

**URGENT FIELD SAFETY NOTICE**

**Medex® Custom Angiographic Kits, Product Code SMA-389**

<b>Affected Devices:</b>	Medex® Custom Angiographic Kits, Product Code SMA-389
<b>Type of Action:</b>	<b>Field Safety Corrective Action - Safety Notice</b>
<b>Date:</b>	30 October 2014
<b>Attention:</b>	Risk/ Safety Managers, Clinicians, Nurses, Interventional Radiologists, Interventional Cardiologists and other users of the device
<b>Details on affected devices:</b>	<b><u>Medex® Custom Angiographic Kits:</u></b> <b>Product Reorder Code: SMA-389</b> <b>Lot Number: 2744359</b>

Dear Valued Customer:

Smiths Medical is providing this Urgent Field Safety Notice to advise its customers of a Field Safety Corrective Action for certain Medex® Custom Angiographic Kits. Smiths Medical is voluntarily taking this Action with the knowledge of the relevant Regulatory Authorities.

Smiths Medical received notice from Perouse Medical who has issued an Urgent Safety Notice for certain lot numbers of their Dolphin Inflation Devices. Smiths Medical includes the Dolphin Inflation Device in Medex® Custom Angiographic Kits (Product Code SMA-389 and Lot Number 2744359).

According to Perouse Medical, their Field Safety Corrective Action was conducted to alert customers of the potential for the inability to raise the pressure beyond 10 atm. This issue may occur when increasing the pressure above 10 atm with no manual locking by the practitioner before inflation. Perouse Medical provides details of this problem and the action for customers to take. Perouse Medical's Urgent Field Safety Notice is attached (see Attachment 1).

Perouse Medical is not aware of any reports of consequences to patients, other than a longer-lasting procedure. Smiths Medical has received no complaints related to this issue.

**Only those Product Code SMA-389 and Lot Number 2744359 are impacted by this Field Safety Corrective Action.**

**Advice on Action to be Taken by the User:**

1. Be aware of this issue and the new information provided by Perouse Medical on the safe use of the Dolphin Inflation Device. Carefully read the information provided in Perouse Medical's Urgent Field Safety Notice.
2. Complete and return the Confirmation Form (Attachment 2), either by fax at 089-242959-204 or by e-mail to: [yvonne.bichlmaier@smiths-medical.com](mailto:yvonne.bichlmaier@smiths-medical.com) within five (5) days of receipt of this notice.

**Transmission of this Urgent Field Safety Notice**

This notice shall be passed on to all personnel who need to be aware within your organization, including points of use or to any organization where the potentially affected devices have been transferred. If you or your facility has distributed these affected products to other persons or facilities, please promptly forward the recipients a copy of this Urgent Field Safety Notice.

Please maintain awareness of this Notice and resulting action for an appropriate period to ensure effectiveness of this Recall.

Customers should report any issues with these products to Smiths Medical's Global Complaint Department at 00 800 76 48 47 00 or [globalcomplaints@smiths-medical.com](mailto:globalcomplaints@smiths-medical.com).

If you should have any questions regarding this information, please contact Smiths Medical's Customer Service Department at 089-242959-309 or by email to [yvonne.bichlmaier@smiths-medical.com](mailto:yvonne.bichlmaier@smiths-medical.com).

Smiths Medical is committed to providing quality products and service to its customers. We apologize for any inconvenience this situation may have caused.

Sincerely,

Marco Savino  
Regional Director, Quality Systems  
Smiths Medical

Enclosures: Attachment 1 – Perouse Medical's Urgent Field Safety Notice  
Attachment 2 – Confirmation Form