



WiSE™ CRT System

INSTRUCTIONS FOR USE Transmitter Model 4100

**CAUTION - Investigational Device.
Limited by United States law to investigational use.**



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1 PRECAUTIONS

PRECAUTION – For use only by Qualified Medical Personnel in professional healthcare environments: The WiSE CRT System is intended to be used by qualified cardiologist physicians and only in professional healthcare facilities. EBR Systems, Inc. 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. Obtaining proper surgical training and technique is the responsibility of the implanting physician. 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 the WiSE CRT System Instructions for Use (LBL-02744-IDE-EN) should be considered as a required supplement for qualified and experienced medical professionals.

1.1 STERILE SINGLE USE DEVICES

- The WiSE CRT Transmitter is sterilized via ethylene oxide gas processes after being packaged. Return any package that does not appear to present a sterile barrier to EBR Systems.
- The WiSE CRT Transmitter is for SINGLE USE only. Do not attempt to sterilize and re-use any WiSE CRT device.

1.2 STORAGE AND HANDLING

- Devices should be stored in their original packages in a dry, clean temperature-monitored environment.
- Allow devices to acclimate to room temperature prior to implanting.

1.3 CO-IMPLANTED PACEMAKER, DEFIBRILLATOR, OR BIVENTRICULAR DEVICE COMPATIBILITY

- The WiSE CRT system is intended to be used to provide bi-ventricular pacing in conjunction with a co-implanted pacemaker, defibrillator, or biventricular pacing device. Program the co-implanted device to deliver right ventricular pacing in the appropriate mode and timing interval settings as would be required for CRT; e.g. a dual chamber pacing modality that utilizes right atrial pacing unless the patient is in permanent atrial fibrillation.
- Specific capabilities and features of the co-implanted device must be reviewed against criteria described in the [Review Specifications and Considerations for the Co-Implant Device](#) section of these instructions for use. This must be reviewed prior to implanting the WiSE CRT Transmitter.

1.4 PRE-IMPLANT DEVICE CHECKING

- Check the device package for the [Use-by Date](#). Do not use devices which are past the [Use-by Date](#) marked on the package.
- Inspect the device package for damage. Do not use the device if the packaging has been damaged, the seals have been opened, or the packaging is wet. Return any package to EBR Systems that does not appear to present a sterile barrier.
- Check the package contents against the content list of the label. Do not use the device if all listed components are not present in the package.
- Check that a pre-implant transthoracic echocardiogram procedure was completed, that the acoustic window was documented, and that the information is available for selecting the implant location for the Transmitter.

1.5 IMPLANT PROCEDURE

- Do not damage/cut the Transmitter Cable. Use fingers to grip the cable connector and insert into the Battery connector/header block; do not use any instruments to hold or insert the cable into the header. Do not kink the cable during handling or during implant. Do not leave a sharp bend radius in the cable implant. Do not allow the cable connector to become wet.
- Careful dissection and blunt force tunneling is required to avoid risk of perforation of the intercostal (ICS) muscle and into the thoracic cavity.

1.6 PROGRAMMING

- Use only the EBR Systems, Inc. Programmer to attempt to communicate with and program the WiSE CRT System.

1.7 EXPLANT AND DISPOSAL

- Program the WiSE CRT operational mode to OFF prior to explant.
- Return all explanted devices to EBR Systems to assist with full life-cycle device traceability and to ensure safe and environmentally sensitive disposal.
- Clean and disinfect WiSE CRT devices prior to sending to EBR Systems, Inc.

2 PRIOR TO IMPLANTING THE TRANSMITTER

2.1 ASSESSING THE ACOUSTIC WINDOW

An acoustic window is commonly known in echocardiography as the location where a transthoracic echocardiography (TTE) probe is placed to view the heart. The term “window” refers a lung-free, cartilage-free pathway for ultrasound to travel between the probe and the heart.

The WiSE CRT Transmitter sends ultrasonic pulses through the chest wall to the Electrode in the heart and thus must be implanted in an adequate acoustic window (at least 1 cm spacing between costal cartilages¹ by 2.5 cm wide) for transmission of ultrasound. This window is typically in the 5th or 6th intercostal spaces (ICS), lateral to the left parasternal border. However due to anatomical variability occasionally the 4th or 7th ICS may be used.

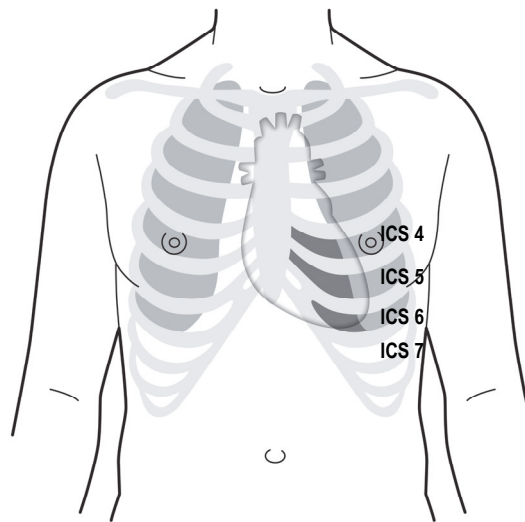


Figure 1: Typical acoustic window options for Transmitter implant

A screening procedure to confirm the existence of an adequately sized acoustic window must be performed prior to the Transmitter implant procedure. This screening is performed using a commercially-available echocardiographic imaging system equipped with a transthoracic echocardiography (TTE) probe and vascular probe. The vascular probe is required to accurately identify the location and spacing of the costal cartilages. The cardiac probe is used to visualize the location (distance and angle) of target Electrode implant sites relative to candidate Transmitter implant sites. It is also used to identify the point along the ICS where lung encroachment occurs. This screening procedure can be performed as an adjunct to standard echocardiography, routinely performed prior to CRT implantation.

The location of the lungs changes with patient movement and respiration. Consequently, the screening is performed in multiple body positions to ensure adequate acoustic window in all postures.

¹ The term costal cartilage is used rather than rib because the Transmitter is typically implanted medial to the transition from true rib bone to costal cartilage. This transition occurs roughly at the location of the nipple.

FOR THIS SCREENING PROCEDURE, YOU NEED:

- Ultrasound Imaging Device with a vascular probe and cardiac probe
- Ribbon tape measure
- Surgical marking pen
- Acoustic Window Screening Form (see section 5)

SCREENING PROCEDURE STEPS:

1. Start with the patient in supine posture. This should include a level of back tilt to appropriately mimic their normal sleeping posture.
2. Mark the center line of the sternum.
3. Identify the location of the 5th costal cartilage: Start at the first costal cartilage with the long axis of the vascular probe oriented in the superior-inferior patient plane directly below the clavicle and continue inferiorly until the 5th costal cartilage is encountered. See Figure 2.

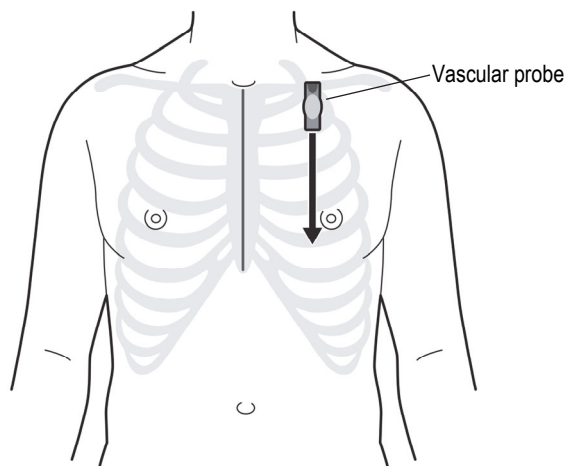


Figure 2: Identify the location of the 5th costal cartilage

4. Maintaining the superior-inferior orientation of the probe slowly sweep the vascular probe from medial to lateral while maintaining the 5th costal cartilage centered in the image. Use this technique to determine the medial lateral course of 5th costal cartilage (e.g. straight vs. curved inferior vs. curved superior). Mark the centerline of the 5th costal cartilage. See Figure 3.

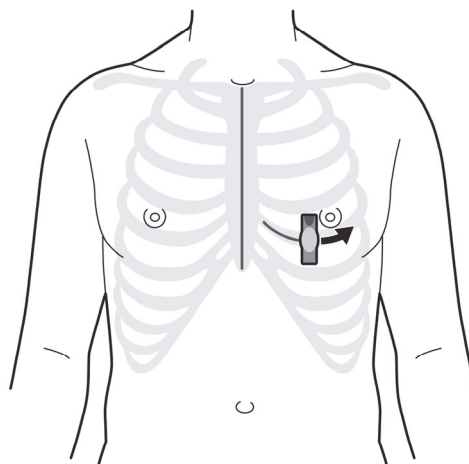


Figure 3: Determine and mark the medial lateral course of 5th costal cartilage

5. Move the vascular probe down to the 6th costal cartilage and repeat the medial-lateral sweep of the probe to determine and mark the centerline of the 6th costal cartilage. As an anatomical reference point, measure and record on the screening form the length from the suprasternal notch to mid-5th ICS. See Figure 4.

