

Medtronic Launches Resolute Integrity Coronary Stent System in Japan

The Associated Press

Part of Global Clinical Program, RESOLUTE Japan Study Supported Novel Heart Device's Regulatory and Reimbursement Approvals in World's Second Largest Med-Tech Market

MINNEAPOLIS -- August 28, 2012 -- Expanding global access to proven cardiovascular treatment options, Medtronic, Inc. (NYSE: MDT) announced today the launch of the Resolute Integrity(TM) Coronary Stent System in Japan, the world's second largest market for medical devices.

Indicated for the treatment of coronary artery disease, the Resolute Integrity drug-eluting stent offers a combination of superior deliverability with powerful performance as demonstrated in its long-term effectiveness and safety in more than 5,000 clinical study patients.

"The launch of the Resolute Integrity drug-eluting stent in Japan continues the strong momentum we've experienced this year with our novel next-generation stent, which is now available in all major markets worldwide," said Sean Salmon, president of Medtronic's coronary and renal denervation business. "The Resolute Integrity stent has been quickly adopted by physicians for its excellent clinical performance and improvement in deliverability; we look forward to now providing these benefits to Japanese physicians and their patients as well."

The device's regulatory and reimbursement approvals earlier this year were supported by the results of RESOLUTE Japan, a prospective, single-arm, open-label study that enrolled 100 patients at 14 Japanese medical centers between March and October 2009.

The study's two-year results, which were presented last month at the 21st Annual Meeting of the Japanese Association of Cardiovascular Intervention and Therapeutics (CVIT), showed the durability of the treatment effect with the Resolute drug-eluting stent. As reported previously, RESOLUTE Japan study met its primary endpoint -- with average in-stent late lumen loss of 0.13 mm at eight months post-implant. The Taxus drug-eluting stent, used as a historical control, had an average eight month in-stent late lumen loss of 0.42 mm.

"In terms of late loss, RESOLUTE Japan demonstrated superiority of the Resolute stent compared to historical control data of the Taxus stent," explained Shigeru

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Saito, M.D., director of Cardiology and Catheterization Laboratories at Shonan Kamakura General Hospital in Kamakura, Japan, and principal investor of RESOLUTE Japan. "The effectiveness of the Resolute stent was further demonstrated with zero target lesion revascularization events out to two years."

Dr. Saito also highlighted the study's two-year safety findings for the audience of interventional cardiologists at CVIT: "The Resolute stent showed excellent safety outcomes in this trial, with no cardiac death and zero stent thrombosis out to 24 months."

The global RESOLUTE clinical program, which includes RESOLUTE Japan, consisted of a large randomized controlled trial and a series of confirmatory single-arm studies involving nearly 250 sites in 32 countries across Europe, Asia, the Pacific Rim, the Middle East, Africa, Latin America and North America. In total, the program enrolled 5,130 patients who received a Resolute drug-eluting stent.

The Resolute Integrity Coronary Stent System features Medtronic's next-generation drug-eluting stent, which uses the Integrity platform to achieve excellent deliverability without compromising radial or longitudinal strength. The Resolute Integrity drug-eluting stent demonstrates superior deliverability compared to other drug-eluting stents on the market. The device is commercially available in most of the world's major markets for advanced medical technology, including Europe, the United States and now Japan.

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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