

WALLACH

ULTRAFREEZE™

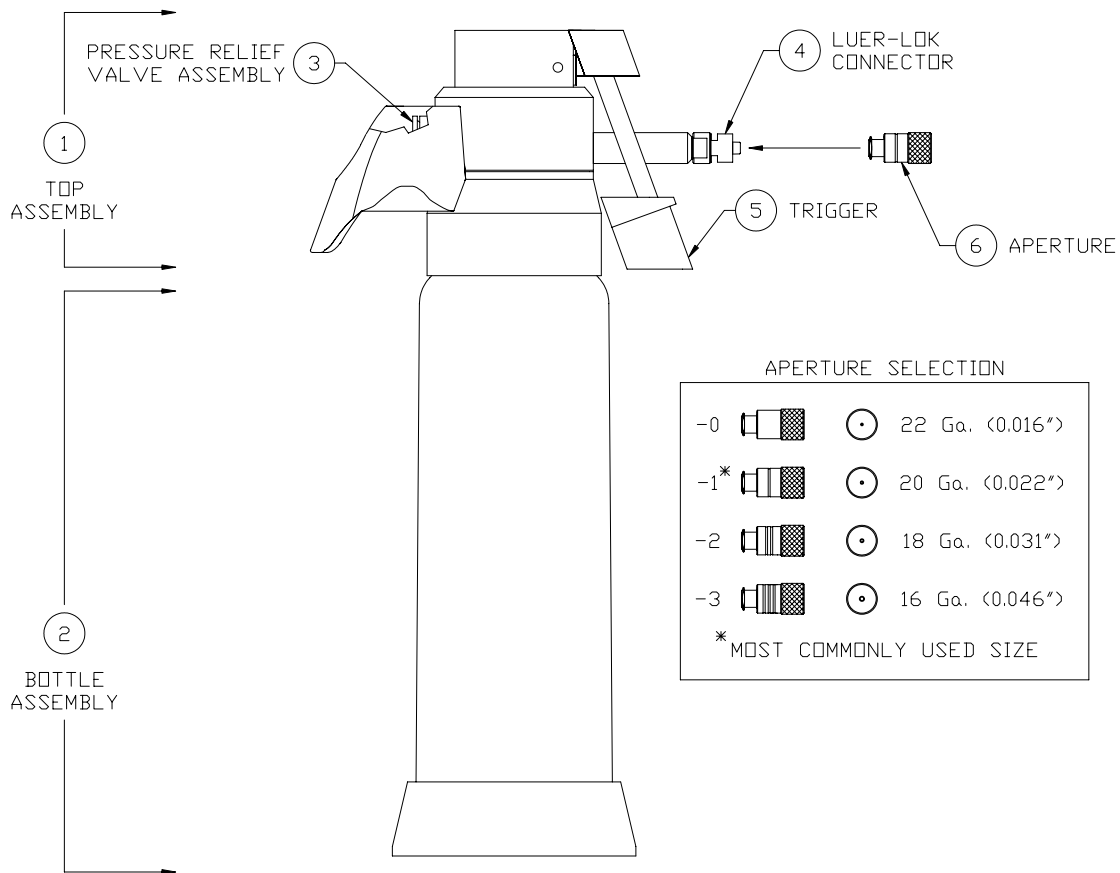
Cryosurgical Instrument

(Including Five Spray Apertures)

REF 900076 - 0.5 liter

REF 900077 - 0.3 liter

This device complies with the EC Medical Device Directive (93/42/EEC)



CAUTIONS:



- **FEDERAL LAW RESTRICTS THIS DEVICE FOR SALE TO, OR ON THE ORDER OF A PHYSICIAN. IT IS INTENDED FOR PROFESSIONAL USE ONLY (LICENSED PHYSICIAN OR VETERINARIAN).**



- **READ ALL OPERATING INSTRUCTIONS BEFORE ATTEMPTING TO FILL OR USE THIS INSTRUMENT.**



- **FOR USE WITH LIQUID NITROGEN ONLY. FOLLOW ALL APPLICABLE SAFETY PRECAUTIONS FOR HANDLING LIQUID NITROGEN (Per MSDS). EYE PROTECTION SHOULD ALWAYS BE WORN WHEN FILLING THE BOTTLE (2). GLOVES AND A PROTECTIVE APRON ARE NECESSARY TO KEEP NITROGEN FROM CONTACT WITH THE SKIN.**

- **LIQUID NITROGEN EXPANDS INSIDE THE BOTTLE TO PROVIDE OPERATING PRESSURE. BEFORE SEPARATING THE TOP (1) AND BOTTLE (2), TO REFILL THE BOTTLE OR DISCARD RESIDUAL FLUID, ENSURE THAT THE INSTRUMENT IS FULLY DEPRESSURIZED. SEE SECTION “INSTRUCTIONS FOR USE” FOR PROPER DEPRESSURIZATION AND FILLING PROCEDURES.**
- **DO NOT FILL THE BOTTLE MORE THAN ¾ FULL. OVERFILLING MAY CAUSE LIQUID NITROGEN TO BOIL OUT OF THE CONTAINER WHEN ATTACHING THE TOP. ALSO, PERFORMANCE OF THE INSTRUMENT MAY BE DEGRADED.**

INTENDED USE:

The ULTRAFREEZE Liquid Nitrogen Sprayer is indicated for treatment of cutaneous lesions amenable to cryosurgery.

The ULTRAFREEZE Liquid Nitrogen Sprayer is contraindicated for any other use.

