Vitreq a company of:

BVI

Vitreq

URGENT Field Safety Notice

Vitreq Vitrectomy fluid/gas handling Instrument
Vitreq Ophthalmic infusion/aspiration cannula, single-use
Voluntary recall of affected lots

December 16, 2019

Dear Customer,
VitreQ B.V. is issuing this Field Safety Notice to inform you about a potential issue that may affect disposable Vitreq products identified below. We are providing this notification, so you can check your inventory immediately.

Details on Affected Devices:

Product Designation	REF#:	GTIN#:	Lot Numbers:
Vitreq 23G BF Blunt Needles	BF23.D51	8719214221126	All
Vitreq 23G BF Brush Needles	BF23.D52	8719214221140	All
Vitreq 25G BF Blunt Needles	BF25.D51	8719214221164	All
Vitreq 25G BF Brush Needles	BF25.D52	8719214221188	All
Vitreq 20G BF Blunt Needles	BF20.D51	8719214221089	All
Vitreq 20G BF Brush Needles	BF20.D52	8719214221102	All
Vitreq 23G PFC Injection Needle	MD23.D01	8719214221362	All
Vitreq 25G PFC Injection Needle	MD25.D01	8719214221386	All
Vitreq 20G PFC Injection Needle	MD20.D01	8719214221409	All
Vitreq 23G VFI Cannula	CN23.D03	8719214221423	All
Vitreq 25G VFI Cannula	CN25.D03	8719214221447	All
Vitreq 27G VFI Cannula	CN27.D03	8719214221461	All
Vitreq 20G VFI Cannula	CN20.D03	8719214221485	All
Vitreq 23G Silicone Tipped Cannula	CN23.D01	8719214221508	All
Vitreq 25G Silicone Tipped Cannula	CN25.D01	8719214221522	All
Vitreq 23G Pick Needles	CN23.D04	8719214221584	All
Vitreq 25G Pick Needles	CN25.D04	8719214221607	All
Vitreq 23G Blunt Needles with luer-lock connector	CN23.D05	8719214221621	All
Vitreq 25G Blunt Needles with luer-lock connector	CN25.D05	8719214221645	All
Vitreq 27G Blunt Needles with luer-lock connector	CN27.D05	8719214221669	All
Vitreq 20G Blunt Needles with luer-lock connector	CN20.D05	8719214221683	All

The intended purpose
The needles and cannulas are intended to facilitate infusion, irrigation and/or aspiration of fluids/gases during ophthalmic surgery.

Description of the Problem:
During routine production, 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 0.51% of manufactured units. These devices are not meeting the internal expectations of VitreQ B.V. or our customers.

Use of a non-sterile device may expose the patient to infectious agents, increasing patient risk of developing infection. VitreQ B.V. has not received any reports of incidents related to this breach of sterile barrier or infection related to these products.

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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.

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:
Vitreq 23G BF Blunt Needles	BF23.D51	8719214221126	All
Vitreq 23G BF Brush Needles	BF23.D52	8719214221140	All
Vitreq 25G BF Blunt Needles	BF25.D51	8719214221164	All
Vitreq 25G BF Brush Needles	BF25.D52	8719214221188	All
Vitreq 20G BF Blunt Needles	BF20.D51	8719214221089	All
Vitreq 20G BF Brush Needles	BF20.D52	8719214221102	All
Vitreq 23G PFC Injection Needle	MD23.D01	8719214221362	All
Vitreq 25G PFC Injection Needle	MD25.D01	8719214221386	All
Vitreq 20G PFC Injection Needle	MD20.D01	8719214221409	All
Vitreq 23G VFI Cannula	CN23.D03	8719214221423	All
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Vitreq 20G Blunt Needles with luer-lock connector	CN20.D05	8719214221683	All

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.

2. 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.

3. Return the **Attachment 1: Response Form** to BVI by e-mail to UKCustomerSupport@bvimedical.com.

4. **Return ALL quarantined product from the affected lots** to our company by contacting the BVI Customer Service at the respective number below:

   TEL: +44 1865 601 256 Option 3

This action has been reported to the relevant competent authorities in your country.

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

Sincerely,

C.M. NEELE

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

Vitreq a company of: BVI

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Attachment 1 - Response Form

Vitreq Vitrectomy fluid/gas handling Instrument
Vitreq Ophthalmic infusion/aspiration cannula, single-use

Please complete and return this response form
no later than December 30th, 2019

Please check the appropriate response(s)

STEP 1: Evaluate your inventory for

Product Designation	REF#:	GTIN#:	Lot Numbers:
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Vitreq 23G BF Brush Needles	BF23.D52	8719214221140	All
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Vitreq 20G Blunt Needles with luer-lock connector	CN20.D05	8719214221683	All

Please check ALL appropriate boxes.

☐ I have read and understand the recall instructions provided in the December 16, 2019 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

Vitreq a company of:

		☐Boxes ☐Pieces
		☐Boxes ☐Pieces
		☐Boxes ☐Pieces
		☐Boxes ☐Pieces
		☐Boxes ☐Pieces
		☐Boxes ☐Pieces
		☐Boxes ☐Pieces
		☐Boxes ☐Pieces

STEP 2: Recipient please complete the form

Your Name: _____

Title: _____

Tel. number: ( ) _____

Firm name: _____

Email: _____

Address: _____

City/state: _____

STEP 3: Return the Form

Please **e-mail this completed Response Form by December 30th, 2019 to** UKCustomerSupport@bvimedical.com.

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