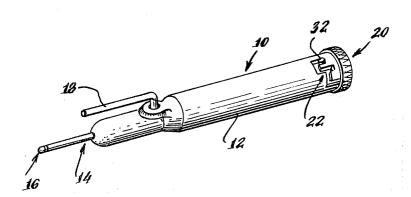
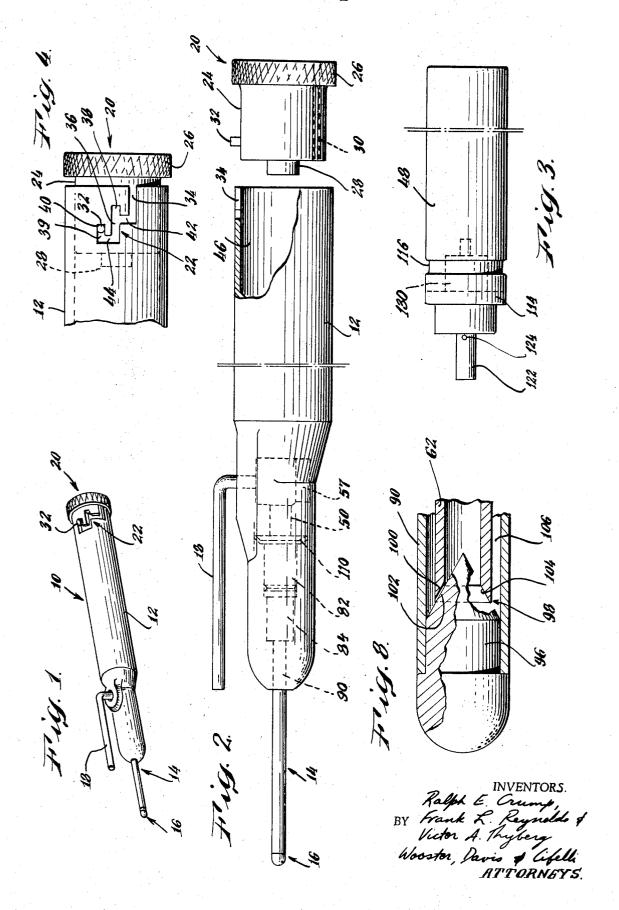
[72] [21] [22] [45] [73]	Appl. No. Filed Patented Assignee	Ralph E. Crump Trumbull; Frank L. Reynolds, Monroe; Thyberg, Fairfield, Conn. 769,065 Oct. 21, 1968 Apr. 20, 1971 Frigitronics of Conn. Inc. Bridgeport, Conn.	Victor A.
[54]	RECHARGEABLE CRYOSURGICAL INSTRUMENT 9 Claims, 8 Drawing Figs.		
[52]	U.S. Cl	•••••	128/303.1,
[51]			62/293 <b>A61b 17/36,</b>
[50]	Field of Sea 400	rch(X), 254, 303, 399, 401; 62/6, 165/24, 27; 62/514; 220/	F25d 3/00 128/400, .55, 292, 293; 40; 128/303.1
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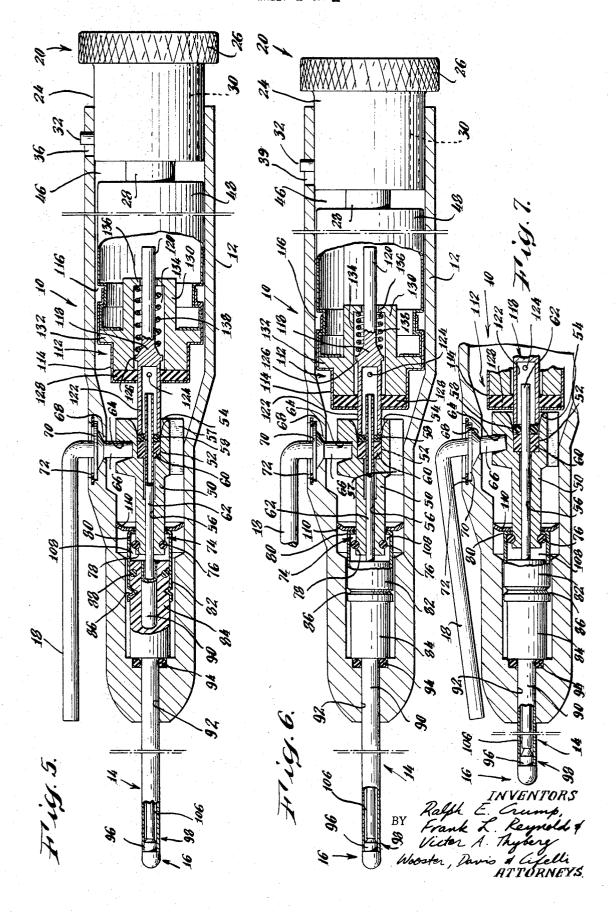
ABSTRACT: This disclosure relates to a rechargeable cryosurgical instrument having operating mechanism located at one end and a refrigerant cartridge-receiving chamber opening to the atmosphere at its other end. A removable end cap closes the open end of the instrument and is selectively positionable to locate a housed refrigerant cartridge in a dispensing or conserving position. In the dispensing position of the end cap, the pressurized refrigerant is dispensed from the cartridge through a delivery tube to a boiler valve located adjacent a cooling tip to reduce the temperature of the tip. The spent refrigerant is exhausted from the housing through an opening in the removable end cap. A selectively operable finger-actuable lever located at the exterior of the housing operates the boiler valve to either cool or warm the cooling tip.



