



CONFIRM Rx™ INSERTABLE CARDIAC MONITOR

WORLD'S FIRST AND ONLY SMARTPHONE-COMPATIBLE ICM



CONVENIENT.



CONNECTED.



CONTINUOUS.



IDENTIFY DIFFICULT TO DETECT ARRHYTHMIAS, INCLUDING ATRIAL FIBRILLATION

Indications: Confirm Rx™ Insertable Cardiac Monitor 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.

Confirm Rx™ ICM is also indicated for patients who have been previously diagnosed with atrial fibrillation or who are susceptible to developing atrial fibrillation.

CONFIRM Rx™ ICM

THE WORLD'S FIRST SMARTPHONE-COMPATIBLE INSERTABLE CARDIAC MONITOR

The Confirm Rx™ ICM is the world's first insertable cardiac monitor that combines a quick and minimally invasive procedure with Bluetooth® wireless technology, allowing patients to connect using their own mobile device. The Confirm Rx™ ICM is designed to be:



CONVENIENT.

Effectively
manage patients

with a quick and minimally invasive procedure and streamlined remote follow-up.



CONNECTED.

Enhance
patient compliance

with smartphone connectivity.



CONTINUOUS.

Empower and
engage patients

with the intuitive myMerlin™ mobile app.



CONVENIENT.
Effectively
Manage Patients

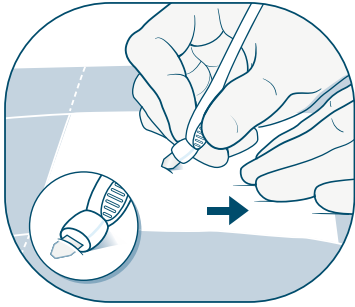


For detailed training and product information:

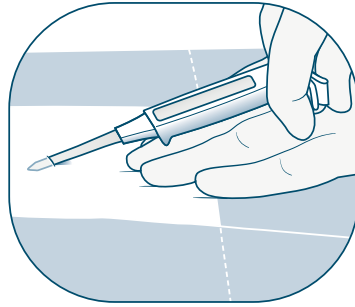
CONFIRM Rx™ ICM: E-Learning Module for Clinicians
SJM.com/ArrhythmiaEducation

A QUICK AND MINIMALLY INVASIVE PROCEDURE

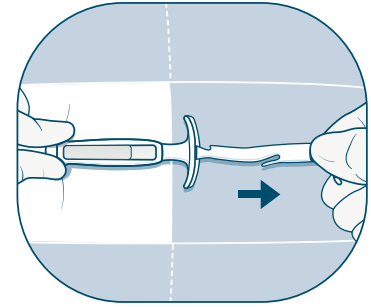
1. Pull back the skin and make incision.



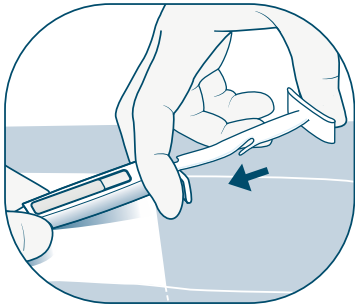
2. Insert the introducer.



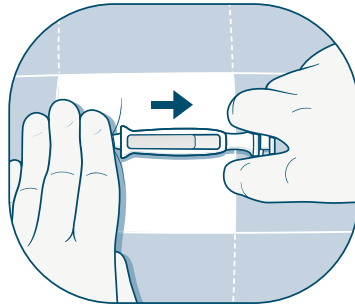
3. Withdraw the plunger.



4. Advance the plunger.



5. Remove the insertion tool.



FINAL STEP:

Apply pressure to the incision site and then remove the insertion tool. If deemed necessary, use the suture hole. Close the incision site.

STREAMLINED REMOTE FOLLOW-UP



FOR IMPLANT:

Simplified Merlin.net™ PCN user interface for Procedure Staff allowing quick patient enrollment and transfer to follow-up clinic.



FOR REMOTE FOLLOW-UP:

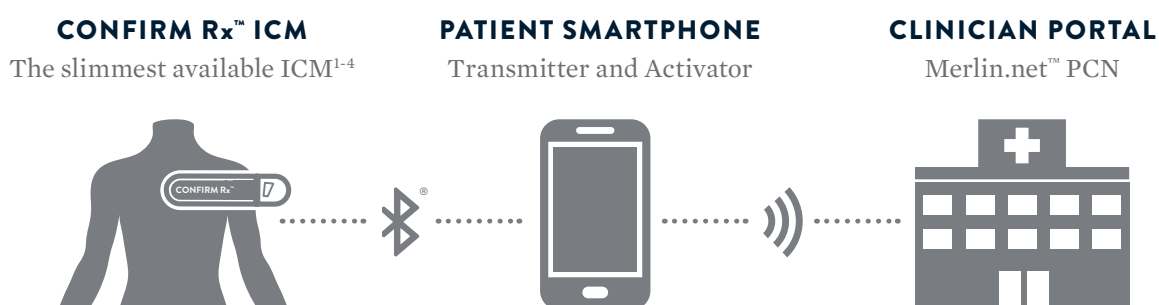
Traditional Merlin.net™ PCN user interface for Follow-up Staff allowing customization of alerts.

CONNECTED.

