-operated apparatus and technique for removal of cataractous-lens tissue.

A specific object is to utilize the known high energy-absorption coefficient of water at a particular

* "Will Laser Become the Cataract Surgery Instrument of the '90's", Ophthalmology Times, August 1, 1990, page 40.

wavelength, for so attenuating a phaco-fragmenting laser irradiation as to minimize potential damage to tissue other than cataractous-lens tissue.

Another specific object is to achieve the above
5 objects with an instrument which embodies its own means of infusing and aspirating a flow of liquid at the situs of fragmentation.

The invention achieves these objects in a hand-held instrument having an elongate stem which enables external
10 manipulation at its proximal end and which at its distal end presents a cutter adjacent an open cavity. Within or adjacent to this open cavity, laser radiation from the discharging distal end of an optical fiber is operative only on nearby cataractous-lens tissue to be fragmented.
15 The particular laser is selected for its radiation wavelength such that laser radiation in water and water-containing cataractous-tissue is absorbed within a radiating distance that is at least no greater than the thickness dimension of the cataractous lens upon which the
20 instrument is to operate.

DETAILED DESCRIPTION

Preferred and other embodiments of the invention will be described in detail, in conjunction with the accompanying drawings. In said drawings:

25 Fig. 1 is a simplified overall view of a phaco-emulsifying instrument of the invention, together with external devices involved in operation of the instrument;

Fig. 2 is an enlarged longitudinal sectional view of the instrument of Fig. 1;

30 Fig. 3 is a sectional view, taken at 3-3 in Fig. 2; and

Fig. 4 is another sectional view, taken at 4-4 in Fig. 2.

The system of Fig. 1 is seen to comprise a hand-held
35 instrument 10 that is centrally open at its distal end 11 and which is manipulable via a handle (a portion of which

is suggested by phantom outline) 12 at its proximal end. Laser radiation from an external source 13, and pursuant to control at 14, is deliverable via an optical-fiber cable 15 that is centrally guides and positioned within the instrument for laser discharge at 16. The location of the fiber end 16 is within a shallow distally open cavity defined by and within a short cylindrical region 17 that is truncated at an angle α to provide a sharpened cutting edge at least in the region of its distally projecting limit 18. Provision is made for a controlled flow of infusion liquid from a source 19 to a first or outer annular cannula within the instrument, for ported external discharge near the distal end, and a second elongate cannula within the instrument, communicates between the distal-cavity region 17 and an external evacuation system which includes a trap 20 for aspiration and accumulation of fragmented lens material.

Referring now to Figs. 2 to 4, the operative portion of the instrument 10 will be seen to be contained within an outer annular cannula having a reduced but elongate cylindrical shell 20 which is exposed distally, and a slightly enlarged proximal-end shell 21, which has means of attachment to handle 12 (not shown in Fig. 2); Fig. 2 will be understood to have been longitudinally foreshortened for better showing of detail. The outer annular cannula is completed by an inner tubular member or shell 22 and by a distal-end closure wall 23 that is ported at spaced locations 24 (Fig. 4) for discharge of infusion liquid, such as a balanced saline solution. The proximal end of the outer cannula is closed by an annular plug or clamp fitting 25, removably secured by threaded engagement to the enlarged proximal-end member 21. For independent integrity of outer-cannula body structure, a fruste-conical element 26 connects outer shells 20, 21 to each other and to the inner tubular shell 22, and an angularly distributed plurality of ports 27 in the

frustoconical element accommodates flow of infusion liquid from an inlet fitting 28 to the discharge ports 24.

Finally, the distal end of inner shell 22 is seen to have the previously described truncated and sharpened formation at 17, 18.

5 The inner cannula 30 is elongate and tubular, deriving guided support from the inner shell 22 of the outer cannula, and having a radial flange 31 at its proximal end such that, upon take-up of the threaded
10 assembly of parts 21, 25 to each other, flange 31 is securely clamped, thus rigidly positioning the inner cannula 30, with its distal end forward of the closure wall 23 of the outer annular cannula. A local sector or strut formation 33 (Figs. 3, 4) in the otherwise open bore
15 of the inner cannula 30 extends longitudinally for central rigid positioning of a piloting tube 34, as of stainless steel, for guided retention of the optical-fiber cable 15. The optical-fiber cable 15 is protected at proximal-end entry into its guide tube, by a resilient elastomeric
20 bushing 35, as of silicone rubber, carried locally by cannula 30 and having light frictional retaining engagement to cable 15, whereby to retain optical-fiber discharge of laser radiation at 16.

