June 24, 1969 V. A. THYBERG 3,451,395

CRYOSURGICAL INSTRUMENTS

Filed Feb. 3, 1967 Sheet 1 of 3

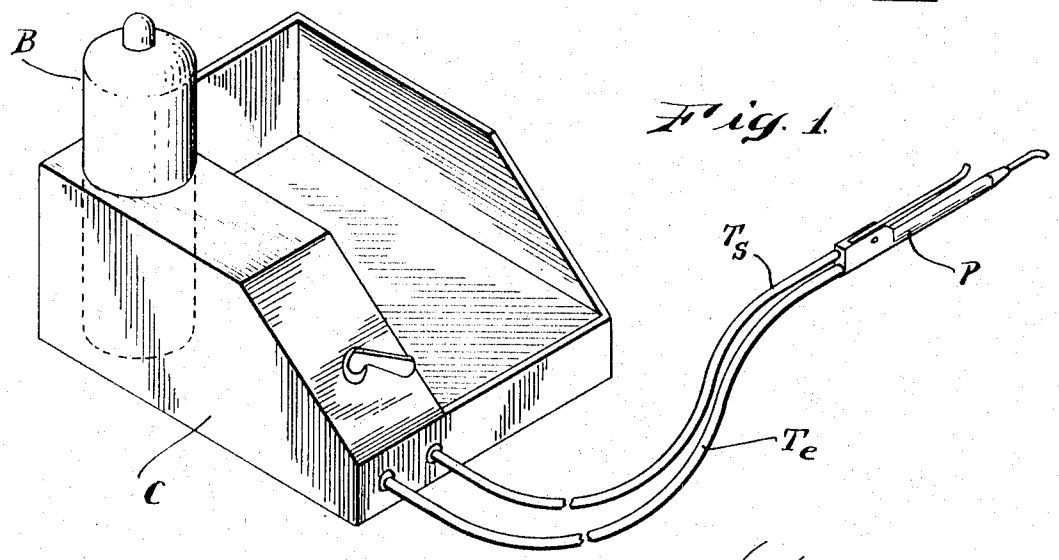


Fig. 1.

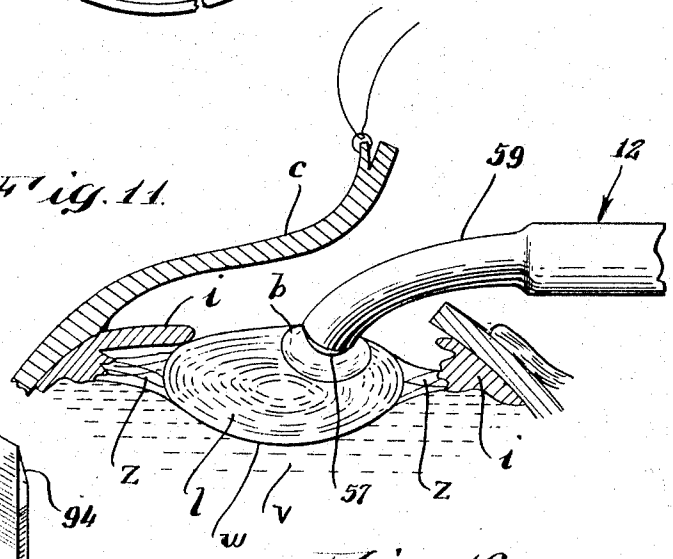


Fig. 11.

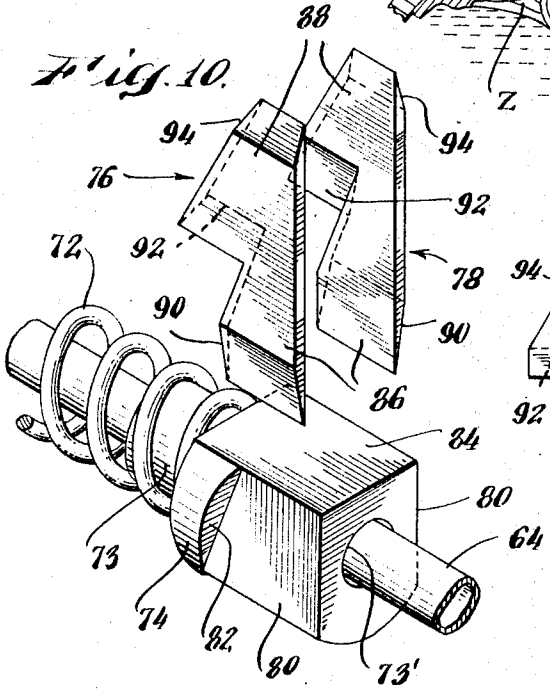


Fig. 10.

