Vitreq a company of: BVI

Vitreq

URGENT Field Safety Notice

VITREQ 25G DISPOSABLE MICRO FORCEPS REF# FC25.D05 AND REF# FC25.D07 Voluntary Recall of Affected Lots

November 30, 2021

Dear Valued Customer,

Vitreq B.V. is issuing this Field Safety Notice to make you aware of a mislabeling of three vitreoretinal ***25G Disposable Micro Forceps*** (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 Forceps, Eckardt Endgripping	FC25.D05	08719214223458	LOT 20214910
25G Forceps, Eckardt Endgripping	FC25.D05	08719214223458	LOT 20215770
25G Forceps, Shah Xtra Grip	FC25.D07	08719214223458	LOT 20215331

The Intended Purpose
Vitreq's Disposable Micro Forceps are hand-held manual instruments designed to grasp and manipulate intraocular tissues during ophthalmic surgery.

Risks to Health
The vitreoretinal forceps facilitate delicate removal of thin and transparent acellular membrane on the surface of the retina. The vitreoretinal surgeon may choose an Eckardt Endgripping, Shah Xtra Grip, Serrated Gripping or ILM Endgripping, for the removal retinal tissue. It should be noted that all products in scope of this risk assessment are the same 25 gauge devices. The selection of a 25G Disposable Micro Forceps with a specific instrument tip is based on user preference. It has been determined by a medical expert in ophthalmology that the risk associated with the use of these products is very low.

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

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

- **FC25.D05** (25G Forceps, Eckardt Endgripping) **LOT 20215770** contains **FC25.D02** (25G Forceps, Serrated Gripping) products.

Product labeled as:
FC25.D05

Actual content:
FC25.D02

- **FC25.D05** (25G Forceps, Eckardt Endripping) **LOT 20214910** contains **FC25.D03** (25G Forceps, ILM Endgripping) products.

Product labeled as:
FC25.D05

Actual content:
FC25.D03

- **FC25.D07** (25G Forceps, Shah Xtra Grip) **LOT 20215331** contains **FC25.D05** (25G Forceps, Eckardt) products

Product labeled as:
FC25.D07

Actual content:
FC25.D05

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PLEASE perform the following actions:

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

Product Designation	REF#:	GTIN#:	Lot Numbers:
25G Forceps, Eckardt Endgripping	FC25.D05	08719214223458	LOT 20214910
25G Forceps, Eckardt Endgripping	FC25.D05	08719214223458	LOT 20215770
25G Forceps, Shah Xtra Grip	FC25.D07	08719214223458	LOT 20215331

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. You are encouraged to use a copy of this recall notification letter when contacting your customers.

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: UKCustomerSupport@bvimedical.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 customer service department. If you need further assistance, you can contact us using the information below.

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

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

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).

Sincerely,

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Attachment 1 - Response Form

VITREQ 25G DISPOSABLE MICRO FORCEPS REF# FC25.D05 AND REF# FC25.D07 Voluntary Recall of Affected Lots

Please complete and return this response form no later than December 24th, 2021

Please check the appropriate response(s)

STEP 1: Evaluate your inventory for

Product Designation	REF#:	GTIN#:	Lot Numbers:
25G Forceps, Eckardt Endgripping	FC25.D05	08719214223458	LOT 20214910
25G Forceps, Eckardt Endgripping	FC25.D05	08719214223458	LOT 20215770
25G Forceps, Shah Xtra Grip	FC25.D07	08719214223458	LOT 20215331

Please check ALL appropriate boxes.

☐ I have read and understand the recall instructions provided in the November 30, 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

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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 December 24th, 2021 to** UKCustomerSupport@bvimedical.com.

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

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