smiths medical
bringing technology to life

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

URGENT: FIELD SAFETY NOTICE – Switzerland - **UPDATED**

CADD™ Infusion System Infusion Sets for use with CADD pumps

19th June 2023

Dear Valued CADD Customers:

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

Update to notice from 09 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.

Please note specific instructions for treatment of patients requiring life sustaining therapy: For infusion of life sustaining medications, use of alternative CADD infusion sets is required. To assure prioritizing availability of alternate infusion sets, please contact Smiths Medical customer service for information on obtaining the alternate CADD infusion sets.

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**.

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.

Actions for Pharmacists:

- Immediately identify affected products in your possession and ensure these products are separated and labeled as affected by this notice to avoid use for life sustaining medications.
- For use with life sustaining medications, please contact Smiths Medical customer service for information on obtaining alternative CADD infusion sets.
- If the pharmacist experiences difficulty with filling the cassettes of affected products, consider changing to a new infusion set and contact Smiths Medical Global Complaint Management to report the event.

Actions for Clinicians and Patients:

- Be aware that if you use products affected by this Field Safety 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.
- For patients requiring life sustaining medications, use of alternative CADD infusion sets is required. Clinicians can contact the specialty pharmacies and discuss availability of alternative CADD infusion sets. Depending on availability and specific patient situations, clinicians may consider switching patients to an alternative pump.
- 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
- Clinicians, share this letter with your homecare patients and educate them to prime the set using the pump as mentioned above.

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 the end of 2019.

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.

Actions for Pharmacists:
- Immediately identify affected products in your possession and ensure these products are separated and labeled as affected by this notice to avoid use for life sustaining medications.
- For use with life sustaining medications, please contact Smiths Medical customer service for information on obtaining alternative CADD infusion sets.

Actions for Clinicians and Patients:
- 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.

- For patients requiring life sustaining medications, use of alternative CADD infusion sets is required. Contact pharmacy to discuss availability of alternative CADD infusion sets. Depending on availability and specific patient situations, clinicians may consider switching patients to an alternative pump.
- 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 notice.
- Clinicians, share this letter with your homecare patients and educate them about the actions above.

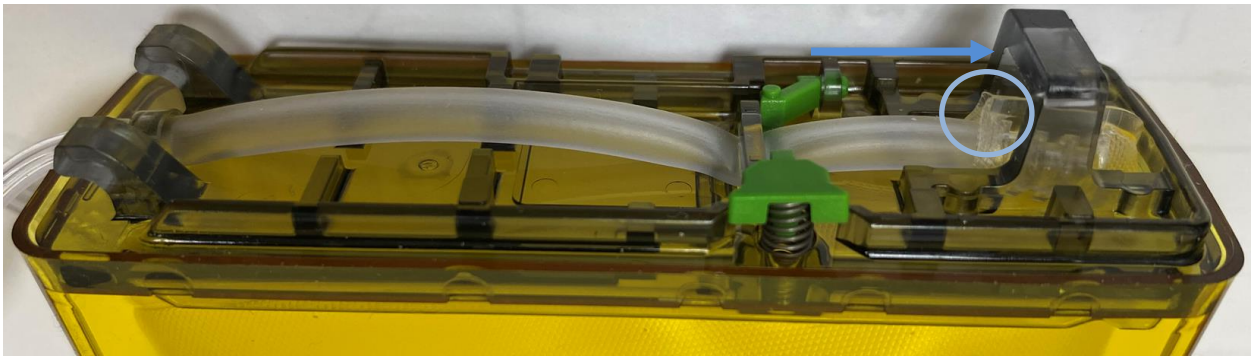


Figure 1. CADD Reservoir

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 Assistance	info@icumed.ch (0) 41 43 388 62 00	Additional information or technical assistance

Smiths Medical's Actions

Smiths Medical implemented corrective actions to address the manufacturing variations that led to these issues.

Customer Required Actions

1. Ensure all users or potential users of these devices are immediately made aware of this notification and proposed mitigations.
2. Complete and return the 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.
3. DISTRIBUTORS: If you have distributed potentially affected products to your customers, please immediately forward this notice to them and ask them to return completed forms to you. When you have received all customer responses from your customers, please compile the information into a SINGLE COMPLETED form and return to EMEA-Quality@icumed.com.

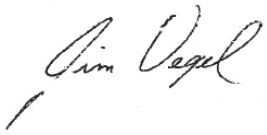
Smiths Medical ASD, Inc. 6000 Nathan Lane N.
Minneapolis, MN 55442
https://www.icumed.com/

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,



Jim Vegel
Vice President of Quality

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

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*

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

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*

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

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*

smiths medical
bringing technology to life

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

UPDATED URGENT FIELD SAFETY NOTICE: RESPONSE FORM

CADD™ Infusion System Infusion Sets for use with CADD pumps

19th June 2023

Check your inventory and complete the information below, even if you do not have the affected product.

Please return the completed form to EMEA-Quality@icumed.com, Smiths Medical Customer Service and 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	

☐ **YES**, I have affected product, I have notified users in my facility and I have followed the instructions provided to me (complete and return this form to the e-mail addresses above)

☐ I have **NO** affected product (complete and return this form to the e-mail addresses above)

☐ Devices transferred/no longer owned; please indicate new owner contact information:

- Business Name: _____
- Address/City/State/ZIP: _____
- Contact Name: _____
- Contact Phone/E-mail Address: _____

- Have you distributed the product further to the retail level? ☐ **YES** ☐ **NO**
  - If yes, have you notified your retail customers by providing them with a response form and asking them to complete it and return it to you? ☐ **YES** ☐ **NO** (if no, explain below)

If you have distributed the product further, please provide the list of your retail customers, inclusive of customer name, address, city, state, zip code, telephone number and quantity of product distributed along with your completed response form to the contact information listed above so Smiths Medical can verify effectiveness of the FSN to the appropriate level.

Adverse events and complaints associated with the use of these products should be reported and emaile d to Smiths Medical's Global Complaint Management Department (globalcomplaints@icumed.com)

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

Updated Urgent Medical Device Field Safety Notice-Switzerland

Smiths Medical is issuing an Urgent Medical Device Field Safety 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 info@icumed.ch/ (0) 41 43 388 62 00.

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 that are not requiring life sustaining therapy 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 required. To assure prioritizing availability of alternate CADD infusion sets, please contact Smiths Medical customer service info@icumed.ch/ (0) 41 43 388 62 00 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 Swtizerland choose to return affected devices, they should contact customer support at info@icumed.ch/ (0) 41 43 388 62 00.

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 info@icumed.ch/ (0) 41 43 388 62 00.

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 Swissmedic?

Yes.

19. I have already responded to the initial FSN do I need to respond to this updated FSN?

Yes.