

[54] **CRYOGENIC APPLICATION
CHAMBER AND METHOD**

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Related U.S. Application Data

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abandoned, which is a continuation-in-part of Ser.
No. 728,536, May 13, 1968.
[52] U.S. Cl. **128/303.1**
[51] Int. Cl. **A61b 17/36**
[58] Field of Search 128/303.1, 400, 401; 62/293,
62/514

[56] **References Cited**

UNITED STATES PATENTS

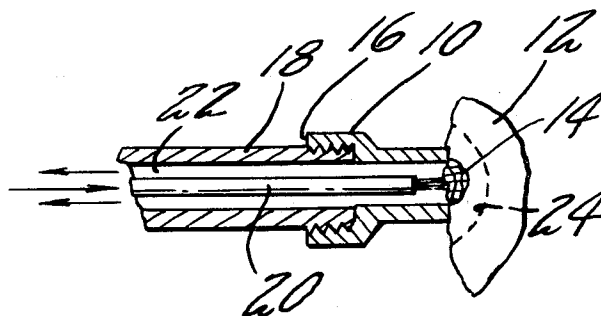
3,411,483 11/1968 Canoy 128/303.1 X
3,504,674 4/1970 Swenson et al. 128/303.1

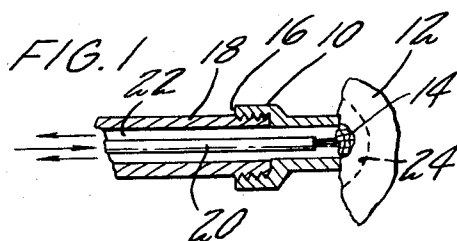
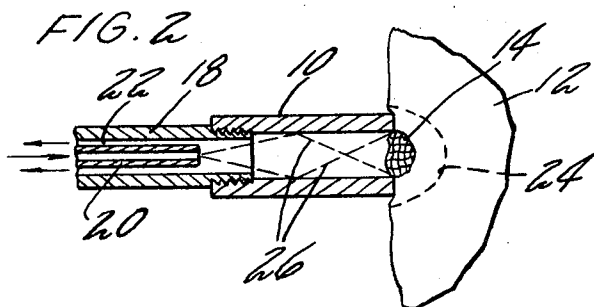
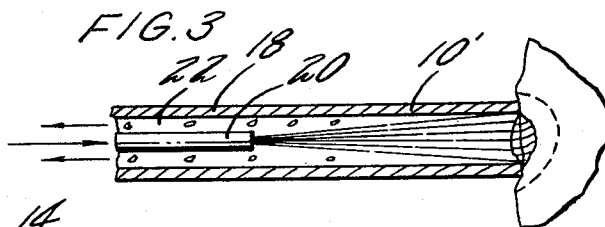
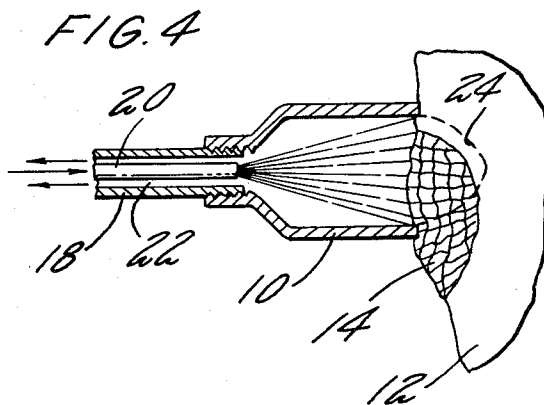
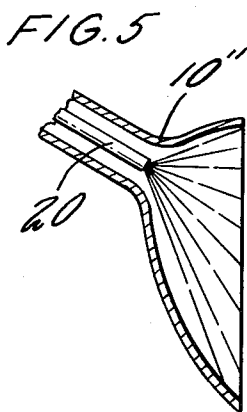
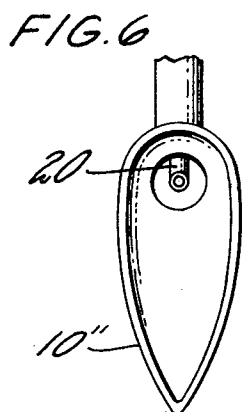
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[57] **ABSTRACT**

