



## URGENT Field Safety Notice

### CryoTrex REF# CT00.D01

### Voluntary recall of affected lots

April 21, 2021

Dear Customer,

Vitrex B.V. (SRN NL-MF-000000424) is issuing this Field Safety Notice to inform you about a potential issue that may affect CryoTrex, a disposable device for ophthalmic cryosurgery identified below. We are providing this notification, so you can check your inventory immediately.

#### Details on Affected Devices:

Product Designation	REF#:	GTIN#:	Lot Numbers:
CryoTrex	CT00.D01	08719214223458	20201169
CryoTrex	CT00.D01	08719214223458	20201679
CryoTrex	CT00.D01	08719214223458	20201776
CryoTrex	CT00.D01	08719214223458	20202426
CryoTrex	CT00.D01	08719214223458	20213725
CryoTrex	CT00.D01	08719214223458	20214150
CryoTrex	CT00.D01	08719214223458	20214155

#### The intended purpose

The CryoTrex is a disposable handheld instrument intended for ophthalmic surgery. It creates a tip at cryogenic temperatures by evaporation of N<sub>2</sub>O that can be utilized to perform cryotherapy based on the destruction of tissue by extreme cold to locally perform cryocoagulation on tissue for various purposes. The intended user is the eye surgeon familiar with the cryogenic eye treatment procedure.

#### Description of the Problem:

As part of quality control inspections, Vitrex B.V. identified a small tear of the sterile pouch in the products listed above. Investigation was conducted and concluded that the incidence of compromised sterile barrier is approximately 5% of manufactured units. These devices are not meeting Vitrex's internal quality standards.

Use of a non-sterile device may expose the patient to infectious agents, increasing patient risk of developing infection. At this stage Vitrex B.V. has not received any quality complaint as described above, nor any report of incidents related to this breach of sterile barrier or infection related to these products.








#### Health Hazard Assessment

Vitrex B.V. has determined through its investigation and risk assessment that there is the potential for infection attributable to the breach of sterile barrier. Instructions for use and/or product labeling contraindicate the use of product with damaged packaging, however the breach of sterile barrier may not be detected prior to use.

IFS num: 1597774


**Advise on Action to be Taken by the User:**

1. Stop using any CryoTreq **IMMEDIATELY**. Examine your inventory and quarantine product from all lots subject to this voluntary recall.

Product Designation	REF#:	GTIN#:	Lot Numbers:
CryoTreq	CT00.D01	08719214223458	 20201169
CryoTreq	CT00.D01	08719214223458	 20201679
CryoTreq	CT00.D01	08719214223458	 20201776
CryoTreq	CT00.D01	08719214223458	 20202426
CryoTreq	CT00.D01	08719214223458	 20213725
CryoTreq	CT00.D01	08719214223458	 20214150
CryoTreq	CT00.D01	08719214223458	 20214155

2. If you have further distributed this product, please identify your customers and notify them of this voluntary product recall. Consider all potential users of this product in your user supply chain. Please provide them with a copy of the present Field Safety Notice.
3. Complete the **Attachment 1: Response Form** enclosed **IMMEDIATELY**, as evidence of the product being returned, and we will credit your account OR complete the response form **even if you do not have product** to return.
4. Return the **Attachment 1: Response Form** by e-mail to: **BVI\_FA\_21\_003@stericycle.com**
5. **Return ALL quarantined product from the affected lots** to our company via pre-paid postal labels, which will be supplied to you by our recall team. If you need further assistance, you can contact us using the information below.

Email: **BVI\_FA\_21\_003@stericycle.com**  
 FAX: **+44 207 660 1508**  
 Phone: **+44 208 705 0533**

This action has been reported to the relevant competent authorities in your country by Vitreco B.V.

We value your business and apologise for any inconvenience this may cause.

Sincerely,



Mr. Christian Neele  
 Group Leader, Regulatory Affairs at Vitreco B.V.

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## Attachment 1 - Response Form

### CryoTreq REF# CT00.D01

Please complete and return this response form  
no later than May 21<sup>st</sup>, 2021

Please check the appropriate response(s)

#### STEP 1: Evaluate your inventory for

Product Designation	REF#:	GTIN#:	Lot Numbers:
CryoTreq	CT00.D01	08719214223458	<small>LOT</small> 20201169
CryoTreq	CT00.D01	08719214223458	<small>LOT</small> 20201679
CryoTreq	CT00.D01	08719214223458	<small>LOT</small> 20201776
CryoTreq	CT00.D01	08719214223458	<small>LOT</small> 20202426
CryoTreq	CT00.D01	08719214223458	<small>LOT</small> 20213725
CryoTreq	CT00.D01	08719214223458	<small>LOT</small> 20214150
CryoTreq	CT00.D01	08719214223458	<small>LOT</small> 20214155

Please check ALL appropriate boxes.

- ☐ I have read and understand the recall instructions provided in the April 21, 2021 letter.
- ☐ I have identified and notified my customers that products affected by this voluntary recall

were shipped to them by \_\_\_\_\_  
(specify date and method of notification);

- ☐ I have checked my stock and have no affected units in inventory.
- ☐ I have checked my stock and have quarantined inventory to be returned consisting of the following:

LOT No.	Quantity	Boxes / Pieces
		<input type="checkbox"/> Boxes <input type="checkbox"/> Pieces
		<input type="checkbox"/> Boxes <input type="checkbox"/> Pieces
		<input type="checkbox"/> Boxes <input type="checkbox"/> Pieces
		<input type="checkbox"/> Boxes <input type="checkbox"/> Pieces
		<input type="checkbox"/> Boxes <input type="checkbox"/> Pieces
		<input type="checkbox"/> Boxes <input type="checkbox"/> Pieces
		<input type="checkbox"/> Boxes <input type="checkbox"/> Pieces
		<input type="checkbox"/> Boxes <input type="checkbox"/> Pieces
		<input type="checkbox"/> Boxes <input type="checkbox"/> Pieces

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**STEP 2: Recipient please complete the form**

Company name: \_\_\_\_\_

Address: \_\_\_\_\_

BVI Customer Account #: (if known) \_\_\_\_\_

If purchased through a distributor, include distributor name: \_\_\_\_\_

Telephone: \_\_\_\_\_

Contact name: \_\_\_\_\_

Title: \_\_\_\_\_ Email: \_\_\_\_\_

Date completed: \_\_\_\_\_

Signature: \_\_\_\_\_

**STEP 3: Return the Form**

Please **e-mail this completed Response Form by May 21<sup>st</sup>, 2021 to**

**BVI\_FA\_21\_003@stercycle.com.**

**\*\*\*\*\*Thank you for your assistance in this matter\*\*\*\*\***

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