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O'Malley et al.

[11] **3,884,238**

[45] **May 20, 1975**

[54] **APPARATUS FOR INTRAOCULAR SURGERY**

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[22] Filed: **Apr. 3, 1974**

[21] Appl. No.: **457,497**

Related U.S. Application Data

[63] Continuation-in-part of Ser. No. 264,166, June 19, 1972, Pat. No. 3,815,604.

[52] **U.S. Cl.** **128/305;** 128/276

[51] **Int. Cl.** **A61b 17/32**

[58] **Field of Search** 128/305, 276

[56] **References Cited**

UNITED STATES PATENTS

3,614,953	10/1971	Moss	128/305
3,776,238	12/1973	Peyman et al.	128/305
3,815,604	6/1974	O'Malley et al.	128/305

FOREIGN PATENTS OR APPLICATIONS

437,932	11/1926	Germany	128/305

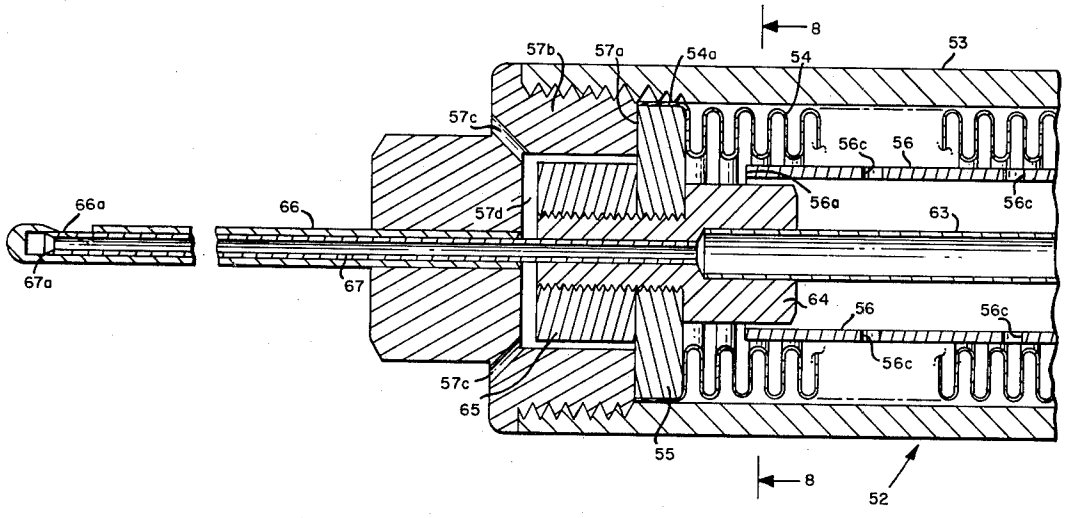
Primary Examiner—Channing L. Pace

Attorney, Agent, or Firm—Ben J. Chromy; Gerald L. Moore

[57] **ABSTRACT**

A pneumatically operated intraocular surgery apparatus which is of very light weight and small size, the cutting device inserted into the eye consisting of concentric tubes having a diameter of 1 mm. or less. Pneumatic means is provided to the device for moving one of the tubes with respect to the other at a slow or fast rate. Said pneumatic means includes a bellows provided with suction so that vitreous sucked into one of the tubes is sheared off by the sharp end of the other tube and the severed vitreous is sucked into a calibrated cylinder. An adjustable bleeder valve is provided in the vacuum line to eliminate residual suction on the interior of the eye when the cutting action is at rest.

