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Instructions for Use – Contact Probes

Intended Use

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

1) Scope

This Instructions for Use applies to the following Brymill Cryogenic Systems products:

- Mini probes, Model 214;
- Conical probes, Model 203;
- Ball probes, Model 201;
- Flat probes, Model 205.

2) Warnings and Cautions:

Extreme care must be taken to properly direct the silicone vent tube which is attached to the base of the probe. This tube will harden after approximately five (5) seconds and remain in a fixed position during the remainder of the procedure.

It is imperative that they be pointed is a safe position away from the patient and the user at the onset of the procedure.

In order to prevent freezing of underlying structures such as tendons, nerves, or blood vessels, pull the probe back slightly to raise the skin away from the underlying structures after the lubricant jelly has adhered to the skin.

3) Technique

a. Select the appropriate contact probe based on the procedure and the size of the target area to be treated.
b. Attach the probe to the permanently affixed Knurled Nut on the Cry-Ac®, Cry-Ac-3®, or Cry-Baby® using finger tight firmness.
c. Ensure the area to be treated is as dry as possible.
d. Apply a small amount of lubricant jelly to cover the lesion.
e. Touch the end of the probe to the jelly but not the skin.
f. Depress the finger trigger to release the liquid nitrogen.
g. As the probe begins to the freeze, the lubricant jelly will harden and attach to the skin (known as cryo-adhesion).
h. "Freeze time" commences upon cryo-adhesion of the lubricant jelly. To limit the depth of the freeze, pull the probe back slightly to raise the skin away from the underlying structures. To obtain a deeper depth of freeze, apply a small amount of pressure to the probe after cryo-adhesion has occurred.
i. Upon completion of freezing, allow the probe to thaw before trying to separate the probe from the lubricant jelly on the skin. If done prematurely, it may result in a skin tear. A slight gentle twisting motion of the unit may expedite the release of the probe.

4) Cleaning

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.

5.) Sterilization

l. 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

m. Replace the silicone vent tubing prior to use.

If you have any other questions or comments, please do not hesitate to contact us on (800) 777-2796 (USA) or +44 (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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