High-Voltage Devices from St. Jude Medical Get FDA Approval

St. Jude Medical

St. Jude Medical (NYSE:STJ [1]) has announced U.S. Food and Drug Administration (FDA) approval of its next-generation Ellipse and SJM Assura portfolio of implantable cardioverter defibrillators (ICDs) and cardiac resynchronization therapy defibrillators (CRT-Ds). The new devices are designed to lower the risk of lead abrasion and to ensure high-voltage therapy delivery.

The Ellipse and SJM Assura family of devices feature the DynamicTx Over-Current Detection Algorithm, which automatically adjusts shocking configurations to ensure the delivery of high-voltage therapy even if an electrical short in one portion of the system were to occur. In addition, the next-generation Ellipse and SJM Assura portfolio of implantable defibrillators have a low-friction coating on the device can, which has been demonstrated in testing to significantly reduce the friction between the device and leads. As such, the low-friction coating provides an extra layer of insulation and is designed to reduce the risk for lead-to-can abrasion, the most common type of lead insulation failure in the industry.

“The new safety features in these devices are an excellent example of innovation that improves patient safety,” said Dr. Anne B. Curtis, Chairman of the Department of Medicine with the University at Buffalo. “The DynamicTx feature in the new Ellipse and SJM Assura devices provides an additional safeguard to ensure the patient receives live-saving therapy delivery even if an electrical short were to occur. In addition, St. Jude Medical is the first company to help address the problem of lead-to-can abrasion by providing increased insulation on the ICD device itself, rather than the lead.”

These advanced technologies provide preventative and adaptive capabilities to address potential failures that can result in the inability to deliver high-voltage therapy when needed, especially in systems using silicone-only insulated defibrillation leads, which are known to be at higher risk of abrasion. It is estimated that over 400,000 silicone-only insulated defibrillation leads from all manufacturers remain active worldwide.

“St. Jude Medical strives to deliver the highest levels of patient safety. The new Ellipse ICD and SJM Assura family of devices support those efforts by providing added features that ensure effective therapy delivery,” said Eric S. Fain, M.D., president of the St. Jude Medical Implantable Electronic Systems Division. “We are pleased that the FDA approved these devices, allowing us to bring important safety and system reliability enhancements to patients.”

The Ellipse and SJM Assura family of devices have also featured expanded protection against inappropriate and unnecessary shocks with SecureSense RV Lead

Noise Discrimination, an algorithm that expands St. Jude Medical ShockGuard Technology. SecureSense RV Lead Noise Discrimination differentiates lead noise (over-sensing of electrical signals) from true ventricular tachycardia (VT) or ventricular fibrillation (VF) episodes requiring therapy. These features also are capable of providing remote patient alerts over the Merlin.net™ Patient Care Network (PCN); a secure, Internet-based remote care system for patients with implanted medical devices.

The St. Jude Medical high-voltage portfolio is augmented by the Durata defibrillation lead with Optim lead insulation. With more than 11,000 leads actively monitored in prospective, active registries and more than 29,000 lead-years of data, independently analyzed by the Population Health Research Institute, the Durata lead is the most studied lead on the market and continues to demonstrate excellent performance.

The Ellipse ICD provides all of the industry-leading features offered by the Fortify Assura ICD inside the smallest volume, high-voltage device on the market. The Ellipse ICD allows for 36 J in delivered energy, providing a downsized option without compromising on energy, longevity, safety or reliability.

The Assura family of devices allows St. Jude Medical to continue to offer 40 J in delivered energy, the highest in the industry, and includes the Quadra Assura CRT-D, the Unify Assura CRT-D and the Fortify Assura ICD.

An ICD is an advanced implantable device that treats potentially lethal, abnormally fast heart rhythms (ventricular tachycardias or ventricular fibrillation), which often lead to sudden cardiac death (SCD). Approximately 325,000 people per year in the U.S. die suddenly of SCD.

A CRT-D device resynchronizes the beating of the heart's lower chambers (ventricles), which often beat out of sync in heart failure patients, and provides back up treatment for SCD, which is a risk factor associated with certain types of heart failure. Studies have shown that CRT (cardiac resynchronization therapy) can improve the quality of life for many patients with heart failure, a progressive condition in which the heart weakens and loses its ability to pump an adequate supply of blood. About five million Americans suffer from heart failure, with 550,000 new cases diagnosed every year, according to the American Heart Association.

Links:
[1] https://www.google.com/finance?q=NYSE:STJ