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Waller et al.

[11] **3,889,681**

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[54] **CRYOSURGICAL SPRAYING APPARATUS**

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[51] **Int. Cl.²** **A61B 17/36**

[58] **Field of Search** ..... 128/303.1, 173 R, 400; 62/293

[56] **References Cited**

UNITED STATES PATENTS

3,651,813	3/1972	Bryne	128/303.1
3,702,114	11/1972	Zacarian	128/303.1
3,739,956	6/1973	Reynolds	128/303.1
3,823,718	7/1974	Tromovitch	128/303.1

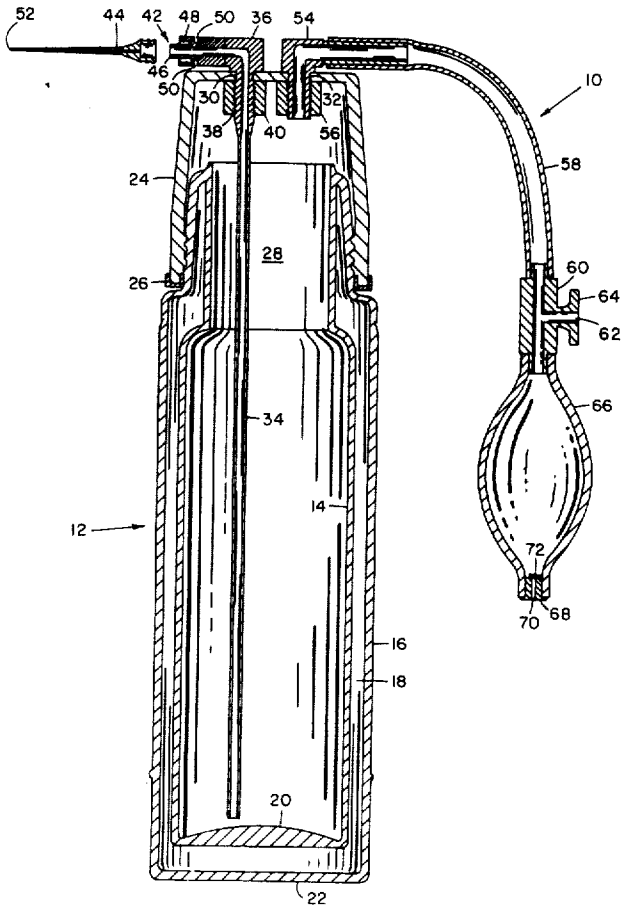
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[57] **ABSTRACT**

An insulated, compact, mobile cryosurgical instrument is provided that has no moving parts in contact with a liquefied gas coolant retained in an insulated container. Upon interrupting normal venting from the container, the liquefied gas coolant will build up a pressure in the container which pressure can be increased by a squeeze pressure device. The pressure will cause the liquefied gas coolant to spray from a nozzle until normal venting is restored.

