

Suggested freezing times

Although not exhaustive, the table below contains suggested freezing times as reported in the literature. These are wide ranges and provide only a guideline for consideration.

| Type of lesion | Literature freeze Time range in seconds |
|-------------------|--|
| Acne | 4 - 6 |
| Actinic Keratosis | 4 - 8 |
| Basiloma | 8 - 9 |
| Cavernous Angioma | 4 - 6 |
| Condyloma | 5 - 12 |
| Granuloma Anulare | 5 - 6 |
| Keloids | 4 - 6 |
| Lentigo | 2 - 5 |

Order information

| | | |
|------------|----------|--|
| REF | CA-S(B) | Cryoalfa® Super in blister with 1 gascartridge 16 gram |
| REF | CA-K-V16 | Cartridge 16 gram with valve* (N ₂ O) |
| REF | CA-K-V25 | Cartridge 25 gram with valve* (N ₂ O) |
| REF | CA-Z-SKA | Cap |
| REF | CA-Z-KS | Case for storage |

- * Cartridge 16 gram, N₂O, full weight ~60 gram, empty weight ~45 gram
- * Cartridge 25 gram, N₂O, full weight ~101 gram, empty weight ~74 gram

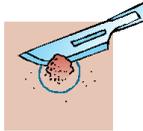
References for Liquid Freezing®

- Hundeiker M, "Liquid freezing®" in esthetical dermatology Dt.Dermat, 51:55-56, 2003
- Hundeiker M, Sebastian G, Bassukas ID, Cryotherapy guidelines for dermatology
- Bassukas ID, Hundeiker M, "Liquid freezing®" A new approach for the cryosurgical treatment of superficial skin lesions
- Hundeiker M, "Simplified cryotherapy" Daily practice 42:311-314, 2001.
- Hundeiker M, Bassukas ID, "Cryosurgery in Office Dermatology" An Update, 2005.

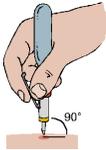
References for cryosurgery in general

- Dockery G, Treating A Child With Multiple, Mildly Pruritic Papules, Podiatry Today, 20:4, 2007.
- Strumia R, La Crioterapia in Dermatologia, Published by Business Enterprise SRL, 2006.
- Dawber R, Colver G, Jackson A, Cutaneous Cryosurgery - Principles and Clinical Practice, Martin Dunitz Publisher, 3:d Edition, 2005.
- Andrews M, CryoSurgery for Common Skin Conditions, American Family Physician, 69:10, 2365-2372, 2004.
- Rubinsky B, CryoSurgery, Annual Review Biomedical Engineering, 02:157-187, 2000.
- Gage A, What Temperature is Lethal for Cells? J Dermatol Surg Oncol, 5-6, 1979.

Simple treatment for success



1. Draw a circle round the lesion to be treated. Measure the size of the lesion to be able to see the treatment result by the next visit, document in a patient journal.



2. Debride the wart to pinpoint bleeding. If the wart is bleeding we recommend you to use homeostatic solution to stop the bleeding (this point only valid for foot warts).

3. Put the patient in such a way that you easily can treat the lesion. The lesion to be treated should point up against the sealing.

4. Place your device with a soft pressure against the lesion which is going to be treated and activate your device by pressing the lever on the side. The angle against the treatment area should be 65-90° to get the best result.



5. The freezing effect is approximately 3 mm deep and 8-10 mm diameter on 12 seconds. The freezing result will vary depending on thickness of the skin, type of lesion and freezing time.

6. Freezing starts immediately, which can be seen by a whitening of the skin. From this moment the patient could feel a shooting feeling or sometimes a slight pain if there are many nerve endings turned downwards in the treated area. Even a small part of healthy skin shall be treated during this process. Approximately 5 minutes after the treatment is completed a skin blush will replace the part which was coloured white by the freezing treatment.

7. If treatment has been done on the footpad we recommend a plaster on the area to relieve the treated area.

8. Reserve a time for next visit within 2 weeks. Sometimes 2 to 3 treatments are necessary before the wart / lesion is removed. By each treatment occasion the prescribed procedure should be taken.

Document Issue: CAS(B)ENG2014387A



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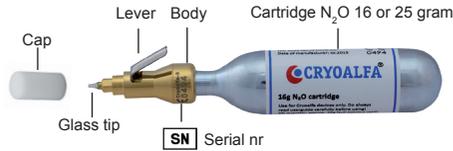
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LIQUID FREEZING®
The innovative way of cryosurgery



CRYOALFA® Super

User's guide



IMPORTANT!

The Cryoalfa® cryosurgical devices should only be used by medically trained personnel. Use by unskilled personnel can result in unwanted damage on dermin causing scar formations or nerve damages. In any case the country specific laws must be respected.

Do not use other than the original Cryoalfa® cartridges to operate the device.

