CME America Announces a Follow-Up on the Voluntary Recall of BodyGuard® Infusion System Administration Sets

GOLDEN, Colo., July 3, 2020 /PRNewswire/ -- CME America, a wholly owned subsidiary of BD (Becton, Dickinson and Company), announced a voluntary recall for all CME America BodyGuard® Infusion System Administration Sets (infusion sets) —used with the company's BodyGuard® infusion pumps—that were distributed beginning May 2016 (see complete impacted product list below). This action was initiated on June 16, 2020.

As part of CME America's commitment to quality, following the previously announced recall (April 27, 2020) of the BodyGuard® Infusion Pump Systems, the company conducted additional flow-rate accuracy testing. This testing revealed that some infusion sets do not meet the ±5% delivery accuracy for the system or the ±13% accuracy identified in the earlier recall notification (https://www.bd.com/en-us/support/recall-notifications/recall-notification---cme-america-bodyguard-infusion-pump-system). Therefore, the use of the pump system potentially could cause over-infusion or under-infusion of therapy and patient harm.

Based on those test results CME America is providing additional information and customer actions regarding its previous recall to include all infusion sets used with the BodyGuard® infusion pump distributed beginning May 2016. CME America has defined four categories of impacted infusion sets based on delivery inaccuracy variability, two of which (Category A and B) can continue to be used in accordance with the instructions in the recall letter (https://www.bd.com/en-us/support/recall-notifications/recall-notification---cmeamerica-bodyguard-infusion-administration-sets).

CME America also announced on April 27, 2020, the decision to suspend distribution of the BodyGuard® infusion pumps and to remove all existing products from the U.S. market. CME America will work with customers to address the latest expanded infusion set recall and will continue to maintain continuity of care during the COVID-19 pandemic. Until such time that the BodyGuard® pumps have been removed from the market, CMEA will supply accessories and infusion sets in "Category A" and "Category B" to support the infusion pumps, and customers can continue to use the products in accordance with the Operator's Manual and the additional mitigations outlined in the customer letter.

Affected Product Types	
BodyGuard BodySet	BodyGuard Microset with Needleless Adaptor
BodyGuard Microsets	BodyGuard Microset w/ Non-Vented Spike Connector
BodyGuard set with Female Luer	BodyGuard Microset w/ 0.2 mic filter and lower y-site with female luer
BodyGuard Microsets with Filter	Standard BodySet with Needleless Connectors
BodyGuard Microset with Filter and Manual Priming Valve	CMExpress Microbore Sets
BodyGuard Microset with Male Luer Connectors	CMExpress Needleless Y Site Microbore Set

See Customer Notification for full list of Affected Product Codes

Customer inquiries related to either recall, as well as adverse reaction/events experienced with the product should be addressed to CME America Support Center at 877-263-0111.

FDA MedWatch Reporting

FDA has been notified of this recall. Adverse reactions/events experienced with the use of any 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-108
- 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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