6 Claims, 2 Drawing Figures



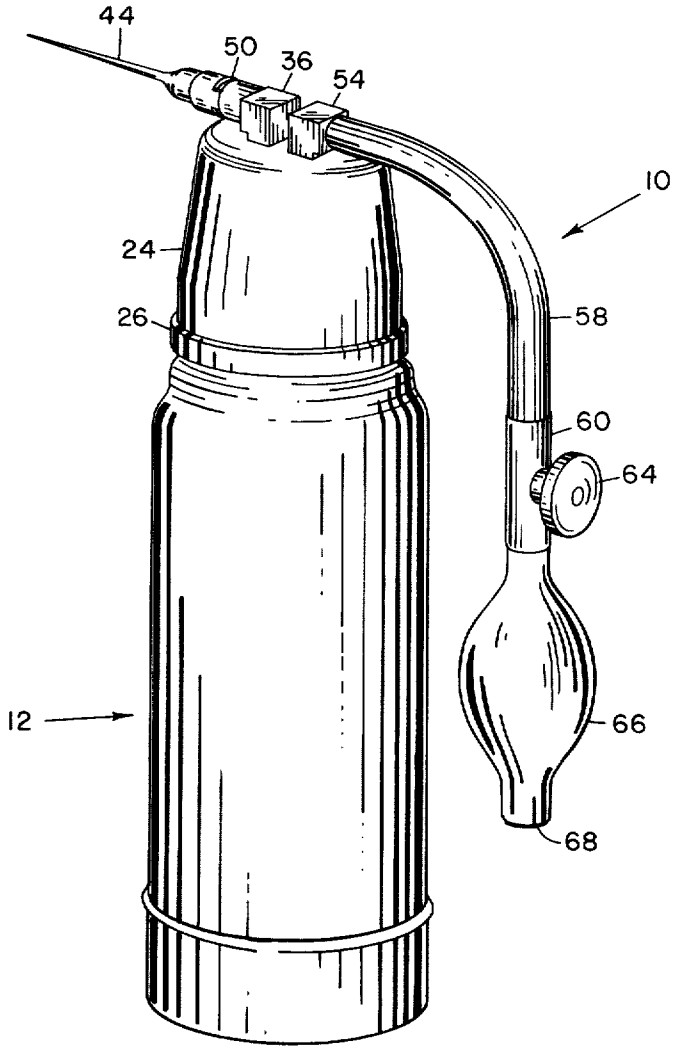


FIG. 1

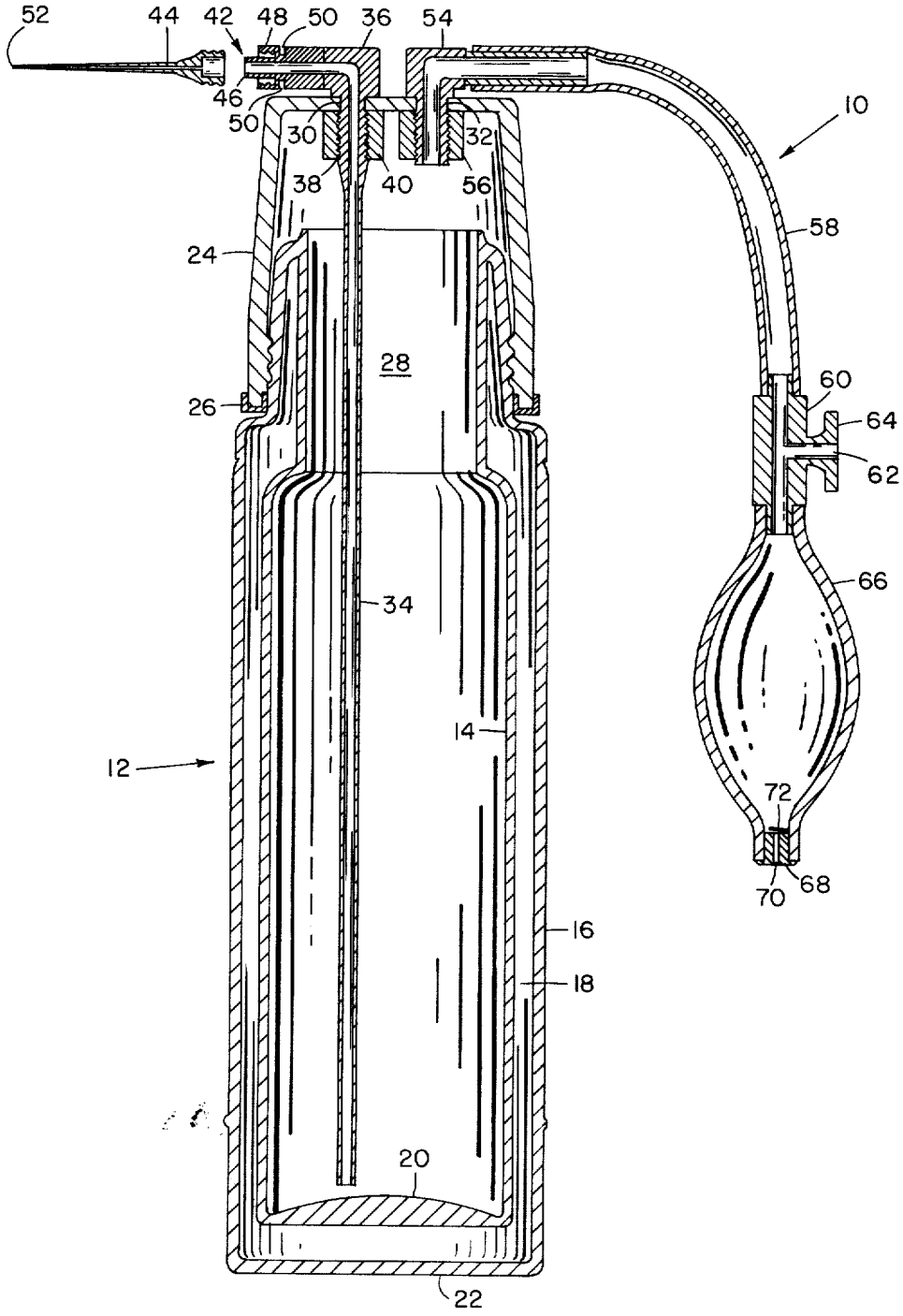

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FIG. 2

CRYOSURGICAL SPRAYING APPARATUS

BACKGROUND OF THE INVENTION

The present invention relates to a cryosurgical instrument and, more particularly, to a liquid nitrogen spray apparatus that can be used in treating lesions, benign or malignant, that respond to cryosurgery.

In the medical practice there have been various types of spraying apparatus used in cryosurgery for the treatment of skin lesions. Using layman's terms the skin lesions may be any type of definite growth in the skin (warts being an example) or an infection in the skin (acne being an example). In recent years cryosurgery has been used to treat cancerous or malignant tumors in the skin. The cancerous areas may be located on either the internal areas of the body or on the exterior skin.

Regardless of the type of cryosurgical instrument that is used, the lesion must be frozen to at least minus twenty degrees centigrade to insure the destruction of all the abnormal cells. Though various types of liquefied gas coolants may be used in cryosurgical instruments, the usual liquefied gas used by the medical profession is liquid nitrogen which has a boiling point of minus 196°C. Because of the extremely low boiling temperature of liquid nitrogen, it must be stored in special containers to prevent evaporation to the atmosphere. Also, if any moving parts come into contact with the liquid nitrogen they may freeze up or stick due to a moisture collection from the atmosphere. Any flexible hosing that may come in contact with the liquid nitrogen becomes very rigid and brittle.

