

Vitrex B.V.
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URGENT Field Safety Notice

CryoTreq REF# CT00.D01

Voluntary recall of affected lots

21st March 2023

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 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	20214450
CryoTreq	CT00.D01	08719214223458	20214366
CryoTreq	CT00.D01	08719214223458	20214367
CryoTreq	CT00.D01	08719214223458	20214518
CryoTreq	CT00.D01	08719214223458	20214522
CryoTreq	CT00.D01	08719214223458	20214615
CryoTreq	CT00.D01	08719214223458	20214744
CryoTreq	CT00.D01	08719214223458	20214745
CryoTreq	CT00.D01	08719214223458	20214961
CryoTreq	CT00.D01	08719214223458	20214962
CryoTreq	CT00.D01	08719214223458	20215203
CryoTreq	CT00.D01	08719214223458	20215204
CryoTreq	CT00.D01	08719214223458	20215479
CryoTreq	CT00.D01	08719214223458	20216263
CryoTreq	CT00.D01	08719214223458	20216264
CryoTreq	CT00.D01	08719214223458	20216010
CryoTreq	CT00.D01	08719214223458	20227952
CryoTreq	CT00.D01	08719214223458	20227950
CryoTreq	CT00.D01	08719214223458	20227951
CryoTreq	CT00.D01	08719214223458	20228408
CryoTreq	CT00.D01	08719214223458	20228657
CryoTreq	CT00.D01	08719214223458	20228897
CryoTreq	CT00.D01	08719214223458	20228898
CryoTreq	CT00.D01	08719214223458	20229034
CryoTreq	CT00.D01	08719214223458	20229138
CryoTreq	CT00.D01	08719214223458	20229334
CryoTreq	CT00.D01	08719214223458	20229460



Product Designation	REF#:	GTIN#:	Lot Numbers:
CryoTreq	CT00.D01	08719214223458	20229630
CryoTreq	CT00.D01	08719214223458	20229748
CryoTreq	CT00.D01	08719214223458	20230261
CryoTreq	CT00.D01	08719214223458	20221083
CryoTreq	CT00.D01	08719214223458	20221140
CryoTreq	CT00.D01	08719214223458	20221364
CryoTreq	CT00.D01	08719214223458	20221746
CryoTreq	CT00.D01	08719214223458	20221894
CryoTreq	CT00.D01	08719214223458	20222365

The intended purpose

The CryoTreq is a disposable handheld instrument intended for ophthalmic surgery. It creates a tip at cryogenic temperatures by evaporation of N₂O 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.

Description of the Problem:

Vitrex B.V. has become aware of two incidents which described that a CryoTreq device suddenly and forcefully disassembled after surgical procedure was completed. Both incidents reported no patient injury and Vitrex B.V. is not aware of any other complaints related to this issue.

Risk to Health

Vitrex B.V. has determined through its investigation and risk assessment that there is the potential for long-term or permanent impairment of patient or user if a CryoTreq device suddenly or forcefully disassembles during a cryosurgery procedure. The timing of when this failure mode could occur after activation remains unclear, and thus BVI advises to stop using CryoTreq immediately.

Advise on Action to be Taken by the User:

1. Stop using CryoTreq **IMMEDIATELY**. Examine your inventory and quarantine product from all lots subject to this voluntary recall.
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: BVICryoTreq2023@sedgwick.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.
6. All device related incidents should be reported to the respective national competent authorities.

Email:

BVICryoTreq2023@sedgwick.com

Phone: +44 20 7660 1528



Credit will be provided to consignees who have replied with confirmation of receiving affected product. Please include in the subject line: Master Case PIR 00424262.

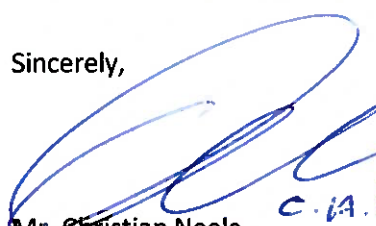
Please direct any questions regarding credit to our customer service department by email:


Country	Customer Service Email
UK	UKCustomerSupport@bvimedical.com
FR	serviceclient@bvimedical.com
DE/ AT	Kundendienst@bvimedical.com
IT	servizioclienti@bvimedical.com
ROW	ROWCustomerSupport@bvimedical.com

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

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

Sincerely,


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


BVI / Vitreq B.V.
Seggelant-Noord 2
3237 MG Vierpolders
The Netherlands
T: +31 (0) 745 090



Attachment 1 - Response Form

CryoTreq REF# CT00.D01

Please complete and return this response form no later than 10th April 2023

Please check the appropriate response(s)

STEP 1: Evaluate your inventory for

Product Designation	REF#:	GTIN#:	Lot Numbers:
CryoTreq	CT00.D01	08719214223458	20214450
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CryoTreq	CT00.D01	08719214223458	20221140
CryoTreq	CT00.D01	08719214223458	20221364
CryoTreq	CT00.D01	08719214223458	20221746
CryoTreq	CT00.D01	08719214223458	20221894
CryoTreq	CT00.D01	08719214223458	20222365



Please check ALL appropriate boxes.

- I have read and understand the recall instructions provided in the **March 21st, 2023** 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



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 10th April 2023 to BVICryoTreg2023@sedgwick.com

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