

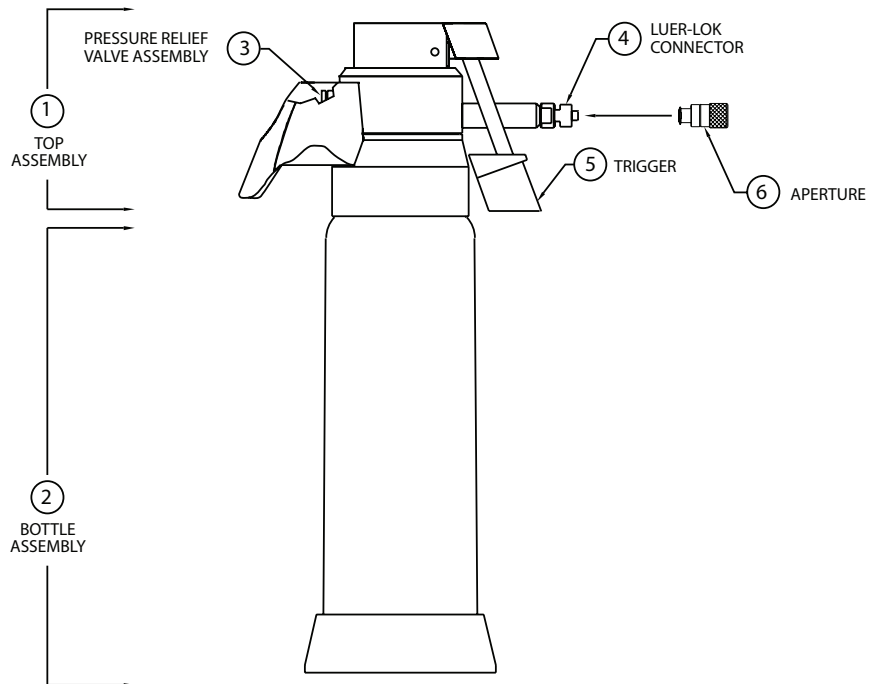


Wallach® UltraFreeze™ Cryosurgical Instrument Instructions for Use



(Including Five Spray Apertures)

REF 900076 - 0.5 liter

CE₂₇₉₇
R_x Only



CAUTIONS:

- R_x Only** • U.S. 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 Wallach® UltraFreeze Liquid Nitrogen Sprayer, a product of CooperSurgical, is indicated for the treatment of cutaneous lesions amenable to cryosurgery.
- The Accu-Shield should be used in conjunction with the Wallach UltraFreeze. The Accu-Shield is used to concentrate liquid nitrogen spray within a limited area for dermatologic procedures by placing the front of the plate against the area to be treated and spraying the liquid nitrogen into the chosen opening.
- The Wallach UltraFreeze Liquid Nitrogen Sprayer is contraindicated for any other use.

INSTRUCTIONS FOR USE:

Device Description

The UltraFreeze Cryosurgical 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) 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: ‘0’ Groove - 22 Ga.; ‘1’ Groove - 20 Ga.; ‘2’ Groove - 18 Ga.; ‘3’ Groove - 16 Ga. Included in the aperture kit is a 20 Ga. Curved Needle Tip for areas difficult to reach with a spray aperture.

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 Aperture tips. 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).

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.

The Wallach UltraFreeze should be cleaned and disinfected after each patient use.

CLEANING AND LOW LEVEL DISINFECTION INSTRUCTIONS

Cleaning

1. Instruments should be cleaned as soon as possible. Do not allow blood and debris to dry on the instrument. If cleaning cannot be performed immediately, keep the tip moist.
2. Prepare an enzymatic, neutral pH cleaner solution according to the Manufacturer’s instructions.
3. Wearing appropriate personal protective equipment. Immerse a clean, lint-free wipe into cleaning solution and thoroughly wring. Thoroughly wipe the black plastic handle including trigger and bottle. Discard the wipe.
4. If it is necessary, using a soft, nylon brush, scrub difficult-to-access areas such as crevices or textured surfaces.
5. Immerse a fresh, clean, lint-free wipe under warm flowing, utility water and thoroughly wring excess water. Thoroughly wipe the black plastic handle including trigger and bottle for at least 30 seconds. Discard the wipe.
6. Repeat steps 5 using a fresh, disposable wipe.
7. Inspect the device for visible soil or debris. If visible soil remains, repeat cleaning steps 3-6 until device is visually clean.

