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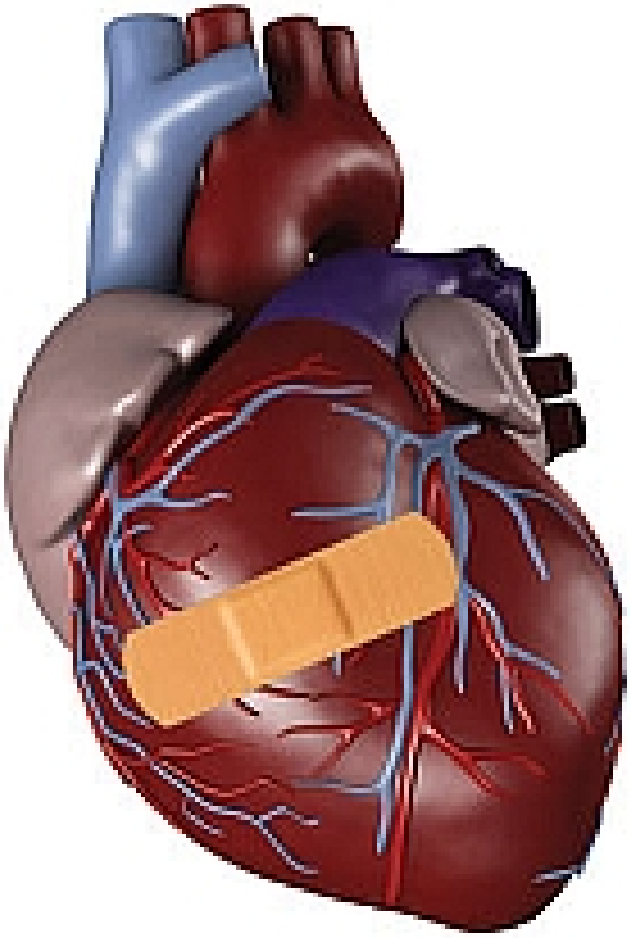
Medtronic launches stent system in Japan

30 August 2012 | News | By BioSpectrum Bureau

Medtronic Launches Resolute Integrity Coronary Stent System in Japan



Singapore: Medtronic launched the Resolute Integrity Coronary Stent System in Japan, which is 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 Mr Sean Salmon, president, coronary and renal denervation business, Medtronic. "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 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 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.