

August 3, 2011



**FDA Safety Announcement: Arrow International, Inc.
Arrow NextStep Antegrade Chronic Hemodialysis Catheter:
Class I Recall**

AUDIENCE: Risk Manager

ISSUE: The FDA has notified healthcare professionals of a Class I recall of certain Arrow NextStep Antegrade Chronic Hemodialysis Catheters, due to reports of breakage and/or separation of the stylet. These products were distributed to medical facilities and physicians in California, Delaware, Florida, Michigan, North Carolina, and Tennessee. Listed below are the affected product and lot numbers which were manufactured between April 14, 2011 and May 9, 2011.

Product Number	Lot Number
CS-15192-IXM	RV1034909
CS-15232-IXM	RV1034911
CS-15272-IXM	RV1034912
CS-15312-IXM	RV1034913
CS-15422-IX	RV1034914
CS-15502-IX	RV1034915

BACKGROUND: The Arrow NextStep Antegrade Catheter is indicated for use in adult patients for attaining long-term vascular access for hemodialysis and apheresis. Chronic hemodialysis catheters are typically placed into a large vein in the patient's neck.

RECOMMENDATION: Customers should check their stock, cease use and distribution, and quarantine all affected product. See the [Recall Notice](#) for additional information. For questions regarding this recall, contact Arrow International Inc. Customer Service at 1-(800)-233-3187.

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/ucm266526.htm>

www.kcercoalition.com/alerts.htm