



INSTRUCTIONS FOR USE

LICENSED PRACTITIONER USE ONLY

For use by a Licensed Practitioner only.

INTENDED USE

The CryoClear® is a multi-use disposable device intended for the removal 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.

Lentigo (Age Spots)

Skin Tags

Actinic Keratosis (Sun Spots)

PRINCIPLE OF ACTION AND BACKGROUND

Evaporation of the liquefied cryogenic gas draws heat from the surroundings. The CryoClear® device serves as a reservoir for the cryogen-CO₂ delivering the gas directly onto the lesion to be treated at -79°C (-110°F).

CryoClear® is designed to superficially treat unwanted benign lesions. Recovery takes about 10 to 14 days, with new tissue growing inwards from the surrounding epidermis and the more deeply situated adnexa (1,2).

Because CryoClear® freezes superficially, several treatments may be used to achieve optimal results. The spray of cold gas is mildly uncomfortable with treatments of 5-10 seconds or less for most lesions.

Cryotherapy is routinely used by Licensed Practitioners to treat a variety of unwanted lesions listed above. 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 aid the overall effectiveness of cryotherapeutic treatments (1,3).

CryoClear® is a self-contained disposable cryo-spray device that delivers a stream of carbon dioxide ice. Cryotherapeutically treated lesions go through a number of phases post treatment that are well documented in the medical literature (4).

These phases are described in the Table below:

Phases After Cryo-Treatment (4,5)	Appearance of Treated Site	Estimated Time Post Treatment
Inflammatory Phase	Redness, slight erythema	Immediately post treatment to 24 hours
Cellular Phase	Area darkens following target tissue damage	1-4 days
Re-epithelialization Phase	Dark areas can slough or fall off	5-10 days
Remodeling Phase	Pink healthy skin replaces dark area	Usually 10-14 days

CRYOCLEAR®—WHAT LICENSED PRACTITIONERS CAN EXPECT:

GENERAL PRECAUTIONS

Cryotherapy is a process that uses cold to destroy unwanted benign lesions. The gas used in CryoClear® (CO₂) may produce some amount of discomfort and burning or tingling during and shortly after treatment. This is completely normal and expected when using Cryotherapy (5).

Cryotherapy can potentially damage melanocytes along with the targeted lesion. Therefore, it is possible for some amount of

hypopigmentation to occur. This is normal following treatment. Skin color should return in weeks to months following treatment (6).

Licensed practitioners should consult the Fitzpatrick Scale prior to initiating treatment being mindful of the location to be treated and the potential for hypopigmentation (6,7). If unsure, you may want to treat a hidden patch of skin and observe any changes in hypopigmentation in the weeks and months following treatment.

Treatments using CryoClear® rely on the Practitioner to properly position and spray the cryogen at the lesion. When treating focused lesions such as a skin tag, point and concentrate the spray at the base of the tag. This will result in more effective treatments while using the least amount of cryogen.

Larger areas may need to be treated by painting the area. At all times the spray must be close enough to produce visible white "snow" on the skin surface for the entire duration of treatment.

Keep in mind that CryoClear® contains a reservoir of Carbon Dioxide (CO₂) cryogen. It is a fixed volume and therefore the number of treatments will be limited by proper use of the device.

When the device runs out of cryogen you will still feel some gas coming out however it will no longer be cold. At that point discard the empty unit and activate a new CryoClear®.

RECOMMENDATIONS

BEFORE CRYOTHERAPY

- Be sure the area to be treated is well hydrated. Dry skin is not optimal for Cryotherapy. For example, soak hands in water or a damp cloth (6).

FOLLOW-UP TREATMENT SUGGESTIONS

- Keep the treated area clean (8).
- Swimming and showering are permitted.
- Immediately following treatment, patients should not pick or scratch the treated area.
- Cryotherapy outcomes are not affected by sun exposure.
- Be sure the area treated continues to be hydrated (6,10,11).
- Removal of thickened lesions such as Actinic Keratosis can be helped by mildly debriding the area before cryotherapeutic treatment (6).
- Mild Debridement of treated areas 5-10 days following cryo-treatment (re-epithelialization phase) will help improve sloughing (6).
- Minimize freezing the margin around lesions treated for cosmetic reasons (6).
- Cryotherapy outcomes may improve when target lesions are treated by pulsing on/off in cycles (6).



UNDESIRABLE EFFECTS-WARNINGS

- A stinging or tingling sensation may be experienced during and after freezing, which will fade rapidly after treatment.
- Licensed practitioners using CryoClear® should be careful to not freeze for excessive periods which in extreme circumstances could damage the dermis and consequently may cause scar formation and/or nerve damage (9).

CONTRAINDICATIONS

Absolute contraindications

- Cryotherapy is contraindicated in patients with cryoglobulinemia.

