carecentrix

Provider Newsflash
February 2023

FDA Recall – Smiths Medical CADD Pump System

Purpose of this communication:

- We are writing to inform you that effective immediately the FDA has issued a Class I recall issued by Smiths Medical of certain CADD Administration Sets and Medication Cassette Reservoirs for the following two potential issues delay, interruption or under-delivery of infusion therapy. Either of these recall issues can cause delay of therapy, interruption of therapy, or under-delivery of medication, which all have the potential to cause serious patient harm or death.
- Manufacturing variations may cause the green CADD Slow Stop arm to compress and partially block the tubing before clinical use. If occlusion does not resolve when the affected reservoir or administration set is connected to the pump, the pump may not detect the occlusion and alarm resulting in under-delivery or non-delivery of the medication while pump displays that infusion is running properly.
- Due to manufacturing variations on certain CADD Medication Cassette Reservoirs with Flow Stop may interfere with detecting a properly attached CADD cassette. The pump will give an audible warning, and if this is not resolved within two minutes, “No Disposable Attached (NDA)” alarm will occur preventing the pump from functioning until the alarm is cleared and the cause of the NDA event before using the pump causing delay or interruption of therapy.

What do I need to do?

- Please review the following recall notice: https://www.fda.gov/medical-devices/medical-device-recalls/smiths-medical-recalls-certain-cadd-system-administration-sets-and-cassette-reservoirs-issues?utm_medium=email&utm_source=govdelivery#recalldatabase.
- 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.

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