# Confirm Rx™

Model DM3500
Insertable Cardiac Monitor

# User's Manual

St. Jude Medical

# Description

This manual describes the following St. Jude Medical™ device:

Table 1. Confirm Rx insertable cardiac monitor

| Name | Model Number | Description | MRI Status |
|---|---|---|---|
| Confirm Rx | DM3500 | Insertable cardiac monitor | MR Conditional |

Table 2. Confirm Rx accessories

| Name | Model Number | Description |
|---|---|---|
| Insertion tool | DM3510 | Tool to insert the Confirm Rx™ ICM |
| Incision tool | DM3520 | Tool to cut the skin during insertion procedure |
| Accessory kit | DM3500A | Contains additional insertion tool and incision tool |

The St. Jude Medical™ Confirm Rx™ insertable cardiac monitor (ICM) is designed to detect

arrhythmias and wirelessly transmit data to the Merlin.net™ Patient Care Network (PCN).

The ICM constitutes the inserted portion of the system. The Merlin™ Patient Care System (PCS) with software version 23.0 (or greater), magnet, myMerlin™ mobile application (app), and Merlin.net PCN constitute the external portion of the system.

The Merlin PCS and magnet are used to interrogate and program the device in the clinic. Remote transmissions are performed using the app. The app also allows patients to record and send EGMs of symptomatic events to the clinic. All remotely transmitted data is made available on Merlin.net where clinicians can log in, review data, and make a diagnosis.

# Indications for Use

The Confirm Rx™ ICM is indicated for the monitoring and diagnostic evaluation of patients who experience unexplained symptoms such as the following: dizziness, palpitations, chest pain, syncope, and shortness of breath, as well as patients who are at risk for cardiac arrhythmias. It is also indicated for patients who have been previously diagnosed with atrial fibrillation or who are susceptible to developing atrial fibrillation.

# Intended Use

The Confirm Rx™ ICM is intended to help physicians monitor, diagnose and document the rhythm in patients who are susceptible to cardiac arrhythmias and unexplained symptoms, as indicated.

Table 3. Accessories and their intended uses

| Accessory | Model Number | Intended use |
|---|---|---|
| Incision tool | DM3520 | Cut the skin, as a first step during the insertion procedure |
| Insertion tool | DM3510 | Deliver the device through the skin incision into the insertion channel |
| Accessory kit | DM3500A | Implant the Confirm Rx™ ICM device |

# Magnetic Resonance Imaging (MRI)

The Confirm Rx™ ICM is conditionally safe for use in the MRI environment when used according to instructions in the MRI Ready Monitor Systems manual.

# Contraindications

There are no known contraindications for the insertion of the Confirm Rx™ ICM. However, the patient's particular medical condition may dictate whether or not a subcutaneous, chronically inserted device can be tolerated.

# Warnings and Precautions

## Sterilization

- The device and the incision and insertion tools have been sterilized with ethylene oxide prior to shipment. They are intended for single use only and should not be resterilized.
- If the sterile package has been compromised, contact St. Jude Medical.
- Do not insert the device if the dot on the ethylene oxide label is purple. Purple indicates that the package has not been sterilized. Return the device to St. Jude Medical.

## Package Inspection

- Check the "use-before" date on the package label. Do not insert the device if its "use-before" date has expired.
- Do not use the device if the packaging is wet, punctured, opened or damaged because the integrity of the sterile packaging may be compromised. Return the device to St. Jude Medical.

## Storage and Handling

- Store the device at 22°C.
- During transport and handling, the device can be exposed to temperatures between -20° and 60°C. Exposure to temperatures outside this range may result in damage to the device or

device malfunction.

- After cold storage, allow the device to reach room temperature before programming or inserting the device because cold temperature may affect initial device function.

## Insertion

- Insert the device in the subcutaneous space, just under the skin. Place the device no deeper than 2 cm to ensure reliable data transmission.

