WiCS-LV System – Instructions for Use

CE
0086
2015

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Symbol Meanings and Compliance Statements

Caution, consult accompanying documents.

The name and address of the manufacturer.

The date that the product was manufactured.

Identifies the product's model designation.

Identifies the product's serial number.

Identifies the product's lot number.

Indicates the Use Before Date for the product. Do not use products beyond the labeled date.

Indicates the low and high temperature requirements associated with transport and storage of the product.

Identifies the Authorized EC Representative in the European Community.

It is mandatory that you read these Instructions for Use in entirety before using the device.

The package contains a Single Use Device that may not be Reused.

Do Not Reuse and Do Not Resterilize. The package contains a Single Use Device that may not be resterilized.

Content of the package was sterilized using an ethylene oxide process.

Indicates the location to peel away the sterile barrier.

Do not use the product if the package is damaged.

Keep dry.

Fragile contents.

This side up.

Do not connect battery to the heart.

Ultrasound is transmitted from the device into the body. The ultrasound is converted by the system to an electrical output in the heart.

1

Quantity of package contents

WiSE CRT System Transmitter Model 4100. Left ventricular pacing system triggered by co-implant.

WiSE CRT System Battery Model 3100. Energy source for the implanted components of the WiSE CRT System.

AT	BE	CH	CZ	DE
DK	FR	ES	GB	IE
IT	NL	PL		

The equipment may be placed and operated in Austria, Belgium, Switzerland, Czech Republic, Germany, Denmark, France, Spain, United Kingdom, Ireland, Italy, Netherlands, and Poland.

The device is intended for indoor use only.
Cet appareil est voulu pour l'usage intérieur seulement.

IP20

Indicates the level of ingress protection: (2 - no probe or finger larger than 12.5mm can gain access to the device) and (0 – there is no protection against fluid ingress).

The Programmer and the Pulse Generator communicate using RF transmissions in the frequency range of 402.000-405.000 MHz.

Class II equipment per IEC 60601-1.

Indicates a direct current (DC) input at the voltage and current indicated with the symbol.

Electrical signal output.

LITHIUM METAL BATTERIES
CONTAINED IN EQUIPMENT
UN 3091

The Battery Module is fully regulated Class 9 Dangerous Goods, in accordance with IATA Dangerous Goods Regulations and 49 CFR, Transportation and must be labeled and transported in accordance with regulations. The label indicates that the package contains Lithium Metal Batteries Contained in Equipment, Hazard Class UN3091.

4G/Y0.4/S/**
USA/+CJ0101

The Battery single unit packaging has been tested to a 4G Combination Package containing a Lithium Carbon Monoflouride Battery, in accordance with the UN Manual of Tests and Criteria for the Transport of Dangerous Goods and 49 CFR, Transportation. The packaging meets Packaging Code 4G, Performance Level Y for Packaging Group II for Gross Mass weight of 0.4 kgG, Solids. The year of manufacture (**) and the manufacturer identification are as indicated on the package.

4GV/X11.1/S/**
USA/+CG0117

The packaging meets Packaging Code 4GV, Performance Level X for Packaging Group I for Gross Mass weight of 11.1 kgG, Solids. The year of manufacture and the manufacturer identification are as indicated on the package.

The alert symbol next to the CE Mark signifies that the radio transmission in which the product operates is outside of the harmonized spectrum and therefore is a Class 2 Radio Equipment per the R&TTE Directive. The responsible national authorities of the countries in which the Programmer is intended to be placed have been appropriately notified.

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The CE mark signifies compliance to the European Directives; Active Implantable Medical Device Directive ver. M4 (90/385/EEC) and Radio & Telecommunications Terminal Equipment (199/5/EC), with Notified Body, BSI. The year of authorization for the AIMD CE Mark is 2015.

Radio equipment to modify operating parameters and to collect data stored in an implantable cardiac pacing system. Equipment is restricted to indoor use.

Funkgerät zur Änderung von Betriebsparametern eines implantierbaren Herzschrittmachers und zum Abrufen der im Schrittmacher gespeicherten Daten. Der Gebrauch dieses Gerätes ist auf den Innenbereich beschränkt.

Les équipements radio servent à modifier les paramètres de fonctionnement et à recueillir des données stockées dans un système de stimulation cardiaque implantable. L'équipement est restreint à une utilisation interne.

Radioapparatuur voor het wijzigen van operationele parameters en voor het verzamelen van gegevens die zijn opgeslagen in een implanteerbare cardiac pacing-systeem. Apparatuur alleen binnenshuis gebruiken.

