



Instructions for Use  
Mode d'emploi  
Gebrauchsanleitung

Instrucciones de uso  
Istruzioni per l'uso  
Gebruiksaanwijzing



ENG - Scan the QR Code with your smartphone

ARA - امسح رمز QR باستخدام هاتفك الذكي

BUL - Сканирайте QR кода със смартфона си

CZE - Naskenujte QR kód pomocí chytrého telefonu

DAN - Scan QR-koden med din smartphone

DUT - Scan de QR-code met uw smartphone

FIN - Skanna QR-koodi älypuhelimellasi

GRE - Σκάνοτε τον κωδικό QR με το smartphone σας

HRV - Pametnim telefonom skenirajte QR kod

HUN - Szkenelje be a QR-kódot okostelefonjával

POL - Zeskanuj kod QR za pomocą smartfona

POR - Digitalize o código QR com o seu "smartphone"

ROM - Scanați codul QR cu smartphone-ul dvs

RUS - Отсканируйте QR-код с помощью смартфона

SLO - Naskenujte QR kód pomocou smartfónu

SWE - Skanna QR-koden med din smartphone



Translated IFUs at  
[CryoConcepts.com/International](http://CryoConcepts.com/International)

## ENG 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.

## FRA UTILISATION PRÉVUE

Le CryoClear® est un dispositif jetable qui peut être utilisé plusieurs fois, destiné à l'ablation de tissus cibles par application de gaz cryogéniques à des températures extrêmement basses. La liste ci-dessous contient des exemples des types de lésions qui peuvent être traités.

## GER BESTIMMUNGSGEMÄSSE VERWENDUNG

CryoClear® ist ein Wegwerfgerät für mehrfache Behandlungen, das für die Entfernung von Zielgewebe durch Anwendung kryogener Gase bei extrem niedrigen Temperaturen vorgesehen ist. In der nachstehenden Liste sind Beispiele für Läsionsarten aufgeführt, die mit diesem Gerät behandelt werden können.

## SPA USO PREVISTO

CryoClear® es un dispositivo desechable y multiusos destinado a la eliminación del tejido objetivo mediante la aplicación de gases criogénicos a temperaturas extremadamente bajas. La siguiente lista muestra ejemplos de los tipos de lesiones que se pueden tratar.

## ITA DESTINAZIONE D'USO

CryoClear® è un dispositivo usa e getta multiuso, destinato alla rimozione del tessuto bersaglio mediante l'applicazione di gas criogenici a temperature estremamente basse. L'elenco riportato di seguito mostra esempi delle tipologie di lesioni trattabili

## DUT BEOOGD GEBRUIK

De CryoClear® is een instrument voor eenmalig gebruik met meerdere toepassingen, bedoeld voor de verwijdering van het te behandelen weefsel door toepassing van cryogene gassen bij extreem lage temperaturen. De onderstaande lijst geeft voorbeelden van de soorten laesies die kunnen worden behandeld.

- 
- ENG
- Lentigo (Age Spots)
  - Skin Tags
  - Actinic Keratosis (Sun Spots)

- 
- FRA
- Lentigo (taches séniles)
  - Acrochordons
  - Kératose actinique (taches solaires)

- 
- GER
- Lentigines (Altersflecken)
  - Fibrome (Stielwarzen)
  - Aktinische Keratose (Sonnenflecken)

- 
- SPA
- Lentigo (manchas de la edad)
  - Excrecencias cutáneas
  - Queratosis actínica (manchas solares)

- 
- ITA
- Lentigo (macchie senili)
  - Escrescenze cutanee
  - Cheratosi attinica (macchie solari)

- 
- DUT
- Lentigo (ouderdomsvlekken)
  - Huidvlekken
  - Actinische Keratose (zonnevlekken)

**LICENSED PRACTITIONER USE ONLY**

For use by a Licensed Practitioner only.

**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-CO<sub>2</sub> 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® (CO<sub>2</sub>) 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 (CO<sub>2</sub>) 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.

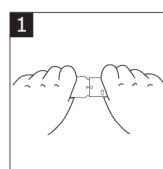
**Relative contra-indications**

- 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.

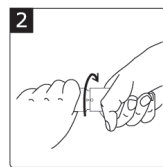
**THE CRYOCLEAR® UNIT CONSISTS OF:**

1. Disposable cryotherapy device complete with a carbon dioxide (CO<sub>2</sub>) gas cartridge.
2. Instructions for use.

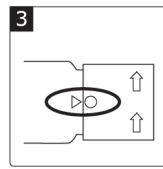
**INSTRUCTIONS FOR ACTIVATION AND USE BY LICENSED PRACTITIONERS**



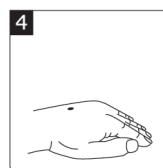
1. While holding the CryoClear® device with one hand, firmly grab the knob at the end of the unit with the other hand.



