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Boston Scientific begins pacing leads' trial

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Singapore: Boston Scientific has implanted the first of its next generation Ingevity pacing leads in a clinical trial that is designed to establish the safety, performance and effectiveness of the leads.

Pacing leads are insulated wires that connect an implantable pacemaker to the heart for treatment of bradycardia, a condition in which the heart beats too slowly, depriving the body of sufficient oxygen. Pacemakers work in conjunction with leads to sense and stimulate (or pace) the heart, thus maintaining an appropriate heart rate for a given level of physical activity.

The Ingevity pacing lead platform is designed to provide key enhancements in maneuverability, reliability, fixation and electrical performance compared to standard leads available today. In addition, Ingevity leads are specifically engineered to function in the magnetic resonance imaging (MRI) environment. Many patients with pacemakers are restricted from undergoing MRI scans, as powerful magnets may interfere with pacemaker functionality.

"Our research and development efforts focus on consistency, repeatability and industry-leading reliability," said Dr Kenneth Stein, senior vice president and chief medical officer, Cardiac Rhythm Management business at Boston Scientific. "We believe Ingevity reflects all of these design principles, with the goal of improving the quality of patient care across the globe."

The Ingevity trial is a prospective, non-randomized, multi-center, global clinical study designed to support US FDA, CE Mark and other regulatory approvals. The trial is expected to enroll approximately one thousand patients at 100 centers worldwide in 16 countries. The Ingevity leads are expected to be paired with the Boston Scientific Ingenio family of pacemakers.