

Histofreezer®

Portable Cryosurgical System

Directions for Use

For medical professional use only

ENG – ENGLISH

The Histofreezer® Portable Cryosurgical System Kit consists of:

1. **Aerosol canister.** Filled with liquified gas, consisting of a mixture of dimethyl ether, propane and isobutane. This gas mixture does not damage the ozone layer.
2. **Applicators.** The package includes: 2mm Small applicators and/or 5mm Medium applicators.
3. **Directions for use.** This contains full details concerning the principle and operation of Histofreezer® Portable Cryosurgical System, and its use in the treatment of warts and benign lesions.

Important

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

Storage and transport

Pressurised container: May burst if heated. Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Do not pierce or burn, even after use. Do not spray on an open flame or other ignition source. Protect from sunlight. Do not expose to temperatures exceeding 50°C/122°F. Does not damage the ozone layer.

Principle of action

Evaporation of the liquified gas mixture draws heat from the surroundings. The applicator, which serves as a reservoir for the cryogen, reaches a working temperature of -55°C.

Its action is based on the fact that different types of skin cells vary in their sensitivity to being frozen. Accordingly, epidermal keratinocytes are many times more sensitive to being frozen than the network of collagen fibres and fibroblasts in the underlying dermis. Melanocytes are also highly sensitive to being frozen. Necrosis of the keratinocytes can result in the development of a blister.

Full recovery takes about 10 to 14 days, with new tissue growing inwards from the surrounding epidermis and the more deeply situated adnexa. If the dermis is undamaged by the treatment then healing will take place without scar formation. All forms of cryotherapy are based on this principle.

Contra-indications

Absolute contra-indications

Cryotherapy is contra-indicated in patients with cryoglobulinaemia.

Precautions

- Uncertainty concerning the diagnosis of the disorder (possibility of skin cancers).
- Depigmentation, as an undesirable effect, can be cosmetically somewhat unattractive in more highly pigmented skin types. In light-coloured skin, depigmentation is barely noticeable, but it does tend to colour differently after exposure to the sun.
- Freezing (to excessive depth) in the region of peripheral arteries in fingers and toes can theoretically produce necrosis distal to the frozen lesions. However, this has never been reported in conjunction with the use of Histofreezer® Portable Cryosurgical System.

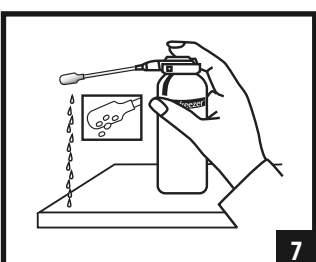
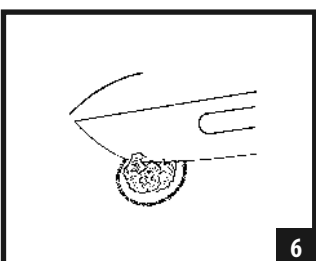
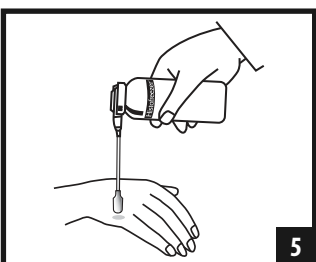
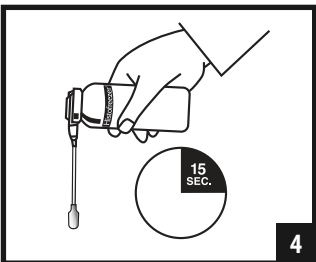
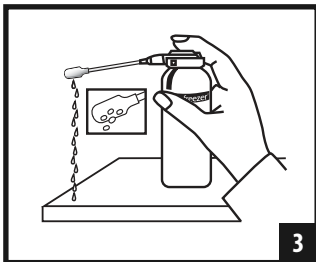
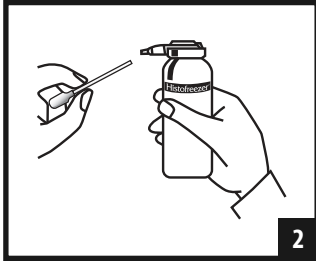
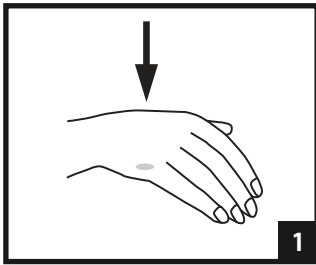
Methods of treatment

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.

