

Topic: Pre-filled 10ml Saline Syringes

Situation:

- There have been three incidents reported by hemodialysis in the month of October 2018 related to pre-filled 10ml saline syringes. While preparing to flush the patient lines to connect patients, it was found that the 10 ml pre-filled saline syringes were filled only with air.
- The defect was identified **after** the syringe was connected to the patient line and blood return checked during the first and second encounter.
- The defect was identified **before** the syringe was connected to the patient line during the third encounter.
- No harm came to either patient that had blood return checked with the empty syringe.
- The syringe lot numbers were 13359 and 13367, expiry date 2020-06. The third lot number is unknown.



3705C – 10ml saline syringe sterile peel pouch



3705C – 10ml saline syringe distinct label

Background:

- Health Mark Product #3705C, pre-filled saline syringes are used throughout renal programs in Health PEI, and can be used as an alternative to BD pre-filled syringes in all acute treatment areas of Health PEI.
- Pre-filled saline syringes are used for a variety of interventions.
- Within the renal program, they are used for flushing hemodialysis central lines and fistula access lines.

Assessment:

- Pre-filled syringes with air pose a significant safety risk if not detected.
- Pushing 10 ml of air into a central line can result in an air embolism which places the patient at risk for heart attack, stroke or respiratory failure.
- Air embolisms are rare; however, they are potentially fatal.

Recommendation:

- All units that use saline pre-filled syringes are to be notified of the potential for air in the syringe.
- Pre-filled syringes are purchased through multiple vendors; it is recommended that a double-check be completed on all pre-filled syringes before use.
- The vendor (Health Mark) has been notified of lot numbers associated with this defect: completed on October 18, 2018.
- A notification was sent to CMDS (Canadian Medical Device Sentinel Network): completed on October 19, 2018.
- An alert was sent to Health Canada: completed on October 19, 2018.

For more information please contact:

Beth Pizio, Quality Risk Coordinator, Quality and Patient Safety Division: 902-438-4092 or eapizio@gov.pe.ca