

URGENT: FIELD SAFETY NOTICE

CADD™ Medication Cassette Reservoirs

5th Sept 2024

Dear Valued Customers:

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.

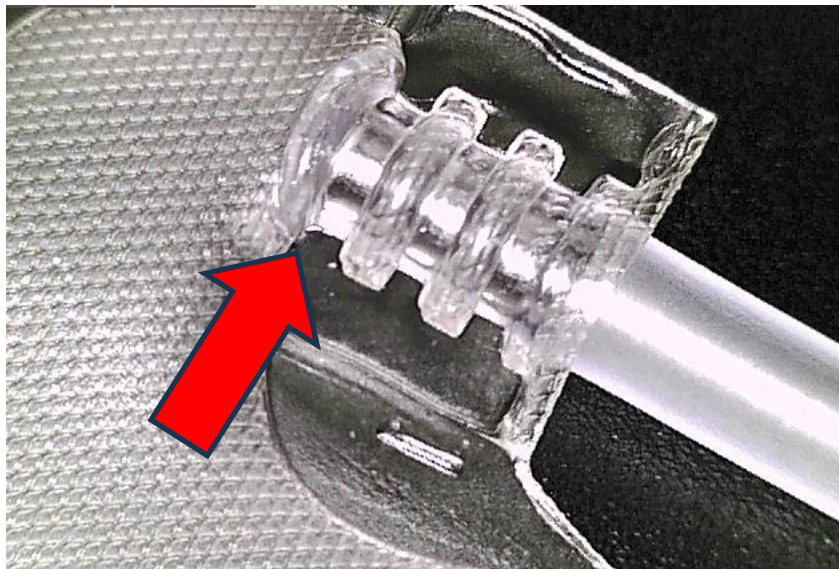


Figure 1. Medication Bag to Tubing Joint Weld

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.

One serious injury and zero 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	3983342, 4013368, 4046817, 4052400, 4060903
21-7002-24	RESERVOIR, CASSETTE, 100ML 12/BX	3977441, 3983314, 4013369, 4013370, 4013371, 4013372, 4025948, 4033993, 4037444, 4040238
21-7301-24	RESERVOIR, CASSETTE, 50ML, FS 12/BX	3983337, 3983338, 3983340, 4013367, 4034019, 4034021, 4034022, 4037748, 4037749, 4040247, 4040248, 4042839, 4042840, 4052405, 4052406, 4052409
21-7302-24	RESERVOIR, CASSETTE, 100ML, FS 12/BX	3971709, 3983315, 3983317, 3983318, 3983320, 3983328, 3983332, 4013356, 4013359, 4013360, 4013361, 4013373, 4013375, 4013376, 4013378, 4019430, 4034024, 4034030, 4037751, 4037752, 4037754, 4037756, 4040251, 4048892, 4052411, 4052412, 4052413, 4053920

Customer Required Actions:

Please contact Smiths Medical customer service 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. Discard all affected products following your institution's process for discarding. If discarding is not immediately possible at your facility, then the product should be quarantined until disposal.

2. Share this notification with all potential users of the device to ensure they are aware of this notification and proposed mitigations. If the devices are used at another location, please ensure this communication is delivered there.
3. **Return the attached Customer Response Form to EMEA-FSN@icumed.com within ten days** of receipt to acknowledge your understanding of this notification and identify any potentially affected product in your possession.
4. **DISTRIBUTORS:** If you have distributed potentially affected products to your customers, please immediately forward this notice to them and request that they complete the response form and return it to **YOU**. Then the **DISTRIBUTOR** must complete a SINGLE form with the required details and return to EMEA-FSN@icumed.com

Follow up actions by Smiths Medical:

Smiths Medical will provide credit to affected customers upon receipt of a completed response form to certify product destruction. Smiths Medical have corrected the manufacturing process that led to the potential for this issue to occur. Note: A new order must be placed if replacement is needed.

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

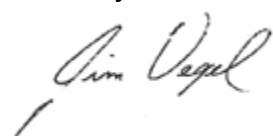
Smiths Medical Contact	Contact Information	Areas of Support
Global Complaint Management	globalcomplaints@icumed.com	To report adverse events or product complaints
Technical Support	servicece@icumed.com	Additional information or technical assistance,
Customer Service	https://www.icumed.com/about-us/contact-us	Questions about product replacement and/or credit.

General Information

Your country regulatory agency has been notified of this action.

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

Sincerely,



Jim Vogel
Vice President, Quality

See below: Customer Response Form

URGENT: FIELD SAFETY NOTICE – RESPONSE FORM

CADD™ Medication Cassette Reservoirs

5th Sept 2024

Check your inventory and complete the information below, even if you do not have the affected product. *Failure to complete all sections of this page may result in improper, delayed or denied credit.*

Please return the completed form to EMEA-FSN@icumed.com, If you have questions about this form please contact EMEA-FSN@icumed.com or your local sales representative.

Name of Hospital / Facility	
Hospital / Facility Address	
Telephone Number	
Name and Title of Person Completing this Form	
Signature of Person Completing this Form	
Date	
If Purchased through a distributor, please list distributor name/location here for traceability purposes	

Please select one:

- ☐ I have **NO** affected products (complete and return this form to the e-mail address above)
- ☐ **YES**, I have affected products, I have notified users in my facility and I have followed the instructions provided to me and destroyed all affected items (see table below)

If you have affected product on hand, please complete table 1 below:

TABLE 1

Item / SKU Number	Lot Number	Quantity in inventory (Eaches)	Quantity Destroyed (Eaches)	Date of Destruction

If you have distributed the product further, please complete table 2 below with collated information received from your customers and respond to ICU Medical with the overall information.

TABLE 2

Item / SKU Number	Lot Number	Quantity destroyed locally (Eaches)	Date of Destruction

Adverse events and complaints associated with the use of this product should be reported and emailed to Smiths Medical's Global Complaint Management Department at globalcomplaints@icumed.com.

ADDITIONAL AFFECTED PRODUCT DESTROYED

[illegible]