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 hemosiderin 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 Kit consists of:

1. Aerosol canister. Filled with liquefied 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
   - 50–5mm Medium applicators
   - 30–2mm Small applicators
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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 medically trained healthcare professionals. It should only be supplied to (para) medically trained healthcare professionals.

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 theooretically 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 or points of cross-infection), the disorder have disappeared.

Step 1: Check the effect of the treatment. Once the treatment has been removed, the patient may experience stinging, burning or, occasionally, painful sensations. 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.

Step 2: 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.

Step 3: Next, place the applicator to the surface of the lesion and wait 15 seconds for it to reach its working temperature. Ensure that the surface of the lesion is to be treated is exposed and facing upwards. Once the applicator has been removed, there may develop after a few days. In areas of cross-infection), the disorder have disappeared.

Step 4: Attach the applicator to the canister. Wait 15 seconds for the canister to be treated is exposed and facing upwards. Once the applicator has been removed, there may develop after a few days. In areas of cross-infection), the disorder have disappeared.

Step 5: Hold the applicator vertically downwards and wait 15 seconds for it to reach its working temperature. Place the applicator to the surface of the lesion and wait 15 seconds for it to reach its working temperature. Ensure that the surface of the lesion is to be treated is exposed and facing upwards. Once the applicator has been removed, there may develop after a few days. In areas of cross-infection), the disorder have disappeared.

Step 6: Next, place the applicator to the surface of the lesion and wait 15 seconds for it to reach its working temperature. Ensure that the surface of the lesion is to be treated is exposed and facing upwards. Once the applicator has been removed, there may develop after a few days. In areas of cross-infection), the disorder have disappeared.

Step 7: After 1 to 2 freeze-thaw cycles are usually administered in the course of a single treatment.

Step 8: 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.
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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. Improper 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 should only be supplied to (para) medically trained healthcare professionals. It should only be available to (para) medically trained healthcare professionals. It should never be used by anyone else.

Principle of action

Evaporation of the liquefied gas mixture draws heat from the surroundings. The applicator, which serves as a reservoir for the cryogen, reaches a working temperature of -55 ºC. 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 undermined by the treatment then healing will take place without scar formation. All forms of cryotherapy are based on this principle.

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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.
• When doing so, it is important that the applicator is pointed directly downwards!

Recommended freezing times

Type of Lesion Approximate Freezing Time Number of Treatments

Gentile Lesions .................................................. 40 sec 1 to 4
Mole/Benign Lending/Pompl .................................. 30 sec 10 sec
Sclerotic Keratosis .................................................. 40 sec 10 sec
Skin Tag .............................................................. 40 sec
Vermicul Plantaris .................................................. 40 sec
Vermicul Vulgaris .................................................. 40 sec
Vermicul Plana ..................................................... 30 sec
Arctic Keratosis (Palm) .......................................... 15 sec
Arctic Keratosis (Non-Palm) .................................. 40 sec
Leishman (Palm) .................................................... 15 sec
Leishman (Non-Palm) ............................................. 40 sec

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

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.

1. Directions for use.

2. Hold the atmospheric pressure to the frozen area.

3. Check the effect of the treatment.

4. Never treat two different patients with the same applicator (possibility of cross-infection).

5. Place the applicator on the diseased tissue to be frozen and exert slight pressure. When doing so, it is important that the applicator is pointing directly downwards!
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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.

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- Remove finger from the dispensing valve;
- Wait 15 seconds for it to reach its working temperature.
- Remove protective cap from the aerosol canister only in combination with the special Histofreezer® Portable Cryosurgical System applicators.
- Attach the applicator to the canister.
- Have patients hold the applicator vertically downwards and wait 15 seconds for it to reach its effective working temperature.
- 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!

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.
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Recommended freezing times

<table>
<thead>
<tr>
<th>Type of Lesion</th>
<th>Approximate Freezing Time</th>
<th>Number of Treatments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Genital Lesions</td>
<td>40 sec</td>
<td>2 or more</td>
</tr>
<tr>
<td>MalBalan Lesions</td>
<td>40 sec</td>
<td>2 to 4</td>
</tr>
<tr>
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</tr>
<tr>
<td>Actinic Keratoses (Face)</td>
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<td>1 to 4</td>
</tr>
<tr>
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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 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.
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- The gas used by this equipment is slightly flammable! Do not use in combination with, or near, diathermy.
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