



Unrivalled Experience



Vitreoret
Vitreoretinal Surgical Products

CryoTreq
Ophthalmic Cryo-Surgery

Unique | Straightforward | Compelling

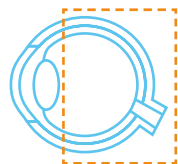
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CryoTreq

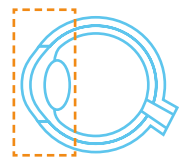
Ophthalmic Cryo-Surgery

REF CT00.D01

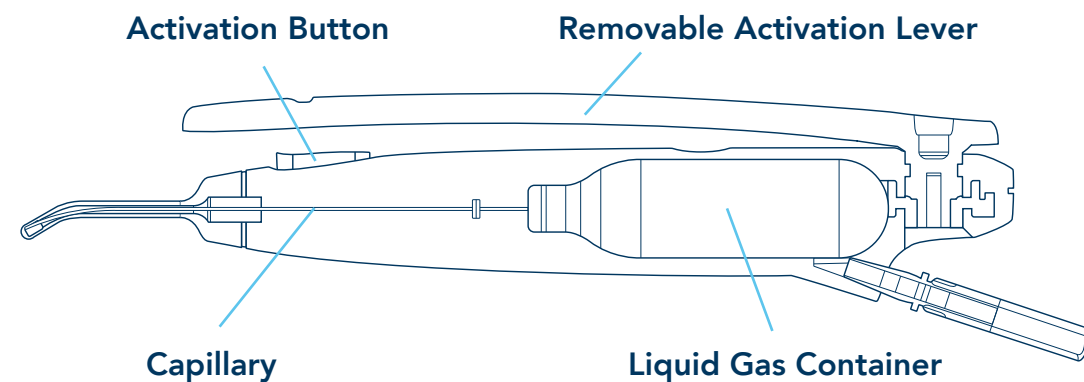
CryoTreq is the only hand-held, single use and stand-alone device for ophthalmic cryo-surgery, a treatment based on locally applying extreme freeze to eye tissues, to perform:



- Cryopexy for retinal detachment
- Treatment for retinopathy of prematurity



- Cataract extraction
- Cryo-destruction of lash follicles for trichiasis



- Preparation requires rotating the lever to pierce and unseal the pressurised liquid gas container with nitrous oxide
- By pressing the activation button, the freezing cycle starts as the liquid circulates toward the metal tip and evaporates

- Gas expansion per Joule-Thomson principle, cools the cryo-tip and an ice ball is formed around the cryo-tip
- Defrosting cycle starts upon releasing the activation button and flushing with irrigating sterile solution (room temperature)



Time to Frost

6 seconds for an **0.8 mm** thickness ice ball to form on the cryo-tip (water bath temperature at 37°C)



Number of Frosting Cycles

Approximately 15 freezing actions are possible with 1 device



Time to Retract the Cryo-probe

After releasing the activation button, it takes **6 seconds** flushing with sterile solution at room temperature to safely retract the probe from the eye



Target Temperature

The lowest cryo-tip temperature achievable is **-88°C**

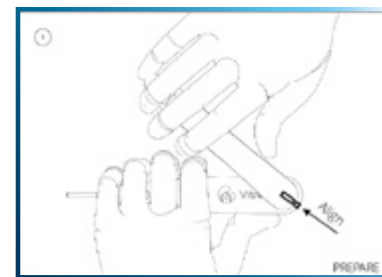


Figure 1. Preparation for activation

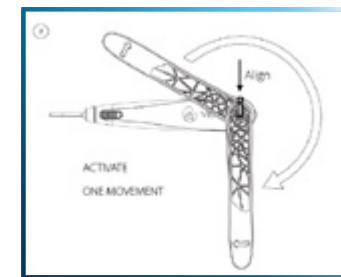


Figure 2. Activation

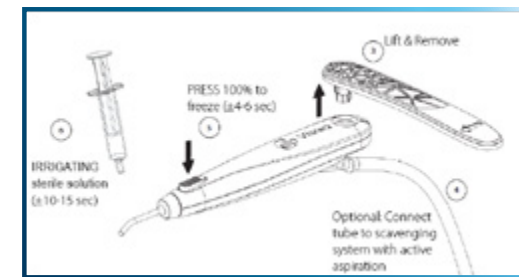


Figure 3. Finalize preparation & use

1. **Circulating nurse** - Visual Check: expiry date, package integrity
2. **Circulating nurse** - Unpack, introduce the device into the OR sterile area
3. **Scrub nurse** - If needed attach the hose to a gas scavenging system, dependent on air exchange rate of OR
4. **Scrub nurse** - Prepare a syringe filled with sterile saline solution at room temperature
5. **Scrub nurse/surgeon** - Rotate CryoTreq's lever (clock-wise), with a fluent motion for 270° to align the marks, then pull the lever upwards and remove it
6. **Scrub nurse/surgeon** - Functional Check (no tissue contact): activate CryoTreq for 2 seconds while pointing the tip down, observe the formation of an ice ball around the cryo-tip

