

Medtronic

OmniaSecure™ MRI SureScan™ 3930M64, 3930M69, 3930M74, 3930M79,
3930M84



Steroid eluting, integrated bipolar, nonretractable screw-in, catheter delivered, transvenous ventricular lead with right ventricle (RV) defibrillation coil electrode

Technical Manual

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

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1 Description

The Medtronic OmniaSecure™ Model 3930M lead is a steroid eluting, integrated bipolar, nonretractable screw-in, catheter delivered, transvenous ventricular lead with an RV defibrillation coil electrode. The lead is designed for pacing, sensing, cardioversion, and defibrillation therapies. The following lead lengths are MR conditional: 64 cm, 69 cm, 74 cm, 79 cm, and 84 cm.

The lead has a nonretractable helical electrode made of titanium nitride coated platinum alloy for active fixation in the endocardium by rotating the lead body in a clockwise direction. Active fixation leads are particularly beneficial for patients who have smooth or hypertrophic hearts where lead dislodgement may be a potential problem.

The distal tip contains a monolithic controlled release device (MCRD) for elution of steroid to reduce inflammatory response within the ventricle. The lead's distal tip contains a target dosage of 72 µg of dexamethasone acetate steroid. Upon exposure to body fluids, the steroid elutes from the lead tip. Steroid reduces pacing thresholds and variability of thresholds.

The RV electrode is a polyurethane backfilled, Pt/Ir clad tantalum defibrillation coil.

The lead features MP35N alloy conductors, silicone inner insulation, and polyurethane outer insulation.

The Medtronic DF4-LLHO¹ four-pole HV inline connector on the lead facilitates device connection during implant. The DF4 connector pin has a color band indicator that may be used to visually confirm proper connection to the device.

¹ DF4-LLHO refers to the international standard ISO 27186, where the lead connector contacts are defined as low voltage (L), high voltage (H), or open (O).

The RV defibrillation coil electrode delivers cardioversion and defibrillation therapies. Pacing and sensing occur between the helix and the RV defibrillation coil electrode. An AccuRead analyzer cable interface tool (ACI tool) is attached to the lead to facilitate accurate electrical measurements during implant.

Note: To implant the Model 3930M lead, a compatible delivery system is required, such as a Medtronic delivery system. Contact your local Medtronic representative for further information regarding compatible delivery systems.

1.1 Medtronic SureScan defibrillation system

A complete SureScan system is required for use in the MR environment. A complete SureScan system includes a Medtronic SureScan device with the appropriate number of Medtronic SureScan leads. Any other combination may result in a hazard to the patient during an MRI scan.

The Model 3930M lead is part of the Medtronic SureScan system. Labeling for SureScan system components displays the SureScan logo and the MR Conditional symbol. To verify that components are part of a complete SureScan system, visit <http://www.mrisurescan.com>.



SureScan logo



MR Conditional symbol. The Medtronic SureScan system is MR Conditional and is designed to allow implanted patients to undergo an MRI scan under the specified MRI conditions for use.

The MRI SureScan feature permits a mode of operation that allows a patient with a SureScan device to be safely scanned by an MRI machine while the device continues to provide appropriate pacing. When programmed to On, MRI SureScan operation disables arrhythmia detection, magnet mode, and all user-defined diagnostics. **Before performing an MRI scan, refer to the SureScan system MRI technical manual for important information about procedures and MRI-specific warnings and precautions.**

1.2 Contents of package

The lead and accessories are supplied sterile. Each package contains the following items:

- 1 lead with anchoring sleeve
- 1 vein lifter
- 1 ACI tool
- Product documentation

1.3 Accessory descriptions

Dispose of all single-use accessories according to local environmental requirements.

Anchoring sleeve – An anchoring sleeve secures the lead to prevent it from moving and protects the lead insulation and conductors from damage caused by tight sutures.

Vein lifter – A vein lifter facilitates catheter or introducer insertion into a vessel.

AccuRead analyzer cable interface (ACI) tool – The ACI tool facilitates accurate electrical measurements during implant and prevents possible connector damage.

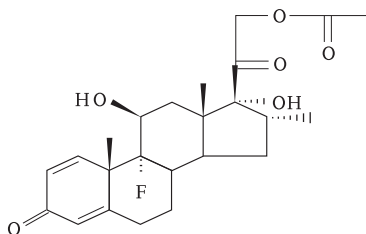
2 Drug component description

The active ingredient in the Model 3930M lead is dexamethasone acetate

[21-(acetyloxy)-9-fluoro-11 β ,17-trihydroxy-16 α -methylpregna-1,4-diene-3,20-dione]. The structural formula for the steroid is shown in *Figure 1*.

Dexamethasone acetate is a white to practically white, odorless powder. It is a practically insoluble ester of dexamethasone, a synthetic adrenocortical steroid.

Figure 1. Structural formula for dexamethasone acetate (DXAC) - C₂₄H₃₁FO₆



The target dosage of dexamethasone acetate is 72 μ g per lead.

3 Indications for use

The Model 3930M lead is intended for use in the right ventricle for sensing, pacing, cardioversion, and defibrillation when a cardiac implantable electronic device is indicated to treat patients who have experienced, or are at significant risk of developing, life-threatening tachyarrhythmias.

This includes adolescent pediatric patients who are at least 30 kg and are also at least 12 years of age, and whose cardiac anatomy is conducive to RV coil placement.

4 Contraindications

The Model 3930M lead is contraindicated for use in the following situations:

Non-right ventricular use – The Model 3930M lead is contraindicated for non-right ventricular implant sites including the His bundle and the atrial side of the tricuspid valve annulus.

Ventricular use – The lead is contraindicated for ventricular use in patients with tricuspid valvular disease or a tricuspid mechanical heart valve.

