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[56]

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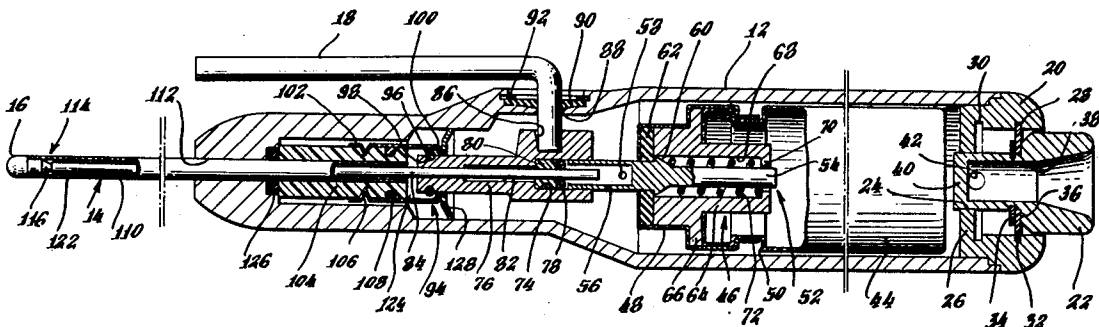
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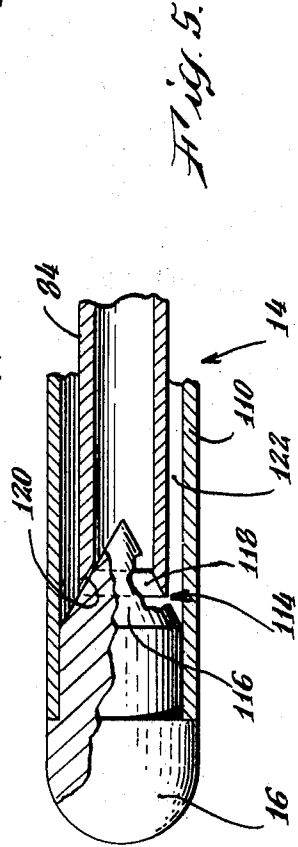
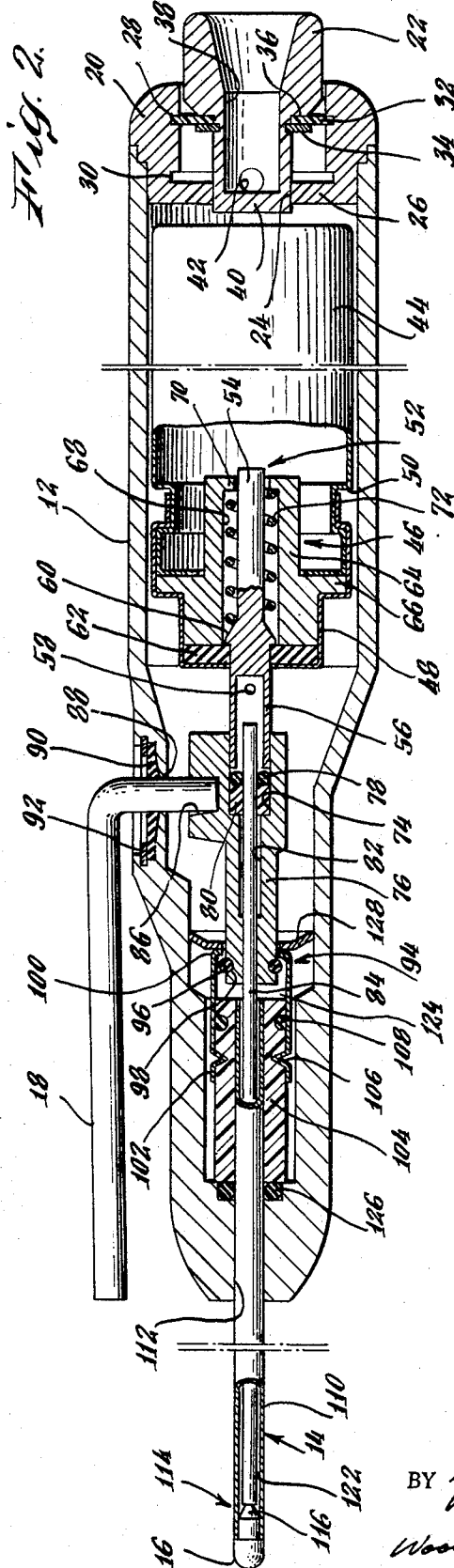
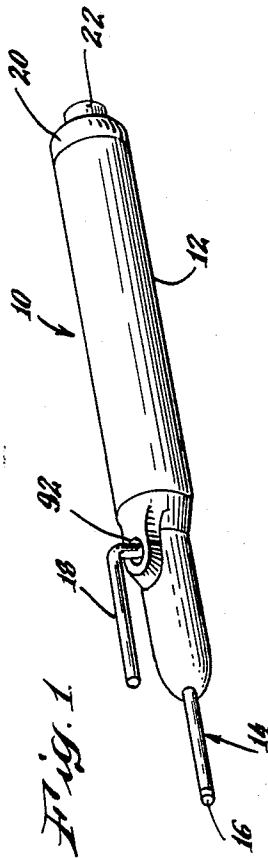
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[54] **DISPOSABLE CRYOSURGICAL INSTRUMENT**
11 Claims, 5 Drawing Figs.

