

**SN**

The serial number is engraved in the cavity.  
Please mention your instrument's serial number  
in all communication with H&O Equipments.

This user manual is applicable for the following products and accessories.

**INSTRUMENT** - *Expected lifetime : minimum 10 years in normal use.*

**REF**

CryoPen B+ with orange/red, white/red, green/red dot micro-applicators..... S-HO-CBPLUS-06

The instrument, the applicators, the tweezer and the user manual come in hard case for easy transportation.

**CARTRIDGES** - *Expiring date printed on the cartridges packaging.*

23,5g N2O cartridges: 1 carton of 12 boxes each box containing 6 cartridges for use  
with CryoPen B+ ..... S-HO-NO23-12-S06

**APPLICATORS**

Orange/red dot micro-applicator for 1-4 mm applications..... S-HO-CCXO-MA-027  
White/red dot micro-applicator for 2-6 mm applications ..... S-HO-CCXO-MA-005  
Green/red dot micro-applicator for 4-8 mm applications ..... S-HO-CCXO-MA-006

The above list of products is correct at the time of printing. Some articles may no longer be available when reading this document. Some articles may not be available in certain countries.

CryoPen® is the registered trademark of H&O Equipments nv/sa for Europe, the Middle East, Africa and Asia Pacific.

CryoPen® is manufactured by H&O Equipments nv/sa.

FDA certificate is available and can be obtained upon simple request.

EC Declaration of Conformity and EC certificate are available and can be obtained upon simple request.

### **Device classification**

CryoPen is a non-invasive, non-sterile, reusable medical device.

### **Intended Use**

CryoPen is dedicated for the cryogenic treatment of the following benign skin lesions : Acrochordon, actinic keratosis and cheilitis, capillary haemangioma, cutaneous leishmaniasis, discoid lupus erythematosus, filiform, flat, vulgar, plantar and anogenital warts, rosacea, lichen sclerosus, granuloma annulare, molluscum contagiosum, seborrheic keratosis, viral lesions by dispensing an extremely precise flow of nitrous oxide applied directly on the lesion.

All mentioned products are manufactured in the European Community by,



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This manual's version: Manual\_CryoPenB+\_20230531.

Attention! Reference is made to the liability waiver at the back of this manual.

## USED SYMBOLS:



Manufacturer



Caution, consult accompanying documents



Consult the user's guide



Do not expose the cartridges to temperatures below  
-30°C/-22°F and above 50°C/122°F



Keep away from sunlight



Catalogue number



Serial number



Batch number



Medical Device



Unique Device Identification



Use-by date



Notified body nr 1639 SGS BELGIUM

## **IMPORTANT NOTICE:**

- When used correctly, the device does not come into contact with the lesion nor the skin.
- When used normally, there is no need to perform any maintenance, cleaning or disinfection.
- Never clean the thread of frontend and backend. The existing coating should be protected.
- Should the applicator touch the patient in case of misuse, the applicator can be cleaned (autoclaved: 134°C/273°F - 4 min or 121°C/250°F – 20 min) and disinfected (use a non-corrosive disinfecting solution, follow the disinfecting solution manufacturer's recommendations with regards to the concentration and time of application).
- Always gently manipulate all components of CryoPen instruments. Never use more than gentle hand force. Never use pliers or other tools to manipulate the instrument.
- Please ensure to only use the cartridges and filter/openers supplied from H&O Equipments nv/sa. Any other cartridges and filter/openers would damage the instrument.
- Incorrect placement of the filter/opener device into the loading cavity will cause irreversible damage to the instrument.
- Residual foreign matters in the loading cavity while placing a new filter/opener can cause instrument failure.
- When loaded, the instrument is under high pressure. Any change to the construction of the instrument may cause a potential risk.
- Never put your hand on the gas release opening while removing the cartridge!
- All external parts can be wiped with a cloth soaked in any noncorrosive disinfecting solution. Never immerse the entire instrument in a disinfecting solution.
- The applicators must be kept away from dust and the cartridges must be kept away from high temperatures (min -30°C/-22°F and max 50°C/122°F). Leave the applicator cap on when not in use.
- The CryoPen should be handled with care. When storing the instrument with a loaded cartridge in its case, position the CryoPen in such a way that the trigger cannot be pressed when closing the lid of the case. This would cause undesired gas flow.
- CryoPen instruments are intended for professional use only.
- The N<sub>2</sub>O cartridges contain both a liquid and a gaseous phase in balance. The proportion of each phase depends on the roomtemperature which affects the output flow. The best performances are achieved when the cartridge temperature is between 19°C and 22°C (66°F and 72°F). Lower and higher temperatures will give different values of pressure and density of the CryoPen. Over 25°C/77°F, the quantity of liquefied N<sub>2</sub>O in the CryoPen jet will decrease.
- Empty cartridges should be discarded as metal scrap.