## Device Replacement

- Replace the device within one month of receiving a low battery alert, if necessary or desired. Replace the device immediately upon receiving a low battery alert if frequent EGMs are being stored and remotely transmitted.

## Explant and Disposal

- Interrogate the device and turn monitoring off before explanting, cleaning or shipping the device to prevent unwanted EGM and episode storage.
- Explant the device with standard surgical tools upon receiving an EOS alert.
- Return all explanted devices to St. Jude Medical.
- Never incinerate the device because of the potential for explosion. Explant the device before cremation.

# Environmental and Medical Therapy Hazards

- Instruct patients to avoid devices that generate a strong electric or magnetic interference (EMI). EMI could cause device malfunction or damage, resulting in inappropriate episode storage or inhibition of episode storage. Moving away from the source or turning it off will usually allow the device to return to its normal mode of operation.

## Hospital and Medical Environments

- Electrosurgical cautery may cause device malfunction or damage. If electrocautery is necessary, keep the current path and groundplate as far away from the device as possible.
- External defibrillation may damage the device. Minimize current flowing through the device by following these precautions when using external defibrillation on a patient with a device:
  - Position defibrillation paddles as far from the device as possible (minimum of 13 cm)
  - Use the lowest clinically appropriate energy output
  - Confirm the device function following any external defibrillation
- Do not direct high radiation sources such as cobalt 60 or gamma radiation at the device. If a patient requires radiation therapy in the vicinity of the device, place lead shielding over the device to prevent radiation damage and confirm its function after treatment.
- Lithotripsy may permanently damage the device. Avoid it unless the therapy site is not near the

device.

- Avoid diathermy, even if the device is programmed off, as it may damage tissue around the device or may permanently damage the device.
- The device should not be exposed to therapeutic levels of ultrasound energy, as the device can inadvertently concentrate the ultrasound field and cause harm that might not be immediately detectable. Diagnostic ultrasound treatment is not known to affect the function of the device.
- Transcutaneous Electrical Nerve Stimulation (TENS) may interfere with device function. To reduce interference, place the TENS electrodes close to one another and as far from the device as possible. Monitor cardiac activity during TENS use.
- Radiofrequency (RF) ablation in a patient with a device may cause device malfunction or damage. Minimize RF ablation risks by:
  - Disabling monitoring
  - Avoiding direct contact between the ablation catheter and the inserted device
  - Positioning the groundplate so that the current pathway does not pass near the inserted device, i.e., place the groundplate under the patient's buttocks or legs

## Home and Occupational Environments

- High-voltage power transmission lines may generate enough EMI to interfere with device operation if approached too closely.

- Communication equipment such as microwave transmitters or high-power amateur transmitters may generate enough EMI to interfere with device operation if approached too closely.
- Home appliances in good working order and properly grounded do not usually produce enough EMI to interfere with device operation. There are reports of device disturbances caused by electric hand tools or electric razors used directly over the device insertion site.
- Wireless communication devices such as computers that operate on a wireless network, cellular phones, smart phones, tablets, and even cordless telephones may generate enough EMI to interfere with device operation.
- A variety of industrial equipment produce EMI of sufficient field strength and modulation characteristics to interfere with proper operation of the device. These include, but are not limited to: arc welders; induction furnaces; very large or defective electric motors; and internal combustion engines with poorly shielded ignition systems.

## Electronic Article Surveillance (EAS)

- Advise patients that the Electronic Article Surveillance/Anti-theft (EAS) systems such as those at the point of sale and entrances/exits of stores, libraries, banks, etc., emit signals that may interact with the device. It is very unlikely that these systems will interact with their device significantly. However, to minimize the possibility of interaction, advise patients to simply walk through these areas at a normal pace and avoid lingering near or leaning on these systems.

## Metal Detectors

- Advise patients that metal detector security systems such as those found in airports and government buildings emit signals that may interact with their device. It is very unlikely that these systems will interact with their device significantly. To minimize the possibility of interaction, advise patients to simply walk through these areas at a normal pace and avoid lingering. Even so, the device contains metal that may set off the airport security system alarm. If the alarm does sound, the patient should present security personnel with their patient identification card. If security personnel perform a search with a handheld wand, the patient should ask that they perform the search quickly, stressing that they should avoid holding the wand over the device for a prolonged period.