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400, 401

ABSTRACT: A cryosurgical instrument having a container of liquefied gas sealed therein. The gas is dispensed from the container through a delivery tube to a boiler valve located adjacent a cooling tip to reduce the temperature of the tip. The spent gas is exhausted from the housing through an opening therein. A selectively operable finger actuated lever located at the exterior of the housing operates the boiler valve.





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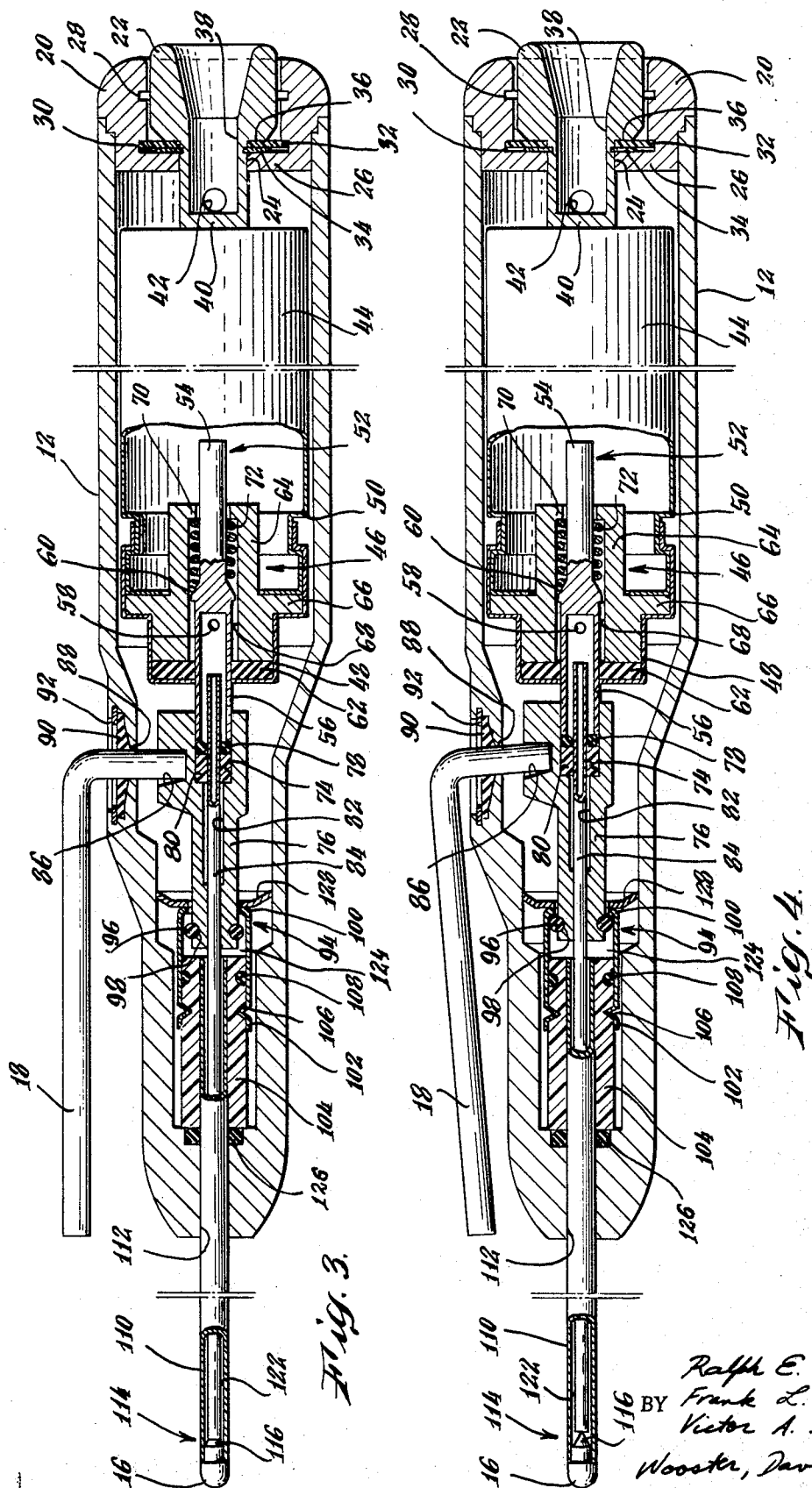


