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

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Ireland based medical devices company, Medtronic has 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, 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. Common among patients with cardiac devices, AF impairs quality of life and increases the risk of hospitalization, stroke and death.

John Liddicoat, M.D., senior vice president, Medtronic, and president of the Cardiac Rhythm and Heart Failure division said, “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. 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."