EBR WiSE® CRT System – Healthcare Provider Brief Statement

Indications

The WiSE® Cardiac Resynchronization Therapy System is indicated for adult patients who are 22 years or older, are indicated for cardiac resynchronization therapy (CRT), have an existing or eligible right ventricular pacing system, and are in the "previously untreatable" or "high-risk upgrade" categories. "Previously untreatable" refers to patients whose previous coronary sinus lead implant was unsuccessful or in whom a left ventricular ("LV") lead is inoperative or programmed off due to improper function such as high thresholds, non-capture, phrenic nerve stimulation, lead failure, dislodgement, or suboptimal LV lead location. "High-risk upgrade" refers to patients with previously implanted pacemakers or implantable cardioverter-defibrillators (ICDs) in whom standard CRT upgrade is not advisable due to known relative contraindications for CS lead or CRT device implantation. There is insufficient evidence to support use in prior CRT non-responders. Safety and effectiveness have not been established with leadless pacemaker co-implants that utilize conductive communication. Use of the system depends on a co-implant device capable of delivering right ventricular pacing.

Contraindications

The WiSE CRT System is contraindicated in patients on triple anticoagulant therapy who cannot safely stop therapy periprocedurally. It is also contraindicated in patients who are allergic to or cannot tolerate procedural anticoagulation, contrast agents, or post-procedural antiplatelet therapy.

Warnings and Precautions

Implantation should be performed only by qualified cardiologist physicians and surgeons. EBR provides training for implant operators. Complications may occur during or after implantation and may require medical or surgical intervention. Failure to follow the Instructions for Use may result in device malfunction, serious injury, or death. Avoid therapeutic ultrasound, diathermy, radiofrequency ablation, therapeutic radiation, and transcutaneous nerve stimulation near the implanted system, as ultrasound energy may cause tissue heating or arrhythmias or extra pacing stimulation. Physicians should maintain continuous ECG monitoring throughout all diagnostic echocardiography procedures. A defibrillator should remain immediately available and ready for use throughout the procedure. If extra pacing stimulation occurs during imaging, discontinue imaging and remove the probe from the patient. Patients may carry a medical alert bracelet or pendant that directs healthcare providers to WiSE CRT System ultrasound precautions webpage. Physicians may request a bracelet or pendant for their patient at no charge by contacting EBR Systems at techsupport@ebrwise.com or

1-408-720-1906. Physicians should position defibrillation pads away from the Transmitter and Battery to prevent device damage. Physicians should avoid apical LV implant locations, where thinner tissue increases arrhythmia risk and creates closer proximity to echocardiographic imaging. Physicians should verify the absence of thrombus before the procedure and perform post-implant evaluation to confirm left ventricular capture and biventricular pacing. For patients prescribed dual antiplatelet therapy, a minimum duration of three months is recommended in accordance with current clinical guidelines and institutional protocols. Continuous monitoring during post-operative follow-up is recommended. All components (except the programmer) are single-use and must be handled as sterile devices. Turn the WiSE CRT System OFF during procedures that may cause operational interference, including radiofrequency ablation, electrocautery, lithotripsy, diathermy, and therapeutic radiation, then return it to prior settings and verify function. The programmer should be used only by trained operators, should not be sterilized, exposed to liquids, or placed near strong electromagnetic sources. Proper storage and room temperature acclimation of all components should be ensured before use.

MRI Considerations

The WiSE CRT System is MR Conditional. MRI scans must follow all conditions in the Instructions for Use, including field strength and device positioning limits. Co-implanted pacemakers must also meet MR Conditional requirements and abandoned or broken leads are not allowed. The programmer has not been evaluated for MRI and should not be brought into the MRI suite. Non-compliance may result in serious and permanent injury, device malfunction, or death.

The WiSE CRT System must be programmed to OFF-mode before the patient enters the MR environment and returned to pre-scan settings with a system check after.

