Vitreq B.V.
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www.bvimedical.com

URGENT Field Safety Notice

VITREQ 25G DISPOSABLE MICRO SCISSORS REF# SC25.D01 AND REF# SC25.D03

Voluntary Recall of Affected Lots

May 12, 2023

Dear Customer,

VitreQ B.V. (SRN **NL-MF-000000424**) is issuing this Field Safety Notice to make you aware of a mislabeling of vitreoretinal ***25G Disposable Micro Scissors*** (see Table 1) that have been sent to your facility. We are providing this notification, so you can check your inventory immediately.

Details on Affected Devices:

Table 1

Product Designation	REF#:	GTIN#:	Lot Numbers:
25G Scissors, Vertical	SC25.D01	08719214220396	LOT 20228851
25G Scissors, Horizontal Curved	SC25.D03	08719214220433	LOT 20228641

The Intended Purpose
VitreQ's disposable micro scissors are hand-held manual instruments designed to cut either anterior or posterior segment tissues during ophthalmic surgery.

Description of the Problem:
VitreQ B.V. became aware of incorrect labeled 25G Disposable Micro Scissors. The product labeling does not accurately describe the type of micro scissors in the product package. See detail below:

- **SC25.D01** (25G Scissors, Vertical) **LOT 20228851** contains **SC25.D03** (25G Scissors, Horizontal Curved) products.

Product labeled as:
SC25.D01

Actual content:
SC25.D03

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- **SC25.D03** (25G Scissors, Horizontal Curved) **LOT 20228641** contains **SC25.D01** (25G Scissors, Vertical) products.

Product labeled as: **SC25.D03**	Actual content: **SC25.D01**
	

Risk to Health
The vitreoretinal scissors facilitate cutting of anterior and posterior segment tissues during ophthalmic surgery. As cutting in tissue is done with 100% visual feedback for the user, there is no physical and direct patient risk for using these mislabeled instruments. As a worst-case assumption, the surgeon requests a new scissors during surgery which will lead to delay of treatment within the procedure. It has been determined by a medical expert in ophthalmology that the risk associated with the use of these products is low.

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Advise on Action to be Taken by the User:

1. **IMMEDIATELY** examine your inventory and quarantine product from all lots subject to this voluntary recall.

Product Designation	REF#:	GTIN#:	Lot Numbers:
25G Scissors, Vertical	SC25.D01	08719214220396	LOT 20228851
25G Scissors, Horizontal Curved	SC25.D03	08719214220433	LOT 20228641

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 replace the items free of charge, 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: recall@bvimedical.com. Reference **PIR# 00443443** in all your communication.

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 customer service department. If you need further assistance, you can contact us using the information below. Reference **PIR# 00443443** in all your communication.

   Email: UKCustomerSupport@bvimedical.com
   Phone: +44 1865 601 256 (option 3)

BVI values your business and is committed to taking the actions necessary to prevent reoccurrence. If you have questions regarding this matter, please call BVI Customer Service Department, at +44 1865 601 256 (option 3).

We value your business and apologize 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 PIR# 00443443

VITREQ 25G DISPOSABLE MICRO SCISSORS
REF# SC25.D01 AND REF# SC25.D03
Voluntary Recall of Affected Lots

Please complete and return this response form no later than May 26th, 2023

Please check the appropriate response(s)

STEP 1: Evaluate your inventory for

Product Designation	REF#:	GTIN#:	Lot Numbers:
25G Scissors, Vertical	SC25.D01	08719214220396	LOT 20228851
25G Scissors, Horizontal Curved	SC25.D03	08719214220433	LOT 20228641

Please check ALL appropriate boxes.

☐ I have read and understand the recall instructions provided in the May 12, 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
		☐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 26th May, 2023 to** recall@bvimedical.com referencing **PIR# 00443443** as email subject.

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