California Medical Device Recall Information

Recall Name
St. Jude Medical Recalls the AMPLATZER TorqVue FX Delivery System Due to a Potential Defect

Recall Date	Product Description	Recalling Firm	Recall Reason
1/18/13	AMPLATZER TorqVue FX Delivery System	**St. Jude Medical** Saint Paul, MN	*Fracturing of the distal end of the core wire of the TorqVue Delivery System has been reported.*
Recall Class	**Product Identification**	**Distribution**	**Affected Dates**
I	AMPLATZER TorqVue FX Delivery System Suspected Lot Numbers Recalled: • 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	**CA**, nationwide	Distributed from October 1, 2012 to January 9, 2013

FOR ADDITIONAL INFORMATION, PLEASE VISIT:

http://www.fda.gov/MedicalDevices/Safety/ListofRecalls/ucm339458.htm