

CONFIRM Rx™ ICM
with SharpSense™ Technology



CAPTURING
THE **RHYTHM**
OF LIFE



BEST PRACTICE GUIDE
IMPLANT, PROGRAMMING,
CONNECTING AND PAIRING TIPS



REMOTE MONITORING HAS NEVER BEEN SO ENGAGING.



Now powered
by **SharpSense™**
Technology



DELIVER CONVENIENTLY

Remote monitoring via smartphone connectivity with an easy-to-use app encourages patient compliance.



DETECT ACCURATELY

New SharpSense™ Technology significantly reduces false detection of AF, Bradycardia and Pause episodes.

DECIDE CONFIDENTLY

Deeper patient insights can guide a better diagnosis. Decide confidently on the best course of action with Confirm Rx™ ICM.

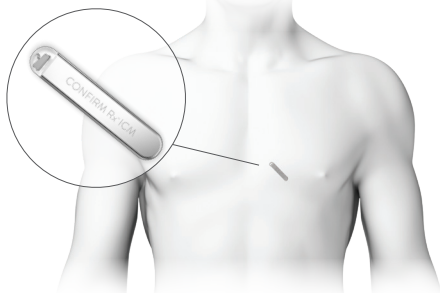
An ICM should not be paired prior to implant. Pairing should only occur after ICM has been successfully implanted.

STEP 1

PATIENT POSITION AND DEVICE PLACEMENT

RECOMMENDATION

- **POSITION** patient supine with chest and head elevated at a 30 degree angle.
- **TARGET DEVICE ORIENTATION**, 45° along the axis of the heart aiming for the ventricular apex.
 - This position helps visualize and accurately mark the 4th intercostal space.
 - Gravity also helps keep the device from migrating back toward the location of the incision.



STEP 2

INSERTION PREPARATION

- **CREATE** incision

REMINDER: Stretch the skin (rather than pinch the skin) when using the incision tool.

- **HOLD** the insertion tool like a syringe.
- **INSERT** at a 45 degree angle until the desired depth is achieved (2-5mm under the skin) and then **FLATTEN** the tool and deliver along a straight plane.

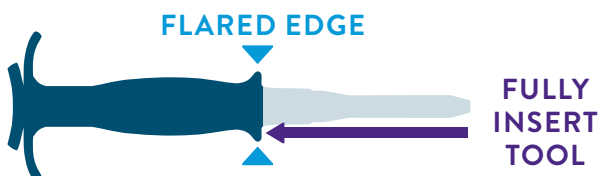


STEP 3

ADVANCE INSERTION TOOL COMPLETELY

RECOMMENDATION

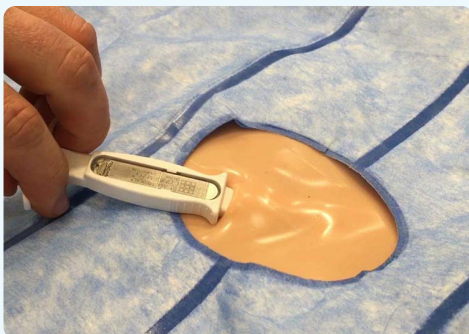
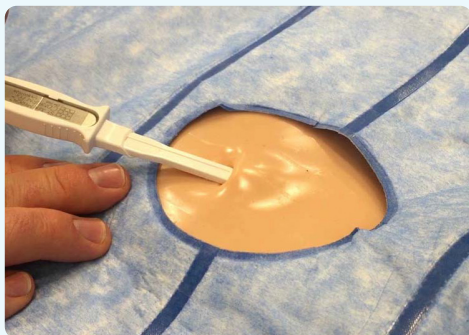
- **ADVANCE** the insertion tool until the flared edge contacts the incision site.



QUICK TIP

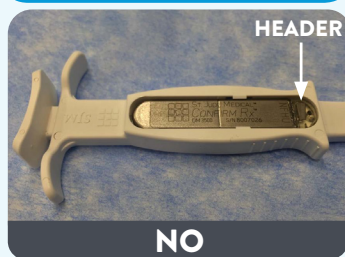
PROPER USE OF THE INSERTION TOOL

- Always **INSERT** in a straight line.
- **DO NOT** wiggle the insertion tool side to side when inserting, this will increase the size of the pocket.