SHEET 1 OF 2



SHEET 2 OF 2



## RECHARGEABLE CRYOSURGICAL INSTRUMENT

## **BACKGROUND OF THE INVENTION**

This invention relates to a rechargeable cryosurgical instrument and, more particularly, to such a device designed for delicate surgery, which is normally cold when in use and may be rapidly warmed as desired, and in which means are provided to conserve the refrigerant when the instrument is not in use.

The phenomenon of moist tissue adhering to cold metal is well known but until recently was seldom surgically utilized. Recently, cryoextraction has become a formidable opthalmological procedure based on this phenomenon. One use now made of this procedure is the intracapsular extraction 15 of cataracts. Cataract surgery, which is one of the most delicate operations that a surgeon is called upon to perform, involves the removal of an opacified lens. Usually the lens, which comprises a very thin membrane containing a fluid, is extracted whole through an incision made at the intersection 20 of the cornea and the outer edge of the iris. Most commonly in the past 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 instruments, they have a tendency to cause the membrane to rupture. With the advent of the procedure of cryoadhesion and the invention of various surgical instruments based upon this principle, it is possible to provide the surgeon with a safe, reliable, and easily manipulatable instrument with which to 30 accomplish the intracapsular extraction. This is done by contacting the lens with a cryosurgical instrument having a tip which may be cooled by a refrigerant that boils at approximately -30° C. The temperature of the tip on the warm lens is apt to be  $-10^{\circ}$  to  $-20^{\circ}$  C, depending on the  $^{35}$ duration of application. This freezes the membrane and forms an intralenticular ice mass contiguous to the probe which assists in distributing the extraction force over a large area of the membrane to prevent its rupture.

The principle of cryoextraction is also utilized in removing 40 nonmagnetic intraocular foreign bodies, such as wood splinters. In such a surgical operation it is possible to introduce the probe of a cryosurgical instrument into the pupil and place it beside the foreign matter. As the tip of the probe is made cold, it freezes the adjacent vitreous and an expanding 45 ice ball engulfs the foreign matter. By withdrawing the probe towards the surface but thawing and refreezing it at frequent intervals, it is possible to extract the ice-encased foreign matter from the vitreous without removing the central portion of the vitreous body in the process. Inevitably, the final removal of the foreign matter involves the loss of some of the surrounding vitreous, but this can be minimized by controlling the exit wound with sutures and by partially thawing the probe in the final stages of extraction.

Various cryosurgical instruments have been developed to utilize the technique of cryosurgery. These fall into three general categories, namely: (1) continuously operating units; (2) disposable instruments which may be used but a single time; and (3) solid probes which are cooled merely by being 60 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 65 the instrument. The latter may also require a suction pump to exhaust the refrigerant to vary the degree of cooling of the tip. These instruments are designed to allow the surgeon to quickly warm the tip so that he may disengage it from the adhered thereto. inadvertently 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 of the cryoadhesion if the 75 showing the cooling tip in detail.

surgeon should accidentally touch adjacent healthy tissue with the tip of the cold probe. This is usually accomplished by irrigating the area with a warm saline solution and generally requires the intervention of another sterile person in the operating room. Alternatively, some prior art instruments are defrosted by means of an electrically heated wire. This creates a potentially dangerous situation in explosive environments and also requires a separate control. 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 cryosurgical instrument in the form of a rechargeable unit having a chamber therein to receive a cartridge of pressurized refrigerant.