8 Claims, 11 Drawing Figures



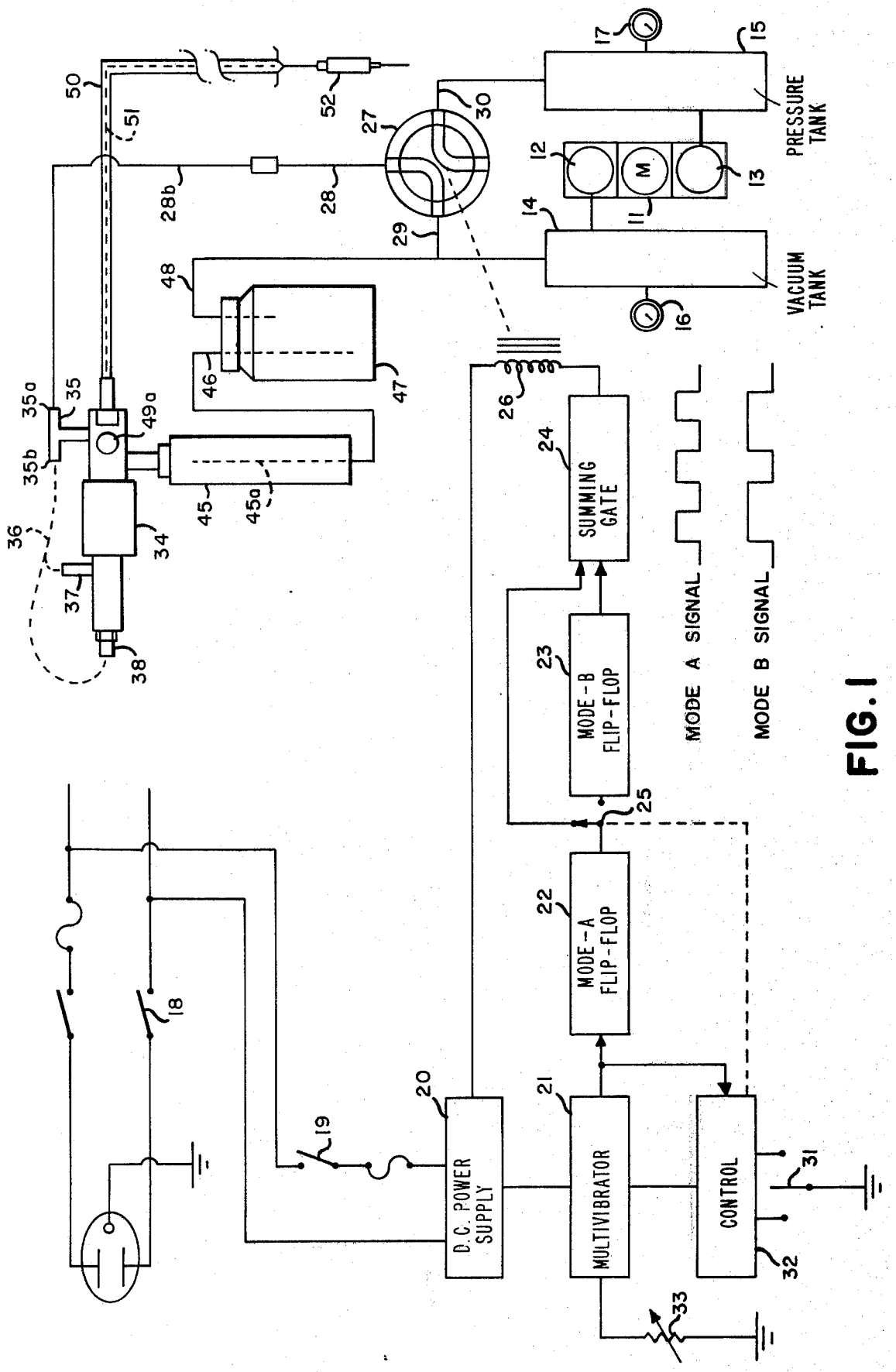

PRESSURE TANK
VACUUM TANK
SUMMING GATE
MODE-B FLIP-FLOP
MODE-A FLIP-FLOP
MODE A SIGNAL
MODE B SIGNAL
D.C. POWER SUPPLY
MULTIVIBRATOR
CONTROL
M

