Medtronic News

Medtronic Announces FDA Approval and U.S. Launch of Next Generation Pacemakers

Azure(TM) with BlueSync(TM) Technology Improves Device Longevity and Provides Automatic, Wireless Remote Patient Monitoring

DUBLIN - November 20, 2017 - Medtronic plc (NYSE: MDT) today announced U.S. Food and Drug Administration (FDA) approval and U.S. commercial launch for its portfolio of Azure(TM) pacemakers with BlueSync(TM)technology. Available in both single chamber and dual chamber models, the Azure XT MRI and Azure S MRI pacemakers offer improved longevity, estimated at 13.7 years (dual chamber) or 27 percent longer than its predecessor,1 so patients likely need fewer device replacements. The new pacemakers also allow patients to have MRI (magnetic resonance imaging) scans in either 1.5 or 3 Tesla (T) machines.

Azure pacemakers feature Medtronic-exclusive BlueSync technology, which enables automatic, secure wireless remote monitoring via the Medtronic CareLink(TM)Network, providing timely alerts of clinically relevant patient events that can be reviewed by a clinician at any time. Security controls implemented and validated on BlueSync enabled devices include access restrictions to protect integrity of device functionality and end-to-end encryption to protect patient data.

The Azure XT pacemaker features the Medtronic Reactive ATP(TM) (atrial-based antitachycardia pacing) algorithm, which was shown in the MINERVA Trial and real-world studies to slow the progression of atrial fibrillation (AF) in patients with implanted cardiac devices.2 Common among patients with cardiac devices, AF impairs quality of life and increases the risk of hospitalization, stroke and death.3

"With the approval of Azure, clinicians managing patients with bradycardia now have pacemakers with improved longevity, and better ability to detect and reduce atrial fibrillation" said John Liddicoat, M.D., senior vice president, Medtronic, and president of the Cardiac Rhythm and Heart Failure division. "BlueSync technology with Azure also enables secure and automatic wireless data transmission to clinicians. Remote monitoring with automatic data transmissions can result in earlier clinical decisions and improved patient monitoring compliance."

In tandem with the approval of these new pacemakers, the Medtronic Percepta(TM) portfolio of quadripolar, MR-conditional cardiac resynchronization therapy pacemakers (CRT-Ps) also now includes BlueSync technology for secure, wireless remote monitoring via the Medtronic CareLink Network.

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 84,000 people worldwide, serving physicians, hospitals and patients in approximately 160 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.

1 Orenga M. Azure longevity Increase Compared to Advisa. September 2017.

Medtronic data on file.

2 Hudnall H. Reactive Atrial-based Antitachycardia Pacing Therapy to Slow

Progression of Atrial Fibrillation. August 2017, Medtronic data on file.

3 Chugh S, Havmoeller R, Narayanan K, et al. Worldwide epidemiology of atrial fibrillation: a global burden of disease 2010 study. Circulation. 2014; 129:837-847.

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