



www.arcroyal.ie
Virginia Road, Kells,
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Tel: +353 (0)46 928 0100
Fax: +353 (0)46 928 0110
Email: info@arcroyal.ie

Field Safety Notice
For ArcRoyal High Pressure Stopcocks
Product Withdrawal
FSN15F002

16th July 2015

Dear Valued Customer:

This letter is to inform you that ArcRoyal is initiating a voluntary withdrawal of all lots of the High Pressure Stopcocks that are in your inventory which are within the product expiry date. This Field safety corrective action is being conducted due to the risk that the Stopcocks blister packaging may contain a hole thus compromising the sterile barrier. Should the user be unaware of a hole in the packaging, a transfer of microorganisms from the stopcock to the patient is possible when the clinician touches the stopcock and then onto the sterile field which may result in the patient contracting an infection.

Details on affected items

Reference	Description	Lot Number
12-001914	High Pressure Stopcocks	All Lots within expiry date
12-002022	High Pressure Stopcocks	All Lots within expiry date
12-002023	High Pressure Stopcocks	All Lots within expiry date
12-002024	High Pressure Stopcocks	All Lots within expiry date

Advice on Action to be taken by the user:

To minimize disruption and ensure continuous patient care, ArcRoyal is recommending the following please...

1. Check your inventory for ArcRoyal High Pressure stopcocks (code listed above).
2. Place the stopcocks in quarantine.
3. Complete the attached verification form Appendix I.
4. Return the completed Field Safety Corrective Action Response Form Appendix I to ArcRoyal (iarmstrong@arcroyal.ie) & (jmalone@arcroyal.ie).
5. Our Customer services department will contact you to coordinate the return process.

Transmission of this Field safety notice:

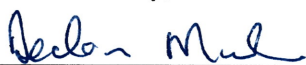
We are committed to patient safety and would appreciate your immediate attention and cooperation to this matter. Please immediately forward this information to all departments within your organisation in which the High pressure stopcock may be stored or distributed.



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We sincerely apologize for any inconvenience that this may cause and thank you for your business and continued support. If you have any questions or concerns please do not hesitate to contact your ArcRoyal representative at +3539280100 / +353 86 856 9732, Jason Malone, jmalone@arcroyal.ie


Yours Sincerely,

 16 Jul 2015

Declan Mulvin
Head of Quality

 16 Jul 2015

Jason Malone
Corporate Account Manager

 16 Jul 2015

Frank Reddan
Chief Operating Officer



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Appendix I

Corrective Action Response Form for FSN15F002

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 & jmalone@arcroyal.ie

I have checked our inventory and found the following number of High Pressure Stopcocks

Product Number	Quantity left in stock of affected packs
12-001914	
12-002022	
12-002023	
12-002024	

This facility has read and understood the information supplied to us through the Field safety corrective action issued by ArcRoyal in relation to the High Pressure stopcocks

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