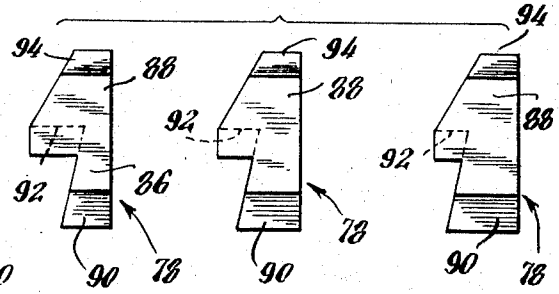


Fig. 12.

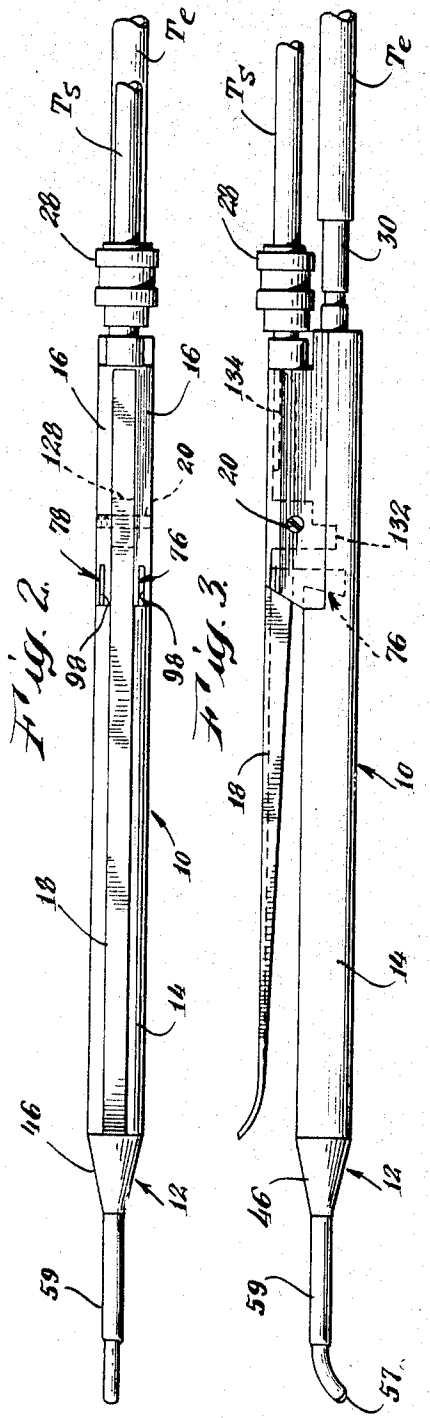
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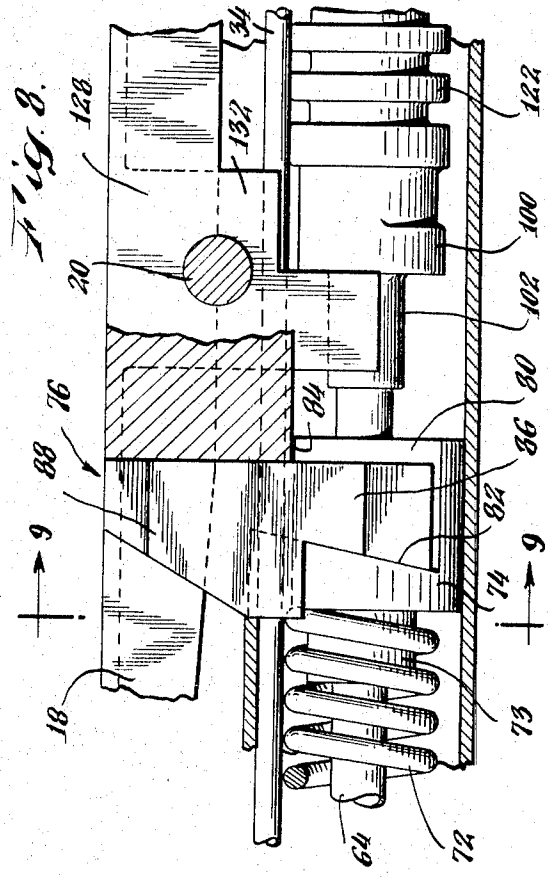
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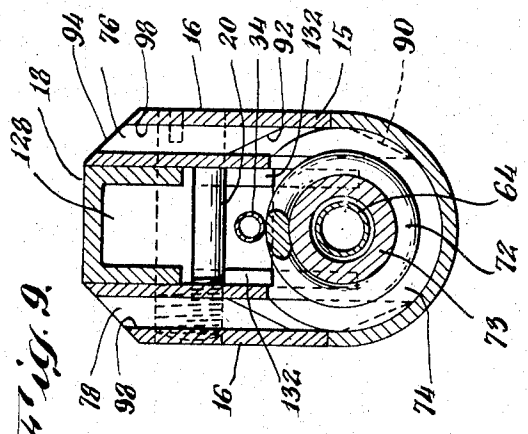
CRYOSURGICAL INSTRUMENTS

