Vitreq a company of:

BVI

Vitreq

URGENT Field Safety Notice

CryoTreq REF# CT00.D01
Voluntary recall of affected lots

April 21, 2021

Dear Customer,

Vitreq B.V. (SRN **NL-MF-000000424**) is issuing this Field Safety Notice to inform you about a potential issue that may affect CryoTreq, 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:
CryoTreq	CT00.D01	08719214223458	LOT 20201169
CryoTreq	CT00.D01	08719214223458	LOT 20201679
CryoTreq	CT00.D01	08719214223458	LOT 20201776
CryoTreq	CT00.D01	08719214223458	LOT 20202426
CryoTreq	CT00.D01	08719214223458	LOT 20213725
CryoTreq	CT00.D01	08719214223458	LOT 20214150
CryoTreq	CT00.D01	08719214223458	LOT 20214155

The intended purpose
The CryoTreq is a disposable handheld instrument intended for ophthalmic surgery. It creates a tip at cryogenic temperatures by evaporation of N_2O 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, Vitreq 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 Vitreq'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 Vitreq 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
Vitreq 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

Vitreq B.V. Seggelant-Noord 2, 3237 MG Vierpolders, The Netherlands, T: +31 181 745090, F: +31 181 478583
E: info@vitreq.com, www.vitreq.com, bank account NL05ABNA0513964088, Chamber of Commerce 60972084

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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	LOT 20201169
CryoTreq	CT00.D01	08719214223458	LOT 20201679
CryoTreq	CT00.D01	08719214223458	LOT 20201776
CryoTreq	CT00.D01	08719214223458	LOT 20202426
CryoTreq	CT00.D01	08719214223458	LOT 20213725
CryoTreq	CT00.D01	08719214223458	LOT 20214150
CryoTreq	CT00.D01	08719214223458	LOT 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 Vitreq B.V.

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

Sincerely,

Mr. Christian Neele
Group Leader, Regulatory Affairs at Vitreq 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 21st, 2021

Please check the appropriate response(s)

STEP 1: Evaluate your inventory for

Product Designation	REF#:	GTIN#:	Lot Numbers:
CryoTreq	CT00.D01	08719214223458	LOT 20201169
CryoTreq	CT00.D01	08719214223458	LOT 20201679
CryoTreq	CT00.D01	08719214223458	LOT 20201776
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CryoTreq	CT00.D01	08719214223458	LOT 20214150
CryoTreq	CT00.D01	08719214223458	LOT 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
		☐Boxes ☐Pieces
		☐Boxes ☐Pieces
		☐Boxes ☐Pieces
		☐Boxes ☐Pieces
		☐Boxes ☐Pieces
		☐Boxes ☐Pieces
		☐Boxes ☐Pieces
		☐Boxes ☐Pieces
		☐Boxes ☐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 21st, 2021 to BVI_FA_21_003@stericycle.com**.

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

IFS num: 1597774