BD Announces FDA Classifications for August 4th Recalls of BD Alaris™ System Hardware for Keypads, Incorrect Module Types and/or Sizes, and Channel Error

Three Recalls Designated as Class I by FDA; One Designated as Class II

FRANKLIN LAKES, N.J., Sept. 21, 2020 /PRNewswire/ -- BD (Becton, Dickinson and Company) (NYSE: BDX), a leading global medical technology company, today provided an update on previously announced voluntary recalls of the BD Alaris™ System.

Three of the recalls, which BD announced on Aug. 4, 2020, have been designated as Class I recalls by the U.S. Food and Drug Administration (FDA), which means that FDA has determined that there is a reasonable probability that the use of the product will cause serious adverse health consequences or death. One of the situations was designated as a Class II recall, which means use of the product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote.

This FDA classification does not change the guidance BD provided in the company's Aug. 4th recall announcements to customers.

BD initiated the voluntary recalls to notify customers of the potential for four hardware situations that may result in the infusion pump not operating as expected. BD has provided instructions to correct and/or mitigate the situations. The four recalls include:

- Alaris PC Unit Model 8015 Front Case with Keypad Replacement Kits (Recall 1 – Class I):
  The pump module keypad may exhibit keys that are unresponsive or stuck as a result of fluid ingress, potentially resulting in a delay to the start of infusion, interruption of infusion or inability to titrate medication.
- Alaris Pump Module Model 8100 Front Case with Keypad Replacement Kits (Recall 2 – Class I):
  Pump Module keypad may exhibit keys that are unresponsive or stuck as a result of fluid ingress, potentially resulting in a delay to the start of infusion or interruption of infusion.
- BD Alaris™ Syringe Module Model 8110 and PCA Module Model 8120 (Recall 3 - Class I):
  The Alaris PC unit may display incorrect syringe type and/or syringe sizes. This could potentially result in delays in infusion, under-infusion or over-infusion.
- BD Alaris™ EtCO2 Module model 8300 channel error (Recall 4 – Class II)
  Infusion pump component defect may result in interruption of patient monitoring.

Customers should review and follow the instructions in each of the recall letters listed above.

Affected Products

Recall 1:

- BD Alaris™ PC Unit model 8015 (manufactured from April 7, 2017 to present)
- PC Unit Front Case with Keypad Replacement Kits:
  - TC10008389 ASSY CASE FRONT W/KEYPAD 8015LS
  - TC10010217 ASSY FRT CASE W/ KEYPAD 8015 M2
  - TC10012515 ASSY FR CASE W/ KEYPAD 8015 M2
  - TC10013702 ASSY, CASE, FRONT W/KEYPAD, 8015LS
  - TC10013664 ASSY FR CASE W/ KEYPAD 8015 M2

Recall 2:

- BD Alaris™ Pump Module Model 8100 (manufactured from December 1, 2016 to January 23, 2019)
- Pump Module Door Assembly Replacement Kits (labeled with a date prior to January 25, 2019)
  - Affected part numbers: 49000239; 49000346; 49000438; 49000439

Recall 3:

- BD Alaris™ Syringe Module Model 8110 (manufactured from March 1, 2010 to present)
- BD Alaris™ PCA Module Model 8120 (manufactured from March 1, 2010 to present)
- Syringe/PCA Sizer Sensor Replacement Kit (manufactured from March 1, 2010 to present)
    - Affected part number: 12278652

Recall 4:

- Alaris™ EtCO2 Module, Model 8300 (manufactured from January 5, 2018 to January 4, 2019)

Note that some affected devices may be branded under the CareFusion name. Customer inquiries related to this action should be addressed to BD's Recall Support Center at 888-562-6018 or SupportCenter@bd.com.

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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