Another object is to provide a cryosurgical instrument of the type described in the above paragraph, wherein the instrument includes valving to render the tip of the probe normally cold and means are provided to selectively warm the tip.

Still another object of this invention is to provide a greatly improved in recent years by the use of better traction 25 rechargeable cryosurgical instrument which is lightweight, compact and inexpensive and which includes means to position the cartridge within the instrument body to prevent discharge of the refrigerant therefrom when the instrument is not in use.

> To accomplish these objects, in one form a rechargeable cryosurgical instrument is provided having a body defining a refrigerant cartridge-receiving chamber opening to the atmosphere at one end and a cooling tip at the other end. The body houses a boiler valve adjacent the cooling tip and valveoperating means between the chamber and the cooling tip. Control means for the valve-operating means extends from the interior of the body to the exterior thereof and is selectively operable to move the boiler valve for cooling or warming the cooling tip. Means are provided for delivering the refrigerant from a refrigerant cartridge in the body chamber to the cooling tip and means are provided to exhaust the spent refrigerant from the cooling tip to the chamber. A removable end cap located in the open end of the body defines a vent therein and includes means for being selectively located in a refrigerant-conserving or in a refrigerant-dispensing position.

### BRIEF DESCRIPTION OF THE DRAWINGS

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

FIG. 1 is a perspective view of the rechargeable cryosurgical 55 instrument constructed in accordance with this invention;

FIG. 2 is a side elevational view of the rechargeable cryosurgical instrument with its end cap removed and partially broken away to show the end cap-positioning slot;

FIG. 3 is a side elevational view of a typical valved refrigerant cartridge;

FIG. 4 is a partial top plan view of the end of the rechargeable cryosurgical instrument showing the end cap relative to the positioning slot;

FIG. 5 is a longitudinal sectional view of the rechargeable cryosurgical instrument shown with the end cap in the refrigerant-conserving position;

FIG. 6 is a longitudinal sectional view similar to that of FIG. 5 showing the rechargeable cryosurgical instrument with the Conventional 70 end cap in the refrigerant-discharging position for normal cooling;

FIG. 7 is a partial longitudinal sectional view similar to that of FIG. 6 showing the instrument in its thawing condition; and

FIG. 8 is an enlarged partial longitudinal sectional view

# DESCRIPTION OF THE PREFERRED EMBODIMENT

With reference to the drawings, there is illustrated in FIG. 1 a rechargeable cryosurgical instrument generally referred to by the numeral 10. It is in the form of a pencillike instrument having a body 12 with a probe 14 at one end, terminating in a tip 16, an operating lever 18 overlying the forward portion of the body, and a removable end cap 20 selectively movable into several positions in positioning slot 22 at its other end. The instrument is lightweight, the body 12 being made, for 10 example, of a suitable metal or plastic material. As this instrument is rechargeable and therefore reusable, as will become apparent hereinafter, the material of which the body is made must be chosen so as to be dimensionally stable and otherwise unaffected by the use of a sterilizing gas such as 15 ethylene oxide. Similarly, the material may be autoclavable.

Turning now to the details of the instrument, the removable end cap 20, also made of metal or plastic, comprises a cylindrical body 24 with an enlarged cylindrical knurled head 26 at one end, a smaller diameter central axial boss 28 at the 20 other end, and an axial vent 30 passing through the body 24 and head 26. A radially extending positioning pin 32 located near the forward end of the body 24 cooperates with the positioning slot 22 defined in the thin wall of the instrument body. The positioning slot is of generally steplike configuration, including an axial entrance leg 34, a first positioning leg 36 terminating at its right end (as viewed in FIG. 4) in a first positioning seat 38, and a second positioning leg 39 having a positioning seat 40. Step portion 42 connects 30 the entrance leg 34 with the first positioning leg and step portion 44 connects the first positioning leg with the second positioning leg 39.