FIG. 1

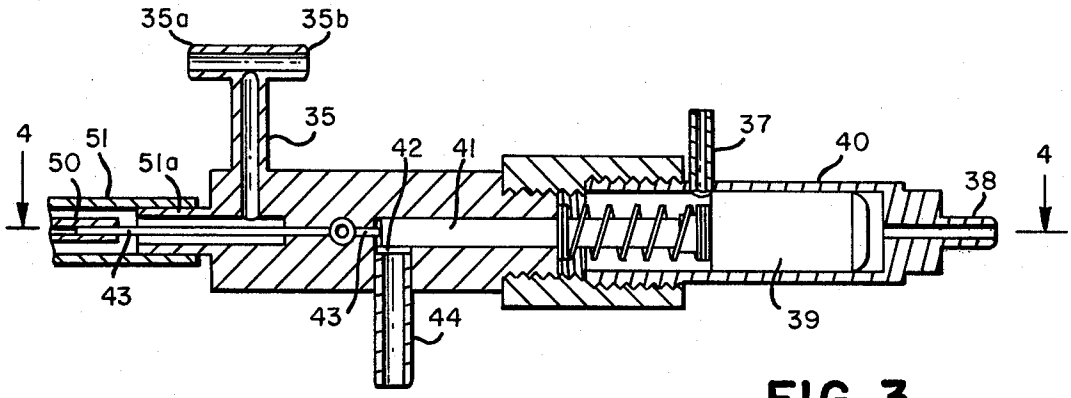


FIG. 3

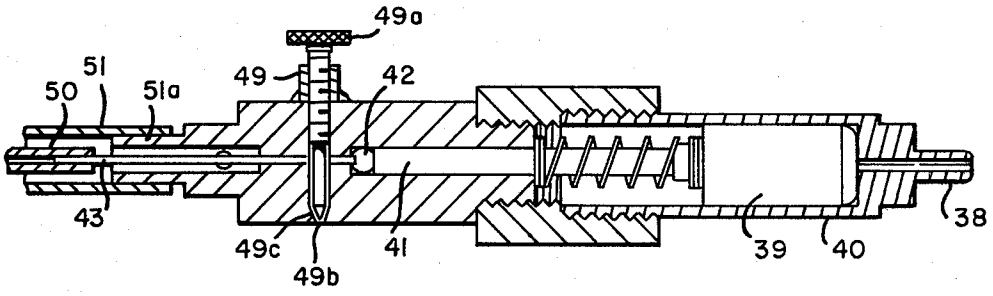


FIG. 4

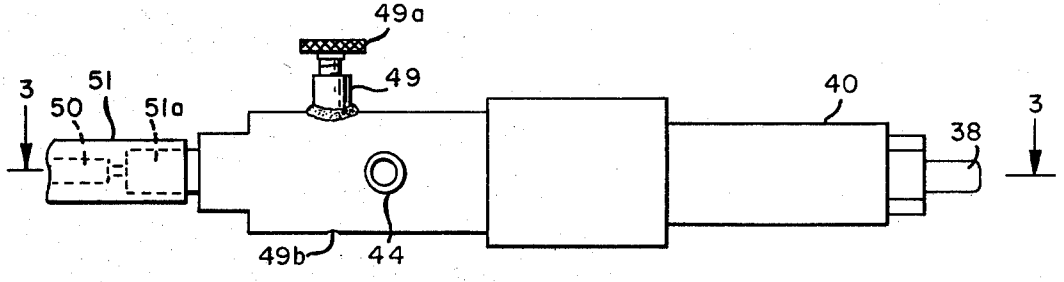


FIG. 2

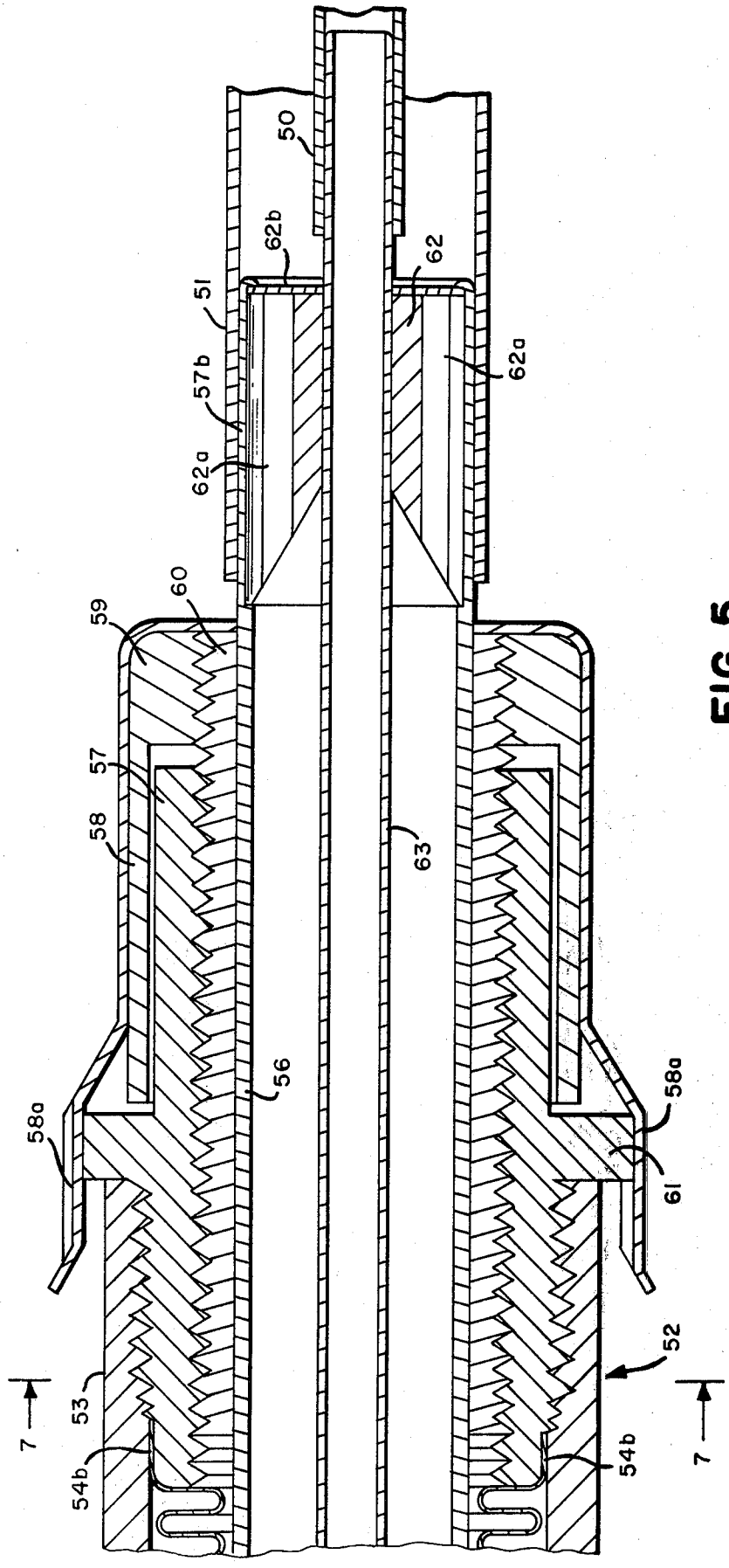

50
62b
62
51
57b
62a
62a
60
59
57
58
63
56
58a
58a
61
52
53
54b
54b
7
7

FIG. 5

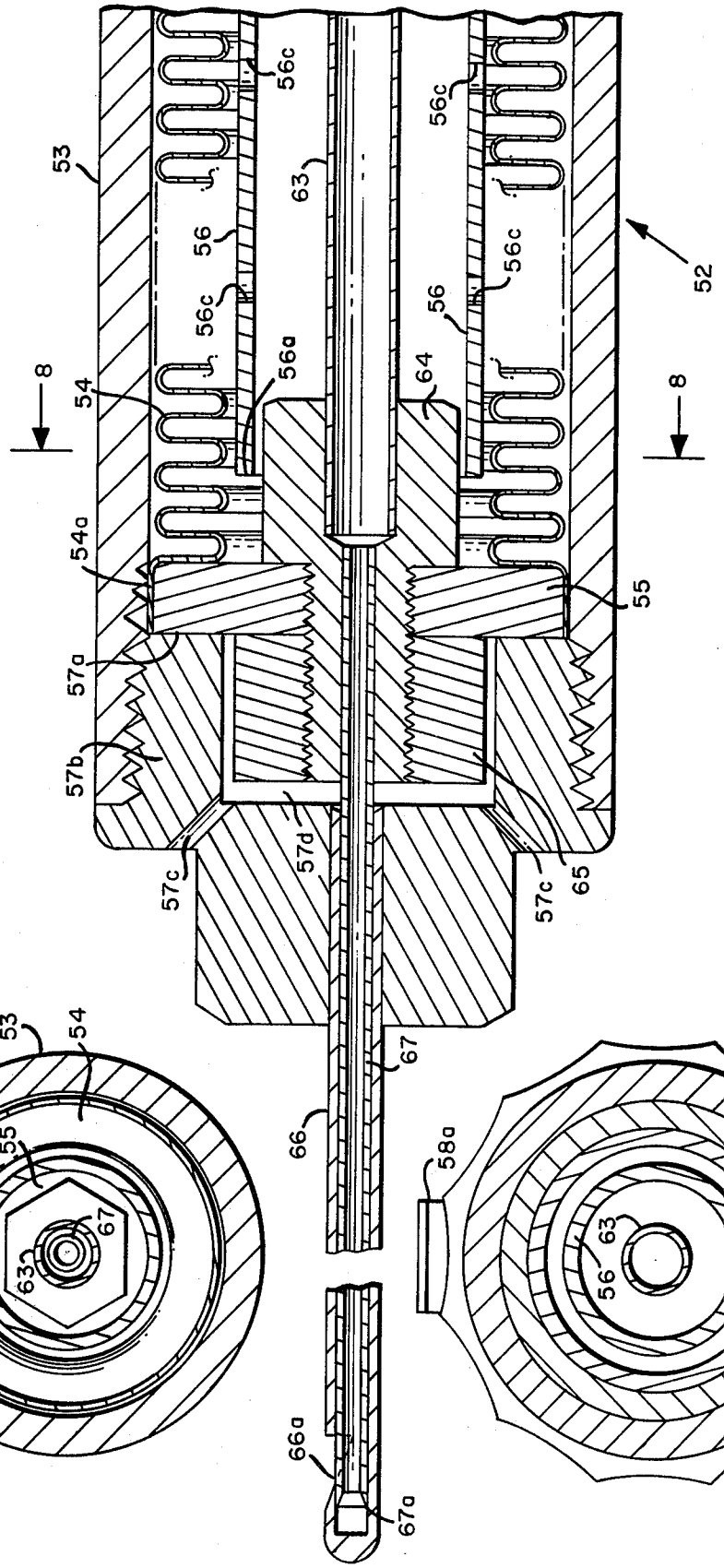


FIG. 6

FIG. 8

FIG. 7

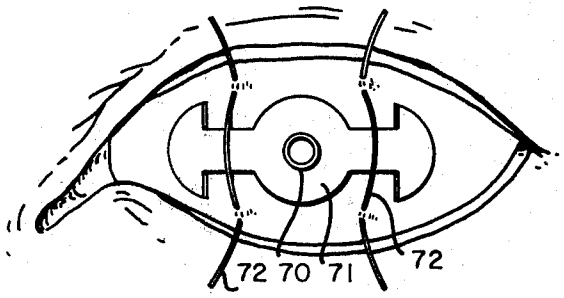


FIG. 9

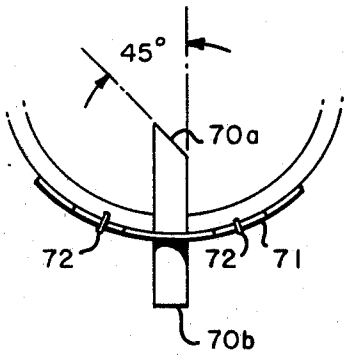


FIG. 10

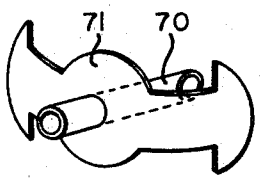


FIG. 11

APPARATUS FOR INTRAOCULAR SURGERY

DESCRIPTION OF THE INVENTION

This application is a continuation-in-part of application Ser. No. 264,166 filed June 19, 1972 now U.S. No. 3,815,604 dated June 11, 1974.

This invention relates to apparatus for use in effecting intricate surgery such as performed by an ophthalmic surgeon.

In certain diseases of the eye or in certain trauma it is necessary to sever the vitreous which is a relatively complex substance composed of a framework of long protein molecules (collagen). In addition the vitreous also includes patches or balls of a second protein molecule (hyaluronic acid) which help to strengthen the vitreous and maintain its form and assist in holding water which comprises over 99 percent of the vitreous. When the surgeon finds it necessary to remove the severed vitreous or extraneous matter from within the vitreous, this removal must be accomplished without damage to the retina, to the choroid which underlies the retina or to the optic nerve or to the blood vessels associated therewith. This, of course, is no easy task as the vitreous cannot be cut by a scalpel or other similar instrument since the vitreous is relatively tough and simply folds over the edge of the knife and refuses to be severed. Various devices have been proposed for vitreous surgery and reference is made to such devices in the following published articles.

