

# TECHNICAL DATA SHEET



**Hand-held, single use, sterile and stand-alone device for ophthalmic cryo-surgery.**




## General Features

- The capacity of the liquid gas container allows around 15 freezing cycles per patient
- First and only disposable, hand-held, and stand alone device for ophthalmic cryo-surgery; no need for external connection to large-quantity gas containers in the operating room
- Overall CryoTreq preparation consists of 6 simple steps, 3 of them are just routine steps, (see IFU)
- Upon completion of device preparation, pressing the activation button for around 6 seconds is enough to freeze the cryo-tip
- It needs to be used in a well ventilated room with a down-flow system (minimum 20 times/hour air refreshment rate). Outside this condition, connect the hose provided with the gas exhaust and a gas scavenging system.

## Warning & Precautions

- See box label and insert

## Product Information

| CryoTreq Disposable Hand-Held Instrument  | Name     | General Device Description  | Qty/Bx | SKU #    |
|---|----------|---|--------|----------|
|  | CryoTreq | GTIN 08719214223458<br>GMDN 11068, Cryosurgical unit, ophthalmology | 3      | CT00.D01 |

**Vitreco**

Vitreoretinal Surgical Products

Hand-held, single use, sterile, and stand-alone device for ophthalmic cryo-surgery.

## Product Information

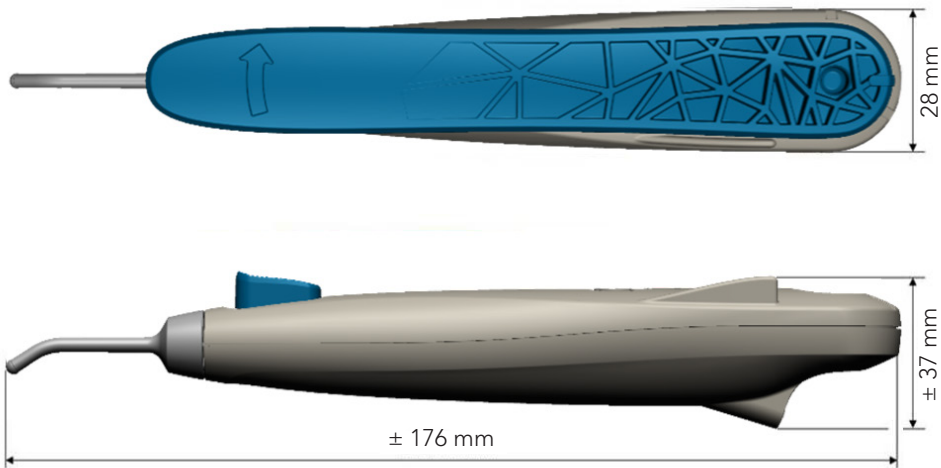
| Manufacturer   | Product Class   |
|--|---|
| Vitrex B.V.<br>Seggelant – Noord 2<br>3237 MG Vierpolders, The Netherlands   | MDD Class IIa sterile, single-use   |
| Packaging  | Absence of  |
| 3 - Sterile devices per box, individually packed in a Tyvek peel pouch<br>1 - Multilanguage Instructions for Use   | Latex/Phthalates/Animal origin components   |
| Intended Purpose / Use and Indications   | Shelf Life  |
| The CryoTreq is a disposable handheld instrument intended for ophthalmic surgery. It creates a tip at cryogenic temperatures that can be utilized to perform cryotherapy based on the process of cryoablation, which means the extreme cold is used to locally perform cryo-coagulation on tissue for various purposes | Three (3) years from manufacturing date   |
| Certification Information  | Product Composition   |
| EC Certification: 527668 MR2<br>CE Mark: CE 0297<br>FDA approval: 510(k)<br>Notified Body: DQS Medizinprodukte GmbH<br><br>EN ISO 13485: 527668 MP2016   | <ul style="list-style-type: none"> <li>• Activation Handle: ABS-GF, Novodur HD M203FC G3               <ul style="list-style-type: none"> <li>- Acrylonitrile</li> <li>- Butadiene</li> <li>- Styrene</li> </ul>               Mevopur color: Blue SB5M176206-ZN             </li> <li>• Tip: X5CrNi18-10 (1.4301; SS304)</li> <li>• Head: PBT Ultradur B 4520 PRO               <ul style="list-style-type: none"> <li>- Polybutylene</li> <li>- Terephthalate</li> </ul> </li> <li>• Knob: ABS-GF, Novodur HD M203FC G3               <ul style="list-style-type: none"> <li>- Acrylonitrile</li> <li>- Butadiene</li> <li>- Styrene</li> </ul>               Mevopur color: Blue SB5M176206-ZN             </li> <li>• Housing: ABS, Novodur HD M203FC               <ul style="list-style-type: none"> <li>- Acrylonitrile</li> <li>- Butadiene</li> <li>- Styrene</li> </ul>               Mevopur color: White SB0M176082-ZN             </li> <li>• Evacuation Tube: PVC (Polyvinyl Chloride)</li> <li>• Gas inside Cartridge: nitrous oxide (N2O)</li> <li>• Absence of: Latex / Phthalates / Animal origin components</li> </ul> |

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| Sterilisation  | Packaging Material  |
|--|---|
| Sterilized using gamma irradiation                             | Primary: Tyvek Peel pouch<br>Secondary: Carton box  |
| Weight of the Device   | OR Requirements   |
| Without scavenging hose ± 63g<br>With scavenging hose ± 89g    | 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.<br>2) Optimal performances achieved at OR temperature between 15-25°C (59 to 77°F). |
| Storage  | Transportation  |
| Dry and clean environment, from +15°C (± 2°C) to +30°C (± 2°C) | From -29°C (± 2°C) to +50° (± 2°C), no air transport permitted  |



**Contact Information:**

[www.bvimedical.com/customer-support](http://www.bvimedical.com/customer-support)

\*from Technical Documentation CryoTreq on file

