Medtronic Canada Newsroom

Medtronic Receives First Health Canada License for MRI Conditional Implantable Cardioverter Defibrillator System

Evera MRI ICD System Licensed for Full Body MRI Scans for Patients at Risk of Sudden Cardiac Arrest

Brampton - December 21, 2015 - Medtronic Canada today announced that it has received the first Health Canada license for an implantable cardioverter defibrillator (ICD) system for use with magnetic resonance imaging (MRI) scans. The Medtronic Evera MRI™ SureScan® ICD System is licensed for MRI scans on any part of the body without positioning restrictions, which means that patients in Canada who depend on life saving ICDs also now have access to MRI scans if and when they need them. The newly licensed system includes the Evera MRI ICD and Sprint Quattro® Secure MRI SureScan® DF4 leads, which must be used together to be considered MRI conditional.

“This is a very important advancement in the medical field since a significant percentage of ICD patients will eventually require an MRI for cardiac imaging modalities and for other organ imaging,” said Dr Blandine Mondésert, Cardiac Electrophysiologist at Montreal Heart Institute.

Sudden cardiac arrest (SCA) is a sudden, abrupt loss of heart function that can result in death if not treated within minutes with an electrical cardioverter shock, which can be delivered by an ICD. According to the Heart and Stroke Foundation, up to 45,000 Canadians die of SCA each year[i]. MRI is considered the gold standard in soft-tissue imaging and is used regularly for the diagnosis of conditions such as stroke, cancer, Alzheimer’s disease, and muscle, bone and joint pain.

Until now, patients with ICD systems have been contraindicated from receiving MRI scans because of potential interactions between the MRI and device function, which might result in risk to patients. These MRI restrictions have resulted in a critical unmet medical need because published data have shown that, within four years, more than one third of patients with ICDs – 36 percent – are likely to need an MRI.[ii]

The Evera MRI ICD system includes hardware and software design enhancements from previous generation devices that allow it to safely undergo full-body MRIs, while maintaining the same longevity, proven shock reduction and physiological size and shape of the original Evera ICD. The device is paired with the Sprint Quattro® Secure MRI SureScan® DF4 leads, part of the only ICD lead family with more than 10 years of proven performance with active monitoring,[iii] now tested for safe use in an MRI environment.

Health Canada license for the Evera MRI ICD system was based on safety and efficacy data from the Evera MRI Clinical Trial, a multi-center, prospective, randomized, controlled clinical trial that enrolled 275 patients at 42 centers around the world. Presented during a late breaking clinical trial session at Heart Rhythm 2015, the Heart Rhythm Society’s 36th Annual Scientific Sessions, and published simultaneously in the *Journal of the American College ofCardiology (JACC*), these data demonstrated that the Evera MRI ICD system is safe and effective when used as directed, and that full body MRI scans did not affect its ability to deliver life-saving therapy.[iv]

“The Evera MRI ICD system underwent comprehensive computer modeling of more than 2.3 million clinical scenarios and this information[v], combined with the safety data from the clinical trial, has resulted in this important regulatory license,” said Neil Fraser, President of Medtronic Canada. “As pioneers in the development of implantable cardiac devices that can be used in an MRI environment, Medtronic is committed to ongoing innovation to address the clinical needs of physicians and patients.”

About the Evera MRI ICD

The Evera MRI ICD is part of the Evera family of ICDs and includes the following key features and benefits:

- A contoured shape with thin, smooth edges that better fits inside the body, increasing patient comfort by reducing skin pressure by 30 percent[vi]
- Industry---leading projected battery longevity (up to 11 years) compared with previous devices[vii],[viii],[ix],[x],[xi],[xii],[xiii],[xiv]
- SmartShock™ 2.0, the Medtronic exclusive, industry-leading shock reduction algorithm that enables the device to better differentiate between dangerous and harmless heart rhythms[xv]
- OptiVol® 2.0 Fluid Status Monitoring and complete diagnostics, which is designed to identify patients at risk of worsening heart failure and atrial fibrillation

In collaboration with leading clinicians, researchers and scientists worldwide, Medtronic offers one of the broadest ranges of innovative medical technology for cardiovascular disease and cardiac arrhythmias. The company strives to offer products and services that deliver clinical and economic value to healthcare consumers and providers around the world.

Multimedia Release

Graphics, animation, and additional background information can be requested by contacting Melicent Lavers-Sailly at Melicent.lavers@medtronic.com.

About Medtronic Canada

Medtronic Canada, headquartered in Brampton, Ontario is a subsidiary of Medtronic PLC, the global leader in medical technology helping to alleviate pain, restore health and extend life for millions of people around the world.

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