G. C. Couvillion, H. M. Freeman, and C. L. Schepens on pages 722 and 723 of Volume 83, June 1970, Arch Ophthal, describe vitreous surgery using scissors. Robert Machemer, Jean-Marie Parel and E. W. D. Norton on pages 462 to 466 of Volume 76, March-April 1972, Tr. Am. Acad. Ophth. and Otol., describe a vitreous-infusion-suction-cutter for vitrectomy. The cutter described in this article is provided with a rotating inner tube that is pushed by a spring against an end of an outer tube. A cutting hole which is slightly laterally displaced, is provided in the end of the tip. In another article entitled "Experimental Vitrectomy", in Volume 86, November, 1971, Arch Ophthal, G. A. Peyman and M. A. Dodich describe an instrument for cutting vitreous strands by a chopping action produced by an inner tube against the plane end of an outer tube. The vitreous to be removed is drawn into the inner tube by suction provided in the inner tube. In this device another tube is attached alongside the outer tube and saline solution is supplied through this tube to replace the removed vitreous. In this device the chopping action is produced by oscillating the inner tube 5 to 50 times per second and this is achieved by electrically energizing a small solenoid that is attached to the inner tube. The June, 1970 issue of Arch Ophthal contains an article by W. D. Cockerham, C. L. Schepens and H. MacKenzie Freeman entitled "Silicone Injection in Retinal Detachment." The authors describe a procedure in which a 10cc syringe which is attached to a blunted No. 18 or No. 20 needle is inserted into the eye through a meridional sclerotomy placed in the middle of the pars plana ciliaris for silicon injection.

It is therefore an object of our invention to provide an improved device for cutting vitreous, severing adhesions, said device having an adjustable and vacuum control means for removing severed parts from the eye.

Another object of this invention is to provide an improved device for use by eye surgeons, said device having an intraocular surgery device operated by pressure and vacuum to which fail-safe vacuum control is provided to abolish any significant residual suction on the interior of the eye when the cutting action is at rest.

Still another object of our invention is to provide improved tools for use by eye surgeons, said tools being so small that they may be inserted into the eye through the pars plana.

A further object of our invention is to provide improved tools for use by eye surgeons, the portion of the tool to be inserted into the eye having a diameter of about 1 mm., or less and the whole instrument being small and lightweight so that it can be hand-held and manipulated with ease and with minimal damage to the eye.

Another object of this invention is to provide an improved device for use by an ophthalmic surgeon for performing surgery in the eye of a patient, said device comprising a cutting device employing extremely small concentric tubes and pneumatic means including a bellows attached to one of said tubes for reciprocating said tube with respect to the other and an adjustable bleeder valve that is controlled by the surgeon to enable him to control the vacuum or suction applied to said cutting device for removing the severed substance from the eye.

Other and further objects of our invention will be apparent to those skilled in the art to which it relates or will be pointed out in detail in the following specification, claims and drawing.

By this invention we have provided the eye surgeon with an operating tool that is characterized by its extremely small size and light weight for performing surgery within the eye of the patient. This instrument may of course be used for cutting material other than vitreous by the operating surgeon. Two types of cutting devices may be used although only one type is illustrated. One of these devices is referred to as the push-cut and the other is referred to as the pull-cut. Both of these types of devices have the same dimensions and weight (about 8 grams) and in each case the length is about 2 inches overall with the body or handle thereof having a length of 1 inch and the cutting tube also having a length of 1 inch. The diameter of the cutting tube is 0.035 inch (**0.9** mm.). The body or handle comprises a cylinder with a bellows in it and the cutting tube is rigidly fastened to the bellows. This cutting tube is positioned inside of an outer tube and is free to slide about 0.020 to 0.040 inch (0.5–1.mm.) between limits set by a manually adjustable member on the handle. Vitreous to be severed is drawn into the port of the outer tube by suction and this vitreous is cut off when the sharp end of the inner tube is moved across the port of the outer tube. The frequency of the traverse of the cutting end of the inner tube across the port of the outer tube is controlled by an electrical circuit which generates timed electrical pulses for controlling air pressure and suction pulses to the piston of the cutting device. This frequency may be controlled by a foot actuated device which is operated by the surgeon employing this instrument. Thus, this frequency may be varied from a stationary condition with the port either open or closed to as many as 60 traverses per second or more. The speed of excursion is dictated by the nature of the material being cut, its proximity to the retina, the optic nerve, blood vessels or other sensitive regions. Air pressure and vacuum are applied to the bellows of the cutting

device through a flexible tube. A debris tube is positioned inside of the tube supplying pressure and vacuum. The annular space between the pressure tube and the debris tube serves to supply the bellow actuating the tube with air pressure and vacuum pulses and the debris tube is supplied with vacuum to suck the debris out of the eye and into a measuring cylinder.

