Health PEI
One Island Health System

Safer Practice Notice

Date: January 25, 2023

Topic: Smith Medical CADD Infusion Pumps – Performance Issue

Situation:
There have been reported incidents of under-delivery of medications, despite the pump displaying that the infusion is running properly.

This is attributed to manufacturing variations which 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 under-delivery, 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.

Background:
Smiths Medical has received reports of eight serious injuries and two deaths potentially related to this issue.

Smiths Medical issued an Urgent Medical Device Correction notice which was then followed by a Health Canada product recall.

Assessment:
If the tubing is occluded under the Flow stop arm, the pump cannot detect the occlusion and may underdeliver even though the pump will display that the infusion is running properly.

Certain CADD Administration Sets and Medication Cassette Reservoirs with Slow Stop are affected

Recommendations:

HPEI is looking at obtaining alternative administration sets to replace the affected products. Once an alternative products has been evaluated and approved by the IV Therapy Team, the affected product will be switched out.

In the meantime, users are advised to take extra care and ensure the following actions are observed:

- Prime the set using the pump.
- 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. **If this occurs:**
  - Keep the administration set (tubing), the package and send both in a biohazard bag to Materials Management at the QEH attention to Greg Wright or Rhonda Garland.
  - Inspect the cassettes to ensure medications have been delivered.
  - Any remaining medication (non-narcotic) should be wasted as per policy.
  - **Any cassettes containing a narcotic or controlled drug (ie morphine, hydromorphone, fentanyl, midazolam) must be returned to pharmacy as per policy.**
  - Monitor the patient for any signs of increased pain, clinical changes, etc.
  - Complete an incident report using the MDI form in the PSMS taking care to include the lot number.
- The priming volume is listed on the packaging for each administration set.

Safer Practice Notices are issued by the Quality and Patient Safety Division of Health PEI to communicate recommended changes as a result of events that have been reported and investigated through the Provincial Safety Management System (PSMS).

For more information please contact:
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