

Date: 2021-04-16

## **Urgent Field Safety Notice**

### **Custom Procedure Trays (CPTs) for ophthalmology containing affected syringes and needles from BD**

**For Attention of:** Distributors / Industry Partners / Clinical Engineering Managers, Clinical Personnel, Risk Managers

Dear Customer,

This letter is to advise you that **Becton Dickinson (BD)** has issued a **Field Safety Notice MPS-18-1209** and **PRODUCT NOTIFICATION– MDS-21-4026** related to the syringes and needles listed in Table 1.

### **Information on Affected Devices**

Table 1: Impacted STS Product IDs

BD ID	Item Description	STS Product ID
Sterile BD branded syringes and needles		
309628	BD 1ml Syringe Luer-Lok™ Tip	
303172	BD Plastipak™ 1ml Luer	<b>B675051-1</b>
305211	BD Blunt Fill Needle with Filter 18G x 1 1/2 (1.2mm x 40mm) (5µm)	<b>B225045-1</b>
302809	BD Microlance™ 3 30G x 1/2" 0,3 x 13mm	
304000	BD Microlance™ 3 30G x 1/2" 0,3 x 13mm	<b>B225097-1</b>
Non-sterile BD branded syringes and needles		
300328	SYRINGE NS 1ML LS	<b>B675051</b>
300745	NEEDLE NS 30GA 1/2IN	
300932	BULK NEEDLE NS 30GA 1/2IN	<b>B225097</b>
301025	SYRINGE 1ML S/T BNS	
301064	SYRINGE 1ML S/T NO SHIELD NO MARKING BNS	
301664	NEEDLE NS 30GA 7/8IN BSG W/O SIL W/O SHD	
302047	NEEDLE NS 30GA 1/2IN BNS YEL HUB TW EURO	
305202	Blunt Filter Needle 19x1-1/2 in. TW BNS	
305236	Blunt Filter Needle 18x1-1/2 in. BNS	<b>B225045</b>
309648	SYRINGE 1ML LL BNS	<b>B675052</b>

### **Reason for Field Safety Corrective Action (FSCA)**

According to information from BD this Field Safety Notice is providing a caution for listed syringes and needles and a recommendation to apply this caution when using the products:

#### **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."*

Up to this point of time neither complaints nor (serious) incidents were registered concerning **STS Medical Group** CPTs regarding the described issue.

BD is now adding a caution "Intraocular use is not validated by BD" to the Instructions for Use (IFU) for the products listed in Table 1.

## Type of Action to mitigate the risk

At **STS Medical Group** the safety of patients and users has the highest priority. Therefore, we will no longer put the affected products within Ophthalmic CPTs. For the remaining CPTs available in our warehouse, appropriate "warning label" will be applied.

**"FSN 21-MSP-041: Do not use BD syringes nor cannulas for intravitreal injections."**

All other CPTs, which are not intended for intravitreal injections, are not affected by this Field Safety Notice, and can be used as usual.

## Action To Be Taken by the User

- Please urgently **check your inventory** and promptly put on quarantine the concerned CPTs.
- CPTs in stock at **STS Medical Group** can only be shipped to customers after labelling and customer confirmation.
- **Do not use the affected BD products for intraocular injections** and remove them from the CPT before use.
- All other components of the respective CPTs are not affected and can be used safely.
- Please ensure that the content of this FSN are read and understood by those who may use the BD syringes and cannulas listed in Table 1 above.
- If you have further distributed affected BD products to other organizations, please identify those organizations and notify them at once of this FSN.
- Complete the acknowledgement form and return by either fax or email as soon as possible, but not later than **May 7th, 2021** and indicate the quantity of CPTs in your stock, to receive the necessary quantity of "warning label".
- Put the received "warning label" on each affected CPT in your stock and on each box under the box label.

**STS Medical Group** continues to look for alternatives for the affected BD products, but for now we are unable to offer an alternative. Thus, new productions of Ophthalmic CPTs will be without the products listed in Table 1.

Our Customer Service will contact you to discuss details for a credit note for the components which have been removed from the CPTs. This Field Safety Notice has been submitted to the Competent Authorities of the concerned countries within the European Economic Area (EEA).

We apologize for the inconvenience caused.

Thank you for your attention and cooperation.



**Attachments:**

1. Customer Acknowledgement Form

## Customer Acknowledgement Form

Please read in conjunction with FSN Ref: **21-MSP-041** and return the completed and signed form as soon as possible or **no later than May 7th, 2021**, to [RegAffairs-SKP@stsmedicalgroup.com](mailto:RegAffairs-SKP@stsmedicalgroup.com)

CPTs concerned by this FSN delivered to you are listed in the below:

Item Number	Quantity warning label required

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

<b>1. Customer Details</b>	
Organisation Name	
Organisation Address	
Department/Unit	
Shipping address if different to above	
Contact Name	
Telephone number	
Email	

<b>2. Customer action undertaken</b>			
<input type="checkbox"/>	I performed all actions requested by the FSN.		
<input type="checkbox"/>	I have destroyed affected devices – enter number destroyed and date complete.	Qty:	Lot/Serial Number:
		N/A	Comments:
<input type="checkbox"/>	I do not have any affected devices.		
Name		Customer print name here	
Signature		Customer sign here	
Date			