Filed Feb. 3, 1967

Sheet 2 of 3







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CRYOSURGICAL INSTRUMENTS

Filed Feb. 3, 1967 Sheet 3 of 3

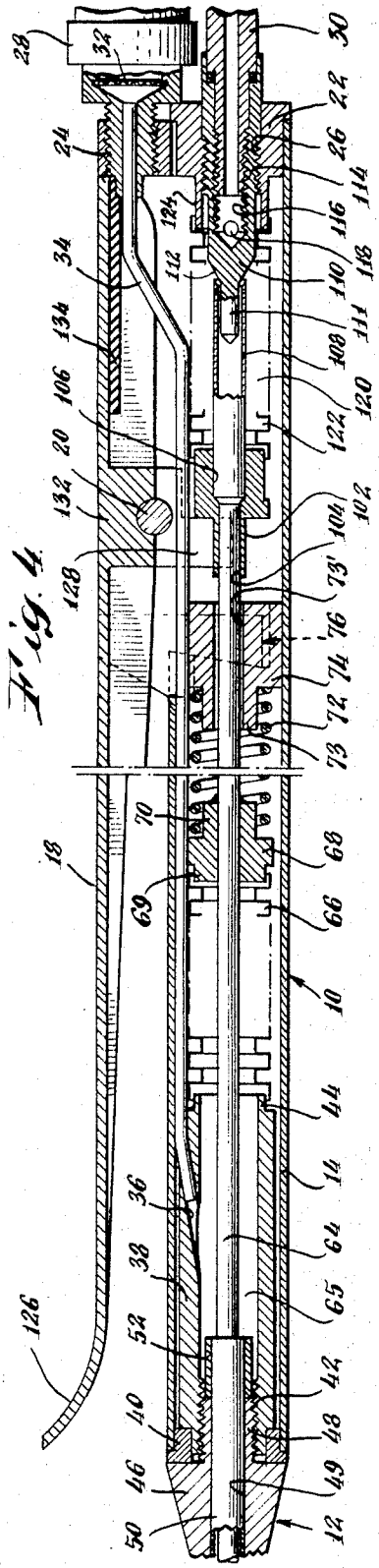


Fig. 4.

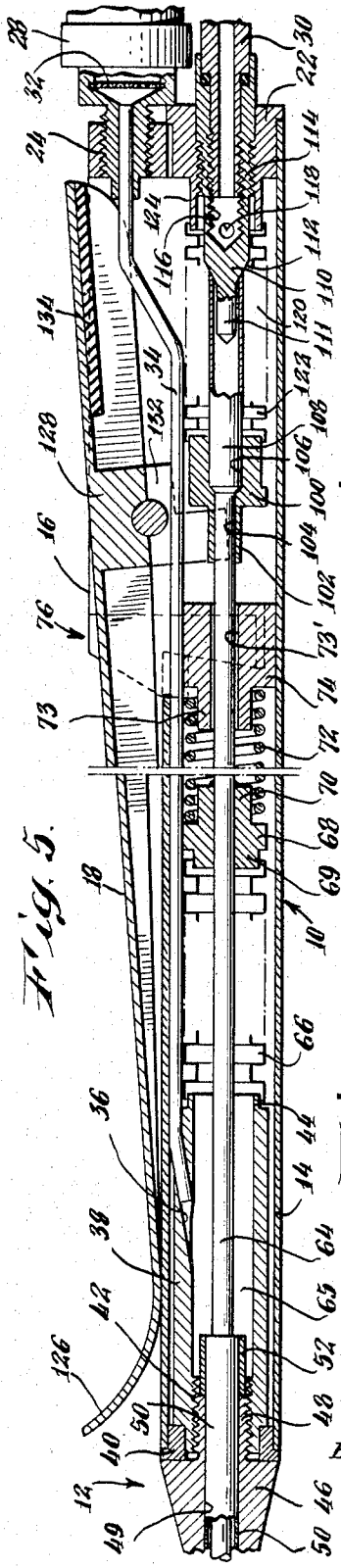


Fig. 5.

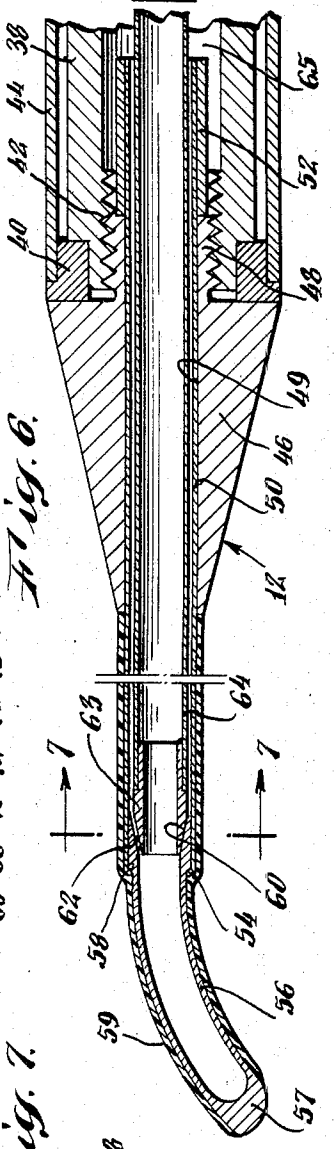


Fig. 6.