Steroid use – The lead is contraindicated in patients for whom a single dose of 1.0 mg of dexamethasone acetate may be contraindicated.

Transient ventricular tachyarrhythmias – If tachyarrhythmias with transient or reversible causes exist, including the following known issues (acute myocardial infarction, drug intoxication, drowning, electric shock, electrolyte imbalance, hypoxia, sepsis).

Intravenous Catheterization – The lead is contraindicated in patients with obstructed or inadequate vasculature for intravenous catheterization.

5 Warnings and precautions

A complete SureScan defibrillation system is required for use in the MR environment. Before performing an MRI scan, refer to the MRI technical manual for MRI-specific warnings and precautions.

Note: Medical procedure warnings and precautions that pertain to the Medtronic implanted system are provided in the manual that is packaged with the device or on the Medtronic Manual Library website (www.medtronic.com/manuals).

Inspect the sterile package – Before opening the sterile package, visually check for any signs of damage that might invalidate the sterility of the package contents or compromise the device functionality. Do not use the device and contact your Medtronic representative if the following situations occur:

- The sterile packaging is wet, punctured, opened, or damaged.
- The sterile package seal is damaged.

Use by date – Do not implant the device after the “Use by” date on the package label.

Storage temperature – Store at 25 °C (77 °F). Excursions from this storage temperature are permitted in the range of 15 to 30 °C (59 to 86 °F). (See USP Controlled Room Temperature.) According to USP excursion conditions, transient spikes up to 40 °C (104 °F) are permitted as long as they do not exceed 24 hours.

Sterilization – Medtronic has sterilized the package contents with ethylene oxide before shipment. This product is for single use only and is not intended to be resterilized.

Single use – This device is intended for single use only. Do not reuse, reprocess, or resterilize this device. Reuse, reprocessing,

or resterilization may compromise the structural integrity of the device or create a risk of contamination of the device that could result in patient injury, illness, or death.

Connector compatibility – Although Medtronic lead connectors conform to International Connector Standards, this lead has not been tested for use with non-Medtronic devices. The known potential adverse consequences of using such a combination may include undersensing of cardiac activity, failure to deliver necessary therapy, or an intermittent electrical connection.

Electrophysiologic testing – Electrophysiologic evaluation and testing should be performed at the discretion of the physician taking into consideration the current clinical guidelines.

Steroid use – It has not been determined whether the warnings, precautions, or complications usually associated with injectable dexamethasone acetate apply to the use of this highly localized, controlled-release steroid component. For a list of potential adverse effects, refer to the *Physicians' Desk Reference*.

External defibrillation equipment – Keep external defibrillation equipment nearby for immediate use during acute lead system testing, the implant procedure, or whenever arrhythmias are possible or intentionally induced during post-implant testing.

Defibrillation and guide wires – Do not defibrillate a patient while a guide wire is in the heart. An electrically conductive guide wire may short the output path and may damage the device or leads. Before taking electrical or defibrillation efficacy measurements, the guide wire must be withdrawn proximal to the defibrillation coils on the lead.

Line-powered and battery-powered equipment – An implanted lead forms a direct current path to the myocardium. During lead implant and testing, use only battery-powered equipment or line-powered equipment specifically designed for this purpose to protect against fibrillation that may be caused by alternating currents. Line-powered equipment used in the vicinity of the patient must be properly grounded. Lead connector pins must be insulated from any leakage currents that may arise from line-powered equipment.

Concurrent devices – Output pulses, especially from unipolar devices, may adversely affect device sensing capabilities. If a patient requires a separate stimulation device, either permanent or temporary, allow enough space between the leads of the separate systems to avoid interference between the sensing capabilities of the devices. Previously implanted pacemakers and implantable cardioverter defibrillators should generally be explanted.

Handling the lead – Handle the lead with care at all times.

- Do not implant the lead if it is damaged. Return the lead to your Medtronic representative.
- Do not attempt to straighten or realign the helix if the helix is deformed. Return the lead to your Medtronic representative.
- Protect the lead from materials that shed particles such as lint and dust. Lead insulators attract these particles.
- Handle the lead with sterile surgical gloves that have been rinsed in sterile water or a comparable substance.
- Do not severely bend, kink, or stretch the lead.

- Do not apply pressure to the helix, defibrillation coil, or MCRD.
- Do not use surgical instruments to grasp the lead or connector pin.
- Do not immerse leads in mineral oil, silicone oil, or any other liquid, except blood, at the time of implant.
- Use an anchoring sleeve with all leads. Ensure that the anchoring sleeve is positioned close to the lead connector pin to prevent inadvertent passage of the sleeve into the vein.
- If it is necessary to wipe the lead before insertion, ensure that the anchoring sleeve remains in position.
- Do not force the guide catheter or leads if significant resistance is encountered. Use of guide catheters or leads may cause trauma to the heart. Resistance can be a result of guide catheter occlusion, i.e. kinking, folding, or thrombosis, or that the lead is in contact with cardiac tissue.
- Keep the helix within the guide catheter of the delivery system if passing through the tricuspid valve to prevent damage to the helix, valve, and/or endocardial tissue.

Repositioning or removal of an acute lead – Successfully repositioning the lead depends on recreating the angle and advancement of the catheter present at the time of initial helix deployment at implant (relative to the lead helix and endocardium). Proper orientation helps transfer torque to the helix. This increases the likelihood of successfully disengaging the helix from the endocardium. Improper removal of the lead by pulling may result in avulsion of the endocardium.

Extraction or removal of a chronic lead – Proceed with caution if a chronically implanted lead must be removed or extracted. Lead extraction procedures should be consistent with the most recent editions of HRS or EHRA expert consensus statements regarding cardiovascular implantable electrode device lead management and extraction. Market released extraction tools or clinically recognized techniques may be used to help facilitate extraction. When the risk of lead extraction outweighs the benefit, it may be preferable to abandon unused leads, and leave in place. Return all removed leads, unused leads, or lead sections to Medtronic for analysis.