IMPORTANT! Note that there is commonly a narrowing and/or conjoining of the 6th and 7th costal cartilage approximately 4-8 cm from the mid sternal line. Appreciation of this anatomical landmark can avoid confusion during the screening procedure and can be useful as an anatomical reference point.

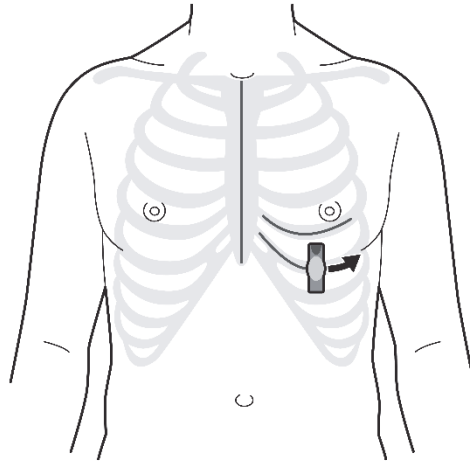


Figure 4: Determine and mark the medial-lateral course of 6th costal cartilage

6. While maintaining the vascular probe over the 6th costal cartilage, move the probe far lateral of the mid sternal line prior to moving the probe down to the 7th costal cartilage. This is important to avoid any potential confusion from the potential co-joining of the 6th and 7th costal cartilages. Repeat the medial-lateral sweep of the probe to determine and mark the location of the 7th costal cartilage. See Figure 5.

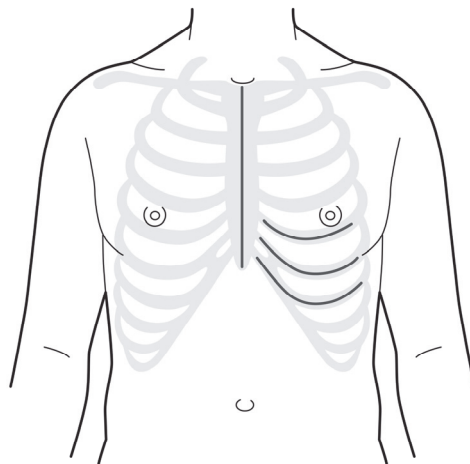


Figure 5: Determining and marking the medial-lateral course of 7th costal cartilage

7. Based on the marks for the 5th and 6th costal cartilages visualize the centerline of the 5th ICS. This is halfway between the two lines. Starting at the sternum slowly sweep the vascular probe along the centerline of the 5th ICS. Make sure that the probe is oriented perpendicular to the centerline. Determine where the spacing between the costal cartilages opens to 1 cm. Mark this location with a line spanning between the 5th and 6th costal cartilage lines. See Figure 6.

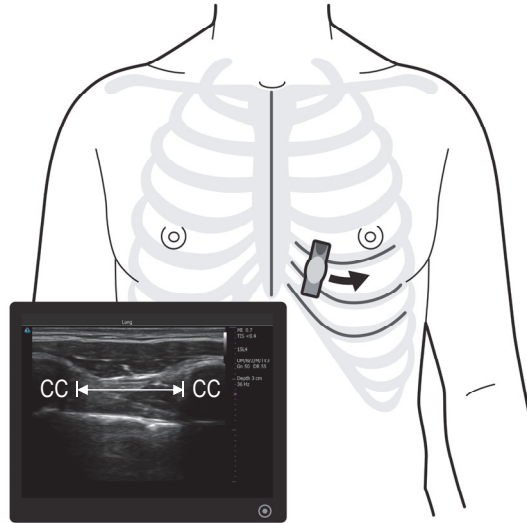


Figure 6: With ultrasound assistance, mark where the 5th ICS opens to 1 cm
The ultrasound image displays the costal cartilages (annotated CC) and the 5th ICS which can be used to determine the location where the spacing between the costal cartilages opens to 1 cm.

8. Continue sweeping laterally along the centerline of the 5th ICS for approximately 6 cm to ensure that a 1 cm spacing is maintained. If there is any narrowing to less than 1 cm over this distance mark this location with a line spanning between the 5th and 6th costal cartilage lines. See Figure 7.

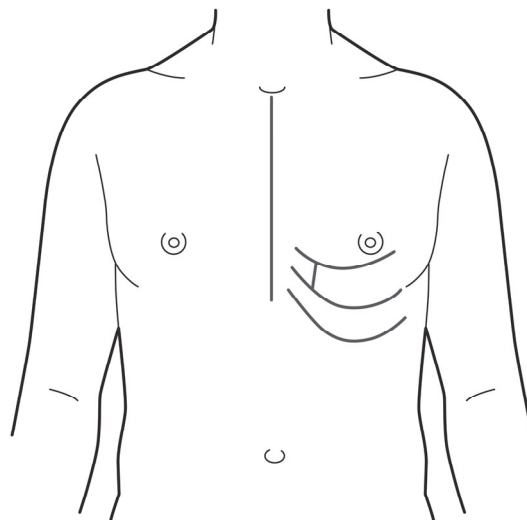


Figure 7: Ensure 1 cm spacing is maintained along the 5th ICS for at least 6 cm.

9. Repeat steps 7 and 8 for the 6th ICS however instead of starting the process at the sternum, start the process lateral to any co-joining or spacing less than 1 cm of the 6th and 7th costal cartilages. See Figure 8.

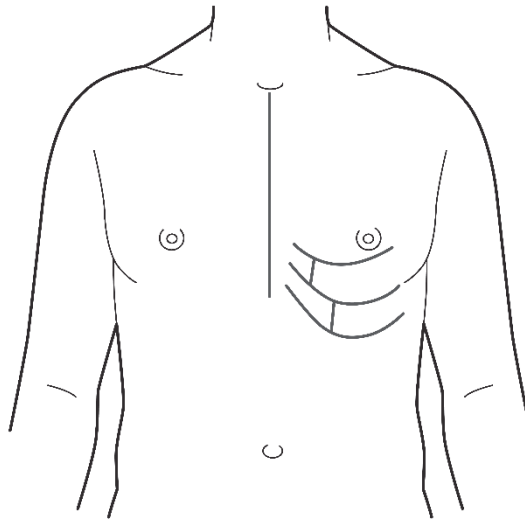


Figure 8: Mark where the 6th ICS opens to 1 cm and ensure this 1 cm spacing along ICS.

10. Switch over to the cardiac probe.
11. Determine the area of ICS that is free of lung encroachment and mark accordingly.
- 11A. Place the probe in the 5th ICS medial to the 1 cm opening point. Orient the probe so the fan beam is parallel with the direction of the ICS. See Figure 9.

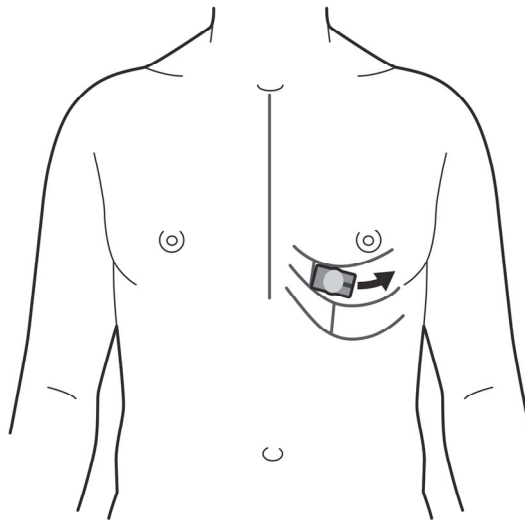


Figure 9: Orient probe so the fan beam is parallel with the direction of the ICS.

- 11B.** While requesting the patient to mimic moderate but not deep inhalation, observe the ultrasound image for the presence of lung encroachment. This is typically evidenced by a white reflective line encroaching laterally in the near-field with a far-field shadowing.
- 11C.** If there is encroachment seen on initial placement, the ICS length is too short (<2.5 cm). No further measurements of the ICS are required.
- 11D.** If encroachment is from a superior rather than lateral direction, it may present as generally poor image quality. In this case, axial rotation of the probe is required to visualize the distinct signature of lung encroachment. See Figure 10.

