WiSE® Cardiac Resynchronization Therapy (CRT) System

INSTRUCTIONS FOR USE

Coupler

For use with:

- **WiSE CRT Coupler (M2050)**

CAUTION: Limited to investigational use outside of the United States.

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LBL-10026 Rev. A

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1 DEVICE DESCRIPTION

The Coupler is an optional accessory for use with the WiSE Delivery Sheath and Electrode Catheter (WiSE Delivery System). The Coupler aids in the positioning and stabilization of the delivery system during the Electrode implantation procedure. The device is single use and provided sterile.

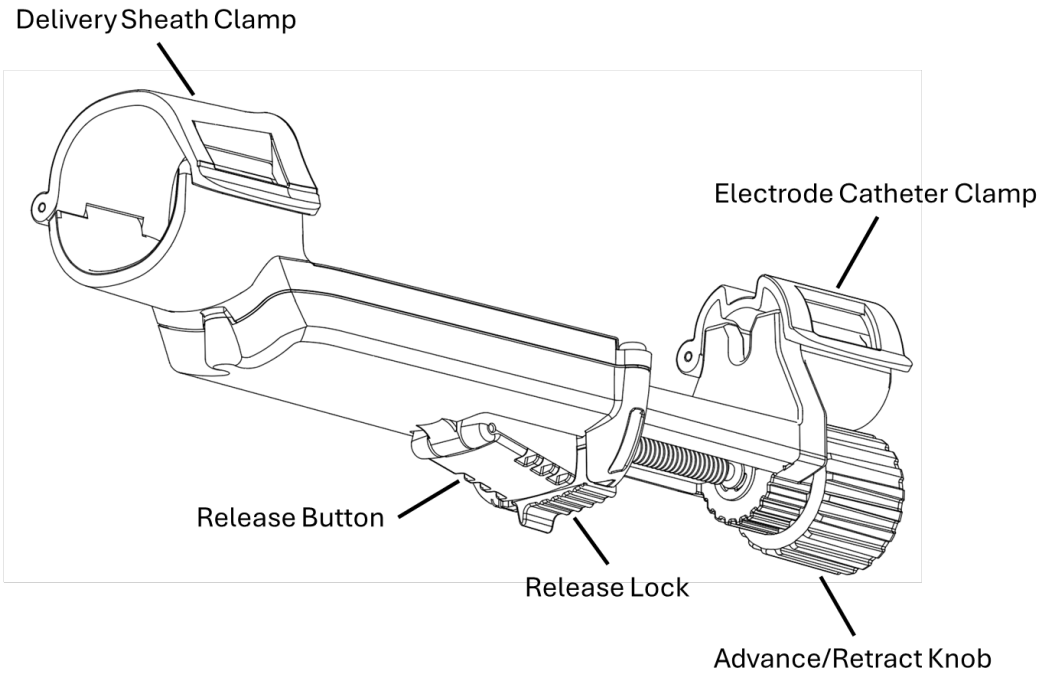


Figure 1: Coupler Key Components

- Electrode Catheter Clamp

  Secures the Electrode Catheter to the Coupler

- Delivery Sheath Clamp

  Secures the Delivery Sheath to the Coupler

- Advance/Retract Knob

  Advances and retracts the Electrode Catheter relative to the Delivery Sheath

- Release Lock

  Prevents unintended activation of the Release Button

- Release Button

  Enables retraction of the Delivery Sheath towards the Electrode Catheter

Note: Refer to the complete Instructions for Use (IFU) for all components of the WiSE CRT System to ensure a full understanding of its intended use and operation.

2 INTENDED USE

The Coupler is intended to aid in the positioning and stabilization of the delivery system during the implantation procedure.

3 INDICATIONS FOR USE

The Coupler is indicated to aid in the positioning and stabilization of the delivery system during implantation of the Electrode in the endocardium in patients who are eligible for treatment with the WiSE CRT System.

4 CONTRAINDICATIONS

None known.

5 PRECAUTIONS

Review the WiSE CRT System Electrode Catheter (M1000) and Delivery Sheath (M2000) IFU (LBL-05301). Warnings and cautions related to the Electrode implantation procedure will continue to apply.

The Coupler is sterilized by gamma irradiation after being packaged. Return any package to EBR that does not appear to present a sterile barrier.

The Coupler is for SINGLE USE only. Do not attempt to re-sterilize or reuse the Coupler if it has previously been used with another patient.

Check the device package for the expiry date/ “use-by” date. Do not use devices that are past the expiry date/ “use-by” date marked on the package.

Inspect the device package for damage. Do not use if the packaging is damaged, the seals have been opened, or the packaging is wet.

6 DIRECTIONS FOR USE

6.1 OPENING STERILE CONTAINERS

The Coupler comes in a tray with a peel away lid. Perform the following steps to ensure safe handling into the sterile field:

6.1.1 Remove the tray containing the Coupler from the outer box package.

6.1.2 Check the label on the tray lid to ensure that the device name and model number match the required device.

6.1.3 Locate the accessible corner of the tray, grip the peelable edge, and peel back the cover.

6.1.4 Using sterile technique, remove the retainer and the Coupler and place the Coupler into the sterile field.

6.1.5 ⚠ Do not rotate the Advance/Retract Knob prior to installing the Delivery Sheath and Electrode Catheter.

6.2 USING THE COUPLER

6.2.1 Note: See the Electrode Catheter and Delivery Sheath IFU for instructions on using the Delivery System. Install the Coupler after the Delivery System is positioned within the free chamber of the left ventricle.

6.2.2 Secure the clamps to the Electrode Catheter and Delivery Sheath as shown in **Figure 2**. Ensure clearance of all attached lines. The Coupler may be removed from and reinstalled to the Delivery System at any time, as needed.

