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Smiths Medical ASD, Inc. 6000 Nathan Lane N.
Minneapolis, MN 55442
https://www.smiths-medical.com/

URGENT MEDICAL DEVICE FIELD SAFETY NOTICE - **UPDATED**

CADD™ Infusion System Infusion Sets for use with CADD pumps in Germany

19 June 2023:

Dear Valued CADD Customers:

- Director of Pharmacy
- Director of Nursing
- Director of Risk Management

Update to notice from 17 January 2023 (updated content shown in red font): Smiths Medical has identified additional lots of CADD Infusion System Infusion Sets that are potentially affected by the issues listed in this notice. This revised communication is being issued to make you aware of the complete range of impacted lots and additional actions taken by Smiths Medical. Please review all product in your inventory to determine if it is affected by the issues in this notice. Tables 1 and 2 have been updated to include the additional lots.

Smiths Medical is issuing this letter to notify you of two potential issues with CADD Infusion System Infusion Sets. This notification details the issues, the affected items, and the required steps to perform.

Affected Products:

Issue 1: Lack of Delivery or Underdelivery related to Tubing Occlusion	Specified medication cassette reservoirs with flow stop and administration sets used with all CADD pumps, as described in Table 1 below
Issue 2: False "No Disposable Attached (NDA)" Alarms	Specified 50 mL and 100 mL medication cassette reservoirs with Flow Stop used with CADD Legacy Infusion Systems, as described in Table 2 below

Issue 1 – Lack of Delivery or Underdelivery related to Tubing Occlusion

Overview of the Issue:
Manufacturing variations may cause the green CADD Flow Stop arm to compress and partially occlude the tubing before clinical use. If this occurs, there is a potential that the occlusion does not resolve when an affected reservoir or administration set is connected to the pump, and the pump may not detect the occlusion. **This may result in underdelivery or non-delivery of medication, despite the pump displaying that the infusion is running properly**.

CADD Flow Stop Medication Cassette Reservoirs and CADD Flow Stop Administration Sets provide free-flow protection. By design, a green, spring-loaded pivoting arm automatically squeezes the tubing closed when the reservoir or administration set is not installed on a pump. Connecting the reservoir or administration set to the pump causes the pump to push the Flow Stop arm, enabling fluid flow through the tubing. **In certain circumstances, the tubing may remain occluded even though the CADD reservoir or administration set is loaded into the pump**.

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Affected Items:
Certain CADD Administration Sets and Medication Cassette Reservoirs with Flow Stop used with all CADD pumps are affected. See Table 1 below for the complete list of affected items.

Potential Risk:
If the tubing is occluded under the Flow Stop arm, the pump cannot detect the occlusion and may not infuse as intended; it may **underdeliver** the fluid/medication or cause an **interruption in therapy**, even though the pump will display that the infusion is running properly. Depending on the medication infusing, an interruption in therapy or underinfusion could cause serious patient harm or death.

To date, Smiths Medical has received reports of fourteen serious injuries and two deaths potentially related to this issue. Smiths Medical could not confirm the deaths were directly caused by the affected product.

Issue 2 – False "No Disposable Attached (NDA)" Alarms

Overview of the Issue:
There is a potential that **CADD-Legacy pumps may not detect that 50 mL and 100 mL CADD Medication Cassette Reservoirs with Flow Stop are attached to the pump when the cassettes are properly attached**. This issue does not impact 250 mL Flow-Stop and non-Flow Stop CADD Medication Cassette Reservoirs.

Manufacturing variations on certain CADD Medication Cassette Reservoirs with Flow Stop may interfere with the pump detecting a properly attached CADD cassette. In such situations, the CADD-Legacy pump will issue a "No Disposable Attached (NDA)" double-beep audible warning if the pump cannot determine that the CADD cassette is properly attached. The pump will initiate an NDA alarm if the NDA double-beep warning is not resolved within 2 minutes. The user must clear the alarm and resolve the cause of the NDA event before using the pump.

As a reminder, Smiths Medical announced the discontinuation of the sale of CADD-Legacy pumps, effective December 31, 2022.

