

Unrivalled Experience



| *From an idea of Professor Stanislao Rizzo* |

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VitreQ

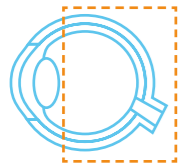
Vitreoretinal Surgical Products

CryoTreq
Ophthalmic Cryo-Surgery

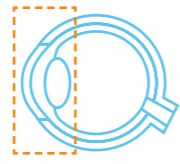
Unique | Straightforward | Compelling



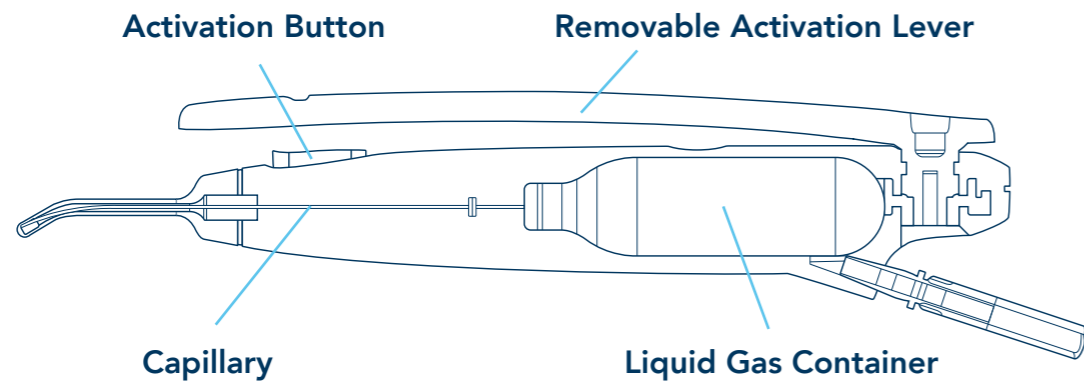
CryoTreq is the only hand-held, single use and stand-alone device for ophthalmic cryo-surgery, a treatment based on locally applying extreme freeze to eye tissues, to perform:



- 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)

6s 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)

15+ Number of Frosting Cycles
Approximately 15 freezing actions are possible with 1 device

6s 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

-88° Target Temperature
The lowest cryo-tip temperature achievable is -88°C

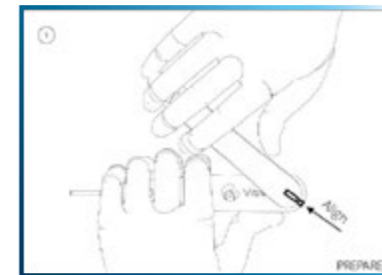


Figure 1. Preparation for activation

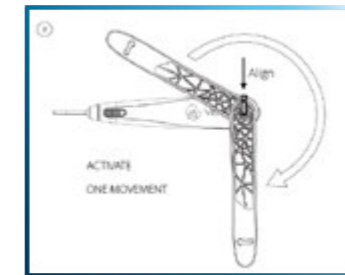


Figure 2. Activation

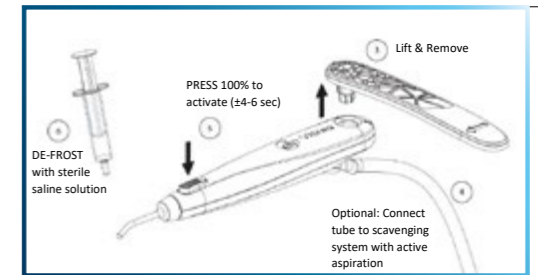


Figure 3. Finalize preparation & use

- 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

CryoTreo

Ophthalmic Cryo-Surgery

REF CT00.D01

1

UNIQUE

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

2

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

3

COMPELLING

- Lowers barriers to cryo-surgery
- 4 second 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	Name: CryoTreo 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	EC Certification: 527668MR2 CE Mark: CE 0297 FDA approval: 510(k) Notified Body: DQS Medizinprodukte GmbH EN ISO 13485:527668 MP2016
Sterilisation	Sterilised using gamma irradiation
Packaging Materials	Primary: Tyvek peel pouch Secondary: Carton box
Absence of	Latex/Phthalates/Animal origin components
Shelf Life	Three (3) years from Manufacturing Date
Weight of the Device	Without scavenging hose: ± 63g With scavenging hose: ± 89g
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	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

Contact Information:

www.bvimedical.com/customer-support/

*from Technical Documentation CryoTreo on file



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