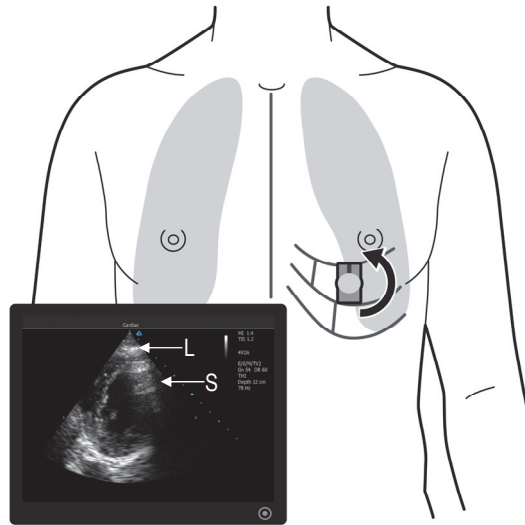


Figure 10: Orient probe so the fan beam is parallel with the direction of the ICS

The ultrasound image shows the reflection artifact due to lung encroachment (annotated L) and associated shadow (annotated S). The shadow can sweep across the ultrasound image during inhalation.

- 11E.** If no encroachment is seen on initial placement, slowly move the probe along the centerline of the ICS until the first sign of lung encroachment is seen. See Figure 11.

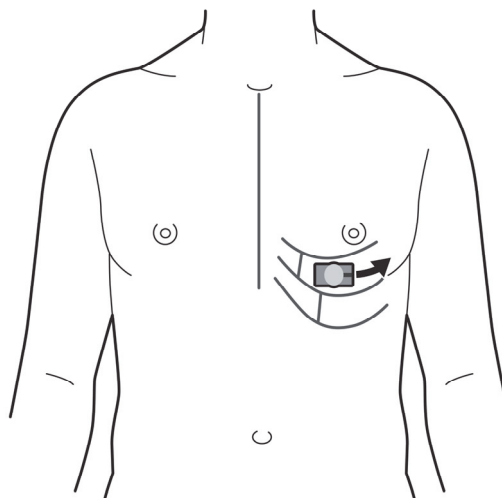


Figure 11: Move probe along ICS centerline until lung encroachment is seen

- 11F.** Once lung encroachment is seen, mark the location of the lateral border of the probe with a line extending between the upper and lower costal cartilage lines. See Figure 12.

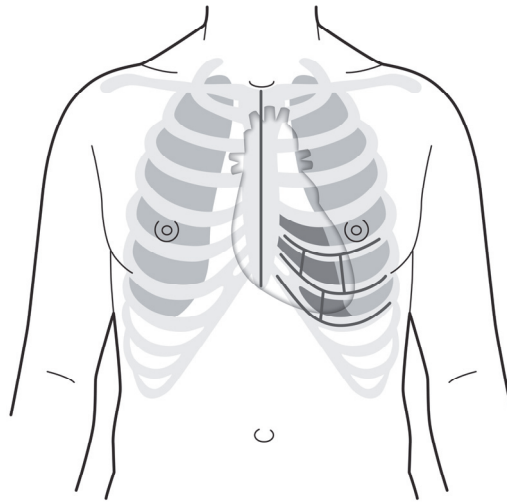


Figure 12: Mark the lung border of the 5th ICS acoustic window

- 12.** Repeat step 11 for the 6th ICS.

- 13.** Repeat steps 11 and 12 with the patient in the following postures:

- Supine laying on right side
- Sitting
- Standing

NOTE: Additional marking is required if the measured length is smaller than previously marked.

- 14.** If neither the 5th or 6th ICS provide a length ≥ 2.5 cm. Repeat the screening process for the 4th and 7th ICS.

- 15.** For the ICS spaces with sufficient length ≥ 2.5 cm, estimate the angulation and distance to potential implant sites for the electrode.

- 15A.** Place the cardiac probe over the potential site for Transmitter implantation. The probe should be oriented with the fan beam parallel with the direction of the ICS with the probe normal to the curvature of the chest wall. See Figure 13.

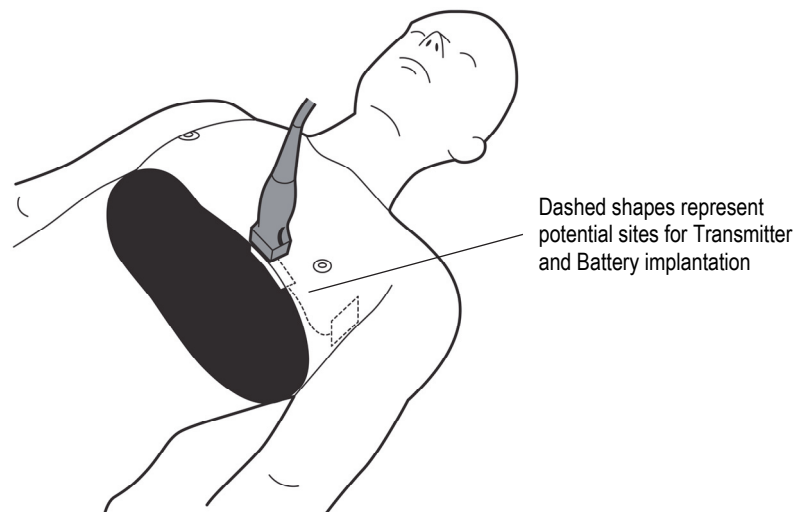


Figure 13: Place the cardiac probe over the potential site for Transmitter implantation

- 15B.** Using the cardiac probe as a proxy for the Transmitter angulation once implanted, hold the probe at the estimated medial-lateral angle that the Transmitter would naturally lay once implanted. See Figure 14.

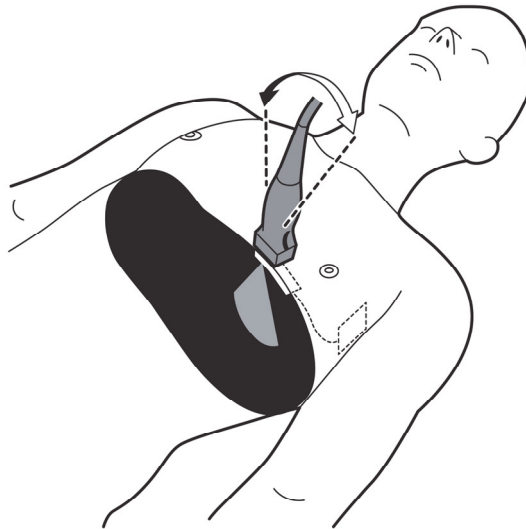


Figure 14: Position probe at estimated medial-lateral angle Transmitter would naturally lay once implanted

- 15C.** While maintaining the medial-lateral angle of the probe in the above step 15B, adjust the cranial-caudal angle of the probe to visualize the targeted electrode implant site on the LV wall becomes visible in the ultrasound image. From a line, perpendicular to the chest, estimate the cranial-caudal angle where the targeted electrode implant site on the LV wall is visible. See Figure 15.

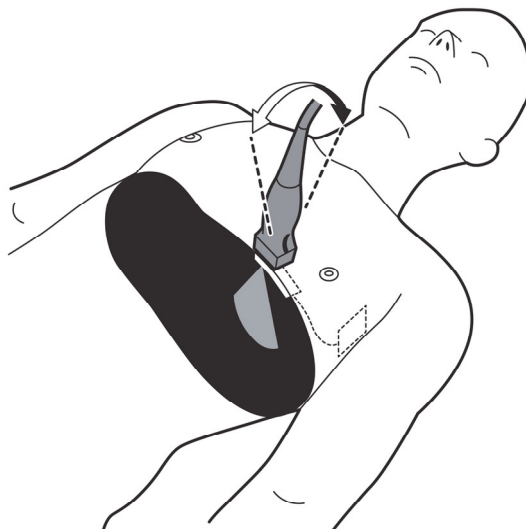


Figure 15: Adjust the cranial-caudal angle of the probe to visualize the targeted Electrode implant site

- 15D.** Holding the probe at the medial-lateral and cranial-caudal angles noted in above steps 15B and 15C, estimate the medial-lateral angle from the centerline of the echo image and measure the distance in the echo image from the approximate location of the anterior surface of the intercostal muscle to the candidate Electrode implant site of interest. See Figure 16.