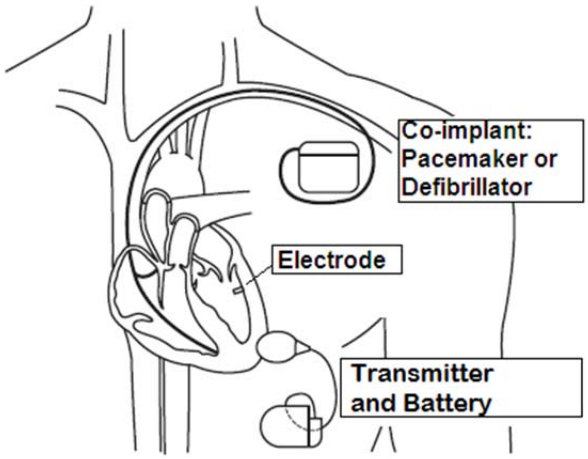
Apparecchiatura radio per la modifica dei parametri di funzionamento di un sistema di cardiostimolazione impiantabile e la raccolta dei dati in esso memorizzati. L'uso dell'apparecchiatura è limitato ad ambienti chiusi.

The system has been tested to and complies with the essential requirements stated in Article 3 of the Council Directive 1999/5/EC (Radio Equipment & Telecommunications Terminal Equipment) for Class 1 and Class 2 equipment.

System Description

The Wireless Cardiac Stimulation® System (WiCS®) from EBR Systems, Inc. is an implantable, cardiac pacing system capable of delivering pacing level energy to the heart without using a lead. The technology used to achieve this leadless, wireless pacing is based on converting ultrasound energy to electrical energy. A subcutaneously implanted ultrasound transmitter initiates an ultrasonic energy pulse that travels through the tissue to intersect an ultrasound receiver implanted in the heart. The receiver converts the ultrasound energy to electrical energy at sufficient amplitudes to stimulate cardiac tissue through pacing electrodes that are integrated into the ultrasound receiver. This receiver is referred to herein as the Electrode.

The WiCS pacing system applies the wireless stimulation technology to endocardial stimulation of the left ventricle (LV). WiCS-LV replaces the pacing function of a coronary sinus (CS) lead when used in conjunction with a typical, commercially-available implanted pacemaker or defibrillator to achieve Cardiac Resynchronization Therapy (CRT). WiCS-LV is co-implanted with a pacemaker or defibrillator system. Sensing electrodes on the outside surface of the transmitter enclosure are used to synchronize the WiCS-LV pacing system with the co-implanted device. Immediately after sensing a right ventricular (RV) pacing output – a pacing spike – from the co-implanted device, WiCS-LV triggers ultrasound pulses targeted at the Electrode to pace the LV. The sequence of sensing, transmitting, receiving, and stimulating the LV is essentially simultaneous with the co-implanted device's RV pacing output and thus provides bi-ventricular pacing operation analogous to CRT pacing devices.



The WiCS-LV System has four modules:

1) ***Electrode***: an ultrasound energy receiver and energy converter implanted on the endocardium to pace the LV;
2) ***Electrode Delivery System***: The ***Electrode*** is implanted using an acute use guiding catheter system.
3) ***Pulse Generator***: an ultrasound energy pulse transmitter implanted subcutaneously in the thorax consisting of two connected modules, referred to separately as the ***Transmitter*** and the ***Battery***; The ***Transmitter*** is implanted using an ***Accessory;*** and
4) ***Programmer:*** the external communication instrument used to adjust parameters on the Pulse Generator and used to assist with implant and follow-up of the system.

⚠ It is important to read the entire Instructions for Use for all modules of the WiCS-LV System to gain a complete description of its use.

Warnings

No Exposure to Magnetic Resonance Imaging (MRI): Do not expose the WiCS-LV system to MRI scanning. The system may be permanently and unpredictably damaged by strong magnetic fields associated with MRI and may cause harm to the patient. The system has not undergone testing for MRI compatibility.

No Exposure to High Intensity Ultrasound or to Continuous Wave Ultrasound: Do not expose the WiCS-LV system to high intensity or continuous ultrasound fields. This type of exposure may cause untimed cardiac stimulation at the Electrode or damage the Transmitter. The system should not be exposed to an ultrasound field >1.9 MI, the maximum specified for transthoracic echocardiography imaging. Whenever you use ultrasound for therapy or imaging in patients implanted with the WiCS-LV system a defibrillator should be available in case a tachyarrhythmia emergency arises.

Precautions

For use only by Qualified Medical Personnel in professional healthcare environments: The WiCS-LV System is intended to be used by qualified cardiologist physicians and only in professional healthcare facilities. EBR Systems provides both hands-on pre-clinical training and didactic training. Before using the system, contact EBR Systems to schedule a one-day training session for implant operators. At least annually, review didactic training materials supplied and presented by support personnel from EBR Systems. Obtaining this training prior to implant procedures is a responsibility of the implanting physician. The information provided in these Instructions for Use and in Instructions for Use of WiCS-LV components should be considered as a required supplement for qualified and experienced medical professionals.