Fig. 3.

Fig. 4.

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DISPOSABLE CRYOSURGICAL INSTRUMENT

BACKGROUND OF THE INVENTION

This invention relates to a self-contained, disposable cryosurgical instrument and, more particularly, to such a device which is designed for eye surgery and which is normally cold when in use and may be rapidly warmed as desired.

Cataract surgery is one of the most delicate operations that a surgeon is called upon to perform, as it involves the removal of an opacified lens. Once the lens has been removed in an otherwise healthy eye, the patient with the aid of glasses may have use of that eye, often with perfect vision. Usually the lens, which comprises a very thin membrane containing a fluid, is extracted whole through an incision made at the intersection of the cornea and the outer edge of the iris. Most commonly this has been accomplished by the exertion of traction thereon by means of a suitable device, for example, specially designed forceps. Although the cataract operation has been greatly improved in recent years by the use of better traction instruments, they have a tendency to cause the membrane to rupture.

More recently, however, it has become the practice to perform this operation with a cryogenic instrument, utilizing the principle of cryoextraction which derives its benefit from the excellent adhesion of a cold metal surface to warm moist tissue. This is accomplished by contacting the lens with a cryosurgical instrument having a probe which may be cooled to approximately -30°C . to freeze the membrane and to form an ice mass at the interior of the lens contiguous thereto which assists in distributing the extraction force over a large area of the membrane to prevent its rupture.

Various cryosurgical instruments have been developed for utilizing the techniques of cryosurgery. These fall into three general categories, namely: (1) continuously operating units; (2) disposable instruments; and (3) solid probes which are cooled merely by being immersed in a cold liquid such as alcohol and Dry Ice. The first category is represented by various high priced systems such as those operating on the Peltier effect which must be connected to a source of electrical power or those having a remote supply tank of a suitable refrigerant which must be piped to the instrument. The latter may also require a vacuum pump to regulate the probe temperature. These instruments are designed to allow the surgeon to quickly warm the tip of the probe so that he may disengage the cold tip from tissue inadvertently adhered thereto. Moreover, these continuously operating units require complete sterilization between each usage. The presently known instruments in the second and third categories, while being considerably less expensive than those of the first category, have the distinct disadvantage of lacking integral warming means and require the application of an externally applied warming medium to the area adjacent the cryoadhesion if the surgeon should accidentally touch healthy tissue with the tip of the probe. This is usually accomplished by irrigating the area with a warm saline solution and generally requires the intervention of another sterile person. Furthermore, the instruments falling in these categories are generally crude and are often of dubious sterility.

SUMMARY OF THE INVENTION

Accordingly, it is the primary object of this invention to provide a cryogenic surgical instrument in the form of a disposable unit which may be normally cold when in use and which may be selectively warmed.

Another object is to provide a cryogenic surgical instrument in which the refrigerant is sterile and cools the probe by its change of state from a liquid to a gas which is discharged to the atmosphere.

