CE 0494

CRYOALFA®

CRYOALFA ORIGINAL®
Made in Germany

Instruction manual
CRYOALFA®
SUPER & LUX

English

Disclaimer

Improper use, including more icing than recommended or excessive icing time, can result in physical injury to patients and equipment operators. Cryoalfa Europe GmbH, and its affiliates, officers, employees, agents, contractors and shareholders assume no responsibility or liability for death, physical or mental damage or injuries, including consequential, incidental, direct, indirect or special damage, punitive or other damage attributable to Cryoalfa products, their condition, specifications, possession or use, based on breach of contract, tort, strict liability, breach of warranty, failure to achieve a material purpose, breach of essential contractual obligations or other legal grounds. This applies even if such death, injury, loss or damage results from errors of judgement by Cryoalfa Europe GmbH or its affiliates, officers, employees, agents or contractors, and even if such parties were aware of the possibility that damage might occur. You waive any and all liability claims against Cryoalfa Europe GmbH and its affiliates, officers, employees, agents, contractors and shareholders for any damage, losses, costs, legal proceedings, fees, penalties and expenses (including legal representation expenses). This includes but is not limited to liability for consequential, incidental, direct, indirect, special and punitive damage, and liability at law or in equity arising out of any action, claim, suit, cause of action or legal proceeding relating to death, injury, loss or damage.

Contents

All products listed in this document are manufactured in the European Union by:

Cryoalfa Europe GmbH
Bernhard-Voss-Str. 25a
01445 Radebeul
Germany

Telephon: +49 351 795 1866
Fax: +49 351 795 1803
E-Mail: info@cryoalfa.de
Website: www.cryoalfa.de

1. Introduction and Purpose

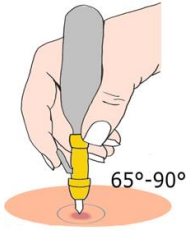
1.1 Purpose: The devices in the Cryoalfa range are reusable devices designed for the controlled elimination of pathologically altered tissue through the application of extreme cold caused by liquid N2O (nitrous oxide, supplied in 16g or 25g disposable cartridges). Pathological indications are benign skin lesions such as: granuloma, dermatofibroma, condyloma, genital lesions, molluscum contagiosum, seborrhoeic keratoses, actinic keratoses, warts on the hands, warts on the feet, lentigo, angiofibroma.

1.2 Indended Users: The treatment of skin lesions is primarily reserved for dermatology. However, many of the everyday lesions can also be treated by other specialists. Cryosurgery has long been used in general medicine, paediatrics, gynaecology, urology, surgery, etc. Plantar warts are also removed in podiatry and liver spots in cosmetology. Cryosurgery is used as well in dentistry and – as various studies show – in veterinary medicine. In general, the device may be used only by appropriately trained personnel and the country-specific regulations must always be observed.

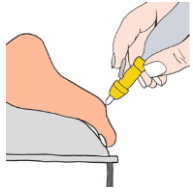
This device is used directly on the patient. For this reason, you must read this manual carefully and strictly follow the instructions and notes it contains! If in doubt, contact your dealer or the manufacturer in Germany!

10. Treatment example - wart

1. Mark the lesion to be treated with a circle. Measure the size of the lesion to assess the success of treatment at the next follow-up visit. Document this in the patient record.
2. Debride the wart until just before the point of bleeding. For bleeding warts, we recommend the use of a haemostatic solution to stop the bleeding (applies only to foot warts).
3. Position the patient to allow the best possible access to the lesion. The lesion to be treated should be turned directly upwards (towards the ceiling of the room).



4. Press the device lightly against the lesion to be treated. Activate the device by pressing the lever on the side. The angle between the device and the area to be treated should be 65-90°. Spraying from a greater distance has no effect.
5. The penetration depth into the skin tissue is about 1mm per 3 seconds of icing time. The duration of icing must be chosen depending on the lesion being treated.
6. The icing starts immediately. At this moment, the patient may experience a sensation of shock or mild pain if many nerve endings converge in the treated area. During the treatment, a small area of healthy skin is always iced as well. About 5 minutes after the treatment, redness appears on the area that has turned white due to the icing.

