10020 Pacific Mesa Blvd
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www.bd.com

Medical Device Recall – Updated Information

Alaris™ Pump Module Model 8100

July 18, 2019

Dear Valued Alaris™ System Customer:
Director of Biomedical Engineering
Director of Nursing
Director of Risk Management

This updated communication is being provided to expedite inspection of the affected pumps. Until the bezels affected by this recall are replaced, customers should inspect bezels of both Priority 1 and Priority 2 pumps as soon as feasible. If damage is found during the inspection, the pump should be removed from service and BD should be contacted for replacement bezels.

It should be noted that there are no additional pumps impacted by this update. Updates to the April 15, 2019 notification are indicated in bold font.

BD initiated a voluntary medical device recall on April 15, 2019 for the Alaris™ Pump Module to include all bezels manufactured between April 2011 and June 2017. All of the bezels subject to this recall expansion were manufactured with a specific type of plastic, called FR-110.

Issue

The component of the Alaris Pump module that is the subject of this recall is the bezel assembly and the issue involves potential separation of the bezel posts. The bezel has 6 posts that connect the pumping mechanism frame to the bezel assembly and are critical to proper performance of the pump. BD's ongoing investigation has determined that the bezel manufacturing process for the FR-110 plastic may have resulted in its weakening. A bezel with weakened plastic may, over time, lead to separation of the bezel post (recall issue) as well as other damage to the bezel (i.e. external cracking). The separation of one or more bezel posts is a potential safety concern and, therefore, BD is initiating this voluntary recall.

Affected Products

The following products are affected by this recall, as they are pumps or pump assemblies with bezels manufactured between April 2011 and June 2017 with the FR-110 plastic.

- Alaris™ Pump Modules Model 8100 manufactured between April 2011 and June 2017 that include FR-110 bezels.
- Alaris™ Pump Modules serviced with LVP Mechanism Sub Assembly (P/N 10942012, P/N 49000007, and P/N 49000203).
- Alaris™ Pump Module Bezel Kit Assembly (P/N 10964559 and P/N 49000204).

Risk

The separation of one or more bezel posts may result in free flow, over infusion, under infusion or interruption of infusion. To date, BD has received **374** reports of separated bezel posts with **14** resulting in injury reports without lasting harm or death. **Two additional injury reports were added since the April 15, 2019 notification.**

Affected pumps have different levels of potential risk. The risk is higher in older pumps and those with weakened plastic. BD is prioritizing remediation efforts based on risk.

1. **<u>Priority 1 pumps:</u>**
   - Pumps manufactured between April 2011 – October 2014, inclusive.
   - All **14** injuries reported to date are associated with Priority 1 pumps.
   - BD will replace all Priority 1 bezels first. **BD is targeting replacement of all Priority 1 bezels within 12 months.**

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2. **Priority 2 pumps:**
   - Pumps manufactured between November 2014 – June 2017, inclusive.
   - To date, there have been no reported patient injuries associated with Priority 2 pumps.
   - **BD will replace Priority 2 bezels and is targeting completion within 24 months.**
   - NOTE: Priority 2 pumps have a reduced likelihood of weakened plastic leading to cracked bezel issues compared to the Priority 1 pumps.

Until the bezels affected by this recall are replaced, customers should inspect bezels of both Priority 1 and Priority 2 pumps as soon as feasible. If damage is found, the pump should be removed from service and BD should be contacted for replacement bezels.

BD has assessed the risk of this issue and determined that affected pump modules, both Priority 1 and Priority 2 pumps, can be used until they are inspected.

Actions by BD
BD is in the process of contacting customers of Priority 1 pumps to initiate scheduling of the inspection of those pumps. BD will contact customers to schedule replacement of bezels in Priority 2 pumps once Priority 1 pumps have been addressed.

BD will cover the replacement of all bezels under warranty (if applicable) or under this recall at no charge to the customer.

Follow-Up Actions for Biomedical Engineering
Share this recall notification with all users of the product within your facility to ensure that they are also aware of this recall.

1. **Until the bezels affected by this recall are replaced, customers should inspect bezels of both Priority 1 and Priority 2 pumps as soon as feasible.** Additionally, customers should continue to inspect bezels of both Priority 1 and Priority 2 pumps during their annual preventative maintenance schedule until all units have been remediated. BD will offer oversight and training on the bezel inspection process. Contact the BD Support Center to coordinate training. Additionally, customers can refer to Service Bulletin 621 for inspection instructions.
2. Damaged bezels must be replaced before the pump can be returned to service. Contact the BD Support Center to schedule bezel replacement.
3. **Pumps that pass the initial inspection and/or at each preventive maintenance interval may be returned to service.**

Identifying Non-Affected Pumps
The recall DOES NOT include Alaris™ Pump Modules or bezel replacement kits (P/N 49000270 or P/N 49000269) manufactured after June 2017. Beginning in June 2017, BD began making bezels with a different plastic material called Valox. Valox bezels have been tested extensively by BD to ensure reliability. There have been no patient injuries or complaints of cracking associated with Valox bezels to date. If your facility has installed Valox replacement bezels into affected pumps, these pumps are not affected by the current recall.

Reporting of Adverse Events

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 be reported to BD and the FDA's MedWatch Program by:
- 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:

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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@bd.com	General Follow-up or Recall Related Questions
BD Customer Advocacy	Phone: 888-812-3266 Phone hours: 7:00am to 5:00pm PT Monday - Friday Email: customerfeedback@bd.com	Adverse Event Reports and Product Complaints
BD Technical Support	Phone: 888-812-3229 Phone hours: 6:00am to 5:00pm PT, Monday – Friday Email: DL-US-INF-TechSupport@bd.com	Technical Questions on the Alaris System

BD's actions continue to be guided by our commitment to patient safety and minimizing disruption of patient care. We regret the inconvenience that may result from this recall, but we are committed to achieving the highest levels of customer satisfaction and serving your infusion product needs.

Sincerely,

[redacted]

Keith McLain
Worldwide Vice President of Quality for Medication Management Solutions

Enclosure:
Alaris™ Pump Module Model 8100 Bezel Assemblies with Separated Posts FAQs