The instrument body 12 is in the form of a generally cylindrical thin-walled shell defining a large chamber 46 to 35 receive a refrigerant cartridge 48. The internal mechanism of the rechargeable cryosurgical instrument will now be described with reference to FIGS. 5, 6 and 7. Located at the left end of the chamber 46 there is a reciprocable shuttle 50 including an axial bore 52 having a chamfered entrance 54 at 40 one end and an axial concentric passage 56 extending to its other end. Several finlike support ribs 57 (one shown) are located at the lower end of the shuttle to assist in positioning it in the body 12 in the absence of the cartridge 48. A sealing Oring 58 and a positioning ring 60 are disposed within the hore 45 52 and a small diameter delivery tube 62 is located within the passage 56, being secured in place within the bore of the positioning ring 60 with the left end of the delivery tube extending out of the body of the instrument. The shuttle 50 further includes a seat 64 defined therein to receive the end 66 50 of the operating lever 18 which passes through an opening 68 in the body formed through the wall thereof. The opening is sealed by a resilient sealing ring 70 encircling the lever which is held in place by means of a snap-type retaining ring 72.

An exhaust valve 74 located at the left end of the shuttle 50 55 includes a sealing O-ring 76 seated in a circumferential groove 78 in the shuttle which cooperates with a radially inwardly turned lip 80 formed at the end of a thin-walled metallic cylindrical shell 82. The shell 82 is secured in a suitable manner to a collar 84 such as by being crimped thereon as at 86. An O-ring 88 seated between the shell and the collar effectively prevents gas leakage between these two members. The collar 84 is securely mounted upon an exhaust tube 90 at coaxially surrounds the delivery tube 62 forming the probe 14 extending outwardly from the body 12 through an axial opening 92 therein which opening is sealed by means of O-ring 94.

form of a metal plug 96 which seals the open end of the exhaust tube 90 to prevent gas flow therefrom. It is made of a suitable metallic material selected to provide a path of high thermal conductivity therethrough. The exterior portion of the tip is shown as being rounded; however, it may comprise 75 port 124 of the aerosol-type valve underlies the resilient

any configuration designed to perform a particular surgical function. A boiling chamber 98 formed at the interior of the probe 14 adjacent the cooling tip 16 includes a boiler valve which when closed will allow the gas to expand through a metering orifice 100. The form of the boiler valve illustrated in FIG. 8 is but one example of the several constructions comprehended by this invention. It includes a conical valve seat 102 integral with the cooling tip 16 which cooperates with the machined open end 104 of the delivery tube 62 in which the metering orifice 100 is cut. An annular passage 106 in the probe 14 between the delivery tube 62 and the exhaust tube 90 extends from the boiling chamber 98 to a chamber 108 defined between the collar 84 and the exhaust valve 74.

The entire assembly of: the shuttle 50 carrying the positioning ring 60, the delivery tube 62 and the O-ring 76, and the collar 84 carrying the exhaust tube 90 and the shell 82 is held in the body 12 against the sealing O-ring 94 by means of a springlike washer-type retaining ring 110. This assembly is the reusable portion of instrument 10 which receives the refrigerant cartridge 48.

The cartridge 48, made of metal for good strength and lightweight, contains approximately 10-12 cc. of a suitable pressurized refrigerant which may be a liquid, such as Freon 12®(a mark of Dupont for dichlorodifluoromethane), or a gas, such as CO2. In the illustrated Freon version, an aerosoltype valve 112 is disposed at one end of the cartridge 48 and is secured by means of a metal cap 114 which may be turned into a circumferential recess 116 in the cylindrical wall of the cartridge. The aerosol-type valve 112 clearly illustrated in FIGS. 5 and 6 includes a valve stem 118 whose right end is in the form of a solid rod portion 120 and whose left end is in the form of a tubular portion 122 open at one end defining a radial port 124 therethrough. A flange 126 girdles the rod adjacent the midpoint thereof. Resilient sealing ring 128 is positioned adjacent the planar end wall of the cap 114 tightly encircling the left end of the valve stem 118 which passes through an opening in the cap end wall. A valve body 180 includes a radially outwardly extending circumferential flange 132 captured between the cap 114 and the mouth of the tank. A central axial bore 134, in the valve body 130, terminates in a lip 136 which receives the rod portion 120 of the valve stem 118 and its associated compression spring 138 which biases the valve stem 118 in a leftward direction. Thus, the port 124 is positioned normally at the exterior of the cartridge 48 to prevent discharge of the refrigerant.

