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Japan launches extravascular implantable cardioverter defibrillator system, Aurora EV-ICD™ MRI device and Epsila EV™ MRI Lead

Taking the patient experience to the next stage

TOKYO – March 3, 2025 – Medtronic Japan Co., Ltd. (HQ: Minato-ku, Tokyo, Japan) today announced that the Aurora EV-ICD™ MRI device and the Epsila EV™ MRI Lead ("The Aurora EV-ICD system"), which are used in the treatment of ventricular arrhythmias, launched successively in Japan.

Aurora EV-ICD™ MRI System Approval number: 30600BZX00218000

Epsila EV™ MRI Lead Approval number: 30600BZX00219000

Arrhythmia is a condition in which an abnormality occurs in the heart's electrical system and causes irregular heart rhythms and pulse. Among the types of arrhythmia, ventricular fibrillation, in particular, is a condition in which the heart is unable to beat rhythmically, and the ventricular muscles become irregularly excited. As a result, the pumping function of the heart stops and blood flow is halted. Dizziness occurs 3 to 5 seconds after the heart's pumping function stops, followed by loss of consciousness in 5 to 15 seconds. If this continues for 3 to 5 minutes, it may lead to brain death. Ventricular fibrillation does not recover naturally, so it is treated with electric shocks.

Ventricular tachycardia is a condition in which the heart beats more than 100 times per minute for three or more beats. When ventricular tachycardia occurs, the heart becomes unable to carry out its pumping function. This reduces blood flow to the brain and causes dizziness and fainting, and may possibly lead to heart failure. If ventricular tachycardia continues, it may progress to ventricular fibrillation. To prevent sudden death from such arrhythmia conditions, approximately 4,000 new implantable cardioverter defibrillators (ICDs) are implanted each year in Japan for patients who have already experienced life-threatening arrhythmia, patients with low cardiac function who are at high risk of developing such arrhythmia in the future, or patients who are susceptible to developing hereditary arrhythmia.

The implantable cardioverter defibrillator (ICD) is a device implanted in the body, which automatically detects sudden occurrences of ventricular fibrillation or ventricular tachycardia and performs electrotherapy to restore the heart to a normal rhythm. It consists of the main implantable defibrillator unit, which is a few centimeters in size, as

well as leads that are connected to the main unit. The Aurora EV-ICD system is revolutionary systems that place the ICD lead under the sternum, which has never been done before. This eliminates the need to place leads inside the blood vessels, making it a less invasive implantable device compared to conventional transvenous ICDs. This product has the same size, shape, and battery life as conventional transvenous ICDs. It is the only extravascular device that treats life-threatening tachyarrhythmia using antitachycardia pacing (ATP), as well as provides cardiac pause backup pacing therapy during bradycardia (an abnormally slow heart rhythm).

According to Dr. Kengo Kusano, Head of the Division of Arrhythmia at the National Cerebral and Cardiovascular Center and Principal Investigator of the EV-ICD Japan Study, "The Aurora EV-ICD system maintains the same size as conventional transvenous ICDs, reduces the risk of complications in the blood vessels as it is placed outside of the blood vessels. It also offers a major advantage in its ability to deliver ATP therapy, which makes it possible to treat life-threatening arrhythmia effectively while avoiding shock therapy. From patients who participated in the clinical trial, the size of the device was well received, and it is expected to bring great benefits to patients who need ICD devices in the future by reducing their burden and preventing a decline in their quality of life."

Satoru Haga, vice president of Cardiac Rhythm Management, which is part of the Cardiovascular Portfolio at Medtronic, said, "Medtronic has developed a wide range of innovative products to date, including leadless pacemakers. The compact Aurora EV-ICD system is one such product, and we are very pleased to be able to offer it to patients in Japan as a new option."

About ICD

An ICD is a device implanted in the body, and which automatically detects sudden occurrences of ventricular fibrillation or ventricular tachycardia and performs electrotherapy to restore the heart to a normal rhythm. Through a pre-programmed method, it first delivers low-energy pacing pulses. If the arrhythmia does not stop, the device administers a high-energy electric shock to terminate the arrhythmia.

About the Aurora EV-ICD MRI system

This system has the same size, shape, and battery life as conventional transvenous ICDs, but unlike them, is implanted below the left armpit (the left midaxillary area) with the lead placed under the sternum. This method is less invasive. As Epsila EV-ICD lead is placed outside the heart and venous vessels, it is possible to avoid complications that have so far been deemed to be problems caused by transvenous ICDs, such as vascular damage and vascular occlusion (narrowing, blockage, and compression of the veins).

The Aurora EV-ICD MRI system allows for non-transvenous implantation. At the same time, it includes features found in Medtronic's transvenous ICDs, as well as features not found in regular subcutaneous ICDs.

- Antitachycardia pacing (ATP): Uses low-energy pacing pulses to stop ventricular arrhythmia and may potentially prevent defibrillation shocks.
- Cardiac pause prevention pacing: Provides backup pacing for temporary bradycardia.
- 40 J of defibrillation energy: Delivers shock therapy to stop arrhythmia using a device that is the same size as a transvenous ICD (33 cc).
- Medtronic's exclusive PhysioCurve™ design: Increases patient comfort and acceptance of implants.
- Predicted battery life of 11.7 years: Reduces the number of device replacement surgeries over a patient's lifetime.

- Smart Sense: Proprietary algorithms that have the potential to reduce further inappropriate shock therapy.
- Conditional MRI compatibility: MRI imaging at 1.5T and 3T is available when MRI imaging conditions are met.

About Medtronic

Bold thinking. Bolder actions. We are Medtronic. Medtronic plc, headquartered in Galway, Ireland, is the leading global healthcare technology company that boldly attacks the most challenging health problems facing humanity by searching out and finding solutions. Our Mission — to alleviate pain, restore health, and extend life — unites a global team of 95,000+ passionate people across more than 150 countries. Our technologies and therapies treat 70 health conditions and include cardiac devices, surgical robotics, insulin pumps, surgical tools, patient monitoring systems, and more. Powered by our diverse knowledge, insatiable curiosity, and desire to help all those who need it, we deliver innovative technologies that transform the lives of two people every second, every hour, every day. Expect more from us as we empower insight-driven care, experiences that put people first, and better outcomes for our world. In everything we do, we are engineering the extraordinary. For more information on Medtronic, visit www.Medtronic.com and follow us on LinkedIn.

Any forward-looking statements are subject to risks and uncertainties such as those described in Medtronic's periodic reports on file with the Securities and Exchange Commission. Actual results may differ materially from anticipated results.

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https://news.medtronic.com/Medtronic-Japan-launches-extravascular-implantable-cardioverter-defibrillator-system,-Aurora-EV-ICDTM-MRI-device-and-Epsila-EVTM-MRI-Lead