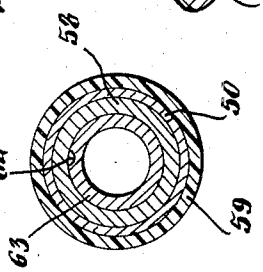


Fig. 7.

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United States Patent Office 3,451,395
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3,451,395

CRYOSURGICAL INSTRUMENTS

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Filed Feb. 3, 1967, Ser. No. 613,800
Int. Cl. A61b 17/36
U.S. Cl. 128—303.1 9 Claims

ABSTRACT OF THE DISCLOSURE

A cryosurgical probe having a metering orifice through which liquid refrigerant flows and expands into a "boiler" tip for cooling the tip under normal operating conditions. A control lever is provided for opening a valve to flood the "boiler" with liquid refrigerant for warming the tip. The valve is delicately and adjustably balanced so as to require application of a very small force upon the control lever to open the valve.

This invention relates to a cryogenic medical apparatus which may be used for eye surgery and, more particularly, to a cryogenic surgical probe which is normally cold when in use and may be rapidly warmed without electrical means.

Cataract surgery is one of the most delicate of surgical procedures as it involves the removal of an opacified lens, the wall or capsule of which has extremely low tensile properties and is easily ruptured. Usually, cataracts are extracted whole (intracapsularly) through an incision made at the intersection of the cornea and the outer edge of the iris. The lens is usually removed by the exertion of traction on the capsule by means of forceps especially designed to grasp the lens or by means of a suitable suction device. These methods have been found to be unsatisfactory as they sometimes result in rupture of the capsule, and contamination of the healthy parts of the eye by the lens fluid.

To prevent rupture of the capsule, it has recently become the practice in some hospitals to perform this operation by placing a cryosurgical instrument against the lens to lower the temperature of the lens to approximately −30° C. thereby producing an ice mass in the interior of the lens which makes an adhesive bond between the instrument tip and the capsule. With the lens thus adhered to the instrument, the surgeon may exert traction on the lens, the tractive force thus being distributed over the surface of the intralenticular ice mass which has become an integral part of the instrument, thereby appreciably reducing the traction on the capsule itself. In cases in which the capsule has already been ruptured, or in which it ruptures during extraction, it is possible to seal the rupture by placing the cryosurgical instrument over the tear in the capsule, thus solidifying the intralenticular fluid, and to continue with the intracapsular extractioin in the same manner as with an unruptured lens.

Various cryosurgical instruments have been developed for utilizing the techniques of cryosurgery. Machined metal probes externally cooled by insertion into a mixture of alcohol and Dry Ice are a simple form of such instruments and are of very limited practicability. Other forms of these instruments include thermoelectrically refrigerated probes based on the Peltier effect, low temperature liquid circulating probes, and "boiler" types probes within which low boiling temperature liquids are caused to vaporize.

The type of cryosurgical instrument to be used is determined to a great extent on the type of operation to

be performed. For example, for complicated cataract removals continuous operation of the instrument is required for a relatively long period of time, since the surgeon may be required to be in the eye for as long as fifteen to twenty minutes. Therefore, it is obvious that the externally cooled instruments would be useless, disposable units would have exhausted their charge in the first few minutes of actual use, and thermoelectrically cooled instruments which are necessarily large, may tire the surgeon's hand over such an extended period of use.

A cryosurgical instrument of the "boiler" type is described in application Ser. No. 516,383, filed Dec. 27, 1965, now Patent No. 3,393,679, invented by Ralph E. Crump and Frank L. Reynolds and assigned to the same assignee as this application. Therein was disclosed a cryosurgical instrument for use in the treatment of detached retina. The instrument of that invention is inserted normally warm, as it must be passed through or by healthy tissue to reach the operating site. Furthermore, in performing the retinal attachment, it is only necessary to reach a very low temperature for a relatively short time in order to "weld" the detached retina to the wall of the eye. Thus, a unique method and apparatus was disclosed therein for rapidly cooling the normally warm instrument tip in response to the depression of a control lever when the surgeon desired to change the state of the instrument.

Since the instrument of the present invention is designed for use in cataract extraction operations wherein it must be maintained at a low temperature for a long period of time while removing the lens from the eye, it would be impractical for the surgeon to use a probe of the type described in the copending application as his hand would become tired after a relatively short period of time if he were required to maintain a control lever depressed. Therefore, the instrument of this invention must be normally cold when in use and must be able to achieve rapid warming if, for example, the surgeon should inadvertently touch some portion of the body other than that to which the low temperature is meant to be applied. Since the probe tip will freeze and adhere to any moist portion of the body to which it comes in contact, it is necessary to be able to rapidly warm the tip by finger actuating a control means that is so delicate in operation that its actuation will not cause appreciable movement of the instrument and tear the tissue to which the instrument is frozen.