## Contraindications:

- Unstable diabetes
- Skin conditions, e.g. skin tumors, esanthema, open wounds, solar hyperkeratosis
- Unexplained, suspicious liver spots and moles
- Cancer tissues and malignant tumors

## The contraindications related to temporary conditions:

- Infections accompanied by fever
- Acute chemotherapy or radiotherapy from four weeks before beginning the therapy to four weeks after finishing the therapy
- Pregnancy or breastfeeding
- Cold intolerance
- Vascular insufficiency

## Reduce possible side-effects:

Although cryotherapy is a relatively low-risk procedure, some side effects may occur as a result of the treatment.

## They include:

- Permanent changes in pigmentation. Both hypopigmentation (lightening of the skin) and hyperpigmentation (darkening of the skin) may occur after cryotherapy. Both generally last a few months, but can be longer lasting. Avoid freezing the basal cell layer where melanocytes (pigment producing cells) are located.
- Sensory impairment. Though rare, damage to nerves is possible, particularly in areas where they lie closer to the surface of the skin, such as the fingers, the wrist, and the area behind the ear. Reports suggest this will disappear within several months.
- Spattering of the cryogen during spraying, when the end nozzle freezes. The innovation of CryoPen is the direct application of nitrous oxide under high pressure (49-53 bar for a cartridge temperature of 66-72°F / 19-22°C). This high pressure jet may cause minor shards of frozen humidity in the air blown away in a circle of approximately 30cm of diameter. They will thaw the moment they would eventually touch healthy skin.
- Hair loss. Hair follicles are easily damaged by cryosurgery and permanent hair loss is not uncommon.

## Further side-effects:

- Edemas
- Bleeding
- Pain and syncope
- Insufflation of subcutaneous tissue
- Retraction caused by freezing next to orifices
- Cartilage defect during treatment of the nose or the ear
- Infection
- Conjunctival ectopy due to treatments of the eyelid
- Milia
- Depressed or atrophic scars

## Interact with your patients

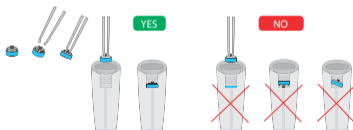
Inform patients that there will be a pain sensation similar to a ballpoint being pushed onto the skin. Generally, little or no discomfort is experienced during the first few seconds when you manage to avoid treatment of healthy tissue. The ice will reach the caudal extent of the lesion after a given amount of time related to the depth of the lesion. From that moment the patient will experience a pain sensation. This may be the moment to stop treatment. You may eventually add a few seconds more depending on the patient's comfort level and upon the clinical evaluation of the operation. There might be a little residual stinging for a few minutes after treatment. Occasionally, a blister might form and persist for a few hours.

## USING THE INSTRUMENT:

### Step 1 Load a new cartridge

The cartridges are packed in peel-pack blisters with an assembled filter/opener included. The filters are used for protection of the applicator, the opener for puncturing the cartridge.

CryoPen B+ can be used with 23,5g cartridges only. Ensure that the loading cavity is empty of all residue. Open the peelpack. Take out the filter/opener with the tweezers. Hold the CryoPen's tip end pointed downward. Place the filter in the instrument and make sure that it is seated flat at the bottom of the loading cavity. The trocar of the opener should be pointed upward! Take the cartridge and put it into the cavity with the narrow side down, on top of the filter/opener.



*Installation of the assembled filter opener*

## Step 2 Puncture the unused cartridge

Gently slide the cartridge into the CryoPen's loading cavity. Go to the point where you feel that the contact between the assembled filter/opener and the cartridge is established. Now, position your hands so that the last turn will be in an uninterrupted movement. Now, rotate quickly until you feel that the end of the rotation is achieved. You may eventually hear a short hissing sound. The shorter the hiss, the better!

## Discharge the used cartridge & empty the cavity

Before loading a new cartridge, release any unused gas from the used cartridge by unscrewing the applicator tip followed by pressing the trigger. Then unscrew the cartridge. Discard the used cartridge and filter/opener. Ensure that the used filter/opener does not remain inside the cavity. You should have the cavity empty of any remaining parts.



*Let's see how to load your device  
let's see our youtube channel*



*Empty loading cavity*

## Important note:

In the case that you would not follow the gas release procedure as described before, the discharge of the gas will pass through the small opening under the on/off button. Extreme attention should be paid to avoid directing the jet of escaping gas to the user's hands, face or any other unprotected body parts. Never cover this opening! Never put your hand on this opening while removing the cartridge! This action must be done in a well ventilated room and by preference at an open window.