Preparatory treatment

Keratin tends to act as a thermal insulator. With highly elevated warts (in excess of a few mm) or warts located at pressure points in the palm of the hand or on the sole of the foot, it can be extremely useful to remove the uppermost layer of keratin with a curette, file or pumice stone, possibly after applying a keratolytic agent. Preparatory treatment can enhance the efficacy of Histofreezer® Portable Cryosurgical System and reduce the number of applications required. **See Helpful Hint #1.**



Treatment Schedule for Common Warts and Benign Lesions

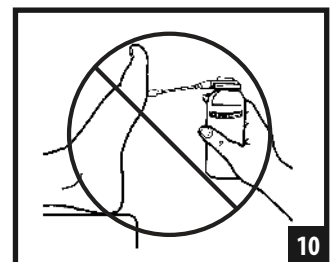
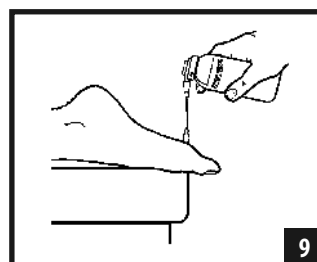
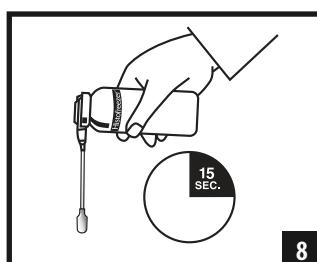
1. Have patients position themselves such that the surface to be treated is exposed and facing upwards.
2. Attach the applicator to the canister.
3. Remove the protective cap from the push button and spray gas into the applicator until droplets emerge from it. Do not spray while in contact with patient's skin. **Keep the aerosol canister upright.**
4. **Hold the applicator vertically downwards and wait 15 seconds for it to reach its effective working temperature.**
5. Next, place the applicator on the diseased tissue to be frozen and exert a slight pressure.

Treatment Schedule for Plantar Warts

6. 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 #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 6.
Have the patient lie face down on an exam table, exposing the plantar surface upward.
7. Hold the HistoFreezer® Portable Cryosurgical System canister in an upright or vertical position; press down on the valve button until the cryogen drips from the foam tip. Then release finger from the valve. See Figure 7.
8. Turn the canister horizontal so that the foam tip is pointing downward and wait 15 seconds before applying to the wart. See Figure 8.
9. Apply the frozen applicator bud to the wart for 40 seconds in a VERTICALLY DOWNWARD POSITION. TREATING AT ANY OTHER ANGLE THAN 90° WILL REDUCE THE EFFECTIVENESS OF THE TREATMENT. See Figures 9 & 10.

| Type of Lesion/Wart | Recommended Freezing Times | Number of Treatments |
|---|----------------------------|---|
| Condyloma Acuminata (Genital Warts) | 40 sec | ↑ 1 to 4, at an interval of 2 weeks ↓ |
| Molluscum Contagiosum | 20 sec | |
| Seborrheic Keratosis | 40 sec | |
| Acrochordon (Skin Tags) | 40 sec | |
| Verruca Plantaris | 40 sec | |
| Verruca Vulgaris | 40 sec | |
| Verruca Plana | 20 sec | |
| Actinic Keratosis (facial) | 15 sec | |
| Actinic Keratosis (non-facial) | 40 sec | |
| Lentigo (facial) | 15 sec | |
| Lentigo (non-facial) | 40 sec | |

- Saturated 2mm applicator will stay cold for 90 seconds and the 5mm applicator will stay cold for 120 seconds during which multiple areas may be treated on the same patient.
- **Freezing starts within a few seconds, as shown by the white discolouration of the skin. From this point on, the patient may experience stinging, burning or, occasionally, painful sensations.**
- During the period of freezing, a narrow strip of healthy tissue should be frozen along with the diseased tissue. If this disappears slowly during the period of freezing, it indicates that the freezing process is not proceeding as well as it should. In this event, re-fill the applicator and repeat the treatment.
- Once the applicator has been removed, the white discolouration of the skin will fade away after a few minutes. An erythema will then develop, equal in size to the frozen area.
- 1 to 2 freeze-thaw cycles are usually administered in the course of a single treatment.
- Lesions over 5mm in diameter will require treatment in sections. **See Helpful Hint #2.**