Accordingly, it is the primary object of this invention to provide an improved cryosurgical instrument designed especially for cataract extraction operations, which will be normally cold when in use and may be rapidly warmed by the application of a very slight force supplied by the surgeon's finger to a control means.

Another object is to provide a cryosurgical instrument which is safe for operating-room use, being completely explosion-proof by virtue of having no electrical switches, lights, plugs, or heating elements.

Still another object is to provide such an instrument which is small and not too unlike instrument shapes and sizes with which the opthalmic surgeon is familiar, and further having a non-electrical warming control means which can be adjusted to respond to the application of any desired force.

To accomplish these objects, in one form, a cryosurgical instrument is provided which comprises: a body or handle; a tip member secured to the forward end of the handle and defining a low temperature "boiler"; a liquid refrigerant delivery means; a fluid exhaust means; a delivery tube located at the interior of the body communicating between the delivery means and the "boiler"; a longitudinally movable exhaust tube located within the body; an expansion valve metering orifice located be-

tween the delivery tube and the "boiler" for causing the liquid refrigerant to vaporize as it flows therethrough, and to cool the "boiler"; an inlet valve and an exhaust valve located at the remote ends of the exhaust tube; actuating means for moving the exhaust tube for substantially simultaneously opening and closing the respective valves; and an adjustable balancing means for urging the inlet valve closed so that the bias may be overcome by application of a slight force to the actuating means.

Other objects and further details of that which I believe to be novel and my invention will be clear from the following description and claims taken with the accompanying drawings, wherein:

FIG. 1 is a perspective view of the cryosurgical instrument of my invention connected to a liquid supply cabinet;

FIG. 2 is a plan view of the instrument of FIG. 1 constructed in accordance with this invention;

FIG. 3 is a side elevational view of the instrument of FIG 2;

FIG. 4 is an enlarged cross sectional view of the instrument when the control level is in its normal position;

FIG. 5 is an enlarged cross sectional view of the instrument when the control level is depressed;

FIG. 6 is an enlarged cross sectional view of the tip, or "boiler," of the instrument;

FIG. 7 is a sectional view taken substantially along the line 7—7 of FIG. 6;

FIG. 8 is an enlarged sectional view of the control lever operator and the force adjusting means;

FIG. 9 is a sectional view taken substantially along the line 9—9 of FIG. 8;

FIG. 10 is an enlarged perspective view of the spring tensioning device;

FIG. 11 is a schematic view showing the probe in use during a cataract extraction operation; and

FIG. 12 is an enlarged view of a portion of a set of locking pins of various sizes.

Referring to the drawings, there is illustrated in FIG. 1 a liquid refrigerant delivery cabinet C carrying a refrigerant supply bottle B. A cryosurgical instrument P is connected to the delivery cabinet by the supply tube T_s and the exhaust tube T_e. The bottle B may contain any conventional liquid refrigerant, such as those refrigerants marketed under the trademarks "Freon 12," "Freon 502," "Freon 22" (a mark of Du Pont) or "uKon" (a mark of Union Carbide Corporation).

With particular reference to FIGS. 2–10 there is illustrated in detail the cryosurgical instrument P shown in perspective in FIG. 1. The probe comprises a main body handle portion **10** and a tip portion **12** secured to the forward end thereof. The handle **10** includes a tubular portion **14** extending approximately two-thirds of its length at the forward end thereof, and a larger portion disposed at the rearward third of the handle, defined by spaced upstanding walls **16**. A control level **18** overlies the handle portion **10** and is pivotally secured to the handle between the spaced walls **16** by means of pivot pin **20**.

The rearwardmost end of the handle **10** carries an end wall **22** (FIGS. 4 and 5) which is welded in place or secured thereto in some other suitable manner. The end wall **22** includes tapped holes **24** and **26** for receiving an inlet coupling **28** and an exhaust coupling **30**. The inlet coupling is provided with a micron filter **32** for preventing contaminating particles from entering the liquid supply line of the surgical instrument. The inlet coupling **28** is bored to received a delivery tube **34** which tube extends substantially through the length or the handle and terminates in a welded joint in an inclined passage **36** formed in a front support block **38**. Block **38** comprises an annular member located at the forwardmost end of the handle **10** and secured therein by being stopped against a ring member **40** which in turn is welded within the tubular portion **14** of the handle **10**. The annular block **38** further includes an internally threaded portion **42** at this forward end and an annular boss **44** at its rearward end.

