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Smiths Medical ASD, Inc.
1265 Grey Fox Road
St. Paul, MN 55112 USA

URGENT FIELD SAFETY NOTICE

For PORT-A-CATH® and PORT-A-CATH® II Implantable Venous and Arterial Access Systems and Introducer Sets

Affected Devices:	PORT-A-CATH® and PORT-A-CATH® II Implantable Venous and Arterial Access Systems and Introducer Sets
Type of Action:	Field Safety Corrective Action - **RECALL**
Date:	September 6, 2013
Attention:	Risk/Safety Managers, Nursing, Emergency Department, Clinicians, Distributors, and other users of these devices
Details on affected devices:	See Attachment 1

Dear Customer,

Smiths Medical is providing this Urgent Field Safety Notice to advise its customers of a voluntary recall of PORT-A-CATH® and PORT-A-CATH® II Implantable Venous and Arterial Access Systems and Introducer Sets, Refer to Attachment 1 for Product Reorder Codes and Lot Numbers. Smiths Medical is voluntarily taking this action with the knowledge of the relevant Regulatory Agencies.

Smiths Medical has become aware of a small number of customer reports regarding the introducer sheath and the introducer opening being too small for the width of the catheter with the use of these Sets. Investigation into this issue found that the supplier inadvertently supplied a smaller size introducer than required. The smaller introducer does not allow for the passage of the catheter through the introducer sheath and opening. This issue could result in a delay of therapy if the clinician is unable to thread the catheter through the introducer sheath and introducer opening. This would most likely lead to another attempt for insertion if another tray is available.

Smiths Medical has received no reports of serious injury or death related to this issue.

Advice on Action to be Taken by the User:

Subject to this Urgent Field Safety Notice, Smiths Medical is requiring its customers to return all unused affected Sets to Smiths Medical for credit or replacement.

1) Inspect your inventory and remove all affected devices from use.
2) Complete and return the attached Urgent Field Safety Notice Confirmation Form by fax to 1-800-237-8033 or by email to portocathintroducers@smiths-medical.com within five (5) days of receipt of this notice. Upon receipt of the

completed form, a customer service representative will contact you to arrange for exchange of your unused affected Sets for credit or replacement.

Transmission of this Urgent Field Safety Notice

This notice needs to 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 Sets 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.

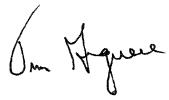
Customers should report any issues with these products to Smiths Medical's Global Complaint Department at 1-866-216-8806 or globalcomplaints@smiths-medical.com.

Any adverse events that may be related to the use of these products may also be reported to the FDA's MedWatch Adverse Event Reporting Program by Fax at 1-800-332-0178, or by mail or online, following the instructions at www.fda.gov/MedWatch/getforms.htm.

If you should have any questions regarding this information, please contact Smiths Medical's Customer Service Department at 800-258-5361.

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

Sincerely,



Tim Giguere
Manager, Quality Systems
Smiths Medical ASD, Inc.

Enclosures: Attachment 1 – List of affected Product Reorder Codes and Lot Numbers
Attachment 2 – Urgent Field Safety Notice Confirmation Form

ATTACHMENT 1 **Smiths Medical ASD, Inc.**

PORT-A-CATH® and PORT-A-CATH® II implantable venous and arterial access systems and introducer sets.

Product Reorder No.	Name/ Description	Lot No.
21-2386-24	Set, INTRO, SUBCLAVIAN, 11 FR 5/BX	1991524
		1997100
		2033224
		2051222
		2116286
		2183921
		2192487
		2210967
		2229821
		2237453
21-8011-24	Tray, PAC, VEN DL, TI/3.4MM, WING-LOCK, 1/EA	1971567
		1979805
		1984078
		1997124
		2006124
		2038001
		2090898
		2151160
		2196530
		2216256
		2249695
21-8052-24	Tray, PAC II,VEN DL, 3.4MM, WING-LOCK, 11FR/INTRO 1/EA	1971572
		2012472
		2022904
		2067947
		2080704
		2146472
		2168988
		2196532
		2207404
		2237458
		2249696
		2269178
		2282158
21-8053-24	Tray, PAC II, VEN DL, PRE-AY, 11 FR/INTRO 1/EA	2168989
		2249697

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URGENT FIELD SAFETY NOTICE CONFIRMATION FORM
For PORT-A-CATH® and PORT-A-CATH® II Implantable Venous and Arterial Access Systems and Introducer Sets

Please complete and return this Form by fax to 1-800-237-8033 or by sending an electronic copy via email to portocathintroducers@smiths-medical.com

Customer Account No. _____

☐ YES – We have affected product in our inventory (please complete the product details on P.2). Please contact me using the details provided below to provide me with instructions on returning my unused products for: (Check one below) ☐ Credit ☐ Replacement.	
☐ NO – We do not have any of the affected products – they have been used/ disposed of.	
☐ We no longer have any of the affected products. We transferred them to the following location: *(please provide name, address, and phone number and email address):*	
Customer/ Facility Name:	Facility Address:
Signature:	Facility Shipping Address:
Print Name:	Date:
Department:	
Email:	Phone Number:

URGENT FIELD SAFETY NOTICE CONFIRMATION FORM
For PORT-A-CATH® and PORT-A-CATH® II Implantable Venous and Arterial Access Systems and Introducer Sets

Customer Account No. _____

Product Reorder No.	Lot No.	Quantity