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09th December 2020

URGENT: FIELD SAFETY NOTICE – MPS-18-1209

BD Syringes and Needles

REF: Refer to Table 1

Type of Action: Advisory

Attention: Clinical Engineering Managers, Clinical Personnel, Risk Managers

This letter contains important information which requires your attention.

Dear Customer,

BD is issuing this Field Safety Notice for the **BD Syringes and Needles** listed in Table 1 below to advise of an added caution. Our distribution records indicate that your organisation may have received the product numbers below.

Table 1: List of impacted products

REF	Product Description
309628	BD 1ml Syringe Luer-Lok™ Tip
303172	BD Plastipak™ 1ml Luer
305211	BD Blunt Fill Needle with Filter 18G x 1 1/2 (1.2mm x 40mm) (5µm)
302809	BD Microlance™ 3 30G x ½" 0,3 x 13mm
304000	BD Microlance™ 3 30G x ½" 0,3 x 13mm

Description of the Problem

It has been identified through post-market surveillance reviews that a caution should be added to the Instructions for Use (IFU) for the products listed in Table 1 above.

This Field Safety Notice is providing the following caution and BD recommends it be applied when using the product.

Intraocular use is not validated by BD

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.

BD became aware of other potential risks associated with intraocular injections, such as endophthalmitis (inflammation of the interior of the eye), which may be associated with failure modes not previously identified by BD.

To reduce this risk of silicone floaters and inflammation or irritation that may occur, HCPs should only use the syringes and needles provided with ocular medications that are specifically designed and labelled for intravitreal injection.

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Following reports of use in intra-ocular procedures BD is updating the IFU and future product being shipped by BD will contain the caution.

Advice on actions to be taken by the user

1. Ensure the contents of this Field Safety Notice, including the contraindications, are read and understood by those within your organisation who may use the BD syringes and needles listed in Table 1 above.
    - If you have further distributed the product to other organisations, please identify those organisations and notify them at once of this Field Action.

2. Please complete the Customer Response form (Page 3) and return the completed form to BD at <<insert email address>> no later than **<<date>>**.

3. If you are no longer in possession of or no longer use the -devices listed in above, please indicate this on the response form and return to BD so we may update our records.

Should you have any questions or experience any issues associated with the product or issue described in this Field Safety Notice, please contact your local BD representative. BD has notified the appropriate regulatory agencies of these actions.

BD is committed to ensuring that safe and effective product is available to customers and this Field Safety Notice is taken with due consideration of this commitment.

Thank you for your attention and cooperation.

Yours sincerely,

William David
Sr. Director, Post Market Quality EMEA

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Customer Acknowledgement Form – MPS-18-1209

BD Syringes and Needles

Please read in conjunction with Field Safety Notice MPS-18-1209 and return the completed and signed form as soon as possible or **no later than <<date>>** to <<email>>.

By completing the information below you confirm you have read, understood and distributed the contents of this Field Safety Notice accordingly.

Name of Facility	
Name of Hospital/s covered by this response:	
Email Address	
Telephone Number	
Name	
Signature	
Date	