The tip portion **12** is threadedly coupled with the threaded portion **42** and comprises a conical member **46** having an annular externally threaded boss **48**, and a bore **49** through which a thin walled tube **50** is extended. In order to prevent the tube **50** from being displaced or removed from its position under the influence of the high pressure liquid refrigrant, a collar **52** is soldered to the tube or secured thereon in some other suitable manner for abutment with the end of the boss **48**. The forwardmost end of the sleeve **50** is necked down at **54** (FIG. 6).

The tip **12** further comprises the boiler **56**, a curved thin walled tube, closed at one end **57** and enlarged at its remote open end **58**, which is captured by the necked down wall portion **54** of the tube **50**. A protective sleeve **59** of a plastic material such as that marketed under the trademark "Teflon" (a mark of Du Pont) is disposed upon the surface of the tip **12** from the forward end of the conical member **46** to the forward end of the probe, exposing only the end **57** of the boiler **56**. The enlarged end **58** of the boiler includes a precision machined conical inlet valve seat **60** which cooperates with a conical inlet valve **63** which is secured firmly in the forwardmost end of an exhaust tube **64**. A machined metering orifice **62** is located upon the concial exterior surface of the inlet valve **63**, the orifice serving as an expansion valve for vaporization of the liquid refrigerant. The exhaust tube **64** is located coaxially with an internally of the tube **50**, and the annular front support block **38** and extends substantially the entire length of the handle **10**, being movable longitudinally relative thereto.

A liquid refrigerant reservoir **65**, located at the forward end of the handle **10**, is defined by the outer surface of the exhaust tube **64**, the inlet valve **60**, **63**, the inner surface of the tube **50**, the inner surface of the annular front support block **38**, a bellows member **66** and a front spring stop **68** which is welded to the exhaust tube **64** for longitudinal movement therewith. The bellows **66** is secured in some suitable manner to the bosses **44** and **69** formed on the annular front support block **38** and the front spring stop **68** respectively. It is apparent that as the pressurized liquid refrigerant enters the reservoir **65** through the delivery tube **34** it will fill the reservoir including bellows **66** and tend to move the front spring stop **68** and exhaust tube **64** in a rearward direction. To counteract this tendency, a compression spring **72** is mounted between the movable front spring stop **68** and a stationary rear spring stop **74**, the spring **72** being mounted upon the bosses **70** and **73** of the front spring stop **68** and the rear spring stop **74**, respectively. The compression spring **72** can be pre-set to deliver a predetermined forward working force responsive to the location of the rear spring stop **74** as determined by the dimensions of a pair of locking pins **76** and **78**.

It can be clearly seen in FIG. 10 that the rear spring stop **74** comprises a partially cylindrical movable body including a spring supporting boss **73** and defining a central axial bore **73'** of a diameter large enough for passage of the exhaust tube **64** therethrough. The spring stop **74** further defines opposed planar side wall portions **80** having inclined shoulders **82** for engagement with the pair of locking pins **76** and **78**, and a planar top wall portion **84** for allowing the delivery tube **34** to pass between the stop **74** and the interior wall of the tubular handle **14** (see FIG. 8). The locking pins **76**, **78** include wedge-shaped lower portions **86** for interlocking on the taper with the inclined shoulders **82**, for preventing inadvertent removal of the pins. The pins **76** and **78** are made for insertion in grooves **98** (FIG. 9) defined in the upstanding walls **16** of the handle and further include enlarged portions **88** designed to conform to the forward end of the upstanding walls **16**. The locking pins **76** and **78** also include bevelled wall portions **90**,

92, 94 (FIG. 10), for preventing interference of the locking pins with the cylindrical body members at the interior of the tubular handle. It should be understood at this point that adjustment of the forwardly directed compression spring working force is determined by the location of the stationary rear spring stop **74** as determined by the size of the pair of locking pins **76** and **78** which are inserted in the grooves **98** of the upstanding walls **16**.

The exhaust tube **64** extending through the rear spring support **74** carries a pressure block **100** (FIG. 5) at its rearwardmost end. Pressure block **100** comprises a substantially cylindrical body having a boss **102** at its forwardmost end defining a bore **104** for snugly receiving the exhaust tube **64**. Communicating with the bore **104** is an enlarged bore **106** extending through the remainder of the pressure block **100** for snugly receiving a tubular valve member **108** therein. An exhaust valve member **110** includes a positioning spindle **111** for centrally locating the tubular valve member **108** with respect to a conical valve seat **112** which cooperates with the valve member **108** for controlling the flow of the exhaust gases through the surgical instrument. The exhaust valve member **110** further includes an externally threaded elongated tubular coupling portion **114** for threaded engagement in the end wall **22**. The member **110** also has an internally threaded portion **116** for threadedly receiving the exhaust coupling member **30** of the exhaust tube T_e. A plurality of radial ports **118** are defined by the tubular coupling member **114** for communication between an exhaust gas chamber **120** and the exhaust coupling **30**. The chamber **120** is enclosed by a bellows **122** which is secured at one end to the pressure block **100** and at its other end to an annular boss **124** disposed on the end wall **22**. Exhaust gases are discharged through the exhaust valve **108, 110** into the exhaust gas chamber **120** from which they are discharged through ports **118** to the atmosphere or withdrawn by a suitable pumping means.

