

CryoNize™

A PRECISE FREEZE



- *New generation of cryosurgical devices developed for practitioners by practitioners.*

INSTRUCTIONS FOR USE

For Medical Professional Use Only

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CONTENTS

- 1 AEROSOL CANISTER:** Filled with cryogenic gas mixture in a pressurized canister that is not harmful to ozone.
- 2 CRYONIZE ZONE APPLICATOR:** Five different sizes are used depending on the desired area of treatment.

Size	Starter Kit Applicators	Replacement Kit Applicators
3mm	2	1
5mm	2	1
7mm	2	1
9mm	2	1
12mm	2	1

3 CRYONIZE FOAM TIP SWABS:

Small	10 Applicators
Medium	5 Applicators
Large	5 Applicators

4 EXTENSION TUBE (5 SPARES): Plastic tube inserted in the actuator to direct the flow of cryogen into the Zone Applicator. One Extension Tube comes inserted in the actuator and 5 spare tubes are included.

5 INSTRUCTIONS FOR USE: Practitioners should read in its entirety before use.

6 PRACTICE PAD

WARNING

Contents are flammable and under pressure. Do not puncture or incinerate canister. Do not expose to temperatures above 120° F, store in direct sunlight, near heat, or near open flame. Avoid spraying in the direction of a flame or any incandescent material. If the CryoNize unit appears damaged at any time, it should not be used.

NOTE

CryoNize is a cryosurgical device that should only be used by a trained medical professional. It is not lawful to sell CryoNize to patients. Unintended use can result in damage to skin and possibly underlying tissues. Use only as directed.

INTRODUCTION

CryoNize is a portable cryosurgical device that was designed to combine safety and efficacy. The metered valve allows precise control of the amount of cryogen dispensed, which helps to prevent under- and over-treating a skin lesion. The CryoNize Zone Applicator enables a well-demarcated area to be treated. CryoNize is easy to use and the practitioner has the ability to operate using only one hand.

MECHANISM OF ACTION

The basis of cryosurgery is tissue injury via ice crystal formation. Crystallization causes irreversible rupture of cellular membranes. In this case, the cells of a skin lesion are destroyed. This occurs when these cells are brought to a temperature level well below freezing. The cryogen used in CryoNize produces a temperature of -55°C , which is effective for cryosurgery.

ABSOLUTE & RELATIVE CONTRAINDICATIONS

This procedure is contraindicated in patients with history of cryoglobulinemia.

Patients with diabetes, peripheral vascular disease, pyoderma gangrenosum and inflammatory bowel disease need to be treated with caution.

No pigmented lesion should be treated excluding seborrheic keratoses.

Avoid treating an area where active infection is present.

PRECAUTIONS

If the diagnosis of the area of treatment is uncertain (i.e. skin cancer), the practitioner should not proceed with cryosurgery.

Use extreme caution when treating near the eyes or the ear canal. Protection with eye shields and ear plugs is advised.

When treating digits, practitioners should consider treating only one side at a time to avoid risk of necrosis due to freezing of the terminal arteries.

Blistering of treatment area may occur.

Excessive freezing can result in possible scar formation and/or nerve damage.

Hypopigmentation and post inflammatory hyperpigmentation are risks of the procedure. Hypopigmentation of dark skin is most common. This should be taken into account, especially when treating the face. Pigmentation changes are usually temporary, but can be permanent.

Bleeding and infection are possible.

PREPARATION

Practitioner should practice freezing with both the CryoNize Zone Applicators and CryoNize Foam Tip Swabs, prior to treating patients. The practice pad can be used for this purpose.

Patient should be fully informed of the potential risks of the procedure and informed consent should be signed.

To increase efficacy in treating warts more than 2 to 3 mm in thickness, a curette or pumice stone should be used to debride the top layer of keratin. Excess keratin can interfere with the efficacy of cryotherapy.

Treatments should be performed in a well ventilated area.