The therapeutic role of the vacuum is threefold:

1. To suck selected target tissue into the cutting mechanism as described above;

2. To hold the target tissue throughout the cutting action which tends to spew it out of the cutting tube back into the eye; and

3. To move the cut specimen (or liquid when applicable) out of the eye through the debris tube.

The target tissues vary widely in mobility and texture. They are usually attached to other tissue (i.e., retina) which vary widely in friability anad mobility. While it is the surgical goal to cut and remove the target tissue, their contiguous attachments frequently must not be cut. Consequently, we have found it important to provide the following two vacuum controls to this apparatus:

a. "Fail-safe" vacuum control

It is essential that there be no active or significant residual suction on the interior of the eye when the cutting action is at rest and it is desirable that this be controlled automatically to preclude the hazards of forgetfulness, etc. This control comprises a means for turning the vacuum off, a sliding valve to isolate the residual suction within the control unit, and a means for abolishing the residual vacuum between the sliding valve and the cutting port. Residual vacuum at the cutting port must be abolished as otherwise a small motion of the surgeon's hand could be transmitted with dire consequences to the retina which is exceedingly easy to tear.

b. Quantitative vacuum control

As the target tissues vary widely in mobility, texture and accessibility a level of suction which might be suitable for one situation might provoke disaster in another eye or in the same eye at a different point in time or space. Consequently, it is highly desirable technically and therapeutically that a range of vacuum be selectively and readily available to the surgeon to serve these everchanging needs as they are identified.

These objectives are met by an additional manual control which varies the vacuum delivered at the cutting opening.

Further details and features of this invention will be set forth in the following specification, claims and drawings in which, briefly:

FIG. **1** is a schematic diagram showing the various controls provided to this apparatus;

FIG. **2** is a side view of the pneumatic control device provided to this invention;

FIG. **3** is a sectional view of the control device taken along the line **3—3** of FIG. **2**;

FIG. **4** is a sectional view of the control device taken along the line **4—4** of FIG. **3**;

FIGS. **5** and **6** show an enlarged view of the vitreous cutting device, the left hand end of FIG. **5** being broken off of the right hand end of FIG. **6**;

FIG. **7** is a sectional view taken along the line **7—7** of FIG. **5**;

FIG. **8** is a sectional view taken along the line **8—8** of FIG. **6**;

FIG. **9** is a front view of a device attached to the eye to inject saline solution into the eye as material is taken out of the eye;

FIG. **10** is a sectional view of the device shown in FIG. **9**; and

FIG. **11** is a perspective view of the device shown in FIGS. **9** and **10**.

Referring to the drawing in detail, reference numeral **11** designates a motor which is mechanically connected to the vacuum pump **12** and air pressure pump **13**. Pumps **12** and **13** are connected by suitable tubes to the tanks **14** and **15**, respectively. A vacuum gauge **16** is connected by suitable tube to the tank **14** and a pressure gauge **17** is connected by a suitable tube to the pressure tank **15**. The motor **11** is connected to a suitable source of electric power such as is available in the conventional wall outlet and a switch (not shown) is provided for turning the motor on and off. An auxiliary switch **19** is provided between the power line and the D.C. power supply **20** which converts the alternating current supplied thereto to direct current for energizing the multivibrator **21** and flip-flops **22** and **23**.

Multivibrator **21** is provided for triggering the flip-flop **22** which produces an output designated as mode A signal which may be supplied to the gate **24** through switch **25** when it is desired to actuate the solenoid **26** driving the valve **27** in this mode. In mode A the valve **27** is actuated to connect the output line **28** for equal intervals to the vacuum line **29** and to the pressure line **30** alternately. When the switch **25** is shifted to connect the output of flip-flop **22** to flip-flop **23** then the apparatus is operated in mode B and the wave form of this mode is supplied to the gate **24** and to solenoid **26** for controlling the valve **27** in accordance with this mode. In mode B the valve **27** is operated so that it connects the output line **28** to the vacuum or suction line **29** for an interval approximately three times as long as the interval during which this line **28** is connected to the pressure line **30**. On the other hand the mode B signal may be used to connect output line **28** to the pressure line **30** for a longer interval than the interval during which it is connected to the vacuum line, if desired.

The desired mode may be selected by operating the switch **31** that is connected to the control box **32**. A suitable foot control may be provided for actuating the switch **31**, if desired. A variable resistor **33** which may also be varied by a conventional foot control, is connected to the multivibrator **21** for controlling the frequency of the pulses in modes A and B. Multivibrator **21** supplies electrical pulses for triggering flip-flop **22** and thus controls the frequency of the pulses produced by this flip-flop.

The tube **28** is connected between the valve **27** and the vacuum control device **34**. The vacuum control device **34** which is shown in detail in FIGS. **2, 3** and **4**, is provided with a T-connection **35** having two arms **35***a* and **35***b* and line **28***b* is connected to arm **35***a*. Arm **35***b* is connected to line **36** which may be connected either to the inlet **37** or inlet **38** of the control device **34** for purposes which will be described more fully hereinafter. The control device **34** is provided with a piston **39** of plastic that is slidable in the cylinder **40** and the ports **37** and **38** lead into this cylinder, one port **37** leading in below the piston **39** and the other port **38** leading in at the top end thereof, and the purpose of this will also be described hereinafter.

A piston rod **41** which is also plastic is attached to the piston **39** and extends into a small cavity **42** into which the small tube **43** also extends. This end of the tube **43** is carefully lapped and polished and provides a seat for the end of rod **41.** Thus the lapped and polished end of tube **43** is alternately opened and closed by the end of the piston rod **41** as the piston **39** is moved back and forth during the operation of this device. The Luer type fitting **44** is attached to the control device **34** and provides a connection between the small cavity **42** and the cylinder **45** which may be of 5 cc. capacity calibrated in 1/10 cc. increments to measure the vitreous or other material removed from the eye of the patient. The standpipe **45***a* in cylinder **45** is connected by the line **46** to the top of the waste overflow bottle **47.** The bottle **47** is also connected to the vacuum line **48** so that vacuum is provided therein.