## Mobile Devices

- The device has been tested for compatibility with handheld wireless transmitters in accordance with the requirements of ISO 14117:2012. This testing covered the operating frequencies (450 MHz - 3 GHz) and pulsed modulation techniques of all of the digital cellular phone technologies in worldwide use today. Based on the results of this testing, the device should not be affected by the normal operation of cellular phones when used more than 15 cm from the device.
- To minimize the possibility of interaction, advise patients not to carry a cellular phone in a breast pocket or on a belt within 15 cm of the device, and to use a cellular phone on the side of their body opposite from the device.

# Potential Adverse Events

Possible adverse events (in alphabetical order) associated with the device, include the following:

- Allergic reaction
- Bleeding
- Chronic nerve damage
- Erosion
- Excessive fibrotic tissue growth
- Extrusion
- Formation of hematomas or cysts
- Infection
- Keloid formation
- Migration

# Clinician Use Information

## Physician Training

Physicians should be familiar with sterile device insertion procedures and with follow-up evaluation and

management of patients with an insertable cardiac monitor (or should refer the patient to such a physician). See the Monitoring Devices Help manual for instructions on programming the insertable cardiac monitor.

## Package Contents

The device is supplied in a sterile tray for introduction into the operating field. The tray contains:

- One monitor
- One incision tool
- One insertion tool

The outer box contains:

- Literature

## Pre-Insertion Device Setup

Prior to opening the sterile package, apply a magnet to the Confirm Rx device for at least three seconds and then remove. Interrogate the device with the Merlin™ PCS and follow the on-screen prompts. The user interface will provide a prompt to insert the device once the required information is entered. See the Monitoring Devices Help manual for instructions on programming the insertable cardiac monitor.

## Opening the Sterile Package

To open the package:

1. Peel back the outer tray cover, starting with the corner labeled with an arrow.
2. Observing sterile technique, lift up the end of the inner tray that rests in the recess in the outer tray or flip over the outer tray so that the inner tray falls onto the table.
3. Peel off the inner tray cover, starting with the corner labeled with an arrow.
4. Use the recessed areas to facilitate removing the tools from the tray.

## Choosing the Insertion Location

The Confirm Rx™ ICM is inserted under the skin in the left pectoral region. Common insertion locations are listed in the table below. Mapping may be beneficial as part of the pre-insertion process, especially for the Anterolateral, inframammary position between the 5th and 6th ribs.

Table 4. Insertion locations

| |
|---|
| 4th intercostal space, 45° relative to the sternum, along axis of the heart |
| 4th intercostal space, parallel to the sternum |
| Anterolateral, inframammary between the 5th and 6th ribs |

NOTE:

- An implant site parallel to the midline, closer to the sternum and away from the lower half of the pectoral region and breast area may help minimize device movement.
- Consider patient comfort when selecting an insertion location.

## General Site Mapping

Either clinical ECG equipment or the Merlin™ PCS may be used to perform surface mapping. See the Monitoring Devices Help manual for a description of how to perform mapping using the Merlin PCS.

When performing pre-insertion surface mapping, use conductive ECG patches spaced approximately 4 cm apart. This distance approximates the Confirm Rx ICM inter-electrode spacing.

