Brymill
CRYOGENIC SYSTEMS

# Cry-Ac®, Cry-Ac-3®
# Cryogun® & Mini Cryogun®

## INSTRUCTIONS FOR USE


**www.brymill.com**

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## 1. General

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

It is recommended that the practitioner familiarize themselves with available literature on cryosurgery 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,**
3rd Edition by Arthur Jackson, Graham Colver and Rodney Dawber
Published in 2006 by Taylor & Francis – **ISBN** - 9781841845524

## 2. Intended Use

A Hand-Held Cryosurgery devise 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®, Cryogun® or Mini-Cryogun® Units are intended for use with Brymill manufactured Sprays, Probes and Accessories only. Brymill Cryogenic Systems cannot be held responsible if injury to the User or Patient occurs as a result of attaching Non-Brymill accessories

This Cryosurgical Unit should only be used by Licensed Physicians or Veterinarians.

## 3. 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.

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

The volume of Liquid Nitrogen needed for adequate functioning is from 33% to 70% full.

It is recommended that for a 3 - 6 hour duration of intermittent use that the Cryosurgical Unit be 70% filled.

However, the physician will find that if the unit is filled approximately 40%, it will be lighter in weight and the Top will remain slightly warmer for further comfort in continued handling.

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 Centre 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.**

## 4. 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.

## 5. 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.

## 6. Operation Instructions

**Caution: When using the Cry-Ac®, Cry-Ac-3®, Cryogun® or Mini-Cryogun® 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 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.

Spray Tips and Probes must be secured to the permanently affixed Knurled Nut with finger tight firmness.

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 stored in a CLOSED position (with the top on) whether or not there is a residual amount of Liquid Nitrogen left in it. This is extremely important in order to eliminate the potential build up of condensation within the unit and tubing.

## 7. Decontamination

It is recommended that the Cry-Ac®, Cry-Ac-3®, Cryogun® or Mini-Cryogun® are cleaned between episodes of patient care.

Since the Cry-Ac®, Cry-Ac-3®, Cryogun® or Mini-Cryogun® when operating in the “spray” mode do not come into direct contact with the patient then the infection risk is classified as “Low” and therefore the unit only requires periodic disinfection using Alcohol wipes.

When the Cry-Ac®, Cry-Ac-3®, Cryogun® or Mini-Cryogun® are used in conjunction with a Contact Probe the same “Low” infection risk applies since there is no breach of the patients dermis.

However, thorough cleaning and then disinfection of the Contact Probe using an Alcohol wipe prior to use is recommended between patient episodes.

### *7.1. Cleaning - Non-immersion method*

#### 7.1.1 Equipment required

A warm water/detergent solution at the correct dilution,

- A clean, disposable, absorbent, non-shedding cloth for application of the detergent solution.
- A clean, disposable, absorbent, non-shedding cloth or mechanical drying facility.
- An appropriate chemical neutralizer, first aid kit and eyewash bottle, in case of splashing with detergent.

### 7.1.2 Procedure for a Cry-Ac® or Cry-Ac-3®, Cryogun® or Mini-Cryogun®

- Wearing appropriate protective clothing, immerse the cleaning cloth in the detergent solution and wring thoroughly.
- Ensure that all outer surfaces are thoroughly wiped.
- Periodically rinsing the cloth in clean water 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.

## 7.2 Recommended Disinfectant: - Alcohol wipes.

**Safety Note** – Always refer to the Health & Safety Data Sheet for appropriate protective clothing before using any Disinfectants.

### 7.2.1 Procedure for a Cry-Ac®, Cry-Ac-3®, Cryogun® or Mini-Cryogun®

- Wearing appropriate protective clothing ensure that all outer surfaces are thoroughly wiped using an Alcohol wipe.
- Ensure all surfaces are carefully hand-dried using a dry cloth or industrial hot-air dryer.
- Safely dispose of alcohol wipes.

### 7.2.2 Procedure for a Contact Probe

- Wearing appropriate protective clothing ensure that all outer surfaces are thoroughly wiped using an Alcohol wipe.
- Ensure all surfaces are carefully hand-dried using a dry cloth or industrial hot-air dryer.
- Safely dispose of alcohol wipes.

## 7.3. Procedure for Sterilization of a Contact Probe

In the event of a Contact Probe breaches the patient's dermis it is recommended that the Contact Probe be sterilized.

### 7.3.1 Cleaning

- Follow the procedure detailed in section 7.2.

### 7.3.2 Sterilizing

- Remove the Silicone Vent Tube from the Contact Probe.
- Place the Contact Probe into a Vacuum Steam Sterilizer and process at 134$^{O}$C (270 degree Fahrenheit) for a time period of 3 minutes.

## 8. 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.

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.

## 9. Troubleshooting

### 9.1 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 4, 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.

### 9.2 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.

### 9.3 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 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.

### 9.4 Problem
Trigger does not operate.

### Solution
The position of the Trigger should be on the left or right hand side of the delivery tube and not at the back of the Unit.

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