Medtronic Recalls 6 French Sherpa NX Active Guide Catheters Due to Separation and Fragmentation Issue

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

- 6 French Sherpa NX Active Guide Catheters
- Model numbers: All models
- Manufacturing Dates: March 10, 2017 to March 14, 2019
- Distribution Dates: April 3, 2017 to April 4, 2019
- Devices Recalled in the U.S.: 106,298
- Date Initiated by Firm: March 15, 2019

Device Use

The 6 French Sherpa NX Active Guide Catheter is used to access veins and arteries inside and outside of the heart (coronary and peripheral vascular systems). It may be used to assist with the placement and exchange of guidewires and other interventional devices and administer drugs or fluids into blood vessels. The primary users of this device are physicians.

Reason for Recall

Medtronic is recalling the 6 French Sherpa NX Active Guide Catheter due to a risk of the outer material separating from the device resulting in detached fragments that could result in the underlying stainless-steel braid wires being exposed. These fragments could be left inside the patient's bloodstream, and this or the attempts made to retrieve the fractured pieces, can cause other serious adverse health consequences such as continued blockage of blood vessels, injury to blood vessel walls, development of blood clots, embolism, heart attack or death.

Medtronic received five customer complaints. No serious injuries or deaths were reported.

Please note, this issue does not affect the Medtronic Launcher Coronary Guide Catheter or other Medtronic coronary stents, balloons or implantable devices.

Who May be Affected

- Health care providers using the 6 French Sherpa NX Active Guide Catheter
- All patients undergoing procedures involving use of these catheters

What to Do

- On June 15, 2019, Medtronic sent a Revised Urgent Medical Device Recall Notice to customers instructing them to:
- Identify and remove any affected catheters from inventory
- Return any affected product(s) to Medtronic. Contact Medtronic Customer Service at 1-888-283-7868 to initiate a product return. The local Medtronic Representative can assist customers in the return of this product and in determining appropriate alternative products.
- Complete the Customer Confirmation Certificate and email to RS.CFQFCA@Medtronic.com (mailto:RS.CFQFCA@Medtronic.com).

Contact Information

Health care professionals can direct questions to their Medtronic Field Representative or Medtronic Customer Service at 1-888-283-7868.

Patients may contact Medtronic Cardiovascular Patient Services at 1-877-526-7890 (Monday-Friday, 7:30am-5pm Central Time).

Additional Resources

- Recall database entry (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRes/res.cfm?ID=172062)

How do I report a problem?

Health care professionals and consumers may report adverse reactions or quality problems they experience using these devices to MedWatch: The FDA Safety Information and Adverse Event Reporting Program (https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home) either online, by regular mail, or by FAX to 1-800-FDA-0178.