



INSTRUCTIONS FOR USE

INTENDED USE—FOR MEDICAL PROFESSIONAL USE ONLY

The CryOmega® is a multi-use disposable device intended for the surgical destruction of target tissue by applying cryogenic gases at extreme low temperatures. The list below shows examples of the types of lesions that can be treated.

- Verruca Vulgaris
- Verruca Plantaris
- Molluscum Contagiosum
- Skin Tags
- Lentigo
- Actinic Keratosis
- Verruca Plana
- Seborrheic Keratosis
- Genital Lesions

BACKGROUND

Cryosurgery is routinely used by medical professionals to treat a variety of lesions. Extreme cold works to destroy tissue through lysis of cells. This may occur through the formation of ice or rapid changes in osmotic pressure. Both can work to increase the overall effectiveness of cryosurgical treatments (1,2). CryOmega® is a self-contained disposable cryosurgical device that sprays a stream of liquid nitrous oxide.

PRINCIPLE OF ACTION

Evaporation of the liquified cryogenic gas draws heat from the surroundings. The CryOmega® device serves as a reservoir for the cryogen-N₂O delivering the liquid gas directly onto the lesion to be treated at -89°C. Following cryo treatment, necrosis of the site can occur. Recovery takes about 10 to 14 days, with new tissue growing inwards from the surrounding epidermis and the more deeply situated adnexa (1,3).

THE CRYOMEGA® UNIT CONSISTS OF:

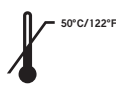
1. Disposable cryogen delivery device complete with N₂O gas cartridge. N₂O does not cause damage to the ozone layer and is not flammable.
2. Instructions for use. This manual contains full details concerning the principle and operation of the CryOmega® and its use.

CryOmega® should be supplied only to and used by healthcare professionals. Imprudent use can lead to unwanted damage to the skin and underlying tissues.

STORAGE, TRANSPORT, AND CLEANING



The gas supply is pressurized. Protect the unit from direct sunlight and do not expose to or store at temperatures in excess of 50°C/122°F.



The CryOmega® can be operated at ambient room temperature. Use CryOmega® in a well ventilated room.



Store CryOmega® away from heat or potential sources of heat.

The CryOmega® may be cleaned with 70% alcohol or 3% hydrogen peroxide as needed.

DISPOSAL

Once the CryOmega® unit is emptied of liquified gas the entire unit may be discarded.

CONTRAINDICATIONS

Absolute contraindications

- Cryotherapy is contraindicated in patients with cryoglobulinemia.

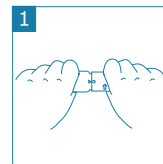
Relative contraindications

- Uncertainty concerning the diagnosis of the disorder (possibility of skin cancers).
- Freezing (to excessive depth) in the region of peripheral arteries in fingers and toes theoretically can produce necrosis distal to the frozen lesions.

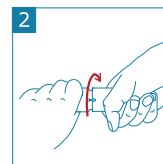
GENERAL PRECAUTIONS

Cryosurgery can produce a painful, burning sensation on the skin. Acceptance of the treatment can be enhanced substantially by informing patients about the potential for pain to occur, the anticipated number of treatments, any preparatory treatment that might be required, possible undesirable effects and follow-up treatment.

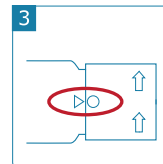
INSTRUCTIONS FOR ACTIVATION AND USE



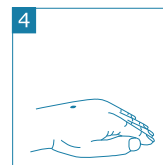
1. While holding the CryOmega® device with one hand, firmly grab the knob at the end of the unit with the other hand.



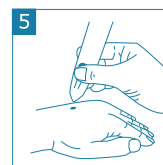
2. Firmly turn the knob clockwise one full rotation, making sure that the white dot on the knob aligns with the arrow on the device. The unit is now ready for use.



3. Make sure that the white dot on the knob aligns with the arrow on the device. **Important: Do not turn the knob back—the unit is now under pressure!**



4. Position the patient such that the surface to be treated is exposed and facing upwards.



5. Hold the CryOmega® device vertically, tip down, and position the spray nozzle directly over the lesion at a 1cm distance. Then press the actuator and spray cryogen directly onto the lesion moving the spray in a small circle to cover the area.

6. **Release** the actuator to **stop** the cryogen spray.

SUGGESTED PATIENT INFORMATION

Cryosurgery works by destructively freezing target tissue. The spray of cryogen evaporates on the skin at a temperature of -89°C. The uppermost layer of skin, together with the diseased tissue, will disappear. It will be replaced by a new healthy layer of skin in 10 to 14 days. Freezing commences once spray is applied to the skin.