A cryosurgical instrument in common use today by the medical profession is shown in U.S. Pat. No. 3,739,956 issued to Reynolds, a copy of which is submitted with this patent application. In Reynolds various types of valving apparatus and moving parts are shown as coming in contact with the liquid refrigerant. All of these valving apparatus may freeze up in a very short period of time. Liquid coolant would be evaporated to atmosphere in a very short period of time. As can be seen from Reynolds, it is a fairly complex apparatus that would be expensive to manufacture.

Another apparatus commonly used by the medical profession is the apparatus as shown in the Bryne patent, U.S. Pat. No. 3,534,739, a copy of which is submitted with the present patent application. Though Bryne has the advantage of having no moving parts in contact with the liquefied gas coolant, the coolant is continuously boiling inside of the container and will completely evaporate in a very short period of time. By stopping of the normal venting from the container the pressure is built up to cause a stream of coolant to be ejected from the nozzle. In a single operation that may require thirty minutes to perform, the apparatus, as shown in Bryne, would have to be filled repeatedly. Many operations require the repeated treatment by the liquid gas coolant over short time intervals to insure a complete destruction of the lesion. Though the Bryne apparatus is inexpensive to manufacture it is extremely wasteful of the liquid coolant as well as being impossible to use for repeated time interval treatments without refilling with coolant. A later version of the same apparatus is shown in U.S. Pat. No. 3,651,813, a copy of which is also enclosed with the patent application.

