



CRYO

PROFESSIONAL

PORTABLE CRYOSURGICAL SYSTEM

INSTRUCTIONS FOR USE





Read instruction for use carefully prior to using this product.

R_x ONLY

Only for use by medical professionals.



DANGER Extremely flammable.



TEMPERATURE Protect from sunlight. Do not expose to temperatures higher than 50° C / 122° F. Store the product in a dry area at maximum room temperature 25° C / 77° F.



CAUTION Do not use if packaging is damaged or opened.



Single use



Reference



Lot code



Expiration date



Medical Device



Manufacturer



Distributor

CONTENTS

2 x 2.7 FL OZ (80 ml) aerosol dispenser contains liquefied gas; Dimethyl ether (DME) with Propane/Butane/Isobutane.

1 x box applicators. The package includes a box of applicators. The product is supplied with a box of either 60 x 2 mm applicators, or 50 x 5 mm applicators, or 60 x mixed (30 x 2 mm and 30 x 5 mm).

WARNING! Do not use other types of applicators. Use of other types of applicators will affect the performance of the product and could lead to unwanted damage to the skin and underlying tissues.



WARNING! Applicators included are single-use disposable. They are for use on one (1) patient only & for treatment of one (1) type of lesion per patient.

1x instruction for use

DEVICE DESCRIPTION

The product is used in the treatment of various skin lesions. Different sizes of applicators supplied are to be used depending on the treatment of the lesion. Different types of skin lesions are treated with different freezing times (see table 1).

INDICATIONS FOR USE

The product is indicated for treatment of the following skin lesions:

- Genital warts
- Molluscum Contagiosum
- Acrochordon (Skin tags)
- Verruca (Plantaris, Vulgaris, Plana)
- Seborrheic Keratosis
- Actinic Keratosis (facial and non-facial)
- Lentigo (facial and non-facial)

CONTRAINDICATIONS

- When there is, or has been a confirmed diagnosis of cancer and treatment for cancer
- For diabetics
- For persons with circulatory problems
- Patients with cryoglobulinaemia
- Patients using immunosuppressant medicines

WARNINGS!

- Pressurized dispenser: do not damage or pierce the dispenser during or after use. Dispose of dispenser in line with local or national regulations
- Do not use the product if the outer packaging or the dispenser is damaged
- Do not use the product in the vicinity of smoke, fire or combustibles. Do not direct the foam-tip and / or dispenser in the direction of a flame or heat or incendiary sources. Dispenser can combust or explode near heat
- Do not use the vicinity of other medical equipment, diathermy equipment or liquid gases
- Do not saturate the applicator when the foam-tip is in contact with the patient's skin
- Avoid eye contact. When the cryogen does come into contact with the eyes, rinse thoroughly with water
Consult an ophthalmologist.
- Do not smoke

PRECAUTIONS

- Hypopigmentation and / or inflammatory hyperpigmentation can occur in highly pigmented and light pigmented skin
- Care should be taken if using this product on pregnant or breast feeding women
- Deep-freezing in regions of peripheral arteries such as in the extremities could result in necrosis distal to the frozen lesions
- When the dermis is not damaged by the cryotherapy, scar formation should be minimal
- As safety of use of the device in pediatric patients has not been established, it is recommended that the device should not be used on patients under the age of 4 years without consultation with a pediatrician

STORAGE OF PRODUCT

- Protect from sunlight
- Do not expose to temperatures higher than 50 ° C / 122 ° F
- Store the product in a dry area at maximum room temperature (25 ° C / 77 ° F)

WARNING! Store product away from diathermy equipment, medical gases and other types of incendiary sources. Exposure of the product to incendiary sources could cause product to catch fire or flame.

Dispose of empty dispensers in line with environmental requirements or protocols in place at the medical facility.

DIRECTIONS FOR USE

1. Determine the type of skin lesion that is to be treated. Review table 1 to determine the freezing-time, i.e., how long the foam-tip is held against the skin lesion.

Caution! The lesions can be treated 1 to 4 times with a 2-week interval between treatments.

Caution! Treat large skin lesions, i.e., > 5 mm, in sections.

Table 1 Recommended freeze times per skin lesion

Skin lesion type	Recommended freezing times
Ano-genital warts (Condyloma acuminatum)	40 seconds
Molluscum Contagiosum	20 seconds
Acrochordon (Skin tags)	40 seconds
Verruca plantaris	40 seconds
Verruca vulgaris	40 seconds
Verruca plana	20 seconds
Seborrheic keratosis	40 seconds
Actinic keratosis (facial)	15 seconds
Actinic keratosis (non-facial)	40 seconds
Lentigo (facial)	15 seconds
Lentigo (non-facial)	40 seconds

2. Use appropriate antiseptic practices to reduce potential of infection of treatment area.
3. For best removal of the skin lesion, determine if preparatory treatment is necessary.
For warts, the use of a keratolytic agent can be applied without effecting the performance of the product.
4. When wart is debrided prior to treatment, stop the bleeding before applying the product.
5. For effective removal of the skin lesion, determine which applicator (2 mm or 5 mm) should be used.
6. Insert the applicator into the nozzle opening located at the front of the activator cap/dispenser (canister).



Illustration for 6

- Remove the protective cap from the top of the activator cap.
- Press the activator button all the way down. Hold it down until the applicator (bud) is saturated.

Caution! Hold the aerosol upright at all times when saturating the applicator. Do not point aerosol in the direction of persons in the room.

- Release the finger from the activator button when droplets start to form on the applicator (bud).
NOTE: A 2 mm applicator will remain saturated and cold for 90 seconds; 5 mm applicator, for 120 seconds.

Caution! Never press the activator button of the aerosol when the applicator (bud) has been placed against the skin of the patient.

Caution! Do not saturate the applicator during use. This affects the overall performance of the product in freezing the lesion.

- Hold the dispenser (canister) with the applicator at a 90° angle so that the applicator (bud) is pointing vertically downwards towards the floor.
- Wait 15 seconds for the applicator (bud) to reach its effective temperature.
- Hold the dispenser (canister) firmly. Do not touch the applicator button with a finger.
- The best way to remove the skin lesion is to ensure the treated area is exposed. The skin lesion must be clearly visible and easily accessible. (see illustrations 13 a & c) on the right for recommended positions.
- Hold the applicator (bud) firmly against the skin lesion to be treated for the recommended times given in table 1.

Caution! Keep the applicator (bud) pointing vertically down (90° angle), facing the floor at all times. For optimum effectiveness, always treat the lesion at a 90° angle.



Illustration for 9



Illustration for 10-12

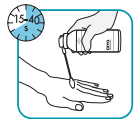


Illustration for 13(a)



Illustration for 13(b)



Illustration for 13(c)

POTENTIAL ADVERSE REACTIONS

Inform the patient accordingly about potential side effects including:

1. A pain or prickling sensation.
2. Blistering.
3. Hypopigmentation.
4. Inflammatory hyperpigmentation.
5. Skin atrophy.
6. Alteration in sensation particularly in the face.

COMPLAINTS AND CUSTOMER SERVICE SUPPORT

Contact Gebauer Company or Koninklijke Utermöhlen NV with any question or to report problems.

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