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Virginia Road, Kells,
Co Meath, Ireland

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Field Safety Notice

Date: 08 May 2017

Commercial Name: Inflation Device 30ATM 12-003704

FSN Identifier: FSN17D001

Type of action: Inspection of the inflation device

Attention: This letter is to inform you of a Field Safety Notice initiated by ArcRoyal

Description of the Problem:

ArcRoyal has been informed by Perouse Medical, the manufacturer of the Inflation Device 30ATM, of a potential defect in the device primary packaging (blister), which may compromise the device sterility. Low level instances have been reported of the blister showing a clearly visible crack located near the handle or the pressure gauge.

Picture 1: Example of crack observed near the inflation device handle

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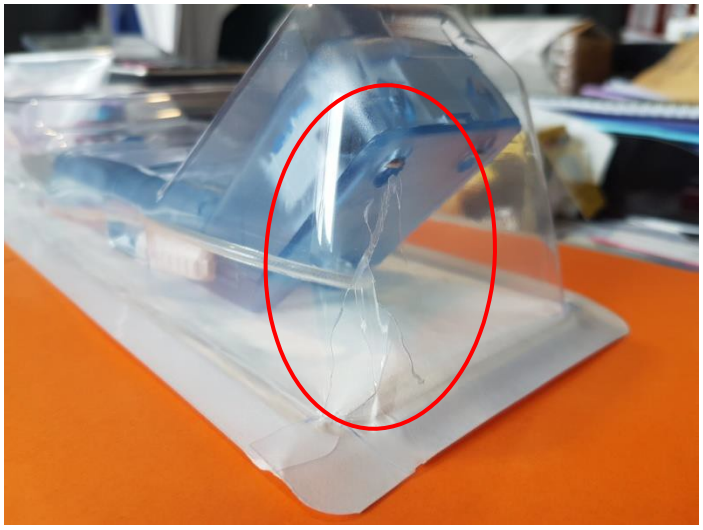


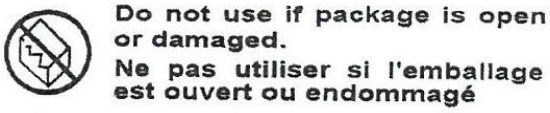
Picture 2: Example of crack observed near the inflation device pressure gauge

Perouse Medical has carried an internal inspection of its entire inventories, and confirms that the identified rate of defect is very low. However, as a preventive measure, Perouse Medical has initiated a safety corrective action by informing all its customers of a potential primary packaging defect.

Patient risk:

There is no risk for the patient if the following instructions are respected.

This defect is detectable by the user during the inspection required prior to its use, as indicated on the labelling of each unit (logo and instruction related to the packaging integrity), and in the Instruction For Use (IFU). Please see picture 3 below.



Picture 3: Indications present on every labelling of unit-of-use and IFU

If the instructions are not followed the patient risk is a risk of microbial contamination (infection) caused using a product in which sterility would not be preserved due to the primary packaging damage.

To date, no adverse effect, regarding health and safety of patients, potentially connected to this problem has been notified.

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Safety Action: Perouse Medical has initiated a field safety notice which indicates that all affected inflation devices are to be 100% inspected. ArcRoyal is issuing this Field Safety Notice to all Customers to provide instructions on how to control the affected Inflation Devices.

Details on affected items:

Device Type	Impacted Supplier batch number	ArcRoyal Reference	Lot Numbers
Inflation Device	Batch code starting from: **1504**XXXXto **1512**XXXX **1601**XXXXto **1612**XXXX	12-003704	15125278, 15125436, 16015523, 16045667, 16045774, 16045775, 16055172, 16055233, 16065135, 16075001, 16075362, 16085004, 16085154, 16085272, 16085727, 16105001, 16105159, 16105405, 16105442, 16105511

All batches affected by this safety corrective action are all Inflation Device batches packaged by Perouse Medical since April 2015. Attached is a list of all Inflation Devices 30ATM which have been supplied to you by ArcRoyal that are affected by this Field Safety Notice.

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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 Inflation devices

2. Control the potential damage of the blister according to the pictures and the instructions mentioned on the labelling and the Instruction For Use: any damaged and/or cracked blister must be immediately discarded.

3. Following review, use the compliant products without risk, the primary packaging will not deteriorate over time. If, to date, there is no crack in the blister, the integrity of the product is not compromised.

4. Do not use the non-compliant products.

5. Complete the attached verification form Appendix I **This should be done even if you have no affected product**

6. Return the completed Field Safety Corrective Action Response Form Appendix I to ArcRoyal (……..)

7. If the device is disposed of at the customer site Appendix II must be completed and returned to ArcRoyal

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Transmission of this Field safety notice:

Please immediately forward this information to all departments within your organisation in which the inflation device may be stored. Additionally, please ensure that a copy of this information is provided to any other organisations to which the affected inflation devices 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,

…….
……..
ArcRoyal uc, an Owens and Minor Company

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Appendix I

Field Safety Notice Corrective Action Response Form – FSN17D001

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 affected Inflation Devices 30ATM

ArcRoyal Reference Number	Batch Number	Quantity of affected devices left in stock

This facility has read and understood the information supplied to us through the Field Safety Notice issued by ArcRoyal in relation to affected Inflation Devices 30ATM

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

I certify that the product(s) listed in the table below have been destroyed and removed from inventory records because of product Field Safety Notice FSN17D001 Instructions received from ArcRoyal.

ArcRoyal Reference Number	Batch Number	Quantity Destroyed

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