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Medical Devices

Maquet Cardiovascular, LLC, Heartstring II Proximal Seal System (HS-1045)

Recall Class: Class I

Date Recall Initiated: May 5, 2010

Product: Maquet Heartstring II Proximal Seal System (HS-1045)

Model Number **Lot Numbers**

HS-1045 12895788, 12946718, 25002866, 25004647, 13029141, 25005045, 25005622

This product was manufactured from September 9, 2009 through February 11, 2010 and distributed from September, 2009 through April, 2010.

Use: This device is used by cardiac surgeons during coronary artery bypass procedures (CABG). It helps to control the flow of blood in the aorta during surgery. This allows the surgeon to create an important connection between blood vessels (proximal anastomosis) without the use of an aortic clamp.

Recalling Firm:

Maquet Cardiovascular, LLC
45 Barbour Pond Drive
Wayne, New Jersey 07470-2094

Reason for Recall: The deployment tube may detach during use due to insufficient adhesive and may result in the failure of the product to operate. This may cause serious injury and/or death.

Public Contact: Customers may contact the company's Customer Service at 1-888-899-2874.

FDA District: San Francisco

FDA Comments:

On May 5, 2010, the firm (MAQUET Getinge Group) sent its customers an "Urgent Device Removal" letter by Federal Express. The letter described the product, the problem and actions to be taken by the customers. The customers were instructed to:

- **IMMEDIATELY EXAMINE** their stocks for the affected product
- **DISCONTINUE DISTRIBUTING** the affected lot
- **COMPLETE** the field Action Response Form
- **IMMEDIATELY CONTACT** other customers if they (the first line customers) acted as distributors
- **ACKNOWLEDGE RECEIPT** of the notification (whether or not they had any of the affected products) by completing the Field Action response Form.
- **FAX** the form (U.S. customers) to: 1-888-899-2874.
- **CONTACT** the local Maquet cardiovascular sales representative or the company's Customer Service at 1-888-899-2874

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 adverse health consequences or death.

Health care professionals and consumers may report adverse reactions or quality problems they experienced using these products to the [FDA's MedWatch Safety Information and Adverse Event Reporting Program](#)¹ either online, by regular mail or by FAX.

Links on this page:

1. <http://www.fda.gov/Safety/MedWatch/default.htm>