U.S. Food and Drug Administration
Protecting and Promoting *Your* Health

Alaris Medley Large Volume Pump (LVP) Frame Membrane by Elite Biomedical Solutions: Class I Recall - Frame Membrane May Allow Over or Under Delivery of Fluid by an Infusion Pump

[Posted 08/27/2015]

AUDIENCE: Risk Manager, Surgery, Critical Care Medicine, Nursing

ISSUE: Elite Biomedical Solutions discovered that the use of this part can result in over or under infusion of fluids to the patient with the potential to cause patient injury or death. See the **Recall Notice (/MedicalDevices/Safety/ListofRecalls/ucm460079.htm)** for a list of part and lot numbers.

BACKGROUND: The Alaris Medley Large Volume Pump (LVP) is an infusion pump used to deliver fluids such as nutrients and medications into a patient's body in controlled amounts. The frame membranes are part of the pump that prevents fluids from leaking into internal components. Infusion pumps are widely used in clinical settings such as hospitals, nursing homes, and in the home.

RECOMMENDATION: On May 21, 2015, Elite Biomedical Solutions sent their customers a Product Advisory Notices. On June 3, 2015, the firm sent their customers an Urgent: Medical Device Part Recall letters. And on June 12, 2015, a press release was issued via ECRI (Emergency Care Research Institute) to all hospitals in the US. In these communications, customers were instructed to take the following actions:

- Immediately examine your inventory and quarantine the affected product.

- If the affected product was further distributed, please identify your customers and notify them at once of this product recall.
- Regardless of whether you have the affected product, complete the Reply Form as soon as possible and return it to Elite Biomedical Solutions.
- Elite Biomedical Solutions will provide your facility with a replacement part for each affected frame membrane, along with a label for product return. Forward a copy of the letter to any facility to which you have further distributed affected product.

Healthcare professionals and patients are encouraged to report adverse events or side effects related to the use of these products to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:

- Complete and submit the report Online: **www.fda.gov/MedWatch/report (http://www.fda.gov/MedWatch/report)**
- **Download form (/Safety/MedWatch/HowToReport/DownloadForms/default.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 to1-800-FDA-0178.

[08/27/2015 - **Recall Notice (/MedicalDevices/Safety/ListofRecalls/ucm460079.htm)** - FDA]

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2013 Safety Alerts for Human Medical Products (/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm333878.htm)

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