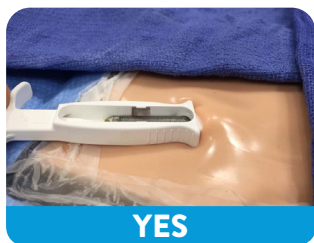


STEP 4**DEVICE INSERTION****THINGS TO AVOID**

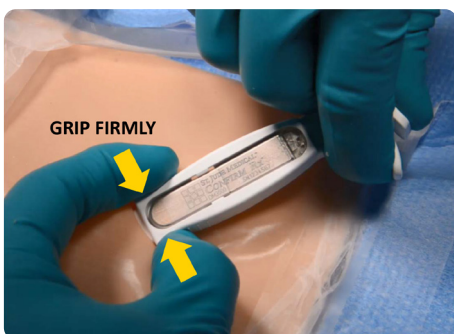
DO NOT flip the device in the insertion tool. This may damage the header or complicate the explant procedure.



- **DO** orient the tool parallel to the body.
- **DO NOT** insert the device into the pocket at an angle.



- Before withdrawing the plunger to deliver the device, **HOLD** the tool firmly in place by gripping the ribbed sides.

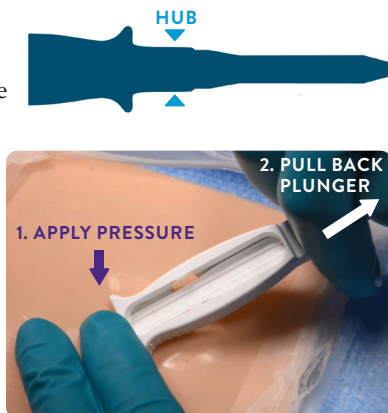


- **INSERT** device by advancing the plunger.

STEP 5**APPLY PRESSURE BEFORE REMOVING INSERTION TOOL****RECOMMENDATION**

- **APPLY** pressure on the incision site before pulling out the insertion tool.

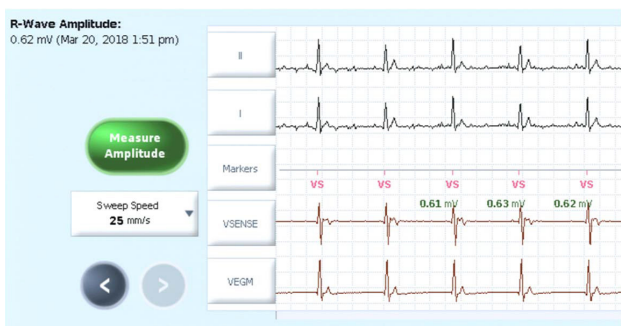
This will help keep the device and header electrode from migrating back toward the incision where the pocket width is larger due to the hub of the insertion tool.

**STEP 6****CHECK SENSING****RECOMMENDATION**

- **CHECK** sensing with the patient in different postures such as upright and lying down.



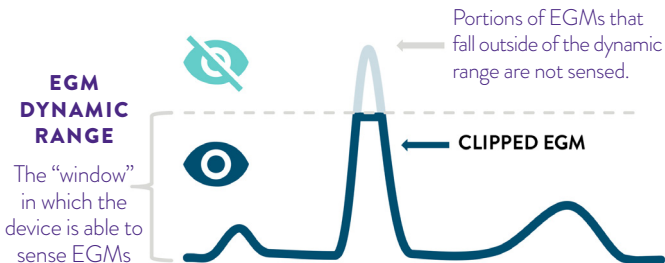
Measured R-wave amplitudes in these positions should have minimal deviation and no artifacts should be seen.



PROGRAMMING EGM DYNAMIC RANGE

EGM DYNAMIC RANGE & MAX SENSITIVITY RELATIONSHIP

Decreasing the Dynamic Range allows for smaller Max Sensitivity values to be programmed which makes the ICM more sensitive.



1

Program the **EGM DYNAMIC RANGE** to ± 1.60 mV.

2

Measure the **R-WAVE AMPLITUDE**.

3

Based on the measured R-wave amplitude, consider programming the **EGM DYNAMIC RANGE** to the value nearest the measured R-wave amplitude.

4

Program **MAX SENSITIVITY** to 1/3rd of the measured R-wave amplitude



CAUTION

Be cautious when programming max sensitivity to **0.05mV***.

* Oversensing may occur and cause noise reversion which inhibits episode recording.

