

CE Mark for MRI-Compatible Pacemaker Leads



St. Jude Medical, Inc. (St. Paul, MN, USA) has received a CE mark approving updated labelling for its Tendril™ STS and IsoFlex™ Optim™ pacing leads, giving existing and future patients with pacing devices access to magnetic resonance imaging (MRI) scans in Europe. The leads are used with the Accent MRI™ pacemaker, an advanced pacing platform that provides the added benefit of MRI scanning capability.

Yearly, about one million pacemakers are implanted worldwide. The updated labelling further indicates the safety of the Tendril STS and IsoFlex Optim pacing leads, the manufacturer said. In actively monitored registries, the Tendril STS and IsoFlex Optim pacing leads have demonstrated proven reliability with over 99 percent survivability in patients, the company noted.

“St. Jude Medical is committed to providing MRI compatible pacing solutions to patients and physicians around the world,” said Eric S. Fain, MD, group president of St. Jude Medical, a global medical device company. “We believe many patients can benefit from pacing therapies with MRI scanning capabilities when they have additional health concerns. We are dedicated to the development of existing and future heart rhythm technologies that are compatible with this important diagnostic tool.”

Leads Use Hybrid Insulation Material for Durability and Flexibility

The Tendril STS and IsoFlex Optim pacing leads are built on the Tendril and IsoFlex lead platforms. They feature the company's exclusive Optim insulation material, which blends the biostability and flexibility of high-performance silicone rubber with the strength, tear resistance and abrasion resistance of polyurethane. Such combination allows for increased durability, while improving flexibility, handling characteristics and control during implant procedures, the company explained.

A lead is a thin insulated wire that is placed through the vein as part of a pacemaker implantation procedure, St. Jude Medical said. Its tip is attached to the heart tissue, while its other end connects to the pacemaker. A lead carries electrical impulses from the pacemaker to the heart and transmits information from the heart back to the implanted device.

Company Plans Updated Labelling for Other Existing Products

St. Jude Medical reported that it also plans to seek updated labelling for many of its existing products to allow patients the ability to safely undergo MRI scans. The company plans to submit testing data in major markets around the world such as Europe, Australia, Japan, and the United States for MRI conditional labelling on several additional existing products including the Fortify™ Assura implantable cardioverter defibrillator (ICD), Ellipse™ ICD, Quadra Assura™ cardiac resynchronisation therapy defibrillator (CRT-D), Durata™ and Optisure™ defibrillation leads.

St. Jude Medical is committed to transforming the treatment of some of the world's most expensive epidemic diseases. The company continuously develops cost-effective medical technologies that save and improve lives of patients around the world. The company's four major clinical focus areas include cardiac rhythm management, atrial fibrillation, cardiovascular and neuromodulation.

Source: MedImaging.net
Image Credit: St. Jude Medical, Inc.

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