CADD™ Infusion System Infusion Sets for use with CADD pumps Field Action FAQ

Urgent Medical Device Field Safety Notice-UK

Smiths Medical is issuing an Urgent Medical Device Field Safet Notice (notice) informing affected customers about potential risks associated with two issues with the CADD infusion sets. Smiths Medical is notifying each affected customer and authorized distributor of these issues.

If customers have further questions, they should contact Smiths Medical's customer service at ukcs@smiths-medical.com .

1. What are the issues?

Smiths Medical is issuing a notice to inform customers of two potential issues with certain CADD Infusion System infusion sets that can potentially impact infusion delivery. The issues, associated risks, recommended user actions, and affected products are described in the notice.

2. What is the potential risk?

The risks and actions to potentially mitigate the risks are described for both issues in the notice. Issue 1 may potentially result in underdelivery or non-delivery and Issue 2 may potentially result in delays in the initiation of therapy or interruption of therapy, as documented in the notice. Depending on a patient's condition and the medication being delivered, the risks for patients may include serious injury or death.

3. What products are affected?

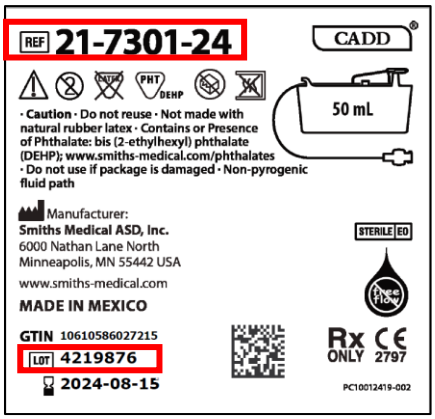
Refer to Tables 1 and 2 of the Medical Device Correction notice for the impacted products and lot numbers. The notice lists a range of affected lot numbers, and only lots associated with a impacted list number are affected.

4. What action is Smiths Medical taking?

Smiths Medical is notifying affected customers via the attached notice. Additionally, Smiths Medical implemented corrective actions to address the manufacturing variations that led to these issues.

5. How can customers identify if a particular set is impacted?

The list number and lot number are printed on every box and individual package:



6. Has there been any patient harm related to the issues in the notice?
Yes. Smiths Medical has received reports of several instances of patient harm, including serious injuries and deaths related to these issues. Smiths Medical could not confirm that the affected CADD Infusion System infusion sets directly caused the deaths. Please refer to the notice for the detailed risk and reported harms associated with each issue.

7. Have there been any customer complaints about these issues?
Yes. Customers have reported complaints about these issues.

8. Can customers continue to use the affected CADD infusion sets?
Yes. Customers can continue to use affected CADD infusion sets by following the "Actions for Clinicians/Patients/Pharmacists" section of the notice to mitigate the potential risks. Please refer to #9 below regarding specific instructions for treatment of patients requiring life sustaining therapy.

9. Are there specific instructions for treatment of patients requiring life sustaining therapy?
For infusion of life sustaining medications, use of alternative CADD infusion sets is recommended. To assure prioritizing availability of alternate CADD infusion sets, please contact Smiths Medical customer service ukcs@smiths-medical.com for information on obtaining the alternate CADD infusion sets.

Depending on availability and specific patient situations, clinicians may consider switching patients to an alternative pump.

10. How is the customer communication sent?
Smiths Medical is sending the notice to the Director of Risk Management, Director of Nursing, and Director of Pharmacy of each facility. All CADD customers and distributors who have purchased any of the affected product directly from Smiths Medical will receive a notice, FAQs, and response form.

Customers who have further distributed the affected product are asked to forward the notice, FAQ, and response form to whom they further distributed the affected product.

11. Where can I obtain a response form?
Customers should contact EMEA-Quality@icumed.com to obtain a response form.

12. Is this a voluntary action?
Yes. Smiths Medical is voluntarily taking this action.

13. Are there alternative products I can use which are not affected by the two issues?
Yes, there are alternative devices for some affected products, please refer to list of alternative devices in Table 1 below. Due to limited inventory, Smiths Medical is prioritizing availability of alternate devices for patients requiring life sustaining therapy.