Patient should expect to have a stinging sensation during the treatment.

DURATION OF FREEZE

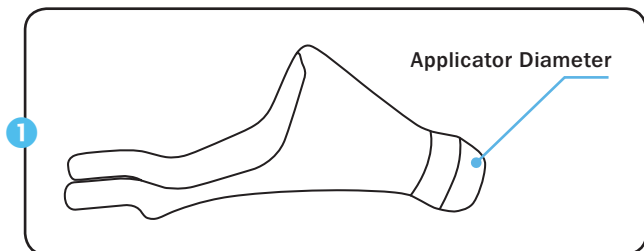
Type of Lesion	Approximate Freezing Time
Verruca Plantaris	40 sec
Verruca Vulgaris	40 sec
Condyloma Acuminata	40 sec
Verruca Plana	20 sec
Seborrheic Keratoses	40 sec
Actinic Keratoses (non-facial)	40 sec
Actinic Keratoses (facial)	15 sec
Molluscum Contagiosum	20 sec
Lentigo (non-facial)	40 sec
Lentigo (facial)	15 sec
Achrochordon	40 sec

These freeze times can be adjusted by the practitioner based on the size and shape of the skin lesion, along with skin thickness.

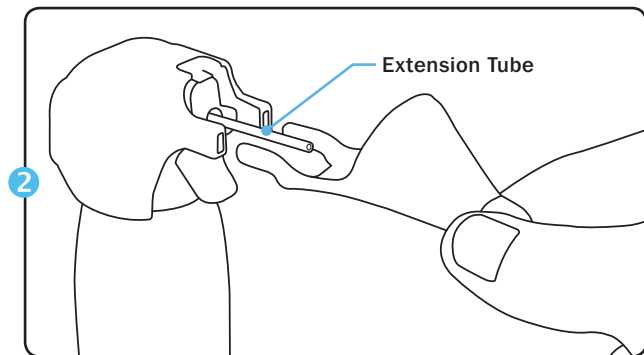
Treatment Method

USING CRYONIZE™ ZONE APPLICATOR

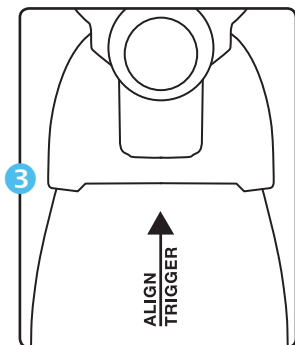
1. Choose appropriate Zone Applicator size to treat desired area: 3, 5, 7, 9, or 12mm diameter.



2. Insert Zone Applicator into canister actuator.



USING CRYONIZE™ ZONE APPLICATOR (CONT.)

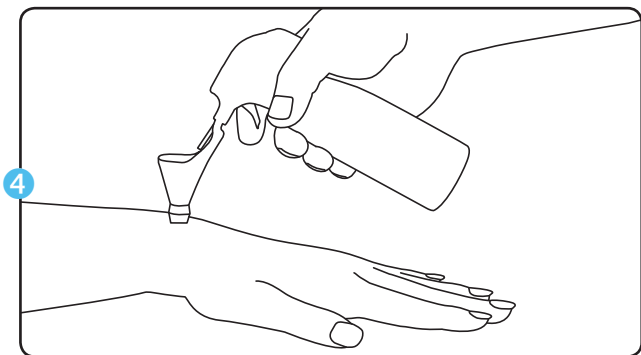


3. Rotate trigger to align with arrow on canister.

4. Position treatment area **horizontally**.

5. Hold applicator tip firmly against skin to **create a tight seal**.

6. Pull trigger several times in rapid succession to create a pool of cryogen approximately 3mm deep.
Do not squeeze and hold trigger.



