

Japan approves Accent MRI Pacemaker

02 July 2013 | Regulatory | By BioSpectrum Bureau



Singapore: St Jude Medical, a global medical device company, has received approval from the Japanese Ministry of Health, Labour and Welfare (MHLW) to launch the Accent MRI Pacemaker and the Tendril MRI lead. Unlike MRI-labeled devices currently available, the Accent MRI pacemaker is the only commercially available system with labeling that allows patients to undergo full-body, high-resolution magnetic resonance imaging (MRI) scans to accommodate their current and future medical needs.

Commenting on the Accent MRI pacemaker, Dr Toshiko Nakai, assistant professor of the Nihon University School of Medicine in Tokyo, said, "We are pleased to see the MRI-conditional pacemaker launched by St Jude Medical. I believe the benefit of full-body scanning with 1.5 Tesla MRI, the 6 millimeter thinness and ability to provide remote monitoring together make this device patient-friendly."

MRI scans are important imaging procedures as they better evaluate the presence of certain diseases and injuries that may not be adequately assessed with other imaging methods, such as X-ray or ultrasound. Patients with traditional pacing systems are discouraged from receiving MRI scans because their device may be affected, which deprives them the standard of care MRI diagnostic technology provides.

"The Accent MRI pacemaker has many advantages over what is currently available for patients. The sophisticated pacemaker functionality and labeling of full-body MRI scans are especially important for patients who may need an MRI scan in the chest and abdominal area. We are excited to offer this innovative technology to hospitals throughout Japan," said Mr William Phillips, senior vice president of St Jude Medical Asia.

The system features an MRI Activator device that provides a simple option for programming the patient's pacemaker to the appropriate MRI mode for use during the MRI scan. The press of a single button on the handheld MRI Activator device can program the specific device parameters to be used during the MRI scan. These parameters are pre-selected by the patient's physician and stored in the memory of the Accent MRI pacemaker. The MRI Activator can then programme the device back to its original parameters after the scan has been completed.

Built on the proven Tendril lead platform, the pacing lead offers unique capabilities for safe, full power MRI scanning, including 6F proximal lead body diameter and excellent handling characteristics. The lead features Optim lead insulation, the first silicone-polyurethane, co-polymer material created specifically for cardiac lead use. The Optim insulation is designed for long-term reliability, while providing physicians with better flexibility and handling to facilitate device implantation.

St Jude Medical develops medical technology and services that focus on putting more control into the hands of those who treat cardiac, neurological and chronic pain patients worldwide.