

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.

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.

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.

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.

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

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

FRA

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

SPA

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

DUT

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

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).

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

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®.

- 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).

- Cryotherapy outcomes may improve when target lesions are treated by pulsing on/off in cycles (6).

- 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).

Absolute contraindications

- Cryotherapy is contraindicated in patients with cryoglobulinemia.

- 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.

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

Diagram 5 shows a hand holding a pen, drawing a small dot on a line.

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

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.

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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 SIMBOLO IDENTIFICA AL IMPORTADOR QUESTO SIMBOLO IDENTIFICA L'IMPORTATORE DIT SYMBOOL IDENTICEERT 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 TEMERATURE SUPERIORI AI 50°C NIET BLOOTSTELLEN AAN TEMPERATUREN BOVEN 50°C
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	AUTHORIZED REPRESENTATIVE IN THE EUROPEAN COMMUNITY DEPOSITAIRE 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 GEAUTORISERDE ZWITSERSE VERTEGENWOORDIGER

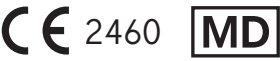
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CryoClear® is a trademark of CryoConcepts LP.
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