Abbott

News Release

Abbott Initiates Voluntary Recall of Specific Lots of Two Coronary Catheters

ABBOTT PARK, Ill., Feb. 20, 2020 — Abbott has voluntarily recalled specific lots of two catheters used in coronary angioplasty procedures: the NC Trek RX Coronary Dilatation Catheter and the NC Traveler Coronary Dilatation Catheter, balloon diameters 4.0mm, 4.5mm and 5.0mm. This recall does not affect patients who have successfully undergone cardiac procedures using these devices.

Abbott issued a Field Safety Notice (FSN) on Jan. 29, 2020, to physicians and hospitals who received coronary catheters from the affected lots and is arranging the return and replacement of all remaining products. The affected products were manufactured between July 29, 2019 – Dec. 19, 2019 and distributed between Aug. 16, 2019 – Jan. 3, 2020. The total number of distributed units from identified lots potentially affected is 40,429.

Coronary dilation catheters are used to open clogged blood vessels to improve blood flow to the heart. The balloons from the impacted lots may not deflate as intended. Potential risks include prolonged cardiac ischemia, air embolism, thrombosis, myocardial infarction and additional intervention, such as surgery that could lead to post-operative complications which include death.

The FDA has classified this as a Class I recall. The frequency of reported events that include slow, partial and failure to deflate the balloon, is 0.12 percent worldwide. At the time the FSN was issued, there were no reports of patient death. Since the issuance of the FSN, Abbott has become aware of one reported case in which the inability to deflate the balloon necessitated intervention, which resulted in post-procedural complications leading to a patient death.

Healthcare providers that received the Jan. 29, 2020 FSN are directed to read the document and follow its instructions.

Adverse reactions or quality problems experienced with the use of this product can be reported to Abbott at (800) 227-9902. Reports may also be sent to the FDA's MedWatch Adverse Event Reporting program by completing Form FDA 3500 online at FDA.gov, https://www.fda.gov/safety/medwatch/, calling 1-800-FDA-1088 of faxing to 1 800 FDA 0178.

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For U.S. Important Safety Information about NC Trek RX, visit https://www.cardiovascular.abbott/us/en/hcp/products/percutaneous-coronary-intervention/nc-trek-coronary-dilation-catheters.html#prodisi

About Abbott
Abbott is a global healthcare leader that helps people live more fully at all stages of life. Our portfolio of life-changing technologies spans the spectrum of healthcare, with leading businesses and products in diagnostics, medical devices, nutritionals and branded generic medicines. Our 107,000 colleagues serve people in more than 160 countries.

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