The rechargeable cryosurgical instrument 10 is presented to the surgeon in the operating room in a sterile condition. The refrigerant cartridge 48, preferably containing a sterile pressurized refrigerant, is also delivered to the surgeon in the operating room in a sterile condition and be packaged in a sterile pouch. In order to utilize the instrument, the refrigerant cartridge 48 is inserted into the body chamber 46 and the tubular portion 122 of the valve stem 118 is directed into the chamfered entrance 54 and the axial bore 52 of the reciprocable shuttle 50 and is seated against the O-ring 58. Then the end cap 20 is inserted into the open end of the body, the positioning pin 32 entering the entrance leg 34 of the positioning slot 22 so that the end cap boss 28 abuts the end of the refrigerant cartridge 48 and drives it leftwardly into the body 12. Initially, the tubular portion 122 of the valve stem 118 is urged into contact with the sealing O-ring 58, then the shuttle 50 is moved leftwardly, urging the delivery tube 62 one end thereof and supports the exhaust tube so that it 65 against the conical valve seat 102. Further insertion of the end cap 20 carries the tank of the refrigerant cartridge 48 over the valve stem 118 compressing the compression spring 138. When insertion of the end cap 20 is stopped as the positioning pin 32 abuts the step portion 42, it should be rotated in a As clearly illustrated in FIG. 8, the cooling tip 16 is in the 70 clockwise direction until the positioning pin abuts the first positioning leg 36. Releasing the end cap allows the compression spring 138 to snap it rearwardly to lodge the positioning pin in the first positioning seat 38. It should be noted with reference to FIG. 5 that in this first position the sealing ring 128 so that the pressurized refrigerant is unable to escape the cartridge. In this first or "ready" position of the rechargeable cryosurgical instrument 10, the refrigerant may be conserved and the instrument is ready for use.

When he wishes to use the cryosurgical instrument, the 5 surgeon may initiate the normal cooling of the tip 16 by pushing the end cap 20 further into the body, moving the cartridge against the bias of the compression spring 138, to move the positioning pin 32 in the first positioning leg until it abuts the step portion 44 and then rotating the end cap in a  $\,^{10}$ clockwise direction until the positioning pin 32 abuts the second positioning leg. Releasing the end cap allows the compression spring 138 to snap it rearwardly to lodge the positioning pin 32 in the second positioning seat. In this position, as shown in FIG. 6, the refrigerant cartridge has been moved leftwardly over the valve stem so that the port 124 communicates the interior of the cartridge with the exterior thereof in the manner of actuating a usual aerosol-type valve. In this condition the pressurized refrigerant may escape the tank through the port 124, passing between the solid rod portion 120 of the valve stem 118 and the bore 134 of the valve body 130 past the compression spring and the flange 126. Since the instrument body is open to the atmosphere through the gas port 30 in the end cap 20, the pressurized 25 refrigerant seeks an escape path thereto and flows from the cartridge 48 through the port 124 and the tubular portion 122 of the valve stem 118, down the delivery tube 62 to the boiling chamber 98 where it passes through the metering orifice 100 in the open end of the delivery tube. The sharp drop in 30 pressure occurring across the metering orifice 100 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. The expanded and warmed spent gas is conducted through the 35 annular passage 106 to the chamber 108 where it flows out the open exhaust valve 74 through the annular passage defined between the refrigerant cartridge 48 and the inside wall of the body 12, and out the gas port 30 to the atmosphere. This is the only path available to the escaping gas since the axial opening 40 92 in the body is sealed by the O-ring 94, and the opening 68 in the body through which the lever end 66 enters is sealed by the resilient sealing ring 70.

