BD Provides Update on Voluntary Recall of Certain BD Alaris™ Pump Infusion Sets

FRANKLIN LAKES, N.J. (Sept. 12, 2025)– BD (Becton, Dickinson and Company) (NYSE: BDX), a leading global medical technology company, today expanded their Class I voluntary recall to include 15 additional impacted BD Alaris™ pump infusion sets, which have been previously discontinued, as well as provide new corrective actions and risk information. The recall was originally initiated in the United States on July 8, 2025 and expanded on July 17, 2025 to inform customers of worst-case performance, under certain use cases, for the BD Alaris™ Pump Module model 8100 when used with a subset of compatible pump infusion sets, as compared to the performance described in the user manual. While discontinued, the 15 additional sets may remain in inventory based on the expiration date.

This issue was identified through internal testing and, to date, BD has not received any complaints associated with this issue. The affected products have the potential to result in patient death or serious adverse events, with a particular higher risk to vulnerable patient populations such as neonates and critically ill patients. The recall has been designated as a Class I recall by the U.S. Food and Drug Administration (FDA).

Pump performance variations as compared to the performance described in the user manual could impact infusion delivery in the following ways:

- Flow rate and loading bolus dose accuracy (over/under infusion),
- Upstream and downstream occlusion alarm delay,
- and post-occlusion bolus volume (POBV) over infusion,

which could adversely impact infusion performance and dose accuracy. The severity and nature of these outcomes depend on the type of medication, fluid, or infusate being administered, as well as the individual patient's condition.

The deviations in performance from the previously published ranges are attributable to these pump infusion sets' design features, such as filters and other in-line components. The products included in the recall were distributed nationwide in the United States, including Guam and Puerto Rico, and in Canada, Belgium and South Africa.

In an update sent to all customers on September 11, 2025, BD shared updated corrective actions, including risk mitigations and recommendations for alternate BD Alaris™ Pump infusion sets to use when available and clinically appropriate. The customer update also included a list of the 15 additional impacted pump infusion sets included in the recall. Information about this recall is available on BD's website or by calling BD at 1-888-562-6018.

Customers should report any complaints experienced with the use of this product to the BD Complaint Center at 1-844-823-5433, Monday – Friday between the hours of 9 a.m. and 6 p.m. ET or by emailing productcomplaints@bd.com.

FDA MedWatch Reporting
Adverse reactions/events experienced with the use of this product should be reported to the FDA's MedWatch Program by:

- **Online:** Complete and submit the report at www.fda.gov/medwatch/report.htm
- **Call** 1-800-FDA-1088 (1-800-332-1088)
- **Regular Mail**: Download form www.fda.gov/MedWatch/getforms.htm or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form or submit by fax to 1-800-FDA-0178.

About BD
BD is one of the largest global medical technology companies in the world and is advancing the world of health by improving medical discovery, diagnostics and the delivery of care. The company supports the heroes on the frontlines of health care by developing innovative technology, services and solutions that help advance both clinical therapy for patients and clinical process for health care providers. BD and its more than 70,000 employees have a passion and commitment to help enhance the safety and efficiency of clinicians' care delivery process, enable laboratory scientists to accurately detect disease and advance researchers' capabilities to develop the next generation of diagnostics and therapeutics. BD has a presence in virtually every country and partners with organizations around the world to address some of the most challenging global health issues. By working in close collaboration with customers, BD can help enhance outcomes, lower costs, increase efficiencies, improve safety and expand access to health care. For more information on BD, please visit bd.com or connect with us on LinkedIn at www.linkedin.com/company/bd1/, X (formerly Twitter) @BDandCo or Instagram @becton_dickinson.

Contacts:

Media:

Fallon McLoughlin
Director, Public Relations
201.258.0361
fallon.mcloughlin@bd.com

Investors:

Adam Reiffe
Sr. Director, Investor Relations
201.847.6927
adam.reiffe@bd.com

---

https://news.bd.com/2025-09-12-BD-Provides-Update-on-Voluntary-Recall-of-Certain-BD-Alaris-TM-Pump-Infusion-Sets