How to work with your Cryoalfa®

- Installation of cartridge:** Unscrew the protection cap of the cartridge and remove the small stopper. Then screw (clockwise) the cartridge into the threads of the Cryoalfa® body, continue to turn until feeling a light stop position. DO NOT USE FORCE!
The cartridge has a built-in filter and valve and can be screwed or unscrewed without any gas loss. When the cartridge is empty replace it with a new one.
- Operation:** Remove the protecting cap from the glass tip. Bring the device into therapy position. The device has to point in the direction of the therapeutical area. By pressing the lever with the finger the liquid flow starts.
- Function Control:** For controlling the streaming quantity of the liquid, hold the glass tip directly onto a grey carton and press the lever in order to open the valve for one second. The liquid puddle which is forming must have a diameter of 5-6 mm.
- Application range:** All typical indications occurring in medical practice, like treatment of all types of warts, haemangioma, papilloma, keratosis, condyloma, lentigo and more.
- Treatment time:** Treatment time lasts only for a few seconds depending on type and size of a lesion and is set at the discretion of the user. See the time table.
- Cleaning:** The glass tip can be cleaned and disinfected with a disinfectant or alcohol. In touch with blood, mucous or any infected area it is mandatory to sterilize it. Screw off the gas cartridge from the body and sterilize the body and glass tip. Use steam sterilizer at 134°C / 273°F, according to EN norms 13060 and 285. All other sterilization methods are excluded.

- Storage:** After use put the device back in the original packing in such a way that the lever is not pressed by the cover; otherwise gas escapes and empties the gas cartridge unintentionally.



Protect the gas cartridge from heat and direct sun exposure; Never expose the gas cartridge for a temperature above +50°C / +122°F.

Store in room temperature 21°C / 70°F. Make sure that the tip is always protected by the cap. Keep the device out of the reach of children and unauthorized users.

- Disposal:** Disposal has to be done in a professional way and according to the country specific laws. Empty cartridge may be disposed of as scrap metal.
- Safety instructions and risk:** Only use the device as described in the user's guide and for the purpose specified therein. Do not try to modify the device. Any manipulations of the device will result in an exclusion of warranty and liability.



Observe the storage instruction since the gas cartridge is under pressure of 50 bar.



Never use a damaged unit. Any device that has been dropped should be checked by us before it is used again.

Do not apply pressure when connecting the components. Put on the feeder's thread perfectly straight when changing the cartridge.

- Warranty:** There is a 2 years warranty against technical defects. The warranty is strictly limited to the exchange of defective parts. Dropped devices or broken tips are not under warranty. Other claims for damages such as loss of working hours, incorrect treatment and their consequences, non executed after treatment and their consequences as well as the non-observance of the safety instructions are excluded from all warranty and liability.

Liquid Freezing®

Cryoalfa® Liquid Freezing® provides a high freezing speed, which is a condition to obtain successful treatment. Our cryosurgical devices are equipped with a specific liquid gas dosing applicator. The operator is able to control the release of sufficient liquid N₂O to treat lesion without wasting gas. With a temperature of -89°C / -128°F the liquid gas is evaporating on the lesion. This removes heat from the surrounding tissue and affects a freezing of the treated area. This low temperature is converted to therapeutic energy with minimal loss.

As a result of this process the tissue cells are destroyed permanently due to the cell membrane rupturing as a consequence of ice crystal formation within the cell.

Please note: The freezing method Liquid Freezing® with N₂O is as efficient as liquid nitrogen (N₂) in most cryodermatologic indications.

Medical considerations

Absolute contraindications

Cryosurgery is contraindicated in patients with cryoglobulinemia. Please consult literature for more information.

Relative contraindications

- Insecurity when making diagnosis of kind of lesions (biopsy by skin carcinoma).
- Depigmentation as a side effect on dark skin can be cosmetically disturbing. On light skin depigmentation can hardly be seen and the skin tends to recover after exposure to the sun.
- Freezing too deep, especially peripherally on fingers or toes can theoretically give tissue damage.
- It is recommended by multiple lesions that freezing is done only on one side of the finger or toe.
- Lesions which in principal could be cryosurgically treated but also are infected should initially be medically treated for infection.
- In case of freezing nerves, continued pains are possible. Nerves or vessels can usually be protected by lifting, folding or moving the lesional skin.
- Treatment of areas on the head can provoke short headaches.
- Please consult literature for more information.

Not getting expected result?

- No result - Treatment probably did not last long enough or the glass tip did not have contact with the skin. Snow and the ice crystals do not effect the result only the liquid placed directly on the skin. Cryosurgery can normally be repeated. A "second freezing" can be applied after about one minute.
- A blister, sometimes filled with blood, may develop after the treatment. Do not puncture the blister; instead cover it with plaster or bandage.

Follow-up treatment suggestions

- Showering and swimming are permitted.
- Keep the treated area clean.
- Patient should not pick or scratch the treated area.