Brymill
CRYOGENIC SYSTEMS

CRY-AC®, CRY-AC-3®, CRY-BABY®

INSTRUCTIONS FOR USE

www.brymill.com

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

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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 which includes eye protection and cryo gloves.
- Follow all instructions for de-pressurizing and filling the bottle.
- Do not fill the bottle more than ¾ full. Overfilling may lead to spillage of liquid nitrogen when attaching the top.
- Liquid Nitrogen expands inside the bottle to provide operating pressure. Before separating the top and bottle, to refill the bottle or discard residual fluid, ensure that the instrument is fully depressurized. See section filling instructions.
- 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

The Cry-Ac® Cryosurgical Devices and Accessories are intended for use as cryosurgical tools in the field of dermatology. The Cry-Ac® Cryosurgical Devices and Accessories are indicated for:

- Ablation or freezing of skin cancers and other cutaneous disorders
- Destruction of skin tags, warts or lesions, angiomas, sebaceous hyperplasia, basal cell carcinoma, basal cell tumors of the eyelid or canthus area, ulcerated basal cell tumors, dermatofibromas, small hemangiomas, mucocele cysts, multiple warts, plantar warts, actinic and seborrheic keratosis, cavernous hemangiomas, perianal condylomata, and palliation of tumors of the skin

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.

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 for Apertures

The tables below provide 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

The apertures should not be used if there are visible cracks or chips on the surface of the device.

7. Instructions for Use of Probes

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

7.1 Warnings and Cautions:

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

c. 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.

7.2 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 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.

	Depth of Freeze	Recommended Freeze Time
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.

The probes should not be used if the Teflon material of the probes show wear.

8. Maintenance

When the Cryosurgical Unit is warm and dry, the top center valve stem should be lubricated with a **DROP** of Silicone Lubricate such as Loctite LB 8801. Remove any excess lubricant with a clean cloth. 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.

9. 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 emptied and dry. To ensure that all liquids are removed from the bottle, the components should air-dry separately, with the bottle and cap inverted. Any foreign materials detected inside the bottle may be removed by wiping or rinsing with 70% IPA alcohol. Do not attempt to use the instrument until the bottle is completely dry. Bottle should be stored in a CLOSED position (with the top on).

10. CLEANING/DISINFECTION INSTRUCTIONS

After each patient use follow the cleaning/disinfecting instructions provided below for the Cry-Ac®, Cry-Ac-3® and Cry-Baby®.

1.Prepare an enzymatic, neutral pH cleaner solution according to the Manufacturer's instructions.

2. Immerse a clean, lint-free wipe into cleaning solution and thoroughly wring. Thoroughly wipe bottle and top assembly surfaces in a circular motion. Discard the wipe.

3. Using a soft, nylon brush, scrub difficult-to-access areas such as crevices or textured surfaces.

4. Immerse a fresh, clean, lint-free wipe under warm flowing, utility water and thoroughly wring excess water. Thoroughly wipe the front panel surface and crevices for at least 30 seconds. Discard the wipe.

5. Rinse a fresh, clean, lint-free wipe under warm flowing, utility water and thoroughly wring excess water. Wipe for at least 30 seconds. Discard the wipe.

6. Inspect the device for visible soil or debris. If visible soil remains, repeat cleaning steps 2-5 until device is visually clean.

7. Using disinfection wipe thoroughly wipe bottle and top assembly surfaces and discard the wipe.Allow the wiped and wetted device to stand for a minimum of the disinfectant product manufacturers labeled contact time. Re-wet the wipes as necessary to ensure that all surfaces remain wet the entire time.

8. Use a 70% IPA wipe, or a low-lint wipe, saturated with 70% IPA, to thoroughly wipe the device.

9. Allow the device to air dry. Once dry, visually inspect the device for any residual soil.

10. Repeat cleaning/disinfection instructions if visible soil is present.

11. Place the cleaned/disinfected device in an appropriate dry storage area 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 and sterilization:

http://www.brymill.com/docs/default-source/PDFs/contact-probes-instruction-for-use.pdf?sfvrsn=2

10.1.1 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.

10.1.2 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.

The Cry-Ac devices should no longer be used when the exterior of bottle is frosted over. This indicates the vacuum inside the bottle has deteriorated due to age or the bottle has been damaged by the end user.

11. Recommended methods of Sterilization, Temperature and times.

If the product is intended to be used in the sterile field the device must be sterilized. 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 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. Use a FDA cleared sterilization tray and/or wrap for this purpose
- 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

⚠ Damage can occur due to improper reprocessing procedures

12. Warrantee & Repairs

All units carry a warrantee 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.

We do not service devices that are older than ten years since the parts are no longer available in inventory.

If repairs are performed by any other party the warrantee 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.

If a repair is needed carefully sanitize and package unit in a protective carton.

13. Troubleshooting

13.1 Problem

If the Cryosurgical Unit does not spray or sprays only intermittently

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.

13.2 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 8 Maintenance.

13.3 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 Value 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 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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