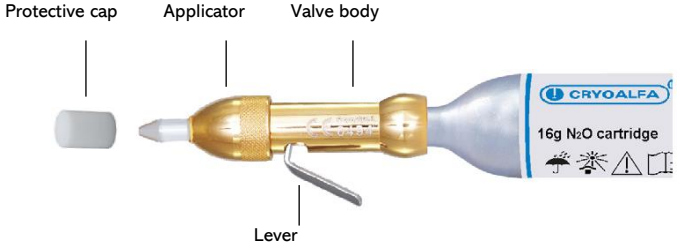


7. For treatments on the sole of the foot, we recommend applying a plaster after treatment to protect the treated area.
8. Schedule a check-up after 2 weeks at the latest. In some cases, 2 to 3 treatments are required to remove warts or other lesions. The steps described must be carried out for each individual treatment.

Literature.

1. Prof. Dr. med. Prof.h.c. Dr.h.c.CC. Zouboulis, Cryosurgery in dermatology, Der Hautarzt, issue 11/2015
2. Strumia, Renata, La Crioterapia in Dermatologia, Published by Business Enterprise SRL, 2006.
3. Hundeiker M, Bassukas ID, "Cryosurgery in Office Dermatology" An Update, 2005. Andrews, Mark, Cryosurgery for Common Skin Conditions, American Family Physician, 69:10, 2365-2372, 2004.
4. Rubinsky, Boris, Cryosurgery, Annual Review Biomedical Engineering, 02:157-187, 2000.
5. Dawber, Rodney, Colver, Graham, et al, Cutaneous Cryosurgery: Principles and Clinical Practice, Martin Dunitz Publisher, 2nd Edition, 1997.
6. Setrag A. Zacarian, Cryosurgery for Skin Cancer and Cutaneous Disorders 1985. Gage, Andrew, What Temperature is Lethal for Cells? J Dermatol Surg Oncol, 5-6, 1979

10. Instructions for Cryoalfa® LUX Applicators



10.1 Replacing the applicator:

Use only original Cryoalfa equipment and applicators! Unscrew the applicator from the Lux valve body and screw the new applicator clockwise into the thread of the device until you feel resistance.

The glass applicators are very sensitive and should be handled with care.
Proceed as described in chapter 6.

2. Legal Notice

Cryoalfa® is a registered trademark of the company Cryoswiss GmbH.
Liquid Freezing® is a registered trademark of company Cryoswiss GmbH.

CE 0494 Number of the notified body: 0494

Please refer to the disclaimer on the back of this manual.

3. Symbols Used

Manufacturer | Date of manufacture | Attention

Upper temperature limit | Keep dry

REF Part number | SN Serial number | LOT Batch number

Use-by date | Protect from sunlight

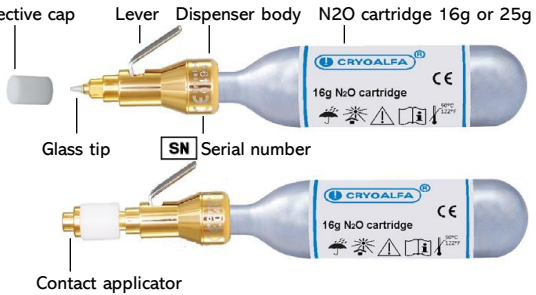
Follow the instructions for use

4. Products

These operating instructions apply to the following products and accessories:

Devices	REF Cryoalfa
Cryoalfa Super	CA-S
Cryoalfa Super Contakt Ø 3mm	CA-S-C3
Cryoalfa Super Contakt Ø 5mm	CA-S-C5
Cryoalfa Super Contakt Ø 7mm	CA-S-C7
Cryoalfa Lux	CA-L
Applicators for LUX	
Cryoalfa LUX Standard Applicator (12mm, Ø 1mm)	CA-M-DST
Dermatological applicator (22mm, Ø 1mm)	CA-M-D1
Dermatological applicator (22mm, Ø 2mm)	CA-M-D2
Dermatological applicator (22mm, Ø 3mm)	CA-M-D3
Dermatological applicator(22mm, Ø 4mm)	CA-M-D4
Contakt applicator Ø 3mm	CA-M-C3
Contakt applicator Ø 5mm	CA-M-C5
Contakt applicator Ø 7mm	CA-M-C7
Gas cardriges with valve	
16g N2O cardriges with valve	CA-K-V16
25g N2O cardriges with valve	CA-K-V25
Further accessories	
Protective cap	CA-L-SKa

5. Product Images



Cryoalfa® SUPER

Liquid Freezing®
Ref.: CA-S

Contact Freezing®
Ref.: CA-S-C

Cryoalfa® LUX

Liquid Freezing®
Ref.: CA-L

Contact Freezing®
Ref.: CA-L-C

Gas cartridge 16g / 25g with valve
N2O cartridge with valve for
Cryoalfa® SUPER und LUX devices

5.1 Applicators for Cryoalfa® LUX

Dermatological applikators
Glass tip Ø 1, 2, 3, 4 mm
Length 22 mm

Contact applicators
Contact surface Ø 3, 5, 7 mm

Undesirable/ unsatisfactory treatment results

A. No discernible treatment success: The treatment was not performed for long enough, the tip was not in contact with the lesion or the tip was too far from the skin. The treatment effect does not result from the formation of crystals, but from the liquid gas contacting the skin. Cryosurgical treatments can usually be repeated. A second icing procedure can be performed about one minute after the first.