A cryosurgical instrument comprises an open-ended chamber pressed into firm contact with tissue to be necrotized. A stream of liquified gas coolant (such as nitrogen), in substantially the liquid phase, impinges directly on the tissue. In one embodiment, the coolant-delivery instrument provides venting of vapors from the chambers through an applicator vent tube. In another embodiment, the cryogenic application chamber comprises a cylindrical tube connected to a source of pressurized coolant, the distal end of the tube being open and adapted for application to a subject, the proximal end adapted for connection with the source, there being a vent hole through the wall of the tube near the proximal end. The chambers may assume a variety of configurations in order to gain easy access to lesions which are to be necrotized. The chambers may be used to apply a bulk of liquid or to confine a controlled, substantially liquid spray, in accordance with methods disclosed herein.

8 Claims, 10 Drawing Figures





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FIG. 7

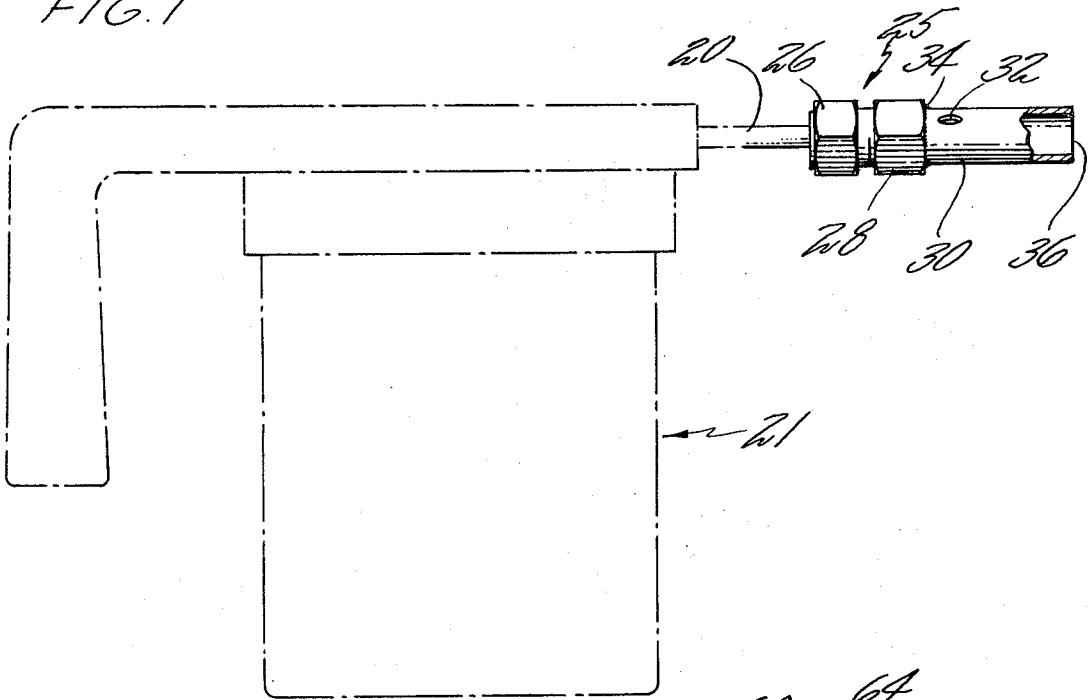


FIG. 10

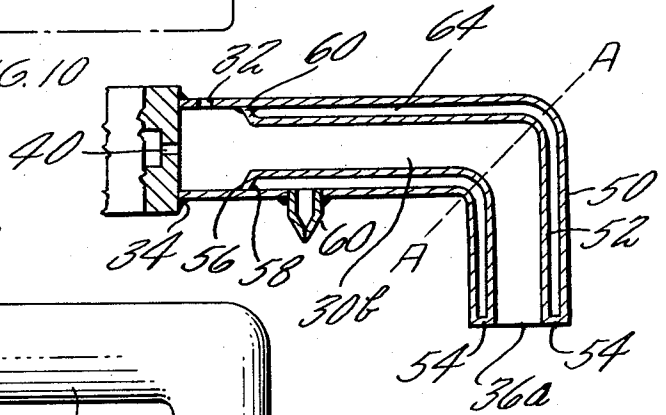


FIG. 8

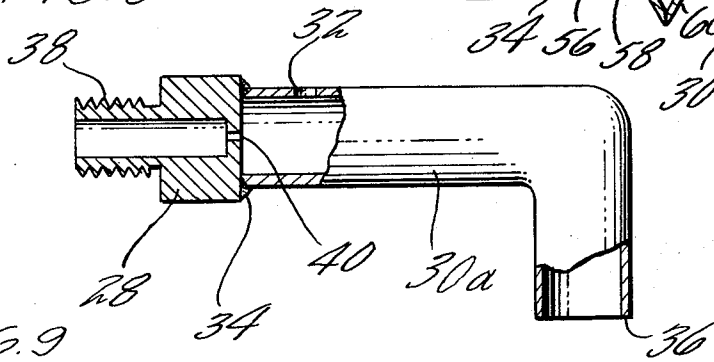
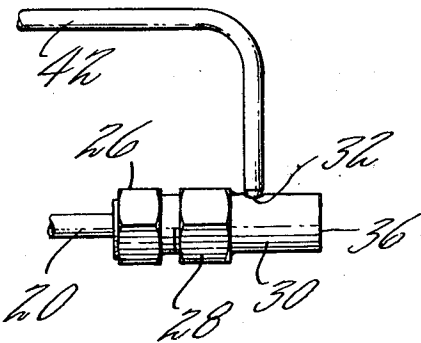


FIG. 9



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CRYOGENIC APPLICATION CHAMBER AND METHOD

CROSS-REFERENCES TO RELATED APPLICATIONS

This is a continuation, of abandoned application Ser. No. 886,260, filed Dec. 18, 1969 which was a continuation-in-part of my application Ser. No. 728,536, filed on May 13, 1968.

A cryosurgical delivery system capable of delivering liquified gas coolant to and venting vapor from application means in accordance with the present invention is disclosed in a copending application of the same inventor entitled CRYOSURGICAL DELIVERY AND APPLICATION OF LIQUIFIED GAS COOLANT filed on Nov. 15, 1967, Ser. No. 683,351.

BACKGROUND OF THE INVENTION

1. Field of Invention

This invention relates to cryosurgery, and more particularly to methods and means for necrotizing tissue through the direct application of liquified gas coolant.

2. Description of the Prior Art