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.

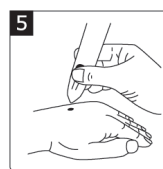


3. Make sure that the blue dot on the knob aligns with the arrow on the device. The unit is now under pressure! **Important:** Never try to turn the knob back counterclockwise.



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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## TABLE OF SYMBOLS

	INSTRUCTIONS FOR USE MODE D'EMPLOI GEBRAUCHSANLEITUNG INSTRUCCIONES DE USO ISTRUZIONI PER L'USO GEBRUIKSINSTRUCTIES
	CAUTION/ATTENTION PRUDENCE/ATTENTION VORSICHT/ACHTUNG PRECAUCIÓN/ATENCIÓN ATTENZIONE/AVVERTENZA VOORZICHTIG/OPGELET
	MANUFACTURER FABRICANT HERSTELLER FABRICANTE PRODUTTORE FABRIKANT
	THIS SYMBOL IDENTIFIES THE IMPORTER CE SYMBOLE PERMET D'IDENTIFIER L'IMPORTATEUR DIESES SYMBOL KENNZEICHNET DEN IMPORTEUR ESTE SÍMBOLO IDENTIFICA AL IMPORTADOR QUESTO SIMBOLO IDENTIFICA L'IMPORTATORE DIT SYMBOOL IDENTIFICEERT DE IMPORTEUR
	PROTECT FROM SUNLIGHT TENIR À L'ABRI DE LA LUMIÈRE SOLAIRE VOR SONNENLICHT SCHÜTZEN PROTEGER DE LA LUZ SOLAR PROTEGGERE DALIA LUCE DIRETTA DEL SOLE BESCHERMEN TEGEN ZONLICHT
	DO NOT EXPOSE TO TEMPERATURES EXCEEDING 50°C NE PAS EXPOSER À DES TEMPÉRATURES SUPÉRIEURES À 50°C NICHT TEMPERATUREN ÜBER 50°C AUSSETZEN NO EXPONER A TEMPERATURAS SUPERIORES A 50°C NON ESPORRE A TEMPERATURE SUPERIORI AI 50°C NIET BLOOTSTELLEN AAN TEMPERATUREN BOVEN 50°C
	MEDICAL DEVICE DISPOSITIF MÉDICAL MEDIZINISCHES GERÄT DISPOSITIVO MÉDICO DISPOSITIVO MEDICO MEDISCH APPARAAT
	AUTHORIZED REPRESENTATIVE IN THE EUROPEAN COMMUNITY DÉPOSITAIRE AGRÉÉ DANS L'UNION EUROPÉENNE AUTORISIERTER VERTRETER IN DER EUROPÄISCHEN GEMEINSCHAFT REPRESENTANTE AUTORIZADO EN LA COMUNIDAD EUROPEA RAPPRESENTANTE AUTORIZZATO NELLA COMUNITÀ EUROPEA VERTEGENWOORDIGER IN EUROPA
	AUTHORIZED SWISS REPRESENTATIVE REPRÉSENTANT SUISSE AUTORISÉ AUTORISIERTER SCHWEIZER VERTRETER REPRESENTANTE SUIZO AUTORIZADO RAPPRESENTANTE SVIZZERO AUTORIZZATO GEAUTORISEERDE ZWITSERSE VERTEGENWOORDIGER



### Manufacturer:

CryoConcepts LP  
1100 Conroy Place  
Easton, PA 18040, USA  
www.cryoconcepts.com



### Emergo Europe

Westervoortsedijk 60  
6827 AT Arnhem  
The Netherlands



### MedEnvoy Global BV

Prinses Margrietplantsoen 33  
Suite 123  
2595 AM The Hague  
The Netherlands



### MedEnvoy Switzerland

Gotthardstrasse 28  
6302 Zug, Switzerland

### Australian Sponsor

Emergo Australia  
Level 20 Tower II Darling Park  
201 Sussex Street, Sydney, NSW 2000  
Australia

 **CryoConcepts**  
THE CRYO EXPERTS

 2460 

CryoClear® is a trademark of CryoConcepts LP.  
U.S. Patent # 8,647,337 - International Patent # WO2011005495