The open bore 36 of cannula 30 establishes a through
25 inner passage which communicates from the distal shallow chamber 17 to a proximal chamber 37 defined by an end-bell portion 38 which, with the annular thread figment 25, is a detachable subassembly to the enlarged shell 21 and to the inner cannula 30, at flange 31. The end-bell portion 38
30 is shown with a port figment 39, adapted for slip-fitted flexible connection to the aspiration device 20. Finally, another elastomeric bushing 40 carried by end-bell 38 loosely and yieldingly provides central protection for the optical-fiber cable, at entry into the instrument.

35 Use of the described construction involves certain mechanical assembly operations. A sterilized length of

optical-fiber cable 15 is threaded through the end-bell bushing 40, and then through the friction engagement of bushing 35 and with guidance by tube 34 until the distal end of the optical fiber is flush with the end of tube
5 (34) support by strut 33. The thus-loaded inner cannula 30 is inserted into the bore of the outer cannula, until limited by its flange (31) engagement of the proximal end of the inner tubular member 22 of the outer cannula. The end-bell subassembly 25, 38, which may be a disposable
10 item, is then thread-engaged to the outer cannula shell 21, thereby completing the mechanical assembly of the instrument, with the inner cannula securely clamped and retained. At this point, visual inspection and minor adjustment can assure correct distal-end positioning of
15 the optical fiber of cable 15. Infusion tubing and aspiration tubing can then be connected, and the vacuum apparatus adjusted to a selected vacuum condition in the range of 100 to 500-mm Hg; the Alcon 10,000 I/V instrument is among those commercially available devices that can
20 provide continuous or interrupted and variable aspiration. Infusion is usually produced by elevating the container 19 to a level between 10 and 65-cm above the level of the patient's eye, a simple gravity flow of infusion fluid being used to maintain intraocular pressure, and to
25 provide liquid transport into the eye while aspiration is underway.

Operation of the thus-prepared instrument 10 is to be differentiated from the devices acknowledged above. Once the cataract is approached, cortical material can be
30 cleared from the anterior surface of the lens, and the nucleus can be engaged by the sharpened truncation of the protruding end 18 of the outer cannula. A small quantity or chunk of cataractous tissue can then be manipulated into close approach to the shallow chamber region 17; if
35 this small quantity does not aspirate directly, short bursts of pulsed laser energy can be directed at the

cataractous tissue, e.g., at the rate of 1 to 25 pulses per second, to break-up the chunk and to transport its fragmented products remotely, by the aspiration mechanism, it being understood that laser energy need only be applied for break-up of lens tissue into smaller particles that can be handled by the aspiration system.

It is a feature of the invention that the particular laser shall be selected from use at 13, for its limited radiation wavelength at or close to one of high water-absorption peaks, e.g., at approximately 2.0, 3.0 and 6.0 microns, whereby laser-beam energy released into shallow chamber 17 is almost totally absorbed within a very short distance. For example, the beam from a Holmium-YAG laser operating at 2.10 microns, is virtually totally absorbed (i.e., 67% absorbed) within a distance of about 0.3-mm^{**}, in a watery medium such as that of cataractous-lens tissue and the liquid environment provided by the described I/A flow. Another possible laser configuration at 13 is the Thulium-YAG laser^{***}, which radiates at 2.01 microns, and which is 67 percent absorbed within 150 microns from the exit port 16 of the optical-fiber cable. There are other lasers that can be recited to serve the short dissipation-distance purposes of the invention, but it should be generally stated that the delivered laser radiation, emanating at 16 from the optical fiber, should meet the following criteria, all of which are met by the indicated Holmium and Thulium, configurations:

- a. The water-absorption coefficient should advisedly be at least 10 cm⁻¹.
- b. The irradiated energy level should be in the range 1 to 350 millijoules/pulse.
- c. The pulse-delivery rate for a given burst should be in the range 1 to 25 Hertz.

** Absorption coefficient = 35 -cm⁻¹

*** Absorption coefficient = 70-cm⁻¹

d. The burst duration should be selectively variable, by adjustment at control means 14, within the range 0.1 to 5 seconds.

5 What has been said for the above criteria applies to delivered or deliverable energy levels at the location 16 of radiation into the aqueous medium, i.e., after allowance for such attenuation as may be attributable to detachable coupling of cable 15 to laster 13 and to distributed attenuation along the length of cable 15.

