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Background Document: **B Braun IV Anti-Siphon Valve**

In 2011, B Braun had a recall on their Infusomat pump that involved the failure of their pump clamp and safety events involving free flow into patient. We validated with vendor that the solution for this recall was a correction to a plastic clip in the pump door. A plastic clip was changed to metal. They continued to offer the ASV as optional as a third precaution against free flow.

https://pubmed.ncbi.nlm.nih.gov/24032154/

Incorrect installation of free-flow clamp in B. Braun Infusomat Space infusion pump may result in gravity flow - PubMed (nih.gov)

- Industry standard is the automatic pump clamp and roller clamp at the distal end of IV tubing in preventing free flow
- Vendor sells IV tubing sets without the ASV

The ASV is designed to prevent free-flow to the patient during tubing manipulation such as removing the tubing from the pump.

- Must prime via pump with the ASV in use
- The ASV prevents backflow, so if it is necessary to verify blood return using port on IV tubing you need to remove the ASV or use bifurcated extension set
- The ASV needs to remove to infuse fluids by gravity
- The ASV needs to be removed prior to a patient going into the OR

Benchmarking:

Provincial Patient Safety reached out to other Canadian Health centers that use the Infusomat and heard back from 6. 2 out of 6 did not use the ASV on IV tubing and zero centers had universal use of the ASV on IV tubing. There was no pattern to which type of unit or clinical care utilized the ASV on IV tubing sets.

IV Tubing Quality issues:

The Field Correction notice for IV tubing sets used in Manitoba resulted in a high percentage of false air in line (AIL) alarms. AIL alarms stop the infusions of fluids/medication into patient. This did result in safety events for example, client deterioration for critical medications such as norepinephrine.

The only valid solution to resolve the poor quality in tubing was to turn over inventory to get to corrected tubing. Supply chain needed time to produce new tubing.

Tips from B Braun to reduce AIL alarms included the use of the ASV. How does the backpressure of the ASV work against the forward pressure of the pump mechanism to infuse fluid?

- Pump mechanism has to have enough pressure to open the ASV
- No scientific evidence identified to demonstrate claim that backpressure works above the level of pump to decrease microbubble formation and thus decrease accumulated AIL alarms
- Child Health Transport team indicate they do not use the ASV (7 years of experience with pump)
- Teams have communicated they feel the ASV did make a difference in reducing AIL alarms, at minimum 5 tips were recommended at once to reduce AIL alarms
- Dose Trac data for Province indicates single large volume bubbles are the primary AIL alarm
- No increase in accumulated AIL alarms for sites who indicate they have stopped using the ASV

Based on Dose Trac data, feedback from safety events and product complaint forms, we can conclude the high prevalence of false AIL were due to the IV tubing field correction notice.

Safety Concerns:

False AIL alarms are a safety concern as it stops IV infusions and with the field correction notice, AIL alarms have been difficult to resolve. Infusions have at times been completed via gravity.

Have there been safety events reported due to the **discontinuation** of the ASV? **NO**

Accumulation of microbubbles over time would result in an AIL alarm (it alarms at 15 minutes if accumulated microbubbles are trending to exceed 3.8 mL of air in 1 hour). Current DoseTrac data indicates this is not the type of AIL alarms we are experiencing.

The ASV would not prevent single large volume bubbles.

Safety events are occurring when we are unable to remove the ASV to convert IV tubing to gravity infusions. Applying higher pressures to force open the valve has resulted in the end of IV tubing bursting apart.

The above situations may result in:

- Delay of therapy and potential client deterioration
- Additional team stress in urgent clinical situations
- Care team members being exposed to medication or blood products if the IV tubing fall apart.

Recommendation - Discontinue use of the ASV

- Lack of evidence for use of the ASV in preventing accumulated AIL alarms
- Accumulated AIL alarms are not a current issue in Manitoba
- Existing safety risks with the use of the ASV
- No validated patient safety risks have been identified if the ASV are not used on the IV tubing
- We are out of the field correction notice for the majority of IV tubing and we should see typical AIL alarms that would require clinical assessment
- Priming by pump is optional, the most important step in purging air in the tubing is inverting the IV ports and tapping the air forward, including at tubing joints that load into the pump

Action:

- Determine clinical implementation plan
- Support change management and monitor Dose Trac data
- Practice reminders, for example, to fill chamber 2/3 full, observe drip flow, utilize roller clamp (Have we become dependent on the ASV to prevent free flow, meaning have we moved away from the practice of closing the roller clamp prior to removing IV tubing from the pump?)
- Discard the ASV upon opening the package and use blue cap as cover to protect tip against contamination
- Assist supply chain management in estimating usage of IV sets without the ASV. We will need to deplete existing inventory as we wait for IV sets to arrive without the ASV

Provincial Clinical Leadership team identified that scientific evidence can be presented by any clinical group who determines indications for the use of the ASV.