The use of liquified gas coolants to freeze tissue, and thereby necrotize the same, has long been known. For instance, one well known liquified gas coolant is liquid nitrogen. This and other coolants have been applied in a variety of ways to living tissue which is to be necrotized. One way is dipping of a swab into the liquid and applying the liquid to the tissue with the swab. However, this method is useful only in dermatological applications, and even then has value only for very small lesions due to the low rate of heat exchange which is possible thereby. Another method is dipping of a metallic element in the nitrogen so as to cool the element, and thereafter applying the element to the lesion. This too is useful only for small lesions, and only where access to the lesion is unlimited. More recent advances in the cryosurgical arts provide for the constant spraying of liquid nitrogen against the inside wall of a metallic probe, the outside wall of the probe being applied directly to the lesion. In many application, this is quite satisfactory, but in others the rate of heat exchange is too small, and sufficient depth or coverage (that is area) of freezing is not obtainable. More specifically, it is impossible to get rigid applicators to conform to the irregular surfaces of a lesion, and therefore the heat exchange must take place through the tissue itself in order to reach other areas which are blocked from contact due to irregularities of surface of the lesion.

In order to overcome these problems, an attempt has been made to utilize all-liquid nitrogen applied directly to the lesion. In this method, the end of the tube or other confinement structure is placed on the lesion, and the tube is filled with liquid, the liquid flowing to the lesion. This method has failed to work because of the fact that great care must be taken to avoid the flow of liquid nitrogen out of the tube or other confinement where freezing may occur to other tissue, which is not desired to be destroyed. Also, replenishment is difficult and risky. Recent innovations, disclosed and claimed in my copending application Ser. No. 683,351, filed on Nov. 15, 1967 and entitled CRYOSURGICAL DELIVERY AND APPLICATION OF LIQUIFIED GAS COOLANT, include the application of a spray directly to the lesion to be necrotized. Spray applica-

tion is very desirable since it supplies substantially liquid nitrogen to the lesion in a form which is well suited to fast and thorough freezing. However, it cannot be used whenever the total area of spray must be closely controlled.