Evaluate potential insertion locations to optimize the following signal characteristics:

- High amplitude R-wave that demonstrates minimal variation in different patient positions, such as sitting versus lying down.
- High R-wave to T-wave ratio

## Inserting the Device

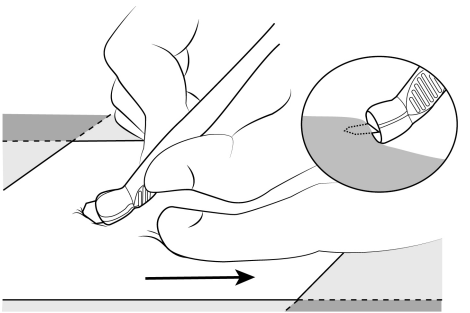
To insert the device:

1. Prepare the insertion site using conventional antiseptic and local anesthetic procedures.

2. Pull back the skin and make an angled cut with the incision tool.

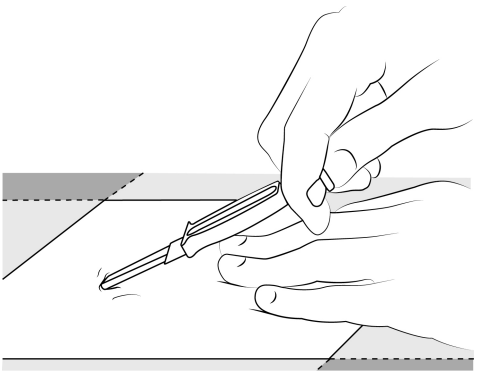
   NOTE: Create the incision above the final insertable cardiac monitor position to reduce the force of gravity acting on the incision site during healing.

Figure 1. Pull back the skin and make incision



3. Hold the insertion tool as shown in the figure below, at approximately a 45 degree angle to the incision. Insert the blunt dissection tip of the insertion tool just past the skin, then adjust the angle to guide the insertion tool almost parallel with the patient's chest. This creates a subcutaneous device pocket parallel to the skin. Advance the insertion tool as far as it can go, until the flared edge contacts the incision site. Keep the flared edge in contact with the incision site for the subsequent steps.

Figure 2. Insert the introducer

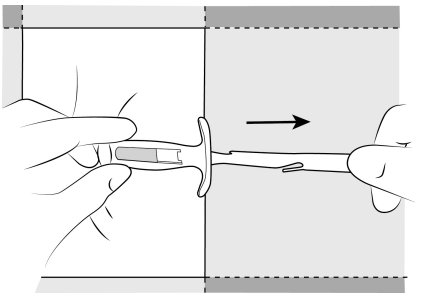


NOTE: The insertion tool is designed to form an ideally sized pocket with some distance between

the device and the incision. Avoid forming a pocket larger than the introducer.

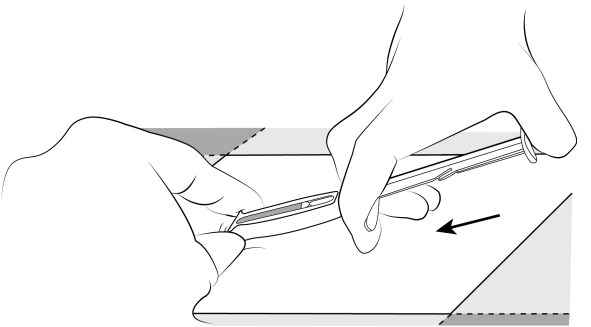
4. Hold the insertion tool firmly at the incision site by gripping the ribbed finger recesses as shown in the following figure. Withdraw the plunger until the plunger stops and the preloaded device drops completely into the insertion channel.

Figure 3. Withdraw the plunger



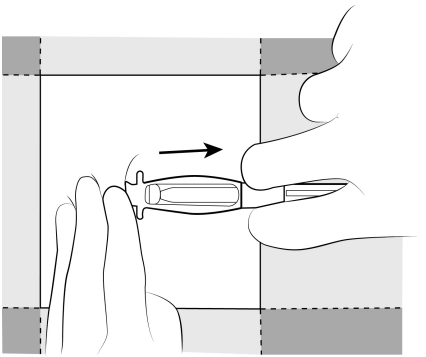
5. Continue to hold the insertion tool firmly at the incision site. Advance the plunger to insert the device. The plunger has a feature to stop the introducer when the device is at the proper depth. Do not force the plunger past the stop feature.

