AngioSculpt "EX" PTCA Scoring Balloon Catheter by AngioScore, Inc.: Recall - Risk of Catheter Separation

FDA MedWatch

AUDIENCE: Cardiology, Risk Manager

ISSUE: The AngioSculpt EX Percutaneous Transluminal Coronary Angioplasty (PTCA) catheters may become separated during use, and fragments of the catheter may become lodged in coronary arteries. This may result in serious injuries, including death. This recall includes all Part/REF Numbers 2034-XXYY with lot numbers less than F09060003. This product was distributed from January 30, 2009 through December 4, 2009.

BACKGROUND: The AngioSculpt PTCA Scoring Balloon Catheter is used to dilate narrowed coronary arteries (stenosis), and to improve blood flow to the heart muscle (myocardial perfusion).

RECOMMENDATION: Customers should inspect their inventory for this recalled product and separate it from their inventory. See the Recall Notice for additional recall instructions.

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.htm [1]
- Download form [2] 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 to 1-800-FDA-0178

[09/08/2010 - Recall Notice [3] - FDA]

SOURCE [4]

Source URL (retrieved on *05/22/2013 - 9:01am*):
http://www.ecnmag.com/news/2010/09/angiosculpt-ex-ptca-scoring-balloon-catheter-angioscore-inc-recall-risk-catheter-separation

Links:
[1] http://www.fda.gov/MedWatch/report.htm
[2] http://www.fda.gov/Safety/MedWatch/HowToReport/DownloadForms/default.htm
[3] http://www.fda.gov/MedicalDevices/Safety/RecallsCorrectionsRemovals/ListofRecalls/ucm225182.htm
[4] http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm225186.htm