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# 1 Introduction and warnings



**With this unit you will operate directly on the patient. Therefore, it is mandatory to read the manual carefully and to follow the instructions in detail. If there are any doubts, please consult your retailer or contact the main distributor in Switzerland listed under point 13.**

**The devices may only be used by specialists who have been trained accordingly. Patients must be informed about possible risks before treatment**

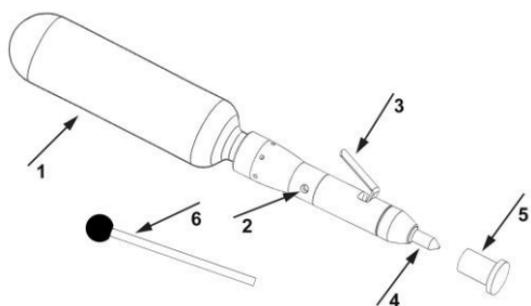
- If the cold performance is too high, there is a risk of irreversible skin damage, and if the cold performance is too low, the treatment will not be successful.
- Use the unit only as described in the instruction manual and only for the intended use.
- Do not modify the device.
- Never use a dropped or damaged unit. It must be checked by a retailer before reuse.
- Never use force when attaching the cartridges.
- Use CRYOSUCCESS devices only with the special gas cartridges manufactured by NMT.
- Keep the device out of reach of children.
- Always wear gloves when changing the cartridge.
- Protect the device and the cartridges from heat, flames and sunlight.
- Only the tips may be sterilized.
- Do not use the cartridges for other purposes.

## 2 CRYOSUCCESS device versions

	Part number
<b>CRYOSUCCESS C-SUC-01</b>	<b>C-SUC-01</b> consisting of
1 plastic box with recesses or alternatively aluminium box matt	C-BN-01 C-BN-02
1 cryo unit body part	C-BP-S
1 standard tip 1 mm (Ø)	C-STS-01
1 protecting cap for standard tip	C-PCS-01
1 tip for dermatology 4 mm (Ø)	C-DTS-04
1 protecting cap for 4 mm tip	C-PCS-01
2 cartridges nitrous oxide N <sub>2</sub> O (laughing gas), content 23,5g	C-CA-23
1 metal pin	C-PI-01
1 instruction manual	

<b>CRYOSUCCESS C-SUC-02</b>	<b>C-SUC-02</b>
Same as C-SUC-01 but without C-DTS-04 and only 1 x C-CA-23	

<b>CRYOSUCCESS C-SUC-03</b>	<b>C-SUC-03</b>
Same as C-SUC-01 but without C-DTS-04, instead with C-GTS-13 gynaecological tip, 13 cm long	



No.	Description
1	Cartridge
2	Hole for metal pin
3	Lever
4	Tip
5	Protective cap
6	Metal pin

### 3 Symbols and safety instructions

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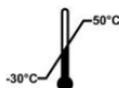


Caution



Serial number

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Temperature limit  
-30 °C / +50 °C



Fragile, handle  
with care

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Keep away from  
sunlight



Manufacturer

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Keep dry



Consult  
instructions for  
use

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### 4 Technical Data

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Refrigerating method: open system ("Liquidfreezing")  
Cold-performance -89 °C

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Cryo unit in metal (brass and stainless steel), gold plated, valve-lever for dosing, safety-filter in the cartridge holder, different PTFE and acrylonitrile-butadiene-caoutchouc seals.

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Tips in metal, gold plated, top in borosilicate glass

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Metal-cartridges with thread and safety valve, containing 23,5 g of nitrous oxide, cartridge content pressure 50 bar

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**Attention! Always use gloves while changing the cartridge**  
**Cartridges are thermosensitive. Never expose the cartridges to temperatures above 50 °C.**

## 5 Indications

The CRYOSUCCESS cryosurgery unit is a cryosurgery system intended for cryosurgical treatment of all kinds of lesions of the skin and mucous membranes in medicine (human and dental medicine) as well as in paramedicine (podiatry and cosmetics).

### **Indications**                      **recommended application time in seconds**

Acne	4-6
Keratosis actinica	5-7
Age pigments	1-2
Basiloma	8-9
Cavernous angioma	4-6
Granuloma anulare	5-6
Hemangiolympangioma	6-8
Juvenile warts	3-4
Keloids	4-6
Senile keratoma	7-8
Condyloma	8-12
Lentigo maligna	4-5
Lentigo senile	2-3
Nevus pigmentosus	8
Plantar warts	15-20
Solar keratosis	4-5
Seborrhoeic warts	6-8
Verruca vulgaris	8-10
Soft fibroma	4-5

**These times are only recommendations based on the experience of specialists around the world.**

**However, application times are always at the discretion of the user. The table shows only a part of the possible skin lesions.**

## 6 Side effects and contraindications

- In the case of very sensitive skin, there may be more pronounced bulge formation, the healing process may take longer and, in extreme cases, scarring or hyperpigmentation may occur. Healing usually occurs within one to three weeks.
- Cryotherapy for the treatment of basal cell carcinoma should only be used in low-risk, superficial tumors, especially in patients who are not candidates for surgery.
- Cryotherapy should also be avoided in cases of cold sensitivity (cold urticaria, cryoglobulinemia/fibrinogenemia), unstable diabetes, esanthem, open wounds.