Figure 4. Advance the plunger



6. Apply pressure to the incision site so that the device does not move, and then remove the insertion tool.

Figure 5. Remove the insertion tool



7. Measure R-wave amplitude and observe the signal quality on the Merlin™ PCS.

   Consider body position and arm movement as part of this assessment. If signals are small or unstable, remove the device, reload the device in the insertion tool, and reposition the device. See the Monitoring Devices Help manual for information about adjusting sensitivity parameters to match implant conditions. If R-wave amplitudes are below 0.2 mV, consider repositioning the device.

   NOTE: The device can be repositioned through the same incision, if desired. When repositioning the device, significantly change the insertion angle to ensure that the new device pocket does not merge with the previous pocket.

8. If deemed necessary, use the suture hole on the device header to secure the device to the underlying tissue.

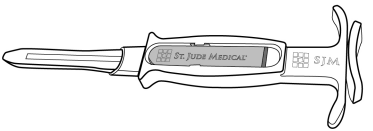
9. Close the incision site. If topical skin adhesive is used, avoid getting adhesive on the sensing electrodes of the device.

## Reloading the Device

To reload the device:

1. Place the device into the insertion tool so that the text on the device reads in the same direction as the text on the insertion tool. Refer to the figure below.

Figure 6. Device placement

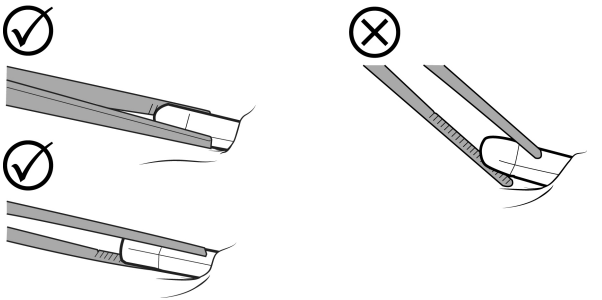



## Explanting the Device

Explant the device using standard surgical tools.

NOTE: Grasp the device with the tool held parallel to the device. Do not grasp the device at an angle, as this could damage the device.

Figure 7. Explant technique



## Patient Education

St. Jude Medical provides a booklet for patients to explain the device and its operation. You can use this to supplement your discussions with the patient and spouse or other interested persons.

## Patient Identification Card

A patient identification (ID) card should be provided to all patients with a Confirm Rx™ ICM. The ID card indicates that the patient has an inserted cardiac monitor.

# Radiopaque Identification

Each device has an x-ray absorptive marker for non-invasive identification. The two-letter model code is visible on a radiograph.

Table 5. X-ray ID code for Confirm Rx device

| Device Model | X-ray ID Model Code |
|---|---|
| DM3500 | CC |

# Additional Information

For additional information on this device, see the Monitoring Devices Help manual or the Merlin™ PCS on-screen help.

To enable communication with the Merlin.net™ Patient Care Network, the insertable cardiac monitor

must be configured for use with the myMerlin™ mobile application on a compatible mobile device . See the myMerlin mobile application user's manual for instructions.

# Physical Specifications

## Device Specifications

Table 6. Device specifications

| Specification[1] | Data |
|---|---|
| Dimensions (h x l x t) (mm) | 49 x 9.4 x 3.1 |
| Weight(g) | 3.0 |
| Displacement volume ($cm^3$) | 1.4 |
| Surface area of can electrode ($mm^2$) | 105.9 |
| Surface area of header electrode ($mm^2$) | 10.8 |
| Shortest distance between electrodes (mm) | 39.85 |
| Can and electrode material | Titanium |
| Header material | Polyurethane and epoxy |
| Coating | Parylene |

[1] The dimensions, weight, and displacement volume are nominal values based on engineering model measurements.

