

INSTRUCTIONS FOR USE

Apertures

Apertures are used with Cry-Ac's which is a Hand-Held Cryosurgical Device for the controlled dispensing of Liquid Nitrogen.

1. Operation Instructions Caution: When using the Cry-Ac®, with Spray Apertures ensure the unit is kept as upright as possible to prevent purging of Liquid Nitrogen from the Relief Valve. The 20g Bent Spray supplied with each Unit allows Open Spraying in any position through 360 degrees and eliminates the need to tip the Unit. This Cryosurgical Unit is designed only for use with other Brymill manufactured products. Your unit is supplied with 4 different sizes of Open Spray Apertures and a 20g Bent Spray. The full range of Open Sprays and Closed Probes can be found on our website. Your selection of Open Spray or Contact Probe will depend upon the size and type of lesion being treated. Spray Tips and Probes must be secured to the permanently affixed Knurled Nut with finger tight firmness.

When you have completed the treatment of a patient, set the Cryosurgical Unit gently on a table. The bottom of the unit may be damaged if it is dropped or repeatedly brought in contact with a hard surface. At the conclusion of an office day, the Cryosurgical Unit should be stored in a CLOSED position (with the top on) whether or not there is a residual amount of Liquid Nitrogen left in it. This is extremely important in order to eliminate the potential buildup of condensation within the unit and tubing.

2. Decontamination It is recommended that the Spray Apertures are cleaned between episodes of patient care. Since the Apertures operating in the "spray" mode do not come into direct contact with the patient then the infection risk is classified as "Low" and therefore the unit only requires periodic disinfection using Alcohol wipes. If for any reason you require your unit to be serviced or repaired the repair must be carried out by a Brymill Authorized Repair Center. If repairs are performed by any other party the warrantee will become invalid. Unauthorized repairing will also absolve Brymill Cryogenic Systems of any claims for injury caused by an unauthorized repaired unit.

3. Cleaning Instructions if Apertures come in contact with the skin

- a. Manual Cleaning Instructions
- b. If applicable, disassemble instruments prior to cleaning and sterilization.
- c. Immediately after the surgical procedure, remove as much debris as possible from each instrument using a water moistened gauze pad, exchanging the gauze pad if it becomes soiled. Instruments should be cleaned immediately after use; soiled instruments must be kept moist to prevent soil from drying. If the instruments cannot be cleaned immediately, wrap them in a moist towel to prevent desiccation.

- d. Immerse each instrument in 70% Isopropyl Alcohol and brush each instrument thoroughly with a soft bristled cleaning brush for a minimum of one minute. Pay particular attention to hard to clean areas such as rough surfaces and joints.
- e. Wipe each instrument thoroughly with 70% Isopropyl Alcohol sanitizing wipe for a minimum of 1 minute to remove gross soil. Pay careful attention to difficult to clean areas such as joints, and rough surfaces.
- f. Clean each instrument again with a fresh 70% Isopropyl Alcohol wipe for a minimum of 1 minute per instrument. Pay careful attention to difficult to clean areas such as joints, and rough surfaces.
- g. Clean each instrument for a third time with a fresh 70% Isopropyl Alcohol wipe for a minimum of 1 minute per instrument. Pay careful attention to difficult to clean areas such as joints, and rough surfaces.
- h. Be sure to thoroughly dry any lumens and rough surfaces present.
- i. Perform a visual inspection on the instruments and verify that they are clean.
- j. If instruments are not visibly clean, repeat cleaning steps c - g.
- k. Verify the instruments are in proper working order prior to sterilization.

4. Sterilization

1. Use the following recommended validated sterilization parameters: of sterilization.

- Moist heat sterilization with Gravity cycle is the recommended method of sterilization. Gravity displacement cycle is not recommended.
- Vaporized Hydrogen (VHP), Ethylene oxide (EO), gas plasma and dry heat are not recommended sterilization methods for reusable instruments.
- The recommended parameters demonstrate the minimum validated steam sterilization time and temperature required to achieve a 1.0 x 10⁻⁶ sterility assurance level (SAL).
- The validated reprocessing instructions are not applicable to trays that include devices not manufactured or distributed by Brymill.

Cycle Time	Temperature	Exposure Time	Dry Time
Gravity	121°C (250°F)	30	15

If you have any other questions or comments, please do not hesitate to contact us on (800) 777-CRYO (USA) or 0 1256 841045 (UK) or email us at brymill@brymill.com.

CAUTION: U.S. Federal law restricts this device to sale by or on the order of a physician or veterinarian.

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