Still another object of the invention is to provide a disposable cryogenic surgical instrument which is lightweight, compact, inexpensive, and which may be delivered to the surgeon in a sterile condition for a single use.

To accomplish these objects, in one form there is provided a disposable cryosurgical instrument including a housing; a cooling tip positioned at one end of the housing; a boiling chamber in the housing adjacent the cooling tip; a container of pressurized refrigerant located within the housing; dispensing means positioned at one end of the container, a reciprocable member positioned within the housing adjacent the dispensing means; selectively operable means to move the reciprocable member connected to the member and extending through the housing to the exterior thereof; a delivery tube secured to the reciprocable member for movement therewith and extending to the cooling tip to pass refrigerant to the boiling chamber; a metering orifice located between the end of the delivery tube and the cooling tip through which the refrigerant may expand into the boiling chamber to reduce the temperature of the cooling tip at one position of the reciprocable member; an exhaust tube firmly secured in the housing for passing the spent refrigerant from the boiling chamber; an exhaust valve operable by the reciprocable member to control the flow of the spent refrigerant through the exhaust tube; and a vent defined in the housing to pass the spent refrigerant to the atmosphere.

BRIEF DESCRIPTION OF THE DRAWINGS

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

FIG. 1 is a perspective view of a disposable cryogenic surgical instrument in accordance with this invention;

FIG. 2 is a longitudinal sectional view of the disposable cryogenic surgical instrument of FIG. 1 shown in its unactivated condition as delivered to the surgeon;

FIG. 3 is a longitudinal sectional view similar to that of FIG. 2 showing the instrument after it has been activated and is in its normal cooling condition;

FIG. 4 is a longitudinal sectional view similar to that of FIG. 2 showing the instrument in its thawing condition; and

FIG. 5 is an enlarged partial longitudinal sectional view showing the cooling tip in detail.

DESCRIPTION OF THE PREFERRED EMBODIMENT

With reference to the drawings, there is illustrated in FIG. 1 a cryogenic surgical instrument generally referred to by numeral 10. It is in the form of a pencil-like instrument having a body 12 with a probe 14 terminating in a cooling tip 16 at one end, an operating lever 18 overlying the forward portion of the body, and a closure cap 20 including an activating button 22 at its other end. The instrument is lightweight, the body 12 being made for example of a suitable plastic material, so that it may be comfortably hand held. When held in use, the operating lever 18 is located under the surgeon's index finger and may be selectively depressed with a very slight pressure for purposes to become apparent hereinafter.

Turning now to the details of the instrument as shown in FIGS. 2-4, there is illustrated the closure cap 20, which may also be made of plastic, which is firmly secured in the open end of the body in a known manner. It is generally cup-shaped, having an opening 24 defined in its planar end wall 26 and circumferential grooves 28 and 30 formed at the interior of the cylindrical wall. The activating button 22 supports a snap ring 32 on its exterior surface by means of a retaining ring 34 which urges the snap ring against a shoulder 36. A bore 38 extends into the button, terminating in an end wall 40 adjacent to which there is formed a gas port 42 in the cylindrical side wall thereof. It is possible to mount the activating button 22 in either of two positions relative to the closure cap 20 by seating the snap ring 32 in one of the grooves 28 or 30, the cylindrical end of the activating button passing through the opening 24.

The body 12 is in the form of a hollow, generally cylindrical shell, the major cavity of which houses a supply tank 44, which may be made of thin gauge metal for good strength and light weight, and holds approximately 10-12 cc. of a pressurized

liquid refrigerant such as Freon 12® (a mark of DuPont for dichlorodifluoromethane). An aerosol-type valve 46 is disposed at one end of the supply tank 44 and is secured by means of a thin-walled metal cap 48 which may be turned into a circumferential recess 50 in the supply tank. The aerosol-type valve 46 includes a valve stem 52, one half of which is in the form of a solid rod portion 54 and the other half is in the form of a tubular portion 56 open at one end and having a port 58 therethrough near the center of the stem. A slightly outwardly flared flange 60 girdles the rod 54 adjacent the midpoint of the stem. A resilient sealing ring 62 positioned adjacent the planar end wall of the cap 48 encircles the valve stem 52 which passes through an opening in the planar end wall. A valve body 64 having a radially outwardly extending circumferential flange 66 which is sealed between the cap and the mouth of the tank holds the stem in position. A central axial bore 68 terminating in a lip 70 receives the rod portion 54 of the valve stem 52 with a compression spring 72 thereon. In this manner, the valve stem 52 is biased in a leftward direction (as viewed in FIGS. 2—4) by the compression spring 72 which lies between the outwardly flared flange 60 and the lip 70.

