Class I Medical Device Recall: St. Jude Medical, AMPLATZER TorqVue FX Delivery System

U.S. Food & Drug Administration

Recall Class: Class I

Date Recall Initiated: January 18, 2013

Product(s): AMPLATZER TorqVue FX Delivery System

Model/catalog/lot numbers:
9-ITVFX06F45/60, 9-ITVFX07F45/60, 9-ITVFX007F45/80, 9-ITVFX08F45/60, 9-ITVFX08F45/80,
9-ITVFX09F45/80, 9-ITVFX10F45/80, 9-ITVFX12F45/80, 9-ITVFX13F45/80

Range of manufacturing and distribution dates:
This product was manufactured August 24, 2012 to September 24, 2012 and distributed October 1, 2012 – January 9, 2013.

Use: The Amplatzer TorqVue FX Delivery System is used to assist the attachment, loading, delivery, and deployment of Amplatzer Occluder devices. Amplatzer Occluder devices are used to close openings between the two upper chambers of the heart.

Recalling Firm:
St. Jude Medical
Cardiovascular and Ablation Technologies Division
177 E County Road B
Saint Paul, MN 55117-1951

Public Reason for Recall: In a small number of cases, the distal end of the core wire of the TorqVue FX Delivery System could potentially fracture. This product may cause serious adverse health consequences, including death.

Public Contact: Customers with questions can contact the company at 651-756-6526.

FDA District: Minneapolis District Office

FDA Comments: On January 17, 2013, St. Jude Medical sent an “Urgent Medical Device Recall Notice” to their customers. The letter advised customers to stop using the device and remove it from their inventory. St. Jude Medical plans to have their sales representatives perform site visits to assist with recall activities, including completion of the product reconciliation form and return of any unused product.

Class I 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 MedWatch: The FDA Safety Information and Adverse Event Reporting Program [1] either online, by regular mail or by FAX.

Links:
[1] http://www.fda.gov/Safety/MedWatch/ucm2005699.htm