Medtronic News

FDA Classifies Medtronic Sherpa Delivery Catheter Field Action Initiated in March 2019 as Class I Recall

DUBLIN, Oct. 09, 2019 (GLOBE NEWSWIRE) -- Medtronic plc (NYSE:MDT) today announced the U.S. Food and Drug Administration (FDA) has classified the company's voluntary field action initiated in March 2019 related to the 6F Sherpa™ NX Active Coronary Guide Catheter as a Class I recall. The catheter is used during coronary and peripheral interventional procedures. This issue does not affect the Medtronic Launcher® Coronary Guide Catheter or other Medtronic coronary stents, balloons or implantable devices.

In response to receiving six complaints, Medtronic conducted a thorough investigation of certain lots of the product and determined that the affected catheters may have a potential to lose outer material from a distal component that could result in the underlying stainless-steel braid wires being exposed after insertion. While Medtronic has received no reports of patient injuries, as a precaution, Medtronic has voluntarily recalled all models of the 6F Sherpa NX Active Catheters due to potential patient risks associated with this issue. The issue has been reported to FDA and other regulatory authorities. Customers using the catheter have been asked to return all affected inventory to Medtronic.

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), and may also view information about this action at http://newsroom.medtronic.com/.

Adverse reactions or quality problems experienced with the use of these products may be reported to the FDA: Online at http://www.fda.gov/Safety/MedWatch/HowToReport/default.htm (form available to fax or mail), or call FDA at +1-800-FDA-1088.

About Medtronic

Medtronic plc (www.medtronic.com), headquartered in Dublin, Ireland, is among the world's largest medical technology, services and solutions companies – alleviating pain, restoring health and extending life for millions of people around the world. Medtronic employs more than 90,000 people worldwide, serving physicians, hospitals and patients in more than 150 countries. The company is focused on collaborating with stakeholders around the world to take healthcare Further, Together.

Any forward-looking statements are subject to risks and uncertainties such as those described in Medtronic's periodic reports on file with the Securities and Exchange Commission. Actual results may differ materially from anticipated results.

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