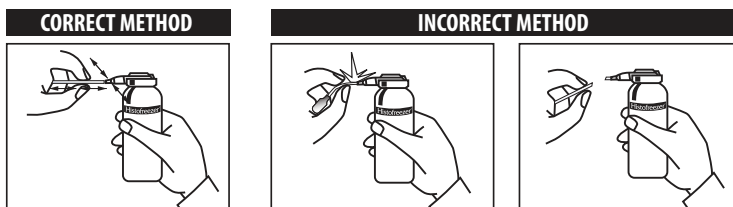


- For treatment on a weight-bearing area, we suggest applying an aperture pad or disbursement dressing for the patient's comfort. It is not advisable to occlude the treated area with any keratolytic agent or vesicant for 24 hours. The wart site may shrink or rise up; however, a vesicular bullous reaction should not occur.
- **See Helpful Hint #3** for recommendations on adjunct therapy with salicylic acid.
- Imprudent use can lead to excessively deep freezing, producing damage to the dermis and consequent scar formation and nerve damage.
- A blister, sometimes filled with blood, may develop after a few days. In areas with a thick layer of callus, such blisters will not necessarily be visible to the unaided eye. Do not lance the blister; instead, protect it by covering it with a tape.
- **Never treat two different patients with the same applicator (possibility of cross-infection).**
- Check the effect of the treatment by arranging to see the patient again after an appropriate interval of time. Only conclude the treatment when it can be established that all traces of the disorder have disappeared.

Once the Histofreezer® application has been administered to the lesion, remove the used custom applicator from the dispensing valve using the following steps:

1. Place your forefinger and thumb securely on either side of the hollow tube end close to the dispensing valve.
2. Gently rock the applicator back and forth while pulling away from the canister until the hollow tube releases itself from the valve.

DO NOT forcibly bend the hollow tube back and forth or up and down from the canister valve as this may inadvertently snap the applicator leaving a small portion remaining in the dispensing valve.



Helpful Hints:

1. Cleanse the lesion with an antiseptic, and then cover it with a water soaked dressing for 5-10 minutes to hydrate the tissue.
2. You must treat the entire wart, not just the center. If the lesion is 5mm in size, freeze 6mm to break the viral/normal skin barrier. Always oversize the treatment area and surround the lesion with petroleum jelly using a cotton applicator to protect the skin you do not want to treat.
3. 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. Do not treat more than four times at two-week intervals. If wart is not resolved in the recommended time, surgical excision may be advisable.

Follow-up treatment

- Keep the treated area of skin clean.
- Swimming or showering are permitted.
- Do not pick or scratch the treated area.
- Use a tape to protect any blisters that may form.
- Do not lance any blisters that may form.

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

- Dispensing additional cryogen causes more water vapour 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.
- Histofreezer® Portable Cryosurgical System should only be used in combination with the special applicators.
- The gas used by this equipment is extremely flammable! Do not use in combination with, or near, diathermy.
- Histofreezer® Portable Cryosurgical System has a shelf-life of up to 3 years under normal storage conditions (see section on storage and transport).















Patient information

It is important that patients be precisely and fully informed concerning treatment with Histofreezer® Portable Cryosurgical System. Histofreezer® Portable Cryosurgical System is a safe, effective and controlled form of cryotherapy. The skin is treated by freezing. The applicator, which is held in contact with the skin, reaches a temperature of -55°C.

The uppermost layer of skin, together with the diseased tissue, will disappear. It will be replaced by a new, healthy layer of skin in 10 to 14 days. Freezing commences once the applicator is placed in contact with the skin. The affected skin will turn white. From this point on you may experience a stinging or burning sensation. This sensation will rapidly fade away after the thawing phase.

Temporary, visible changes in the intensity of pigmentation may occur following treatment. Cryotherapy sometimes gives rise to blisters. Under no circumstances should you lance the blister, instead protect it with tape. Keep the treated area clean and do not pick or scratch it. Swimming or showering are permitted. Some disorders may require a series of treatments.

EXPLANATION OF SYMBOLS

| | |
|---|---|
|  Authorized Representative in the European Community |  Caution – consult accompany documents |
|  Batch Code |  DANGER - Extremely flammable aerosol |
|  Manufacturer |  Use By |
|  Date of Manufacture |  Contents |
|  Applicators |  Cryosurgical Gas Canister |
|  Dimethyl Ether |  Isobutane |
|  Propane |  For Medical Professional Use Only |

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