BD Provides Update on Voluntary Recalls of Alaris™ Pump Module Model 8100 and Certain Alaris™ Pump Infusion Sets

FRANKLIN LAKES, N.J., July 18, 2019 /PRNewswire/ -- BD (Becton, Dickinson and Company) (NYSE: BDX), a leading global medical technology company, today provided an update on two voluntary recalls related to certain Alaris™ Pump Modules Model 8100 manufactured between April 2011 and June 2017 and certain model codes and lot numbers of the Alaris™ Pump Infusion Sets used with the Alaris™ Pump Model 8100. BD has already notified customers affected by these recalls. Both products were formerly marketed under the CareFusion brand, which BD acquired in March 2015.

Both actions have been designated as a Class I recall by the U.S. Food and Drug Administration (FDA). Both recalls have been associated with medical device reporting (MDR) submissions, several of which are associated with serious injuries.

Alaris™ Pump Module Model 8100

In a recall notification sent on April 15, 2019, BD informed clinicians that the bezel assemblies in the Alaris pump modules subject to this recall expansion were manufactured with a specific type of plastic material. The company conducted an investigation and determined that the bezel manufacturing process resulted in weakened plastic. Over time, further weakening of the plastic has the potential to lead to separation of the bezel posts, as well as other damage to the bezel, which may result in free-flow, over-infusion, under-infusion or interruption of infusion.

No products manufactured after June 2017 are affected by this recall, including the BD Alaris™ PCU and BD Alaris™ Pump Module that were introduced in March 2018.

BD is contacting the customers affected by the Alaris Pump Module Model 8100 bezel recall to schedule replacement of bezel assemblies. On April 15, 2019, the BD customer notification instructed customers to inspect all pumps included in this action during the annual preventive maintenance, and if damage is found, the pump should be removed from service and BD should be contacted. **The revised recall notification indicates that until the bezels affected by this recall are replaced, customers should inspect both Priority 1 and Priority 2 pumps as soon as feasible.** In addition to posting the updated recall notification on BD's website, this updated notification will be sent to all customers by July 31, 2019.

There are no changes to the affected product list. Customers should continue to refer to the attachments included in the recall notification issued on April 15, 2019.

Information about this recall, including the original and updated recall notification, is available on BD's website at alaris.bdproductnotice.com or call BD at 888-562-6018.

Alaris™ Infusion Sets

In a recall notification sent on May 6, 2019, BD confirmed that an incomplete occlusion can occur on the pumping segment of certain Alaris™ Pump Model 8100 infusion sets. This is caused by a variation in the wall thickness of the pumping segment of the affected infusion sets. Use of the affected products has the potential to lead to unintended delivery of medication when the pump module is not in running status, 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. Instructions for customers, including a full list of affected product codes, lot numbers and expiration dates are included on the BD website at https://www.bd.com/en-us/support/recall-notifications/recall-notification-alaris-pump-infusion-sets. BD is instructing customers to destroy all Alaris Infusion Sets affected by this recall.

Customer inquiries related to this action should be addressed to BD's Regional Customer Quality team at 888-237-2762.

FDA MedWatch Reporting

Adverse reactions/events experienced with the use of either of these products should also be reported to the FDA's MedWatch Program by:

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

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 65,000 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.

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