Ultrasound Sources

Ultrasound devices for transthoracic echocardiography imaging must be used cautiously. There is a known potential that the Electrode will receive ultrasound pulses and convert them to stimulation pulses. Do not use ultrasound imaging sources if the WiCS-LV System is operating in the RV Synchronous mode as there is the potential for over sensing pacing pulses. Directing any ultrasound beam in the direction of the Electrode or using high intensities of ultrasound throughout the body increases the potential for this extra stimulation. In the event of extrastimulation during a transthoracic echocardiography procedure immediately remove the imaging probe from the patient, discontinue imaging, and reduce the intensity of the imaging system output. Only transthoracic echocardiography imaging has been tested in clinic investigations.

At Home and at Work

Instruct patients to avoid any areas that have signs or are otherwise documented as restricted for persons with implanted pacemakers. Instruct patients to avoid close proximity and extended exposure to sources of electromagnetic interference. Electromagnetic interference may cause implanted medical devices to inappropriately sense, inhibit therapy or operate incorrectly. The following are specific sources to be avoided:

AC and DC motors/power sources including automobile alternators
Arc welding equipment
Large RF transmit sources such as radar
Hand-held radio transmitters (e.g. remote control devices)
Electronic article surveillance (antitheft) devices

Do not expose the WiCS-LV devices to pressure above 1.5 atm. Elevated pressures, for example, due to hyperbaric chamber exposure or scuba diving may damage the ultrasound transducers in the Transmitter.

Cell Phones and Personal Music Players

Portable and mobile RF communications equipment can affect medical electrical equipment.

Instruct patients to keep cell phones away from implanted devices by using the ear opposite the implant side of the body when in conversation. Instruct patients to avoid carrying cell phones or personal music players (e.g., ipod, mp3) in shirt or pant pockets and on belts in close proximity (within 15 cm) to implanted medical devices.

In Medical Environments

Instruct medical personnel on the potential for operational interference or damage to devices within the medical environment, such as hospitals, medical clinics, and outpatient service sites. Some devices used in medical environments may damage implanted devices or cause implanted medical devices to inappropriately sense, inhibit therapy or operate incorrectly. Instruct medical personnel on this potential for interference from the following types of devices and procedures:

- Radiofrequency-based devices used for programming and communicating with other implantable devices such as pacemakers, defibrillators, and nerve stimulators. These devices have the potential to interfere with communications between the WiCS-LV Programmer and the Pulse Generator.
- Radiofrequency-based devices used for tissue ablation and/or cauterization
- Lithotripsy therapy which delivers high intensity ultrasound to dissolve calcific deposits
- Diathermy which heats tissue by delivery of high frequency electromagnetic radiation, electric current, or ultrasonic waves
- Ultrasound physiotherapy or any form of therapy which produces high intensities of ultrasound for heating tissue
- Radiation therapy, particularly focused radiation close to implanted devices
- Magnetic Resonance Imaging – see Warning Section
- Mechanical ventilators
- Transcutaneous Electrical Nerve Stimulation (TENS) devices or other neurological stimulation devices

Magnetic Resonance Imaging may damage the devices. If patient is inadvertently exposed, verify correct operation and programmed settings as device parameters may have been reset.

Indications

The WiCS-LV System is indicated for patients with heart failure meeting standard criteria for CRT based upon the most recent European Society of Cardiology / European Heart Rhythm Association (ESC/EHRA) guidelines ***AND*** *meeting criteria for one of these three categorizations:*

1. *Patients with previously implanted pacemakers or ICD's and meeting standard indications for CRT but in whom standard CRT is not advisable due to known high risk - referred to as "upgrade".*
2. *Patients in whom acute coronary sinus lead implantation was unsuccessful, or where a chronically implanted lead has become non-functional – referred to as "untreated"*
3. *Patients with previously implanted CRT device, who have not responded to CRT (no change or worsening of symptom or NYHA functional class after 6 months of treatment confirmed by the following physician) – referred to as "non-responders."*

Upgrade:
This includes:

- Patients that have a relative contraindication for a CS lead implant such as difficult subclavian access, venous thrombosis, venous occlusion, risk of lead dislodgment, or other justification documented by the prescribing physician.
- Patients that have a relative contraindication for revising an implanted device to a CRT device such as previous pocket erosion, previous pocket infection, previous explantations, or other justifications documented by the prescribing physicians.