*Blistered cartridge and  
assembled filter/opener*

## Step 3 Use the CryoPen B+

Remove the applicator cap. Gently squeeze the trigger switch to start the working. Releasing the trigger will close off the flow of cryogenic liquid. You may observe that during 1 or 2 seconds after releasing the trigger, the remaining gas in the applicator is discarded. A cartridge can be used for several treatments and patients.



## SELECT YOUR APPLICATORS:

Applicators with various flow rates are available depending of the lesion size. Ask your distributor or check on [www.ho-equipments.com](http://www.ho-equipments.com). The table below gives the estimated application with a continuous flow time depending on the applicator and the cartridge size. The measurements were performed between 19°C/66°F and 22°C/72°F.

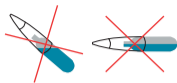
	23,5g	Lesion size	Power
Orange/Red	375-400s	1-4mm	█
White/Red	200-250s	2-6mm	██
Green/Red	150-170s	4-8mm	███



## Position the CryoPen for treatment

The instrument must be held vertically with the tip directed downward.

An angle of less than 45° must be avoided.



*Position the CryoPen correctly*

## Effective application

Before starting treatment take into account age, location, size and number of lesions, skin type, degree of tanning and season.

The applicator tip (from where the liquefied N<sub>2</sub>O flows) should be held 0,5 to 3 mm from the lesion. Further than 5 mm from the applicator tip the liquefied N<sub>2</sub>O will have expanded into gas phase which is not effective for achieving therapeutic results.

By approaching the lesion with the gas flowing you will observe the focal point of the jet on the tissue. The closer you approach the lesion, the more freezing power you apply to the tissue. It is recommended to keep a greater distance for the smaller and more delicate procedures.

The amount of liquid N<sub>2</sub>O that you wish to apply can be controlled by moving the applicator quickly towards and away from the tissue. Circular and crossing movements have the same effect.

Condensation of humidity in the air may in some cases create an ice field on top of the lesion. This 'igloo of ice' will hinder the effective working of the liquid phase of the cryogen (at -89°C/-128°F) and should be removed.

The learning curve for utilizing the CryoPen is short. CryoPen provides the possibility to have full control in the application of freezing power. Start practicing on the regular lesions and treat the more delicate ones after having acquired some experience.



*Distance to lesion*



*Treatments Videos  
Kijk op ons YouTube-kanaal*

## **Duration/Depth of the treatment**

Hold the tip of the applicator as close as possible to the lesion. In all literature, the rapid drop of temperature (thermal shock) is described as a critical criterion. However, always relate to the part of the body where the operation is applied. In some parts, skin is thinner which requires more caution.

A typical freeze on viral infections may last from 5 to 10 seconds for a small flat wart, and up to 45 seconds for a full thickness plantar wart. For general purposes most lesions take about 2 to 30 seconds.

The duration of the treatment will depend on the surface and the thickness of the tissue being treated. Thickness must be estimated based on clinical experience. After the first freezing cycle the tissue should be allowed to thaw for about 30 seconds followed by a second freeze. Note that the tissue will freeze faster than during the first freezing cycle. This 'freeze-thaw-freeze' technique offers the best opportunity for success.

You will find this procedure in most literature on cryotherapy. A follow-up visit is recommended after 2 to 4 weeks to confirm that all pathological tissue has disappeared and check if a follow-up treatment is necessary.

## Liability waiver

Improper use, including excess freezing levels beyond those, which are recommended or for an excessive duration, may result in bodily injury to clients/patients or to operator. H&O Equipments nv/sa and their affiliates, respective directors, officers, shareholders, employees, agents and contractors are not liable or responsible, regardless of whether such liability or responsibility is based on breach of contract, tort, strict liability, breach of warranties, failure of essential purpose, fundamental breach or otherwise, for any death or injury, whether physical or mental, or for any incidental, consequential, indirect, special or punitive damages, arising out of the CryoPen, its design, specifications, possession and use, and treatment procedures, and whether or not any such death, injury, loss, damage(s) result from the negligence, default or error in judgment by H&O Equipments nv/sa, their affiliates, respective directors, officers, shareholders, employees, agents and contractors, and even if advised of the possibility of such damages. You agree to indemnify H&O Equipments nv/sa, their affiliates, respective directors, officers, shareholders, employees, agents and contractors, from and against any and all liability, damages, losses, costs, judgments, fines, penalties and expenses (including legal expenses) of any kind or nature, including, without limitation, incidental, consequential, indirect, special or punitive damages, arising out of claims, demands, actions, causes of action, proceeding or suits, whether in law or in equity, due to any death, injury, loss, damage or damages as hereinbefore referred to.



For more information  
visit our website: [www.ho-equipments.com](http://www.ho-equipments.com)