- Lead removal may result in avulsion of the endocardium, valve, or vein causing internal bleeding, tamponade, and tricuspid valve insufficiency.
- Lead junctions may separate, leaving the lead tip and bare wire in the heart or vein. Careful consideration should be used when deciding if removal is warranted.
- Abandoned leads should be capped to avoid transmitting electrical signals.
- Abandoned severed leads should have the remaining lead end sealed and the lead body sutured to adjacent tissue.

Removal of a chronic lead and the SureScan defibrillation system – When implanting a SureScan defibrillation system, consider the risks associated with removing previously implanted leads before doing so. Abandoned leads or previously implanted non-SureScan labeled leads compromise the ability to safely scan the SureScan defibrillation system during MRI scans.

Magnetic resonance imaging (MRI) – An MRI is a type of medical imaging that uses magnetic fields to create an internal view of the body. If certain criteria are met and the warnings and

precautions provided by Medtronic are followed, patients with an MR Conditional device and lead system are able to undergo an MRI scan; for details, refer to the MRI Technical Manual that Medtronic provides for an MR Conditional device.

Diathermy treatment (including therapeutic ultrasound) – Diathermy is a treatment that involves the therapeutic heating of body tissues. Diathermy treatments include high frequency, short wave, microwave, and therapeutic ultrasound. Except for therapeutic ultrasound, do not use diathermy treatments on cardiac device patients. Diathermy treatments may result in serious injury or damage to an implanted device and lead. Therapeutic ultrasound (including physiotherapy, high intensity therapeutic ultrasound, and high intensity focused ultrasound) is the use of ultrasound at higher energies than diagnostic ultrasound to bring heat or agitation into the body. Therapeutic ultrasound is acceptable if treatment is performed with a minimum separation distance of 15 cm (6 in) between the applicator and the implanted device and lead, as long as the ultrasonic beam is pointing away from the device and lead.

AccuRead tool – The AccuRead tool reduces the risk of connector damage, and reduces the risk of bridging and shorting that may occur while taking electrical measurements during implant. The potential for connector damage, bridging, and shorting is due to variations in analyzer cable terminals, as well as to the connector ring width and the proximity of the rings on the DF4 connector.

6 Potential adverse events

The following are known potential complications associated with the use of this product.

Note: Implant and usage of this product may result in adverse events, which may lead to injury, death, or other serious adverse reactions.

- Allergic reaction
- AV fistula
- Bradyarrhythmia
- Cardiac arrest
- Cardiac inflammation
- Cardiac perforation
- Cardiac tamponade
- Cardiac valve damage
- Discomfort
- Dislodgement
- Dizziness
- Dyspnea
- Embolism
- Erosion
- Extracardiac stimulation
- Excessive fibrotic tissue growth
- Fever
- Hiccups
- Heart block
- Heart failure decompensation (hospitalization)
- Hematoma

- Hemorrhage
- Hemothorax
- Hospitalization
- Inappropriate shock
- Infection
- Insulation failure
- Lead fracture
- Lethargy
- Loss of capture
- Loss of pacing
- Mental anguish
- Nerve damage
- Oversensing
- Palpitations
- Pericardial effusion
- Pneumothorax
- Return of cardiac symptoms
- Seroma
- Skeletal muscle sensation or twitching
- Skin disorders
- Stroke
- SVC tear
- Syncope
- Tachyarrhythmia
- Threshold elevation
- Thrombosis
- Tissue trauma
- Toxic reaction
- Tricuspid valve regurgitation
- Undersensing
- Vascular tear
- Venous occlusion
- Vessel perforation

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

7 Drug information

7.1 Steroid mechanism of action

Steroid suppresses the inflammatory response that is believed to cause threshold rises typically associated with implanted pacing electrodes. Dexamethasone acetate is a synthetic steroid of the glucocorticoid family. Glucocorticoids have potent anti-inflammatory actions via direct and indirect effects on major inflammatory cells. Glucocorticosteroids bind to a cytoplasmic glucocorticoid receptor as well as a membrane-bound receptor. Binding to the cytoplasmic receptor leads to receptor activation and translocation to the nucleus. The receptor interacts with specific DNA sequences within the regulatory regions of affected genes. Thus, glucocorticoids inhibit the production of multiple cell factors that are critical in generating the inflammatory response.

7.2 Pharmacodynamics of the Model 3930M lead

Pharmacokinetics – The pharmacokinetics (local drug levels and systemic levels) of dexamethasone acetate (DXAC) and its

metabolites following lead implantation were not evaluated in human clinical trials. When delivered intra-muscularly, the lipid-soluble dexamethasone acetate is slowly absorbed throughout the tissue.

Metabolism – The conversion of DXAC to dexamethasone occurs within hours. The dexamethasone alcohol (dexamethasone) is the active glucocorticoid used in Medtronic leads. Steroid is applied to the tip and eluted through the electrode tip to the tissue interface where it will be used. Dexamethasone acetate is hydrolyzed into dexamethasone, which is readily absorbed by the surrounding tissue and body fluids. Glucocorticoids, when given systemically, are eliminated primarily by renal excretion of inactive metabolites.

Mutagenesis, carcinogenicity and reproductive toxicology – The mutagenesis, carcinogenicity, and reproductive toxicity of the Model 3930M lead have not been evaluated. However, the mutagenesis, carcinogenicity, and reproductive toxicity of dexamethasone acetate has been evaluated previously.