10 The described invention will be seen to meet stated objects. When needed to break up a chunk of cataractous tissue, the tissue can be fragmented by laser-energy levels which, by virtue of wavelength selection restricted to water-absorption properties, are inherently incapable
15 of such penetration as might be in any way harmful to other tissues within the eye.**** In other words, as long as the surgeon exercises normal caution to avoid instrument contact with the corneal endothelium and other components that are irrelevant to cataract surgery, and as
20 long as he operates upon what he can see by operational-microscope viewing through a clear cornea and a dilated iris, the laser energy emanating at 16 is incapable of causing damage to the patient's eye.

By contrast, it is indicated that the Neodymium-YAG radiation which is suitable for use in the closed-chamber embodiments of another patent application (attorney Docket 1042) filed on or about July 19, 1991 has a water-absorption coefficient = 0.8 cm^{-1} , involving an extremely high transmission of 12.5-mm in an aqueous environment.

WHAT IS CLAIMED IS:

1. Phaco-extractor means for fragmenting cataractous-lens tissue and for removing fragmented tissue from the situs of fragmentation, comprising an elongate hand-held instrument extending from a proximal handle region to the operating end of a distal region, said distal region comprising an inner tubular member with an inner aspiration passage and containing a central guide tube for an inserted optical-fiber cable, means at the proximal handle region for releasable retaining the inserted position of an optical-fiber cable such that the distal end of the cable is located substantially at the distal end of the guide tube, an annular outer tubular member having a bore for concentric support of said inner tubular member and having an elongate passage for irrigating liquid delivery to the distal end of said outer tubular member, and means at the proximal handle region for releasable clamping the proximal ends of said tubular members.

2. Phaco-extractor means for fragmenting cataractous-lens tissue and for removing fragmented tissue from the situs of fragmentation, comprising a hand-held instrument having an elongate stem with separate irrigation and aspiration passages to the distal end region of the stem, said instrument having a proximal end with separate connections to said passages, said stem having a distally open end of circular section, and a guide tube centrally supported within said stem; separate detachable and flexible irrigation and aspiration connections to the respective passage connections of said instrument, laser means separate from said instrument, and a flexible optical-fiber cable detachably connected at one end to said laser, with the other end of said cable extending within said tube, to an inserted position of fiber-end exposure at the distal end of said tube, and

means including an elastomeric friction element forming part of the proximal end of said instrument for fictionally and releasable retaining said cable in its said position of fiber-end exposure.

5 3. Phaco-extractor means for fragmenting cataractous-lens tissue and for removing fragmented tissue from the situs of fragmentation, comprising a hand-held instrument having an elongate stem with separate irrigation and aspiration passages to the distal end
10 region of the stem, said instrument having a proximal end with separate connections to said passages, said stem having a distally open end of circular section, and a guide tube centrally supported within said stem; separate detachable and flexible irrigation and aspiration
15 connections to the respective passage connections of said instrument, laser means separate from said instrument, and a flexible optical-fiber cable detachably connected at one end to said laser, with the other end of said cable
20 extending within said tube, to an inserted position of fiber-end exposure at the distal end of said tube, said laser being selected for its active lacing substance taken from the group comprising Holmium, Thulium and Erbium and for substrate material selected from the group comprising yttrium-aluminum-garnet and glass.

25 4. Phaco-extractor means for fragmenting cataractous-lens tissue and for removing fragmented tissue from the situs of fragmentation, comprising a hand-held instrument having an elongate stem with separate irrigation and aspiration passages to the distal end
30 region of the stem, said instrument having a proximal end with separate connections to said passages, said stem having a distally open end of circular section, and a guide tube centrally supported within said stem; separate detachable and flexible irrigation and aspiration
35 connections to the respective passage connections of said instrument, laser means separate from said instrument, and

a flexible optical-fiber cable detachably connected at one end to said laser, with the other end of said cable extending within said tube, to an inserted position of fiber-end exposure at the distal end of said tube, said laser producing radiation having a water-absorption coefficient of at least 10-cm^{-1} .

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5. The phaco-extractor means of claim 4, in which said laser has a pulsed output and the irradiated energy level of said laser is in the range 1 to 350 millijoules/- pulse.

6. The phaco-extractor means of claim 5, in which the pulse-repetition rate for said pulsed output is in the range 1 to 25 Hz.

7. The phaco-extractor means of claim 6, in which said laser includes control means that is selectively variable to determine bursts of pulses, wherein a selected burst is in the range 0.1 to 5 seconds.

