6000 Nathan Lane N.
Minneapolis, MN 55442

URGENT MEDICAL DEVICE RECALL

CADD™ Medication Cassette Reservoirs

26 June 2024

Dear Valued Customers:
Director of Biomedical Engineering
Director of Nursing
Director of Risk Management

Smiths Medical is issuing this letter to notify you of a potential issue with specific models and lots of 50 mL and 100 mL CADD Medication Cassette Reservoirs. This letter details the potential issue, the affected models, and the required steps to perform.

Issue:
Certain CADD Medication Cassette Reservoirs may exhibit a weakened weld joint between the medication bag and tubing due to a production equipment malfunction. This could result in a medication leakage at or near the location specified in Figure 1.

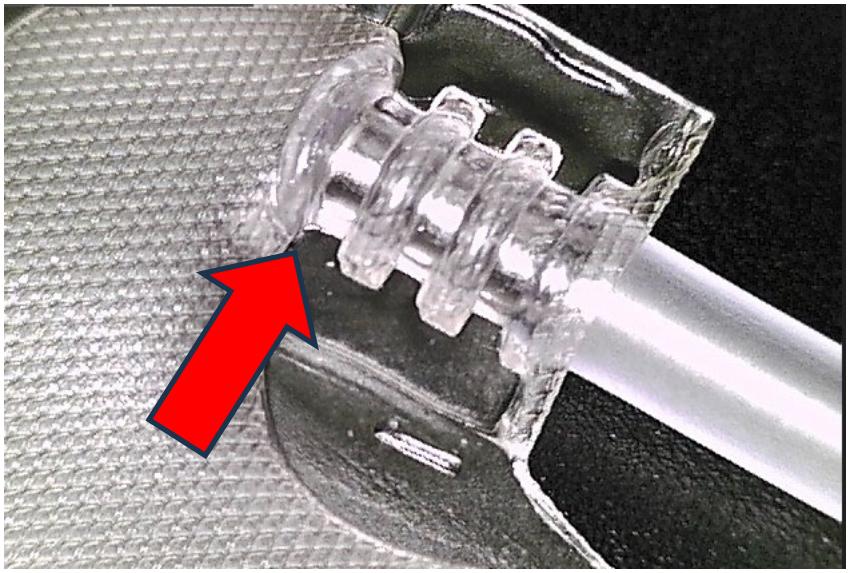

Figure 1. Medication Bag to Tubing Joint Weld

Potential Risk:
Leakage from a weakened weld at the medication bag to tubing joint could potentially result in delay or interruption of therapy, under delivery of medication, exposure to infectious or toxic agents, or air embolus.

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No serious injuries or deaths have been reported to Smiths Medical for this issue. However, because the potential exists for serious adverse health consequences such as permanent disability or death, the products listed below are being recalled.

Affected Models:
Certain lots of CADD Medication Cassette Reservoirs in Table 1 are potentially affected.

Table 1: Potentially Affected Product Models

Model Number	Product Name	Affected Lot Numbers
21-7001-24	RESERVOIR, CASSETTE, 50ML 12/BX	Refer to Attachment 3
21-7002-24	RESERVOIR, CASSETTE, 100ML 12/BX	Refer to Attachment 3
21-7300-24	RESERVOIR, CASSETTE, 100ML, FS, YELLOW 12/BX	Refer to Attachment 3
21-7301-24	RESERVOIR, CASSETTE, 50ML, FS 12/BX	Refer to Attachment 3
21-7302-24	RESERVOIR, CASSETTE, 100ML, FS 12/BX	Refer to Attachment 3

Customer Required Actions:

Please contact Smiths Medical customer service (1-(800)-258-5361) for information on obtaining alternative CADD medication cassette reservoirs.

1. Review your inventory of CADD Medication Cassette Reservoirs to confirm if any of the models/lots listed in Table 1 are in your possession and quarantine them.

2. **Return the attached Customer Response Form to** smithsmedical8697@sedgwick.com **within ten days of receipt** to acknowledge your understanding of this notification and identify any potentially affected product in your possession. **Return of this form initiates the return and replacement processes.**

3. **DISTRIBUTORS:** If you have distributed potentially affected products to your customers, please immediately forward this notice to them. Request that they complete the Response Form and return it to smithsmedical8697@sedgwick.com.

Follow up actions by Smiths Medical:
Smiths Medical will provide replacement devices for all returned affected products. Smiths Medical corrected the manufacturing process that led to the potential for this issue to occur.

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For further inquiries, please contact Smiths Medical using the following information:

Smiths Medical Contact	Contact Information	Areas of Support
Global Complaint Management	productcomplaints@icumed.com 1-(866)-216-8806	To report adverse events or product complaints
Technical Support	1-(800)-241-4002, option 3 tsc.support@icumed.com	Additional information or technical assistance, including Technical Service Manuals

General Information

This notification is being performed with the knowledge of regulatory authorities, including the US Food and Drug Administration (FDA).

Report any adverse health complaints experienced with the use of this product to Smiths Medical. Events may also be reported to the FDA's MedWatch Adverse Event Reporting Program:

If you wish to contact the FDA regarding any adverse events or quality problems associated with this notice, use the following contact information.

- www.fda.gov/medwatch

1-(888)-INFO-FDA

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

Sincerely,

Jim Vegel
Vice President, Quality

Enclosures:
Attachment 1 - Urgent Medical Device Correction
Attachment 2 - Customer Response Form
Attachment 3 - List of Potentially Affected Lot Numbers