

Brymill

CRYOGENIC SYSTEMS

CRY-AC[®], CRY-AC-3[®], CRY-BABY[®]

INSTRUCTIONS FOR USE



www.brymill.com

May 2019

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

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Instruction for Use in the following languages

English
German
French
Italian
Dutch
Swedish
Danish
Portuguese
Spanish
Japanese

Can be found and downloaded from the web site at

<http://www.brymill.com>

INSTRUCTIONS FOR USE

1. General

Please read these Instructions in full before proceeding to use your new Cryosurgical Unit.

It is the responsibility of the physician/practitioner to familiarize themselves, with available literature, on cryosurgery treatments using Liquid Nitrogen before proceeding with any treatment of a patient.

Suggested literature

Cryosurgery for Common Skin Conditions

This is an article by Mark D. Andrews, M.D., available as a download from www.aafp.org/afp

Cutaneous Cryosurgery, Principles and Clinical Practice, Fourth Edition, 2015. By Richard P. Usatine, Daniel L. Stulberg and Graham B. Clover ISBN-13:978-1-4822-1373-4 (Hardback)

Training Videos

Learn how to use Brymill Cryogenic System's industry-leading cryosurgical products in these instructional videos at the below website.

<http://www.brymill.com/training-documentation/videos>

2. Cautions

- Read all operating instructions before attempting to fill or use this product.
- For use with liquid nitrogen only. When handling Liquid Nitrogen ensure you are familiar with the information contained in the Material Safety Data Sheet for Liquid Nitrogen and that you are wearing the appropriate recommended Personal Protective Equipment.
- Follow all instructions for de-pressurizing and filling the bottle.
- Do not overfill the bottle. Overfilling may lead to spillage of liquid nitrogen.
- When using the Cry-Ac[®], Cry-Ac-3[®], Cry-Baby[®] ensure the unit is kept as upright as possible to prevent purging of Liquid Nitrogen from the Relief Valve.

3. Intended Use

A Hand-Held Cryosurgery device used for the controlled dispensing of Liquid Nitrogen to freeze skin lesions via Open Spray or Contact Probe techniques.

The Cry-Ac[®], Cry-Ac-3[®], or Cry-Baby[®], are intended for use with Brymill manufactured Sprays, Probes and Accessories only.

4. Filling Instructions

Caution – When handling Liquid Nitrogen ensure you are familiar with the information contained in the Material Safety Data Sheet for Liquid Nitrogen and that you are wearing the appropriate recommended Personal Protective Equipment.

The enclosed Cryosurgical Unit is easily filled warm or refilled cold after prolonged use.

To fill the bottle, unscrew the cap from the bottle.

Liquid Nitrogen may be carefully poured into the bottle (slowly when warm) or by any standard pressure withdrawal device from a Liquid Nitrogen Storage Dewar.

It is recommended that for a 3 - 6-hour duration of intermittent use that the Cryosurgical Unit be 70% filled. Fill enough fluid to allow for completion of the cryosurgical procedure.

Before replacing the top, ensure that the rubber gasket is still in place inside the cap. If it is missing the Cryosurgical Unit may not pressurize correctly and the top may become stuck. In this event the Cryosurgical Unit must be returned to an Authorized Repair Center for proper removal.

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After filling a warm Cryosurgical Unit, allow 30 to 60 seconds for the initial boiling of the Liquid Nitrogen to subside before attempting to replace the top. If a large number of cryosurgery procedures are scheduled, the reservoir of Liquid Nitrogen may be topped off after the first boiling, and the unit has cooled off.

Caution - To refill a Cryosurgical Unit after it has been in use you must ensure that the unit is depressurized before removing the top.

To Depressurize the Cryosurgical Unit, unscrew the top a quarter to half turn only. The pressurized gas inside will begin to vent from the hole situated in front of the Valve Body. Once the hissing has stopped the top can be unscrewed and removed.

5. Liquid Nitrogen (LN2)

Liquid Nitrogen is an extremely cold substance, i.e. **-196°C**, and should be treated with extreme caution at all times. For full details regarding Liquid Nitrogen you should contact your supplier of Liquid Nitrogen and obtain a copy of the Material Safety Data Sheet (MSDS).

The physician should always maintain a clean supply of Liquid Nitrogen. To help ensure the Liquid Nitrogen remains free of particulate matter, such as ice crystals, carbon dioxide slush, lint, etc., the storage Dewar used should be completely emptied at least 4 times a year just prior to having it refilled. This is accomplished by vigorously agitating the residual amount of Liquid Nitrogen in the Dewar and discarding it in a safe, outdoor area.

6. Suggested Temperature Settings and Freeze Times

The table below provides suggested freeze times to reach a depth of freeze of 1 – 2 mm and a temperature of -40°C when used at a distance of 2.54 cm (1 inch) from the skin.

	Depth of Freeze	Recommended Freeze Time
Aperture A (0.04 in)	1 mm	3 – 4 seconds
	2 mm	4 – 6 seconds
Aperture D (0.0164 in)	1 mm	11 – 14 seconds
	2 mm	19 – 25 seconds
3 cm Flat Probe	1 mm	32 – 35 seconds
	2 mm	45 – 50 seconds
Sharp Mini Probe	1 mm	8 – 11 seconds
	2 mm	35 – 40 seconds

Suggested freeze times, depth and temperatures may vary dependent upon the type of skin lesion as well as size of probes and apertures as determined by the Physician. Suggestions are applicable to all Brymill Cryogenic System Cry-Ac® devices and accessories.