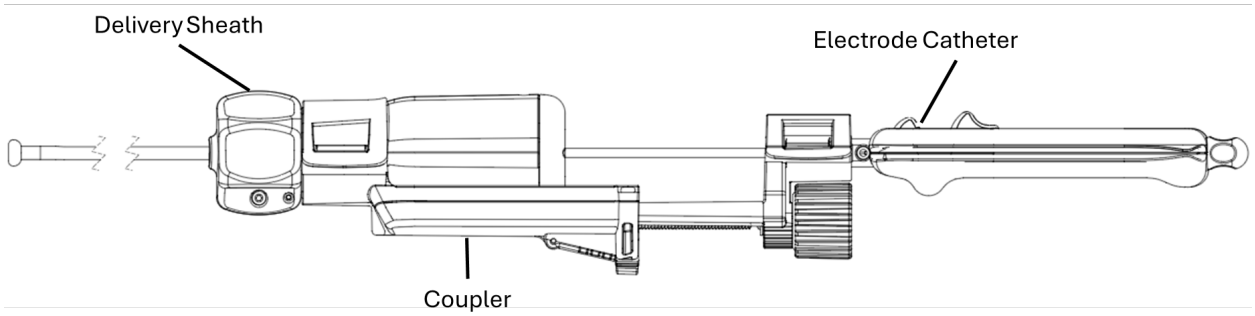


Figure 2: Coupler with Delivery Sheath and Electrode Catheter Clamped

6.2.3 To advance (or retract) the Electrode Catheter

- Rotate the Advance/Retract Knob while stabilizing the position of the Delivery Sheath.

6.2.4 To release the Electrode after detachment

- Stabilize the Electrode Catheter with the right hand.
- Disengage the Release Lock.
- Depress and hold the Release Button.
- Slowly retract the Delivery Sheath with the left hand. When the Delivery Sheath reaches its travel limit, continue retracting both hands together to clear the Delivery Sheath and Electrode Catheter from the Electrode.

6.2.5 To retract the Electrode Catheter post release, prior to system removal

- Stabilize the Delivery Sheath with the left hand.
- Retract the Electrode Catheter with the right hand until the Electrode Catheter reaches its travel limit.

7 HOW SUPPLIED

7.1 CONDITIONAL PACKAGING AND STERILIZATION

The Coupler is individually packaged and sterilized using gamma irradiation.

7.2 STORAGE

The Coupler should be stored in the original packaging in a dry, room-temperature environment.

8 DISPOSAL AND CLEANING

The Coupler is a single-use, disposable device and should be disposed of in accordance with the facility's procedures for handling medical waste. If a device needs to be returned to EBR, contact EBR to obtain the appropriate materials for returning the device.

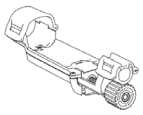
9 SYMBOL GLOSSARY

9.1 SYMBOLS FROM STANDARDS

SYMBOL	STANDARD REFERENCE	STANDARD TITLE	SYMBOL TITLE	EXPLANATORY TEXT
	ISO 15223-1: 2021, Clause 5.1.1	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied.	Manufacturer	Indicates the medical device manufacture
	ISO 15223-1: 2021, Clause 5.1.3	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied.	Date of manufacture	Indicates the date when the medical device was manufactured
	ISO 15223-1: 2021, Clause 5.1.4	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied.	Use-by date	Indicates the date after which the medical device is not to be used
	ISO 15223-1: 2021, Clause 5.1.6	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied.	Catalogue number	Indicates the manufacturer's catalogue number so that the medical device can be identified
	ISO 15223-1: 2021Clause 5.2.11	Medical devices - Symbols to be used with information to be supplied by the manufacturer	Single Sterile Barrier Sterilized using irradiation	Indicates a medical device that has been sterilized using irradiation and has a single sterile barrier
	ISO 15223-1: 2021, Clause 5.4.2	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied.	Do not reuse	Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure

SYMBOL	STANDARD REFERENCE	STANDARD TITLE	SYMBOL TITLE	EXPLANATORY TEXT
	ISO 15223-1: 2021, Clause 5.2.6	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied.	Do not resterilize	Indicates a medical device that is not to be resterilized
	ISO 15223-1: 2021, Clause 4.3	Medical devices - Symbols to be used with information to be supplied by the manufacturer	Consult instructions for use or consult electronic instructions for use.	Refer to electronic format of instruction manual/booklet.
	21 CFR 801.109, Subpart D	Exemptions from Adequate Directions for Use Sec. 801.109 Prescription devices.	Prescription Use Only	Indicates that only professionals licensed by the law of the State in which the practitioner practices to use or order the use of the device can prescribe this device
	ISO 15223-1:2021, Clause 5.2.8	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied.	Do not use if the package is damaged.	Indicates a medical device that should not be used if the package has been damaged or opened
	ISO 15223-1: 2021, Clause 5.7.7	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied.	Medical device	Indicates the item is a *medical device*
1	ISO 80000-1: 2009 Section 3.1, note 3	Quantities and units — Part 1: General	Quantity	Quantity of package contents

9.2 SYMBOLS NOT FROM STANDARDS

SYMBOL	REFERENCE	REFERENCE TITLE	SYMBOL TITLE	EXPLANATORY TEXT
	EBR Systems, Inc.	Not Applicable	WiSE CRT Coupler M2050	Positioning and stabilization device for use with the compatible WiSE CRT Delivery System.

10 TECHNICAL SPECIFICATIONS

PHYSICAL SPECIFICATIONS

Coupler (M2050)	
Advance/Retract Resolution	2 mm per Knob revolution; 1/8 mm per Knob tactile click
Advance/Retract Adjustability, Maximum	39 mm
Delivery Sheath Release Stroke Distance	9 mm