8. Phaco-extractor means for fragmenting cataractous-lens tissue and for removing fragmented tissue from the situs of fragmentation, said means comprising a hand-held instrument with elongate tubular means having a distal working end and a proximal manipulation end, said tubular means containing divider means for defining first and second elongate passages each of which has at least one opening at the distal end, an infusion-port connection to one of said passages near the proximal manipulation end, an aspiration-port connection to the other of said passages near the proximal manipulation end, and laser means including a fiber-optic delivery system supported by and within said tubular means and terminating at said distal end for laser-energy discharge from said distal end.

9. Phaco-extractor means according to claim 8, wherein said passages are defined by and radially between two elongate concentric annular cannulas, the inner one of

said cannulas including means centrally supporting said fiber-optic delivery system.

5 10. Phaco-extractor means according to claim 9, in which said last defined means comprises an elongate guide tube sized for sliding guidance of a fiber-optic cable insertably receivable via the proximal end of said guide tube to the point of optical discharge at the distal end of said tube, and means including at least one radial strut within the inner cannula for radially positioning of
10 said tube.

11. Phaco-extractor means according to claim 8, in which said laser means is of a variety which radiates at a wavelength which is at or close to a high water-absorption peak.

15 12. Phaco-extractor means according to claim 9, in which said tubular means includes an internal annular wall at the proximal end, and in which said outer cannula comprises a subassembly of spaced inner and outer tubular members having removable connection to said wall and
20 having a distal-end closure wall that has angularly spaced ports for infusion-liquid discharge.

13. Phaco-extractor means according to claim 12, in which said inner cannula comprises an elongate tube having a radially outward flange at its proximal end for abutment
25 with said cannula wall, the inner tubular member of said outer cannula having a concentric sliding engagement with said elongate tube and retaining said outward flange in clamped engagement with said annular wall when said subassembly is connected to said wall.

30 14. Phaco-extractor means according to claim 12, in which the inner tubular member of said subassembly projects distally beyond the outer tubular member of said subassembly, and in which the distal end of said inner tubular member is truncated t an acute angle to the
35 central axis of said inner tubular member.

15. Phaco-extractor means according to claim 14, in which the peripheral edge of the distal truncation is a sharpened edge of tissue-cutting quality.

16. Phaco-extractor means for fragmenting
5 cataractous-lens tissue and for removing fragmented tissue from the situs of fragmentation, comprising a hand-held instrument having an elongate stem with separate irrigation and aspiration passages to the distal end region of the stem, said instrument having a proximal end
10 with separate connections to said passages, said stem having a distally open end of circular section, and a guide tube centrally supported within said stem; separate detachable and flexible irrigation and aspiration connections to the respective passage connections of said
15 instrument, laser means separate from said instrument, and a flexible optical-fiber cable detachably connected at one end to said laser, with the other end of said cable extending within said tube, to an inserted position of fiber-end exposure at the distal end of said tube, said
20 laser being selected for its active lacing substance taken from the group comprising Holmium, Thulium, Erbium, Cobalt, and Magnesium.

17. Phaco-extractor means according to claim 16,
wherein substrate material of said laser is selected from
25 the group comprising YAG, YLF, YSGG and glass.

