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

Advisory Notice

Date: 24Oct2014

Commercial Name: Dolphin Inflation Device 12-003704

FSN Identifier: FSN14J001

Type of action: Additional clarification on the use of the inflation device

Attention:
This letter is to inform you of an Advisory notice initiated by ArcRoyal's Supplier of the Dolphin Inflation Device. Please see appendix I.

Description of the Problem
Several cases of inability to raise the pressure beyond 10 atm have been reported. The reported cases have not generated, to our knowledge, any consequences for the patient, except a longer-lasting procedure.
These difficulties may occur when increasing the pressure above 10 atm with no manual locking by the practitioner before inflation. In case of multiple inflations, the automatic return to the lock position after inflation may be incomplete due to excessive friction between the device components. Therefore, if the practitioner does not manually lock the buttons before inflation, the system can be unlocked if the pressure goes higher than 10 atm. In that case, the pressure would drop and it would be necessary to lock the device manually to carry on a new cycle of pressure rise.

Safety Action
ArcRoyal is issuing an advisory notice to provide additional clarification on the use of the inflation device. In the Instructions for Use (IFU), it is specified that to inflate the balloon, the user must: "pull the Buttons, gently turning the handle clockwise until the desired position is reached "
ArcRoyal adds the following clarification: it is necessary BEFORE EACH INFLATION to manually lock the buttons by pulling them toward the user as shown in the picture below, and check the lock. This information will be included as an additional label on each primary packaging.

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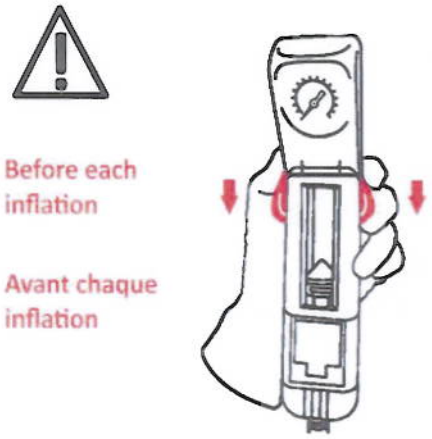
TEMPLATE LABEL



Details on affected items

Below is a list of all Products which have been supplied to you from ArcRoyal that is affected by this Advisory

Product Code	Lot Number	Quantity of Product
12-003704	14031488	478
12-003704	14031616	347
12-003704	14052717	80
12-003704	14052718	315
12-003704	14052840	366
12-003704	14062509	180
12-003704	14062607	341
12-003704	14072726	595
12-003704	14072798	376

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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 product
2. Place on Hold any product that are affected
3. Complete the attached verification form Appendix II **This should be done even if you have no affected product**
4. Return the completed Field Safety Corrective Action Response Form Appendix II to Arcroyal (iarmstrong@arcroyal.ie)

On receipt of the completed verification form Appendix II, ArcRoyal will forward you with additional labelling and labelling instructions.

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 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,

Irene Armstrong

Irene Armstrong
Compliance Engineer
ArcRoyal.

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Appendix I

Safety Notice Dolphin official Letter

PEROUSE MEDICAL

ArcRoyal
Virginia Road, Kells,
Co Meath.
Ireland

Ivry-le-Temple, October 13th 2014

Dear Partner,

This letter is to inform you that PEROUSE MEDICAL has issued a voluntary corrective action notice regarding the DOLPHIN Inflation Device. Several cases of inability to raise the pressure beyond 10 atm have been reported to us. The reported cases have not generated, to our knowledge, any consequences for the patient, except a longer-lasting procedure. Please see attached the Safety Notice (Attachment N°1).

The Inflation Devices 30atm 12-003704 supplied to ArcRoyal which batch numbers begin with 1403, 1404, 1405, 1406, 1407 may met the same problem. As these products are CE marked by ArcRoyal as OBL Manufacturer, you should take the necessary actions. Of course we will provide you all the necessary support to help you.

Moreover, as immediate curative action, we decided to provide additional clarification on the use of the Inflation Device thanks to a label stuck on each primary packaging (see Attachment N°2). We propose to supply to ArcRoyal these labels and authorize the Company to stick them by itself according to the Operating Mode MO 0185NA-1 Rev00 *Blister Labelling* (see Attachment N°3). On its side, ArcRoyal will give to PEROUSE MEDICAL the batch numbers and the number of devices per batch reworked.

We sincerely apologize for the inconvenience and thank you in advance for your understanding and cooperation.

Best regards,

Agnès JORDAN
Corporate Regulatory Affairs Manager

Siège social
Route du Manoir
60173 Ivry le Temple, France
Tél. : 33 (0)3 44 08 17 00
Fax : 33 (0)3 44 08 17 01

Divisions Oncologie & Cardiovasculaire
Route du Manoir
60173 Ivry le Temple, France
Tél. : 33 (0)3 44 08 17 00
Fax : 33 (0)3 44 08 17 01

Divisions Imagerie Interventionnelle & BtoB
135, Route Neuve
69540 Irigny, France
Tél. : 33 (0)4 72 39 74 14
Fax : 33 (0)4 78 51 89 67

www.perousemedical.com

SAS au capital de 1 316 702 euros
SIREN 317 883 999 RCS Beauvais
N° TVA intracommunautaire :
FR 01 317 883 999

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Appendix II

Advisory Corrective Action Response For

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 Inflation devices.

Lot Number	Quantity left in stock (if none please indicate 0)
14031488	
14031616	
14052717	
14052718	
14052840	
14062509	
14062607	
14072726	
14072798	

This facility has read and understood the information supplied to us through the advisory notice issued by ArcRoyal in relation to the Dolphin inflation device

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