



THE FUTURE IS HERE

Meet LINQ II™

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Indications, Safety, and Warnings

If you are located in the United States, please refer to the brief statement(s) at right to review applicable indications, safety and warning information. See the device manual for detailed information regarding the implant procedure, indications, contraindications, warnings, precautions, and potential complications/adverse events. For further information, please call Medtronic at 1-763-514-4000 and/or consult the Medtronic website at medtronic.com.

If you are located outside the United States, see the device manual for detailed information regarding instructions for use, the implant procedure, indications, contraindications, warnings, precautions, and potential adverse events. If using an MRI SureScan™ device, see the MRI SureScan technical manual before performing an MRI. For further information, contact your local Medtronic representative and/or consult the Medtronic website at medtronic.com.



www.medtronic.com/manuals

Consult instructions for use at this website. Manuals can be viewed using a current version of any major internet browser. For best results, use Adobe Acrobat Reader® with the browser.

Important Reminder: This information is intended only for users in markets where Medtronic products and therapies are approved or available for use as indicated within the respective product manuals. Content on specific Medtronic products and therapies is not intended for users in markets that do not have authorization for use.

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Brief Statement

Medtronic LINQ II™ Insertable Cardiac Monitor System (ICM) and Remote Monitoring

Indications

The LINQ II ICM is an insertable automatically activated and patient-activated monitoring system that records subcutaneous ECG and is indicated in the following cases:

- Patients with clinical syndromes or situations at increased risk of cardiac arrhythmias
- Patients who experience transient symptoms such as dizziness, palpitation, syncope, and chest pain that may suggest a cardiac arrhythmia

The device has not been tested specifically for pediatric use.

Contraindications

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

Warnings and Precautions

Patients with the LINQ II ICM should avoid sources of diathermy, high sources of radiation, electrosurgical cautery, external defibrillation, lithotripsy, therapeutic ultrasound, and radiofrequency ablation to avoid electrical reset of the device, and/or inappropriate sensing as described in the Medical procedure and EMI Warnings, Precautions and Guidance Manual. MRI scans should be performed only in a specified MR environment under specified conditions as described in the LINQ II MRI Technical Manual.

Wireless accessories available for use with LINQ II may experience connectivity or performance issues. See product manuals for details and troubleshooting instructions.

Potential Adverse Events

Potential adverse events from the LINQ II ICM include, but are not limited to, device rejection phenomena (including local tissue reaction), device migration, infection, and erosion through the skin.

There are no known adverse events associated with the use of any LINQ II ICM wireless accessory.

See the device manuals for detailed information regarding the implant procedure, indications/intended use, contraindications, warnings, precautions, and potential complications/adverse events. For further information, please call Medtronic at 1-800-328-2518 (Technical Services), 1-800-551-5544 (Patient Services), and/or consult the Medtronic website at medtronic.com.

Caution: Federal law (USA) restricts prescription devices to sale by or on the order of a physician.