Affected Items:
50 mL and 100 mL Medication Cassette Reservoirs with Flow Stop when used with CADD-Legacy infusion pumps. See Table 2 below for the complete list of affected items.

Potential Risk:
An NDA alarm will be initiated if the pump does not detect the cassette when the user attempts to start an infusion. This situation results in the pump displaying "No disposable, pump won't run" and **delays the initiation of therapy**. During infusion, if the pump does not detect the cassette and triggers an NDA alarm, the pump will stop delivery and display "No disposable, clamp tubing," resulting in an **interruption of therapy**. Depending on the medication infusing, a delay or interruption in therapy could cause serious patient harm or death.

To date, Smiths Medical has received eleven reports of serious injuries, and zero (0) reports of deaths potentially related to this issue.

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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	globalcomplaints@icumed.com	To report adverse events or product complaints
Customer Service	Tel: +49 (0)89 242959 - 0 Fax: +49 (0)89 242959 – 310 Email: bestellung@icumed.com	Additional information or technical assistance

Smiths Medical's Actions

- Smiths Medical implemented corrective actions to address the manufacturing variations that led to these issues.
- This Field Safety Notice includes removal of affected devices in Germany. Smiths Medical is working to increase production of corrected product and will replace products affected by issues 1 and 2 listed in this notice in Germany as supply levels permit.

Customer Required Actions

1. If affected product is used to infuse therapy in critical situations, such as infusion of life sustaining medications, and corrected products are not readily available, refer to the actions listed below to mitigate potential risk when using the affected product.
2. Locate and quarantine affected product in your possession. See Tables 1 and 2 below for the complete list of affected items.
3. Ensure all users or potential users of these devices are immediately made aware of this notification. Clinicians, share this letter with your homecare patients.
4. Complete and return the attached response form on the last page, by email to EMEA-Quality@icumed.com **within ten days of receipt** to acknowledge your understanding of this notification. Smiths Medical will contact you after receipt of the response form to arrange return and replacement of affected product.
5. Upon receipt of the affected product, or upon receipt of a Certificate of Destruction, Smiths Medical will credit you for any product returned/destroyed. You will only receive credit for product that you return or that you certify has been destroyed locally.
   NOTE: Credits for product purchased through distributor will be credited by the distributor.
6. DISTRIBUTORS: If you have distributed potentially affected products to your customers, please immediately forward this notice to them and ask them to return completed response forms and affected product to you. When you have received all completed response forms and affected product from your customers, please compile the information into a SINGLE COMPLETED form detailing ALL AFFECTED ITEMS, LOT NUMBERS, and QUANTITIES and return this SINGLE COMPLETE FORM to EMEA-Quality@icumed.com.

NOTE: If you elect to destroy the product at your facility, please complete the enclosed Certification of Destruction along with the Recall Acknowledgement and Product Inventory Response Form to EMEA-Quality@icumed.com.

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Actions to Mitigate Risk and Continue Use of Affected Product when Corrected Replacement Product is Not Readily Available

In instances where the benefits of using affected products in table 1 and 2 are greater than the potential risk associated with removing affected product from use, we recommend the steps below:

Issue 1: Lack of Delivery or Underdelivery related to Tubing Occlusion

- Be aware that if you use products affected by this notice with your CADD pump, the medication may appear to be infusing normally, but due to the occluded tubing, may not be infusing at all or may be underinfusing, and the pump will not alarm.
- When using products affected by this notice, always prime the set using the pump and watch the fluid flow closely during this process. If the fluid doesn't flow properly or takes an abnormally long time to prime, or if the pump displays a higher than expected priming volume, replace the reservoir or set. The priming volume is listed on the packaging for each administration set.
- If medication remains in the reservoir at the completion of the infusion, contact your clinician and Smiths Medical Global Complaint Management to report the event.

