Provider Newsflash
November 2024

FDA Recall – Smiths Medical

Purpose of this communication:

- We are writing to inform you that the FDA has issued notice of a Class I recall by Smiths Medical for update of use instructions for all Lots of their CADD-Solis Rechargeable Battery Packs that are used with CADD-Solis ambulatory infusion pumps used for treatments that require continuous infusions of intermittent larger dose (bolus) and or patient controlled on-demand doses of medication. The update is due to a potential issue where battery pack damage may lead to a short within the battery that melts the pack casing and stops the battery from being able to charge. Use of the affected products may cause serious adverse health consequences including burns, injuries related to delayed or interrupted therapy and death. This recall involves updating instructions for device use and does not involve removal of the device.

What do I need to do?

- Please review the following recall notice: Battery Pack Correction: Smiths Medical Updates Use Instructions for CADD-Solis Li-ion Rechargeable Battery Packs Due to Risk That Pack Damage May Cause a Circuit Short and Prevent Recharge | FDA
- Notify impacted patients and facilitate the repair, replacement and/or resolution of the recall, according to the guidelines issued by the manufacturer in the FDA notification.
- Confirm if you have any CareCentrix patients affected by this recall and notify the CareCentrix Quality Department by faxing information to: 919-792-6718 Attn: Quality Department.

Thank you in advance for your cooperation and continued partnership.