Boston Scientific iCross and Atlantis SR Pro 2 Coronary Imaging Catheters: Recall â€“ Catheter Tip Can Break Inside of the Patient

U.S. Food & Drug Administration

ISSUE: The catheter tip can break inside of the patient and embolize causing tissue and blood vessel injury, heart attack or other serious events requiring additional unplanned surgery.

BACKGROUND: The Boston Scientific iCross and Atlantis A SR Pro2 coronary imaging catheters are intended for ultrasound examination of coronary intravascular pathology only. Intravascular ultrasound imaging is used on patients who are candidates for transluminal coronary interventional procedures.

RECOMMENDATION: Boston Scientific Corporation notified customers by letter on May 27, 2011 describing the problem, the potential hazard, and the action to be taken. Customers were instructed to discontinue use and return all products to Boston Science.

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

[06/14/2011 – Recall Notice [3] - FDA]

SOURCE [4]

Source URL (retrieved on *01/27/2015 - 8:37pm*):
http://www.mdtmag.com/news/2011/06/boston-scientific-icross-and-atlantis-sr-pro-2-coronary-imaging-catheters-recall-%C3%A2%E2%82%AC%E2%80%9C-catheter-tip-can-break-inside-patient?qt-most_popular=0

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/ucm259063.htm

[4] http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm259097.htm