The vacuum control unit **34** is also equipped with a bleeder valve **49** which is manually adjustable by means of the small knob **49***a*. Turning the knob **49***a* opens or closes the opening 49*b* by retracting the pointed valve member **49***c* from the opening or advancing this member into the opening. The valve cavity **49***d* cuts across the small tube **43** so that an adjustable amount of the vacuum or suction supplied to this tube from tube **44** leaks therefrom through the bleeder valve **49.** Thus, bleeder valve **49** abolishes residual suction from the debris tube **50** that is connected to the small tube **43.**

Tube **50** is positioned inside of the tube **51** which is attached to the projection **51***a* of the unit **34.** The tubes **50** and **51** are attached to a cutting and debris extracting device such as indicated at **52** which may be either of the pull cut off type or of the push cut off type as disclosed in our application Ser. No. 264,166 or it may be of the type illustrated in FIGS. **5–8** of the drawing.

The cutting device **53** shown in FIGS. **5** to **8** inclusive, is provided with a housing **53** which also serves as a handle. A bellows **54** which is made of metal, is positioned inside of the handle and the end **54***a* of the bellows is cupped and soldered to the member **55** which forms part of a piston structure. The other end **54***b* is likewise cupped and soldered to member **57** which is threaded into one end of the housing **53.** The inner end **56***a* of the tube **56** forms one stop for the piston **55** and wall **57***a* of of plug **57***b* in the other end of the housing forms a stop for the out strokes. The other end **56***b* of tube **56** extends out of the housing and the plastic hose or tube **51** is attached thereto. The position of the end **56***a* of tube **56** may be adjusted by rotating finger grip **58** so that the length of the stroke of the piston structure is adjustable.

The finger grip **58** is attached to member **59** which is threaded and soldered to sleeve **60** and sleeve **60** is soldered to tube **56.** Thus, tube **56** may be rotated by the finger grip **58.** Also sleeve **60** is threaded to member **57** which is threaded into the housing **53.** Member **57** is provided with a scalloped flange **61** having evenly spaced scallops around its circumference as shown in FIG. **7.** The scallops are engaged by the resilient fingers **58***a* of the finger grip **58.** The distance between the scallops represents a predetermined angle of rotation of the finger grip **58** and tube **56.** Thus, the length of the piston stroke as limited by the stop **56***a* may be set by the surgeon using this device. The surgeon determines the desired increase or decrease of the length of this stroke simply by keeping track of the number of scallops the fingers **58***a* traverse as he adjusts the finger grip **58.**

A bearing member **62** is positioned in a slightly recessed part in the end **56***b* of the tube **56.** This bearing member is supported in the tube **56** by radially extending vanes **62***a* shown in FIGS. **5** and **7** and the central part of the bearing member slidably receives the small tube **63,** a portion of which extends outward beyond the bearing **62** and the plastic tube **50** is attached to this external portion. The small tube **63** extends into the tubular member **56** and the inner end thereof is attached to the member **64.** Member **64** is provided with a hole for receiving the end portion of the small tube **63** which is soldered thereto. Member **64** is provided with a portion of reduced diameter which is threaded and the piston **55** is attached to this threaded portion. A nut **65** is also attached to this threaded portion to prevent the bellows end plate **55** from becoming loose. The plug **57***b* is threaded into the end of the housing **53** and the outer member **66** of the telescoping tubular members is soldered into a pole provided in the plug. The inner telescoping tubular member **67** extends from the outer tubular member **66** and plug **57***b* into a hole in member **64.** Thus, the hole in the tubular member **67** communicates with the hole in the tubular member **63.** The outer telescoping tubular member **66** is provided with a sharpened aperture or port near the outer end thereof so that vitreous or other substance to be severed may be drawn therein and severed by the sharp edge **67***a* of the inner tube **67.** The outer end of tubular member **66** is heliarc welded closed and round and polished. All of the parts of the cutting device **53** are made of metal such as stainless steel so that the device may be disassembled and sterilized at a suitable temperature in an autoclave.

In the operation of this device the electronic apparatus as shown in FIG. **1** periodically energizes the solenoid **26** which is mechanically coupled to the valve **27** so that the vacuum line **29** is connected to the line **28** alternately with the air pressure line **30.** Line **28** is connected to line **28**b which is connected to the fitting **35** of the control device **34.** Thus, vacuum and pressure are alternately supplied to the hose **51** through the fitting **35** of the control device **34.** Thus vacuum and pressure are alternately supplied into the tube **56** of the cutting device through the space between the vanes **62***a* of the plug **62.** Tubular member **56** is provided with a plurality of holes **56**c through which vacuum and pressure are alternately supplied into the inside of the bellows **54.** The ends **54***a* and **54***b* of bellows **54** are cupped and soldered to the piston **55** and member **57,** respectively, to provide a good and lasting seal so that vacuum and pressure alternately move the piston **55** against the stop **56***a* and stop **57***a*. As the piston **55** is reciprocated between the stops **56***a* and **57***a* it moves the inner cutting tube **67** back and forth inside of the outer telescoping tube **66** so that the sharpened end **67***a* of the tube **67** is swept back and forth across the sharpened port **66***a* of the outer tube **66.** At the same time as the tube **67** retracted and the port **66***a* is opened, vacuum or suction is applied through the port. This vacuum or suction is controlled by the control device **34** in which the piston **39** moves the piston rod **41** so that the end of the small tube **43** is alternately opened and closed. Vacuum or suction applied to the cavity **42** through the connection **44** is supplied into the tube **43** and hose **50** when piston rod **41** is retracted

from the end of tube **43**. The hose **50** is connected to the small tube **63** in the cutting device and this small tube extends into the member **64** so that the hole therethrough communicates with the hole through the inner telescoping tube **67** and suction is thus supplied to port **66***a*.