SUMMARY OF INVENTION

The object of the invention is to provide improved methods and means for necrotizing lesions cryosurgically.

In accordance with the present invention, an open ended chamber connected to a liquified gas coolant delivery instrument is held against tissue which is to be necrotized by freezing, and a stream of liquified gas coolant is directed, in substantially liquid form, directly on the tissue; the area of tissue upon which the liquid impinges is completely surrounded and sealed off from the atmosphere by the chamber; vapor from the area under treatment is vented out of the chamber. This provides maximum coolant in the liquid phase directly at the tissue so that the heat exchange between the coolant and the tissue is maximum, and the heat absorbed from the tissue is maximum due to the heat of transfer resulting from vaporization of the coolant. Since the stream is broken up and the chamber is continuously vented, there is no vapor thermal barrier. Proper venting of the vapor also eliminates the problem of vapor clouds in the area under treatment whereby maximum visibility to the surgeon is ensured.

According to the present invention in one form, a source of low pressure liquified gas coolant in a substantially liquid form is connected to a chamber having an ambient vent therein, the chamber being supplied with substantially liquid coolant, and gaseous coolant being automatically vented therefrom, at low pressure, as a result of the pressure of gasification thereof. In accordance further with the invention in this form, a short tube of a diameter sufficiently large to create substantially no back pressure can be fitted to the vent to carry vapor a distance from the chamber.

According further to the invention, the chambers may be provided with evacuated, double-walled construction to insulate the outer wall from the low temperatures obtaining within the confinement into which coolant is delivered.

In further accord with the present invention, lesions may be necrotized by supplying liquid coolant to a vented chamber, the bulk liquid directly contacting the tissue under treatment.

In still further accord with the present invention, the chambers may be pre-cooled and frozen directly to the tissue to be treated, thereby providing a firm sealing relationship.

The present invention provides a relatively simple method of controlled liquified gas coolant application for the necrotization of lesions in confined locations. The invention permits usage of simple delivery systems, including those not having coaxial venting tubes. The present invention provides for maximum heat exchange in the application of coolant fluid to tissue in a confined area, utilizing simple coolant delivering means. Confined application of liquified coolant may be achieved at extremely low pressures.

The present invention is significant in the treating of tissue, including the necrotization of lesions. It enables

successful necrotizing of large lesions; irregular lesions; and both internal and external lesions.

The foregoing and other objects, features and advantages of the present invention will become more apparent in the light of the following detailed description of preferred embodiments thereof, as illustrated in the accompanying drawing.

BRIEF DESCRIPTION OF THE DRAWING

FIGS. 1-4 are sectioned side elevation views of various forms of the present invention illustrating the application thereof to lesions;

FIG. 5 is a sectioned elevation of an irregularly shaped chamber in accordance with the present invention;

FIG. 6 is a front elevation of the chamber illustrated in FIG. 5;

FIG. 7 is a partly sectioned, side elevation of a short, straight self-venting embodiment of apparatus in accordance with the present invention illustrating a simplified cryosurgery coolant delivery apparatus in perspective;

FIG. 8 is a partially sectioned side elevation of a longer, bent embodiment of apparatus in accordance with the present invention;

FIG. 9 is a side elevation of the embodiment of FIG. 7 employing a vent-extending tube; and

FIG. 10 is a sectioned side elevation of a vacuum insulated embodiment of the present invention.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

Referring now to FIG. 1, a chamber 10 is pressed directly against unfrozen tissue 12 so as to completely surround a lesion 14 (shown randomly hatched in FIGS. 1-4). The chamber 10 may be provided with threads 16 so that it may be fixed to the end of a suitable delivery system, which may include an outer tube 18 and an inner tube 20. The inner tube 20 conducts liquified gas coolant (such as liquid nitrogen) in the liquid phase and sprays it or delivers a stream of it directly onto the lesion 14. Coolant which vaporizes within the chamber 10 is vented through the annular passage 22 between the inner tube 20 and the outer tube 18. A delivery system suitable for use with the chamber 10 as illustrated in FIG. 1 is described in detail in my aforementioned copending patent application Ser. No. 683,351. Other suitable delivery systems are currently available and well known in the art.