B. Blood-filled blisters may form after treatment. Do not puncture such blisters, but cover them with plaster or bandage. In extreme cases, scarring or hyperpigmentation may occur.

9. Recommended treatment times

The medical literature recommends different icing durations for cryosurgical treatments.

Thickness, position and moisture content of the tissue to be treated have an influence on the treatment result. Medical professionals using Cryoalfa® must have experience with cryosurgical treatment methods.

The following table contains example recommendations for icing duration taken from the specialist literature. The figures allow for a great deal of leeway in decision-making and are intended only as a guide.

Indication	freezing time range (in seconds)	Literature
pedunculated warts	5-10	4,6
verruca vulgaris	10-20	2,4,6
verruca plantaris	10-20	6
verruca plana	3-15	2,6
molluscum contagiosum	3-10	6
lentigo	2-5	2,4,6
actinic keratosis	5	4,6
seborrheic keratosis	5-10	6
genital lesions	5-12	6

8.3 Relative contraindications

Special care should also be taken with:

- Autoimmune diseases such as collagenosis or lupus erythematosus
- Raynaud's syndrome (intermittent paling of the fingers or toes)
- Wound healing disorders, e.g., due to circulatory disorders, diabetes mellitus, old age
- Currently undergoing chemotherapy or radiotherapy
- Acute febrile infection

In these cases, the Cryoalfa devices may only be used after careful consideration of the risk-benefit ratio by a physician. Further information can be found in the relevant literature.

To avoid known risks, please note the following relative contraindications:

- Areas of the body with generally delayed wound healing such as the shins
- Hairy skin areas
- Treatment sites where the skin cannot be lifted off over superficial nerves, e.g., on the outer sides of the fingers
- In case of multiple lesions, it is recommended to ice only one side of the finger or toe
- (Highly) Pigmented skin

8.4 Risks and effects

Cryotherapy is one of thw low-risk treatment methods, but side effects can still occur during treatment. These include:

- Oedema, blistering
- Bleeding
- Local pain (also headache in the case of treatments in the head area)
- Cartilage damage during treatment of the nose an ears
- Infections, ulcerations
- Milia
- Flat or atrophic scars
- Hair and hair follicle loss (alopecia)
- Pigmentation disorders (hypo/hyper-pigmentation)
- Nerve damage, sensory disturbances

8.5 Recommendations for follow-up care – Patient information

Keep the treated area clean. Swimming and showers are allowed. Patients should avoid touching or scratching the treated area if possible. Any blisters that may have formed should be protected with a plaster/bandage and never picked open. Fresh treatment sites should not be exposed to the sun.

6. Working with your Cryoalfa®

6.1 Inserting the N O cartridge:
Only use original Cryoalfa® cartridges with the device! Unscrew the protective cap from the cartridge and remove the protective plug from the valve. Then screw the cartridge clockwise into the thread of the device until you feel a slight resistance. SCREW IN CAREFULLY AND DO NOT OVERTIGHTEN! The cartridge is equipped with a valve. It can be connected to and disconnected from the device without leaking gas. Empty cartridges must be replaced with new ones.

6.2 Function test: A function test must be carried out before each treatment. To check the amount of liquid gas flowing out, place the glass capillary directly on a piece of greyboard and open the valve for one second by pressing the lever. The resulting pool of liquid must have a diameter of at least 5-6mm. Never use defective devices!

6.3 „Liquid Freezing" treatment method: Remove the protective cap from the glass tip. Position the device in the area of the lesion. The angle between the device and the area to be treated should be 65-90°. N2O applied by pressing the lever on the dispenser.

6.4 "Contact Freezing" treatment method: Pressing the lever on the applicator starts the icing of the contact applicator. After about 15 seconds, the applicator reaches the working temperature of -50°C/ -58°F, so you can start the treatment. The iced contact applicator is pushed directly onto the lesion with pressure

6.5 Treatment duration: The duration of treatment depends on the depth of each treatment. You will find more information about this in the Treatment times chapter.

