Medtronic News

Medtronic Receives FDA Approval of Integrity(R) Coronary Stent

Superior Deliverability Distinguishes New Medical Device Based on Engineering Advance of Continuous Sinusoid Technology

MINNEAPOLIS, Sep 20, 2010 (BUSINESS WIRE) --

Delivering another innovation for interventional cardiology, Medtronic, Inc. (NYSE: MDT), announced today the U.S. Food and Drug Administration (FDA) approval of the Integrity Coronary Stent System. The new platform for Medtronic's coronary stents, including the Integrity bare-metal stent, is based on an advance in biomedical engineering called continuous sinusoid technology that enables the exploration of other breakthrough device concepts such as a polymer-free drug-filled stent.

Now available in the United States, the Integrity Coronary Stent System has been shown in bench testing and in blinded *in vivo* physician assessment studies to be highly deliverable. In this context, deliverability relates to the ability of the device to traverse the patient's vasculature and reach the narrowed heart artery targeted for treatment.

Dr. Mark Turco, director of cardiac and vascular research at Washington Adventist Hospital in Tacoma Park, Md., was among the first interventional cardiologists in the United States to use the Integrity Coronary Stent System in clinical practice.

"The Integrity stent system sets a new gold standard for deliverability thanks to the advance of continuous sinusoid technology," Dr. Turco said. "This new platform negotiates the twists and turns of the coronary anatomy remarkably well. Credit goes to Medtronic for continuing to improve stent technology, as continuous sinusoid technology should prove to be an excellent platform for future product development."

Medtronic set the standard for deliverability with the modular design of the Driver bare-metal and Endeavor drug-eluting stents. These devices are made from rings of a cobalt alloy that are shaped into crowns and, to maximize flexibility, laser fused where only certain points on the crowns meet. The Integrity stent is also made from cobalt alloy and is laser fused in a similar pattern.

Instead of rings, continuous sinusoid technology enables each stent to be made from a single wire, comparable to a flexible spring. Coupled with the MicroTrac delivery system, this engineering advance offers exceptional deliverability without compromising other important stent design characteristics like radial strength. Like the Driver stent, the Integrity stent is also highly conformable. Conformability is a measure of the stent's ability to conform to the natural shape of the vessel. For these and other reasons, continuous sinusoid technology represents Medtronic's platform of the future for coronary stents.

Medtronic offers a portfolio of bare-metal and drug-eluting stents to address the spectrum of clinical needs for patients with coronary artery disease. In the United States, the Integrity bare-metal stent joins the Endeavor drug-eluting stent, which has demonstrated durable safety and efficacy out to five years of patient follow-up in rigorous clinical studies, including low rates of adverse events.

The Integrity Coronary Stent System received the CE (Conformité Européene) mark in February and is currently available in approximately 100 countries outside the United States. In the ensuing six months, it enabled Medtronic to achieve the market-leading position for bare-metal stents in Western Europe and Central Asia.

"Clinicians clearly appreciate the superior deliverability of the Integrity stent," said Sean Salmon, vice president and general manager of Medtronic's coronary and peripheral division. "They are also intrigued at what else might be possible with continuous sinusoid technology, including the potential for a drug-filled stent, which could obviate the need for a polymer to regulate drug elution by using holes on the surface of a hollow tube."

Medtronic is committed to advancing the treatment of cardiovascular disease through collaboration with leading clinicians,

researchers and scientists worldwide.

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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