As liquid coolant impinges upon the lesion 14, it will gradually freeze not only the lesion but some of the surrounding tissue as illustrated by the dotted line 24. The freeze line will be substantially a hemisphere centered about and overlapping with the periphery of the chamber 10. The tissue within the freeze area will become a substantially solid block of ice in a very short time.

FIG. 2 illustrates that the chamber 10 need not be necked down (in contrast with FIG. 1). Also illustrated in FIG. 2 is the fact that the delivery tube 20 may be foreshortened with respect to the chamber 10 without hindering the operation of the invention. As illustrated by the lines 26, the liquified gas coolant may impinge upon the walls of the chamber 10, as well as directly on the lesion 14 without altering the operation of the in-

vention. This is due to the fact that the liquified coolant is forced out of the delivery tube 20 due to some nominal pressure in the reservoir (as is known in the art), whereas venting of the vapor formed within the chamber 10 through the annular space 22 takes place as a result of the pressure which forces the liquid into the chamber 10. In other words, there is no vacuum applied to the annular vent space 22. This is also due to the fact that the liquid can splash around within the chamber 10 since it is relatively well sealed by being pressed against the warm tissue 12, before freezing starts and any blood or plasmic fluid completes the seal when frozen. Thus, liquid will not run along tissue externally of the chamber 10, nor will vapor escape the chamber 10 to obscure the field of vision.

FIG. 3 illustrates that a specific chamber 10 need not be provided, the essential characteristic of the invention being that the coolant be completely contained in both its gaseous and liquid phases.

In FIG. 4 is illustrated a larger chamber 10, and a lesion 14 which is too big to be treated from a single position of the chamber 10. As illustrated in FIG. 4, application of coolant may result, in the case of a large lesion, in freezing only a portion of the lesion. However, once the freeze line 24 is established for the position shown in FIG. 4, then the chamber 10 may be moved to one or more additional spots and the application repeated, whereby complete freezing of the lesion may be achieved. This is a most advantageous utilization of the present invention in the case of very large lesions, where a high rate of heat exchange must be achieved (of importance as one of the mechanisms of cryosurgical tissue destruction) and a large area needs to be treated.

FIGS. 5 and 6 illustrate that the generally cylindrical chambers shown in FIGS. 1-4 are not essential to the invention, although they are a simple and suitable form for practicing the invention. In FIGS. 5 and 6, an irregularly shaped chamber 10' is illustrated. Such a chamber, or a different irregularly shaped chamber, may most advantageously be used in the case of an internal cryosurgical operation where care must be taken to completely surround a particular area of tissue to be frozen, yet limiting the freezing of adjacent tissue, or where access to the lesion is difficult. Also, FIGS. 5 and 6 illustrate that a suitable angle may be provided to permit the delivery apparatus to be other than orthogonal to the surface of a lesion being treated. In other words, the present invention may be practiced by providing a structure adjacent the tissue to be frozen which, together with the tissue, fully confines the area into which coolant is sprayed and from which vapor is vented.

Referring now to FIGS. 7 and 8, liquified gas coolant is provided by a source which may include the tube 20 which comprises the delivery tube of a cryosurgical delivery unit 21 (shown in phantom in FIG. 7). This unit may take the form of the simpler embodiment fully disclosed in my aforementioned patent application Ser. No. 683,351. On the distal end of the delivery tube 20, a compression fitting 25 may comprise a female portion 26 and a male portion 28, there being a chamber 30 having a vent hole 32 therein, suitably disposed on the male portion 28. The chamber 30 may comprise a cylinder of stainless steel or other suitable material,

and, providing that the male portion 28 of the compression fitting 25 is of a suitable material, such as brass, the cylinder 30 may be silver soldered, or otherwise metallurgically bonded thereto at the junction 34. The cylinder 30 is open at the distal or application end 36. As seen in FIG. 8, the male portion 28 of the compression fitting 25 may be provided with a plurality of male threads 38, and may have an aperture 40 in the wall near the junction 34 where the male portion 28 and the proximal end of the cylinder 30a are joined. Also illustrated in FIG. 8 is the fact that the cylinder 30a may be bent in any convenient fashion so as to permit reaching tissue in hard to get areas, such as at the base of the tongue. The chamber 30 may be of any desired configuration, though a cylinder is simple and effective in most applications.