Issue 2: False "No Disposable Attached (NDA)" Alarms

- Be aware that the pump may not adequately detect the cassette before or during an infusion due to this issue, and an alarm will be triggered. If a pump displays an NDA alarm, the user can attempt to resolve the alarm by repositioning the CADD Medication Cassette Reservoir while connected to the pump, repositioning the reservoir by disconnecting from the pump and reattaching it to the pump, or replacing the reservoir.
- Alternatively, the user can remove the reservoir from the pump and push the plastic ridge highlighted in the circle below towards the arch on the reservoir as indicated by the arrow in Figure 1.
- If the user cannot resolve the NDA alarm, replace the cassette reservoir, though the issues may recur if that product is also affected by this recall.

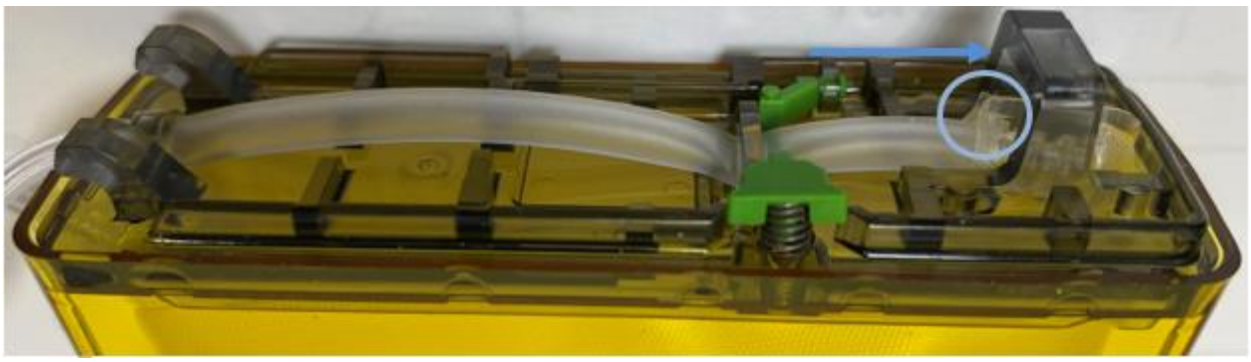

Figure 1. CADD Reservoir

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General Information

Your national competent authority has been notified of this Field Safety Notice.

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

Sincerely,

[redacted]

Enclosures: Attachment 1 – Urgent Medical Device Field Safety Notice Response Form
Attachment 2 – Frequently Asked Questions
Attachment 3 – Certificate of destruction

Table 1: Updated: Affected Items for Issue 1 – Lack of Delivery or Underdelivery related to Tubing Occlusion

Changes to the affected lot ranges from the initial notice are listed with * and in red font in the table below.

List Number	Description	Affected Lot Number Range	
		Beginning Lot Number	Last Lot Number
21-7300-24	100-mL Yellow CADD Medication Cassette Reservoir	3630772	4321035
21-7301-24	50-mL CADD Medication Cassette Reservoir	3630747	4329608*
21-7302-24	100-mL CADD Medication Cassette Reservoir	3617363	4329630*
21-7308-24	250-mL CADD Medication Cassette Reservoir with flow stop, clamp, and female Luer Nonvented stopper included	4053922	4334070*
21-7309-24	250-mL CADD Yellow Medication Cassette Reservoir with flow stop, clamp, and female Luer Nonvented stopper included	4062405	4330870*
21-7310-24	250-mL CADD Blue Medication Cassette Reservoir with flow stop, clamp, and female Luer Nonvented stopper included	4062404	4330874*
21-7321-24	CADD Administration Set with female Luer, flow stop, clamp, one-way checkvalve with male Luer	3773534	4308545*
21-7322-24	CADD Administration Set with bag spike, flow stop, clamp, one-way checkvalve with male Luer	3776375	4334318*
21-7323-24	CADD Administration Set with bag spike, flow stop, clamp, one-way checkvalve with male Luer	3776373	4315950
21-7324-24	CADD Administration Set with bag spike, flow stop, clamp, one-way checkvalve with male Luer	3773527	4321316*
21-7333-24	CADD Administration Set with bag spike, flow stop, 1.2µ air-eliminating filter, clamp, Luer activated needleless injection site, and one-way checkvalve with male Luer	3776362	3984144
21-7336-24	CADD Administration Set with bag spike, flow stop, 0.2µ air-eliminating filter, clamp, spiral outlet tubing and one-way checkvalve with male Luer	3776360	4025381
21-7339-24	CADD Administration Set with bag spike, flow stop, 0.2µ air-eliminating filter, clamp, and one-way checkvalve with male Luer	3780565	4009665