The tubular portion 56 of the valve stem 52 extends into an axial bore 74 defined in the end of a reciprocable shuttle 76 which houses a sealing O-ring 78 and a ring 80 within the bore 74. An axially extending passage 82, concentric with the bore 74, extends therefrom to the opposite end of the shuttle receiving a small diameter delivery tube 84. The ring 80 is mounted on the delivery tube 84 and secures it in place within the shuttle 76, the left end of the delivery tube extending out of the body 12. The shuttle has a seat 86 defined therein to receive the end of the operating lever 18 which passes through an opening 88 formed through the wall of the body 12. The opening 88 is sealed by a resilient sealing ring 90 encircling the lever which is held in place with a retaining ring 92.

An exhaust valve 94 is formed adjacent the left end of the shuttle 76 and includes a sealing O-ring 96 seated in a circumferential groove 98 in the shuttle and which cooperates with a radially inwardly turned lip 100 formed at the end of a cylindrical shell 102. The shell 102 is secured in a suitable manner to a collar 104 such as by being crimped thereon as at 106. An O-ring 108 seated between the shell and the collar effectively prevents gas leakage between these two members. The collar 104 is mounted upon an exhaust tube 110 at one end thereof and supports the exhaust tube so that it coaxially surrounds the delivery tube forming the probe 14, which extends outwardly from the body 12 through an axial opening 112 in the body.

The cooling tip 16 is in the form of a metal plug which seals the open end of the exhaust tube 110 preventing gas flow therefrom. It is made of a suitable metallic material selected to provide a path of high thermal conductivity therethrough. It may be observed that the exterior portion of the tip is illustrated as being rounded; however, it may comprise any configuration designed to perform a particular surgical function. A boiling chamber 114 formed at the interior of the probe 14 adjacent the cooling tip includes a boiler valve which when closed will allow the gas to expand through a metering orifice. The form of the boiler valve illustrated in FIG. 5 is but one example of the several constructions comprehended by this invention. It includes a valve seat having a conical portion 116 integral with the cooling tip 16 which cooperates with the machined open end 118 of the delivery tube 84. The open end is shown with a chamber; however, the valve will operate satisfactorily even if the open end 118 is cut perpendicular to the axis of the tube. A metering orifice 120 is cut in the open end. In one alternative construction the valve seat 116 may be in the form of a sphere mounted on the interior of the cooling tip 16. The side of the sphere will enter the open end 118 when the boiler valve 114 is closed and the metering orifice 120 will cause the gas to expand into the boiling chamber 114. An annular passage 122 in the probe 14 extends from the boiling chamber 114 to a chamber 124 defined between the collar 104 and the exhaust valve 94.

The entire assembly of: the shuttle 76 carrying the ring 80, the delivery tube 84, and the O-ring 96; and the collar 104 carrying the exhaust tube 110 and the shell 102, is urged leftwardly in the body against a sealing O-ring 126, which closes the body opening 112, by means of a spring washer-type retaining ring 128.

The disposable instrument 10 is presented to the surgeon in the operating room in a sterile condition, packaged in a sterile pouch. As mentioned above, the pressurized liquid refrigerant has also been treated so as to be sterile. In the unactivated condition as illustrated in FIG. 2, the activating button 22 is located in a first position in the closure with the snap ring 32 located in the right-hand circumferential groove 28. In this position, the refrigerant supply tank 44 is loosely seated within the body 12 so that the valve stem 52 does not abut the O-ring 78 and the port 58 is located on the left side of the sealing ring 62.

