

Medtronic Begins U.S. Study of Drug-Eluting Stents to Evaluate Treatment of Bifurcation Lesions in Patients with Coronary Artery Disease

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 Medtronic plc

Medtronic Received IDE Approval from FDA to Generate Clinical Evidence with Resolute Onyx DES to Support Future Application for Expanded Indication in U.S.

DUBLIN - May 16, 2018 - Medtronic plc (NYSE: MDT) today announced the initiation of a clinical study in the U.S. to assess the safety and efficacy of drug-eluting stents (DES) for the treatment of bifurcation lesions, which account for approximately 20 percent of all percutaneous coronary interventions (PCI).¹ The Bifurcation Cohort, part of the RESOLUTE ONYX Post-Approval Study, will include patients with coronary artery disease (CAD) receiving the Resolute Onyx(TM) DES in sizes ranging from 2.0 mm - 5.0 mm in diameter. The Resolute Onyx DES is not approved for the treatment of bifurcation lesions in the U.S.

Bifurcation lesions occur when plaque builds up around the junction of two coronary arteries - where one branches off another. These lesions are considered challenging to treat because of anatomical variations in the vessels and the difficulty associated with reaching the side branches. Treatment of bifurcation lesions are commonly associated with lower success rates and increased rates of long-term adverse cardiac events.¹

"Patients with bifurcation lesions present a unique challenge for interventional cardiologists. This study will help us evaluate these patients in a controlled setting, which will help expand our knowledge base," said Matthew J. Price, M.D., interventional cardiologist at Scripps Clinic in La Jolla, Calif., and national principal investigator of the Bifurcation Cohort of the RESOLUTE ONYX Post-Approval Study. "The unique design of Resolute Onyx DES may be well-suited to treat bifurcation lesions in a wide range of vessel sizes."

The Resolute Onyx DES platform is the first-and-only DES to feature Core Wire Technology, an evolution of Continuous Sinusoid Technology (CST). CST is a unique Medtronic method of stent manufacturing, which involves forming a single strand of cobalt alloy wire into a sinusoidal wave to construct a stent. Core Wire Technology enables thinner struts while maintaining structural strength and visibility.

The multi-center, single-arm study intends to enroll 250 patients with bifurcation lesions from 30 sites in the United States and Europe. The primary endpoint is target vessel failure (TVF) at 12 months. Study participants will be followed for three years and receive regular follow-up health assessments. Data from the study will be used to support an application for an indication expansion to include bifurcation lesions for the Resolute Onyx DES from the U.S. Food and Drug Administration (FDA).

"As a leader in next-generation coronary stent technology, we continue to invest in generating robust clinical evidence to address unmet needs in interventional cardiology," said Dave Moeller, vice president and general manager of the Coronary and Renal Denervation business, which is part of the Cardiac and Vascular Group at Medtronic. "We look forward to working with participating centers to begin enrolling patients in this important study."

Resolute Onyx DES received CE (*Conformité Européene*) Mark in September 2014 and FDA approval in April 2017. Resolute Onyx DES is currently indicated in the United States for improving coronary luminal diameters in patients, including those with diabetes mellitus, with symptomatic ischemic heart disease due to de novo lesions of length \leq 35 mm in native coronary arteries with reference vessel diameters of 2.0 mm to 5.0 mm.

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 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 84,000 people worldwide, serving physicians, hospitals and patients in approximately 160 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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¹ Sawaya, F., et. al. Contemporary approach to coronary bifurcation lesion treatment. *Journal of the American College of Cardiology*. September 2016; 18: 1861-1878. <http://interventions.onlinejacc.org/content/9/18/1861>

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