Carcinogenesis, mutagenesis, impairment of fertility – No adequate studies have been conducted in animals to determine whether corticosteroids have a potential for carcinogenesis (tumor initiation or promotion). Dexamethasone was genotoxic in assays for clastogenicity (including sister chromatid exchange in human lymphocytes) but not in an assay for mutagenicity in Salmonella (Ames test).

Adrenocorticoids have been reported to increase or decrease the number and mobility of spermatozoa in some patients.

Pregnancy – Pregnancy category C. Dexamethasone acetate has been shown to be teratogenic in many species when given in doses equivalent to the human dose. There are no adequate and well-controlled studies in pregnant people. Dexamethasone acetate should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. Studies in mice, rats, and rabbits have shown that adrenocorticoids increase the incidence of cleft palate, placental insufficiency, and spontaneous abortions, and can decrease the intrauterine growth rate.

Breastfeeding or chestfeeding – Systemically administered corticosteroids appear in human milk and could suppress growth, interfere with endogenous corticosteroid production, or cause other untoward effects in breastfeeding or chestfeeding infants. Because of the potential for serious adverse reactions in breastfeeding or chestfeeding infants from corticosteroids, a decision should be made whether to discontinue breastfeeding or chestfeeding or to use a non-steroidal lead, taking into account the importance of the lead and the drug to the patient.

8 Clinical study

Information regarding the Model 3930M lead clinical study is available on the Medtronic Manual Library website:

1. Point your browser to <http://www.medtronic.com/manuals>.
2. Follow the instructions on the website to locate, view, print, or order the Clinical Study Summary.

If you do not have web access, you can order a printed copy of the Model 3930M Clinical Study Summary from your Medtronic representative or by calling the toll-free number located on the back cover.

9 Directions for use

Warning: Before implanting a SureScan system, consider the risks associated with removing previously implanted leads. Abandoned leads or previously implanted leads not tested for MRI compatibility compromise the ability to safely scan the SureScan system during MRI scans.

Warning: Do not force the guide catheter or lead if significant resistance is encountered. Use of guide catheters or leads may cause trauma to the heart.

Note: To implant the Model 3930M lead, a compatible delivery system is required, such as a Medtronic delivery system. A compatible delivery system includes a guide catheter and an introducer valve which allows passage through or removal from a DF4 connector. Contact your local Medtronic representative for further information regarding compatible delivery systems.

Proper surgical procedures and sterile techniques are the responsibility of the medical professional. The following procedures are provided for information only. Some implant techniques vary according to physician preference and the patient's anatomy or physical condition. Each physician must apply the information in these instructions according to professional medical training and experience.

9.1 Recommended methods for minimizing lead implant difficulties

The potential difficulties associated with the lead implant can be minimized using the following recommendations:

Table 1. Recommended methods for minimizing Model 3930M lead implant difficulties.

Potential difficulties	Recommendation
Catheter kinks, folds, or creases during lead implant, resulting in increased lead resistance during deployment.	Extend lead to distal tip of catheter prior to deflecting catheter.
Cardiac perforation from catheter during catheter positioning.	Track catheter over a guide wire to implant location.

Table 1. Recommended methods for minimizing Model 3930M lead implant difficulties. (continued)

Potential difficulties	Recommendation
Cardiac perforation from catheter during lead positioning	When distal tip of guide catheter is near desired location for lead placement, gently advance the lead while retracting the guide catheter to align the distal end of the defibrillation coil with the catheter tip. Avoid extending catheter up against wall.
Cardiac perforation during lead fixation	Avoid over-rotation of the lead; recommend 3-4 turns to affix the helix
Excessive force on lead during the slitting process results in lead dislodgement	Confirm helix fixation, gently advance lead and retract catheter to provide adequate lead slack. Slit off catheter, then establish final amount of slack on lead.

9.2 Preparing the delivery system

Prepare the delivery system for lead implant according to the instructions in the product documentation packaged with the delivery system.

Note: Backup pacing should be readily available during implant. Use of the delivery system or leads may cause heart block.

9.3 Selecting an insertion site

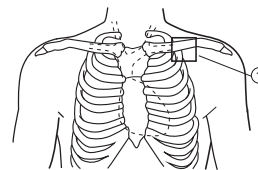
Caution: When using a subclavian approach for insertion, use a more lateral approach to minimize the risk of first rib clavicular crush. First rib clavicular crush may subsequently fracture the lead body.

Caution: Certain anatomical abnormalities, such as thoracic outlet syndrome, may pinch and subsequently fracture the lead body.

The guide catheter assembly may be inserted through several different venous routes, including the right or left cephalic vein, other subclavian branches, or the external or internal jugular vein.

Select an insertion site. See *Figure 2* for an example insertion site.

Figure 2.



1 Example entry site

9.4 Inserting the guide catheter assembly

The guide catheter assembly may be inserted using either the vein lifter in the lead package or the method described in the delivery system product documentation.

The guide catheter assembly may be inserted using venotomy through several venous routes, including the right or left cephalic vein or other subclavian branches. It is recommended to use a guide wire when inserting a guide catheter assembly. Advance the guide catheter over the guide wire to facilitate positioning of the guide catheter and to minimize the risk of tissue damage.

Insert the guide catheter assembly using the vein lifter:

1. Insert the tapered end of the vein lifter into the incised vein (*Figure 3*).

Figure 3.



2. Gently push the tip of the guide catheter assembly underneath the vein lifter and into the vein.

See the delivery system product documentation for the recommended method of inserting the guide catheter assembly.

9.5 Positioning the guide catheter

See the delivery system product documentation for details about positioning the guide catheter in the right ventricle.

9.6 Inserting the lead into the guide catheter

Warning: Keep the helix within the guide catheter's distal tip when passing through the tricuspid valve to prevent damage to the helix, valve, or endocardial tissue.

