Class I Recall: Cardinal Health, Various Modules of the Alaris System

The FDA notified healthcare professionals of the Class I recall of various modules of Cardinal Health’s Alaris System, electronic infusion pumps that deliver controlled amounts of medications or other fluids to patients through an intravenous, intra-arterial, epidural, and other routes of administration. The firm initiated the recall after identifying five problems that affected the Alaris System, including failure of the occlusion warning message, syringe volume warning message, electrostatic discharge protection circuitry and fluid ingress tubing. It was determined that the five failures may result in patients experiencing under- or over-infusion which may result in serious injury or death. The device is intended for use with adult and pediatric patients in hospitals including critical care units, emergency rooms, outpatient surgical centers, hospices, and nursing homes.

Recall Class: Class I
Date Recall Initiated: June 12, 2009

Product: Alaris Point-of-Care (PC) Unit (Model 8000 and 8015) (formerly Medley PC unit)

- Occlusion Warning Message for Alaris Pump Module
- Syringe Volume Warning Message for Alaris Patient-Controlled Analgesia (PCA) Module (formerly Medley PCA Module)
- Electrostatic Discharge (ESD) Protection Circuitry

Alaris Pump Module (Model 8100) (formerly Medley Pump Module) – Direct for Use (DFU) update

- Fluid Ingress (fluid entering the pumping mechanism)

Alaris System (Formerly Medley System) – DFU Update
• IUI (Inter-Unit Interface) Connectors

Use: Electronic infusion pumps deliver controlled amounts of medications or other fluids to patients through an intravenous (IV), intra-arterial (IA), epidural, and other acceptable routes of administration.

Recalling Firm: Cardinal Health 303 dba Cardinal Health
10020 Pacific Mesa Boulevard
San Diego, California 92121-4386

NOTE: In July 2009, Cardinal Health 303 dba Cardinal Health announced that they will change their name to CareFusion. The firm expects the official name change to occur on September 1, 2009.

Reason for Recall:
The following are potential risks of the system:

• Failure of the Occlusion Warning Message to adequately guide users to clear blocked (occluded) IV tubing may result in under infusion.
• When the Alaris PC unit is used with the PCA module, the pump verifies that the programmed infusion can be delivered with the volume of therapy in the pump. If the programmed infusion rate exceeds the volume of therapy in the pump, the PC unit displays a Syringe Volume Warning Message. If the clinician ignores this warning, proceeds with the infusion, AND the patient presses the button (Dose Request Handset) to request more therapy, the pump may inject the contents of the syringe into the patient, resulting in over-infusion.
• Failure of the Electrostatic Discharge Protection Circuitry can cause: (1) the key pad to be unresponsive, (2) key entries without key presses or (3) key entries to register incorrectly. The malfunctions may result in under or over-infusion.
• Failure of IV tubing may result in fluid entering the pumping mechanism, resulting in an over-infusion of therapy.
• The firm is updating their instructions for use for the Alaris system to require inspection of the IUI connectors for blue or green discoloration (corrosion) before every use of the device.

Public Contact:
Customers may contact the firm at the following numbers:

• For general questions, contact the CareFusion Recall Center at 1-888-562-6018, Monday through Friday, 7am to 5pm (Pacific Time).
• To report adverse events, contact the Customer Advocacy at: 1-800-854-7128. Select Option 1, Option 1 and Option 3 through the automated prompts, 24 hours a day, seven days a week. Or, patients can email Customer Advocacy at customerfeedback@carefusion.com.
• For technical questions about the Alaris System, contact Technical Support at 1-888-812-3229, Monday through Friday, 6am to 5pm (Pacific Time).

FDA District: Los Angeles FDA Comments:

On June 12, 2009, the company sent letters to each of their customers informing them of the problems. Customers were asked to promptly complete and return the enclosed Customer Response Card to speed up the correction process. The letters also contained very detailed instructions to correct each of the above problems.

On July 29, 2009, the company sent an updated letter to each of their customers. The update contained an additional required action that users must take when the Syringe Volume Warning Message appears on the Alaris System. The additional step
involves removing the patient-controlled Dose Request Handset from the patient prior to reprogramming the infusion pump.