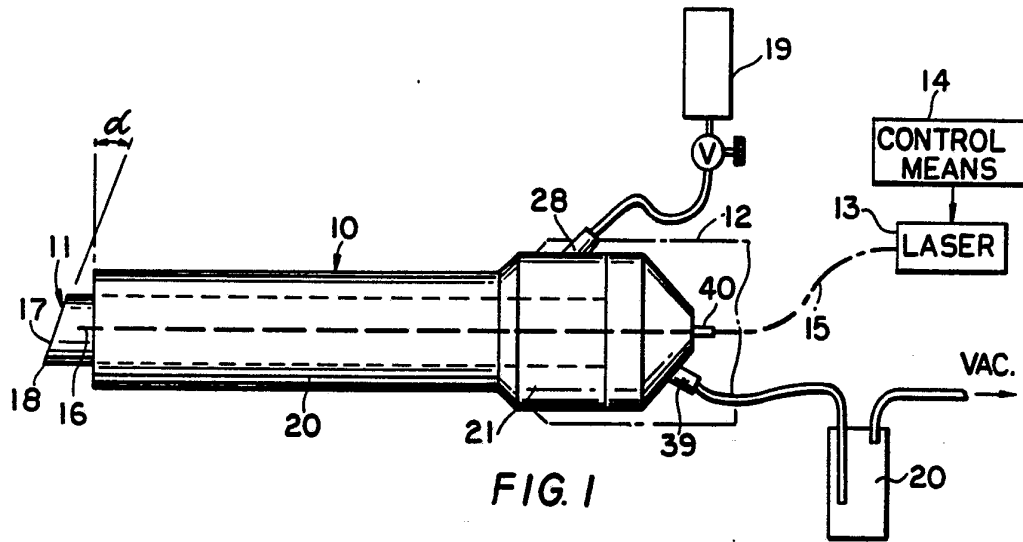


FIG. 1

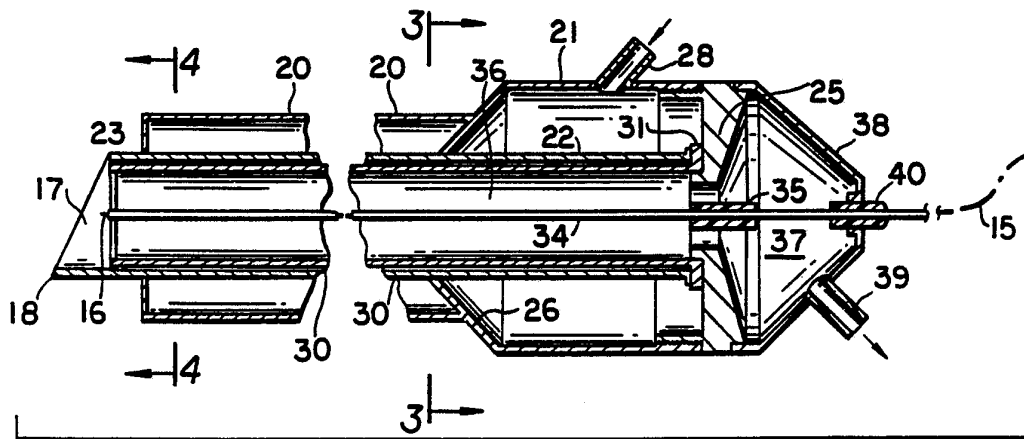


FIG. 2

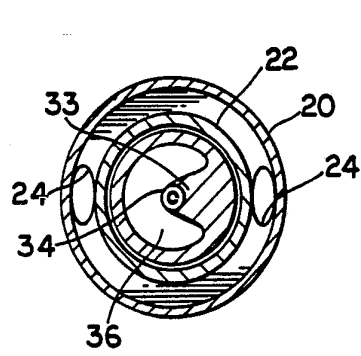


FIG. 4

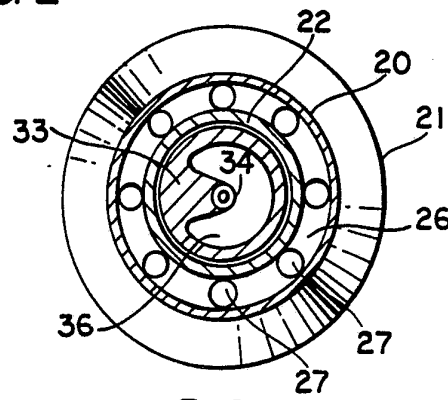


FIG. 3

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US92/05636

A. CLASSIFICATION OF SUBJECT MATTER		
IPC(5) :A61B 17/36 US CL :606/06 According to International Patent Classification (IPC) or to both national classification and IPC		
B. FIELDS SEARCHED		
Minimum documentation searched (classification system followed by classification symbols) U.S. : 606/6, 7, 4, 13-16; 128/395, 398		
Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched		
Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)		
C. DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US, A, 4,959,063 (KOJIMA) 25 SEPTEMBER 1990 See column 1, line 56 - column 4, line 10.	1-2
Y,E	US, A, 5,129,896 (HASSON) 14 JULY 1992 See column 6, lines 49-56.	1-11, 16-17
Y	US, A, 4,819,630 (DEHART) 11 APRIL 1989 See column 3, line 43 - column 4, line 13	1-11, 16-17
Y	US, A, 4,988, 163 (COHEN ET AL) 29 JANUARY 1991; See column 3, line 40 - column 4, line 39.	3-11, 16-17
A,P	US, A, 5,123,902 (MULLER ET AL) 23 JUNE 1992 See column 5, line 30 - column 12, line 64	
<input type="checkbox"/> Further documents are listed in the continuation of Box C. <input type="checkbox"/> See patent family annex.		
* "A"	Special categories of cited documents: document defining the general state of the art which is not considered to be part of particular relevance	"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
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Date of the actual completion of the international search 18 SEPTEMBER 1992		Date of mailing of the international search report 12 NOV 1992
Name and mailing address of the ISA/ Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231		Authorized officer <i>Jeffrey A. Schmidt</i> SCHMIDT, JEFFREY A.
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