Caution: If wiping the lead is necessary prior to insertion, avoid snagging the helix in gauze and ensure that the anchoring sleeve remains in position.

Pass the lead through the valve to minimize the backflow of blood. Insert the lead into the guide catheter.

Caution: If more than 5 insertions are required, it is recommended to use a new lead.

9.7 Positioning the lead in the ventricle

Warning: To minimize the occurrence of perforation and dissection, avoid known infarcted or thin ventricular wall areas.

Warning: If there is reason to believe the patient has an unusually thin wall at the apex of the right ventricle, the implanter may want to consider another site for the placement of the lead.

Warning: Excessive torque or tip pressure may cause acute trauma to the endocardium, including possible perforation. The acute trauma may result in temporary high impedance or threshold values.

Warning: Damage to a guide wire may prevent the guide wire from performing with accurate torque response and control and may cause vessel damage.

Position the lead in the ventricle:

1. Using fluoroscopy, position the tip of the guide catheter in the ventricle. See the delivery system product documentation for details about positioning the guide catheter in the ventricle.
2. When the distal tip of the guide catheter is near the desired location for lead placement, gently advance the lead while retracting the guide catheter to align the distal end of the defibrillation coil with the catheter tip.
3. Use fluoroscopy in both right anterior oblique (RAO) and left anterior oblique (LAO) positions as needed to facilitate accurate lead placement. Ensure that the tip is not lodged in the coronary sinus.
4. Rotate the lead body clockwise to affix the helix in the endocardium. Rotate the entire lead body 3 to 4 complete (360°) rotations, depending on patient anatomy, so that the helix is fully embedded in the endocardium.
Note: Use either the lead serial number label or the anchoring sleeve to visually count the number of turns while using fluoroscopy.

Accurate positioning of the electrode is essential for stable pacing and sensing. The above procedure usually results in a satisfactory position.

9.8 Verifying electrode fixation and placement

1. Advance lead and withdraw catheter to watch for slack to build up distal to the catheter to verify fixation. A properly fixated helix will remain in position. If the helix is not properly fixated, the lead tip will move into the right atrium or may become loose.
2. After confirmation of helix fixation, gently advance the lead to provide lead slack in the ventricle to prevent tip dislodgement.
3. Verify that the defibrillation coil electrode is positioned in the right ventricle, below the tricuspid valve annulus.

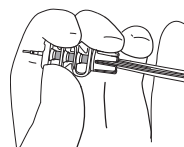
4. Obtain electrical measurements to verify satisfactory placement and electrode fixation. Refer to *Section 9.9*.
5. If a lead must be repositioned or removed, proceed with caution. Refer to the *Section 9.10*.

9.9 Taking electrical measurements

Take electrical measurements:

1. Ensure that the guide catheter is pulled back enough to fully expose the RV defibrillation coil electrode to prevent interference with electrical measurements.
2. Attach the ACI tool. The ACI tool is used to facilitate accurate electrical measurements during implant.
3. Grasp the ACI tool in the most convenient location (See *Figure 4*).

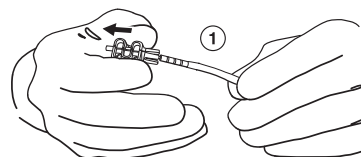
Figure 4.



Caution: The AccuReadtool reduces the risk of connector damage, and reduces the risk of bridging and shorting that may occur while taking electrical measurements during implant. The potential for connector damage, bridging, and shorting is due to variations in analyzer cable terminals, as well as to the connector ring width and the proximity of the rings on the DF4 connector.

Note: The ACI tool may be removed or attached at any time during the procedure. (See *Figure 5*).

Figure 5.



1 Removing the ACI tool from the connector pin

Use the following steps to take electrical measurements:

1. Ensure that the lead connector is completely inserted into the ACI tool. The connector pin will be completely accessible if the ACI tool is properly attached (See *Figure 6*).

Figure 6.



1 When properly attached, all 3 contacts are visible through the ACI tool openings.

2. Attach a surgical cable to the ACI tool. Line up the cable clips with the contacts on the ACI tool to ensure that accurate readings are obtained. (See Figure 15 for specific contacts.)
3. Use a testing device, such as a pacing system analyzer, for obtaining electrical measurements (See Table 2 for recommended measurements). For information on the use of the testing device, consult the product literature for that device.
4. After the electrical measurements are complete, remove the surgical cable from the ACI tool before removing the tool from the lead.

Table 2. Recommended measurements at implant (when using a pacing system analyzer)

Measurements required	Acute ^a lead system	Chronic ^b lead system
Capture threshold (at 0.4 ms pulse width)	≤1.0 V	≤3.0 V
Pacing impedance	200–1500 Ω	200–1500 Ω
Filtered R-wave amplitude (during sinus rhythm)	≥5 mV	≥3 mV

^a <30 days after implant.

^b >30 days after implant.

If initial electrical measurements deviate from the recommended values, it may be necessary to repeat the testing procedure 15 min after final positioning. Initial electrical measurements may deviate from the recommended values:

- Initial impedance values may exceed the measuring capabilities of the testing device, resulting in an error message.
- Values may vary depending upon lead type, implantable device settings, cardiac tissue condition, and drug interactions.

If electrical measurements do not stabilize to acceptable levels, it may be necessary to reposition the lead and repeat the testing procedure.

For more information about obtaining electrical measurements, consult the product documentation supplied with the testing device.

9.10 Repositioning or removal of an acute lead

Warning: Successfully repositioning the lead depends on recreating the angle and advancement of the catheter present at the time of initial helix deployment at implant (relative to the lead helix and endocardium). Proper orientation helps transfer torque to the helix. This increases the likelihood of successfully disengaging the helix from the endocardium. Improper removal of the lead by pulling may result in avulsion of the endocardium.