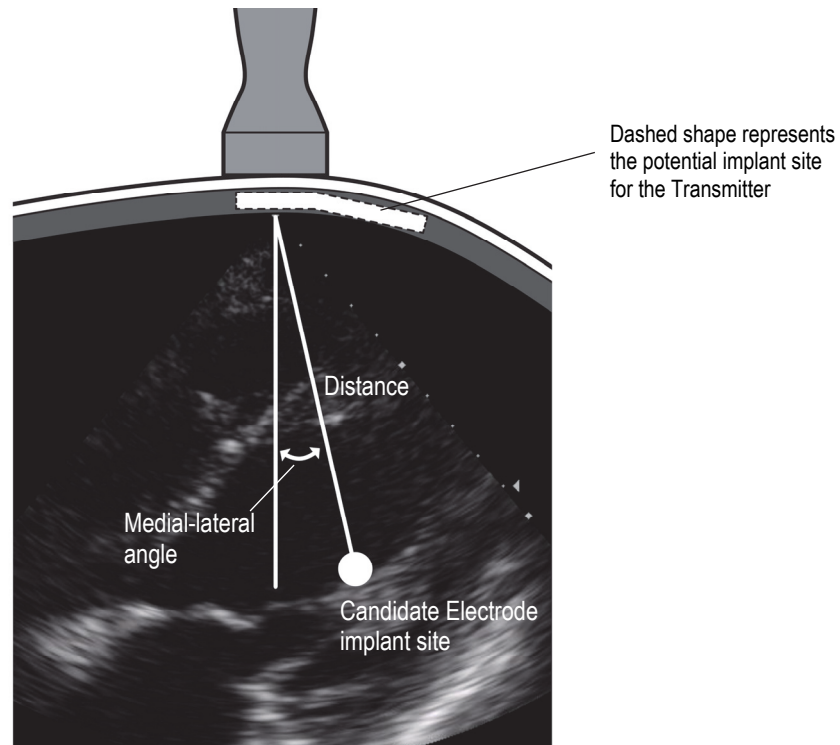


Figure 16: Measure distance to the electrode implant site of interest

- 15E.** Record the following data for each candidate ICS on the screening form:
- Distance from mid sternal line to 1 cm spacing of costal cartilages
 - ICS length: Shortest distance (across different postures) from 1 cm spacing of costal cartilages to point of lung encroachment
 - Location of assumed candidate Electrode implant site.
 - LV wall thickness
 - Estimated medial-lateral angle to candidate Electrode implant site
 - Estimated cranial-caudal angle to candidate Electrode implant site
 - Distance to candidate Electrode implant site

IMPORTANT! When multiple acoustic windows are available for WiSE CRT Transmitter implantation, the distance and angle between the Transmitter and Electrode, Transmitter implant positioning and the ICS dimensions must be considered. For optimal transmission, the distance should be 10 cm or less with a transmission angle (both medial-lateral angle and cranial-caudal angle) less than 30 degrees. Positioning the Transmitter as medial as possible minimizes the possibility of reduced performance due to lung encroachment and should always be a primary objective, regardless of the acoustic window selected. The ICS with larger dimensions should be favored.

IMPORTANT! To confirm the Transmitter implantation site, a shortened version of the screening process must be repeated at the start of the implant procedure before sterile preparation of the patient (see section 3, Implanting the Transmitter).

2.2 REVIEW SPECIFICATIONS AND CONSIDERATIONS FOR THE CO-IMPLANT DEVICE

WARNING – Co-implanted Pacemaker, Defibrillator, or Biventricular Pacing Use: Warnings and cautions related to the co-implanted device will apply to the WiSE CRT system after implant. Review co-implant device technical manuals and instructions for use for a complete description of warnings and cautions.

WiSE CRT replaces the pacing function of a coronary sinus (CS) lead when used in conjunction with a typical, commercially-available implanted pacemaker, defibrillator, or biventricular pacing device to achieve Cardiac Resynchronization Therapy (CRT). The WiSE CRT System will trigger a left ventricular (LV) pacing pulse immediately after sensing the right ventricular (RV) pacing output from the pacing lead of the co-implanted device.

Review the Instructions for use that is associated with the co-implanted device. Program the co-implanted device to deliver right ventricular pacing in the appropriate mode and timing interval settings as required for CRT.

The WiSE CRT System functionality relies on detection of the RV pacing spike from the co-implant device. The WiSE CRT measures the pulse width of RV pacing signals to synchronize to the RV pacing output. In single chamber pacing modes this is straight forward, however, to do this reliably in dual chamber pacing modes, the system must distinguish right ventricular pacing from right atrial (RA) pacing. The WiSE CRT Transmitter must be initialized with the pacing pulse widths being used by the co-implanted device. The right ventricular pacing pulse width of the co-implant pacemaker must be programmed at or above 0.35 ms. In dual chamber modes, where atrial pacing may be expected, the right atrial pacing pulse width of the co-implant pacemaker must be programmed at least 0.2 ms above or below the right ventricular pulse width. In single chamber, right ventricular pacing modes, where there is no atrial pacing, the right ventricular pacing pulse width of the co-implant pacemaker must be programmed at or above 0.35 ms.

CO-IMPLANT SETTING EXAMPLE		
Mode	RV Pulse Width	RA Pulse Width
Dual Chamber (e.g. DDD)	0.4 ms	≤0.2ms or ≥0.6ms
Single Chamber (e.g. VVI)	0.4 ms	Not applicable

WiSE CRT may be implanted with any co-implanted pacemaker, defibrillator or biventricular pacing device with the following capabilities and required settings:

- ✓ Right ventricular pacing lead implanted and functional
- ✓ Programmed pacing modality that utilizes right ventricular pacing
- ✓ Pacing pulse width settings for the right ventricular lead programmable above 0.35 ms
- ✓ Separately programmable atrial pacing pulse width settings in dual chamber modes that allow for differences of 0.2 ms or greater than those used for right ventricular pacing
- ✓ Auto Capture or lead impedance measurement algorithms that automatically adjust the pulse width of the co-implant device must be programmed to OFF
- ✓ Any other feature or operation, for example thoracic impedance sensing, that initiates an electrical output must be programmed to OFF

The WiSE CRT system will synchronize to the co-implanted RV pacing signal (the pacing spike) and track rates up to 140 ppm (minimum 430 ms pacing interval). Pacing by the co-implanted device above 140 ppm will inhibit the WiSE CRT system from providing bi-ventricular pacing until the pacing rate drops below 140 ppm. High rate pacing by the co-implanted device, for example for pace termination of ventricular tachycardia, may result in WiSE CRT bi-V pacing the LV, but only to a maximum rate of 140 ppm.

WARNING - Co-implanted CRT-D or CRT-P use: Enabling coronary sinus pacing from a co-implanted CRT-P or CRT-D with the WiSE CRT may inhibit WiSE CRT pacing. Disable coronary sinus pacing modes in a co-implanted CRT-P or CRT-D device.

IMPORTANT! During the Electrode implant procedure, patients should have an external defibrillator attached. Ensure that any co-implant anti-tachy therapies are disabled or reprogrammed to avoid having the co-implant deliver anti-tachy therapy. This also ensures that peri-procedural pacing with the WiSE CRT is not sensed by the co-implant's detection algorithms. After the procedure, ensure that anti-tachy therapies are enabled in the co-implant.

3 IMPLANTING THE TRANSMITTER

3.1 OPENING STERILE CONTAINERS

The Transmitter module is separately packaged in a double tray (a tray inside a tray) each with a sterile barrier sealed lid. The Transmitter tray contains:

- One Transmitter with a permanently integrated cable. Figure 17 illustrates the Transmitter's top and bottom views.

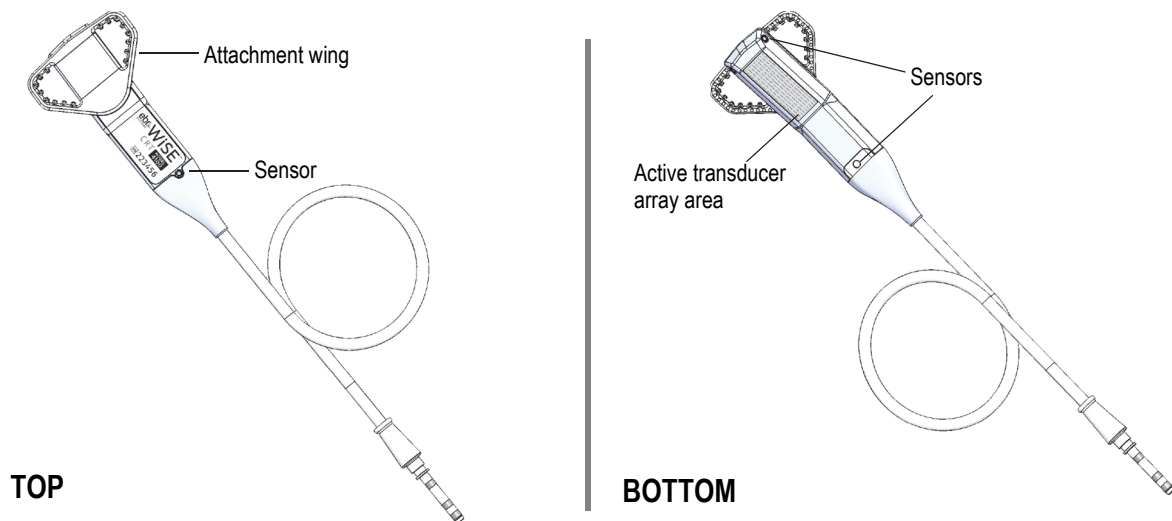


Figure 17: Transmitter Model 4100, top and bottom views

The following should be performed carefully to ensure safe handling onto the sterile field:

1. Check the device package for the Use-by Date. Do not use devices which are past the Use-by Date marked on the package.
2. Remove the device tray and the contents from the outer boxes. Retain the registration materials.
3. Check the label on the tray lid to ensure that the device name and model number match the required device.
4. Inspect the device package for damage. Do not use the device if the packaging has been damaged, the seals have been opened, or the packaging is wet.
5. Locate the accessible corner of the outer tray lid, grip the peelable edge, and peel back the cover.
6. The inner tray and its contents are sterile and should be removed by a sterile gloved hand and placed on a sterile surface, or without touching, by emptying the contents of the package onto a sterile surface.
7. Discard the trays and covers.

