FSN Ref: PHFSN 2021-1 FSCA Ref: FSCA-PHFSN 2021-1

Date: 12-01-2021

Urgent Field Safety Notice
Custom Procedure Packs
Type of Action: Advisory

For Attention of*:Clinical Engineering Managers, Clinical Personnel, Risk Managers

Contact details of local representative (name, e-mail, telephone, address etc.)*
Pennine Healthcare, 300 City Gate, London Rd, Derby, DE24 8WY

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Urgent Field Safety Notice (FSN)
Custom Procedure Packs
Type of Action: Advisory

1. Information on Affected Devices*	
1.	1. Device Type(s)*
	Custom Procedure Packs
1.	2. Commercial name(s)
	Pennine Healthcare
1.	3. Unique Device Identifier(s) (UDI-DI)
1.	4. Primary clinical purpose of device(s)*
	Cardiac surgery, Embryo transfer pack, knee replacement tray, plastic surgery, Laparoscopic Gastric, shoulder pack, chin pack, shoulder pack, nose pack, cataract and eyelid pack, General surgery packs.
1.	5. Device Model/Catalogue/part number(s)*
	OMS-41700-1, OMS-13101-2, AUM-01500-0, AUM-14600-0, AUM 25200-0, BDI-00301-0, BOU-00203-0, MMN-06402-1, CTP-04500-1, CTP-02100-1, VNM-00100-1, OMS-40601-0, OMS-03702-4, OMS-03401-2, OMS-02802-2, OMS-02703-2, OMS-03602-3, OMS-02502-3, OMS-03201-2, OMS-42100-1, OMS-39302-0, MCG-58401-0, MCG-58601-0, OMS-37202-0, OMS-43700-1, OMS-03303-0, CTP-04500-1, OUP-09001-0
1.	6. Software version
1.	7. Affected serial or lot number range
1.	8. Associated devices

2 Reason for Field Safety Corrective Action (FSCA)*	
2.	1. Description of the product problem*
	BD Syringes/Needles are used in the above Pennine's custom procedure packs. BD has issued a FSN for its Syringes and Needles to advise of a new caution. "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. 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 (**see attached BD FSN for further details).** Pennine Healthcare has included impacted devices with the custom procedure packs listed above. The new caution issued by BD is to be communicated to the customers who received its products.
2.	2. Hazard giving rise to the FSCA*
	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.
2.	3. Probability of problem arising
	N/A
2.	4. Predicted risk to patient/users
	See above.
2.	5. Further information to help characterise the problem
2.	6. Background on Issue
2.	7. Other information relevant to FSCA
	This FSCA is advisory only to the users of Pennine's custom procedure pack which contain BD syringe and needle. The syringes and needles must not be used for ocular medications due to the increased potential for adverse eye conditions. "Intraocular use is not validated by BD"

	3. Type of Action to mitigate the risk*
3.	**1. Action To Be Taken by the User***

☐ Identify Device ☐ Quarantine Device ☐ Return Device ☐ Destroy Device

☐ On-site device modification/inspection

☐ Follow patient management recommendations

☐ Take note of amendment/reinforcement of Instructions For Use (IFU)

☒ Other ☐ None

1. Ensure the contents of this Field Safety Notice, including contraindications, are read and understood by those within your organisation who may use BD syringes and needles supplied with the procedure pack.
2. If you have further distributed the product to other organisations, please identify those organisations and notify them at once of this Field Action and supply them with a copy of BD FSN.
3. Please complete the customer response form supplied within this FSN and return the completed form to Pennine Healthcare at recalls@penninehealthcare.co.uk
4. If you no longer in possession or no longer use the devices listed in this FSN, please indicate this on the response form and return to Pennine Healthcare.

"Procedure pack supplied with syringe and needles are NOT to be used for ocular medications due to the increased potential for adverse eye conditions."

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3.	2. By when should the action be completed?	
3.	3. Particular considerations for: Choose an item. Is follow-up of patients or review of patients' previous results recommended? No N/A. The FSN is advisory only to let the user about the new caution identified from the syringe and needle supplier	
3.	4. Is customer Reply Required? * (If yes, form attached specifying deadline for return)	Yes 26 Feb 2021
3.	**5. Action Being Taken by the Manufacturer** ☐ Product Removal ☐ On-site device modification/inspection ☐ Software upgrade ☐ IFU or labelling change ☐ Other ☐ None 1. Communicate the new caution to Pennine customer who received packs containing syringes and needles that are supplied by BD.	
3	6. By when should the action be completed?	Specify where critical to patient/end user safety
3.	7. Is the FSN required to be communicated to the patient /lay user?	No
3	8. If yes, has manufacturer provided additional information suitable for the patient/lay user in a patient/lay or non-professional user information letter/sheet?	
	Choose an item. Choose an item.	

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	4. General Information*	
4.	1. FSN Type*	New
4.	2. For updated FSN, reference number and date of previous FSN	
4.	**3.** For Updated FSN, key new information as follows:	
	Summarise any key difference in devices affected and/or action to be taken.	
4.	4. Further advice or information already expected in follow-up FSN? *	No
4	5. If follow-up FSN expected, what is the further advice expected to relate to:	
4	6. Anticipated timescale for follow-up FSN	
4.	7. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	**Ivor Shaw Ltd. t/a Pennine Healthcare**
	b. Address	**300 City Gate London Road, Derby, DE24 8WY**
	c. Website address	
4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. * MHRA, Swedish Medical Products Agency, Netherlands (Dutch Health and Youth Inspectorate), Finnish Medicines Agency, Germany (Federal Institute for Drugs and Medical Devices), Poland (Office for Registration of Medicinal Products, Medical Devices and Biocidal Products)	
4.	9. List of attachments/appendices:	**FSN supplied by BD** **Customer acknowledgement form**
4.	10. Name/Signature	.... **Head of Regulatory Affairs** **Ivor Shaw Ltd. t/a Pennine Healthcare**

	Transmission of this Field Safety Notice
	This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. (As appropriate) Please transfer this notice to other organisations on which this action has an impact. (As appropriate) Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action. Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback..*

Note: Fields indicated by * are considered necessary for all FSNs. Others are optional.