

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

Perform the manual cleaning procedure as follows:

- a. Prepare a bath of ambient temperature utility (tap) water.
- b. Moisten a lint-free cloth in the utility water bath and wipe the Aperture for 1 minute to remove as much debris as possible. Use a fresh lint-free cloth as necessary. NOTE: Take care not to get water inside the lumens.

- c. Prepare an Enzol bath using lukewarm utility water, (31-40 degrees C), with a recommendation of 1 oz/gallon.
- d. Immerse each Aperture in detergent solution. NOTE: Take care not to get water inside the lumens.
- e. After the 1-minute soak time but while immersed, wipe each Aperture thoroughly with a lint-free cloth for at least 1 minute.
- f. Pay particular attention to hard to clean areas such as rough surfaces and joints. NOTE: Take care not to get water inside the lumens.
- g. Using a fresh lint-free cloth moistened with (deionized) water, wipe each Aperture thoroughly to remove residual detergent.
- h. Pay careful attention to difficult to clean areas such as joints, and rough surfaces.
- i. Using a lint free cloth to thoroughly dry the Apertures, including any lumens and rough surfaces. NOTE: Be certain the devices are thoroughly dried before use.

4.) Sterilization

Use the following recommended validated sterilization parameters: of sterilization.

- a. Moist heat sterilization with Gravity cycle is the recommended method of sterilization.
- b. Vaporized Hydrogen (VHP), Ethylene oxide (EO), gas plasma and dry heat are not recommended sterilization methods for reusable instruments.
- c. 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).
- d. Sterilize the instruments after placing them in a Stainless-Steel Sterilization Tray and wrapping the tray is double layer of Bioshield Sterilization Wrap using the envelope technique.
- e. 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.

EU Authorized Representative –

Rosa Maria Sallent Moya, Calle Jaime Balmes, 59, 08830 Sant Boi de Llobregat SPAIN Phone: +34 616602892
 Email: brymill.internationalsales@gmail.com



1639