The control device **34** is provided with a bleeder valve **49** which is connected to the small tube **43** and bleeds off some of the vacuum or suction provided to this small tube. This bleeder valve abolishes residual vacuum or suction from the small tube **43**, hose **50**, tube **56**, inner cutting tube **67** and port **66***a*.

The plug **57***b* provided to the cutting device **52** is provided with several small holes **57***c* which vent the cavity **57***d* to the outer atmosphere. The threaded nut **65** is positioned in the cavity **57***d* and moves in this cavity when the piston **55** is reciprocated during the operation of this device. Thus, during the outstroke of the member **65** in the cavity **57***d* air is fed into the cavity and then exhausted from the cavity during the instroke.

In FIGS. **9**, **10** and **11** there is illustrated a device for attaching a small tube **70** to the eye of the patient. The tube **70** is provided with a sharp end **70***a* that is inserted into the eye and the other end **70***b* is attached by a small hose to a container (not shown) of saline or other solution to be supplied to the inside of the eye to replace material removed from the eye by the device previously described herein. The tube **70** may be of stainless steel or the like material and it is attached to the arcuate plate **71** that is curved to the outer contour of the eye. Plate **71** is held on the outside of the eye by threads **72** that are inserted a short distance into the eye as shown in FIGS. **9** and **10**.

While we have shown and described a preferred embodiment of the invention, it will be understood that the invention is capable of variation and modification from the form shown so that its scope should be limited only by the scope of the claims appended hereto.

What we claim is:

1. Apparatus for intraocular surgery such as cutting or severing and removal of vitreous or other material from the eyeball of a patient comprising the combination of a pair of telescoping tubular members, a hollow handle, said tubular members including an inner end fixed to the handle and an outer end projecting from one end of the hollow handle, said tubular members each having vitreous shearing means comprising a sharp edge and a port at the outer end thereof with the ports being positioned to coincide when the tubular members are in the telescoped position, a bellows positioned in said handle, an end plate connected to one of the tubular members, means connecting said bellows to the end plate, sources of compressed air and vacuum, means connected to said sources for alternately supplying compressed air and vacuum to said bellows, means connecting said source of vacuum to one of said tubular members for drawing the material to be severed into said port, said bellows and said end plate being reciprocated by said compressed air and vacuum so that said material is drawn into said port to be severed by the sharp edge of one tubular member being moved across the port of the other tubular member, said connecting means intermittently connecting said source of vacuum to the inner one of said telescoping tubular members for drawing the severed vitreous out of said inner tubular member, and means abolishing residual vacuum from said port after the severing of said material is interrupted.

2. In apparatus for intraocular surgery for cutting or severing and removal of vitreous or other material from the eyeball of a patient, the combination comprising a first tube of very small diameter having a port near one end thereof, a second tube concentric with said first tube, said tubes fitting snugly together and one of said tubes being slidable with respect to the other, the end of said second tube adjacent the port of the first tube being honed and polished to provide a sharp cutting edge, a source of vacuum, means for connecting said source of vacuum to the inner one of said tubes for drawing vitreous into the first tube through said port, means reciprocating one of said tubes with respect to the other so that sharp end of the second tube crosses said port of the first tube and shears off said vitreous sucked into said port, a bleeder valve attached to said vacuum connecting means, said bleeder valve abolishing residual vacuum from said tubes and preventing vitreous from being drawn into said port when said reciprocating means is interrupted.

3. Apparatus as set forth in claim **1**, further characterized in that the inner one of said telescoping tubular members is attached to said end plate, said handle having stop means limiting the reciprocating motion of said end plate.

4. Apparatus as set forth in claim **3**, further comprising means for adjusting said stop means so that the stroke of said end plate is adjustable.

5. Apparatus as set forth in claim **4**, further characterized in that said adjusting means comprises a rotatable member supported by said handle, and a member in said handle supporting said adjustable stop means, said rotatable member being attached to said last memtioned member.

6. Apparatus as set forth in claim **1**, further comprising an elongated member having an inner end in said handle, the inner end of said elongated member forming a stop for the out stroke of said end plate, said elongated member being hollow and the other end thereof extending out of said handle, said sources of compressed air and vacuum being connected to said other end to supply compressed air and vacuum into said bellows.

7. Apparatus as set forth in claim **6**, further comprising a rotatable member on said handle for adjusting said elongated member to adjust the out stroke of said end plate.

8. Apparatus as set forth in claim **7**, further comprising spring means attached to said rotatable member, a scalloped member attached to said handle, parts of said spring means engaging said scalloped member to control the rotation of said rotatable member in predetermined steps permitting the control to be positioned in the dark by feel.

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