6.6 Cleaning: The device must be reprocessed as soon as possible after it has been used! The contact bodies may not be cleaned/disinfected for at least 10 minutes after use. Remove the gas capsule! Remove surface contamination with a disposable/paper towel.
Manual cleaning: Prepare the cleaning solution in accordance with the manufacturer's instructions (e.g., Bomix 1%). Immerse the applicator in the cleaning solution. Make sure that the entire surface of the glass applicator is wetted with cleaning solution. Immerse in cleaning solution for at least 5 minutes. Take out the device from the cleaning solution. Place the device in a tub of water (at least drinking water quality) for at least 1 minute. Check the device for cleanliness. If dirt is still visible, repeat the manual cleaning steps mentioned above.

Disinfection: Prepare the disinfectant solution in accordance with the manufacturer's instructions (e.g., Bomix plus 2%). Immerse the applicator in the disinfectant solution. Make sure that the entire surface of the glass applicator is wetted with disinfectant solution. Exposure time in the disinfectant solution in accordance with the manufacturer's instructions for the disinfectant (e.g., Bomix plus 2%, 5 minutes). Take out the device from the disinfectant solution. Place the device in a tub of demineralised water for at least 1 minute. Repeat the process once with fresh demineralised water to completely remove the residues of the disinfectant. Wipe with a lint-free disposable cloth, or dry with medical compressed air.

Disinfection in the steriliser: Device Steriliser according to DIN EN 285 or small steam steriliser according to DIN EN 13060, type B Procedure.

6.7 Storage: Store the device in its original packaging when not in use. Make sure that the lever cannot be operated unintentionally during storage. Operating the lever will cause gas to escape.

Protect the gas cartridge from heat and direct sunlight. The cartridge must never be exposed to temperatures above +50°C / +122°F.

6.8 Disposal: must be carried out in accordance with local legal requirements. Empty gas cartridges can be disposed of as scrap metal.

6.9 Safety instructions and risks: The device may be used only for the purposes described in this document. Do not make any changes to the device. Any modification of the device will void the warranty and liability claims. .

The cartridges are very highly pressurised. Strictly follow the safety instructions.

Never use a damaged device. Devices that have accidentally fallen to the ground sholuld be checked by the manufacturer before further use.

Do not apply pressure when assembling the individual components. When changing the cartridge, make sure that it is placed on the thread and screwed in perfectly straight.

6.10 Warrenty: The warranty is limited to the replacement of defective parts. Claims cannot be made against physical damage to the device caused by improper use or storage or non-compliance with the transport regulations. Furthermore, there are no warranty or liability claims in connection with lost work time, incorrect handling, treatment not carried out and the consequences thereof, or in connection with the non-observance of safety instructions.

7. Liquid Freezing®

Cryoalfa® Liquid Freezing® provides a fast freezing rate, which is a condition for successful treatment. The Cryoalfa® cryosurgical devices are equipped with a special liquid gas dispenser. The devices allow the controlled, lossless delivery of liquid N O. The liquid gas vaporises at a temperature of -89°C / -128°F on the treated skin lesion. For best results, a freeze-thaw-icing method is recommended. In this process, cells are destroyed by rupturing of the cell membrane due to the formation of ice crystals inside the cell.

Please note: According to clinical studies, the "Liquid Freezing®" method with N2O is as efficient as liquid nitrogen (N2) in most cryodermatological indications.

8. Medical Advice

8.1 General recommendation

A cryosurgical procedure may cause pain or a burning sensation on the skin. Acceptance of the treatment can be significantly improved if patients are informed about the possible occurrence of pain, the planned number of treatments, any preparatory treatments that may be required, as well as possible side effects, follow-up treatments and possible risks of recurrence.

8.2 Absolute contraindications

Cryosurgery/cryotherapy is contraindicated in persons with a known intolerance to the refrigerant N2O or a general intolerance to cold.
Absolute contraindications are:

- Cold urticaria
- Cryoproteinemia, cryofibrinogenemia, cryoglobulinemia, agammaglobulinemia
- Dyscrasia of unknown cause
- (Drug) Immunosuppression
- Multiple myeloma
- Pyoderma gangraenosum
- Arterial occlusive diseases

The following lesions must not be treated with Cryoalfa devices due to their possible depth extension

- Cancerous tissue, malignant changes/tumours
- Unexplained, conspicuous liver spots/moles