Various other types of cryosurgical instruments are shown in the following patents:

INVENTOR	U.S. PAT. NO.
Langue	3,537,458
Zacarian	3,702,114
Basiulis	3,736,937
Posch	2,645,097
Nelson	1,659,663
Reynolds	2,258,863

Though the applicant will not discuss in detail the above referenced patents, copies are included with the present patent application for the convenience of the examiner. Previous discussions of the prior art apply to the referenced patents.

Another apparatus that is being sold in the market today is the TT-32 Liquid Nitrogen Sprayer by Physicians Products Inc., Box 44, Millbrae, Calif. 94030. Copies of the sales literature is included for the convenience of the examiner. Since the liquid coolant is contained in a vacuum bottle, considerable waste of the liquid coolant is avoided. The pressure built up inside the vacuum bottle would not normally be enough to cause a continuous ejection of the liquid coolant from the nozzle. The valving mechanism immediately above the squeeze bulb is inconvenient to operate. One hand must be used to squeeze the bulb and the thumb and forefinger of the same hand or the other hand being used to operate the valve. The hand not being used on the bulb and valve, or a second person, must hold the spray nozzle on the skin lesion and hold the vacuum bottle. After squeezing the squeeze bulb with the valve closed liquid nitrogen is ejected from the nozzle; however, liquid nitrogen will continue to eject from the nozzle until pressure inside the vacuum bottle has been dissipated. This may result in an excess of the liquid coolant reaching the skin lesion or adjacent normal areas with resultant damage to skin tissue. Because the valve is a screw type valve it is not easy to rapidly open and close resulting in a loss of the delicate control of the amount of coolant delivered which is so highly desirable in such a unit especially in treating very sensitive areas about the eyes, face, genitalia, etc.

In the present apparatus a continuously open vent is provided immediately above the squeeze bulb that may be closed by placing the thumb over the opening. Immediately upon removing the thumb from the opening, the pressure inside the vacuum bottle immediately decreases to stop the ejection of the liquid coolant. This venting mechanism provides an extremely delicate and precise control of the amount of coolant delivered.

In the TT-32 Liquid Nitrogen Sprayer a safety vent valve is provided immediately above the vacuum bottle stopper. This valve, which allows for the venting to the atmosphere of any excessive pressures has the potential problem of freezing up due to moisture from the atmosphere. Should this valve freeze up, excess pressures could build up within the unit if the valve above the squeeze bulb is closed. Once the vent valve freezes the apparatus must be taken apart to allow the vent valve to thaw before the TT-32 Sprayer can be used again. The present invention with its continuous open, simple, thumb controlled venting completely eliminates any possibility of excess pressure building up within the unit. Also, the flexible hose from the vent valve to the spray nozzle of the TT-32 Sprayer is impractical. Once liquid nitrogen flows through the flexible hose it be-

comes very rigid and brittle. This hose may break even under hospital conditions due to the extremely brittle conditions caused by the low temperature. Although the TT-32 is inexpensive and does not waste the liquid nitrogen as long as the vent valve remains open, its use under hospital conditions is very awkward and inconvenient. The present invention eliminates the problem of the freezing of the vent valve, the breaking of the flexible hose through which the liquid nitrogen flows and the inconvenient operation of the squeeze bulb valve. The present apparatus prevents an excess of liquid nitrogen from being applied to the skin lesion because of the extremely precise and delicate control made possible by the thumb controlled venting. The present invention also incorporates a standard Leur lock head for the rapid and easy attachment of tips (needles) of any diameter and length necessary to treat lesions of any size and location.