# Battery Specifications

Table 7. Battery specifications

| Parameter | Data |
|---|---|
| Manufacturer | Eagle Picher |
| Model | ICM Battery |
| Chemistry | CFx |
| Number of cells | One cell |
| Battery voltage (beginning of service) | 3.40 V |
| Elective replacement voltage (ERI) | 2.81 V |
| End-of-service voltage (EOS) | 2.67 V |

Table 7. Battery specifications

| Parameter | Data |
|---|---|
| Longevity | 2 years, under the following usage scenarios:<br>▪ Average of 1 auto-detected episode per day<br>▪ Average of 1 patient-activated symptom episode per month<br>▪ Up to 6 month shelf storage time<br>**NOTE:** At a maximum shelf storage time of 18 months, longevity is reduced by approximately 5 months. |

# FCC Statement

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses, and can radiate radiofrequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television

reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/ TV technician for help.

Operation is subject to the following two conditions:

- This device may not cause harmful interference.
- This device must accept any interference received, including interference that may cause undesired operation.

Modifications not expressly approved by the manufacturer could void the user's authority to operate the equipment under FCC rules.

# Statement of Compliance with License-Exempt RSS Standard (Canada)

This device complies with Industry Canada license-exempt RSS standard(s). Operation is subject to the following two conditions: (1) this device may not cause interference, and (2) this device must accept

any interference, including interference that may cause undesired operation of the device.

## Class B Instrument (South Korea)

This instrument is registered as an electromagnetically compatible instrument for home use and may be used at home and all other locations.

## ANATEL (Brazil)

This equipment is not entitled to protection against harmful interference and may not cause interference in duly authorized systems.

## Identification Information for Product Registration

This device has a label that contains, among other information, a product identifier in the following format:

Table 8. Registration identification information

| Identifier Type | Registration Identifier |
|---|---|
| FCC registration number | RIASJMRFICMDM3500 |

Table 8. Registration identification information

| Identifier Type | Registration Identifier |
|---|---|
| Industry Canada (IC) registration number | 8454A-DM3500123 |
| ANATEL homologation number | 00035-18-04852 |

# Wireless Technology Information

The following table summarizes the technical details of the Bluetooth®[2] low energy (Bluetooth LE) technology as it is implemented in the device.

Table 9. Bluetooth low energy information

| Parameter | Data |
|---|---|
| Antenna type | Embedded antenna in header |
| Antenna dimensions | 1.257 cm x 0.127 cm |
| Modulation | GFSK |

[2] Bluetooth® is a registered trademark of Bluetooth SIG, Inc.

Table 9. Bluetooth low energy information

| Parameter | Data |
|---|---|
| Magnetic field strength (at 2 m distance) | 34.69 uA/m |
| Electric field strength (at 2 m distance) | 13.07 mV/m |
| Output power (EIRP*) | 1 mW (0 dBm) typical, 10 mW (+10 dBm) maximum |
| Range | 2 m typical |
| Center frequency | 2.44 GHz |
| Channel | 40 channels |
| Bandwidth | 2 MHz per channel |
| Data flow | Bi-directional |
| Protocol | Bluetooth LE |
| *EIRP = Equivalent isotropically radiated power | |

# Radio Transmitter, Cables, Transducers

The device contains a radio transmitter/receiver with the following parameters.

Radio transmitter parameters:

- Frequency (range): 2.4000 to 2.4835 GHz
- Bandwidth (-15dB): 2.398 to 2.4855 GHz
- Channel: 40 channels using AFH
- Modulation: GFSK
- Radiated output power: 10 mW (+10 dBm) maximum
- Magnetic field strength (at 2 m distance): 34.69 uA/m
- Duty cycle: Variable, but low (<5%)
- Semi-duplex capability

The radio receiver in the device is using the same frequency and bandwidth as the transmitter.

Cables and transducers:

Cables and transducers are not used during normal use of the device nor while programming the device.

# Quality of Service for Wireless Technology

Bluetooth® low energy (Bluetooth LE) wireless technology enables communication between the monitor and the clinician programmer, smart phone, or tablet. The requirements for the quality of service (QoS) vary depending on the use environment (operating room, recovery room, and home environment).