The control lever **18**, overlying substantially the entire handle **10**, comprises a narrow lever arm seated between the upstanding walls **16** having a finger receiving curved forward portion **126**. It is pivoted near its rear to provide the surgeon with a substantial mechanical advantage. A pivot block **128** in control lever **18** is bored to receive a pivot pin **20** which passes through one of the upstanding walls **16**, through the pivot block **128** and is threadedly engaged with the outer wall **16**. The pivot block **128** further comprises a pair of bifurcated legs **132** extending into the handle, between which the delivery tube **34** may pass, and which extend to a position adjacent the pressure block **100** for moving the pressure block **100** rearwardly when the control lever is depressed (see FIG. 6). The rearward movement of the pressure block causes the exhaust tube **64** carrying the front spring stop **68**, to move in the same direction, thus further compressing the spring **72**. Upon release of the depressing force from the control lever **18**, it will return to its upward position (see FIG. 4) since the exhaust tube **64** carrying the pressure block **100** will be moved forwardly by the compression spring **72**. The control lever **18** further includes a resilient pad **134** at its rearwardmost end for acting as a bumper for preventing damage to the delivery tube **34** and the inlet coupling when the lever is returned to its upward position by the compression spring **72**.

Operation

Warm liquid refrigerant at room temperature flows from the bottle B, seated in the cabinet C, through the supply tube T_s and enters the rear section of the surgical instrument through the inlet coupling **28** which is threadedly engaged in the rear wall **24** of the instrument. The warm liquid is piped to the front section of the instrument through an internal delivery tube **34**, and enters the liquid refrigerant reservoir **65**, wherein it forms an annulus which acts as a thermal insulator for protecting the hand of the surgeon and the adjacent eye tissue from freezing temperature. This comparatively large volume of near-stagnant liquid refrigerant also serves as a capacitor for preventing surging of the liquid as it is metered into the boiler **56**.

The amount of liquid refrigerant which is metered to the boiler **56** through the precision machined metering orifice **62** is exactly regulated to effect the required low degree of temperature and rate of freeze, the two important parameters necessary for cryogenic surgery. Careful regulation of the liquid refrigerant flow is necessary so as to form a steady state intralenticular iceball within a few seconds after application of the instrument to the lens. It is desirable to freeze only approximately 25% of the lens fluid since, if the lens volume is excessively frozen, the vitreous *v* and adjacent tissues, such as the iris *i* and the zonules *z* (FIG. 11), may be damaged. Therefore, as has been noted, the metering orifice **62** has been precisely machined in the conical inlet valve **63**. The inlet valve is held closed by the force of the compression spring **72** which biases the conical inlet valve **63** carried by the exhaust tube **64** axially forward into the conical inlet valve seat **60**. When the inlet valve **63** is closed, the exhaust valve **108, 110** is opened through exhaust tube T_e to the atmosphere or to a suitable vacuum pumping means. This causes the liquid refrigerant entering the boiler **56** through the metering orifice **62** to expand and to vaporize. This expansion and change of state reduces the temperature of the refrigerant.

The pressure of the refrigerant in its liquid phase (approximately 120 lbs. per square inch at 70° F.) has a tendency to expand bellows **66** and move the front spring stop **68** rearwardly, therefore the spring force is adjusted to overcome this rearward bias and maintain inlet valve **63** normally closed. The near equilibrium condition between the fluid pressure force and the spring force which maintains the inlet valve closed is necessary in order to provide a delicately balanced surgical instrument. By depressing the lever **18** with a force so small that the tip of the instrument itself will not be moved downwardly to displace the tissue to which it is frozen, the delicate equilibrium condition may be overcome by the surgeon for opening the inlet valve **63**, flooding and rapidly warming the boiler **56**. The compression spring **72** is compressed to deliver a predetermined forward working force which is adjustable. Such an adjustment is made by removing the pair of locking pins **76** and **78** and replacing them with a larger or smaller pair of pins selected from a set of locking pins of various sizes (see FIG. 12) which may be interposed between the rear spring stop **74** and the upstanding walls **16** of the handle within the grooves **98**. Of course, access to the rear spring stop **74** is blocked by the control lever **18** which must be removed prior to the insertion of a special tool which aids in displacing the rear spring stop **74** for removal of the locking pins **76** and **78** and reinsertion of a different pair.

