Medtronic News

Medtronic Adds New Resolute Onyx(TM) Drug-Eluting Stent Sizes and Expands Indications

New Extra-Large Vessel Stent Sizes and Indications in the EU Expand Treatment Options for Patients with Coronary Artery Disease

DUBLIN - February 1, 2016 - Medtronic plc (NYSE: MDT) today announced the recent CE (Conformité Européene) Mark and commercial launch for an expanded size matrix of the Resolute Onyx DES, a next generation drug-eluting stent that is now available in 4.5mm and 5.0mm diameter sizes. The CE Mark also approved several new product indications including treatment of left main vessels and small vessels. Many coronary vessels are large in diameter of which a sub-set are left main, and now physicians can treat these large vessels with optimally sized stents that provide appropriate drug concentration. Resolute Onyx is the first DES available in these sizes among major manufacturers, offering the broadest size matrix to optimize the treatment of complex clinical scenarios. The Resolute Onyx DES is not commercially available in the United States.

Treatment of the left main coronary artery is critical as the artery supplies the majority of blood to the left side of the heart; a narrowing in this vessel can place the patient at high risk for life-threatening events. Due to the lack of optimally sized drug-eluting stents available to date to treat large coronary arteries, these patients historically have been treated with undersized stents or with coronary artery bypass graft surgery (CABG). CABG can be more invasive and may require a longer recovery period than treatment with drug-eluting stents, while under-sized stents may have compromised stent scaffold integrity and disrupted polymer coating when over-expanded.

Resolute Onyx DES is well suited to treat large coronary vessels including the left main coronary artery with its optimal sizes and conformability in bifurcation lesions due to Continuous Sinusoid Technology.

"My initial clinical experience with the large sizes of the Resolute Onyx DES has been exceptional, as they alleviate many of the procedural challenges that existed when smaller stents were often the only option for large vessels," said David Hildick-Smith, M.D., principal investigator of the EBC Main Study who performed the first patient case with the larger sized Resolute Onyx from the Brighton and Sussex University Hospitals NHS Trust in Brighton, United Kingdom. "In addition, the left main indication of Resolute Onyx, coupled with its advanced stent design, provides physicians with a novel device that maintains its scaffold integrity with increased radial force, which is especially beneficial when treating bifurcation lesions in large vessels."

Built on the proven clinical performance and superior deliverability of the Resolute Integrity DES, the expanded sizes feature the same CoreWire Technology that allows the stent to have a denser core metal wrapped in a cobalt alloy outer layer. This technology enables increased radiopacity (i.e., visibility during the procedure) and has thinner struts to help improve deliverability without compromising radial and longitudinal strength. The full size matrix of Resolute Onyx features a delivery system with PowerTrac(TM) technology that provides enhanced deliverability through challenging lesions.

"The expanded size matrix of Resolute Onyx, and the new indication to treat the left main vessel, further delivers on our promise to provide the interventional community with stent innovations that address unmet clinical needs seen in everyday clinical practice," said Jason Weidman, vice president and general manager of the coronary and renal denervation business unit at Medtronic. "We now have a stent that treats a broader range of patient anatomies - from large to small - than any other major DES on the EU market."

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 85,000 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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