smiths medical

6000 Nathan Lane N.
Minneapolis, MN 55442

URGENT MEDICAL DEVICE CORRECTION

All CADD-Solis™ 21-2160-XX* Li-ion Rechargeable Battery Packs

16 July 2024:

Dear Valued CADD-Solis Customers:

- Director of Biomedical Engineering
- Director of Nursing
- Director of Risk Management

Smiths Medical is issuing this letter to notify you of an issue with all CADD-Solis Li-ion Rechargeable Battery Packs (List Number 21-2160-XX*). The lithium-ion battery packs provide an alternate source of power for the CADD-Solis ambulatory infusion pump.

Smiths Medical is notifying all affected CADD-Solis customers of this issue for awareness. This notification details the issue and the affected product models.

Affected Models:

Table 1: Affected Products(s)

Product Name	List Number
CADD-Solis Li-ion Rechargeable Battery Packs	21-2160-XX*

*Please note that the XX suffix is region specific.

Overview of the Issue:
Smiths Medical identified three (3) reports in which damage to the battery pack may have caused a short to a capacitor within the battery pack. While the battery encasement is designed to be flame retardant, a short to the capacitor may potentially lead to melting of the battery pack case. If this issue occurs, the battery pack charging circuit may become inoperable.

Potential Risk:
Damage to the battery pack may lead to a delay in therapy or interruption of therapy. The user would be alerted with the normal "Low Battery" or "Depleted Battery" alarms. The presence of excessive heat in the event of a melted battery pack casing is also possible, which may result in a thermal injury.

To date, Smiths Medical has not received any reports of serious injuries or deaths related to this issue.

Actions for Users:
Inform all affected CADD Solis users of rechargeable battery packs of this notice. Provide the instructions below:

1. Examine the external condition of the battery pack and look for evidence of damage to the outer case. As stated in the battery pack Instructions for Use, if the battery pack housing is cracked or otherwise damaged, replace the battery pack. NEVER use a battery pack that appears damaged. A rechargeable battery pack must be replaced with either another CADD-Solis rechargeable battery pack or with 4 AA batteries.
2. Users with damaged battery packs should submit complaints per the contact information below.
3. Ensure all users or potential users of these products are immediately made aware of this notification.

4. Complete and return the attached Response Form to smithsmedical5437@sedgwick.com **within ten days of receipt** to acknowledge your understanding of this notification, even if you do not have the affected product. Please contact your local representative for credit.
5. **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 smithsmedical5437@sedgwick.com

Follow up Actions by Smiths Medical:
Smiths Medical is continuing to investigate this matter to determine if additional actions may be warranted.

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 1-866-216-8806	To report adverse events or product complaints
Technical Support	TSC.Support@icumed.com 1-800-241-4002, option 3	Additional information or technical assistance

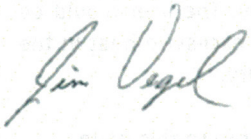
This notification is being performed with the knowledge of regulatory authorities, including the US Food and Drug Administration (FDA).

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 patient safety and is focused on providing exceptional product reliability and the highest level of customer satisfaction. Thank you for your prompt support on this important matter. We appreciate your cooperation.

Sincerely,



Jim Vegel
Vice President of Quality

Enclosures:
- Response Form (separate document)

6000 Nathan Lane N.
Minneapolis, MN 55442

URGENT MEDICAL DEVICE CORRECTION: RESPONSE FORM

CADD-Solis™ Ambulatory Infusion Pump Rechargeable Battery Pack

16 July 2024

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

Complete this form and return it to Sedgwick via fax at 1- 844-801-9147 or email to smithsmedical5437@sedgwick.com. If you have questions about this form, please call Sedgwick at 1-888-665-0463 (M-F, 8am-5pm ET).

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 to return all affected items. (complete and return this form to Sedgwick via the fax/e-mail above). Please fill out the table below.

☐ I have **NO** affected product (complete and return this form to Sedgwick via the fax/e-mail 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 and asked them to contact Sedgwick at 1-888-665-0463 (M-F, 8am-5pm ET) to obtain a response form? **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 recall notification to the appropriate level.

Adverse events and complaints associated with the use of these products should be reported and emailed to Smiths Medical's Global Complaint Management Department (globalcomplaints@icumed.com) or to the FDA at the contact information provided with this notification.