FIG. 11 illustrates the cryogenic instrument in use during a cataract extraction operation. The surgeon has made an incision in the cornea *c* and lifts the cornea away from the lens in order to introduce the exposed tip of the instrument to the lens *l*. The instrument is allowed to remain in contact with the lens *l* before beginning the extraction, in order to adhere the tip **57** of the instrument to the lens wall or capsule *w* and for forming an intralenticular iceball *b* which assists in the distribution of the tractive force over a greater area of the capsule *w*. The instrument is then raised, thereby stretching the zonules *z* in order that a tool may be inserted to rupture the zonules prior to extracting the lens *l*. After the zonules *z* have been ruptrued, the lens may be completely extracted. It should be noted that the "Teflon" sleeve **59** which protects the forward end of the instrument, leaving only the tip exposed, prevents adhesion of the instrument to any portion of the eye to which it may come incontact. Should

the iris *i*, cornea *c* or any other part of the eye inadvertently be contacted with the tip **57** of the instrument, the control lever **18** may be depressed, thereby warming the tip and allowing the instrument to be released.

It is to be understood that the present disclosure has been made only by way of example, and that numerous changes in details of construction and the combination and arrangement of parts may be resorted to without departing from the true spirit and scope of the invention as hereinafter claimed.

What I claim as new and desire to secure by Letters Patent of the United States is:

1. A cryosurgical instrument which comprises: a body member; a tip member secured to one end of said body member defining a low temperature boiling chamber; fluid supply means for delivering a fluid to said body; means for exhausting a fluid from said body; a delivery tube in fluid flow relationship between said fluid supply means and said boiling chamber; means defining a metering orifice located between said delivery tube and said boiling chamber for allowing the fluid to vaporize and to cool said boiling chamber; inlet valve means for communicating said delivery tube with said boiling chamber; an axially movable exhaust tube disposed within said body in fluid flow relationship between said boiling chamber and said fluid exhausting means; exhaust valve means for communicating said exhaust tube with said fluid exhausting means; actuating means for opening and closing said inlet valve means while simultaneously closing and opening said exhaust valve means; and balancing means disposed within said body for urging said inlet valve closed for allowing said actuating means to be operated in response to the application of a very slight force.

2. The cryosurgical instrument defined in claim **1** wherein: said exhaust tube extends from an inlet valve seat to an exhaust valve seat, and comprises an inlet valve disposed at a first end and an exhaust valve disposed at a second end; and means for axially moving said exhaust tube in response to the movement of said actuating means for opening and closing said inlet and exhaust valves.

3. The cryosurgical instrument defined in claim **1** wherein said balancing means comprises: rearward axial force exerting means; forward axial force exerting means; and a forward stop member firmly secured to said exhaust tube upon which said axial force exerting means operate for maintaining said stop member biased in a forward direction for maintaining said inlet valve closed.

4. The cryosurgical instrument defined in claim **3** wherein said rearward axial force exerting means is an expansible pressure chamber responsive to the introduction of pressurized fluid through said delivery tube.

5. The cryosurgical instrument defined in claim **3** wherein: said forward axial force exerting means is a compression spring; and further comprising a rear stop member adjustably axially positionable within said body and supporting one end of said compression spring, the other end of said compression spring biasing said first stop member forwardly.

6. The cryosurgical instrument defined in claim **5** further including positioning means selectively axially locating said rear stop member.

7. The cryosurgical instrument defined in claim **6** wherein said positioning means comprises a set of pairs of locking pins of different sizes selectively replaceable with one another positioning said second stop member either closer to or further from said first stop member for varying the forward axial force exerted by said compression spring.

8. The cryosurgical instrument defined in claim **5** wherein: said rear stop member comprises a body defining planar opposed side wall portions, each wall portion having a shoulder inclined with respect to the longitudinal axis of said body member; and further including axial positioning means comprising a pair of wedge-shaped locking pins each engaging said rear stop member at one of said inclined shoulders, for preventing inadvertent removal of said locking pins.

9. The cryosurgical instrument defined in claim **1** further comprising: a pressure block firmly secured to said exhaust tube for axial movement therewith; and wherein said actuating means comprises a control lever overlying said body, mounted thereon for pivotal movement with respect thereto, and having force applying means thereon for moving said pressure block axially in response to a slight force applied to said lever for overcoming said balancing means.

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RICHARD A. GAUDET, *Primary Examiner.*

JOHN D. YASKO, *Assistant Examiner.*

U.S. Cl. X.R.

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(5/69)

UNITED STATES PATENT OFFICE
CERTIFICATE OF CORRECTION

Patent No. 3,451,395 Dated June 24, 1969

Inventor(s) Victor A. Thyberg

It is certified that error appears in the above-identified patent and that said Letters Patent are hereby corrected as shown below:

Column 4, line 1, cancel "this" and substitute --its--.

See page 7, line 17 of specification as filed.

Column 8, line 14, before "positioning" insert --for--.

See line 4 of claim 7 as filed.

SIGNED AND
SEALED
APR 28 1970

(SEAL)
Attest:

Edward M. Fletcher, Jr.
Attesting Officer

WILLIAM E. SCHUYLER, JR.
Commissioner of Patents