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Virginia Road, Kells,
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Fax: +353 (0)46 928 0110

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URGENT: Field safety notice

Date: 16April2013

Customer Name: XXX

Commercial Name: ArcRoyal. Custom procedural trays (CPTs)

FSCA Identifier: FSCA13D001 - BD Plastipak 50ml Leur Lok Syringes

Type of action Field safety corrective action – Medical device safety advisory notice and product Recall

Attention:

This letter is to inform you of a Field safety corrective action that is a result of a recall initiated by BD Medical for their Plastipak 50ml Leur Lok Syringes. The affected BD codes are 300223 (ArcRoyal ref 10-000049) Please refer to annex 1 for the field safety notice issued by BD Medical

Details on affected items

Recalled BD Medical Plastipak 50ml Leur Lok Syringes are included in the below list of ArcRoyal custom procedure trays (CPTS) which may be in your inventory or supplied to you shortly.



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Pack Reference	Lot Number	Quantity of Syringes
XX	XX	XX
XX	XX	XX
XX	XX	XX
XX	XX	XX

Description of the Problem

Please see attached Field Safety notice from BD Medical Annex 1.

Advice on Action to be taken by the user:

The above listed ArcRoyal custom procedure Trays, which may be in your inventory contain recalled BD Medical Plastipak 50ml Leur Lok Syringes. Sterile replacement BD Medical Plastipak 50ml Leur Lok Syringes will be made available to you by ArcRoyal in the coming days. To minimize disruption and ensure continuous patient care, ArcRoyal is recommending the following:

1. Check you inventory to identify affected ArcRoyal custom procedure trays
2. Please complete and return the attached FSCA response form (Annex II) to ArcRoyal via fax or email. This should be done even if you have no effected product
3. Do not use any affected ArcRoyal customer procedure Trays until the replacement product is received at your facility and available for use
4. Upon opening an affected ArcRoyal custom procedure Tray, Health care professionals should remove the BD Medical Plastipak 50ml Leur Lok Syringes and use the replacement product shipped to you
5. Retain and quarantine the recalled BD Medical Plastipak 50ml Leur Lok Syringes for return to ArcRoyal.

Transmission of this Field safety notice:

Please immediately forward this information to all departments within your organisation who may be using or ordering ArcRoyal Custom procedure trays. Additionally, please ensure that a copy of this information is provided to any other organisations to which the affected devices have been transferred.



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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,

Irene Armstrong
Compliance Engineer
ArcRoyal.



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Annex I

Field Safety Notice from BD Medical



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Annex II

Field Safety Corrective Action Response Form



Field Safety Corrective Action Response Form

Please read the attached Field Safety Notice. After reading 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: iarmstrong@arcroyal.ie

I have checked our inventory and found the following number of affected ArcRoyal Custom procedure Trays

CPT pack Ref	CPT Lot Number	Quantity (if none please indicate 0)

Tick Box for yes response

1. This facility agrees to utilize the supplied sterile replacement product and will remove the recalled BD Plastipak 50ML Leur Lok syringe upon opening the ArcRoyal CPT

2. This facility agrees to retain and quarantine the recalled BD Plastipak 50ML Leur Lock syringe for return to ArcRoyal

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