Abbott Vascular Recalls Coronary Catheters Due to Risks Stemming from Difficulty Removing Balloon Sheath

The FDA has identified this as a Class I recall, the most serious type of recall. Use of these devices may cause serious injuries or death.

Recalled Product(s):

- Abbott NC Trek RX Coronary Dilatation Catheter, Abbott NC Traveler Coronary Dilatation Catheter, Abbott NC Tenku RX PTCA Balloon Catheter
- Model/Item Numbers: See "**Full List of Affected Devices**"
- Lot Numbers: See "**Full List of Affected Devices**"
- Manufacturing Dates: January 1, 2015 to January 2, 2017
- Distribution Dates: January 1, 2015 to March 14, 2017
- Devices Recalled in the U.S.: 132,040

Device Use

Abbott's Coronary Dilatation Catheters are indicated for use in the following cardiac procedures:

- balloon dilatation of the stenotic portion of a coronary artery or bypass graft stenosis, for the purpose of improving blood flow to the heart;
- balloon dilatation of a coronary artery occlusion (*blocked or clogged artery*), for the purpose of restoring coronary blood flow in patients with ST-segment elevation myocardial infarction (*heart attack*); and
- balloon dilatation of a stent after implantation (2.00 mm - 5.00 mm balloon models only).

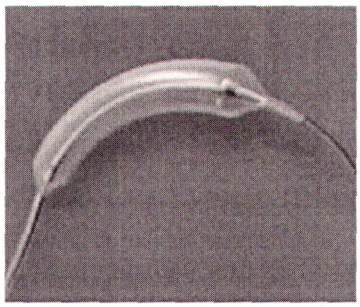

Image of the Abbott Vascular NC Trek RX Coronary Dilatation Catheter

Reason for Recall

Abbott has initiated a voluntary recall of specific lots of three catheters due to 19 reports of injury, and 1 report of death associated with difficulty removing the protective balloon sheath, resulting in issues with inflating or deflating the balloon.

Abbott is recalling products from the identified lots because physicians may experience difficulty in removing the protective balloon sheath. This can result in issues with inflating or deflating the balloon during procedures and may cause serious adverse health consequences including: air embolism, thrombosis (clot in the artery), myocardial infarction (heart attack), and death.

Who May be Affected

- Hospitals and health care professionals using Abbott Vascular's NC Trek RX Coronary Dilatation Catheter, NC Traveler Coronary Dilatation Catheter, and/or NC Tenku RX PTCA Balloon Catheter.
- Patients undergoing cardiac procedures involving these catheters.

What to Do

On March 22, 2017, Abbott sent a "Field Safety Notice" letter to health care providers and risk managers informing them of the device's risks, and corrective actions that would be implemented to ensure ongoing product performance.

The letter asked health care providers and risk managers to:

- Reference the list of affected part numbers and lot numbers.
- Immediately stop using the devices from the identified lots and remove or quarantine them.
- Contact Abbott Vascular to obtain a Return Authorization Number.
- Return all affected and unused products to Abbott Vascular.
- Acknowledge receipt of the notification by returning the "Effectiveness Check Form" provided by Abbott Vascular by email to: **AVRegulatoryCompliance@av.abbott.com (mailto:AVRegulatoryCompliance@av.abbott.com)**, or via fax to: 1-951-914-5951
- Share the notification with other relevant personnel in their organization

Contact Information

Customers with questions may contact their local Abbott Vascular Representative, or contact Abbott's Customer Service Department at (800) 227-9902.

Date Recall Initiated

March 22, 2017

Full List of Affected Devices

- **Abbott NC Trek RX Coronary Dilatation Catheter (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=154375)**
- **Abbott NC Traveler Coronary Dilatation Catheter (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=154376)**
- **Abbott NC Tenku RX PTCA Balloon Catheter (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=154377)**

Additional Resources

- **Abbott Field Safety Notice (March 22, 2017) (https://www.vascular.abbott/content/dam/bss/divisionalsites/av/products/Coronary-Catheter-FSN-3-16-17.pdf) (http://www.fda.gov/AboutFDA/AboutThisWebsite/WebsitePolicies/Disclaimers/default.htm)**
- **Press Release: Abbott Initiates Voluntarily Recall of Specific Lots of Three Coronary Catheters (May 12, 2017) (/Safety/Recalls/ucm558592.htm)**
- **Important Safety Information on NC Trek Catheters (https://www.vascular.abbott/content/dam/bss/divisionalsites/av/products/AP2936324_NC_Trek_RX_OTW_WIPCA.pdf) (http://www.fda.gov/AboutFDA/AboutThisWebsite/WebsitePolicies/Disclaimers/default.htm)**

How do I report a problem?

Health care professionals and consumers may report adverse reactions or quality problems they experienced using these devices to **MedWatch: The FDA Safety Information and Adverse Event Reporting Program (/Safety/MedWatch/HowToReport/default.htm)**. Health care professionals employed by facilities that are subject to **FDA's user facility reporting**

requirements (/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/ReportingAdverseEvents/default.htm) should follow the reporting procedures established by their facilities.

More in Medical Device Recalls (/MedicalDevices/Safety/ListofRecalls/default.htm)
2017 Medical Device Recalls (/MedicalDevices/Safety/ListofRecalls/ucm535289.htm)
2016 Medical Device Recalls (/MedicalDevices/Safety/ListofRecalls/ucm480134.htm)