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List Number	Description	Affected Lot Number Range	
		Beginning Lot Number	Last Lot Number
21-7343-24	CADD Administration Set with bag spike, flow stop, 1.2µ air-eliminating filter, clamp, Luer activated needleless injection site and oneway checkvalve with male Luer	3965344	4334332*
21-7346-24	CADD Administration Set with bag spike, flow stop, 0.2µ air-eliminating filter, clamp, spiral outlet tubing and one-way checkvalve with male Luer	3776356	4320785*
21-7349-24	CADD Administration Set with bag spike, flow stop, 0.2µ air-eliminating filter, clamp, and one-way checkvalve with male Luer	3926579	4320791
21-7359-24	CADD Administration Set with male Luer, flow stop, clamp, one-waycheckvalve with male Luer	3776315	4308547*
21-7363-24	CADD Administration Set with bag spike, flow stop, 1.2µ air-eliminating filter, clamp, spiral outlet tubing and one-way checkvalve with male Luer	3773412	4315935*
21-7383-24	CADD Administration Set with bag spike, flow stop, 1.2µ air-eliminating filter, clamp, spiral outlet tubing and one-way checkvalve with male Luer	3780549	3971523
21-7390-24	CADD Administration Set with female Luer, flow stop, 7.6cm Y-extension,clamps, one-way checkvalve with female Luer and one-way checkvalve with male Luer	3780548	4308567
21-7391-24	CADD Administration Set with bag spike, flow stop, 7.6cm Y-extension, clamps, one-way checkvalve with female Luer and one-way checkvalve with male Luer	3773276	4315953*
21-7394-24	CADD Administration Set with bag spike, flow stop, 0.2µ air-eliminating filter, clamp, one-way checkvalve with male Luer	3774739	4315948
21-7395-24	CADD Administration Set with female Luer, flow stop, 0.2µ air-eliminating filter, clamp, one-way checkvalve with male Luer	3808536	4290737
21-7600-24	100-mL CADD Yellow Medication Cassette Reservoir with NRFit™ connector with flow stop, yellow-striped tubing, clamp and female NRFit™ connector. Yellow stopper included	4084914	4329633*

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List Number	Description	Affected Lot Number Range	
		Beginning Lot Number	Last Lot Number
21-7609-24	250-mL CADD Yellow Medication Cassette Reservoir with NRFit™ connector with flow stop, yellow-striped tubing, clamp and female NRFit connector. Yellow stopper included	4072200	4334088*
21-7624-24	CADD Yellow Administration Set with NRFit™ connector with bag spike, flow stop, yellow-striped tubing, clamp and one-way checkvalve with male NRFit connector	4092506	4309481*
21-7649-24	CADD Yellow Administration Set with NRFit connector with bag spike, flow stop, yellow-striped tubing, 0.2µm air-eliminating filter, clamp, and one-way checkvalve with male NRFit connector	4076410	4308542*

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Table 2: Affected Items for Issue 2– False "No Disposable Attached (NDA)" Alarms

50 mL and 100 mL Medication Cassette Reservoirs with Flow Stop when used with **CADD-Legacy Infusion Systems**. Changes to the affected lot ranges from the initial notice are listed with * and in red font in the table below.

List Number	Description	Affected Lot Number Range	
		Beginning Lot Number	Last Lot Number
21-7300-24	100-mL Yellow CADD Medication Cassette Reservoir	3630777	4315903
21-7301-24	50-mL CADD Medication Cassette Reservoir	3630748	4315907
21-7302-24	100-mL CADD Medication Cassette Reservoir	3630803	4315911
21-7600-24	100-mL CADD Yellow Medication Cassette Reservoir with NRFit™ connector with flow stop, yellow-striped tubing, clamp and female NRFit™ connector. Yellow stopper included	4168766	4299610*