1 ArcRoyal
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Virginia Road, Kells,
Co Meath, lreland

Tel: +353 (0)46 928 0100
Fax: +353 (0)46 928 0110

Field Safety Notice

Date: 07 March 2017

Commercial Name: Custom Procedure Trays Containing 100ml syringe 10-005358

Identifier: FSN17B001

Type of action: Removal of BO Plastipak 100 ml Syringe 10-005358

Attention:
This letter is to inform you of a field safety notice initiated by BO

Description of the Problem:

BO are conducting a voluntary field safety corrective action for all lots of BO 100 ml Plastipak Catheter Tip Syringes with a 5-year expiration date. The field safety notice has been initiated as syringes showed leakage past the stopper during routine real time stability tests, with failures beginning at the 2-year point.

Safety Action
BO has initiated a recall which indicates that all affected syringes are to be removed from the market. ArcRoyal has placed the affected BO 100 ml syringes into Custom Procedure Trays (CPTs). ArcRoyal is issuing this Field Safety Notice to all Customers to provide instructions on how to control the affected BO 100 ml syringes.

Details of affected items

Reference	Description	Lot Number
10-005358	BO 100 ml Syringe	Refer to attached listing

Attached is a list of all CPTs which have been supplied to you by ArcRoyal that are affected by this Field Safety Notice. We can offer replacement BO 100 ml Syringes, if you wish to avail of this replacement, please communicate your request to us.

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www.arcroyal.ie

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Advice on Action to be taken by the user:
To minimize disruption and ensure continuous patient care, ArcRoyal is recommending the following:

1. Check your inventory to identify affected CPTs
2. Place on hold any CPTs that are affected
3. Complete the attached verification form Appendix I **This should be done even if you have no affected product**
4. Return the completed Field Safety Corrective Action Response Form Appendix I to ArcRoyal (emma.russell@owens-minor.com)
5. On use of the CPT the affected BO 100 ml Syringe is to be removed
   The affected BO 100 ml Syringe can be returned to ArcRoyal or disposed of at the hospita!
6. If the BO 100 ml Syringe is disposed of at the hospita! Appendix II must be completed and returned to ArcRoyal

Transmission of this Field safety notice:

Please immediately forward this information to all departments within your organisation in which the 100 ml Syringes may be stored. Additionally, please ensure that a copy of this information is provided to any other organisations to which the affected Syringes have been transferred. Please maintain awareness on this notice and resulting corrective action for an appropriate period to ensure effectiveness of the corrective action

We appreciate your immediate attention and cooperation and sincerely regret any inconvenience that this may cause you. Should you have any questions or concerns about the matter, please don't hesitate to contact me.

Yours Sincerely,

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ArcRoyal uc, an Owens and Minor Company

1 ArcRoyat

www.arcroyal.ie

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Appendix 1

Field Safety Notice Corrective Action Response Form

Please acknowledge that you have received, read and understood the actions to be taken by completing the information below.

The completed response form should be immediately returned via fax or email to

Fax: 00353469280110 Email: emma.russell@owens-minor.com

I have checked our inventory and found the following number of CPTs containing the affected BD 100 ml Syringe

Product Number	Lot Number	Quantity left in stock of affected packs

This facility has read and understood the information supplied to us through the Field Safety Notice issued by ArcRoyal in relation to CPTs containing the affected BD 100 ml Syringe

Facility Name	
Facility Address	
Your Printed name and Title	
Signature and Title	
Phone Number/Fax Number	

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Appendix II

Certificate of Destruction

1certify that the product(s) listed in the table below have been destroyed and removed from inventory records as a result of product Field Safety Notice FSN178001
1nstructions received from ArcRoyal.

Product Number	Lot Number	Quantity Destroved

Authorized Signature:
Name:
Position:
Date:
Destruction of the medical devices listed above was completed on