When he is ready to use the instrument 10 the surgeon initiates the operation thereof by forcing the activating button 22 into the body so that the snap ring 32 is permanently transferred from groove 28 to groove 30, as illustrated in FIG. 3. This movement urges the supply tank 44 leftwardly to force the tubular portion 56 of the valve stem 52 into contact with the O-ring 78 to move the ring 80 and the shuttle 76 and to urge the delivery tube 84 against the conical portion 116 of the tip 16. When the forward movement of the delivery tube 84 is stopped by the tip 16, the continuing forward movement of the supply tank 44 compresses the compression spring 72, and carries the tank over the valve stem 52 so that the sealing ring 62 passes the port 58 in the manner of actuating a usual aerosol valve. In this condition the pressurized liquid refrigerant may escape the tank through port 58 passing between the solid rod portion 54 of the valve stem 52 and the bore 68 of the valve body 64 around the turns of the compression spring 72. Since the body 12 is open to the atmosphere through the gas port 42 in the activating button 22, the pressurized liquid refrigerant seeks an escape path thereto. The refrigerant flows from the supply tank 44 through the port 58, the tubular portion 56 of the valve stem 52, down the delivery tube 84 to the boiling chamber 114 where it passes through the metering orifice 120 in the open end 118 of the delivery tube 84. The sharp drop in pressure occurring across the metering orifice permits the refrigerant to expand rapidly, absorbing heat from the area of the cooling tip 16, to cool it rapidly to a temperature low enough to cause cryoadhesion of the tip to warm moist tissue, such as a cataractous lens. The expanded and warmed gas is conducted through the annular passage 122 to the chamber 124, where it flows out the open exhaust valve 94 through the annular passage defined between the supply tank 44 and the inside wall of the body 12, and out the gas port 42 to the atmosphere. This is the only path available to the escaping gas since the axial opening 112 in the body is sealed by the O-ring 126 and the opening 88 in the body through which the lever 18 enters is sealed by the resilient sealing ring 90.

If, as the operation progresses, the surgeon inadvertently contacts adjacent healthy tissue, such as the cornea or the iris, these tissues will also freeze and adhere to the cooling tip 16. In such case the surgeon must immediately disengage the tip. This may be quickly and easily accomplished by depressing the lever 18, which is positioned under his index finger. Warming of the tip takes place in the following manner: The lever 18 is pivoted about the edge of the opening 88, thereby applying a force against the right side of the seat 86 moving the shuttle 76 against the compression spring 72 through the ring 80, the O-ring 78 and the valve stem 52, as shown in FIG. 4. Movement of the ring 80 toward the right withdraws the delivery tube 84 slightly from the conical valve seat 116 permitting a flood of warm liquid refrigerant to flow into the annular passage 122 and into the chamber 124. The lip 100 of the shell 102 and the O-ring 96 forming the exhaust valve 94 are disposed in such a relationship that when the lever 18 is pivoted and draws back the shuttle 76, the exhaust valve 94 will be closed after a small amount of warm liquid refrigerant

is permitted to escape from the chamber 124 to ensure that the chamber and the annular passage 122 are full. When the exhaust valve 94 has been completely closed the pressure built up within the chamber 124 and the annular passage 122 prevents the refrigerant from boiling with the resultant heat absorption. Thus, the sensible heat of the liquid refrigerant brought into the end of the probe 14 is sufficient to warm the tip 16 and to permit disengagement of the tip from the tissue.

As long as the lever 18 is maintained in the depressed position, the tip will be warm. It is merely necessary for the surgeon to release the lever to cause the shuttle 76 and the delivery tube 84 to move leftwardly under the bias of the compression spring 72 and return the instrument 10 to the normally cold operating condition as illustrated in FIG. 3.

It should also be understood that there often exist conditions which require that the probe 14 be introduced to the tissue in a warm condition prior to cooling. If, for example, the lens has been displaced from its normal position and has slipped back into the vitreous, it must first be located with the tip of the probe and then the lever may be released to quickly freeze the lens to the tip so that it may be withdrawn from the vitreous. Therefore, it is within the comprehension of this invention to reverse the operation of this disposable cryosurgical instrument by having the cooling tip 16 normally warm and rendering it cold by manual actuation of a control lever.

Having described this invention of a disposable cryogenic surgical instrument, it should be readily appreciated by those skilled in this art that there is provided an instrument which is simple in design, low in cost and ingenious in operation. As set forth in the objects, there is provided a disposable instrument that may be selectively heated or cooled at the option of the surgeon and which is compact and easy to handle.

