ASEPTIC MEDICAL DEVICES
Newmarket Drive, Derby DE24 8SW
Tel: +44 (0) 1332 755622
Email: sales@asepticmedical.com
Website: www.asepticmedical.com

Urgent: Field Safety Notice

Aseptic Medical Devices (AMD)

Sterile Transfer Sets and Accessories

FSCA-Identifier – 2021/01

Type of Action – Field Safety Corrective Action

Date: 4th February 2021

Attention: All AMD customers who use packs containing 01ml BD Syringes and BD 18G Blunt Fill Filter Needles, and Distributors.

All batches of the below devices have been identified as containing devices in the Product Notification **MDS-21-4026** from Becton Dickinson.

Pack details:

Device Code	Unit of Sale UDI (Carton)	Device Code	Unit of Sale UDI (Carton)
BAR2501	5060466656802	**L05A01P**	5060466656680
BCUA002	5060466656284	**L05A01R**	5060466654112
CAST002	5060466656956	**L10A01S**	5060466658325
CHRI001	5060466655881	**L25A01S**	5060466654518
CHUR001	5060466655225	**PENN003**	5060466657038
CHUR002	5060466655232	**PRIN001**	5060466655805
CITY001	5060466658523	**S05A01A**	5060466652866
DAST006	5060466656307	**S05Q01A**	5060466657175
DERR001	5060466653306	**S10A01A**	5060466652927
DERR004	5060466656321	**S10A01B**	5060466654198
F05A06B	5060466656048	**S10Q01A**	5060466657311
F05Q06B	5060466658387	**S25A01A**	5060466650084
F10A06B	5060466655195	**SCHM001**	5060466658264
GWYN002	5060466657823	**SCHM002**	5060466658288
HERE001	5060466658141	**SOUT004**	5060466656147
ITHP001	5060466651319	**STJA001**	5060466656970
ITHP002	5060466651326	**STJA002**	5060466656994
L05A01N	5060466655935	**STOK001**	5060466657960

Description of the problem:

BD have alerted their industry partners of an issue regarding Bulk non-sterile purchased 1ml Syringes and Needles. Through post-market surveillance activities, BD have become aware that the intraocular use of the sterile, 01ml BD branded syringes and some Blunt Fill Filter Needles have been associated with events such as “floaters” and endophthalmitis (inflammation of the interior of the eye). BD is adding the following caution to its sterile product: *Intraocular use is not validated by BD.* Accordingly, BD recently issued a Field Safety Notice for these sterile, BD branded products (MPS-18-1209).

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Following BD's action and a risk review, AMD is adding the following caution to affected Device code specifications: *'Silicone lubricated syringes and needles have been associated with intraocular events such as 'floaters' and endophthalmitis (inflammation of the interior of the eye). Intraocular use is not validated by BD or AMD'.*

Action to be taken:
1. Ensure the contents of this Field Safety Notice are read and understood by those within your organisation who may use any of the products listed in the table. If you have further distributed the product to other organisations, please identify those organisations and notify them at once of this Field Safety Notice.
2. **For Customers –** Please complete the customer response form at the end of this document and return the completed form to Lyndon Boyer – Regulatory & Technical File Specialist regulatory@riversidemedical.co.uk no later than 05/03/2021
3. **For Distributors –** Please pass this Field Safety Notice to all customers and complete the Distributor response form at the end of this document and return the completed form to Lyndon Boyer – Regulatory & Technical File Specialist regulatory@riversidemedical.co.uk no later than 05/03/2021
4. If you are no longer in possession of or no longer use the devices listed in this notice, please indicate this in the response form and return to AMD so we may update our records.

Transmission of this Field Safety Notice:
Please pass this notice on to all those who need to be aware within your organization and to all customers where the affected devices have been or may have been transferred.
Please maintain awareness of this notice and accept our apologies for the inconvenience caused by this action.
Please complete and return the attached reply form, this will allow AMD to show appropriate action with informing customers and Distributors.
I can confirm that this FSN has been notified to the MHRA, our Notified Body and our EU Authorised Representative.
If you have any questions regarding this communication, please contact Clive Thornley on telephone number +44 7790 023996 or email Quality@riversidemedical.co.uk

Alternatively contact, for support:
Ian Strange – AMD Product Manager Tel +44 7884 868346

Yours Sincerely

Clive Thornley
Quality Manager

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Customer Reply Form

Urgent: Field Safety Notice – FSCA Identifier 2021/01

Aseptic Medical Devices (AMD) Sterile Transfer Sets and Accessories

Please complete:

Company Name		
Company Address		
Email Address		
Telephone Number		
Name and Job title		
☐	I confirm receipt of the Field Safety Notice and have read and understood its content.	
☐	I have performed all actions requested by the FSN.	
☐	The information and required actions have been brought to the attention of all relevant users and executed.	
☐	I do not have any affected devices.	
☐	I have a query please contact me (e.g. for clarification).	

Print Name	
Signature	
Date	

Please return completed form by email to: regulatory@riversidemedical.co.uk

It is essential that you complete and return this form, to allow Riverside to close the loop for customer notification.

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Distributor Reply Form

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Aseptic Medical Devices (AMD) Sterile Transfer Sets and Accessories

Please complete:

Company Name		
Company Address		
Email Address		
Telephone Number		
Name and Job title		
☐	I confirm the receipt, the reading and understanding of the Field Safety Notice.	
☐	I have identified customers that received or may have received this device	
☐	I have attached customer list	
☐	I have informed the identified customers of this FSN	
☐	I have received confirmation of reply from all identified customers	

Print Name	
Signature	
Date	

Please return completed form by email to: regulatory@riversidemedical.co.uk

It is essential that you complete and return this form, to allow Riverside to close the loop for importer/distributor notification.

Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

What are FSNs and FSCAs?

A ‘field safety notice’ (FSN) is an important communication about the safety of a medical device that is sent to customers by a device manufacturer, or their representative.

FSNs provide new information and tell you what you need to do to reduce the specified risks of using the medical device.
The actions are referred to as ‘field safety corrective actions’ (FSCAs).

If you receive a field safety notice from a manufacturer, **always act on it**.

Do not wait for a communication from the MHRA.

It is important that your organisation takes the actions detailed in the FSN and that you tell the manufacturer that you have received the FSN.

Your organisation's reply is the evidence that the manufacturer, and the MHRA, needs to monitor the progress of the corrective actions to ensure patient safety.

Without your reply the manufacturer can’t know if their important message has been received and the MHRA may need to issue a safety communication.