Caution: If you determine that the lead requires repositioning, consider the possibility that the helix may become deformed and/or entangled as a result of manipulating the lead.

Note: Failure to recreate the orientation of the catheter, present at the time of initial helix deployment, may increase the amount of torque necessary to disengage the helix from the tissue.

9.10.1 Repositioning of an acute lead

Reposition the lead:

1. Recreate the angle and advancement of the catheter present at the time of initial helix deployment (relative to the lead helix and endocardium).
2. Rotate the lead body counterclockwise to withdraw the helix from the implant site.

Note: The number of counterclockwise rotations needed to withdraw the helix from the implant site before applying traction may be greater than the number of revolutions required for fixation.

Note: Release the lead body after 10 complete counterclockwise (360°) turns to allow the lead to unwind. Repeat this process until the helix is withdrawn to the implant site. This action prevents excessive torsion and potential lead damage.

Note: If the helix is still imbedded in the endocardium, additional turns on the lead body should be applied rather than applying a retraction force.

3. Counterclockwise rotation should be continued throughout the repositioning process to decrease the possibility of damage to the cardiovascular tissue.
4. Repeat the positioning procedure and the verifying helix electrode fixation procedure. Use the guide catheter to reposition the lead.

9.10.2 Removal of an acute lead

Remove the lead:

1. Recreate the angle and advancement of the catheter present at the time of initial helix deployment (relative to the lead helix and endocardium).

2. Rotate the lead body counterclockwise to withdraw the helix from the implant site.

Note: The number of counterclockwise rotations needed to withdraw the helix from the implant site before applying traction may be greater than the number of revolutions required for fixation.

Note: Release the lead body after 10 complete counterclockwise (360°) turns to allow the lead to unwind. Repeat this process until the helix is withdrawn from the implant site. This action prevents excessive torsion and potential lead damage.

Note: If the helix is still imbedded in the endocardium, additional turns on the lead body should be applied rather than applying a retraction force.

3. Counterclockwise rotation should be continued throughout the removal process to decrease the possibility of damage to the cardiovascular tissue.
4. Remove the lead from the guide catheter while leaving the guide catheter in place.
5. Remove any tissue from the helix. Verify that the helix electrode, defibrillation coil electrode, and MCRD are not damaged or deformed for reuse.
6. See *Section 9.6* to implant the lead. If the lead cannot be implanted, return the lead to Medtronic for analysis.

9.11 Removing the guide catheter from the lead

Once the lead is in the final position, remove the guide catheter from the lead. See the delivery system product documentation for details. Verify that there is enough lead slack before surgical closure. Repeat electrical measurements; see *Section 9.9*.

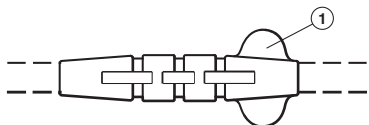
Note: Catheters compatible with the Model 3930M lead are not tested for use with non-Medtronic slitters.

9.12 Anchoring the lead

Caution: Use care when anchoring the lead.

- Use an anchoring sleeve with all leads.
- Do not use absorbable sutures to anchor the lead.
- Do not secure the sutures so tightly that they damage the vein, the lead, or the anchoring sleeve.
- Do not use the anchoring sleeve tabs for suturing (*Figure 7*).
- Do not tie a suture directly to the lead body (*Figure 8*).
- Do not dislodge the lead tip.
- Do not attempt to remove or cut the anchoring sleeve.
- Do not remove the tabs on anchoring sleeves. Tabs are provided to minimize the possibility of the sleeve entering the vein.
- Do not allow the anchoring sleeve to pass into the guide catheter or the venous system.

Figure 7.



1 Tab

Figure 8.



1. Position the anchoring sleeve against or near the vein.
2. Anchor the lead using all three grooves (*Figure 9*, *Figure 10*).
 - Suture all three suture grooves with a non-loosening knot.
 - Use a minimum of one suture around only the anchoring sleeve groove and lead body. Do not tie this knot to fascia.
 - Use a minimum of one suture to secure the anchoring sleeve and the lead body to the fascia with a non-loosening and non-necrosing knot.

Figure 9.

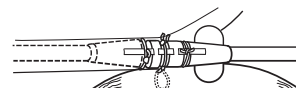
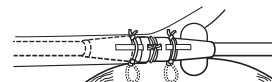


Figure 10.

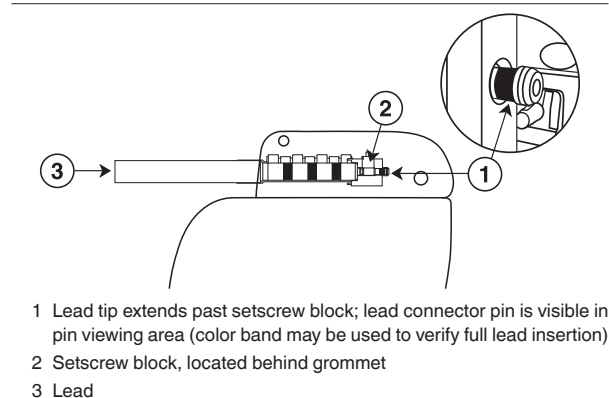


9.13 Connecting the lead

Use the following steps to connect the lead to an implantable device:

1. Make sure that all accessories have been completely removed. When removing the accessories, grip the lead firmly just below the ACI tool on the connector to prevent dislodgement.
2. Push the lead connector into the header block until the color band on the tip of the lead connector pin is visible in the pin viewing area (see *Figure 11*). The color band will be visible when the lead is fully inserted. Consult the product literature packaged with the implantable device for instructions on proper lead connections.