Enhance Patient Compliance

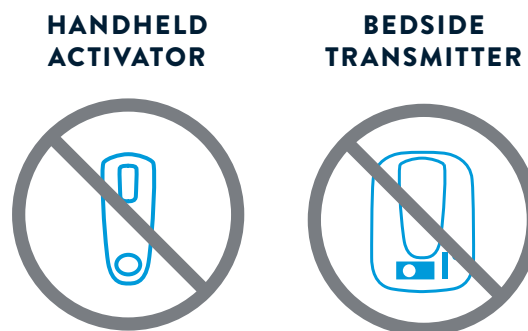
SMARTPHONE CONNECTIVITY

Bluetooth® wireless technology and the myMerlin™ app allow the Confirm Rx™ ICM to connect directly to a patient's existing smartphone. By allowing patients to record and transmit symptoms with the mobile app, Confirm Rx™ ICM brings continuous remote monitoring to patients without the need for a home-based transmitter or patient activator.



PROVIDING GREATER PATIENT FREEDOM AND MOBILITY

An all-in-one integrated transmitter and symptom recorder, the Confirm Rx™ ICM with the myMerlin™ mobile app is the first-and-only monitoring system to eliminate the need for a bedside transmitter and separate activator.



SYSTEM SECURITY MEASURES

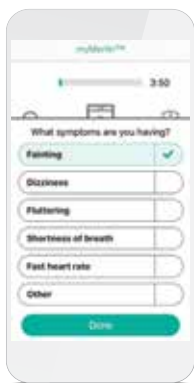
- The ICM encrypts its wireless communication using AES 128-bit encryption and is designed to limit communications to only a single authenticated and paired myMerlin™ mobile app at any given time.
- The ICM uses the pairing procedure specified in Bluetooth® wireless technology low-energy protocols and a proprietary pairing protocol as an added security measure. Pairing requests are authenticated using cloud-based public key cryptography authentication.
- The ICM creates a unique 128-bit key for the paired mobile app and verifies it at the onset of every communication. If the unique key is not verified, the monitor denies access.
- The ICM uses an authorization protocol, which limits a paired mobile app's access based on clinician settings.
- The myMerlin™ mobile app encrypts wireless communication to Merlin.net™ PCN through a secure TLS connection using SHA256 cryptographic protection.
- Merlin.net PCN is housed in a secured data center and is ISO27001:2013 certified. Access to patient data in Merlin.net PCN is restricted to authorized users as set by the clinic administrator. ICM data is encrypted using AES 128-bit encryption.
- Merlin.net PCN is successfully certified through the EU-U.S. Privacy Shield program to transfer patient information from the EU to the U.S.

CONTINUOUS. Empower and Engage Patients

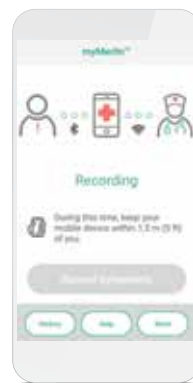
INTUITIVE myMerlin™ MOBILE APP

By engaging patients in their own monitoring, the myMerlin™ mobile app allows clinic staff to focus attention on care and less on managing scheduled checks and transmissions. Data is proactively transmitted by the app per a schedule set by your clinic, thereby minimizing interruptions to your patients' daily lives.

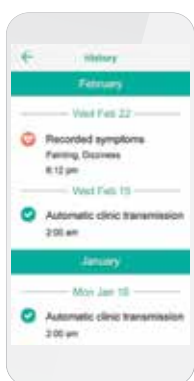
Designed with patient input, the myMerlin™ mobile app allows your Confirm Rx™ ICM patients to:



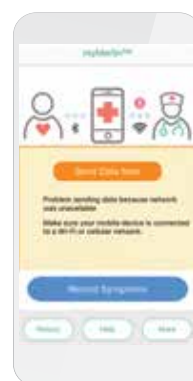
Annotate symptoms with keywords, such as “fainting” or “fluttering,” providing additional clinician insight for a confident diagnosis.



Send symptom transmissions to the clinic without the need to wait for a nightly sync with a traditional transmitter. The app also educates patients on judicious use of this capability to help minimize data burden to the clinic.



View their transmissions and symptom history without having to contact the clinic to confirm successful data transfers.



Receive gentle automatic notifications when patients miss device checks or scheduled transmissions.

Patients may use their own or Android® or Apple® mobile digital 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 connection enabled and data coverage (cellular or Wi-Fi®) available. The myMerlin™ app provides periodic patient monitoring based on clinician configured settings. For further details, refer to the Limitations statement located on the last page.

CONFIRM Rx™ INSERTABLE CARDIAC MONITOR

CONVENIENT. CONNECTED. CONTINUOUS.

For more information, contact your Abbott sales representative or visit www.sjm.com/monitoring

Reference:

1. Abbott. Data on file, Confirm Rx User's Manual. ARTEN100154277 C, 2017/09.
2. Data from BioMonitor 2 Technical Manual. M4183-B 06/17.
3. Data from Medtronic REVEAL LINQ[®] LNQi1 ICM, M955773A001 F, 8/26/15.
4. Data from Medtronic REVEAL[®] XT 9529 ICM, M942691A001D, 11/20/13.

Abbott

One St. Jude Medical Dr., St. Paul, MN 55117 USA, Tel: 1 651 756 2000
SJM.com
St. Jude Medical is now Abbott.

Brief Summary: Prior to using these devices, please review the Instructions 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.

Contraindications: There are no known contraindications for the implantation of the Confirm Rx™ ICM. However, the patient's particular medical condition may dictate whether or not a subcutaneous, chronically implanted 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.

Precautions: 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 or Android[®] or Apple[®] mobile digital 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 connection enabled and data coverage (cellular or Wi-Fi[®]) 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.

© 2018 Abbott All Rights Reserved.

27036-SJM-CFM-1117-0051(2)a | Item approved for global use/A4.

