

INSTRUCTIONS FOR USE

CRYOCHAMBERS

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

1. Operating Instructions

Place the open edge of the Chamber on the surface of the tumor to be treated.

Make certain that the entire 360-degree edge is sealing on the surface.

A more uniform freeze will be achieved if the Chamber is held in a vertical position, therefore, we have included the Malleable Extension to facilitate this.

If the vertical position is maintained, the pool of liquid nitrogen will create an extremely deep symmetrical freeze.

2. Cautions

The vent tube should be pointed in a safe direction away from the operator and the patient. As the freezing progresses, a wet liquid level line will appear on the outside of the Chamber. This line can be maintained with intermittent pressing of the trigger on your CRY-AC. It does not have to be filling the Chamber continually. This will require a pressure of 1 to 2 pounds.

We emphasize the depth of 3cm to 4cm of destruction may be achieved, therefore significant caution should be taken

3. Cleaning Instructions

- i) Manual Cleaning Instructions
- ii) If applicable, disassemble instruments prior to cleaning and sterilization.
- iii) 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.

- iv) 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.
- v) 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.
- vi) 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.
- vii) 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.
- viii) Be sure to thoroughly dry any lumens and rough surfaces present.
- ix) Perform a visual inspection on the instruments and verify that they are clean.
- x) If instruments are not visibly clean, repeat cleaning steps #3 - 7.
- xi) 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

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

If you have any other questions or comments, please do not hesitate to contact us on (800) 777-2796 (USA) or (0) 1256 841045 (UK) or email us at brymill@brymill.com.

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