Potential Adverse Events

Potential adverse events include cardiac complications (e.g., perforation, pericardial effusion, tamponade, pulseless electrical activity, arrhythmias), vascular complications (e.g., hematoma, retroperitoneal bleeding, ischemia, arterial perforation), neurological events (e.g., stroke, transient ischemic attack), pocket-related events (e.g., hematoma, infection, erosion, dehiscence), device-related events (e.g., migration, dislodgement, embolization, failure to capture, component malfunction), pulmonary embolism, thromboembolism, tissue effects from ultrasound energy, and death. Refer to the Instructions for Use for a complete list of adverse events.

Additional Information

For full Instructions for Use, call EBR Systems, Inc. at 1-408-720-1906 or visit www.ebrsystemsinc.com. Follow proper disposal instructions as described in the IFU. USA Rx only.

EBR WiSE® CRT System – Patient Brief Statement

Indications

The WiSE® Cardiac Resynchronization Therapy System is for adults 22 years or older who need cardiac resynchronization therapy ("CRT") and already have, or are eligible for, a pacemaker or defibrillator capable of right ventricular pacing. It is intended for patients whose previous attempts to implant a left heart ("LV") lead were unsuccessful, or whose LV lead is not working or has been turned off due to high pacing thresholds, lead failure, dislodgement, phrenic nerve stimulation, or poor placement. It is also intended for patients with a pacemaker or defibrillator who cannot safely have a standard CRT upgrade because of risks such as blockage in the veins, recent device surgery, infection, or certain heart conditions. The safety and effectiveness of WiSE in patients who did not respond to previous CRT therapy have not been established. It has not been tested with leadless pacemakers that communicate with each other by sending electrical signals through the body.

Contraindications

The WiSE CRT System should not be used in patients on triple anticoagulant therapy who cannot safely stop it for the procedure, or in patients who are allergic to or cannot tolerate the medications, contrast dye, or antiplatelet therapy used during or after the procedure.

Warnings and Precautions

Complications can occur during or after the procedure and may require treatment. All device components are single-use and sterile. Avoid therapies such as ultrasound, heat, radiation, or nerve stimulation near the device, because these may cause injury or tissue heating. Your doctor will check for blood clots before the procedure and determine whether it is safe for you. After the implant, your doctor will confirm that your heart is responding properly to the device and will monitor your progress during early follow-up visits. Your doctor will give you an Implant Card that identifies you as a recipient of the WiSE CRT System and lists your implanted components. Always carry this card with you and show it to any healthcare provider before you undergo other diagnostic or therapeutic procedures, because some procedures require special precautions or may need to be avoided. EBR Systems will provide a medical alert bracelet or pendant at no charge if you request one. To request one, contact the physician who implanted your WiSE CRT System or reach EBR Systems directly at techsupport@ebrwise.com. Avoid any area marked as restricted for persons with implanted pacemakers or ICDs. Avoid using any devices that are prohibited for people with pacemakers or ICDs. Avoid close proximity to and extended exposure to sources of electromagnetic interference, which

may cause your implanted devices to malfunction. Defibrillation pads should not be placed directly over the device.

MRI Safety
The WiSE CRT System is MR Conditional, meaning it is safe for MRI scans only if instructions are followed carefully, including field strength and positioning limits. Co-implanted pacemakers must also meet MR Conditional requirements, and broken or abandoned leads are not allowed. Carry your Implant Card with you at all times and show to medical personnel before getting an MRI scan. The WiSE CRT System must be turned off before you enter the MRI scanner and turned back on afterward. Your doctor will perform a system check after the MRI.

Potential Adverse Events
Possible complications include heart problems such as irregular heartbeat or fluid around the heart (pericardial effusion), bleeding or hematoma, stroke, infection, swelling or skin problems at the implant site, device migration, dislodgement, or failure to capture the heart, blood clots in the lungs (pulmonary embolism), or other thromboembolic events, tissue injury from ultrasound energy, and death.

More Information
For more information, consult with your doctor. You can also call EBR Systems, Inc. at 1-408-720-1906 or visit www.ebrsystemsinc.com. Your doctor should review the product guide before using the system. USA Rx only.