

Histofreezer®

Portable Cryosurgical System

OZONE-FRIENDLY



Directions For Use

For medical professional use only



Histofreezer®

Portable Cryosurgical System

The Histofreezer Portable Cryosurgical System is a registered trademark of OraSure Technologies, Inc.

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U.S. Patents #5738682 and #6092527 and various international patents.

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Made in the USA

Visit our Product website at:
www.histofreezer.com

The Histofreezer® Portable Cryosurgical System Kit consists of:

1. **Aerosol canister.** Filled with a cryogenic gas mixture that is flammable but does not damage the ozone layer.
2. **Applicators.** The package includes: 2mm Small applicators and/or 5mm Medium applicators.
3. **Directions for use.** The operating principle behind the Histofreezer Portable Cryosurgical System unit and its use for the removal of warts and other benign skin lesions is contained herein.

Important

The Histofreezer Portable Cryosurgical System should only be supplied to and used by medically trained healthcare professionals. Improper use can lead to unwanted damage to the skin and underlying tissues. It is prohibited to sell or give the Histofreezer Portable Cryosurgical System kit to patients. Use the aerosol canister only in combination with the special Histofreezer Portable Cryosurgical System applicators.

Storage and transport

The canister is pressurized and its contents are flammable. Protect it from direct sun light and do not expose it to temperatures in excess of 50°C. Even after use, do not pierce or burn. Do not spray in the direction of a flame or any incandescent material.

Operating Principles

The Histofreezer Portable Cryosurgical System achieves its effect on epidermal lesions by freezing resulting in a separation between the epidermis and the basal membrane. All cryogenic methods are based on this principle. A small quantity of the cryogen is sprayed into the Histofreezer Portable Cryosurgical System applicator, which serves as a reservoir for the coolant. The coolant evaporates immediately, and the applicator reaches an effective temperature of approximately -55°C. Following treatment, the frozen epidermis peels away in about two to three days and new epidermis grows in its place. Blistering of treated area may occur. One to four treatments with intervals of two weeks may be required. Please read all directions prior to use of the Histofreezer Portable Cryosurgical System.

Contra-indications

Absolute contra-indications

Cryotherapy is contraindicated in patients with cryoglobulinaemia.

Precautions

- Do not use if uncertain of diagnosis (possibility of skin cancers).
- Depigmentation of dark skin may occur. In light-colored skin, depigmentation is barely noticeable, but may color differently after exposure to sun. Hyperpigmentation is rare; however, caution should be exercised when using the product on facial areas.
- Freezing to excessive depth in the vicinity of terminal arteries (fingers and toes) could lead to necrosis. Necrosis has not been observed with use of the Histofreezer Portable Cryosurgical System. It is advisable to treat only one side of fingers and toes at a time to avoid freezing arteries or veins.

- Warts that include an infected area should first be treated medically to resolve the infection prior to cryosurgical treatment.

Methods of treatment

General

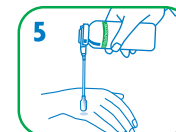
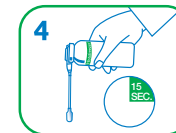
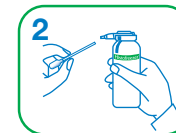
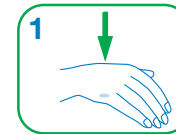
Cryotherapy can produce a painful, burning sensation on the skin. Acceptance of the treatment can be enhanced substantially by informing patients about the degree of pain that can be expected, the anticipated number of treatments, any preparatory treatment that might be required, possible undesirable effects and the follow-up treatment. It is also advisable to inform patients that the location and size of warts may affect resolution rates. References regarding resolution rates in relation to anatomical location are available from OraSure Technologies, Inc.

Preparatory Treatment

Keratin tends to act as a thermal insulator. With highly elevated warts (in excess of a few mm), it can be useful to remove the uppermost layer of keratin by lightly debriding with a curette, file or pumice stone. Preparatory treatment can enhance the efficacy of the Histofreezer Portable Cryosurgical System product and reduce the number of applications required.

Treatment Procedure

1. Position the patient to expose the skin surface to be treated.
2. Insert the applicator into the canister valve with a twisting motion, and then remove the protective cap from the upright canister.
3. Hold the canister and applicator away from skin and press the dispensing valve until the first droplet emerges from the foam tip, then release finger from valve. The droplets will not harm clothing or office furnishings.
4. **Keep finger off the valve and turn the canister, so the applicator is in a vertical position (90-degree angle). Then wait 15 seconds for the applicator to reach its effective temperature.**
5. Continue to hold canister in the same position and with light pressure, place the applicator on the treatment area for the recommended time listed on the canister label or Directions for Use. Treating at any other angle will reduce the effectiveness of the treatment.



Important: Do not press valve while the Histofreezer applicator is in contact with patient's skin.

- A saturated 2mm applicator will stay cold for 90 seconds and the 5mm applicator will stay cold for 120 seconds. This is long enough to perform 1 to 2 applications on the same patient.
 - After first use, lift applicator from contact with skin and hold it in a vertical position again (90-degree angle), then wait for 15 seconds for it to return to the treatment temperature. Now it is ready to apply to the next "like" wart or section of lesion.
6. A small ring of healthy tissue around the lesion should also be frozen during the process.
- Freezing begins within a few seconds and may appear as white discoloration of the skin. The patient experiences a tingling/itching feeling and sometimes a slight stinging sensation of the region.
 - The skin will lose its white color a few minutes after the applicator has been removed. Erythema then appears the same size as the frozen region. Tingling or itching felt during freezing usually stops quickly after treatment.
 - Blistering may occur (sometimes filled with blood) within a few days. The blistering may not be macroscopically visible on sites with a thick, horny layer.