The affected skin will turn white. From this point on, the patient may experience a stinging or burning sensation. This sensation will fade rapidly after the thawing phase. Temporary, visible changes in the intensity of pigmentation may occur following treatment.

Cryosurgery can produce blisters which you should not lance. Instead, protect it with a covering or bandage. Keep the treated

area clean and do not pick or scratch it. Swimming and bathing are permitted. Some lesions or warts may require multiple treatments.

ADDITIONAL INSTRUCTIONS AND WARNINGS

- Freezing starts immediately as shown by the white discoloration of the skin. From this point on, the patient may experience stinging, burning or, occasionally, painful sensations.
- Cryosurgical research suggests that a narrow strip of healthy tissue should be frozen along with the target tissue for maxi-mum effectiveness (3).
- Once the cryogen spray has stopped, the white discoloration of the skin will fade away after a few minutes followed by erythema.
- A blister, sometimes filled with blood, may develop after minutes to a few days following freezing. In areas with a thick layer of callus, such blisters will not necessarily be visible to the unaided eye. Do not lance the blister; instead, protect it by covering it with a tape or bandage.
- The CryOmega® is empty when the spray is no longer cold and visible. The unit should be discarded once this occurs and a new unit should be activated.
- Examples of types of lesions for treatment are listed. Treatment of other types of tissue should only be performed based on the professional's experience.

FOLLOW-UP TREATMENT SUGGESTIONS

- Keep the treated area clean.
- Swimming or showering are permitted.
- Patients should not pick or scratch the treated area.
- Use a bandage to protect any blisters that may form.
- Do not lance any blisters that may form.



UNDESIRABLE EFFECTS AND WARNINGS

- A stinging or painful sensation may be experienced during and after freezing, which will fade rapidly after treatment.
- Changes in the intensity of pigmentation may occur. This will generally take the form of hypopigmentation; how-ever, post-inflammatory hyperpigmentation due to melanin or haemosiderin can also occur.
- Imprudent use may lead to excessively deep freezing, pro-ducing damage to the dermis and consequent scar formation and nerve damage.

The depth of freezing using the CryOmega® will be dependent on the time and distance of the spray from the treated surface. The medical literature has many reports of varying cryogen spray times. In addition to the distance of the spray from the lesion, the thickness, location and hydration of the target tissue can affect outcomes. Medical professionals should be familiar with cryosurgical techniques when using the CryOmega®.

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.

Indication	Literature Freeze Time Range	Reference Number*
Verruca Vulgaris	10-20 sec.	3,4,5
Verruca Plantaris	10-20 sec.	4
Molluscum Contagiosum	3-10 sec.	4,6
Skin Tags	5-10 sec.	3,4
Lentigo	2-5 sec.	3,4,5
Actinic Keratosis	5 sec.	3,4
Verruca Plana	5-15 sec.	4,5
Seborrheic Keratosis	5-10 sec.	4
Genital Lesions	5-12 sec.	4

WARRANTY

Each CryOmega® unit is warranted against technical defects for 1 year while unactivated and kept in the original packaging. This warranty will exchange defective units for new units. The warranty assumes normal use and compliance with storage and handling instructions.

REFERENCES

- Rubinsky, Boris, *CryoSurgery, Annual Review Biomedical Engineering*, 02:157-187, 2000.
- Gage, Andrew, *What Temperature is Lethal for Cells? J Dermatol Surg Oncol*, 5-6, 1979.
- Andrews, Mark, *CryoSurgery for Common Skin Conditions, American Family Physician*, 69:10, 2365-2372, 2004.
- Dawber, Rodney, Colver, Graham, et.al., *Cutaneous Cryosurgery: Principles and Clinical Practice*, Martin Dunitz Publisher, 2cd Edition, 1997.
- Strumia, Renata, *La Crioterapia in Dermatologia*, Published by Business Enterprise SRL, 2006.
- Dockery, Gary, *Treating A Child With Multiple, Mildly Pruritic Papules, Podiatry Today*, 20:4, 2007.

TABLE OF SYMBOLS

	INSTRUCTIONS FOR USE
	CAUTION/ATTENTION
	MANUFACTURER
	THIS SYMBOL IDENTIFIES THE IMPORTER
	PROTECT FROM SUNLIGHT
	DO NOT EXPOSE TO TEMPERATURES EXCEEDING 50°C
	MEDICAL DEVICE
	AUTHORIZED REPRESENTATIVE IN THE EUROPEAN COMMUNITY
	AUTHORIZED SWISS REPRESENTATIVE



Manufacturer:
CryoConcepts LP
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Easton, PA 18040, USA
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EC REP

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