

04 March 2013

URGENT FIELD SAFETY NOTICE EXTENSION

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|--|--------------------|---|--------------------|
| COMMERCIAL NAME OF AFFECTED PRODUCTS: | | Berman Angiographic Balloon Catheters | |
| | | Reverse Berman Angiographic Balloon Catheters | |
| TYPE OF ACTION: | | Advisory Notice | |
| PART NUMBER | PART NUMBER | PART NUMBER | PART NUMBER |
| AI-07130 | AI-07130-J | AI-07131 | AI-07132 |
| AI-07133 | AI-07134 | AI-07135 | AI-07136 |
| AI-07137 | AI-07138 | AI-07035 | AI-07037 |

Dear Customer,

1. Details of affected devices

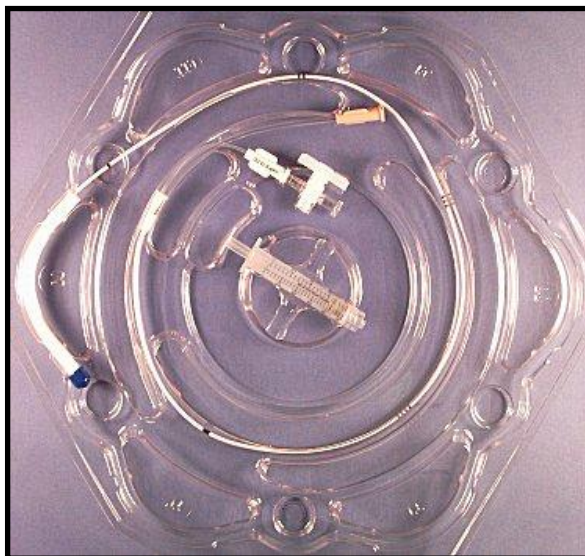
Arrow International Inc. ("Arrow") has issued an extension to the voluntary Field Corrective Action for the above referenced products.

2. Description of the problem

Arrow International, Inc. ("Arrow") are notifying its customers that the labelling for the product numbers listed above formerly referenced Renografin-76 contrast medium (viscosity of 8.4 cP/mPa.s¹), which is no longer available. Arrow is in the process of updating the labelling and Instructions for Use ("IFU") for these products. In the meantime, when choosing an alternative contrast medium, health care providers are instructed to select a contrast medium with a viscosity of 8.4 cP/mPa.s or lower for use with the pressure and flow settings specified in the current IFU.

If a contrast medium with a viscosity higher than 8.4 cP/mPa.s is used at the specified pressure and flow settings, this can create excess stress on the catheter body and could lead to leaks or ruptures in the catheter body near the hub, which is outside the patient's body. Although these catheter ruptures do not pose a threat to the patient or user, they can necessitate removal and replacement of the catheter.

While the labelling and IFU are being updated, you will notice that Arrow is placing an insert card in kits for the product codes listed above alerting our customers that Renografin-76 is no longer available and to select a contrast medium with a viscosity of 8.4 cP/mPa.s or lower for use with the pressure and flow settings specified in the current IFU.



¹ 1 Centipoise = 1 mPa s (Millipascal Second)

3. **FIELD SAFETY CORRECTIVE ACTION INSTRUCTIONS:**

Advice on action to be taken by Medical Staff

1. Select a contrast medium with a viscosity of 8.4 cP/mPa.s or lower for use with the pressure and flow settings specified in the current IFU.
2. Please provide this Field Safety Notice to all those who need to be aware of it within your organization.

Instruction for Distributors of affected product

If you are a distributor, provide this field safety notice to all of your customers which have received product of the Field Actioned batches.

Please be aware that all European Economic Area/Switzerland (EEA/CH) and Turkey Member State Competent Authorities in which ARROW distribute directly will be notified by Teleflex.

If you are a distributor and/or have a reporting responsibility within or outside the EEA/CH and Turkey area, please notify your local Competent Authority of this action. Please forward the notification and all communication with your local competent authority to Teleflex.

4. **Transmission of this Field Safety Notice**

This notice should be passed on all persons who need to be aware within your organization or to any organization where the listed devices have been transferred. Please consider end users, clinicians, risk managers, supply chain/distribution centres etc. in the circulation of this notice.

Maintain awareness of this notice until all required actions have been completed in your organisation.

5. **Contact reference person**

Should you require any further information or support concerning this issue, please contact:

Customer Service:

Contact: Lucie Fuchsova

Telephone: 495759122 nebo 731443950

FAX: 495759345

E-mail: lucie.fuchsova@teleflex.com

Arrow is committed to providing high quality, safe and effective products. We sincerely apologize for any inconvenience this action may cause your operations.

If you have any other questions, feel free to contact your local sales representative or Customer Service at lucie.fuchsova@teleflex.com.

For and on behalf of Arrow:

Padraig Hegarty

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Senior Director of Quality, EMEA