If, as the operation progresses, the surgeon inadvertently contacts adjacent healthy tissue, such as the cornea or the iris, 45 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 (note FIG. 7) which is located under his index finger. Warming of the tip takes place in the following manner. The lever end 66 is pivoted about the edge of the opening 68, thereby applying a force against the right side of the seat 64 to move the shuttle 50 against the compression spring 138 through O-ring 58 and the valve stem 118. Movement of the shuttle 50 toward the right withdraws the delivery tube 62 slightly from the conical valve seat 102, permitting a flood of warm refrigerant to flow into the annular passage 106 and into the chamber 108. The lip of the shell 80 such a relationship that when the lever 18 is pivoted and draws back the shuttle 50, the exhaust valve 74 will be closed after a small amount of warm refrigerant is permitted to escape from the chamber 108 to ensure that the chamber 108 and the annular passage 106 are full. When the exhaust valve 74 has 65 been completely closed, the pressure built up within the chamber 108 and the annular passage 106 prevents the refrigerant from boiling with the resultant heat absorption. Thus the sensible heat of the refrigerant brought into the end of the probe is sufficient to warm the tip 16 to permit 70 disengagement of the tip from the tissue.

As long as the lever 18 is maintained in the depressed position the tip 16 will be warm. It is merely necessary for the surgeon to release the lever to cause the shuttle 50 and the delivery tube 62 to move leftwardly under the bias of the 75

compression spring 138 and return the instrument 10 to the normally cold operating condition as illustrated in FIG. 6.

If the surgeon desires to utilize some other surgical instrument, the cryosurgical instrument of this invention may be temporarily deactivated to conserve the refrigerant charge. This may be accomplished by moving the end cap 20 to the first position, as clearly illustrated in FIG. 5. When the refrigerant has been exhausted, the end cap 20 can be removed to dispose of the spent cartridge and a second cartridge may be inserted if necessary.

It should also be understood that there often exist conditions which require that the probe 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 must 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 rechargeable cryosurgical instrument by having the cooling tip normally warm and rendering it cold by manual actuation of the control

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

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 scope of the invention as hereinafter claimed.

We claim:

1. A rechargeable cryosurgical instrument comprising a body defining a refrigerant cartridge-receiving chamber, opening to the atmosphere, at one end and a cooling tip at the other end; boiler valve means in said body adjacent said cooling tip; a reciprocable member in said body located between said chamber and said cooling tip, carrying a delivery tube at one end and having an opening in its opposite end to receive the dispensing tube of a refrigerant cartridge; control means connected to said reciprocable member and extending to the exterior of said body, being selectively operable to move said boiler valve means for cooling or warming said 50 cooling tip; means for exhausting spent refrigerant from said cooling tip to said chamber; a removable end cap seated in the open end of said body; and positioning means on said end cap and said body cooperating to selectively locate said end cap in a first position for retaining a refrigerant cartridge in said 55 chamber in a nondispensing condition and a second position forcing the dispensing tube of said cartridge against said reciprocable member to release refrigerant into said delivery tube.

2. The rechargeable cryosurgical instrument defined in and the O-ring 78 forming the exhaust valve 74 are disposed in 60 claim 1 wherein said positioning means linearly guides said end cap between said first and second positions.

3. The rechargeable cryosurgical instrument defined in claim 1 wherein said positioning means includes a positioning slot defined in the wall of said body adjacent said open end, and a radial positioning pin located on said end cap.

4. The rechargeable cryosurgical instrument defined in claim 3 wherein said positioning slot has a first pin-receiving seat to position said end cap to urge a housed replaceable refrigerant cartridge into a refrigerant conserving position.

5. The rechargeable cryosurgical instrument defined in claim 3 wherein said positioning slot has a second pin receiving seat to position said end cap to urge a housed refrigerant cartridge into a refrigerant-dispensing position.

6. The rechargeable cryosurgical instrument defined in claim 1 wherein said end cap defines a vent therethrough.

7. The rechargeable cryosurgical instrument defined in claim 1 wherein said positioning means includes a positioning slot defined in the wall of said body adjacent said open end and a radial positioning pin located on said end cap, said positioning slot having a first pin-receiving seat to position said end cap relative to said body to urge a housed refrigerant cartridge into a refrigerant-conserving position and a second pin-receiving seat to position said end cap to urge a refrigerant cartridge into a refrigerant-dispensing position, and said end cap defines a vent therethrough.

8. The rechargeable cryosurgical instrument defined in claim 1 wherein support means are provided on said

reciprocable member to maintain said reciprocable member in position to receive the dispensing tube of a refrigerant cartridge.

9. The rechargeable cryosurgical instrument defined in claim 1 wherein said control means comprises a pivotable lever; said reciprocable member includes a seat formed therein to receive one end of said lever; and said body 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.