Untreated:
This includes:

- Patients that have had an attempted but failed CS lead implant due to such complications as venous occlusion, difficult CS access or anatomy, poor lead stability or previous CS repositioning procedures.
- Patients with a previously implanted CS lead that is programmed off due to such complications as high pacing threshold, non-capture, phrenic nerve stimulation, lead failure, lead dislodgement, or other justifications due to lead issues documented by the prescribing physician.

Previously implanted or newly implanted pacemakers, ICD, and CRT devices must provide RV pacing: in dual-chamber pacing modes if the patient has sinus rhythm; in single-chamber pacing modes if the patient is in permanent AF. The need for an ICD capability in the co-implant will be based on physician's judgment.

Contraindications

The WiCS-LV system has not been studied in patients with the following contraindications:

Triple anticoagulation therapy (warfarin, clopidogrel, ASA, or other agents)
Stage 4 or 5 renal dysfunction defined as GFR <30
Grade 4 mitral valve regurgitation
Thrombocytopenia (platelet count <150,000)
Non-ambulatory (or unstable) NYHA class 4
Contraindication to heparin
Contraindication to both chronic anticoagulants and antiplatelet agents
Contraindication to iodinated contrast agents
Insufficient acoustic window to the LV as assessed from diagnostic transthoracic echocardiography
Left atrial or left ventricular thrombus
Attempted implant of a Pacemaker, ICD, or CRT device within 3 days
Life expectancy < 12 months
Chronic hemodialysis

Myocardial infarction within one month
Major cardiac surgery within one month
Incompatible electrical stimulation therapy devices, for example transcutaneous electrical nerve stimulation (TENS) or other neurological stimulation devices
Exposure to magnetic resonance imaging (MRI)
Use of diathermy
Use of therapeutic ultrasound
Use of echocardiography imaging using vascular, intracardiac, Doppler, and trans-esophageal probes and systems
Use of ionizing radiation treatments

Adverse Events and Device Complications

Potential Adverse Events

Potential adverse events associated with the implant procedure and use of the WiCS-LV system are derived from review of information related to similar medical procedures including pacemaker, defibrillator, and associated lead implants, and from cardiac catheterization procedures employing transaortic or transseptal left ventricular insertion such as for radiofrequency cardiac ablation.

Air embolism
Allergic reactions to sedatives, and other materials and drugs used in the course of sterile implant procedures including renal failure from sensitivity to contrast media
Aortic valve damage
Arterial perforation
Arrhythmias
Cardiac tamponade/pericardial effusion
Chronic nerve damage
Death
Dissection of aorta or branch vessels including femoral artery
Electrochemical burns
Embolization of the Electrode or other Delivery System material
Excessive bleeding
Excessive fibrotic growth
Fluid accumulation in implant pockets
Foreign body reaction
Hematoma at surgical incision or arterial insertion sites
High rate or competitive ventricular pacing
Infection
Invasive procedure or worsening heart failure
Migration of device requiring surgical revision
Mitral valve damage
Myocardial infarction
Myocardial tissue injury or perforation
Overexposure to X-ray fluoroscopic radiation - Radiation skin burns
Pain
Phrenic nerve stimulation, diaphragmatic pacing
Pneumothorax
Psychological disturbances (dependency, depression, fear of battery depletion, fear of malfunction)
Skin erosion overlying implanted device
Stroke or transient cerebrovascular episodes
Thrombus formation and thromboembolism

Potential System Complications that may contribute to Adverse Events

Potential system complications may contribute to adverse events. Potential system complications are derived from review of information related to similar medical devices including pacemakers, defibrillators, and associated leads, and from review of the most significant system failure modes.

- Embolization of devices, air bubbles, or materials
- Early battery depletion
- Electronic or mechanical component failure
- Inadvertent device reprogramming
- No pacing therapy or no pacing capture
- Inappropriate synchronization – over sensing and under sensing
- Breach of battery or battery connections
- Fracture or damage to battery connection cable
- Inability to target ultrasound energy on Electrode
- Insufficient acoustic window to transfer energy for pacing
- Reset of programmed device parameters
- Other ultrasound sources interfering with performance or activating the Electrode to pace the heart

Observed Adverse Events and System Complications

Adverse events that have been observed during clinical investigations with the system include:

- Cardiac tamponade/pericardial effusion
- Myocardial tissue perforation
- Hematoma at surgical incision and arterial insertion sites
- Pneumothorax
- Migration of device (Transmitter) requiring surgical revision
- High rate ventricular pacing
- Early Battery depletion
- No pacing therapy or no pacing capture
- Inappropriate synchronization – over sensing and under sensing
- Inability to target ultrasound energy on the Electrode's location
- Reset of programmed device parameters
- Other ultrasound sources interfering with performance or activating the Electrode to pace the heart