CME America Provides Update on Two Previously Announced Voluntary Recalls Related to Ambulatory Infusion Pumps and Sets

Recalls for BodyGuard® Infusion Pumps and Certain Lots of CMEAmerica BodyGuard® Microsets Designated as Class I Recalls
Company Announces Removal of CMEAmerica BodyGuard® Infusion Pumps from U.S. Market

GOLDEN, Colo., April 27, 2020 /PRNewswire/ -- CME America, a wholly owned subsidiary of BD (Becton, Dickinson and Company), a leading global medical technology company, today issued the following update regarding two previously announced voluntary recalls, one related to all models of CMEAmerica BodyGuard® infusion pumps (FDA Recall Number: Z-1474-2020) and the other related to one of the device's infusion sets (FDA Recall Number: Z-1442-2020).

Both previously announced recalls have now been designated as Class I recalls by the U.S. Food and Drug Administration (FDA), which means the FDA believes that there is a reasonable probability that use of the recalled product(s) will cause serious adverse health consequences or death.

CME America previously notified customers affected by each recall and provided guidance on the potential impact to device performance when the affected products were used. Today, the company has issued an updated customer letter with additional guidance and to inform customers of the decision to suspend distribution of the BodyGuard® infusion pump system and to remove all existing products from the U.S. market. The following is a summary of each individual product recall details:

CMEAmerica BodyGuard® Infusion Pump Recall Details

On Jan. 6, 2020, the company initiated a voluntary recall to notify customers of certain scenarios where pumps may not deliver fluid at the accuracy specified in the instructions for use that could result in a slower than expected delivery of medication (under-infusion), and/or faster than expected delivery of medication (over-infusion). Results indicate that pumps may have a delivery inaccuracy of up to ~13%. To date, no reports of patient injury has been received related to this previously announced voluntary recall.

CME America has assessed the potential risks associated with the issues outlined in the initial voluntary recall and determined that the BodyGuard® infusion pump may continue to be used in certain situations in accordance with the Operator's Manual and the additional mitigations outlined in the updated customer letter until the pumps have been removed from the market.

To ensure customers retain access to critical medical equipment, particularly as the COVID-19 pandemic continues to evolve in the United States, CME America will implement a phased market removal and will continue to support the following activities in order to help limit clinical disruption and maintain patient focus during the COVID-19 pandemic:

- Use of products in the field in accordance with the Operator's Manual and the additional mitigations outlined in the updated customer letter;
- Product service and repair activities at CME America and Authorized Service Depots; and
- Supply of infusion sets and accessories to support the infusion pumps remaining in the field.

The BodyGuard® infusion pump is designed to deliver fluids or medications into a patient's body in controlled amounts. The pump administers fluids through an infusion tubing set into a patient's vein or through other cleared routes of administration. The system is intended for patients who require maintenance medications, PCA therapy, parenteral nutritional fluids, and general IV fluid therapy in hospital and home care environments. Typical applications for the BodyGuard® infusion pumps include but are not limited to chemotherapy, pain management, TPN, enteral nutrition fluids and antibiotics.

The recall and market removal affect approximately 28,400 devices, including all models of BodyGuard® infusion pumps listed below. These devices are primarily used in outpatient settings.

- BodyGuard 121
- BodyGuard 323
- BodyGuard 545*
- BodyGuard 575*
- BodyGuard 545 ColorVision
- BodyGuard 575 ColorVision
- CMExpress

*Note: These two pump models were inadvertently left out of the initial customer notification

CMEAmerica BodyGuard® Microset Infusion Set Recall Details

On Sept. 16, 2019, the company initiated a voluntary recall to notify customers that certain lots of BodyGuard® Microset infusion sets, when used with the BodyGuard® infusion pump, may under-deliver fluids up to 50% at the highest flow rates. At the time of the recall, CME America informed customers in the recall announcement to discard all remaining inventory of the infusion sets (Catalog #A120-003XYVA) and committed to reimbursing impacted customers.

To date, no reports of patient injury has been received related to this previously announced voluntary recall. CME America immediately stopped shipments of the affected infusion sets. This FDA classification does not change the previous guidance provided in the company's September recall announcement to customers.

Affected products include:

- CMEAmerica BodyGuard® Microset, Catalog #A120-003XYVA.

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

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
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