SUMMARY OF THE INVENTION

It is an object of the present invention to provide a cryosurgical instrument for treating skin lesions, benign or malignant.

It is another object of the present invention to provide an insulated, compact, mobile cryosurgical instrument that is very easy to use and inexpensive to manufacture.

It is a further object of the present invention to provide a cryosurgical instrument that minimizes waste of the liquid coolant, such as nitrogen.

It is yet a further object of the present invention to provide a cryosurgical instrument with no moving parts that contact the liquid nitrogen and, simultaneously, be very economical to manufacture and easy to use in a hospital or office.

It is yet another object of the present invention to provide an insulated, compact, mobile cryosurgical instrument wherein pressure can be applied to the liquefied gas coolant and released immediately by movement of one hand while the other hand maintains the nozzle on the skin lesion being treated.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is a perspective view of the cryosurgical spraying apparatus.

FIG. **2** is an elevated cross sectional view of the cryosurgical spraying apparatus.

DESCRIPTION OF THE PREFERRED EMBODIMENT

Referring now to FIGS. **1** and **2** in combination, the cryosurgical spraying apparatus is represented generally by the reference numeral **10.** The cryosurgical spraying apparatus **10** has an insulated container **12** that is similar to a common vacuum bottle. The insulated container **12** has an inner wall **14** and outer wall **16** with a space **18** contained therebetween. The space **18** also extends between the bottom **20** of inner wall **14** and bottom **22** of outer wall **16.** The upper portion of the insulated container **12** consists of a cap **24** threadably connected to the upper portion of outer wall **16** with a sealing ring **26** providing a good seal therebetween. The upper portion of the insulated container **12** contains an opening **28** through which a liquefied gas coolant may be inserted upon removing the cap **24.**

The cap has holes **30** and **32** contained therein. Through hole **32** extends tubing **34** to nearly the bottom **20** of inner wall **14.** The tubing **34** should be of a suitable noncorrosive metal substance for receiving a liquefied gas coolant contained inside of the insulated container **12.** The upper portion of the tubing **34** which extends through hole **30** has a ninety degree bend **36** to the left. Immediately below the 90° bend **36** are thread connections **38** of tubing **34** to which a suitable retaining nut **40** may be attached. The retaining nut **40** securely locates the tubing **34** and the ninety degree bend **36** to the cap **24.** To provide a good seal with the cap a resilient washer could be used; however, because of the extremely low temperature of liquid nitrogen and the brittle nature of a resilient washer at these temperatures, a clear epoxy type sealant is used in the preferred embodiment.

The leftmost portion of the ninety degree bend **36** provides a large nozzle **42** to which needle **44** may be attached. The large nozzle **42** has a Leur type locking head formed by inner tubing **46** and outer structure **48** for retaining the needle **44.** Slots **50** have been provided in the outer structure **48** to provide ease of installation of the needle **44** by preventing the trapping of pressurized air behind the needle **44.** The needle **44** has a small tip to provide the application of the liquefied gas coolant to a very localized area. Other types of needles or nozzles may be used according to the particular needs of the individual case.

Through hole **32** of cap **24** is inserted a ninety degree flange fitting **54.** The lowermost portion of the flange fitting **54** is threadably connected to nut **56.** Again a clear epoxy type sealant is being used to prevent the escape of pressurized gas through holes **32,** but it should be understood that other types of seals may be utilized. A flexible rubber hose **58** is connected to flange fitting **54** for fluid communication with the inside of insulated container **12.** The opposite end of the flexible rubber hose **58** is connected to T-valve **60** with one side of the T-valve having an opening **62** to atmosphere. The opening **62** terminates in a thumb press flange **64** whereby a thumb of the operator of the cryosurgical spraying apparatus **10** may cover the opening **62** when the apparatus is being used. The other side of the T-valve **60** is connected to a squeeze bulb **66** which may be utilized to pressurize the inside of insulated container **12** via flange fitting **54,** tubing **58** and T-valve **60.** The bottom of squeeze bulb **66** has a one-way Reed valve **68** that allows air to flow into the squeeze bulb **66** but not vice-versa. The Reed valve **68** consists of an opening **70** inside of the squeeze tube **68** which is covered with a thin metal strip **72.** Upon squeezing the squeeze bulb **66** the thin metal strip **72** covers the opening **70** to prevent the escape of air through opening **70.**