3.2 CLEANING AND DISPOSAL OF DEVICES

Explanted Transmitter devices should be wiped clean using typical hospital cleaning and disinfecting solutions and then sterilized by ethylene oxide processes used by the hospital. All explanted Transmitter devices must be returned to EBR Systems.

3.3 ASSESSING PATIENT AND PROCEDURAL STATUS

The subcutaneous implant of the Transmitter and Battery are usually performed before implanting the Electrode. This order of procedures allows the WiSE CRT System to best align the Electrode implant with the location of the Transmitter.



See the WiSE CRT System Electrode Instructions for Use for Electrode implant procedures.

Prior to Transmitter and Battery implantation, assess the patient's procedural status for the following:

1. To reduce the risk of excessive bleeding, the patient's Activated Clotting Time (ACT) should be below 180 seconds before beginning the implant of the Transmitter and Battery.
2. The location for the implant of the Battery should be selected on the mid-axillary line of the patient's lateral chest wall.
3. When selecting the implant site for the Battery, account for the 30 cm length of the cable between the Transmitter and the Battery. The distance between the implant sites of the Transmitter and Battery must be less than 30 cm so that the cable connection can be easily made without straining the cable. Patient movement and comfort should also be considered for Battery implant site selection.
4. Prepare the left chest and left axillary for sterile surgery.
5. Ensure the availability of the Transmitter, Battery, and Programmer.

3.4 IMPLANT PROCEDURE

In order to achieve consistent performance, the Transmitter must be stable relative to the acoustic window during patient movement and respiration. This requires the Transmitter to be positioned on the anterior surface of the intercostal muscle, beneath overlying muscle layers. Depending on the ICS used, these may include pectoralis, rectus abdominus, serratus, and/or external oblique muscle layers. The Transmitter is stabilized within the ICS by suturing the device's attachment wing to the costal cartilage.



The Transmitter Model 4100 is implanted together with and connected to a WiSE CRT Battery. See the WiSE CRT System Battery Instructions for Use for additional directions specific to the Battery.

Figure 18 reflects general positioning for the Transmitter and Battery. The Transmitter position will be dependent on the selected ICS (typically in the 5th or 6th ICS, occasionally the 4th or 7th ICS may be used). The cable must exit the Transmitter position laterally. The Battery position is typically along a superior/inferior direction on the mid-axillary line.

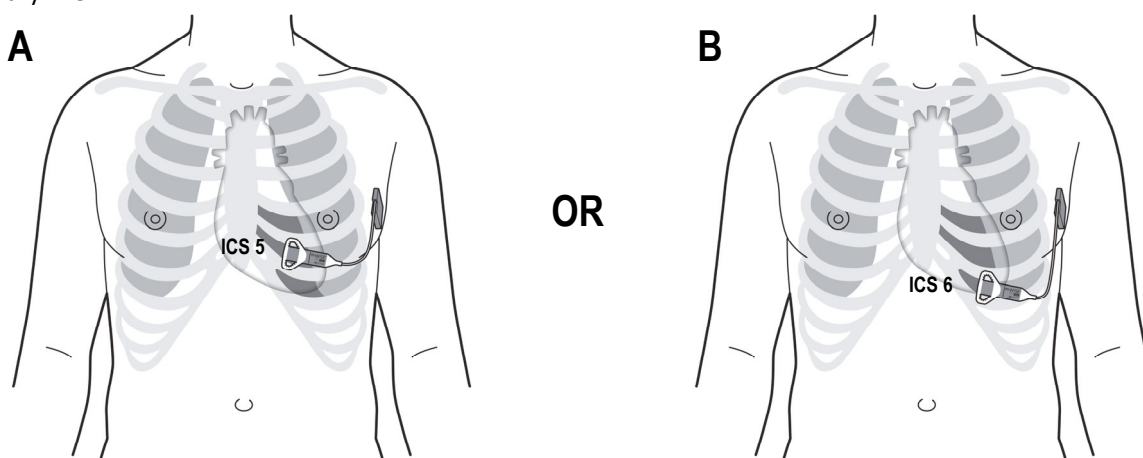


Figure 18: Typical positioning for the Transmitter and Battery

Surgical dissection down to the anterior surface of the intercostal muscle is required for the sub muscular implant and stabilization of the Transmitter. A channel along the anterior plane of the intercostal muscle is formed as a conduit from the Transmitter incision to the Battery pocket. The Transmitter is then inserted into the medial aspect of this channel. Careful dissection and blunt force tunneling are required to avoid risk of perforation of the ICS muscle and pleural cavity.

FOR THIS IMPLANT PROCEDURE, YOU NEED:

- Transmitter Model 4100
- Battery compatible for use with the Transmitter Model 4100
- Programmer with compatible software
- Surgical tools including:
 - Small retractor (AESCULAP BT012R or equivalent)
 - Tunneling tool (AESCULAP 'Randal Kidney Stone Forcep' EF051R or equivalent)
 - Dilator (AESCULAP 'Hegar Uterine Dilator' EM237R or equivalent)
 - Spreader (AESCULAP BV104R or equivalent)
- Routing Tube (Medline 0.375" (9.5mm) Sterile Latex Penrose Drain)
- Transmitter sutures and needle holder (non-absorbing 2-0 sutures with a Tapercut needle, Ethicon V-5 or V-7. For deep incisions, a needle holder is recommended, AESCULAP 'Adson Needle Holder' BM224R).
- Battery sutures (non-absorbable 2-0/C-15/26mm cutting Syneture SS-685G suture)
- Ultrasound Imaging Device with a vascular probe and a cardiac probe
- Completed Acoustic Window Screening Form (see section 5)

IMPLANT PROCEDURE STEPS:

Confirming Acoustic Window and Transmitter Implantation Site

1. Perform a shortened version of the screening process at the start of the implant procedure before sterile preparation of the patient. This is required to confirm the Transmitter implant location because oftentimes the marks from the screening are no longer present and even if they are present the patient is generally in a fully supine posture at the implant different from that used during screening, making the marks inaccurate. Additionally, this additional screening must be performed with the patients left arm retracted back to expose the battery implant site, as is required for the implant. This is important because movement of the arms can shift the location of skin markings. See **Figure 19**. At a minimum, the shortened screening should include:
 - Counting of the costal cartilages with the vascular probe to identify the target ICS
 - Identification of any co-joining of the 6th and 7th costal cartilages as an anatomical reference
 - Identification of the location where the costal cartilage opening exceeds 1 cm
 - Confirmation of angulation and distance from the ICS to candidate electrode implant locations

IMPORTANT! The previously completed Acoustic Window Screening Form and associated measurements should be used as a guide.

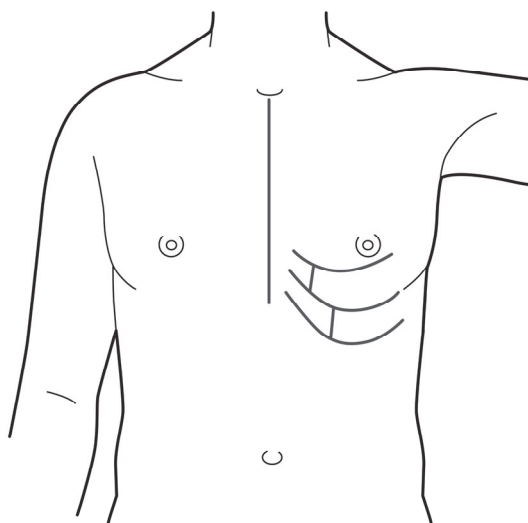


Figure 19: Pre-implant acoustic window screening with left arm retracted

Preparing the Transmitter and Battery Implant Locations and Cable Channel

2. Make a 4 cm vertical skin incision along the medial edge of the acoustic window in the ICS selected for the Transmitter implant.
3. Incise through the subcutaneous fat until the first muscle layer is exposed.
4. Palpate the overlying muscle layer to locate the superior costal cartilage. As a safety consideration, incise through the muscle layers over the superior costal cartilage.

5. Using the small retractor, retract the muscle layers to visually identify the anterior surface of the superior costal cartilage. See Figure 20.

