

Medtronic



Medtronic rotatable connector 5944RL

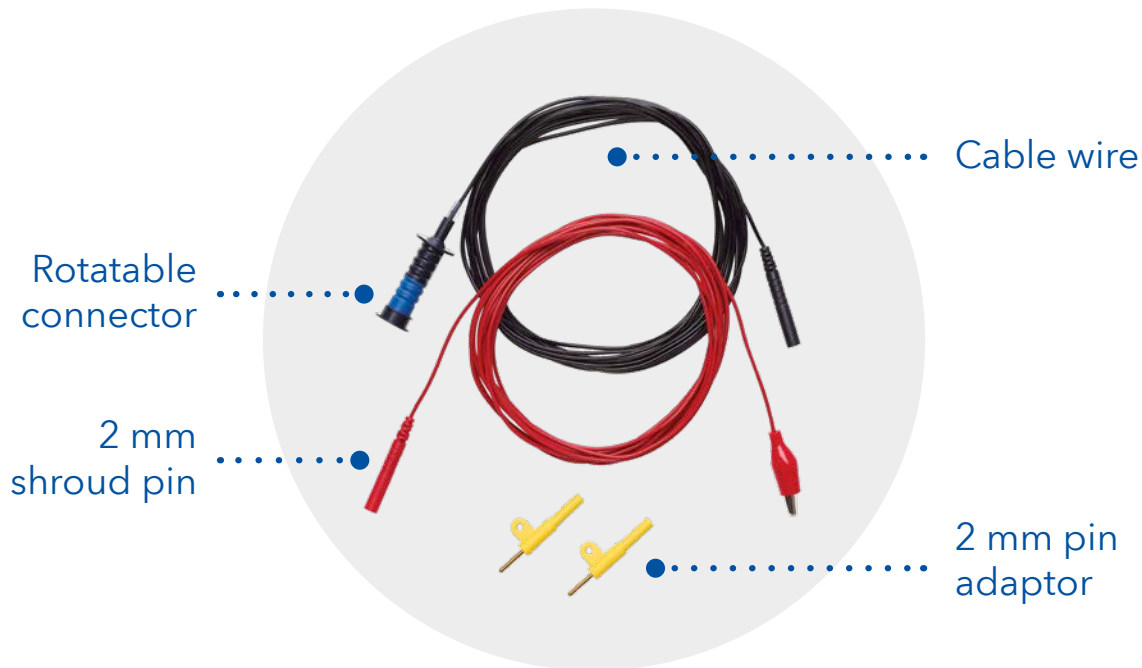
Providing continuous signal
monitoring for SelectSecure™
MRI SureScan™ Model 3830

Streamline the Medtronic 3830 procedure experience

The 5944RL Rotatable Connector is a single-use specialty tool designed to guide implant success and drive procedure efficiencies during Medtronic CSP procedures.

This device consists of a pair of connection cables, which includes:

- Cathode cable (black wire)
- Anode cable (red wire)
- A pair of shrouded pin adaptors



Intended to guide implant success and drive procedure efficiencies with a single point of connection:

- ④ Designed to help achieve target implant location through continuous visualization of ECGs, impedance and 12-lead morphology.
- ④ Eliminates the need to switch between signal monitoring and lead deployment.
- ④ Intended to minimize additional torque resistance during lead rotation.

The rotatable connector is intended to be used with the following Medtronic products:

- Cardiovascular stimulating instruments
- IS-1 leads
- IS-4/DF-4 lead



Compatible with the SelectSecure™ MRI SureScan Model 3830 lead, the first FDA-approved MR Conditional lead for CSP, when paired with single- or dual-chamber Medtronic MRI SureScan systems.



Caution: Federal Law restricts this device to sale by or on the order of a physician (U.S.A.). Please refer to the instructions for use for a complete listing of the indications, contraindications, precautions, and warnings, where applicable.

Indications

The rotatable connector is intended for use as part of a temporary cardiac pacing system. It connects a cardiovascular stimulating instrument to a Medtronic cardiac pacing lead. It is intended for use by trained clinicians in a clinical environment.

For more information about the temporary cardiac pacing system, including indications for use, refer to the technical manuals for the cardiovascular stimulating instruments.

The device is used as part of a temporary cardiac pacing system based on the principle of transmitting electrical signals between the cardiovascular stimulating instrument and the cardiac pacing leads. The device allows real-time continuous and accurate pacing and sensing electrical connection during lead implantation. After the implantation procedure is finished, the device is disconnected and discarded.

The rotatable connector is intended to be used with:

- Medtronic cardiovascular stimulating instruments
- implanted IS-1 leads
- implanted IS-4/DF-4 leads

Contraindications

There are no known contraindications for the Model 5944RL rotatable connector.

General warnings and precautions

Cable handling - When handling the cables, do not allow the exposed metal to contact electrically conductive surfaces or wet surfaces other than the cardiac pacing leads. Do not touch the exposed metal conductive surfaces.

Connection order - Connect the rotatable connector cable system to the cardiovascular stimulating instrument before connecting it to the pacing leads and/or unipolar reference. When disconnecting the cable, disconnect from the pacing leads and/or unipolar reference before disconnecting from the cardiovascular stimulating instrument.

Do not modify - Do not modify this equipment. Modifications may reduce system effectiveness and impact patient health and safety.

Humidity - Do not expose the cable to humidity greater than 95%.
If the package information is damaged - If any information on the outer package is defaced or damaged so that you cannot read it, do not use, and notify Medtronic.

Inspecting the sterile package - Inspect the sterile package and cables with care before opening it.

- Contact a Medtronic representative if the seal, package, or cable is damaged.
- Do not use the product after its expiration date.

Product compatibility - This accessory has not been tested for use with non-Medtronic products.

Review the system documentation - Because the cable system is part of a cardiac pacing system, review all applicable documentation for warnings, complications, precautions, and instructions.

Single-use - This device is intended for single use only. Do not reuse, reprocess, or resterilize this device for the purpose of reuse. Reuse, reprocessing, or resterilization may compromise the structural integrity of the device which could impact performance or create a risk of contamination of the device that could result in patient injury, illness, or death.

Storage temperature - Do not expose the cables to storage temperatures above 30°C (86°F) or below 15°C (59°F).

Transit temperature - Do not expose the cable package to transit temperatures above 70°C (158°F) or below -40°C (-40°F).

Technical manual information - If you find information in this manual that is incorrect or illegible, contact your Medtronic representative.

Product Disposal - The device described in this document must be disposed of in compliance with local, state, or federal guidelines regulating the disposal of such products.

Potential adverse events

These are the potential adverse events that can occur or can require intervention when using this device:

- Allergic reaction
- Cardiac arrest
- Discomfort
- Dizziness
- Fever
- Infection
- Lethargy
- Patient cut, or skin pinched or irritated
- Property or environmental damage
- Skin disorders
- Syncope and/or medical intervention
- Toxic reaction

Note: If a serious incident related to the device occurs, immediately report, immediately report the incident to Medtronic and the applicable competent authority or regulatory body.

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