INSTRUCTIONS FOR USE:

PRODUCT DESCRIPTION

The Instrument has two major components, the Top (1) and Bottle (2) Assemblies. The Top Assembly comprises the Pressure Relief Valve (3), the Luer-Lok Connection (4) and the Main Valve Trigger (5). It has an ergonomic grip and is fully insulated with Delrin® components. The Bottle Assembly (2) is an insulated pressure vessel with Delrin® components: a collar for comfort; a skirt for stability. The Top is secured to the Bottle using a threaded connection, with an O-Ring, and is separated with a counter-clockwise rotation.

As the Liquid Nitrogen within the Bottle becomes gaseous, the pressure within increases. The Instrument is equipped with a Pressure Relief Valve (3), which will maintain the internal pressure below a predetermined level. In normal operation, the user may perceive a ‘hissing’ sound as excess pressure bleeds off. The flow of Liquid Nitrogen to the patient is initiated by pulling the Trigger (5) toward the Bottle. The closer the Trigger is to the Bottle, the greater the flow will be. A variety of Open Apertures (6) or Closed Tips can be attached to the Luer-Lok Connector (4). The Aperture orifice size is indicated by circumferential grooves adjacent to the connector. The orifice size increases with the number of grooves present. The ‘quarter-turn’ lock allows for a quick change or reposition.

FILLING THE ULTRAFREEZE

Liquid Nitrogen can be purchased through your local gas supplier.

To fill the Bottle (2), unscrew the Top (1) from the Bottle. Fill by carefully pouring the liquid into the Bottle or by using any standard dewar with a low pressure filler system. The recommended volume of liquid for a period of 3-8 hours of intermittent use is 3/4 full. Use enough fluid to perform the procedure.

To refill the Bottle, first depressurize by applying ‘vertical or lateral pressure to the edge of the “Brass Plunger” portion of the Pressure Relief Valve (3). Next, unscrew the Bottle one-half turn and wait until remaining pressure is released. Remove the Top, add fluid, and reassemble.

To hasten pressurization of the instrument, gently shake until gas begins to escape from the Pressure Relief Valve (3).

The user should maintain a clean source of Liquid Nitrogen, as water or other foreign substances may interfere with the operation of the instrument. To keep the supply clean, it is recommended that the storage container be emptied completely at least four times a year.

OPERATING INSTRUCTIONS

Use of the ULTRAFREEZE requires the attachment of a Closed Tip or Open Aperture. The Aperture size is dictated by the type of lesion, the size and shape of the treatment area, and the amount of Liquid Nitrogen to be delivered. The spray apertures with a larger orifice should be used for large, deep lesions. Apertures with smaller orifices should be used for warts and keratoses.

Once the ULTRAFREEZE has been filled with Liquid Nitrogen, the proper Aperture or Closed Tip must be attached. The desired Aperture (6) is attached to the Connector (4) by inserting the base and rotating approximately 1/4 turn clockwise. The instrument is now ready for use. The flow of nitrogen, delivered to the patient, is controlled by the amount of pressure applied to the Trigger (5).

CARE OF ULTRAFREEZE:

At the end of the day, empty and dry the unit. To ensure that all liquids are removed from the bottle, the components should be air-dried separately, with the bottle and cap inverted. Foreign materials inside the bottle, even in small amounts, will cause the instrument to malfunction (clogged tubes, valves held open, etc.). Any foreign materials detected inside the bottle may be removed by wiping or rinsing with alcohol; DO NOT attempt to use the instrument until the bottle is completely dry. To clean the exterior of the instrument, reassemble and wipe with soap and water. Separate, invert and air-dry the two components. Once both components are completely dry, reassemble the unit and store the unit upright. This will prevent foreign debris from entering the system and minimize the possibility of mechanical damage.

Since the Bottle is constructed of stainless steel, slight dents and abrasions of the surface can be expected with use. Minor damage of this type will not affect the operation of the unit, unless the seal is compromised and the vacuum has dissipated.

TROUBLESHOOTING

Problem	Probable Cause	Solution
A. No Pressure	1) System leaking.	1) Ensure Top is fully seated on Bottle. 2) Actuate Pressure Relief Valve. 3) Listen carefully to locate source of leakage and call Repair Technician.
B. Excessive Frost on Bottle	1) Punctured bottle (cannot maintain pressure; non-operational)	1) Call Repair Technician and replace unit.
C. No flow of Liquid Nitrogen	1) Clogged Aperture or Instrument.	1) Clean Aperture with a pin or needle. 2) Call Repair Technician.
D. Main or Pressure Relief Valve stuck open	1) Valve frosted over or frozen.	1) Depressurize and remove Top. Thaw at room temperature, wipe dry. Reassemble and test. 2) Call Repair Technician.

SERVICE/REPAIR:

In case of malfunction, call the factory at (203) 799-2000 and ask the Repair Department for assistance. If a repair is needed, carefully sanitize and package unit in a protective carton. Include a note stating the problem and ask for a repair estimate. **DO NOT ATTEMPT IN-HOUSE REPAIRS; THIS WILL VOID YOUR WARRANTY.**

WARRANTY:

The Wallach UltraFreeze is supported by a three-year warranty from date of purchase covering any failure of the device due to defective workmanship or components, when used in compliance with the product's indicated use. Only Wallach Surgical Devices is authorized to service or repair this unit. If repair is attempted outside the factory, the warranty will be considered void.

WALACH

SURGICAL DEVICES
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EXPLANATION OF SYMBOLS



For Professional Use Only



Extreme Cold



See instructions for use

REF

Reorder Number

SN

Serial Number



CE Mark (for medical devices only) made in accordance with 93/42/EEC medical devices directive

Authorized European Representative:

Leisegang Feinmechanik GmbH
Leibnizstrasse 32
D-10625, Berlin GERMANY