

January 5, 2011

**FDA Safety Announcement: AngioScore Inc.,
AngioSculpt Percutaneous Transluminal Angioplasty (PTA)
Scoring Balloon Catheter OTW 0.018" Platform - Class I
Recall**



AUDIENCE: Risk Manager, Cardiology

ISSUE: This device has been identified for recall due to a design defect that can lead to unintended "fracture and peeling" of the bond and/or detachment of the distal end of the scoring element. Continued use of recalled devices may lead to retained device fragments or significant arterial injury which may lead to death or the need for surgical intervention. The recall targets 17,682 units distributed between 9/2007 and 11/2010, including the following model part (REF) numbers and includes all sizes and lot codes for each model listed: 2076-4020, 2076-5020, 2076-6020, 2092-6020, 2105-6020.

BACKGROUND: The AngioSculpt PTA Scoring Balloon Catheter OTW 0.018" Platform is used for dilatation of lesions in the iliac, femoral, ilia-femoral, popliteal, infra popliteal, and renal arteries, and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae.

RECOMMENDATION: AngioScore Inc. advises customers to immediately discontinue the use of any affected product, examine their inventory, and quarantine all affected product.

Healthcare professionals and patients are encouraged to report adverse events or side effects related to the use of this product to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:

- Complete and submit the report Online: www.fda.gov/MedWatch/report.htm
- [Download form](#) 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

Read the MedWatch safety alert, including a link to the FDA recall notice, at:

<http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm239029.htm>

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www.kcercoalition.com/alerts.htm