PROGRAMMING SUMMARY

**MEASURED
R-WAVE
AMPLITUDE****> 1.2 mV****0.6 – 1.2 mV****DYNAMIC
RANGE
SETTING****1.6 mV****0.8 mV****MAX
SENSITIVITY
SETTING****0.15 mV****0.125 mV
(nominal) and
Consider ↓
to 0.1 mV****THRESHOLD
START
SETTING****No Change****No Change****DECAY DELAY
SETTING****No Change****No Change**

0.3 – 0.6 mV

< 0.3 mV

0.4 mV

0.2 mV

0.075 mV

0.075 or 0.05* mV

No Change

Consider ↓

No Change

Consider ↓

* Oversensing may occur and cause noise reversion which inhibits episode recording.

IDEAL SMARTPHONE WORKFLOW



PROVIDE PATIENT BROCHURE

Brochures available through your Abbott representative.

REMIND PATIENT TO VIEW WEBSITE

Remind patients to visit the patient website at **ConfirmYourRhythm.com**, where they can watch educational videos and learn more about the device.



DOWNLOAD THE myMERLIN™ MOBILE APP

If possible, download the app prior to the procedure. **REMINDER:** Check device for compatibility.

Patient should contact the clinic if unable to do any of the following:

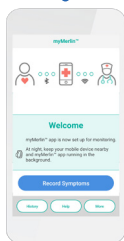
- Download the app
- Install the app
- View the app demo



PAIR CONFIRM Rx™ ICM WITH myMERLIN™ MOBILE APP PROMPTLY

It is best to pair the Confirm Rx™ ICM with the patient's smartphone **within 7 days of the implant**. The cardiac monitor is broadcasting a Bluetooth® signal more frequently during this time.

IMPOTANT NOTE: An ICM should not be paired prior to implant. Pairing should only occur after ICM has been successfully implanted.



KNOWN INCOMPATIBLE SMARTPHONE AND OS COMBINATIONS

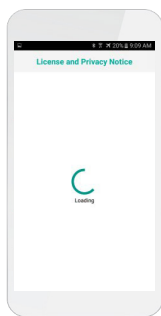
Always report smartphone and OS incompatibility issues to **Remote Care Customer Support** so the below list can be kept up to date.

MANUFACTURER	HANDSET NAME	MODEL NUMBER
HUAWEI	Y5II	CUN-L01
HUAWEI	Y5II	CUN-L21
HUAWEI	HONOR 4C PRO	TIT-L01
MOTOROLA	MOTO G3	XT1032
SAMSUNG	J3	SM-J320F
SAMSUNG	J5	SM-J500FN
SAMSUNG	GALAXY S4	SGH-1337M
LG GOOGLE	NEXUS 5	N/A
OPPO	F1S	N/A
LG	TRACFONE	DESTINY
APPLE	iPHONE	5
APPLE	iPHONE	5C

myMERLIN™ MOBILE APP TIPS

LAUNCHING APP

When opening the myMerlin™ mobile app for the first time, the app may take several minutes to load while data is downloaded from the cloud.



If the app does not load after several minutes, try restarting the phone or reinstalling the app.

END SESSION

Before pairing the Confirm Rx™ ICM to the patient's smartphone, end the device interrogation by pressing **End Session** on the Merlin™ PCS programmer.

The Confirm Rx ICM may only communicate with one device at a time.

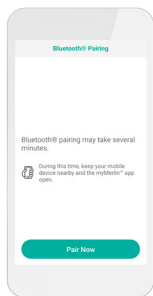


PAIR DEVICE

Tap "Pair Now" on the phone.

If the phone requires a Bluetooth® pairing code, a pairing request for "DM" message will appear.* Enter the code shown above the keypad. **

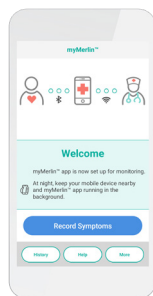
Keep your smartphone within 5 ft/1.5 m of you.



PRACTICE TRANSMISSION

Send a practice transmission after pairing the Confirm Rx ICM to the patient's smartphone. Instruct the patient to **PRESS RECORD SYMPTOMS**.

Discuss practice transmissions with the device clinic before implementing.



KEEP myMERLIN™ MOBILE APP OPEN

Educate the patient on keeping the myMerlin™ mobile app open in the background.

**If your smartphone's text size is too large, you may not see the code.


***If it is an Android[®] device, type in 0000 or 1234.

IMPORTANT TIP













DO NOT close the app or **disable** Bluetooth. Doing so will impact the functionality of the app, including Daily Device Checks and Scheduled Transmissions.