7. Maintenance

When the Cryosurgical Unit is warm and dry, the top center valve stem should be lubricated with a **DROP** of silicone lubricant or WD-40. Lubrication should be carried out every 3 to 6 months.

CAUTION:

If an excessive amount of lubricant is applied the trigger mechanism could freeze open.

8. Operation Instructions

Caution: When using the Cry-Ac[®], Cry-Ac-3[®], Cry-Baby[®] 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, a 20G X 1.0in Straight Spray, 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.

Once the bottle is filled with liquid nitrogen, attach the appropriate Spray Tip or Probe to the permanently affixed Knurled Nut by turning the spray tip or probe until the threads are fully engaged with finger tight firmness. Depress the finger trigger to dispense and control the flow of liquid nitrogen.

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 cleaned and stored in a CLOSED position (with the top on).

9. Cleaning and Sterilization

It is recommended that the Cry-Ac[®], Cry-Ac-3[®] and Cry-Baby[®] and associated sprays and probes are cleaned at the end of the Clinic Day.

When used with open sprays, the Cry-Ac[®], Cry-Ac-3[®] or Cry-Baby[®] and the associated accessories do not come into direct contact with the patient; therefore, the risk of infection is low and the unit and accessories may be cleaned. If the products are intended to be used in the sterile field, they may be autoclaved per the recommendations below.

Contact Probes are directly in contact with the patient, please refer to the Instructions for Use supplied with each Contact Probe or go to the following link for specific instructions on cleaning, decontamination, and sterilization:

<http://www.brymill.com/docs/default-source/PDFs/contact-probes-instruction-for-use.pdf>

9.1.1 Equipment required

Alcohol Wipe –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 hot-air dryer

A First Aid kit and eyewash bottle - In case of splashing with Alcohol Wipe.

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9.1.2 Procedure for a Cry-Ac®, Cry-Ac-3® or Cry-Baby®

- **Safety Precaution: Ensure the Cry-Ac®, Cry-Ac-3®, or Cry-Baby® is empty of Liquid Nitrogen before commencing cleaning. Refer to Section 4 to depressurize the Unit and refer to the MSDS for the disposal of any remaining Liquid Nitrogen.**
- Wear appropriate protective clothing and ensure that all outer surfaces are thoroughly wiped.
- Periodically change the alcohol wipe 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.

9.1.3 Recommended methods of Sterilization, Temperature and times.

If the product is intended to be used in the sterile field, sterilize the Cry-Ac®, Cry-Ac-3®, or Cry-Baby® using the recommended validated parameters below:

- i) Use the following recommended validated sterilization parameters: of sterilization.
 - Moist heat sterilization with Gravity cycle is the recommended method of sterilization.
 - 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 1.0×10^{-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

10. Warranty & Repairs

All units carry a warranty against manufacturing defects for a period of 3 years from the date of purchase. 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 warranty will become invalid. Unauthorized repairing will also absolve Brymill Cryogenic Systems of any claims for injury caused by an unauthorized repaired unit. A list of Brymill Approved Repair Centers is detailed on the web site.

11. Troubleshooting

11.1 Problem

If the Cryosurgical Unit does not spray or sprays only intermittently

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Solution

Spray Tip may be clogged. Remove tip. If the Cryosurgical Unit sprays without a tip, clean the opening of the tip with a fine needle or bang the tip gently on a table or counter to dislodge any foreign matter. Then check the Liquid Nitrogen supply for contaminants that can clog the tips and unit. (see Section 5, Liquid Nitrogen, paragraph 2 for information on how to keep Liquid Nitrogen supply clean).

The Unit has been over filled and there is insufficient air space inside the bottle to create an adequate build up of pressure to enable that is required for the Liquid Nitrogen to spray.

Check that the Gasket is in place inside the cover and is not split or missing. Always ensure you have spare Gaskets available.

11.2 Problem

Trigger Handle sticks open

Solution

Valve Stem sticking. Depressurize the unit immediately by unscrewing the top a quarter to one half turn. Lubricate valve stem as detailed in Section 5, Maintenance.

11.3 Problem

Unit appears to be "Leaking" or "Hissing" from the Relief Valve.
This may or may not be a problem and depends on the following conditions.

Solution

During normal operating conditions, if the Unit is left standing for a period of time the constant evaporation of the Liquid Nitrogen inside the bottle will result in the temporary opening of the Relief Valve venting the excess pressure. This "hissing" is also heard when the Unit is picked up. **THIS IS NOT A PROBLEM.** The Relief Valve is just operating as designed.

If the Exterior of Bottle is frosting over there will be excessive Relief Valve activity (hissing). **THIS IS A PROBLEM.** The vacuum inside the bottle has deteriorated due to age or the bottle has been damaged. Replacement of Bottle is necessary. Return the complete Cryosurgical Unit to an Authorized Repair Center.

If you experience any problems with your Cryosurgical Unit contact an Authorized Repair Center immediately.



**World Leader in Design and Manufacture of
Cryosurgical Equipment since 1966**

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