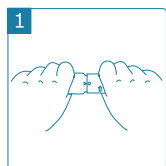
Relative contra-indications

- Do not treat a lesion if not sure of its diagnosis (possibility of skin cancer).
- Over Freezing (to excessive depth) in the region of peripheral arteries in fingers and toes theoretically can produce necrosis distal to the frozen lesions.

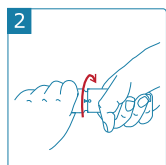
THE CRYOCLEAR® UNIT CONSISTS OF:

1. Disposable cryotherapy device complete with a carbon dioxide (CO₂) gas cartridge.
2. Instructions for use.

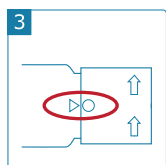
INSTRUCTIONS FOR ACTIVATION AND USE BY LICENSED PRACTITIONERS



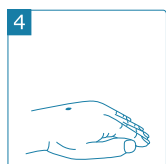
1. While holding the CryoClear® device with one hand, firmly grab the knob at the end of the unit with the other hand.



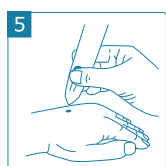
2. Firmly turn the knob clockwise one full rotation, making sure that the blue dot on the knob aligns with the arrow on the device. The unit is now ready for use. **Important: Turning the knob beyond one turn may damage the device.**



3. Make sure that the blue dot on the knob aligns with the arrow on the device. The unit is now under pressure! **Important: Never try to turn the knob back counterclockwise.**



4. Position the patient such that the surface to be treated is exposed and facing upwards.
5. Hold the CryoClear® device vertically, tip down, and position the spray nozzle directly over the lesion at a distance of approximately 0.5cm. Then press the actuator button and spray cryogen directly onto the lesion.



6. Release the actuator to stop the cryo-spray after 5 and no more than 10 seconds.
- Once the cryogen spray has stopped, the white discoloration of the skin will fade away after a few minutes followed by redness and some tingling.
- The CryoClear® is empty when the spray is no longer cold and visible. The unit should be discarded once this occurs and a new CryoClear® unit should be activated.

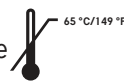
Although not exhaustive, the table below contains suggested freezing times as reported in the literature. These are ranges and provide only a guideline for consideration. CryoClear® has been typically used for no more than 10 second treatments on age spots and skin tags.

Indication	Literature Freeze Time Range	Reference Number*
Lentigo (Age Spots)	5-10 sec.	2,6,9,12,13
Skin Tags	5-10 sec.	2,6,9,12
Actinic Keratosis (Sun Spots)	5-10 sec.	2,6,9,12,13

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 65°C/149°F. The CryoClear® can be operated at ambient room temperature. Use CryoClear® in a well ventilated room. The CryoClear® may be cleaned with 70% alcohol or 3% hydrogen peroxide as needed.



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

DISPOSAL










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

WARRANTY

Each CryoClear® unit is warranted against technical defects for 1 year while inactivated 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

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3. Gage, Andrew, *What Temperature is Lethal for Cells?* J Dermatol Surg Oncol, 5-6, 1979.
4. Zitelli, John, *Wound Healing for the Clinician*, Adv Dermatol, 2:243-266, 1987.
5. Kuflik EG, Gage AA, *Cryosurgical Treatment for Skin Cancer*, IGAKU-SHOIN Medical Pub, 113-141, 1990.
6. Prendergast PM, Shiffman MA(eds), *Aesthetic Medicine, Aesthetic Cryotherapy*, Springer-Verlag, 151-155, 2011.
7. Fitzpatrick, T.B. *The validity and practicality of sun reactive skin types I through VI*. Arch Dermatol 124:869-871, 1988.
8. Golsen BJ, *Wound Healing for the Dermatologic Surgeon-Review*, J Dermatol Surg Oncol, 14:9, 959-972, 1988
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10. Whitehouse, H, *Liquid Air in Dermatology: Its Indications and Limitations*. JAMA, 49, 371-377, 1907
11. Brodthagen H, *Local Freezing of the Skin by Carbon Dioxide Snow*. Munksgaard-Copenhagen Publisher, 1961.
12. Carpenter, CC, *Cryotherapy for Common Skin Diseases*, Journal of the Medical Society of NJ, 354-357, Sept, 1943.
13. Morgan, AJ, *Cryotherapy*, Medscape article 1125851, pp 1-9, Oct 8, 2012.

TABLE OF SYMBOLS	
	INSTRUCTIONS FOR USE
	CAUTION/ATTENTION
	MANUFACTURER
	THIS SYMBOL IDENTIFIES THE IMPORTER
	PROTECT FROM SUNLIGHT
	DO NOT EXPOSE TO TEMPERATURES EXCEEDING 65°C
	MEDICAL DEVICE
	AUTHORIZED REPRESENTATIVE IN THE EUROPEAN COMMUNITY
	AUTHORIZED SWISS REPRESENTATIVE



Manufacturer:
CryoConcepts LP
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