DEVICE SETTINGS

To stay connected to the myMerlin™ mobile app, keep your smartphone on these settings:

 = iPhone⁺ settings

 = Android⁺ settings

 Bluetooth®, cellular data/Wi-Fi ⁺	ON
 Bluetooth®, location services & cellular data/Wi-Fi ⁺	ON
 Background app refresh	ON
 Background data usage	ON
 Automatically update apps	ON
 Automatically update apps	ON
 Font size STANDARD	ON
 Font size NORMAL	ON
 Battery Low Power Mode	OFF
 Battery Saver	OFF
 Offload unused apps	OFF
 Battery optimization for “Confirm Rx™” app	OFF



AVERAGE MONTHLY
DATA USAGE **< 10 MB**
per month****

**** With normal usage

EXAMPLE SYMPTOM EPISODE

PATIENT INITIATES EPISODE RECORDING

Record

Alert Type

HOW ARE DIRECTALERTS™ NOTIFICATIONS CONFIGURED?

Symptom Episode




TRANSMISSION

HOW IS THE DEVICE PROGRAMMED?

On (All Symptoms) OR

RESULT ON MERLIN.NET™ PCN BASED ON RHYTHM


DirectAlerts™ Alerts List

	Symptom Episode
---	-----------------

Symptom Episode Recorded During Sinus Rhythm

OR

DirectAlerts™ Alerts List

	Brady Episode Symptom Episode Tachy Episode
---	---

Symptom Episode Recorded During Tachy/Brady

Symptoms

Alert Classification

Yellow



Off



Data sent at next scheduled follow-up or alert initiated transmission (ex. AF)

SENT IMMEDIATELY

On
(With Detection)

Symptom Episode Recorded During Sinus Rhythm

A symptom episode is recorded and uploaded without alerts

OR

Symptom Episode Recorded During Tachy/Brady

DirectAlerts™ Alerts List	
●	Brady Episode Tachy Episode Symptom w/Detection

CUSTOMER SUPPORT

TECHNICAL SERVICES

CONTACT FOR Device | Programming | Episodes



1-800-722-3774 **US**
+46-8-47-44147 **INTERNATIONAL**



CRMTechnicalServices@abbott.com
US AND INTERNATIONAL

REMOTE CARE TECHNICAL SUPPORT

CONTACT FOR myMerlin™ Mobile App | Merlin.net™ PCN



1-877-696-3754 **US**
+46-8-47-44756 **INTERNATIONAL**



mymerlin@abbott.com **US**
remote.monitoring@abbott.com **INTERNATIONAL**

Abbott

One St. Jude Medical Dr., St. Paul, MN 55117 USA, Tel: 1-651-756-2000

RX ONLY

Brief Summary: Prior to using these devices, please review the Instruction for Use for a complete listing of indications, contraindications, warnings, precautions, potential adverse events and directions for use.

Indications: The Confirm Rx™ ICM is indicated for the monitoring and diagnostic evaluation of patients who experience unexplained symptoms such as: dizziness, palpitations, chest pain, syncope, and shortness of breath, as well as patients who are at risk for other cardiac arrhythmias. It is also indicated for patients who have been previously diagnosed with atrial fibrillation or who are susceptible to developing atrial fibrillation. The Confirm Rx™ ICM has not been specifically tested for pediatric use.

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 insertion device can be tolerated.

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 and Migration. Refer to the User's Manual for detailed indications, contraindications, warnings, precautions and potential adverse events.

Additional Information: Clinicians must log onto Merlin.net™ Patient Care Network to view transmissions from patients' Confirm Rx™ ICM. On Merlin.net™ PCN they can configure transmission schedule and enable or disable features on patient's myMerlin™ mobile app. Review of transmissions is dependent on the clinician and may not happen immediately following delivery of such transmissions.

Limitations: Patients may use their own Apple[®] or Android[®] mobile device to transmit information from their Confirm Rx™ ICM using the myMerlin™ mobile app. To do so the device must be powered on, app must be installed, Bluetooth[®] wireless technology enabled and data coverage (cellular or WiFi[‡]) available. The myMerlin™ app provides periodic patient monitoring based on clinician configured settings. Transmission data is resent if not sent successfully. However there are many internal and external factors that can hinder, delay, or prevent acquisition and delivery of ICM and patient information as intended by the clinician. These factors include: patient environment, data services, mobile device operating system and settings, ICM memory capacity, clinic environment, schedule/configuration changes, or data processing.

An Abbott mobile transmitter is available for patients without their own compatible mobile device.

™ Indicates a trademark of the Abbott group of companies.

‡ Indicates a third party trademark, which is property of its respective owner. Bluetooth and the Bluetooth logo are registered trademarks of Bluetooth SIG, Inc.

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