Medtronic News

Medtronic Announces FDA Clearance and U.S. Launch of the Accurian Radio Frequency System for Nerve Tissue Ablation

Medtronic Expands Pain Portfolio with Minimally Invasive Therapy to Support Patients Throughout the Care Continuum

DUBLIN - February 27, 2019 - Medtronic plc (NYSE:MDT) today announced U.S. Food and Drug Administration (FDA) 510(k) clearance of the Accurian(TM) RF ablation platform, which conducts radio frequency (RF) ablation of nerve tissues. RF ablation is a minimally invasive procedure in which current produced by radio waves heats up a small area of nerve tissue to stop it from sending pain signals, thereby reducing pain. The Accurian system combines proprietary hardware and quad core processing with advanced software for power and temperature control resulting in consistent and predictable lesion formation. It also offers independent channel management and advanced smart features that may support procedural efficiency.

"The Accurian RF ablation platform is a significant addition in my practice because I know I'll get the same lesion every time in every channel due to how responsive the generator is in managing power and temperature," said Leo Kapural, M.D., Ph.D., a pain physician at Carolinas Pain Institute and Center for Clinical Research in Winston-Salem, North Carolina. "RF ablation requires both precision and flexibility. Accurian is intuitive and easy to use and enables me to easily upgrade the system and perform enhanced lesions with cooled RF probes."

The Accurian RF ablation platform can perform standard, pulsed, and enhanced procedures using internally-cooled probes to create a comprehensive range of lesion shapes, sizes, and volumes. It has independent channel control and chip-enhanced probes for easy on-screen identification, as well as smart features, such as downloadable procedure reports to support ease of use and efficiency. The Accurian system has been extensively tested for lasting reliability and is upgrade-ready as technology advances.

"Medtronic has a long-established track record of bringing to market improved options to support clinicians with state-of-the-art technology, like the Accurian RF ablation system, which was designed for consistency and efficiency," said Marshall Stanton, M.D., senior vice president and president of Medtronic's Pain Therapies division, which is part of the Restorative Therapies Group. "Medtronic is committed to advancing the treatment of pain as we introduce new options to help patients throughout the care continuum."

About Chronic Pain

Chronic pain, which lasts more than three to six months, is a disabling condition that adversely affects wellbeing and can interfere with working, sleeping, and participating in physical activities, ultimately affecting quality of life. At least 100 million American adults - more than those affected by heart disease, cancer, and diabetes combined - are affected by chronic pain.1 It is estimated that the cost to treat chronic pain in the U.S., as well as related lost productivity, is as high as $635 billion annually.2

About Medtronic Pain Therapies

Medtronic has more than a 40-year history of developing innovative medical devices that have been shown to alleviate pain in different disease states and has a broad portfolio of device-delivered therapies that are alternatives or adjuncts to oral opioids.3 Medtronic strives to be at the forefront of medical device innovation and to develop high-quality pain therapies that reduce pain and improve quality of life. While Medtronic pain therapies do not treat opioid addiction, we are committed to leveraging our capabilities and product portfolio in partnership with stakeholders - patients, providers, payers, regulators, elected officials, patient advocacy groups and employers - to address the unmet needs of pain patients and to support efforts to prevent opioid misuse due to chronic intractable pain.

About Medtronic

Medtronic plc (www.medtronic.com), headquartered in Dublin, Ireland, is among the world's largest medical technology, services and solutions companies - alleviating pain, restoring health and extending life for millions of people around the world. Medtronic employs more than 86,000 people worldwide, serving physicians, hospitals and patients in more than 150 countries. The company is focused on collaborating with stakeholders around the world to take healthcare Further, Together.

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:

Sara Thatcher

Public Relations

+1-901-399-2098

Ryan Weispfenning

Investor Relations

+1-763-505-4626

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