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Name
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URGENT FIELD SAFETY NOTICE

Product Name:	**Alaris™ Pump Administration Sets Various Models**
Product Number:	**10015489, 11426965, 2120-0500, 2420-0007, 2420-0500**
Batch Numbers:	**Batches manufactured during January 2017 through March 2018 (Lot number format YYMMXXXX). For example, 17011234 was manufactured in January 2017.**
FSCA Identifier:	**RA-2018-05-01**
Date:	**May 2018**
Type of Action:	**Continue using the product as per the guidelines mentioned in this letter**

ATTENTION: Clinical Personnel, Risk Managers, Biomedical Personnel

Description of the Problem

BD has received increased reports of difficultly or failing to prime the pump administrative sets from model codes; 10015489, 11426965, 2120-0500, 2420-0007, 2420-0500.

The Alaris Infusion pump administration sets require priming prior to patient use as described in the directions for use. It is during the priming process that partial or complete flow restriction can be observed. The bounding of the identified lots was determined from when the complaint trend was noticed until manufacturing corrective action was implemented. This issue is highly detectable.

Steps for detecting this issue during priming:

- Open administrative set package, remove set and close roller clamp.
- Insert administrative set spike into the IV bag or bottle and hang container 20 inches above the Pump module.
- Fill drip chamber to 2/3 full.
- Open the roller clamp.
- Drops into the drip chamber will be very slow or absent.

Potential Risk

A partial or complete flow restriction in the administration set line can prevent the ability to prime the set, rendering the administration set unusable. The inability to prime can contribute to the delay of the start of the infusion. There have been no reports of patient harm as a result of this issue.

Products Potentially Affected

Product Number:	10015489, 11426965, 2120-0500, 2420-0007, 2420-0500
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Required Action for users

You can continue to use the product as this issue is highly detectable. If during priming you experience a difficultly or inability to prime, BD recommends you follow these steps:

1. Begin by removing the IV set from the package and close the roller clamp.
2. Spike the bag of IV fluid and hang. Fill the drip chamber 2/3 full.
3. Slowly open the roller clamp and observe if there are drops in the drip chamber indicating the set is able to prime.
4. If no flow or restricted flow is observed, gently squeeze the bag at the fluid level with one hand once. Observe if set is able to prime.
5. If no flow or restricted flow is observed repeat the gentle squeeze up to 3 times.

If this method is not effective, discard the administration set and obtain another administration set. For clinical areas administering high risk infusion, consider having additional administration sets readily available.

In addition to the actions above, we request you to complete and return the Acknowledgement Form (Appendix 1) to your BD representative no later than 31 August 2018

Your competent authority has already been notified of this Field Safety Corrective Action by BD's Authorised EU Representative.

We sincerely apologise for any inconvenience this action may have caused you or your staff.

Should you have any questions or require assistance relating to this Field Safety Corrective Action, please contact your local BD representative.

Transmission of this Field Safety Notice

Please distribute this notice to all those who need to be aware of this action within your organisation.

Sincerely,

BD Representative

BD

Appendix 1

URGENT FIELD SAFETY NOTICE – Acknowledgement Form

Product Name:	**Alaris™ Pump Administration Sets Various Models**
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Section A

Name of Hospital / Facility	
Hospital / Facility Address	
Telephone Number	
Name	
Signature	
Date	

Section B

☐ I have read and understood the contents of this Field Action and confirm that the information has been passed to all other relevant departments in our organisation.

Please return to:
Postal Address or Email