Table 1. Alternative Products

Affected Products		Alternative Products	
Item Number	**Description**	**Item Number**	**Description**
21-7300-24	RESERVOIR, CASSETTE, 100ML, FS, YELLOW 12/BX	21-7002-24	RESERVOIR, CASSETTE, 100ML 12/BX
21-7301-24	RESERVOIR, CASSETTE, 50ML, FS 12/BX	21-7001-24	RESERVOIR, CASSETTE, 50ML 12/BX
21-7302-24	RESERVOIR, CASSETTE, 100ML, FS 12/BX	21-7002-24	RESERVOIR, CASSETTE, 100ML 12/BX
21-7322-24	SET, ADMIN, CADD, 78", SPIKE, FS, TOTM 12/BX	21-7022-24	SET, ADMIN, CADD, 60", SPIKE, ASV 12/BX
21-7323-24	SET, ADMIN, CADD, 78", SPIKE, BLUE STRIPE, FS, TOTM 12/BX	21-7023-24	SET, ADMIN, CADD, 60", SPIKE, ADD-ON ASV, BLUE STRIPE 12/BX
21-7324-24	SET, ADMIN, CADD, 123", SPIKE, YELLOW STRIPE, FS, TOTM 12/BX	21-7024-24	SET, ADMIN, CADD, 105", SPIKE, ASV, YELLOW STRIPE 12/BX
21-7359-24	SET, ADMIN, CADD, 69", M/M, FS, TOTM 12/BX	21-7059-24	SET, ADMIN, CADD, 69", M/M, ADD-ON ASV, BLUE STRIPE 12/BX
21-7390-24	SET, ADMIN, CADD, 102", F/M, CHECKVALVE, FS, TOTM 12/BX	21-7090-24	SET, ADMIN, CADD, F/M, CHECKVALVE, ASV 12/BX
21-7391-24	SET, ADMIN, CADD, 108", SPIKE/M, CHECKVALVE, FS, TOTM 12/BX	21-7091-24	SET, ADMIN , CADD, SPIKE/M, CHECK VALVE, ASV 12/BX
21-7343-24	SET, ADMIN, CADD, 114", SPIKE, 1.2 FLTR, NAC, FS, TOTM 15/BX	21-7091-24 or	SET, ADMIN , CADD, SPIKE/M, CHECK VALVE, ASV 12/BX or
		21-7364-24	SET, ADMIN, HIGH VOL, 1.2 FLTR, NAC, FS, TOTM 15/BX
21-7346-24	SET, ADMIN, CADD, 94", SPIKE, 0.2 FLTR, COILED TUBE, FS, TOTM 15/BX	21-7094-24	SET, ADMIN, CADD, SPIKE, 0.2 MICRON FLTR, ASV 12/BX
21-7363-24	SET, ADMIN, CADD, 93", SPIKE, 1.2 FLTR, COIL TUBE, FS, TOTM 15/BX	21-7022-24 or	SET, ADMIN, CADD, 60", SPIKE, ASV 12/BX
		21-7386-24	SET, ADMIN, HIGH VOL, 1.2 FLTR, FS, TOTM 15/BX
21-7349-24	SET, ADMIN, CADD, 130", EPID, SPIKE, 0.2 FLTR, YELLOW STRIPE, FS, TOTM, 12/BX	21-7024-24 or	SET, ADMIN, CADD, 105", SPIKE, ASV, YELLOW STRIPE 12/BX
		21-7094-24	SET, ADMIN, CADD, SPIKE, 0.2 MICRON FLTR, ASV 12/BX
21-7394-24	SET, ADMIN, CADD, 108", SPIKE, 0.2 MICRON, FLTR, FS, TOTM 12/BX	21-7094-24	SET, ADMIN, CADD, SPIKE, 0.2 MICRON FLTR, ASV 12/BX
21-7395-24	SET, ADMIN, CADD, 102", LUER, 0.2 MICRON FLTR, FS, TOTM 12/BX	21-7095-24	SET, ADMIN, CADD, F. LUER, 0.2 MICRON FLTR, ASV, 12/BX

14. Can customers return affected CADD infusion sets?

Please note that this is a correction notification and not a product removal. No product return is necessary. Customers should carefully read and follow instructions in the notice to mitigate the potential risks.

Due to limited inventory, Smiths Medical is prioritizing availability of alternate devices for patients requiring life sustaining therapy. However, if customers in the United Kingdom choose to return affected devices, they should contact customer support at ukcs@smiths-medical.com.

15. Will Smiths Medical offer any compensation to customers for the corrective action?

Please note that this is a correction notification and not a product removal. No product return is necessary. However, if customers choose to return affected products, Smiths Medical will provide replacement products or issue a credit.

16. Whom should customers contact if they need technical assistance or have additional questions?

Customers can contact Smiths Medical's customer support at ukcs@smiths-medical.com.

17. Is Smiths Medical continuing to ship the affected CADD infusion sets?

Yes. Because Smiths Medical has provided actions for users to take to mitigate the risks associated with the issues in the customer notice, and to prevent a supply disruption, Smiths Medical is continuing to ship the affected CADD infusion sets.

18. Has Smiths Medical notified the MHRA?

Yes.