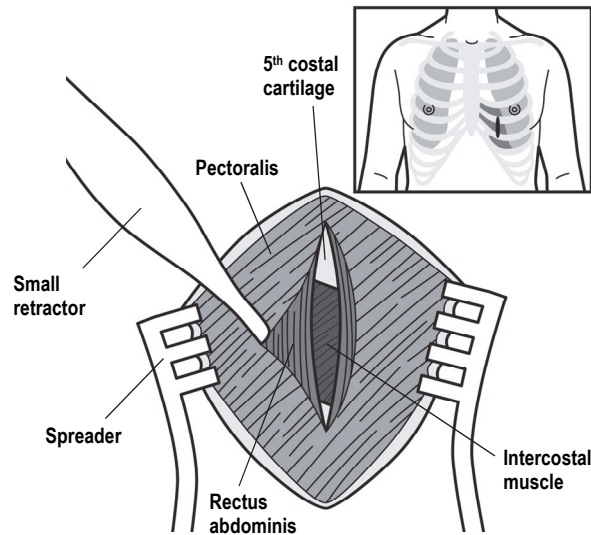


Figure 20: 4 cm vertical skin incision along medial edge of acoustic window with muscle layers retracted to expose anterior surface of the superior costal cartilage

6. Working from the inferior edge of the exposed cartilage, use the small retractor to retract back the overlying muscle to expose the anterior plane of the intercostal muscle. The intercostal muscle is identifiable as a fibrous sheet of muscle running diagonally between the costal cartilages. See Figure 21.

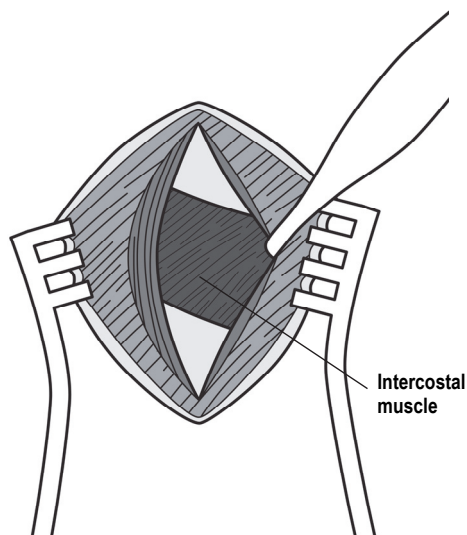


Figure 21: Overlying muscle retracted to expose the anterior plane of the intercostal muscle

7. Dissect through the overlying muscle inferiorly exposing the full span of the intercostal muscle between the two costal cartilages. Once the inferior cartilage is reached excise any muscle insertions from the anterior surface of the inferior costal cartilage.

8. Insert the tunneling tool and advance laterally into the plane defined by the anterior surface of the intercostal muscle. See Figure 22.

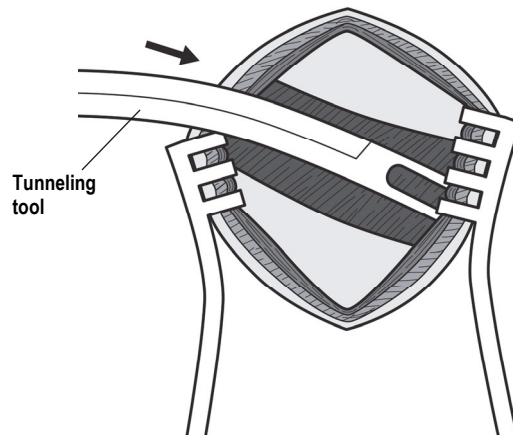


Figure 22: Advancing Tunneling Tool

9. Remove spreader as it can interfere with tunneling
10. Orient the tunneling tool horizontal to the chest/sternum and advance laterally along the anterior surface of the ICS to tunnel toward the preferred Battery pocket location. A vascular ultrasound probe can be used to track the tip of the tunneling tool within the muscle layers. Tunneling resistance should be minimal along the layer. If resistance is felt retract the tunneling tool completely and re-assess the insertion site prior to repeating this tunneling step to ensure that it is located over of the anterior surface of the ICS muscle. See Figure 23.

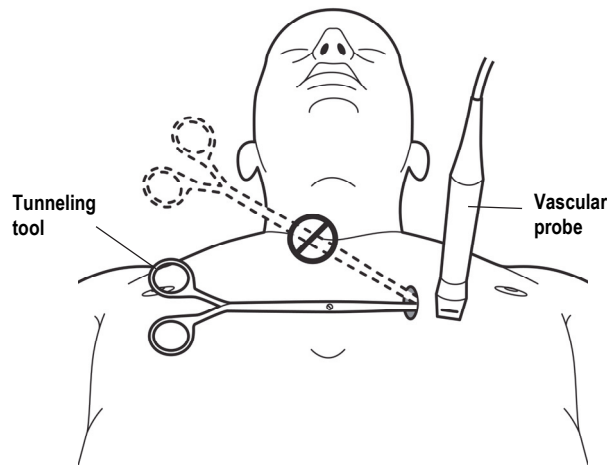


Figure 23: Advance Tunneling Tool using ultrasound assistance

11. Form a device pocket for the Battery implant along a superior/inferior direction on the mid-axillary line. The pocket's incision length should be equal to the Battery dimension that is to be inserted into the pocket. The pocket for the Battery is then formed inferior to the incision. The pocket is typically formed beneath subcutaneous fat and superficial to the abdominal muscles, in a manner and sizing similar to conventional pulse generator pockets.

IMPORTANT! Do not remove protective plug from the battery header if performing a test fit with the battery in the pocket.

12. For proper stabilization, the tunnel must traverse the anterior surface of the intercostal muscle for at least 9 cm. After this point the tunneling tool can be directed through anterior tissue layers until the distal tip of the tunneling tool enters the Battery pocket. See Figure 24.

IMPORTANT! When selecting the implant site for the Battery, account for the 30 cm length of the cable between the Transmitter and the Battery. The distance between the implant sites of the Transmitter and Battery must be less than 30 cm so that the cable connection can be easily made without straining the cable. Patient movement and comfort should be considered for Battery implant site selection.

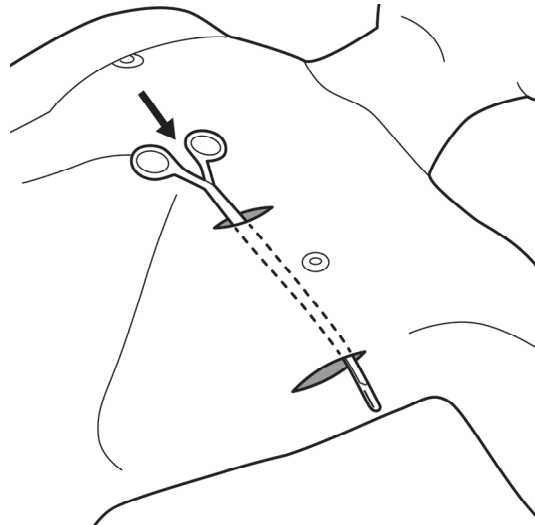


Figure 24: Direct Tunneling Tool through intercostal muscle and anterior tissue layers from Transmitter incision to Battery pocket

13. The Routing Tube is used as a conduit for routing of the cable. Loop the tube through the distal tip of the tunneling tool. Pull the tunneling tool back through the tunnel, leaving the tube in place traversing between the Battery pocket and Transmitter incision. See Figure 25.

IMPORTANT! Use this Routing Tube methodology to avoid damaging the cable connector. DO NOT route the cable by pulling the cable through the channel with surgical instruments. NEVER grasp the cable or cable connector with surgical instruments

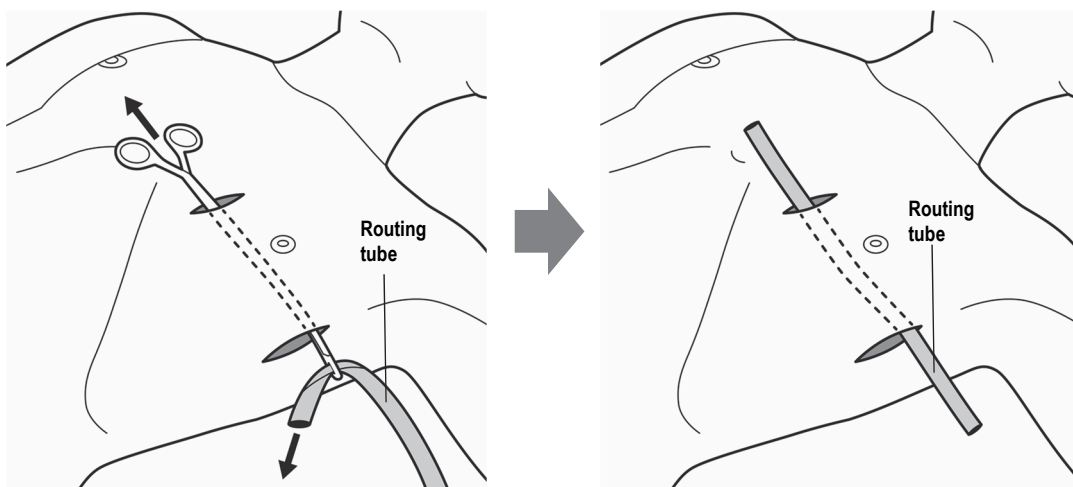


Figure 25: Place Routing Tube for use in Transmitter implant

Positioning and Securing the Transmitter

14. In order to prevent shifting of the transmitter with patient movement, the attachment wings of the Transmitter must be placed on the anterior surface of the costal cartilage with no muscle between the wings and the costal cartilage. Using the small retractor, expose a sufficient area of the costal cartilage to accommodate the attachment wings.
15. The Transmitter must be permanently secured within a tight space to minimize movement of the device. Following the course of the tunnel and with the Routing Tube in place, advance the dilator approximately 7 cm to form a small space for the body of the Transmitter. See Figure 26.