The position of the vent hole 32 may be adjusted so that vapors can be directed in any desired radial direction simply by loosening the connection between the male portion 28 and the female portion 26 of the fitting 24, rotating the entire unit relative to the delivery tube 20, and then re-tightening the portions 26, 28 together once more.

As shown in FIG. 9, a tube 42 may be pressed into the vent hole 32 so as to lead vapor away from the work area. This may comprise simple plastic tubing of about 1/8 inch diameter, and may be several inches long. Other sizes may be chosen as necessary.

Referring to FIG. 10, a chamber 30b may be provided with an evacuated double-wall structure to insulate at least a substantial portion of it from surrounding tissue. The chamber 30b may include an outer wall 50 and an inner wall 52 joined by an end wall 54. The walls 50, 52 may be metallurgically bonded at either side 56, 58 of their proximal junction 60, as well as being suitably joined to the end wall 54. On the other hand, the end wall 54 may comprise a simple joint of the wall 50, 52, one or both of which may be bent toward the other (similar to the junction 60). Evacuation may be accomplished as is well known in the art by means of a pump-down tube 62, fitted in vacuum-tight relation through the outer wall 50 and in fluid communication with the void 64 formed between the walls 50, 52. The tube 60 is connected to a vacuum source and the void 64 is pumped down to a suitably low pressure; the tube 60 is pinched-off and sealed.

The chamber 30b may be bent as shown in FIG. 10, or may be straight (as is the chamber 30 of FIGS. 7 and 8). If bent, it may be made by bending two tubes, or, more simply, by metallurgically bonding four suitably-shaped, substantially straight tubes along the line A—A of FIG. 10. With a suitable vacuum, readily achieved by known techniques, the outer wall 50 can touch living tissue with only a mild, slightly cool sensation while the inner wall is as cold as -196°C (as with liquid nitrogen coolant). Of course, the embodiments of FIGS. 1-6 may be provided with the evacuated, double-walled construction illustrated in FIG. 10.

In use, the unit 21 may be operated so as to provide coolant, such as nitrogen, in substantially liquid form in the delivery tube 20, which passes through a rather large aperture 40 and into a confinement formed by the chamber 30 and the tissue closing the distal end 36 of the chamber. Depending on the characteristics of the unit 21, and the manner of operating it, sufficient cool-

ant in liquified form may be pumped into the confinement defined by the chamber 30 so as to fill the confinement with substantially completely liquid coolant. Thus, the tissue adjacent the end 36 is in contact with coolant in its liquid form, which provides an excellent heat exchange due to the heat of vaporization of the liquid coolant. As the confinement tends to fill with liquid, the gases may vent through the hole 22. When sufficient coolant exists in the confinement, the unit 21 may be shut off so that no further coolant is added thereto, and in many cases, the amount of coolant needed to fill the confinement would be sufficient to necrotize the lesion involved. It has been found that, due to the extreme cold of the chamber 30 when it has liquid (such as nitrogen) therein, droplets of liquified air will form on the outside of the chamber giving an indication of the level of the liquid therein. Thus, particularly in the case when the chamber 30 is inclined at an angle, it becomes a simple matter to determine when the chamber 30 needs a replenishment of liquid coolant.

Another mode of operating the present invention contemplates directing a stream of liquid coolant into a chamber 30 with short bursts thereof from the unit 21. The liquid falls directly on the tissue near the open end 36 of the chamber 30, and gases resulting from the expansion and warming of the liquid will vent through the hole 32.

In either mode of operation, by running the unit for a short period of time, prior to applying it to the tissue, the end 36 can be brought very nearly to the temperature of the liquid coolant (for nitrogen, on the order of minus 160°C) so that when the chamber is applied to the tissue, it will freeze to it, thus sealing the ends so that liquid will not run out of the confinement formed by the chamber 30 and the tissue frozen to the distal end 36 thereof. When freezing is completed, the ice formed at the joint between the end 36 and the tissue to which it is applied is sufficiently cold that it will shatter easily and the unit can be removed without difficulty. On the other hand, a warm saline solution can be applied to the distal end 36 so as to free it from the frozen tissue.