- Pregnant woman should avoid exposure to nitrous oxide
- Refrain from touching the tip of the probe when CryoTreq is activated
- CryoTreq is contraindicated in patients with intraocular gas tamponades within 3 months after eye surgery. The nitrous oxide gas released by CryoTreq may cause a rapid expansion of the intraocular gas bubble resulting in a sight threatening elevation of intraocular pressure
- Activate the device until cryo-coagulation is visually observed



OR Temperature: **15 - 25°C (59 to 77°F)**. Above 25°C a reduced performance may be observed



Store in a **dry and clean environment at room temperature**



Air Refreshment Rate: **well ventilated room with a downflow system (minimum 20 times/hour air refreshment rate)**. Outside this condition, connect the hose provided with the gas exhaust and a gas scavenging system



Avoid activating the device longer than **2 seconds** when not in contact with tissue to avoid risk of clogging



UNIQUE

It's the first and only disposable, hand-held stand-alone device for ophthalmic cryo-surgery.



STRAIGHTFORWARD

- Already sterile, 6 simple steps to use it
- Stand-alone, just one button for frosting/defrosting
- Single use advantage
- Only one "REF" covers your needs for cryo-surgery



COMPELLING

- Lowers barriers to cryo-surgery
- 4 seconds activation to frost the cryo-tip
- Approximately 15 freezing cycles at one patient

Technical Sheet*									
Packaging	3 - Sterile devices per box, individually packed in a Tyvek peel pouch 1 - Multilanguage Instructions for Use								
General Device Description	<table> <tr> <td>Name</td><td>CryoTreo</td></tr> <tr> <td>Reference Code</td><td>CT00.D01</td></tr> <tr> <td>GTIN</td><td>08719214223458</td></tr> <tr> <td>GMDN</td><td>11068, Cryosurgical unit, ophthalmology</td></tr> </table>	Name	CryoTreo	Reference Code	CT00.D01	GTIN	08719214223458	GMDN	11068, Cryosurgical unit, ophthalmology
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Reference Code	CT00.D01								
GTIN	08719214223458								
GMDN	11068, Cryosurgical unit, ophthalmology								
Product Class	MDD Class IIa sterile, single-use								
Manufacturer	Vitrex B.V. Seggelant – Noord 2 3237 MG Vierpolders, The Netherlands								
Certification Information	<table> <tr> <td>EC Certification</td><td>527668MR2</td></tr> <tr> <td>CE Mark</td><td>CE 0297</td></tr> <tr> <td>Notified Body</td><td>DQS Medizinprodukte GmbH</td></tr> <tr> <td>EN ISO 13485:527668 MP2016</td><td></td></tr> </table>	EC Certification	527668MR2	CE Mark	CE 0297	Notified Body	DQS Medizinprodukte GmbH	EN ISO 13485:527668 MP2016	
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Sterilisation	Sterilised using gamma irradiation								
Packaging Materials	<table> <tr> <td>Primary</td><td>Tyvek peel pouch</td></tr> <tr> <td>Secondary</td><td>Carton box</td></tr> </table>	Primary	Tyvek peel pouch	Secondary	Carton box				
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Secondary	Carton box								
Absence of	Latex/Phthalates/Animal origin components								
Shelf Life	Three (3) years from Manufacturing Date								
Weight of the Device	<table> <tr> <td>Without scavenging hose</td><td>± 63g</td></tr> <tr> <td>With scavenging hose</td><td>± 89g</td></tr> </table>	Without scavenging hose	± 63g	With scavenging hose	± 89g				
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OR Requirements	1) Air Refreshment Rate: well ventilated room with a downflow system, (minimum 20 times/hour air refreshment rate). Outside this condition, connect the hose provided with the gas exhaust and a gas scavenging system. 2) Optimal performances achieved at OR temperature between 15-25°C (59 to 77°F).								
Storage & Transportation	<table> <tr> <td>Storage</td><td>Dry and clean environment, from +15°C (± 2°C) to +30°C (± 2°C)</td></tr> <tr> <td>Transportation</td><td>From -29°C (± 2°C) to +50° (± 2°C), no air transport permitted</td></tr> </table>	Storage	Dry and clean environment, from +15°C (± 2°C) to +30°C (± 2°C)	Transportation	From -29°C (± 2°C) to +50° (± 2°C), no air transport permitted				
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