Figure 11. Lead connector pin viewing area

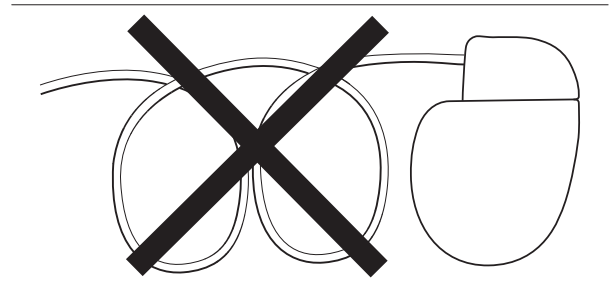


9.14 Placing the device and lead into the pocket

Caution: Use care when placing the device and leads into the pocket.

- Ensure that the leads do not leave the device at an acute angle.
- Do not grip the lead or device with surgical instruments.
- Do not coil the lead. Coiling the lead can twist the lead body and may result in lead dislodgement (*Figure 12*).

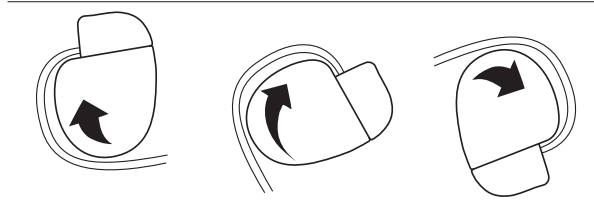
Figure 12.



Use the following steps to place the device and leads into the pocket:

1. To prevent undesirable twisting of the lead body, rotate the device to loosely wrap the excess lead length (*Figure 13*).

Figure 13.



2. Insert the device and leads into the pocket.
3. Before closing the pocket, verify sensing, pacing, and cardioversion. In order to demonstrate reliable defibrillation efficacy, obtain final defibrillation measurements for the lead system.

Warning: If the implanted lead system fails to terminate a VF episode, rescue the patient promptly with an external defibrillator. At least 5 min should elapse between VF inductions.

9.15 Post-implant evaluation

After implant, monitor the patient's electrocardiogram until the patient is discharged. If a lead dislodges, it usually occurs during the immediate postoperative period.

For verifying proper lead positioning include x-rays and pacing and sensing threshold measurements.

In the event of a patient death, explant all implanted leads and devices and return them to Medtronic with a completed Product Information Report form. Call the appropriate phone number on the back cover if there are any questions on product handling procedures.

10 Specifications

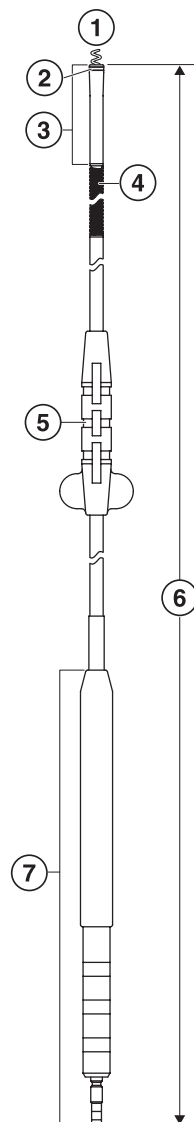
10.1 Specifications

Parameter	Model 3930M
Type	Integrated Bipolar
Chamber	Right ventricle
Fixation	Nonretractable screw-in
Length	64 cm, 69 cm, 74 cm, 79 cm, 84 cm
Connector	DF4-LLHO
Material	Conductors: MP35N
	Connector pin: MP35N
	Connector ring: MP35N
	Inner insulator: Silicone rubber/ETFE
	Outer insulator: Polyurethane

Parameter		Model 3930M
Electrode material	Anchoring sleeve:	Silicone rubber
	Helix:	Titanium nitride coated platinum alloy
	Defibrillation coil:	Pt/IR clad tantalum
Electrode surface area	Helix:	3.6 mm ²
	Defibrillation coil:	371 mm ²
		12.0 mm
Tip to coil spacing		1.6 mm (4.7 Fr)
Lead body diameter		1.8 mm (5.3 Fr)
Helix length (exposed)		1.8 mm
Conductor resistance	Pacing (pin to tip):	25 Ω (64 cm)
		27 Ω (69 cm)
		29 Ω (74 cm)
		31 Ω (79 cm)
		33 Ω (84 cm)
	Defibrillation (connector ring to RV coil):	3.3 Ω (64 cm)
		3.5 Ω (69 cm)
		3.7 Ω (74 cm)
		3.9 Ω (79 cm)
		4.1 Ω (84 cm)
Steroid		Dexamethasone acetate
Target dose of steroid		72 μ g

10.2 Specifications drawing

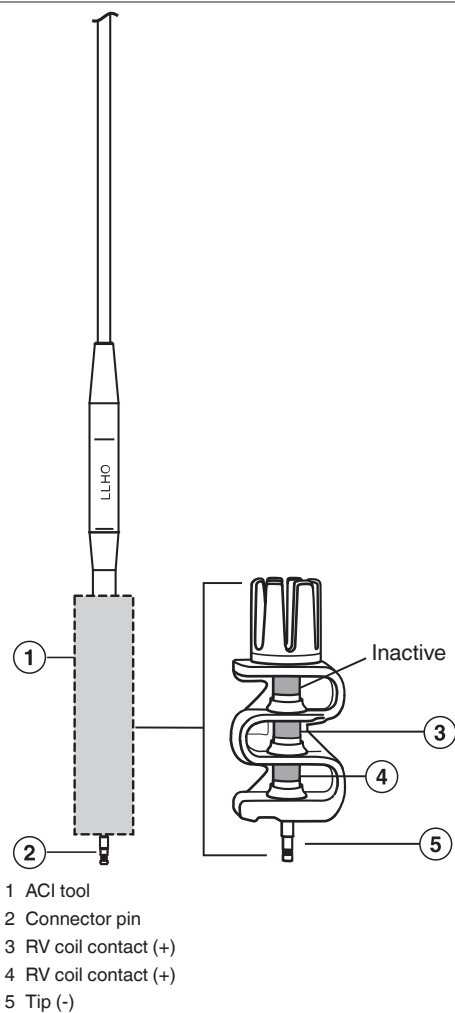
Figure 14.