Disinfection

1. Using a fresh, moist disinfectant wipe, CaviWipes®, thoroughly wipe the black plastic handle including trigger and bottle. Discard the wipe.

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2. Using a fresh wipe repeat step 1. Discard the wipe. Allow the wiped and wetted device to stand for a minimum of time, re-wetting the wipes as necessary to ensure all surfaces remain wet for the entire time.
3. Use a sterile 70% IPA wipe, or a low-lint wipe, saturated with sterile 70% IPA, to thoroughly wipe the device.
4. Allow the device to air dry. Once dry, visually inspect the device for any residual soil. Repeat cleaning/disinfection instructions if visible soil is present.
5. Place the cleaned/disinfected device in an appropriate dry storage area.

CLEANING STEPS FOR TIPS

1. Ensure the Cryosurgical Tip is assembled
2. Prepare an enzymatic, neutral pH cleaner solution in accordance with manufacturer's instructions.
3. Grasp the shaft end of assembled device and point tip/probe end at a downward angle.
4. Immerse a clean, lint-free wipe into cleaner solution and thoroughly wring.
5. Beginning just above the shaft joint, thoroughly wipe device with moistened wipe for a minimum of 20 seconds.
6. Use a beaker to pour enzymatic solution, for a minimum of 20 seconds, down the outside of the device, from just above the shaft joint to the tip.
7. After pouring solution, use a clean, soft bristle brush to scrub mated surfaces of the shaft/stem joint and the creases of any welded joints for a minimum of 20 seconds.
8. Rinse the wipe under flowing Utility water and repeat steps 5 through 7.
9. Adjust flowing Utility water to maintain a steady stream at 35-40 °C. Thoroughly rinse device (angled downward), beginning above the shaft joint to the tip, for a minimum of 30 seconds.
10. Pat device dry using a clean, dry lint-free wipe.
11. Holding the device at a downward angle, carefully remove the tip from the shaft.
12. Moisten a lint-free wipe in flowing Utility water and wring thoroughly.
13. Wipe protected area (the stem) of the probe and inside threads of any shaft and stem with moistened wipe. Rinse wipe in flowing Utility water and repeat wiping of these areas for 30 seconds until no visible detergent remains.
14. Pat device dry with a clean low-lint wipe. Visually inspect device for detergent residue.
15. If needed, reconnect tip/probe to shaft and repeat rinse steps 9 through 14 until no visible detergent residue remains.
16. Apply Isopropyl alcohol (70% or greater) to a low-lint wipe (do not saturate). Wipe down the entire device.
17. Dry the device using a clean lint-free wipe.

STERILIZATION OF TIPS: Tips can be steam sterilized by Gravity or Pre-vacuum using the following Instructions:

Set-up	Stage / Process	Parameter Set-Points	
		Gravity	Pre-Vacuum
Pre-Exposure (Conditioning)	Chamber Purge	1 minute	1 minute
Exposure (Steam Injection)	Sterilization Temperature	132 °C (270 °F)	132 °C (270 °F)
	Sterilization Time	15 minutes	4 minutes
Post-Exposure (Exhaust/Dry)	Dry Time	15 minutes	20 minutes

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.

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Problem	Probable Cause	Solution
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 CooperSurgical Service and Repair Department at (203) 799-2000 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 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 authorized service and repair professionals are permitted to repair this unit. If repair is attempted outside the factory, the warranty will be considered void.

EXPLANATION OF SYMBOLS

 Reorder number	 This side up	 Not made with natural rubber latex
 Serial number	 Consult instructions for use	Rx Only Caution: U.S. Federal law restricts this device to sale by or on the order of a physician.
 Extreme Cold	 Caution	EC REP Authorized European Representative in the European Community
 Keep Dry	 Non-sterile	 Manufacturer
 Fragile	 Do not use if package is damaged	

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