After the clinician programmer, smart phone, or tablet is paired with a monitor, the Bluetooth symbol is visible on the clinician programmer, smart phone, or tablet. When the Bluetooth LE connection is not active, the symbol appears dimmed.

Other requirements include a semi-duplex transmission with a required acknowledge, a transmission latency in each direction (2x), and a receive-to-transmit mode (RX-to-TX) time. Data is resent if not sent successfully.

## Wireless Security Measures

The insertable cardiac monitor is designed to include several features to enhance the security of wireless communications. Design features include the following:

- The monitor encrypts its wireless communication.
- The monitor is designed to limit its communications to authenticated paired smart phones or tablets.
- The monitor is designed to pair with a single smart phone or tablet at a time.
- The monitor uses a proprietary pairing protocol in addition to the pairing procedure specified in

Bluetooth low energy protocols.

- The monitor authenticates the pairing requests using a standard cloud-based authentication.
- The monitor uses an authorization protocol, which limits a paired smart phone or tablet's access to data appropriate for its functionality.
- The monitor creates a unique key for the paired unit and verifies it at the onset of every communication. If the unique key is not verified, the monitor denies access.

# Technical Support

St. Jude Medical maintains 24-hour phone lines for technical questions and support:

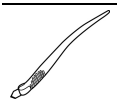
- 1 818 362 6822
- 1 800 722 3774 (toll-free within North America)
- + 46 8 474 4147 (Sweden)
- + 61 2 9936 1200 (Australia)
- manuals.sjm.com

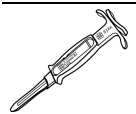
For additional assistance, call your local St. Jude Medical representative.

# Symbols

The symbols below and harmonized symbols may be found on the product or product label. For

harmonized symbols, refer to the Universal Symbols Glossary at https://manuals.sjm.com.

| Symbol | Description |
|---|---|
|  | Follow instructions for use on this website |
|  | Manufacturing facility |
|  | Product literature |
|  | Accessories |
|  | Storage temperature. Temperature value is indicated adjacent to the symbol. |
|  | Incision tool |

| Symbol | Description |
|---|---|
|  | Insertion tool |
|  | Insertable Cardiac Monitor |
|  | Warning; sharp element |
|  | Shipped settings off |
| FCC ID: XX00000 | Federal Communication Commission Number (FCC ID: #) |
| IC: 0000X-000 | Industry Canada Radio Communications License (IC: #) |

| Symbol | Description |
| --- | --- |
|  | The device contains a battery and the label is affixed to this device in accordance with European Council Directives 2002/96/EC and 2006/66/EC.<br><br>These directives call for separate collection and disposal of electrical and electronic equipment and batteries. Sorting such waste and removing it from other forms of waste lessens the contribution of potentially toxic substances into municipal disposal systems and into the larger ecosystem.<br><br>Return the device to St. Jude Medical at the end of its operating life. |
|  | Australian Communications and Media Authority (ACMA) and New Zealand Radio Spectrum Management (RSM) Regulatory Compliance Mark (RCM) |
|  | This equipment is certified for type certification pursuant of Article 38-24 of the Japan Radio Law |
|  | Korea Certification mark for electrical devices |

| Symbol | Description |
|---|---|
|   | Malaysian Communication and Multimedia Commission (MCMC) certification mark for products meeting applicable MCMC Technical Codes |
|   | Prescription only |
| **Made in USA** | Made in USA |
|   | European conformity, affixed according to the relevant provisions of AIMD directive 90/385/EEC and RE directive 2014/53/EU Annex III. Hereby, St. Jude Medical declares that this device complies with the essential requirements and other relevant provisions of these directives.<br><br>The full text of the European Union RE directive 2014/53/EU declaration of conformity is available at the following internet address: www.sjmglobal.com/euconformity.<br><br>This product operates in the 2.4-2.4835 GHz band with an RF output power of less than 0.04 mW EIRP. |

| Symbol | Description |
| --- | --- |
|  | Double sterile barrier |

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