Medtronic News

Medtronic Launches First 2.0 mm Drug-Eluting Stent in United States Designed to Treat Patients with Small Vessels

FDA Approved, Resolute Onyx 2.0 mm DES Technology Tackles Clinical Challenge of Treating Coronary Artery Disease in Previously Untreatable Patients

DUBLIN - February 26, 2018 - Designed specifically for small vessels, Medtronic plc (NYSE: MDT) today announced the U.S. Food and Drug Administration (FDA) approval and U.S. launch of the Resolute Onyx(TM) 2.0 mm Drug-Eluting Stent (DES) - the smallest sized DES on the market. The new stent is intended to help interventional cardiologists treat patients with coronary artery disease (CAD) who have small vessels often untreatable with larger stent technologies during percutaneous coronary intervention (PCI). It is estimated that approximately 65 percent of smaller vessels (<= 2.25 mm) are in critical locations of the heart, making them significant lesions to treat.1

"Patients with lesions in small vessels or complex vasculatures can present unique challenges for physicians during PCI procedures," said Matthew J. Price, M.D., interventional cardiologist at Scripps Clinic in La Jolla, Calif., and national principal investigator of the RESOLUTE ONYX 2.0 mm Clinical Study, which supported the recent FDA approval. "The Resolute Onyx 2.0 mm DES is an extremely deliverable stent that, when needed, can be post-dilated to 3.25 mm to treat lesions in difficult-to-reach areas of the heart."

The first-and-only 2.0 mm DES size available in the U.S., the newly approved stent joins the unique Resolute Onyx 4.5- and 5.0-mm DES to provide physicians with the broadest DES size matrix available, expanding treatment options for patients with the smallest coronary vessels to the largest, from the simplest of anatomies to the complex. In addition, the stent is engineered with the lowest crossing profile of any DES (less than 1 mm) enabling exceptional deliverability. Once delivered, the Resolute Onyx 2.0 mm DES is engineered to expand from 2.0 mm to the maximum labeled expansion diameter of 3.25 mm.

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.

"Furthering our core objective of developing technologies that address unmet patient needs, the introduction of the Resolute Onyx 2.0 mm DES allows physicians to expand treatment options for patients with smaller vessels," 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. "The Resolute Onyx DES is an incredibly deliverable product that incorporates various design enhancements enabling physicians to optimize treatment for a wide range of patients."

The Resolute Onyx 2.0 mm DES is supported by the RESOLUTE ONYX 2.0 mm Clinical Study, which was presented at the 2017 EuroPCR Annual Meeting and simultaneously published in the *Journal of the American College of Cardiology (JACC): Cardiovascular Intervention.* In the study, the Resolute Onyx DES met its pre-specified performance goal with low target lesion failure (5 percent), low target lesion revascularization (2 percent), no episodes of stent thrombosis and no cardiac death at 12 months.

The Resolute Onyx DES is available for use in all sizes in the United States, as well as in Europe and other countries that recognize the CE (*Conformité Européene*) Mark.

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 more than 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 Schunkert et al. *JACC* July 1999

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