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## 1. Introduction and warnings



With this unit you will operate directly on the patient. Therefore it is mandatory to go carefully through the manual and to follow the instructions in detail. If there are any doubts please consult your dealer or contact the main distributor in Switzerland listed under point 15.

Only skilled specialists are allowed to use the units. Patients must be informed about eventual risks prior to start the treatment.

## 2. Package contents of CRYOSUCCESS complete C-SUC-01

	Part number
1 Plastic box with recesses	C-BN-01
1 Cryo unit CRYOSUCCESS with 1mm (Ø) standard tip	C-SUC-02
1 Protecting cap for standard tip	C-PCS-01
1 Additional 4 mm (Ø) tip <i>(optional in some markets)</i>	C-DTS-04
1 Protecting cap for 4 mm tip	C-PCS-01
1 Cartridge nitrous oxide N <sub>2</sub> O (laughing gas), content 23,5g	C-CA-23
1 spare cartridge <i>(optional in some markets)</i>	C-CA-23
1 Metal pin	C-PI-01
1 Instruction manual	
1 Quick instruction	

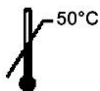
### 3. Symbols

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**Warnings!!**

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**Upper temperature limit 50°C**

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**Part number**

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**Serial number**

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**Protect from direct sun exposure**

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**Producer**

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**Steam sterilization**

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**Handle with care**

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**Protect from rain and wetness**

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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-caoutchuc seals.

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Tips in metal, gold plated, top in borosilicate glass

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Metal-cartridges with thread and 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 and under no circumstances expose the cartridges to temperatures above 50° C.**

## 5. General information

Cryosurgery has been used in dermatology for several decades to treat skin lesions. Different methods were and are still used. The difference is in general the cold performance which is decisive for the success of the treatment. A too high cold performance may end up with the risk of an irreversible skin damage with a too low cold performance the successful treatment may fail. Other factors like the treatment times, the type of skin lesion and their depth are also relevant. The advantage of cryosurgery is mainly seen in the easy application, the short treatment time, the low or even non-existent pain, the high success rate, the relative seldom skin damage, the also relatively seldom scar formations and the moderate treatment costs.

CRYOSUCCESS works based on liquid nitrous oxide in small, handy cartridges, which are under pressure. At the pressure release of the liquid gas a transformation is formed (evaporation). Heat is drawing from the environment. This leads to an icing effect which is used, almost without any loss, as treating energy.

## **6. Applications**

Cryosurgery is suitable for treating almost all kind of skin lesions. E.g. warts, age pigments, hemangiolympangioma, fibroma, condyloma and more.

We refer to the relevant literature, the high number of published studies all over the world and the special application lists.

## **7. Professional Users**

The treatment of skin lesions is primarily reserved for dermatology. Many of the daily lesions can also be treated by other medical specialists. For a long time already cryosurgery entered into general medicine, paediatrics, gynaecology, urology, surgery and more. Plantar warts for instance are also removed in podiatry and age pigments in cosmetic.

Cryosurgery is also used in the dental field and from looking at different studies is also a proven tool in veterinary medicine.

The use in general should only be performed by trained specialists. In any case the country specific laws must be respected. The responsible authorities must be consulted in all uncertain situations.

## **8. Usage**

### ***8.1 Attaching the cartridge***

Take the unit in your hand and put the metal pin in the intended hole in the unit body. This helps to grip the body without damaging the lever.

Screw the cartridge in a clockwise direction quickly and fully into the body of the unit.

Make sure to align the cartridge straight and never to force the thread.

No noise of escaping gas should be heard whilst attaching the cartridge.

Thereafter the unit is ready for use.

## **8.2 Replacing the cartridge**



**Always use gloves while changing the cartridge. You protect therewith your skin against an accidental gas contact.**

Once the cartridge is empty and no cold performance felt, the cartridge can be replaced as follows:

- use the metal pin to grip the body
- unscrew the cartridge in a counter clockwise direction.
- if the cartridge is empty, it can be detached very easily.

However if there is any residual gas remaining, then you are working against the pressure and you will need more effort to be able to unscrew the cartridge. Therefore it doesn't make sense to remove cartridges still containing gas. In addition you will also hear a hissing whilst removing a cartridge still containing gas. This noise arises from the residual gas in the small chamber in front of the valve, but there is no danger at all.

Afterwards attach a new cartridge as described under point 8.1

## **8.3 Working with the unit**

To work with CRYOSUCCESS is very easy.

Remove the protective cap from the tip and place the tip vertically on the area to be treated. The liquid gas must be brought directly onto the skin, the contact between the tip and the skin is a **MUST**.

Then apply the liquid gas onto the skin by pressing the lever.

The lever allows you a time guided and precise application. The application time depends on the type of skin lesion. For further details see points 8.4 and 8.5

#### **8.4 Duration of treatment**

For the majority of lesions the duration of treatment is of a few seconds only. It is dependent on the type and size of the lesion and is entirely up to the user and their experience. The majority of lesions can normally be removed in just one treatment. Some lesions can be rather persistent, especially plantar warts, disappearing sometimes only after a second or further applications. This is not linked to the performance of the unit. The main reasons are mistakes in the application like a missing skin contact or non respected application time. The application times should be therefore guided according to your personal experience or by using the recommended times – see below point 8.5.

The success depends on the one hand of the cold performance and on the other hand on the duration of the treating time. Unfortunately it doesn't mean that in any case a higher cold performance or a longer application time or even both together would be the right solution. Too high cold performance and too long application times could lead to an undesired destruction of the surrounding tissue.