- 1 Helix electrode surface area: 3.6 mm²
- 2 White silicone steroid monolithic controlled release device (MCRD)
- 3 Tip to coil spacing: 12 mm
- 4 RV defibrillation coil electrode surface area: 371 mm²
- 5 Anchoring sleeve

- 6 Lead length: 64 cm, 69 cm, 74 cm, 79 cm, and 84 cm
7 DF4 connector

Figure 15. Model 3930M proximal lead components



10.2.1 Expected device lifetime

Cardiac leads do not have a defined service life after which they must be removed.

11 Explanation of symbols

Refer to the package labels to see which symbols apply to this product.

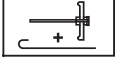
Table 3. Explanation of symbols on package labeling

Symbol	Explanation
	Do not use if package is damaged
	Do not reuse
	Sterilized with ethylene oxide
	Consult instructions for use at this website
	Date of manufacture
	Manufacturer
	Manufactured in
	Use by
	Authorized representative in the European Community
	Reorder number
	Serial number
	Lot number
	A-V distance
	Lead length
	Model number

Table 3. Explanation of symbols on package labeling (continued)

Symbol	Explanation
	Open here
	Package contents
	Product documentation
	Accessories
	Inner diameter
	Outer diameter
	Lead
	Transvenous cardiac vein pacing lead
	Transvenous ventricular lead
	Transvenous atrial lead
	Transvenous lead with one defibrillation electrode
	Transvenous lead with two defibrillation electrodes
	Pace
	Sense
	Defibrillation
	Non-retractable screw-in

Table 3. Explanation of symbols on package labeling (continued)

Symbol	Explanation
	Steroid eluting dexamethasone acetate (DXAC)
	Lead introducer with guide wire
	Catheter
	Catheter delivered
	MR Conditional
	SureScan logo
	Medical Device
	Single sterile barrier system with protective packaging
	Nonpyrogenic
	Contains a medicinal substance
	DF4
	DF4-LLHO

12 Medtronic warranty

For complete warranty information, see the accompanying warranty document.

13 Service

Medtronic employs highly trained representatives and engineers located throughout the world to serve you and, upon request, to provide training to qualified hospital personnel in the use of Medtronic products. Medtronic also maintains a professional staff to provide technical consultation to product users. For more

information, contact your local Medtronic representative, or call or write to Medtronic at the appropriate telephone number or address listed on the back cover.

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www.medtronic.com
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Medtronic USA, Inc.
Toll-free in the USA (24-hour technical consultation for
physicians and medical professionals)
Bradycardia: +1 800 505 4636
Tachycardia: +1 800 723 4636

Technical manuals
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Medical professionals should review manuals before implanting a device, using a device, or performing a follow-up session. Manuals are available from the Medtronic website. To view, download, print, or order manuals for this product, go to www.medtronic.com/manuals or contact your Medtronic representative.

If the product warranty information or the implanted system registration form is not contained in the product package, go to www.medtronic.com/manuals to download a copy.

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USA
www.medtronic.com
+1 763 514 4000

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physicians and medical professionals)
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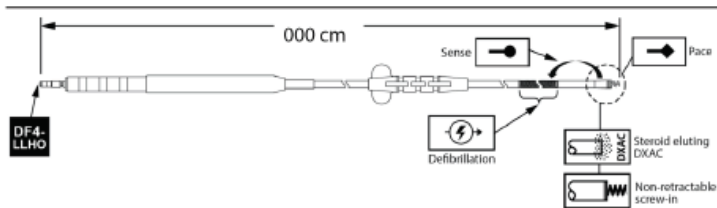
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2018-10-30





DF4 OmniaSecure™ MRI SureScan™ 3930M - 000 cm

Dexamethasone acetate steroid eluting, integrated bipolar, screw-in, catheter delivered, transvenous ventricular lead with RV defibrillation coil electrode.



CAUTION: To prevent suture site damage, the anchoring sleeve provided must be used. See the technical manual for details.

Store at 25°C (77°F). Excursions permitted to 15 - 30°C (59-86°F) [See USP Controlled Room Temperature]

The distal tip contains a nominal dosage of 72 ug dexamethasone acetate.

Lead Body Diameter: { 1.6 mm (4.7 French)
Insertion Diameter: { 1.8 mm (5.3 French)



3930M
REF Prod#000
SN WWW000000W
2000-00-00
YYYY-MM-DD
2000-00-00
YYYY-MM-DD

PIN: W000WVW00W

Medtronic, Inc., 710 Medtronic Parkway, Minneapolis, MN 55432 USA

Manufactured in: Villalba, Puerto Rico, USA

Product of USA

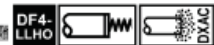
www.medtronic.com

Rx Only

Medtronic

OmniaSecure™ MRI SureScan™ 3930M - 000 cm

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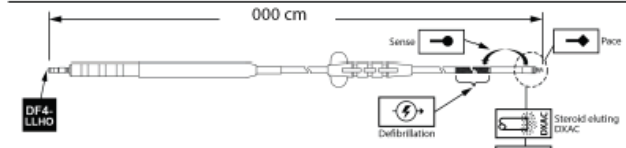


(01)00000000000000(17)000000(21)WWW000000W(20)01



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3930M
REF Prod#000
SN WWW000000W
2000-00-00
YYYY-MM-DD
2000-00-00
YYYY-MM-DD

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Sterile Pack Label



FYR Labels