Follow-up treatment

- Keep the treated area of skin clean.
- Swimming or showering are permitted.
- Do not pick or scratch the treated area.
- Do not lance any blisters that may form. If blisters open, protect with adhesive bandage.

Undesirable effects

- A stinging or painful sensation during and after freezing, which will rapidly fade away after the thawing phase.
- Changes in the intensity of pigmentation may occur. This will generally take the form of hypopigmentation; however, post-inflammatory hyperpigmentation due to melanin or haemosiderin can also occur.

Remarks

- **DO NOT REFREEZE AN APPLICATOR**
- Dispensing additional cryogen causes more water vapor to condense onto the applicator, thereby making it so damp as to impair its function as a reservoir. Visible ice crystals then form. If this should occur, replace the applicator with a new one.
- If tissue does not appear to be freezing, saturate applicator. Hold canister so tip is vertically downward and wait 15 seconds. This will allow applicator to reach the optimal freezing temperature.
- Improper use can lead to excessively deep freezing, producing damage to the dermis and consequent scar formation and nerve damage.
- To avoid cross contamination, do not treat two patients with the same disposable applicator.

See reverse side for
Recommended Freezing Times
and Recommended Procedure for
Plantar Wart Treatment

Histofreezer®

Portable Cryosurgical System



Recommended Procedure for Plantar Wart Treatment

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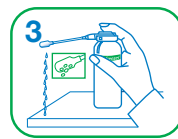


Treatment Procedure

1. Have the patient lie face down on an exam table, exposing the plantar surface upward.
See Figure 1.
 - Draw a circle around the outermost edge of the plantar wart(s) to be treated and measure. Recording the size of the lesion will help you determine the response of the wart site during subsequent visits.
See Helpful Hint #1
2. Debride the wart to pinpoint bleeding. We suggest using a hemostatic solution to stop the bleeding. Do not use silver nitrate to stop the bleeding, as it will cause irritation.
See Figure 2.



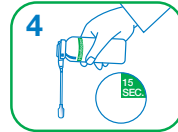
3. Insert the applicator into the canister valve with a twisting motion, and then remove the protective cap from the upright canister.



Hold the canister and applicator away from skin and press the dispensing valve until the first droplet emerges from the foam tip, then release finger from valve.

The droplets will not harm clothing or office furnishings.
See Figure 3.

4. **Keep finger off the valve and turn the canister, so the applicator is in a vertical position (90-degree angle). Then wait 15 seconds for the applicator to reach its effective temperature.**
See Figure 4.



5. Continue to hold canister in the same position and with light pressure, place the applicator on the treatment area for the recommended time listed on the canister label or Directions for Use. Treating at any other angle than a 90-degree angle will reduce the effectiveness of the treatment.
See Figures 5a & 5b.



Important: Do not press valve while the Histofreezer applicator is in contact with patient's skin.

- A saturated 2mm applicator will stay cold for 90 seconds and the 5mm applicator will stay cold for 120 seconds. This is long enough to perform 1 to 2 applications on the same patient.
- After first use, lift applicator from contact with skin and hold it in a vertical position again (90-degree angle), then wait for 15 seconds for it to return to the treatment temperature. Now it is ready to apply to the next "like" wart or section of lesion.

NOTE:

The applicator supplied with the Histofreezer® Portable Cryosurgical System kit freezes 2mm or 5mm across. Lesions larger than the diameter of the applicator will require treatment in sections.

See Helpful Hint #2

7. For treatment on a weight-bearing area, we suggest applying an aperture pad or disbursement dressing for the patient's comfort. It is not advisable to occlude the treated area with any keratolytic agent or vesicant for 24 hours. The wart site may shrink or rise up however, a vesicular bullous reaction should not occur.

Recommended Freezing Times

Type of Lesion	Approximate Freezing Time	Number of Treatments
Acrochordon (Skin Tags)	40 seconds	1 to 4, at an interval of 2 weeks.
Actinic Keratosis (Facial)	15 seconds	
Actinic Keratosis (Non-Facial)	40 seconds	
Condyloma Acuminata (Genital Warts)	40 seconds	
Lentigo (Facial)	15 seconds	
Lentigo (Non-Facial)	40 seconds	
Molluscum Contagiosum	20 seconds	
Seborrheic Keratosis	40 seconds	
Verruca Plana (Flat Warts)	20 seconds	
Verruca Plantaris (Plantar Warts)	40 seconds	
Verruca Vulgaris (Common Warts)	40 seconds	

Dependent on the nature and extent of the lesion, and the thickness of the skin, the treatment time can be adapted appropriately. Contact with skin for more than 40 seconds may lead to deep freezing with damage to the dermis, and possibly scarring and/or nerve damage. It is advisable to treat only one side of fingers and toes at a time to avoid freezing arteries or veins.

8. See **Helpful Hint #2** for recommendations on adjunct therapy with salicylic acid.

See reverse side for main Directions for Use

9. Schedule the patient for a return visit in two weeks. This gives the treated area time to slough. Most plantar warts will resolve within four treatments, at two-week intervals. At each subsequent visit, perform the entire procedure again.

Check with your medical supplier for available Histofreezer product configurations.

Helpful Hints:

1. Always oversize the treatment. If the lesion is 5mm in size, freeze 6mm to break the viral/normal skin barrier. You must treat the entire wart, not just the center.
2. Resolution may occur in one to four treatments on warts of 5mm or less without any adjunct therapy. For lesions over 5mm in diameter, we suggest that the patient apply a 17% salicylic acid preparation twice daily, beginning 24 hours after treatment with Histofreezer Portable Cryosurgical System, continuing until the next visit. Before treating the lesion with salicylic acid, protect the skin area around it by applying petroleum jelly with a cotton tip.

For additional information, call toll-free 1-800-869-3538 or visit www.histofreezer.com