IMPORTANT! Do not form a pocket for the Transmitter, using tools, fingers or other means, as this will lead to an oversized area for the Transmitter, reducing its stability, and potentially impacting performance and battery life of the implanted system.

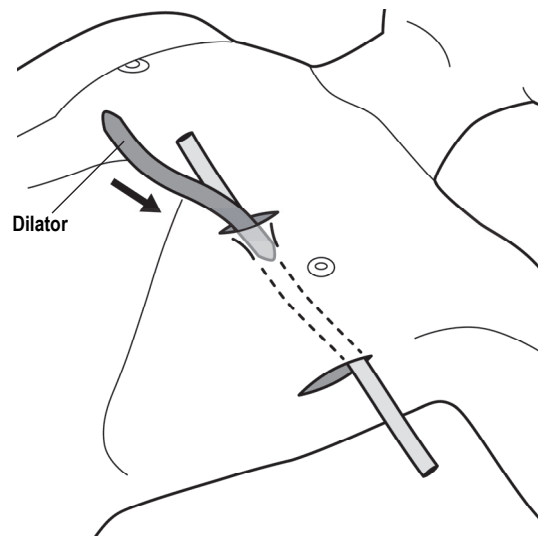


Figure 26: Advance dilator 7 cm to form a small space for the Transmitter's body

16. Insert the Transmitter's cable into the Routing Tube. Slide the Transmitter into the tunnel while also pulling the Routing Tube from the Battery pocket. See Figure 27.

IMPORTANT! Handle the Transmitter cable carefully.

- Do not damage/cut the Transmitter cable.
- Use fingers to grip the cable connector and insert into the Battery connector/header block; do not use any instruments to hold or insert the cable into the header.
- Do not kink the cable during handling or during implant.
- Do not leave a sharp bend radius in the cable implant.
- Do not allow the cable connector to become wet.
- Do not suture around or through the cable

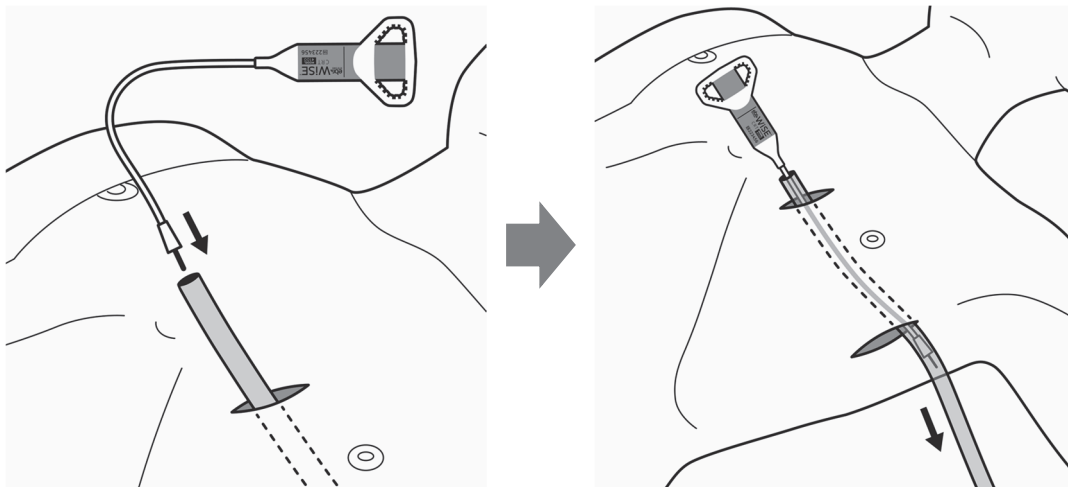


Figure 27: Use the Routing Tube to direct the Transmitter cable into place

17. Remove the Routing Tube from the Transmitter tunnel, leaving the Transmitter and cable in place.

- 18.** Position the Transmitter as medial in the channel as possible while maintaining a stable position of the attachment wings on top of the costal cartilages. The Transmitter with the label should be facing up and the attachment wings on the top of the Transmitter should span the two adjacent cartilages. See Figure 28.

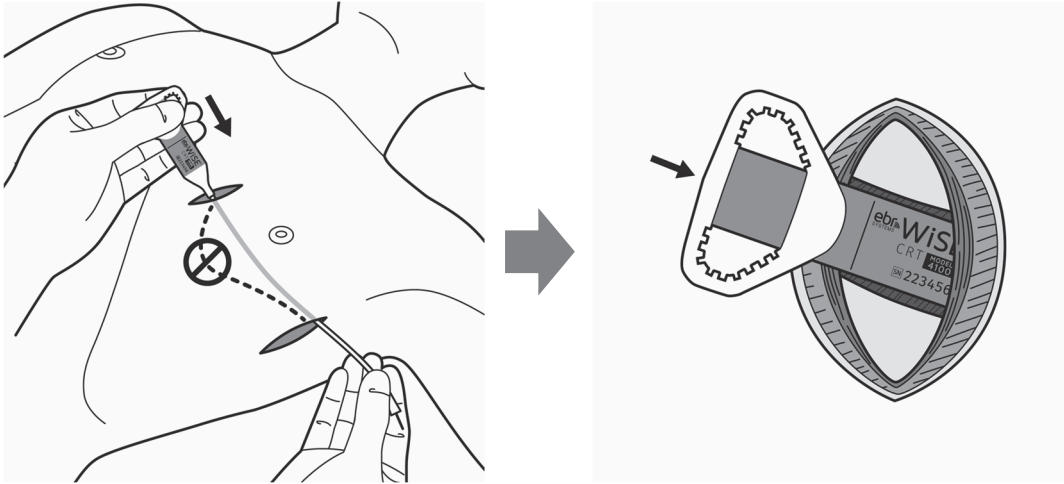


Figure 28: Positioning the Transmitter into the tunnel

- 19.** Retract any muscle tissue under the attachment wings that prevents the wings from sitting directly on top of the costal cartilages. See Figure 29.

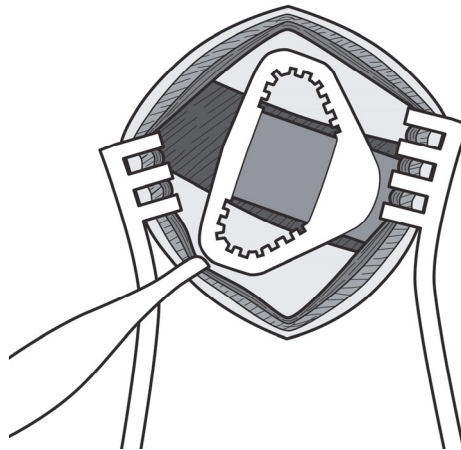


Figure 29: Ensure the Transmitter's attachment wings sit directly on top of the costal cartilages

20. The Transmitter is secured within the ICS with sutures placed through the outer layer (perichondrium) of the costal cartilage and tied over the attachment wings. For deep incisions, use the needle holder. Engage the suture needle through the perichondrium of the costal cartilage. Install a minimum of 1 suture into the superior costal cartilage and a minimum of 1 suture into the inferior costal cartilage. To accommodate variations in the curvature and profile of the costal cartilages, the sutures can be installed anywhere around the perimeter of the attachment wings. To prevent Transmitter movement, tighten all sutures such that they engage the catch features on the internal surface of the attachment wings. See Figure 30.

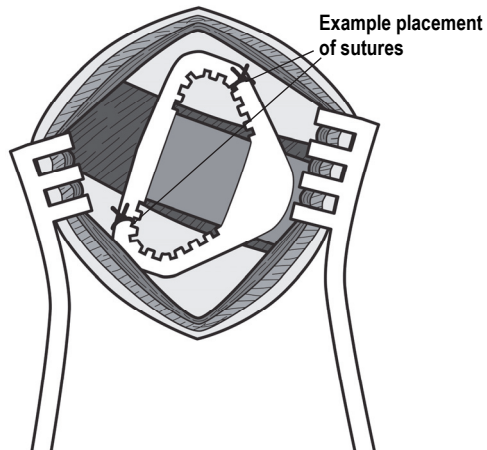


Figure 30: Secure the Transmitter with sutures tied over the attachment wings

Connecting the Transmitter Cable to the Battery

21. The Battery tray contains the Battery with a protective plug in the header block and contains a torque wrench (see Figure 31). To remove the protective plug from the Battery header, insert the torque wrench into the screw port and loosen (counter clockwise) the set screw by carefully unscrewing only two (2) complete rotations. Pull the protective plug from the header and discard.

