Medtronic News

Medtronic Launches 'TOTAL Across' Crossing Catheter in Europe

New Peripheral Device Targets Challenging Lesions in Lower-Extremity, Including Below-the-Knee, Arteries Associated with Critical Limb Ischemia

MINNEAPOLIS -- Feb. 13, 2014 -- Aligned with its commitment to provide innovative medical technology for the interventional treatment of peripheral artery disease, Medtronic, Inc. (NYSE: MDT) has initiated the European launch of the TOTAL across crossing catheter, which recently received the CE *(Conformité Européene)* mark as a tool for improving blood flow through narrowed or occluded lower-extremity arteries, including those in the especially challenging below-the-knee (BTK) vessel bed.

The company has also submitted an application to the U.S. Food and Drug Administration (FDA) for 510(k) clearance of the new peripheral device that is currently under review. The FDA has not yet cleared the TOTAL across crossing catheter or approved any of the IN.PACT drug-eluting balloons. The TOTAL across crossing catheter is not approved for commercial use in the United States.

With 0.014-inch wire compatibility, the TOTAL across crossing catheter is intended to guide and support a guidewire, including the crossing of a target lesion, during the access of peripheral arteries with obstructive disease and to allow for wire exchanges. The device is also intended to provide a conduit for the infusion of saline solutions or diagnostic contrast agents.

Distinguishing features of the TOTAL across crossing catheter include the device's spiral cut stainless steel hypotube construction and 2-French tapered tip. The spiral cut stainless steel hypotube construction affords exceptional pushability and unparalleled catheter visualization, while the tapered tip allows the catheter to cross lesions smaller than the device profile. These features address the specific challenges often encountered in patients with critical limb ischemia (CLI) caused by BTK lesions.

"BTK lesions are a common cause of CLI, which is a particularly difficult condition to treat," explained Andrej Schmidt, MD, an angiologist and cardiologist in the Center for Vascular Medicine at Park-Hospital Leipzig in Germany. "The TOTAL across crossing catheter represents a tangible step forward in microcatheter design, providing extraordinary support and stability combined with one of the lowest crossing profiles available to better deal with the clinical challenge of distal BTK revascularization."

Dr. Schmidt is among the first European physicians to use the new device.

"The TOTAL across crossing catheter expands our portfolio of medical devices for the interventional treatment of peripheral artery disease," said Tony Semedo, a senior vice president at Medtronic and president of the company's Endovascular Therapies business. "It's a prime example of our focus on developing lesion-specific solutions and our ongoing commitment to addressing BTK lesions specifically. We are excited to be introducing this new device in Europe and look forward to bringing it to the United States in the near future."

The TOTAL across crossing catheter is the first of three new products to address the clinical challenge of BTK CLI that Medtronic plans to introduce around the world over the next two years.

Other devices in Medtronic's peripheral product portfolio aimed at treating lower-extremity disease include the Complete SE (self-expanding) vascular stent, the IN.PACT line of drug-eluting balloons, and the Admiral, Pacific and Amphirion families of percutaneous transluminal angioplasty (PTA) balloon catheters. The Pacific and Amphirion PTA balloons are designed specifically for use in BTK arteries.

In collaboration with leading clinicians, researchers and scientists, Medtronic offers the broadest range of innovative medical technology for the interventional and surgical treatment of cardiovascular diseases and cardiac arrhythmias. The company strives to offer products and services that deliver clinical and economic value to healthcare consumers and providers 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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Contacts:

Joseph McGrath
Public Relations
+1-612-819-6421

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

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