Patient Safety Alert

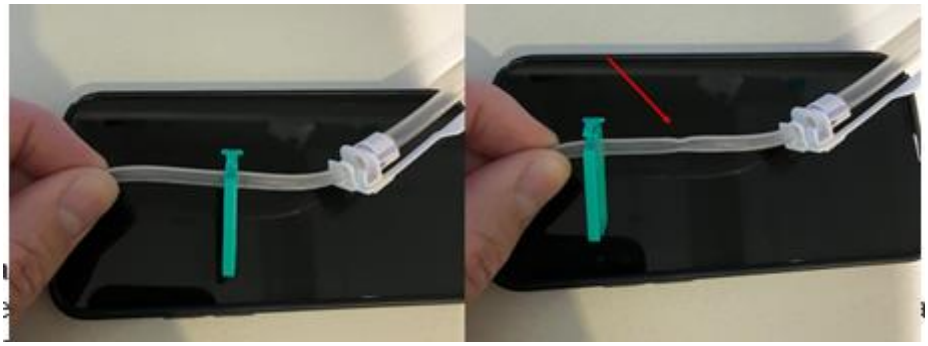
Date: April 15, 2024

To: All Clinical Care Staff, Anesthesiologists

From: Mary-Ellen Lee, RNBN
Provincial Patient Safety Lead, Shared Health
Heath Services Integration and Quality

Re: **B Braun - Crimping found in the IV tubing may contribute to false alarms**

This alert is to share the importance of assessing B Braun IV tubing for crimping in the section of tubing that loads into the pump. Crimping refers to a tube that is not smooth all the way around.



Clamp found partially closed in the packaging

Crimp identified when clamp moved to load into the pump

Situation

Increasing occurrences of false air in line (AIL) during blood transfusions has occurred from several sites in the province. This alarm stops the infusion and can result in delays in treatment, loss of blood product and workarounds that do not follow best practices for IV infusions in an attempt to provide timely client care.

Background

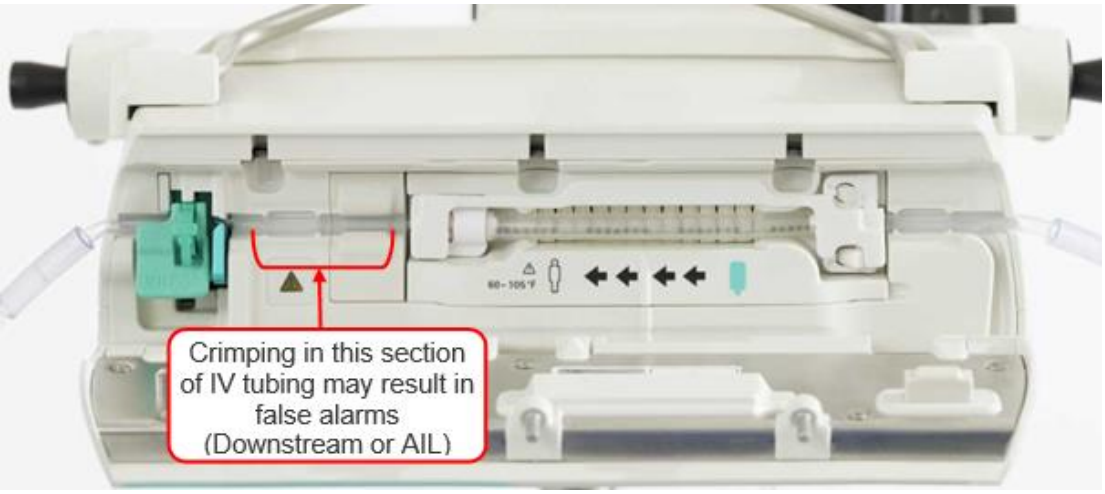
Through the vendor product complaint process, over 12 events involving false AIL during blood transfusions have been reported in the last 3-4 weeks.

Patient safety is at risk when transfusions are delayed and clinicians are faced with a difficult decision to either discard blood products or to transfuse the remaining products by gravity. Clinicians have observed that some tubing coming out of packaging has crimping in the IV tubing. The pump clamp has been found to be partially closed in the packaging, leaving a crimp that does not return to normal cylindrical shape.

During a recent random audit of IV tubing sets at two sites in Manitoba, it was noted that a significant portion of the sets in the cases exhibited crimps in the tubing around the clamp area. These crimps showed varying degrees of indentation. Avoiding all tubing with crimps could potentially lead to shortages of IV tubing sets. Supply Chain team is proactively monitoring inventory levels and replenishing as needed to prevent items being out of stock.

Assessment
The presence of crimps in the IV tubing section that loads into the pump can lead to an improper fit into the groove where downstream occlusion and air-in-line sensors monitor the IV fluid.

Clinical Engineering has conducted some tests and have demonstrated that crimping of the IV sets interferes with readings from the AIL sensor. Readings from the sensor improve once tubing has been rolled between fingers to improve shape.



We are working closely with the vendor to determine the root cause for the crimping and remedy. Unfortunately, we are not in a position to stop using all affected IV sets as there is no alternate product available.

The following recommendations are based on what we understand today. We encourage ongoing communication and ask you to take into consideration the type of medication/fluid being infused for your decision making.

If you assess the degree (depth) of the crimp to be mild to moderate and used the IV tubing and an alarm occurred, please document your observations through patient safety submissions and a product complaint form. This information is helpful in developing further recommendations.

Recommendations in consultation with Supply Chain Management Shared Services (SCMSS)

- Assess the IV tubing for crimps in the line upon opening the package
- If crimping is found in the pump sensor zone, attempt to return tubing to normal shape by rolling tubing between fingers
- If this is not successful, and you and your team consider the depth of the crimp to be severe don't use the IV tubing
- Place the IV tubing set that can't be used and its packaging into your unit's identified bin to facilitate follow-up with the supplier
- Alert your site's Supply Chain if your unit is finding that the majority of the IV tubing in your supply room unusable
- Continue to complete safety events/occurrence reporting and vendor product complaint forms for safety events that reach the patient

This is a great example of how communication from front line teams can make a difference to improve safe patient care through the vendor product complaint process. By providing important details such as **lot numbers** and your observations we have the action plan above.

Concerns have also been shared with Health Canada through our voluntary product complaint reporting process. We will continue to monitor and provide updates as we learn more information on this concern.

Thank you for your attention to this safety matter and please reach out to your clinical practice leads (for example, nurse educator) and your supply chain team members if you have any questions or suggestions.