Medtronic News

Medtronic Announces CE Mark and European Launch of TYRX(TM) Absorbable Antibacterial Envelope

MINNEAPOLIS - Sept. 22, 2014 - Medtronic, Inc. (NYSE: MDT) has received CE (*Conformité Européenne*) Mark for the TYRX(TM) Absorbable Antibacterial Envelope. This innovative mesh envelope covers an implantable cardiac device to help stabilize the device after implantation and reduce surgical-site infections.

The efficacy of the previous generation, non-absorbable TYRX(TM) Antibacterial Envelope* has been shown in three published studies, with new six-month follow-up data from the CITADEL/CENTURION Study presented at Cardiostim 2014. Six months following implantation, patients who received a single- or dual- chamber implantable cardioverter-defibrillator (ICD) or cardiac resynchronization therapy (CRT) replacement device with a TYRX Antibacterial Envelope experienced lower infection rates than a historical cohort of patients who were implanted without the envelope.

Specifically, infection occurred in 0.2 percent of patients who received the envelope during an ICD or CRT implant, compared to 1.9 percent of patients who did not receive the envelope ($p<0.001$). Additionally the rate of device mechanical complications was low (4.0 percent) in patients who received the envelope.

CITADEL/CENTURION is a multicenter study involving 55 sites in the United States that prospectively treated more than 1,000 patients undergoing an ICD or CRT replacement with the TYRX Antibacterial Envelope; the primary endpoints were major infection (involving any site other than skin or subcutaneous tissue of the incision or endocarditis) and device mechanical complication.

"The TYRX envelope seems to offer physicians a simple, yet highly effective method of reducing surgical-site infections, particularly among those high-risk patients who are undergoing a repeat procedure," said Charles Kennergren, M.D., Ph.D., Sahlgrenska University Hospital, Gothenburg, Sweden. "We have high expectations for this novel product, both in terms of reducing infection rates as well as avoiding device migrations." Dr. Kennergren recently performed the first implant of the envelope in Europe.

The TYRX Absorbable Antibacterial Envelope, covering a cardiac implantable electronic device (CIED) such as a pacemaker, ICD or CRT device, releases rifampin and minocycline to the surgical site to help prevent infection. The envelope stabilizes the CIED, then dissolves and is fully absorbed approximately nine weeks after implantation. The TYRX Absorbable Antibacterial Envelope is currently cleared for use in the United States and approved in Canada and Israel. Medtronic acquired U.S.-based TYRX in January 2014.

"While the risk of infection is low for most patients receiving an implantable device, the TYRX envelope offers an extra layer of protection," said John Liddicoat, M.D., president of the Cardiac Rhythm and Heart Failure business and senior vice president of Medtronic. "The TYRX envelope provides physicians with a proven solution to make implantable device procedures safer for their patients."

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.

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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* The TYRX Antibacterial Envelope was previously marketed as the AIGISRX® Antibacterial Envelope.

Contacts:
Tracy McNulty
Public Relations
+1-763-526-2492

Jeff Warren
Investor Relations
+1-763-505-2696

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