Applicator Size	Approximate Number of Pulls
3mm	2
5mm	3
7mm	4
9mm	5
12mm	6

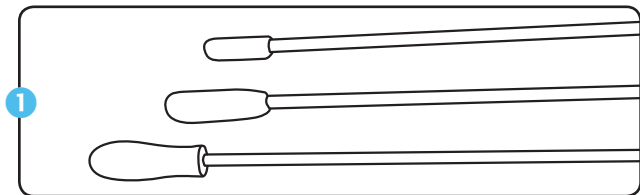
7. Observe bubbling of cryogen (evaporation) for 15-40 seconds (See page 8, Duration of Freeze). Keep tip **firmly** against skin to prevent leakage.
8. After evaporation is complete, remove applicator.
9. An ice ball will have formed.
10. Allow to thaw for approximately 60 seconds.
11. For lesions \geq 5mm or plantar warts, we usually recommend 2 to 3 freeze/thaw cycles based on practitioner discretion.

** Zone Applicators are reusable, but must be cleaned with sterilizing solution OR discarded after treatment.*

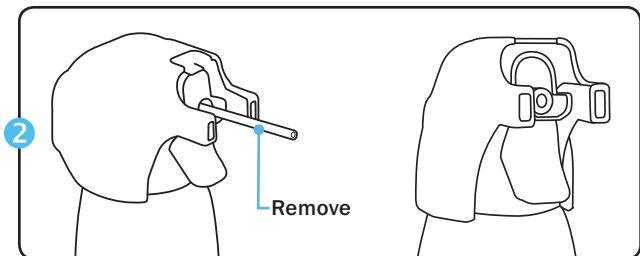
** Keep Extension Tube in place between treatments.*

USING CRYONIZE™ FOAM TIP SWAB

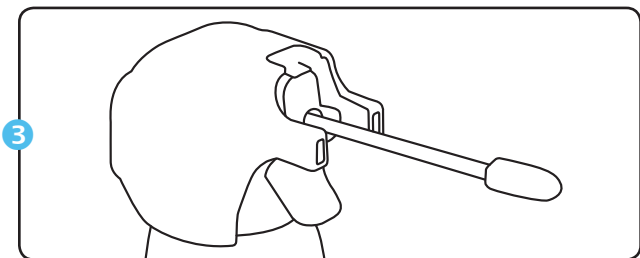
1. Choose appropriate Foam Tip Swab size to treat area.



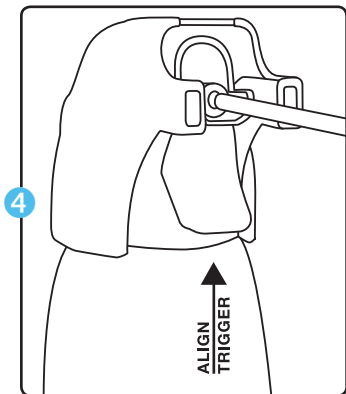
2. Remove Extension Tube from the Actuator.



3. Insert Foam Tip Swab into the Actuator.



4. Rotate trigger to align with arrow on canister.



5. Pull trigger multiple times to **saturate** the Foam Tip Swab. **Do not squeeze and hold trigger.**
6. Press saturated Foam Tip Swab to treatment area for 15-40 seconds (See page 6, Duration of Freeze).

7. Remove Foam Tip Swab from treatment area. An ice ball will have formed.
8. Allow to thaw for approximately 60 seconds.
9. For lesions ≥ 5 mm or plantar warts, we usually recommend 2 to 3 freeze/thaw cycles based on practitioner discretion.
10. Discard Foam Tip Swab after use.

POST-TREATMENT

After treatment, erythema will appear immediately after the ice ball completely thaws. Within a few days, a blister or scab may form. If blistering occurs, it will contain either a clear or bloody fluid. Keep area clean and dry. During showering, area should be covered. If blister ruptures, the patient should cover with a clean bandage.

One to four treatments can be done in two week intervals.

TECHNICAL ASSISTANCE

Please call 855-636-2796 (CRYO).



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