Medtronic News

FDA Approves Longer Lengths of Medtronic's Resolute Integrity Stent

New Sizes of Implantable Medical Device Target Long Coronary Lesions Common Among Diabetes Patients

MINNEAPOLIS -- Feb. 25, 2013 -- Expanding the applicability of its marquee product for the interventional treatment of coronary artery disease in the United States, Medtronic, Inc. (NYSE: MDT) announced today that the U.S. Food and Drug Administration (FDA) has approved the 34mm and 38mm lengths of the Resolute Integrity drug-eluting stent in diameters of 3.0mm, 3.5mm and 4.0mm with an indication for patients with diabetes.

Now available to cardiac catheterization laboratories nationwide, these new sizes of the Resolute Integrity stent enable the treatment of long coronary lesions, which are generally considered to span more than 27mm.

Like the core sizes approved by the FDA in February 2012, the 34mm and 38mm lengths of the Resolute Integrity stent are uniquely indicated for treating the coronary artery disease of patients with diabetes, who commonly present with long lesions.

"Long coronary lesions and diabetes represent two distinct but often interrelated clinical challenges," said Ronald Caputo, M.D., director of cardiac services and cardiology research at St. Joseph's Hospital in Syracuse, N.Y. "The new sizes of the Resolute Integrity drug-eluting stent address both challenges in a single device. They have the potential to reduce procedure time and cost for clinicians and hospitals, as well as vessel trauma and contrast exposure for patients."

FDA approval of the 34mm and 38mm lengths of the Resolute Integrity stent is based on data from the global RESOLUTE clinical program -- specifically, a pre-specified analysis of one-year outcomes in patients with long coronary lesions who participated in the RESOLUTE US and RESOLUTE Asia studies.

The analysis included data on 222 patients who received a 38mm Resolute stent for the treatment of coronary lesions of no greater than 35mm in length. The primary endpoint for the analysis was target lesion failure (TLF) -- a composite of cardiac death, target vessel myocardial infarction and clinically-driven target lesion revascularization (TLR) -- at one year of follow-up.

The long-lesion analysis met its primary endpoint, with a one-year TLF rate of 4.5 percent. Among the 38 percent of patients with diabetes, the one-year TLF rate was similarly low at 6.0 percent. The one-year rates of clinically driven TLR for all patients and the subset of diabetes patients were 1.4 percent and 2.4 percent, respectively.

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, Inc. (www.medtronic.com), headquartered in Minneapolis, is the global leader in medical technology -- alleviating pain, restoring health and extending life for millions of people around the world.

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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Coronary Artery Disease and Diabetes Backgrounder
Drug-Eluting Stent Procedural Animation
Resolute Integrity DES Long Lesion Image
Resolute Integrity Fact Sheet
HUG#1680616

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