Cooling has been described as being accomplished by "boiling" a pressurized liquid refrigerant; however, the cryogenic surgical instrument described will operate in a similar manner with a pressurized gas refrigerant which expands to cool.

It should 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 the scope of the invention as hereinafter claimed.

We claim:

1. A self-contained, disposable cryosurgical instrument comprising: a housing formed to be easily hand held; a cooling tip located at one end of said housing; a boiling chamber in said housing adjacent said cooling tip; a container of pressurized refrigerant located within said housing; dispensing means positioned at one end of said container; a reciprocable member positioned within said housing adjacent said dispensing means; selectively operable means connected to said member and extending to the exterior of said housing to move said reciprocable member; a delivery tube having one end secured to said reciprocable member its other end extending to said cooling tip for receiving the refrigerant from said dispensing means and passing it to said boiling chamber; means defining a metering orifice between said other end and said cooling tip to expand the refrigerant passing therethrough at one position of said reciprocable member; an exhaust tube firmly secured in said housing, having one end extending to said cooling tip for passing the spent refrigerant from said boiling chamber; an exhaust valve operable by said reciprocable member to control the flow of the spent refrigerant through said exhaust tube; and a vent defined in said housing to pass the spent refrigerant to the atmosphere.

2. The cryosurgical instrument defined in Claim 1 wherein said reciprocable member comprises a body having an axial bore which loosely receives a portion of said dispensing means in one end and said one end of said delivery tube is fixedly mounted in the other end.

3. The cryosurgical instrument defined in Claim 1 wherein: said selectively operable moving means includes a pivotable lever; said reciprocable member comprises a body having a seat formed therein receiving one end of said lever; and said housing defines an opening therein through which said lever passes, positioned to be in substantial alignment with said seat, the rim of said opening forming a fulcrum about which said lever pivots.

4. The cryosurgical instrument defined in Claim 3 wherein a sealing ring is mounted on said housing adjacent said opening and tightly encircles a portion of said lever to prevent blow-by of the spent pressurized refrigerant.

5. The cryosurgical instrument defined in Claim 3 wherein said lever is substantially L-shaped, including a short leg which passes through said opening into said seat, and a long leg positioned to overlie the forward portion of said housing which may be selectively depressed to move said reciprocable member from said first position to a second position.

6. The cryosurgical instrument defined in Claim 1 wherein said exhaust valve comprises sealing means carried by said reciprocable member, and a valve seat secured to said one end of said exhaust tube.

7. The cryosurgical instrument defined in Claim 1 wherein said exhaust tube is coaxial with and surrounds said delivery tube and supports said cooling tip in said other end, said delivery tube being axially movable within said exhaust tube.

8. The cryosurgical instrument defined in Claim 7 wherein said exhaust valve comprises a cylindrical shell secured to said one end of said exhaust tube having a radially inwardly extending lip, and a sealing ring carried by said reciprocable member cooperable with said circular lip.

9. The cryosurgical instrument defined in Claim 1 wherein biasing means are provided at the other end of said housing to urge said container toward said reciprocable member to activate said dispensing means and to move said reciprocable member to said first position.

10. The cryosurgical instrument defined in Claim 9 wherein said biasing means comprises: an activating button extending through said other end of said housing; a snap ring mounted upon said activating button; and a circular groove defined in said other end of said housing receiving said snap ring to maintain said activating button biased against said container.

11. The cryosurgical instrument defined in Claim 1 wherein: said selectively operable moving means includes a substantially L-shaped lever having a short leg passing through said housing to said reciprocable member and a long leg positioned to overlie the forward portion of said housing and being selectively movable to move said reciprocable member from said first position to a second position; said exhaust tube is coaxial with and surrounds said delivery tube and supports said cooling tip in said other end, said delivery tube being axially movable within said exhaust tube; said exhaust valve comprises a cylindrical shell secured to said one end of said exhaust tube having a radially inwardly extending lip, and a sealing ring carried by said reciprocable member cooperable with said circular lip; and further in combination biasing means to urge said container toward said reciprocable member to activate said dispensing means and to move said reciprocable member to said first position.