Medtronic News

Medtronic Receives FDA "Breakthrough Device Designation" for TYRX Driveline Wrap Device

DUBLIN, Sept. 22, 2020 /PRNewswire/ -- Medtronic plc (NYSE:MDT), the global leader in medical technology, has received Breakthrough Device Designation status from the U.S. Food and Drug Administration (FDA) for the TYRX™ Absorbable Antibacterial Driveline Wrap, which is intended to securely hold a percutaneous driveline in patients receiving a ventricular assist device (VAD).

A vital component of VAD systems, the driveline connects the implanted heart pump to an external controller that is powered by an AC or DC adapter, or external batteries. The pump increases the amount of blood that circulates through the body in patients with advanced heart failure. Because the driveline extends outside the body, it is susceptible to infection. To help reduce driveline complications, Medtronic will leverage its TYRX™ technology platform, currently utilized in the TYRX™ Absorbable Antibacterial Envelope, which is constructed from a multifilament, knitted absorbable mesh, and releases antimicrobial agents, minocycline and rifampin, over a minimum of seven days.[1] It is fully absorbed by the body approximately nine weeks after implantation,[1,2] and stabilizes a cardiac implantable electronic device (CIED) such as a pacemaker or implantable defibrillator, or an implanted neurostimulator.

The FDA Breakthrough Device Program is intended to help patients receive more timely access to breakthrough technologies that have the potential to provide more effective treatment or diagnosis for life-threatening or irreversibly debilitating diseases or conditions. Under the program, the FDA will provide Medtronic with priority review and interactive communication regarding device development, through to commercialization decisions. *The Medtronic TYRX Driveline (DL) Wrap device is in early-stage research and development, and is not available for sale anywhere in the world.*

In collaboration with leading clinicians, researchers and scientists worldwide, Medtronic offers the broadest range of innovative medical technology for the interventional and surgical treatment of cardiovascular disease and cardiac arrhythmias. The company strives to offer products and services of the highest quality that deliver clinical and economic value to healthcare consumers and providers around the world.

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.

[1] Huntingdon Life Sciences Study TR-2013-001.

[2] Sinclair Labs Study D13599.

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