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Smiths Medical ASD
1265 Grey Fox Rd
St. Paul MN 55112

URGENT FIELD SAFETY NOTICE

For CADD™ Medication Cassette Reservoir, 50ml

Affected Devices:	**CADD™ Medication Cassette Reservoir, 50ml**
Type of Action:	Field Safety Corrective Action –Recall
Date:	2 February 2015
Attention:	Risk/Safety Managers, Biomedical Professionals, Clinicians who oversee the use of CADD® pumps, Distributors, and other users of these devices
Details on affected devices:	Product Reorder Number 21-7001-24, Lot Numbers 14X-297 and 14X-323; and Product Reorder Number 21-7301-24, Lot Number 14X-324

Smiths Medical is providing this Urgent Field Safety Notice to advise its customers of a Field Safety Corrective Action for certain CADD™ Medication Cassette Reservoir, 50ml ("Cassettes") for use with CADD® Ambulatory Infusion Pumps. Smiths Medical is voluntarily taking this action with the knowledge of the relevant Regulatory Agencies.

Smiths Medical has received a small number of complaints of leakage associated with the above-referenced Cassettes. A small amount of leaking has been found to occur at the welding of the tube to the internal reservoir bag on some Cassettes. If the leakage is noticed during Cassette filling, it could result in a delay of therapy while an alternative Cassette is obtained. If the leakage is noticed during fluid delivery with the patient, it could result in an interruption in therapy while the Cassette is replaced.

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

Only those CADD™ Medication Cassette Reservoirs with Product Reorder and Lot Numbers listed above are affected by this Action.

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 Cassettes listed above. Cassettes which are currently in use should be monitored for any signs of leaks and changed at the next scheduled interval. If any leaks are observed, the Cassette should be replaced as soon as possible.

1. Inspect your inventory for the Cassettes listed above and quarantine the affected Cassettes.
2. Complete and return the attached Confirmation Form (see Attachment A) by Fax to +44 (0)1233 722153 or by email to recall.response@smiths-medical.com within 10 days of receipt of this letter.

3. Upon receipt of the completed form, a customer service representative will contact you to arrange for exchange of your unused affected Cassettes for replacement.

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 action.

Customers shall 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.

If you should have any questions regarding this information, please contact Smiths Medical's Customer Service Department at +44 (0)845 850 0445.

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 A –Confirmation Form

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ATTACHMENT A

<for Distributor's Customers>

URGENT MEDICAL DEVICE RECALL NOTICE CONFIRMATION FORM
For CADD™ Medication Cassette Reservoir, 50ml

2 February 2015

Customer Account No. _____

Please complete and return this Form by fax to +44 (0)1233 722153 or by sending an electronic copy via email to recall.response @smiths-medical.com

☐ **YES** – I do have unused inventory of **CADD™ Medication Cassette Reservoir, 50ml** which I will return for replacement. Please complete products details on page 2	Total number of affected products:
☐ **NO** – I do not have any of the affected products. ☐ I no longer have any of the affected products. I transferred them to the following location: *(please provide name, address, and phone number):* ☐ I did have affected products; however, they were already used or disposed of.	
Facility Name:	Facility Address:
Name of Distributor who you received the affected products from:	
Signature:	Facility Shipping Address:
Print Name:	Date:
Department:	
Email:	Phone Number: ( )

<for Distributor's Customers>

URGENT DEVICE RECALL NOTICE CONFIRMATION FORM
For CADD™ Medication Cassette Reservoir, 50ml

Customer Account No. _____

Product Reorder Number	Lot Number	Quantity (enter quantity below and indicate whether eaches / cases)