

Histofreezer[®]

Portable Cryosurgical System

Directions For Use

**For medical professional
use only**



OraSure Technologies, Inc.

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:
60–2mm Small applicators
or
50–5mm Medium applicators
or
30–2mm Small applicators and
30–5mm 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.

Important

Histofreezer® Portable Cryosurgical System should only be supplied to (para) medically trained healthcare professionals. It should only be used by and be available to (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

The canister is pressurized. Protect it from direct sunlight 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 a glowing object.

COMBUSTIBLE. 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.

Relative contra-indications

- 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.

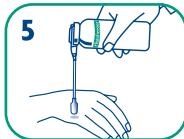
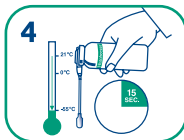
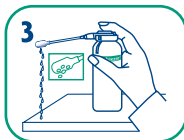
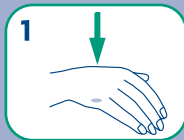
Preparatory treatment

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.

- Remove finger from the dispensing valve; do not spray again during treatment.
- 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

Treatment schedule

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. **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. **When doing so, it is important that the applicator is pointing directly downwards!**



Recommended freezing times

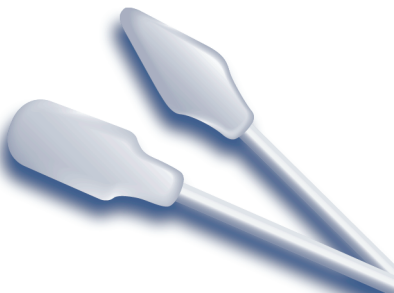
Type of Lesion	Approximate Freezing Time	Number of Treatments
Genital Lesions	40 sec	1 to 4, at an interval of 2 weeks
Molluscum Contagiosum	20 sec	
Seborrheic Keratoses	40 sec	
Skin Tags	40 sec	
Verruca Plantaris	40 sec	
Verruca Vulgaris	40 sec	
Verruca Plana	20 sec	
Actinic Keratoses (Facial)	15 sec	
Actinic Keratoses (Non-Facial)	40 sec	
Lentigo (Facial)	15 sec	
Lentigo (Non-Facial)	40 sec	

Depending on the nature and extent of the lesion, and the thickness of the skin, the treatment time can be adapted appropriately.

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.
- 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 yourself 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.



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

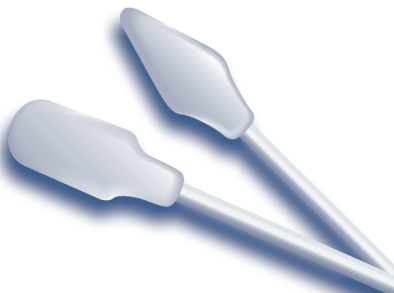
- A stinging or painful sensation during and after freezing, which will rapidly fade away after the thawing phase.
- Changes in the intensity of pigmentation may occur. This will generally take the form of hypopigmentation; however, post-inflammatory hyperpigmentation due to melanin or haemosiderin can 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.
- Imprudent use can lead to excessively deep freezing, producing damage to the dermis and consequent scar formation and nerve damage.
- The gas used by this equipment is slightly flammable! Do not use in combination with, or near, diathermy.
- Histofreezer® Portable Cryosurgical System has a shelf-life of 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 a 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.





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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