These modes of operation appertain to the embodiments of FIGS. 1-6 as well. In cases where fissures, fistulas or excess blood hamper the freezing of the chamber to the tissue with a gas-tight seal, the low pressure embodiment of FIGS. 7-10 is to be preferred over the embodiment of FIGS. 1-6.

The embodiments of FIGS. 7-10 may be used on a vented source of coolant, as shown in FIGS. 1-6; the vent 20, however, will provide little venting, however, since most gas will escape through the vent hole 32. These embodiments may also have coolant delivered close to the distal end, as is illustrated in FIG. 1.

From the foregoing, it is apparent that the present embodiment of the invention provides a means of applying a liquified gas coolant in substantially liquid form to a lesion in a confined fashion utilizing an unvented source 20 of coolant, and is sufficiently simple and easy to operate so as to make it attractive to a wide variety of applications, by either of two methods, at low pressure.

The cryosurgical chambers in accordance with the invention may assume a wide variety of sizes and con-

figurations for a variety of applications. The diameter may, for instance, vary from under 5 mm to over 5 cm. However, 1 cm has been found to be generally useful. Chambers of about 1 cm diameter and 6 inches long have been successfully used in treating a primary squamous cell carcinoma on the floor of the mouth and a recurrent squamous cell in the tonsil and hypopharyngeal areas. A chamber one inch long has been successfully used in treating eyelid and inner canthus basal cells.

Although the invention has been shown and described with respect to preferred embodiments thereof, it should be understood by those skilled in the art that the foregoing and other changes and omissions in the form and detail thereof may be made therein without departing from the spirit and scope of the invention.

Having thus described typical embodiments of my invention, that which I claim as new and desire to secure by Letters Patent of the United States is:

1. A cryosurgical instrument adapted for use in the freezing of tissue comprising:

means including a walled confinement structure having an open distal end adapted for contact with the tissue to be frozen for providing a confined volume including and surrounding at least a portion of the tissue to be frozen;

means for filling said confined volume with liquified gas coolant in liquid form to a level above the level of tissue to be frozen; and

means for venting vapors of said coolant from said confined volume above said level of liquid.

2. The instrument according to claim 1 wherein said walled structure comprises a generally cylindrical wall having an axis extending in at least one direction.

3. The instrument according to claim 2 wherein said walled structure comprises a compound cylindrical wall extending in more than one direction.

4. The instrument according to claim 1, wherein said walled structure comprises a generally elongated, bent wall.

5. A cryosurgical instrument for the freezing of tissue comprising:

an open walled chamber for providing a confined volume including and surrounding at least a portion of the tissue to be frozen; and

means including a vent tube having a coolant delivery tube disposed coaxially therewith for directing a flow of liquified gas coolant toward tissue to be frozen within said confined volume and for venting vapors of said coolant from said confined volume, said open walled chamber being fastened to the outer one of said tubes.

6. The cryosurgical instrument according to claim 5 wherein said outer tube and said chamber are adapted to releasably engage one another, whereby said chamber may be removed from the end of said tube.

7. A cryosurgical method which comprises positioning one open end of an annular containment shield against the tissue to be frozen with sufficient force to form a hermetic seal thereat;

directing a flow of cryogenic liquid through the shield toward said one end into contact with the tissue to be frozen and vaporizing liquid thereat; venting the vaporized liquid upstream of said one end;

and maintaining the hermetic seal until the tissue has been frozen and the liquid has been vaporized.

8. A method of cryosurgically treating living tissue comprising the steps of:

providing a walled confinement structure having an open distal end and a proximal end connected to a source of liquified gas coolant, said structure composed, at least at its distal end, of a material having the characteristic of adherence with ice, said source of liquified gas coolant having a boiling point sufficiently low so as to freeze moisture thereby to form ice;

cooling said structure, by causing coolant to pass therethrough, until said structure achieves a temperature below that at which ice will form;

disposing said distal end of said structure into contact with living tissue to be treated, thereby establishing a confinement about at least a portion of tissue to be treated, said portion of tissue comprising a portion of said confinement, said confinement being sealed with a layer of ice between said structure and said tissue; and

flowing said liquified gas coolant in liquid form from said source into said confinement toward said portion of tissue to be treated.

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