Class 1 recalls are the most serious type of recall and involve situations in which there is a reasonable probability that use of these products will cause serious injury or death.

Health care professionals and consumers may report adverse reactions or quality problems experienced with the use of these products to the FDA’s MedWatch Adverse Event Reporting Program either online, by regular mail or by FAX.

CORPORATE PRESS RELEASE

CareFusion issues update regarding previously disclosed June 12, 2009 recall of the Alaris® system

SAN DIEGO, July 29, 2009 – CareFusion Corporation, which is expected to become a public company following its planned spinoff from Cardinal Health, today issued the following update regarding its previously disclosed recall of the Alaris System:

On June 12, 2009, the company sent an urgent Medical Device Recall Notification to customers of its Alaris® System addressing potential risks identified with the Alaris System. The affected devices have one or more failures associated with the Occlusion Warning Message, Syringe Volume Warning Message, Electrostatic Discharge protection circuitry, and Fluid Ingress into the device’s pumping mechanism. This recall also updates the labeling for the Inter Unit Interface (IUI) connectors on the Alaris® System. The potential risks may lead to improper infusion therapy, which could cause serious adverse health consequences or death.

Serial numbers of affected devices, as well as CareFusion’s short term instructions to customers, and the firm’s strategy to fix the
affected devices can be found at: cardinalhealth.com/alaris/medical-device-recall/.

Following the FDA’s 510(k) clearance of the firm’s software correction in July 2009, CareFusion is now implementing corrections for units in the field.

In addition, CareFusion today began sending customers using the Alaris Patient Controlled Analgesia (PCA) module an update to the June 12, 2009, Medical Device Recall Notification. The update contains an additional required action to mitigate potential risk before completion of the field corrective action related to the Syringe Volume Warning Message that may appear while using the Alaris PC unit with the Alaris PCA module. The additional step involves removing the patient-controlled dose request handset from the patient prior to reprogramming the infusion pump.

“Implementation of the corrective action plan is an important area of focus for CareFusion and our customers, to ensure our medical devices in the field are operating as safely and effectively as possible,” said Dwight Winstead, chief operating officer of CareFusion. “We continue to work closely with the FDA under our new quality system with the goal of manufacturing and supporting products that are among the safest in the industry.”

The company recorded an $18 million reserve in its 2009 fiscal third quarter for all actions related to the corrective action plan and continues to believe the amount to be sufficient to fulfill its remediation obligations.

Instructions to customers
Customer inquiries related to this action should be addressed to the CareFusion recall center at 888-562-6018. Additional information about the recall can be found at cardinalhealth.com/alaris/medical-device-recall/.
CareFusion will work with customers to minimize disruption while correcting units at their facilities.

In the interim, customers should follow steps outlined in the June 12 Medical Device Recall Notification and the updated Notification for customers using the Alaris PCA module to minimize potential risk before implementation of the software and hardware updates.

CareFusion notified customers by registered letter on June 12, 2009, posted the customer letter on the company’s web site and set up a dedicated call center for customer support. The FDA has also been apprised of this action.

Any adverse reactions experienced with the use of this product, and/or quality problems should also be reported to the FDA’s MedWatch Program by phone at 800.FDA.0178, by Fax at 800.FDA.0178, by mail at MedWatch, HF-2, FDA 5600 Fishers Lane, Rockville, MD 20852-9787, or at www.fda.gov/medwatch.

About CareFusion Corporation
CareFusion Corporation, a wholly owned subsidiary of Cardinal Health (NYSE:CAH), is expected to become a public company with the planned spinoff of the clinical and medical products businesses of Cardinal Health. The global company serves the health care industry with products and services that help hospitals measurably improve the safety and quality of healthcare. CareFusion develops market-leading technologies including Alaris® IV pumps, Pyxis® automated dispensing and patient identification systems, AVEA and Pulmonetic Systems™ ventilation and respiratory products, ChloraPrep® for infection prevention and MedMined™ services for infection surveillance, neurological monitoring and diagnostic products, V. Mueller® surgical
instruments and an extensive line of products that support interventional medicine.

CareFusion employs more than 15,000 people across its global operations. The company has been authorized to have its shares of common stock listed on the New York Stock Exchange under the ticker symbol “CFN.” More information may be found at carefusion.com.