

Report Form

Field Safety Corrective Action

Medical Devices Vigilance System

(MEDDEV 2.12/1 rev 7)

new case, keep base data

Version 2.7en
2012-12-03

1 Administrative information

To which NCA(s) is this report being sent?

Presafe Denmark (DGM)

Type of report

- ☒ Initial report
☐ Follow-up report
☐ Final report

Date of this report

2015-07-16

Reference number assigned by the manufacturer

FSN15F002

FSCA reference number assigned by NCA

Incidence reference number assigned by NCA

Name of the co-ordinating NCACompetent Authority (if applicable)

2 Information on submitter of the report

Status of submitter

- ☒ Manufacturer
☐ Authorised Representative within EEA and Switzerland
☐ Others: (identify the role)

3 Manufacturer information

new

Name

ArcRoyal

Contact Name

Irene Armstrong

Address

Virginia Road Kells Co Meath Ireland

Postcode

N/A

City

N/A

Phone

+353 46 9280100

Fax

+353 46 9280110

E-mail

iarmstrong@arcroyal.ie

Country

IE - Ireland

4 Authorised Representative Information

new

Name As Above	
Contact Name As Above	
Address As Above	
Postcode As Above	City As Above
Phone +353 46 9280100	Fax +353 46 9280110
E-mail iarmstrong@arcroyal.ie	Country IE - Ireland

5 National contact point information

new

National contact point name ArcRoyal	
Name of the contact person Irene Armstrong	
Address Virginia Road Kells Co Meath Ireland	
Postcode N/A	City N/A
Phone +353 46 9280100	Fax +353 46 9280110
E-mail iarmstrong@arcroyal.ie	Country IE - Ireland

6 Medical device information

new

Class

- ☐ AIMD Active implants
☐ MDD Class III
☐ MDD Class IIb
☒ MDD Class IIa
☐ MDD Class I
- ☐ IVD Annex II List A
☐ IVD Annex II List B
☐ IVD Devices for self-testing
☐ IVD General

Nomenclature system (preferable GMDN)

GMDN

Nomenclature code

P33961

Nomenclature text

Accessories, Surgical

Commercial name/ brand name / make

ArcRoyal

Model number

See attached

Catalogue number

See attached

Serial number(s)

N/A

Lot/batch number(s)

See attached

Device Mfr Date

Expiry date

Notified Body (NB) ID-number

0543

Accessories / associated devices (if applicable)

N/A

Software version number (if applicable)

N/A

7 Description of the FSCA

Background information and reason for the FSCA

A FSN was received into ArcRoyal from Elcam in regards to the Stopcocks they manufacture for ArcRoyal. There may be a hole in the blister packaging that may compromise the sterile barrier

Description and justification of the action (corrective / preventive)

ArcRoyal has initiated a FSN to inform all their customers of the problem. All customers have been informed of the FSN and have been given a list of affected codes.

Advice on actions to be taken by the distributor and the user

Customers are to identify what affected codes they still have in stock. The customers are to reply to us with the quantity.

Progress of FSCA , together with reconciliation data (Mandatory for a Final FSCA)

1. The attached FSN has been distributed to the customer in English
2. The attached FSN will be distributed to the customer in all other relevant languages
3. The customer is to fill out the FSN response form and return it to ArcRoyal indicating the quantity of affected codes in stock.

Time schedule for the implementation of the different actions

1. Complete
2. TBC
3. TBC

Attached please find

- ☒ Field Safety Notice (FSN) in English
☐ FSN in national language
☐ Others (please specify)

FSN Status

- ☐ Draft FSN
☒ Final FSN

The medical device has been distributed to the following countries:

within the EEA and Switzerland

- | | | | | | | | |
|-----------------------------|--|-----------------------------|-----------------------------|-----------------------------|-----------------------------|-----------------------------|-----------------------------|
| <input type="checkbox"/> AT | <input checked="" type="checkbox"/> BE | <input type="checkbox"/> BG | <input type="checkbox"/> CH | <input type="checkbox"/> CY | <input type="checkbox"/> CZ | <input type="checkbox"/> DE | <input type="checkbox"/> DK |
| <input type="checkbox"/> EE | <input type="checkbox"/> ES | <input type="checkbox"/> FI | <input type="checkbox"/> FR | <input type="checkbox"/> GB | <input type="checkbox"/> GR | <input type="checkbox"/> HU | <input type="checkbox"/> IE |
| <input type="checkbox"/> IS | <input type="checkbox"/> IT | <input type="checkbox"/> LI | <input type="checkbox"/> LT | <input type="checkbox"/> LU | <input type="checkbox"/> LV | <input type="checkbox"/> MT | <input type="checkbox"/> NL |
| <input type="checkbox"/> NO | <input type="checkbox"/> PL | <input type="checkbox"/> PT | <input type="checkbox"/> RO | <input type="checkbox"/> SE | <input type="checkbox"/> SI | <input type="checkbox"/> SK | <input type="checkbox"/> TR |

Candidate Countries

☐ HR

☐ All EEA, candidate countries and Switzerland

Others:

8 Comments

Submission of this report does not, in itself, represent a conclusion by the manufacturer and/or authorised representative or the National Competent Authority that the content of this report is complete or accurate, that the medical device(s) listed failed in any manner and/or that the medical device(s) caused or contributed to the alleged death or deterioration in the state of the health of any person.

Signature

Irene
Armstrong

I affirm that the information given above is correct
to the best of my knowledge

print

check

send XML-data by E-Mail



www.arcroyal.ie
Virginia Road, Kells,
Co Meath, Ireland
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 (jarmstrong@arcroyal.ie) & (jmalone@arcroyal.ie).
5. Our Customer services department will contact you to coordinate the return process.

Transmission of this Field safety notice:

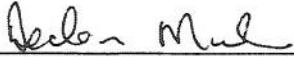
We are committed to patient safety and would appreciate your immediate attention and cooperation to this matter. Please immediately forward this information to all departments within your organisation in which the High pressure stopcock may be stored or distributed.




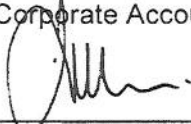
www.arcroyal.ie
Virginia Road, Kells,
Co Meath, Ireland
Tel: +353 (0)46 928 0100
Fax: +353 (0)46 928 0110
Email: info@arcroyal.ie

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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Email: info@arcroyal.ie

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	

To: ArcRoyal

Attention: Lesley McGee

From: Elcam Medical Quality Assurance and Regulatory Affairs

Date: June 15, 2015

RE: Quality issue information regarding punctured blister packages

Dear Lesley,

We would like to share with you initial information regarding quality issue that was detected in some of Elcam's individual blister packaging.

Some blisters were found punctured during our production.

Please note that CAPA investigation was initiated and braking actions were conducted.

Relevant part number:

Description	Customer PN#	Elcam PN#
STP HP 1W LN4 BLS ARCROYAL	12-002022	575001
STP HP 1W HPR BLS ARCROYAL	12-001914	575003
STP HP 3W HPR BLS ARCROYAL	12-002023	575301
STP HP 3W LN4 BLS ARCROYAL	12-002024	575303

As a caution activity until we will have additional information regarding this quality issue (e.g. extent of this failure, root cause, delimitation), we would like to recommend ArcRoyal to hold distribution of the above part numbers to the market.

In respect of planned shipments of these parts to your facility and any open orders – you will be contacted by our Sales Department for schedule updates.

If any further information is required, please do not hesitate to contact us.

Best Regards,

Marta Lino

Marta Lino

QA Customer Service

Elcam Medical