## 7 Usage

**Never hold the device by the operating lever.  
Always screw the cartridge straight into the thread,  
never use force.**



**Always wear gloves.**

**Only unscrew completely empty cartridges.  
If you hear a hissing sound when removing the  
cartridge, it means that the cartridge was not  
completely empty. However, there is no danger.**

### 7.1 Attaching the cartridge



**Always use gloves while attaching a cartridge.**

- Insert the enclosed metal pin (6) into the provided hole on the unit body (2).
- Screw the cartridge in a clockwise direction quickly and fully into the body of the unit.
- Unscrew an empty cartridge (as soon as there is no more cooling capacity) using the metal pin.
- Attach a new cartridge as described above.

## 7.2 Working with the unit

- Explain the treatment and eventual risks to the patient.
- Consider the contraindications and side effects.
- Remove the protective cap from the tip and place the tip on the area to be treated.
- The liquid must be applied directly onto the skin. Contact between the tip and the skin is a **MUST**.
- **Spraying at a distance has no effect.**
- Then apply the liquid gas to the skin by pressing the lever.
- The application times depend on the type of skin lesions. See details under point 5.
- A bulb formation, a longer healing process, a hyper pigmentation or a scar formation depend on the type of skin and the area to be treated.

In general, the patient does not feel much during the treatment as the cold has a slightly anaesthetic effect. Afterwards a slight tickle usually occurs, similar to a mosquito bite. With longer application times it can hurt a little bit. However, the sensitivities are very individual. Anaesthesia is not common.

## 7.3 Post treatment

- The affected area must always be protected after treatment, especially against sun, to avoid pigmentary abnormality.
- In case of a bulb formation it is important to treat this area like any other open wound to avoid infections.
- Bleeding or infected areas need a special care.

## 8 Storage

- Always put the protective cap on the tip after use.
- Place the device in the box after use to protect it optimally against damage.
- Make sure that the lid of the box does not press on the operating lever.
- Protect the device from heat and sunlight. The storage temperatures are in the range of  $-30\text{ }^{\circ}\text{C}$  to max.  $+50\text{ }^{\circ}\text{C}$ .



**Never expose cartridges to temperatures above 50 °C.**

## 9 Cleaning, disinfection and sterilization

The tips of the devices can normally be cleaned and disinfected with a disinfectant or alcohol. However, if the tips have come into contact with blood, mucous membrane or a source of infection, they must be reprocessed before reuse. This applies to all CRYOSUCCESS tips C-ST5-01, C-DTS-02, C-DTS-03, C-DTS-04 and C-GTS-13.

In accordance with the generally applicable rules and regulations in force in most countries, products to be sterilized must be cleaned and disinfected first. Proceed as follows:

- Unscrew the tip from the unit and immerse it in a disinfectant solution such as Gigasept Instru AF or an equivalent disinfectant. The exposure time depends on the concentration specified in the instructions for use for the corresponding product.
- After removing the tip from the disinfectant solution, check it for any damage (e.g. broken glass part).
- **Defective tips must not be used again.**
- Clean the tip with a brush and rinse thoroughly with demineralized water. Let it dry afterwards.
- Then wrap the tip in a sterilization container or a pouch and sterilize it in an autoclave (steam sterilizer) at 134 °C for 18 minutes.

**Cleaning and disinfection must be performed manually**

**Hot air sterilization can damage the tip and should be avoided under all circumstances.**



**In any case, the country-specific rules and regulations must be observed, even if they differ from our specifications. In case of doubt or ambiguity, please contact your retailer or the main distributor in Switzerland listed under point 13.**

**Gloves must be worn during all cleaning, disinfection and sterilization work.**

## **10 Disposal**

The materials must be disposed of professionally and in accordance with the country-specific regulations. **Cartridges may only be disposed of as scrap metal when empty.**

## **11 Warranty**

The warranty period is 2 years from delivery to the end user. The warranty is strictly limited to the replacement of defective parts. Dropped units and broken tips are not covered by the warranty. Cartridges are subject to multiple checks. The filling weight is thus guaranteed and replacements under guarantee are excluded. Further claims, in particular due to loss of work, incorrect handling and its consequences, failure to carry out subsequent treatment and the resulting consequences, and failure to observe the warning notices are excluded from the guarantee and from any liability claim.

**The life span is 5 years.**

## **12 Certificates**

The cryo unit CRYOSUCCESS meets the EC Directive for medical products (93/42/EEC) and the prescribed conformity clearance procedure according annexe V. The conformity has been assessed by SQS (NB No. 1250)

## 13 Manufacturer and distribution

The cryo unit CRYOSUCCESS is manufactured by the company New Medical Technologies (NMT) GmbH in Switzerland. Marketing and worldwide distribution are carried out by the partner company United Medical Partners (UMP) AG.



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Schweiz

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