



Field Safety Notice - March 2021 Immediate Attention Required

BVI's CustomEyes® Kits and Malosa® Kits containing BD Syringes and/or Needles

Dear Doctor and Customer,

Beaver-Visitec International, Ltd., Bidford, UK (BVI) has received the attached Becton Dickinson (BD) Field Safety Notice (Urgent FSN: MPS-18-1209, dated 8 Jan 2021) and the BD Product Notification (MDS-21-4026, dated 28 Jan 2021) in relation to a potential risk identified regarding their BD Syringes and/or Needles.

Description of the Problem





One or more of the following BD Syringes and/or Needles are components supplied in your BVI CustomEyes® Kits and Malosa® Kits. The BD FSN related to their selected syringes and needles 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 Syringes and/or Needles components may be supplied within your BVI CustomEyes® Kits and Malosa® 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 Images
Syringes	
Syringe 1ml Luer Lock (BVI Kit Component #309628)	

Syringe - 1ml Luer Lock (BVI Kit Component #MMSU0024)	
1 ml Luer Lock Syringe (BVI Kit Component #60300139)	
Luer Slip Syringe 1ml (BVI Kit Component # 300328)	
Syringe 1ml Luer Slip (BVI Kit Component # 301025)	
Needles	
Blunt filter needle 5 micron, 18G x 1 ½ in. (1.2mm x 40mm) (BVI Kit Component #305211)	 (Preparation and filling syringe only)
Needle 30g x 1/2 in. (BVI Kit Component #304000)	

* See Attached BD FSN and Product Notification

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 Syringes and/or Needles.

Regulatory requirements place restrictions on how devices, such as syringes and needles, 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 and needles 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 and Malosa® Kits on the market. Please know that BVI is currently assessing suitable alternatives and will inform you about the result as quickly as possible.

Action Required

NOTE: All affected Kits include a lot number of 3366671 or lower. To find the lot number of your Kit, see example below:

LOT 3366671

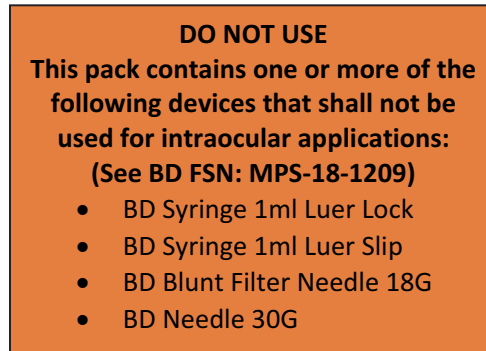
Please be advised that it is the customer's decision on how to proceed with product labeling or destruction as BVI is not requesting the product to be returned. However, BVI is asking you to take the following action as part of this awareness:

- (a) Please **check your stock of kits affected 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** to the BVI CustomEyes® Kits and Malosa® Kits containing BD Syringes and/or Needles concerned by this letter.
- (b) Please **complete the table below and customer acknowledgement response card and return by 31 March 2021** 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.



Orange label (example provided below as Figure 1) to be affixed to the BVI CustomEyes® Kits and Malosa® Kits containing a syringe and/or needle concerned by this letter.

Figure 1:



Depending on the number of BVI CustomEyes® Kits and/or Malosa® 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 BVI_FA_21_001@Stericycle.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 and Malosa® Kits.

BVI aims for high-quality and compliant products that support you in preserving your patient's vision and regrets this inconvenience. As of 26 February 2021, your pack price will be reduced to reflect the missing items until an alternative is included.

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.

For additional questions or concerns please do not hesitate to contact BVI or for more information contact details at BVI_FA_21_001@Stericycle.com.

Sincerely,

A handwritten signature in black ink, appearing to read "Robin Rowe".

Robin Rowe, MSc, RAC
Sr. Director Regulatory and Medical Affairs
RRowe@bvimedical.com



Field Safety Notice - March 2021
ACKNOWLEDGMENT OF RECEIPT OF THE NOTIFICATION

Response Form
BVI CustomEyes® Kits and Malosa® Kits
Return by 31 March 2021

Please be aware the following BD Syringes and/or Needles components may be supplied within your BVI CustomEyes® Kits and Malosa® Kits. You can identify these components by the name on the BVI Kit Content label.	
Note: No other components within your kit(s) are affected.	
BVI <i>Kit Content</i> label description	BVI Component # internal reference only.
Syringes	
Syringe 1ml Luer Lock	#309628
Syringe - 1ml Luer Lock	#MMSU0024
1 ml Luer Lock Syringe	#60300139
Luer Slip Syringe 1ml	# 300328
Syringe 1ml Luer Slip	# 301025
Needles	
Blunt filter needle 5 micron, 18G x 1 ½ in. (1.2mm x 40mm)	#305211
Needle 30g x 1/2 in.	#304000

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 and Malosa® Kits containing BD Syringes and/or Needles concerned by this letter.
2. **Complete the table below regarding affected kits and the customer information in the acknowledgement response form on the following page and return by 31 March 2021** 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.

RESPONSE FORM		
Product Information		
BVI Product Description	Customer checked stock. Quantity on-hand. Number of extra labels required.	
	Number of kits on-hand / Lot Number(s).	Number of extra labels required.
BVI CustomEyes® Kits		
BVI Malosa® Kits		



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:
BVI_FA_21_001@Stericycle.com .

ATTN: **BVI_FA_21_001**