

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

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 cryochamber 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 cryochamber 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 cryochamber 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 cryochamber thoroughly to remove residual detergent.
- h. Pay careful attention to difficult to clean areas such as joints, and rough surfaces.
- i. Use a lint free cloth to thoroughly dry the cryochambers, including any lumens and rough surfaces. NOTE: Be certain the cryochambers are thoroughly dried before use.

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).
- Sterilize the instruments after placing them in a Stainless-Steel Sterilization Tray and wrapping the tray in a double layer of Bioshield Sterilization Wrap using the envelope technique.
- 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

- Replace the silicone vent tubing prior to use.

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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