



Field Safety Notice
BVI_FA_22_003
Immediate Attention Required
BVI CustomEyes® Kits (Syringe 1ml LS 40IU)

Date: 10 June 2022

Dear Device Customer/Distributor,

Beaver-Visitec International, Ltd., Bidford, UK (BVI) has received a Field Safety Notice (FSN) from Becton Dickinson (BD) (Urgent FSN: MPS-18-1209, dated 8 Jan 2021). An additional notification, with a similar matter, in the form of the BD Customer Notification (FY22-04-0004, dated 20 APR 2022) that identifies a potential risk regarding the BD Syringes as described below.


Description of the Problem

You may have received the following BD Syringe supplied as part of your BVI CustomEyes® Kits. The BD FSN related to their selected syringe is for intraocular injections is stated below:

BD has become aware that when syringes and needles are used for intraocular injections, the potential exists for “floaters” in patients’ eyes which are believed to be due to silicone. (Note: Syringes and needles manufactured by BD have silicone applied to the inside of the barrels to provide lubrication for the plunger stopper, allowing it to move easily). The potential hazard is deposition of silicone oil (SO) droplets in the vitreous. The potential harm could be symptomatic “floaters” in the patient’s field of vision which, normally, are tolerable and resolve over a few months. However, if sufficiently bothersome, floaters may lead to a vitrectomy for their removal.

Please be aware the following BD Syringe may be supplied within your BVI CustomEyes® Kits. You can identify these components by the name on the BVI **Kit Contents** label (See Table 1). **Note: No other components within your kit(s) are affected.**

Table 1

BVI Kit Content Label Description	Representative BD Device Image
Syringe 1ml LS 40IU (BVI Kit Component #303173)	

Next steps

BVI is taking this immediate action to inform you of the BD FSN risks, as explained above, of the potential hazard and harm that may occur with the use of the BD Syringe.

Beaver-Visitec International Sales Limited | Centurion Court, 85b Park Drive, Milton Park | Abingdon, Oxon OX14 4RY |
bvimedical.com



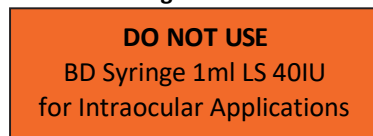
Regulatory requirements place restrictions on how devices, such as syringes, can be placed on the market for specified intended use and/or medical indication. Because BD has communicated that they will begin labelling their syringes to state, "Not Validated for Intraocular Use," BVI will no longer be able to place the new BD labelled devices within the BVI CustomEyes® Kits on the market.

Action Required

Please be advised that it is the customer's decision on how to proceed with product labeling or destruction as BVI is not requesting the product to be returned. However, BVI is asking you to take the following action as part of this awareness:

- (a) Please check your stock of kits affected (Fig.2) by this safety information. Users should stop using and distributing all affected kits and immediately quarantine them until the following action is completed:
 - a. Affix the attached orange label (Fig. 1) to the BVI CustomEyes® Kits containing the BD Syringe concerned by this letter. Contact at OUS-BDSyringe@Sedgwick.com if additional labels are needed.
- (b) Please complete the table below and customer acknowledgement response card and return by **23 June 2022** to assist BVI in making sure all our customers have received and understood this communication. In the event you have further distributed this product please provide a copy of this notice to your customers as well.

Figure 1:



Depending on the number of BVI CustomEyes® Kits to relabel, BVI will send you labels so that you can organize their re-labeling; some are provided to you along with this FSN. Please contact OUS-BDSyringe@Sedgwick.com for additional labels if needed. The orange warning labels should be affixed in the immediate vicinity of the bag label of each BVI CustomEyes® Kits. Note, the remaining stock within BVI distribution centers will be delivered to you as appropriate **with the same orange labels affixed** as above.

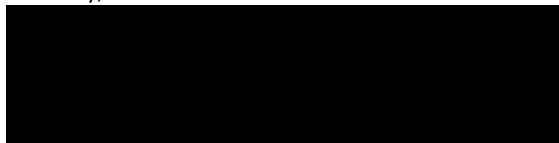
Please pass this notice on to end users, physicians, risk managers, logistics / distribution centers, etc. Please distribute this Field Safety Notice until all necessary action has been taken within your organization. The market surveillance authority in your country has been notified following the applicable legislation of this communication to customers.

Recommendations for distributors

If you are a distributor, please pass this Field Safety Notice on to all of your customers who have received products affected by this Field Safety Notice. Your customer will then be required to complete the acknowledgment form and return it to you.

BVI aims for high-quality and compliant products that support you in preserving your patient's vision and regrets this inconvenience. For additional questions or concerns please do not hesitate to contact BVI or for more information contact details at OUS-BDSyringe@Sedgwick.com.

Sincerely,





Field Safety Notice - BVI_FA_22_003
ACKNOWLEDGMENT OF RECEIPT OF THE NOTIFICATION

Response Form
BVI CustomEyes® Kits (Syringe 1ml LS 40IU)
Return by 23 June 2022

Required Actions:

Please be advised that it is the customer's decision on how to proceed with product labeling or destruction as per your facilities local disposal policies as BVI is not requesting the product to be returned. However, BVI is asking you to take the following action as part of this awareness:

1. **Check your stock of kits affected by this safety information.** Users should stop using and distributing all affected kits and **immediately quarantine them until the following action is completed:**
 - a. **Affix the orange label** to the affected BVI CustomEyes® Kits containing the BD Syringe concerned by this letter. **Number of extra labels required.**
2. **Complete the table below regarding affected kits and the customer information in the acknowledgement response form on the following page and return by 23 June 2022** to assist BVI in making sure all our customers have received and understood this communication. In the event you have further distributed this product please provide a copy of this notice to your customers as well.
3. **Pass this notice on** to end users, physicians, risk managers, logistics / distribution centers, etc.

Your signature indicates you have taken the above actions.

Customer Name: _____

Customer Title: _____

Customer Signature: _____

Email address: _____

Telephone: () _____

Company Name: _____

Company Address: _____

Company Country: _____

Please complete the section above, sign, and return this form, via email, to: OUS-BDSyringe@Sedgwick.com .
ATTN: **BVI_FA_22_003**