IMPORTANT! Any time it is necessary to loosen the setscrew, take care not to disengage the screw from the port.

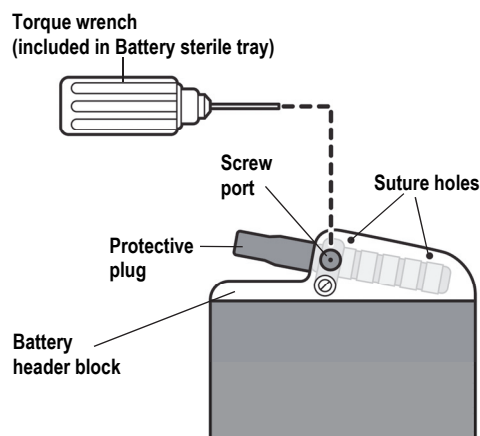


Figure 31: Remove protective plug from Battery

22. Inspect the end of the cable connector. If any fluids are present on the connector contacts, carefully wipe dry.
23. Inspect the Battery header. Ensure that there is no fluid or other material inside the connector block.
24. Insert the cable connector straight into the header block of the Battery until it is fully seated.
25. Visually inspect the header block and verify that there is only a small gap (approximately 1 mm, as shown in Figure 32) between the cable strain relief and the battery header block. If the gap appears larger, loosen the setscrew in ½ turn increments while attempting to insert the connector fully into the battery header.

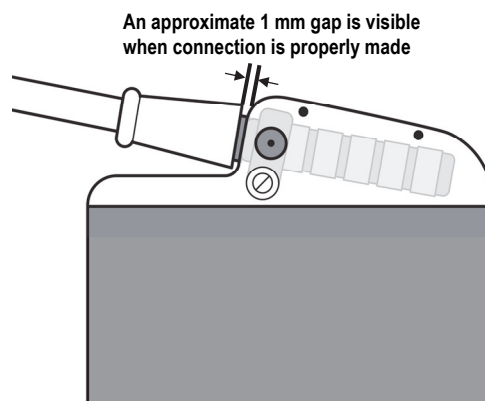


Figure 32: Inspect cable connection to Battery

26. Insert the torque wrench into the screw port and tighten the screw.

IMPORTANT! The screw must be tightened with the torque wrench until the wrench emits an audible click. This audible click indicates that the screw is fully seated.

Confirming functional WiSE CRT System with the Programmer

27. On the WiSE Programmer, select the CONNECT screen from the main menu, then press SEARCH. The Programmer should find the Transmitter and display it by serial number. Select the device then press CONNECT, and confirm that the Programmer connects to the Transmitter then displays a device report screen.



See the WiSE CRT System Programmer Instructions for Use for setup and operating instructions.

Positioning the Battery in the Pocket

- 28.** Check that the cable is secured in place by the setscrew by gently trying to disconnect the cable.
- 29.** Loosely coil any excess cable under the Battery ensuring that the cable is not twisted or kinked.
- 30.** Insert the Battery and cable into the pocket such that the connector block is near the top of the pocket, the logo side is facing anterior (up) and any extra cable is coiled underneath the battery. Consider patient comfort when determining the orientation of the Battery in the pocket. Visualize the location of the suture holes in the battery header and identify proximal tissue for installation of sutures.
- 31.** Remove the battery and cable from the pocket while maintaining the same rotation of the battery and cable coiling if possible.

Securing the Battery in the Battery Pocket

- 32.** The Battery must be permanently secured within the pocket to minimize movement of the device. The Battery header block contains two suture holes for this purpose (see Figure 31). Sutures are used to secure the Battery. The suture holes have been sized for a 2-0/C-15/26 mm cutting Syneture SS-685G suture. Using a non-absorbable suture, install and tie off two sutures at the tissue locations identified in step 30.
- 33.** Thread one end of each tied off suture through the suture holes in the battery header.
- 34.** Insert the coiled cable and battery back into the pocket, sliding the battery down over the tied off sutures.
- 35.** Tighten and tie off both sutures checking to make sure that they are not pinching any portion of the cable.

Completing Implantation of the Transmitter and Battery

- 36.** Flush the Transmitter incision and Battery pocket with sterile saline.
- 37.** Suture closed the Battery pocket and then the Transmitter incision.
- 38.** For the Transmitter incision, suture the overlying muscle layers over the Transmitter such that the Transmitter is secured beneath the overlying muscles. It is important to remove any air from both the Transmitter and Battery implantation sites. While suturing closed the Battery pocket, press on the pocket to force air up and out the Transmitter pocket. Remove any air from the Transmitter incision while suturing it closed.
- 39.** Suture closed the skin layers of the Transmitter Incision and Battery pocket.
- 40.** Complete and review the registration materials provided in the packaging and return the completed registration forms to EBR Systems

4 TECHNICAL SPECIFICATIONS

4.1 TRANSMITTER ULTRASOUND SPECIFICATIONS

TRANSMISSION VALUES			
Ultrasound frequency	921.25 kHz		
Targeting zone	90 deg (+/- 45 deg); range 3-16 cm		
Targeting transmissions per cardiac cycle	Rate: 1-2 kHz (typical)		
	Bursts per cardiac cycle: 5 (typical) -128 (max)		
	Pulse width range: 16 μs		
Pacing transmission	Rate: 2.33 Hz (max)		
	Bursts per cardiac cycle: 1		
	Pulse width range: 0.01 ms – 4.4 ms		
EXPOSURE LEVEL			
	Mechanical Index	Ispta (mW/cm2)	Isppa (W/cm2)
Global Maximum	0.43	49.6	4.44
Nominal	0.17	0.34	0.65

4.2 TRANSMITTER PHYSICAL AND MATERIAL SPECIFICATIONS

TRANSMITTER MODEL 4100 AND CABLE	
Volume (Enclosure)	6 cc
Width x Height x Thickness (Enclosure)	17.4 x 83.0 x 6.8 mm
Length x Diameter – Volume (Cabling)	300 mm x 4 mm (12F) – 4 cc
Mass	22.8 g
Sensing electrode area-Material	2.1 mm ² – Platinum/Iridium
Number of sense electrodes	4
Adjacent sense electrode spacing	Vertical pair spacing: 16 mm
	Horizontal pair spacing: 51 mm
	Front-Back pair spacing: 7 mm
Patient contact materials	Titanium, Alumina, Platinum/Iridium, Epoxy, Silicone, Polyethylene, Parylene

4.3 TRANSMITTER SHIPPED AND RESET VALUES

PERMINENT PARAMETERS		
	Shipped	Reset
Mode	OFF	Saved Memory
Transmit Level	1	Saved Memory
Pulse Width (ms)	0.4	Saved Memory
RV Pacing Spike Detection	Not initialized	Saved Memory
DATA		
	Shipped	Reset
Patient Information	Cleared	Saved Memory
System Counters	Cleared	Cleared
TEMPORARY VOO PARAMETERS		
	Shipped	Reset
Pacing Rate (bpm)	70	Saved Memory
Transmit Level	1	Saved Memory
Pulse Width (ms)	0.4	Saved Memory

4.4 TRANSMITTER PARAMETER TOLERANCES

OPERATIONAL TIMING		
	Range	Tolerance
Sensed Pulse Width Measurements (ms)	0.35 – 2.0	±30.5µs
Transmit Pulse Width (ms)	0.07 – 4.4	±1.1µs
VOO Pacing Intervals (ms)	400 – 2000	±Target delay
Nominal Synch/Targeting Delay (ms)	3	
Max Synch/Targeting Delay (ms)	12.55	

CO-IMPLANT PULSE CHARACTERISTICS		
	Range	Tolerance
Pulse Width Accuracy		±40µs or ±5%
Pulse Width Leading Edge Rise	< 10µs	
Charge Balance Edge Delay	< 200µs	
No Pulse Output after RV Pace (ms)	> 100	

4.5 TRANSMITTER RADIO SPECIFICATION

RADIO OUTPUT POWER			
	Low Frequency	High Frequency	Rated RF Power Output
Medical Implant Comm. Service (MICS)	402 Mhz	405 Mhz	447 uW

4.6 FEDERAL COMMUNICATIONS COMMISSION (FCC)

The FCC ID for this device is 2AMRX-4100.

This device may not interfere with stations operating in the 400.150-406.000 MHz band in the meteorological aids, meteorological-satellite, and earth exploration-satellite services, and must accept any interference received, including interference that may cause undesired operation.