In the present invention needle **44** is shown with a small tip **52;** however, other types of needles or nozzles may be used including a nozzle that would spray a large area for treatment of skin conditions such as acne. Particular types of spraying attachments may be desirable when treating a cancerous growth, or other skin lesions. Many other types of needles may be utilized depending upon the particular situation.

METHOD OF OPERATION

The cap **24** is unscrewed from the insulated container **12.** The liquid nitrogen is then poured through the opening **28** into the insulated container **12** and the cap **24** is placed back on the insulated container **12.** The

cap **24** should be tightened until the seal ring **26** provides a good seal with the outer wall **16.** The liquefied gas coolant inside of insulated container **12** (usually liquid nitrogen) would need a vent to atmosphere to keep excessive pressures from building up because of the extremely low temperature. In the cryosurgical spraying apparatus **10** a vent is provided through flange fitting **54,** flexible rubber hose **58,** T-valve **60** and out opening **62.** Normally one filling of insulated container **12** will last an entire working day of 8 hours without refilling.

Whenever the cryosurgical spraying apparatus **10** is needed a person such as a medical doctor could immediately pick up the apparatus, put the small tip **52** of needle **44** to the area being treated and squeeze the squeeze bulb **66** while simultaneously placing his thumb over opening **62.** The squeezing of the squeeze bulb **66** will create a pressure inside of insulated container **12** thereby forcing the liquid nitrogen up tubing **32** through 90° bend **36** and out through the needle **44.** As soon as the desired amount of liquid nitrogen has been applied to the skin lesion, the thumb can be removed from thumb press flange **64** thereby uncovering opening **62.** This will immediately relieve the pressure inside of insulated container **12** thereby stopping the flow of the liquid nitrogen out needle **44.** This process can be repeated as many times as cryosurgical treatment is necessary during an operation. Because the container is well insulated the liquid nitrogen will last for an extended period of time for repeated treatments.

In the present apparatus there are no moving parts that will come in contact with the liquid nitrogen and therefore be subject to freezing due to moisture condensation. Also pressure inside of the container can be relieved immediately by simply removing the thumb from the thumb press flange **64,** thereby stopping the flow of liquid nitrogen thus enabling the treating physician to apply a very controlled amount to a localized area.

We claim:

1. A cryosurgical instrument for treating skin lesions comprising:

an insulated container for holding a liquefied gas coolant;

cap means for said insulated container;

a combination vent/pressure line communicating with the inside of said insulated container;

tubing means extending from near the bottom of said insulated container to the outside thereof;

nozzle means attached to said tubing means for spraying said liquefied gas coolant upon pressurization from said vent/pressure line;

said vent/pressure line being connected to atmosphere through a first opening and to a source of pressurized air through a second opening, said first opening being covered before pressurization through said second opening.

2. The cryosurgical instrument as recited in claim **1** further comprises a manual squeeze bulb for said pressurization through said second opening.

3. The cryosurgical instrument as recited in claim **2** wherein said first opening is adapted for covering by the thumb of the operator of said squeeze bulb to stop venting before pressurization, and to instantaneously remove pressurization upon uncovering said first opening.

4. The cryosurgical instrument as recited in claim **3** wherein said vent/pressure line and said tubing means extends through said cap means in an airtight manner.

5. The cryosurgical instrument as recited in claim **4** wherein said insulated container is a vacuum bottle and said cap means is a cap for said vacuum bottle.

6. The cryosurgical instrument as recited in claim **1** wherein said nozzle means is interchangeable.

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