10020 Pacific Mesa Blvd
San Diego, CA 92121
1-888-876-4287 (toll-free)

www.bd.com

Medical Device Safety Notification

AFFECTED DEVICES: Alaris™ Syringe Module Model 8110 and Alaris™ PCA Module Model 8120

November 17, 2017

Dear Valued Alaris™ System Customer:

Director of Biomedical Engineering
Director of Nursing
Director of Risk Management

BD has identified a potential issue with certain Alaris Syringe and Alaris PCA modules. We have received reports of Syringe and PCA plunger grippers not closing automatically during maintenance or service when the gripper control knob was closed. The following information describes the potential issue and the recommended actions to take.

Affected Products:

- Alaris Syringe modules model 8110 and Alaris PCA modules model 8120 manufactured between May 1, 2013 and April 30, 2017
- Alaris Syringe modules model 8110 and Alaris PCA modules model 8120 serviced between May 1, 2013 and April 30, 2017 that received an affected part (P/N TC10002874)
- Alaris Syringe and Alaris PCA module kits shipped between May 1, 2013 and April 30, 2017 with the following part numbers:

10010997	BOM HOUSING ASSY SERVICE
49000213	KIT DRIVE HOUSING ASSY PCA/SYR ROHS
49000226	KIT LOWER HSG/CARRIAGE BLOCK ASSY ROHS
148188-100	KIT LOWER HOUSING/CARRIAGE BLOCK ASSY

See **Attachment A** for a list of affected serial numbers. If applicable, **Attachment A** will include the quantity of kits shipped.

Issue:
The syringe plunger grippers may fail to automatically close around the syringe plunger press when the gripper control knob has been closed (Figure 1). It is important to note that the syringe plunger gripper can be manually closed by the user. If the user follows the Alaris System User Manual and ensures the syringe plunger gripper is closed (Figure 2), there is no risk of harm to the patient.

Attachment B is an excerpt from the User Manual on BD's current labeling for properly installing the syringe and ensuring the plunger gripper is closed around the syringe plunger.

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Figure 1: Plunger Grippers Not Automatically Closing

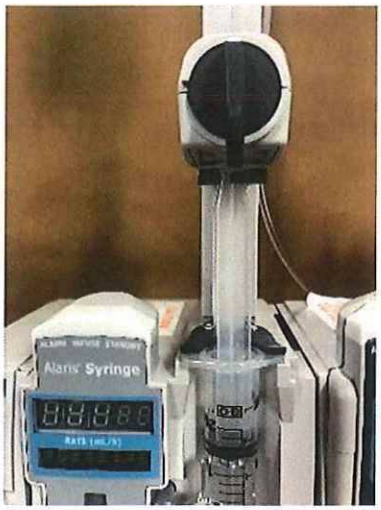

Figure 2: Plunger Gripper closed around the syringe

Potential Risk:
If the clinician follows the User Manual and closes the syringe plunger gripper, there is no risk of harm to the patient. If however, the gripper is not closed around the syringe, there is a negligible risk of siphoning. Under worse case conditions, if the gripper is not closed around the syringe, siphoning could occur after syringe installation if the clinician does not follow the User Manual with regard to head height and instrument positioning. If the clinician follows the User Manual with regard to head height and instrument positioning, then there is no risk of siphoning even if the gripper is not closed around the syringe. We have not received any reports of injury or death.

Required Action for Users:
Clinicians can continue to use the device and should follow the Alaris System User Manual for proper loading of the syringe. In accordance with the User Manual, clinicians should ensure that the plunger grippers lock and hold the syringe plunger in place.

Biomedical Engineering can detect if the device has this issue by rotating the plunger gripper control knob clockwise 90 degrees. Under normal conditions, when the knob is released from the 90 degree position the gripper will automatically spring closed. Under the defect condition, when the gripper is released from the 90 degree position, the gripper will not automatically spring closed and will remain in the open position until the user manually closes the gripper.

If the user experiences the issue described in this notification, contact BD Support Center at 888-562-6018 or email SupportCenter@carefusion.com to schedule service of the device at the BD Service Depot.

Follow-up Actions by BD:
The US Food and Drug Administration has been notified of this action. Any adverse reactions experienced with the use of this product, and/or quality problems should also be reported to the FDA's MedWatch Program by:

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- Web: MedWatch website at www.fda.gov/medwatch
- Phone: 1-800-FDA-1088
- Fax: 1-800-FDA-0178, or by
- Mail: MedWatch, HF-2, FDA, 5600 Fishers Lane, Rockville, MD 20852-9787

If you have any questions regarding the products, please contact:

BD Contact	Contact Information	Areas of Support
BD Support Center	Phone: 888-562-6018 Phone hours: 7:00am to 4:00pm PT, Monday - Friday Email: SupportCenter@carefusion.com	General Follow-up or Safety Notification Related Questions
Customer Advocacy	Phone: 888-812-3266 Phone hours: 24 hours a day, 7 days a week Email: customerfeedback@bd.com	Clinical Inquiries Product Complaints Clinical Troubleshooting
Technical Support	Phone: 888-812-3229 Phone hours: 5:00am to 5:00pm PT, Monday – Friday Email: DL-US-INF-Tech-Support@bd.com	Technical Questions Regarding the Alaris System

Please promptly complete and return the enclosed Customer Response Card to acknowledge receipt of this notification.

BD sincerely regrets the inconvenience this may cause you. BD is committed to serving your infusion product needs and our primary objectives are patient safety, exceptional product reliability, and the highest level of customer support.

Sincerely,

[redacted]

Keith McLain
Vice President, Quality Assurance
Infusion Solutions

Enclosures:

- **Attachment A: Affected Serial Numbers**
- **Attachment B: Excerpt from the User Manual**
- **Customer Response Card**