#### **8.5 Application times**

It is obvious that diverse cells show different resistance and the surrounding tissue as well. The cold performance of  $-89^{\circ}\text{C}$  is apparently optimal as are the applications times shown below. These times are only recommendations and are based on the experience of specialists and the experience of many users all over the world. Nevertheless all application times are entirely up to the user, last but not least based on their daily experience. The table shows just a part of the possible skin lesions and serves as a sample.



## 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

### **8.6 Procedure for treatment**

Explain the treatment and eventual risks to the patient. Take care of the known contra indications of cold. On a very sensitive skin a stronger bulb formation may occur, the healing process may be longer and in an extreme case it might lead to a scar formation or a hyper pigmentation.

Remove the protection cap from the tip and place the tip vertically onto the area to be treated. By pressing the lever the gas is applied directly onto the skin and the gas flow can be guided in an optimal way. There must always be a contact between the tip and the skin.  
**Spraying on distance has absolutely no effect.**

Apply the gas according to the treatment times, or based on your experience. After the treatment it is recommended to put the protection cap back on and place the unit in the box.

Depending on the location and the type of skin, skin reactions may differ. This may go from a non visible reaction up to an immediate bulb formation. In any case a light reddening will appear and after a few days a necrosis, which will peel off the skin a few days later. The duration for an entire re-pigmentation can differ and is dependent on the colour of the skin. Dark skin takes more time than lighter skin.

In general the patient does not feel much during the treatment due to the anaesthetized effect of the cold. Afterwards a light tickle, similar to a mosquito bite, is felt. At longer application times it can hurt sometimes, whereby the duration can differ. The sensibility is definitely different. However anaesthesia is rarely necessary.

### **8.7 Post treatment**

After the treatment, patience is necessary. According to the lesion it may vary between a few days (e.g. age pigments) and up to a few months (plantar warts) until a result is visible. Factors include the necrosis and the re-pigmentation. Therefore patients should be called back for a further consultation only after an adequate period. In case of an unproprate result, a treatment with a probable longer application time can be repeated.

The area concerned must always be protected after a treatment. In case of bulb formations it is important to treat this area like any other open wound in order to avoid infections. In addition this area should also be protected against sun influence until an entire pigmentation is observed.

Bleeding or infected areas need a special care to exclude any infection risks.

## **9. Storage**

Always protect the tip of the unit after use with the protective cap. Put the unit back into the box where it is well protected against damage. Make sure the cover of the box does not press onto the lever to avoid unintended gas flow. Protect the unit against heat and sun influence. The storage temperature is between - 10° C to max. + 45° C.



**Never and under no circumstances expose cartridges to temperatures above 50° C.**

## **10. Cleaning**

Normally the tips of the unit can be cleaned and disinfected with a disinfectant or alcohol. If they are in touch with blood, mucous or an infected area they must be sterilized prior to be reused.



**To sterilize, unscrew the tip from the unit. Wrap it in a pouch and sterilize it according the EN norms 13060 and 285 for sterilization in a steam sterilizer. All other sterilization methods are excluded.**



**A hot air sterilization may damage the tip and must be avoided under all circumstances.**

According to valid rules in general and the valid regulations in the majority of countries, products to be sterilized must pre-common be undergone to cleaning and disinfecting. Normally these parts are first immersed in a disinfecting solution and afterwards either cleaned in a thermo-disinfector or an ultrasound bath. Possibly even both procedures are applied. An improper action may lead to a blockage of the tips. Small particles can be deposited at the entrance of the tip and at the renewed use they are pressed by the high gas pressure into the capillary (the lumen has only 80 $\mu$ ) and the gas flow therefore blocked. De-blocking is not possible and the tips must be replaced. To avoid this the following has to be absolutely taken in account:

**Tips taken out from a disinfecting bath or an ultrasound bath must immediately be rinsed with demineralised water, if possible with pressure. Never let them dry without rinsing, they will be blocked. In a thermo-disinfector they are rinsed and according to the type of machine even dried. Blocked tips are not object of a warranty performance.**

## 11. Disposal

The disposal of the material must be done in a professional way and according the country-specific laws. Units and accessories as well as cartridges can be returned to your distributor. The material must be separated (metal, glass, plastic parts) according to the regulations and be brought to the waste disposal in case of home disposal. **Only empty cartridges may be disposed of as scrap metal.**

## 12. Safety instructions and risks

Use the unit only as described in the instruction manual and only for the intended purpose. Do not try to modify the device. Any manipulation of the device will result in an invalidation of warranty and liability. Note the storage instruction, especially for the cartridges.



**Never use a dropped or damaged unit. They should be definitely checked by a dealer, prior to be reused.**

Do not apply force when connecting the components. Use only cartridges with a corresponding thread and equipped with a safety valve.

Keep the device out of the reach of children, wear gloves while changing the cartridge, protect the device and the cartridges from heat, flames and sun exposure, sterilize only the tips and not the body of the unit. Do not use the cartridges for any other purpose. For all other questions, please contact your dealer or the main distribution, see below in point 15.



**CRYOSUCCESS devices are to be used only with the accordingly special gas cartridges delivered by NMT. The use of other cartridges represents a safety hazard and leads automatically to a termination of warranty and all liability claim. Under all circumstances, never use the gas cartridges for any other purpose.**

## **13. Warranty**

There is a 2 year warranty valid from the moment of delivery to the end user. The warranty is strictly limited to the exchange of defective parts. Dropped units and broken tips are not under warranty. Cartridges are checked several times and undergo very strict quality control. The gas weight is fully guaranteed and a warranty exchange is excluded. Other claims for damages such as loss for 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.

## **14. Certificate**

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)

## 15. Manufacturer and distribution

The cryo unit CRYOSUCCESS is manufactured in Switzerland by the company New Medical Technologies GmbH (NMT). The marketing and the worldwide distribution is exclusively done by the company United Medical Partners AG (UMP).



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