

INSTRUCTIONS FOR USE - CONTACT PROBES

1. Intended Use

This Instruction for Use applied to the following range of Contact Probes only: -
214- Mini Probes, 216,203- Conical Probes, 201- Ball Probes, 205- Flat Probes, 202 Concave Probe
and 213 Hemorrhoid Probe.

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 in a safe position away from the patient and the user at the onset of the procedure.

1.1 Technique

- Ensure the area to be treated is as dry as possible.
- Apply a small amount of Lubricant Jelly to the lesion, enough to cover it. ⁽¹⁾
- Touch the end on the Probe to the Jelly but not the Skin.
- Begin the freeze
- As the Probe begins to freeze so does the Jelly and after approximately 5 – 7 seconds the Jelly will begin to freeze and attach the skin. This is known as Cryo-adhesion
- Now your “Freeze Time” commences.
- Once freezing has finished allow the probe to sufficiently thaw before trying to separate the probe from the jelly – if this is done prematurely, the skin may tear! A slight gentle twisting motion of the unit may expedite the release of the probe.

1.2 Advantages to using Contact Probes

- Underlying structures such as Tendons, Nerves or Blood Vessels – In order to prevent any possible freezing to these structures once the Jelly has frozen and is attached to the skin the probe can now be pulled back slightly thus raising the skin away from the underlying structures.
- For deeper freezing of a lesion this can be achieved quicker if you apply a small amount of pressure once the Jelly has frozen and is attached to the skin.

2.0 Decontamination

The following procedures have been generated from information obtained from the MHRA MAC Manual Part1, 2 & 3 (3rd edition May 2010).

Classification of infection risk associated with the decontamination of medical devices.

| Risk | Application of Item | Recommendation |
|---------------------|--|---|
| High | <ul style="list-style-type: none">In close contact with a break in the skin or mucous membraneIntroduced into sterile body areas. | Sterilization |
| Intermediate | <ul style="list-style-type: none">In contact with mucous membraneContaminated with particularly virulent or readily transmissible organismsPrior to use on immunocompromised patients. | Sterilization or disinfection required |
| Low | <ul style="list-style-type: none">In contact with healthy skinNot in contact with patient | Cleaning |

2.1 LOW Risk

For Contact Probes used in treatments of **LOW** risk **Cleaning (manual non-immersion)** is recommended.

2.1.1 Equipment required

Alcohol Wipe – Specification: Biocidal for use on Hard Surfaces. Isopropyl Alcohol 70% by Vol.

Protective Clothing Safety Note – Always refer to the Health & Safety Data Sheet associated to the Wipes for appropriate protective clothing before using.

Drying Cloth - A clean, disposable, absorbent, non-shedding cloth or mechanical drying facility.

*A First Aid kit and Eyewash bottle - **in case of splashing with detergent.***

2.1.2 Procedure for a Contact Probes

- Safety Precaution: Ensure the Contact Probe has been disconnected from the Cry-Ac[®], Cry-Ac-3[®], Cryogun[®] or Mini-Cryogun[®] before commencing cleaning.**
- Wearing appropriate protective clothing, ensure that all outer surfaces are thoroughly wiped.
- Periodically change the Wipe and repeat the above steps until all surfaces have been cleaned.
- Ensure all surfaces are carefully hand-dried using a dry cloth or industrial hot-air dryer.
- Safely dispose of cleaning materials.

2.2 INTERMEDIATE or HIGH Risk

For Contact Probes used in treatments of **INTERMEDIATE** or **HIGH** risk procedures, **Sterilization** is required.

2.2.1. Procedure for Sterilization of a Contact Probe

2.2.2 Cleaning

- Remove Silicone Vent Tube from the Contact Probe.
- Follow the procedure detailed in section 1.2

2.2.3 Sterilizing

Recommended methods of Sterilization, Temperature and times.

Always refer to the manufacturers Instructions for Use provided with the Sterilizing equipment to be used.

The times and temperatures in the tables below are recommended combinations of time and temperature given in HTM 2010, Part 3 (Hospital Technical Memorandum series of documents)

Steam Sterilization

| | | | | |
|--|-----|-----|-----|-----|
| <i>Sterilization temperature (°C)</i> | 115 | 121 | 126 | 134 |
| <i>Max allowable temperature (°C)</i> | 118 | 124 | 129 | 137 |
| <i>Minimum holding time (minutes)</i> | 30 | 15 | 10 | 3 |

Dry heat

| | | | | |
|--|-----|-----|-----|-----|
| <i>Sterilization temperature (°C)</i> | 160 | 170 | 180 | 134 |
| <i>Max allowable temperature (°C)</i> | 170 | 180 | 190 | 137 |
| <i>Minimum holding time (minutes)</i> | 120 | 60 | 30 | 3 |

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-CRYO (USA) or 0800 838 274 (UK) or email us at brymill@brymill.com.

⁽¹⁾ Dawber BP, Colver G, Jackson A. Cutaneous Cryosurgery – Principles and Clinical Practice 3rd Edition.

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