30 Tuas Avenue 2
Singapore 639461
Registration No.
201114149N

bd.com

URGENT Medical Device Recall – MDS-19-1531
BD Alaris™ Pump Infusion Set

18 Jun 2019

Dear Distributor,

BD is conducting a voluntary medical device recall for certain model codes and lot numbers of the Alaris™ Pump Infusion Sets used with the Alaris™ Pump Model 8100. BD distributed the affected lots beginning in August 2018.

In addition, out of an abundance of caution and to minimize the overall impact on affected customer sites while internal testing is on-going, BD is instructing customers to discard all product model codes, as noted in the response form, with expiration dates between and including 05/2019 and 08/2020 (manufactured between and including 05/2016 and 08/2017). BD will provide replacement for all discarded inventory.

Description of the problem and health hazard(s):
BD has confirmed that an incomplete occlusion can occur on the pumping segment of affected AlarisTM Pump Model 8100 infusion sets. This is caused by a variation in the wall thickness of the pumping segment of the affected infusion sets. The issue has the potential to lead to unintended delivery of medication when the pump module is not in running status or can result in faster than expected drug delivery flow when the pump is infusing.

This issue may lead to flow inaccuracies through the pumping cycle process resulting in an over-infusion and the potential for serious patient injury depending on the type of medication that is being delivered.

BD is continuing its investigation and is working in collaboration with the supplier of the extruded tubing to assure corrective actions are taken to prevent recurrence of this issue.

Please Take the Following Actions:
1. Immediately review your inventory for the specific model codes and lot numbers listed in the response form. Destroy all product subject to the recall based on the affected product following your institutions process for destruction. A credit note will be issued for the affected inventory upon receiving the destruction certificate.

2. BD is instructing distributor to discard all model codes and lot numbers with an expiration date between and including 05/2019 and 08/2020 in addition to the model codes and lot numbers listed in the response form.

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3. Share this recall notification with all users of the product within your facility to ensure that they are also aware of this recall.

4. Complete the attached Distributor Response Form and return to the BD contact (sunny.peh@bd.com) whether you have any of the impacted material or not, so that BD may acknowledge your receipt of this notification and provide product replacement.

Actions Taken by BD:

1. BD will provide replacement sets for all discarded inventory.
2. BD and the raw material supplier have implemented corrective actions including improved process controls and enhanced inspection criteria to prevent recurrence. Additional actions maybe implemented upon completion of the investigation.

For all other inquiries please contact your local BD representative and they will ensure that you are put in contact with the most appropriate individual to address your concerns.

BD is committed to advancing the world of health. Our primary objectives are patient and user safety and providing you with quality products. We apologize for any inconvenience this issue may have caused you and thank you in advance for helping us to resolve this matter as quickly and effectively as possible.

Yours Sincerely,

[redacted] 18 Jun 19

Phua Ai Tin
Quality Manager, Quality & Compliance
Greater Asia

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DISTRIBUTOR RESPONSE FORM

MDS-19-1531-FA

Alaris™ Pump Infusion Sets

Please fill in the information below so that we may acknowledge your receipt of this notification. Simply complete and return the completed form to your local BD contact [redacted] by 09 July 2019.

Please tick as appropriate.

☐ We do **NOT** have any affected product(s) in inventory.

☐ We have affected product(s) in inventory and shall destroy all products subject to the recall following my institution's process for destruction.

Cat.Number/ Description	Lot Number	Quantity received	Quantity sold*	Remaining Quantity in inventory to be returned for destruction
10010454	17016514			
10013854	17035775			
10015862	17016179			
10015862	16127191			
11426964	16125097			
11426965	17016815			
2200-0500	16036873			
2200-0500	16036076			
2200-0500	16046328			
2200-0500	16057809			

*For sold quantity, please complete the overview sheet with details of the distribution to customers.

Completed by:

Name: _____

Signature: _____

Date: _____

Facility: _____
Please use full, current facility name. Do not use initials

Street Address: _____

Telephone No.: _____