SUMMARY OF SAFETY AND EFFECTIVENESS DATA (SSED)

I. GENERAL INFORMATION

Device Generic Name: OmniaSecure™ MRI SureScan™

Device Trade Name: OmniaSecure™ MRI SureScan™ Lead Model 3930M

Device Procode: NVY

Applicant's Name and Address: Medtronic, Inc.
Cardiac Rhythm Management
8200 Coral Sea Street NE MVC7
Mounds View, MN 55112

Date(s) of Panel Recommendation: None

Premarket Approval Application (PMA) Number: P240036

Date of FDA Notice of Approval: 04/22/2025

Breakthrough Device: Granted breakthrough device status on November 23, 2021 because of the potential benefit of a small diameter defibrillation lead to the adolescent pediatric population.

II. 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.

III. 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.

IV. WARNINGS AND PRECAUTIONS

The warnings and precautions can be found in the Model 3930M lead labeling.

V. DEVICE DESCRIPTION

The Model 3930M lead (Figure 1) 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.

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.

The RV electrode is a polyurethane backfilled, Platinum/Iridium clad tantalum defibrillation coil.

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

The Medtronic DF4-LLHO 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.

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.

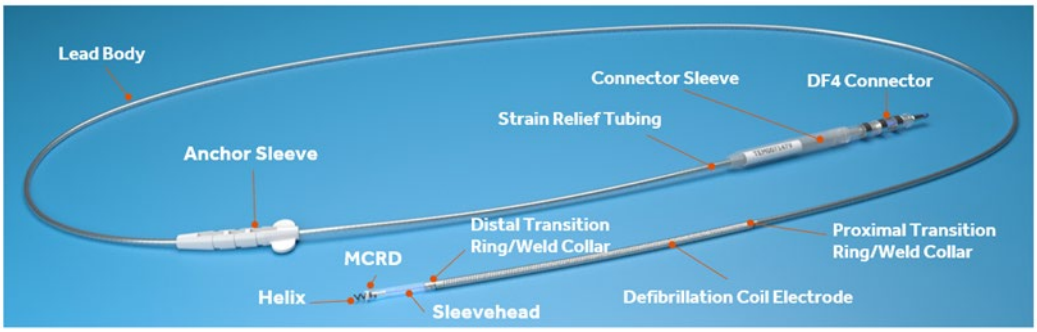

Figure 1: Model 3930M lead

VI. ALTERNATIVE PRACTICES AND PROCEDURES

There are several other alternatives for the correction of life-threatening tachyarrhythmias. These include the use of antiarrhythmic or heart failure medication, electrical ablation and cardiac surgery, and other commercially available implantable cardioverter defibrillators or cardiac resynchronization therapy devices. Each alternative has its own advantages and disadvantages. A patient should fully discuss these alternatives with his/her physician to select the method that best meets expectations and lifestyle.

VII. MARKETING HISTORY

The Model 3930M lead has not been marketed commercially in the United States or any foreign country.

VIII. POTENTIAL ADVERSE EFFECTS OF THE DEVICE ON HEALTH

Below is a list of the potential adverse effects (e.g., complications) associated with the use of the device.

- 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

For the specific adverse events that occurred in the clinical study, please see Section X below.

IX. SUMMARY OF NON-CLINICAL STUDIES

A. Overall Summary of In Vitro Studies

The Model 3930M lead has been evaluated through in-vitro (non-clinical) testing to assure suitability and reliability for its intended use. Design verification and validation demonstrated that the devices meet their design specifications and requirements.

1. Design Validation

Validation was performed by evaluating the compatibility, interaction, and functional operation of the lead using actual and simulated use scenarios. Key areas that were evaluated include: Implantability, Therapy Delivery, Reliability, MRI, and Usability. These areas were evaluated through clinical study, pre-clinical study, human factors testing, analysis, and modeling. Based on the testing, analysis, and review completed, the Model 3930M lead is validated for its intended use.

Implantability and Therapy Delivery:
Reference preclinical study results in Section IX(B) below. Also reference the LEADR clinical study results in Section X. Results show that the Model 3930M lead has been successfully used with respect to implantability and therapy delivery.

Usability:
The validation complies with summative testing requirements described in IEC 62366-1:2015+*AMD1:2020*. New safety mitigations in the instructions for use (IFU) that are associated with critical tasks were evaluated via testing. The goal of validation was to demonstrate that the new language introduced in the Model 3930M lead instructions for use (IFU) as risk controls are understood by intended users to ensure safe and effective use of the lead. The validation study was executed with no deviations from

the plan or protocol. All participants accurately paraphrased and summarized the sections of the user manual they were asked to read and interpret in their own words, without any use errors or close calls, demonstrating a clear understanding of the new language introduced in the Model 3930M lead instructions. Safety mitigations that were not new, unique or different compared to leads already on the market with similar designs, that are associated with critical tasks were evaluated via complaint analysis. Results of the analysis found the Model 3930M lead to be validated for the intended users, uses, and use environments.

MRI:
MRI interactions with the Model 3930M lead have been demonstrated to be safe via in-vivo modeling, analysis, and bench testing per test methods and requirements of ANSI/AAMI PC76-2021 "Active implantable medical devices—Requirements and test protocols for safety of patients with pacemakers and ICDs exposed to magnetic resonance imaging." The safety of the Model 3930M lead, when used with a compatible Medtronic MRI SureScan device, was confirmed by assessing the risks of MRI induced lead electrode heating, MRI induced force and torque on the lead, and potential unintended cardiac stimulation or device malfunction due to the electromagnetic fields of the MRI system. There were no ferromagnetic materials identified in the leads therefore MRI induced force and torque will be safe. The probability of pacing capture threshold increase due to lead electrode heating was confirmed to be low and aligned with marketed leads. The probability of unintended cardiac stimulation was confirmed to be low. Additionally, appropriate device behavior was seen during standardized MRI device malfunction testing per ANSI/AAMI PC76-2021. The results of all testing, analysis, and modeling confirm that the Model 3930M lead, when utilized with a compatible Medtronic device, functions as intended during and following exposure to the MRI environment. The Model 3930M lead is labeled as MR Conditional under specified conditions.

Reliability Modeling:
Reliability was demonstrated via modeling and an understanding of use conditions within a subset of LEADR patients. The modeling was published in the article “High predicted durability for the novel small-diameter Model 3930M lead” in Heart Rhythm September 2024. The reliability modeling projects a 98.2% (95% credible interval, 96.4%–99.7%) fracture-free survival rate of the Model 3930M lead at 10 years, including a10-year fracture-free survival rate of 97.9% (95% credible interval,95.9%–99.5%) in adolescents, exceeding both the modeled and clinical 10-year performance of the highly reliable, larger diameter Sprint Quattro lead.

2. ***Design Verification***

Verification was performed to confirm the lead meets finished device specifications and included the following areas:

- Environmental / Mechanical / Electrical: Nonclinical design verification was conducted on environmental, mechanical, and electrical requirements to demonstrate the Model 3930M lead meets functional requirements (describe what

the components should do), performance requirements (how well the components should perform the functions and electrically), and physical requirements (physical characteristics of the component).

- Connector Testing: Verification was conducted to assure the lead is compliant with the International Standard ISO 27186 (Active implantable medical devices — Four-pole connector system for implantable cardiac rhythm management devices — Dimensional and test requirements).
- MRI Testing: Verification was conducted on MRI requirements in accordance with ISO Standard 10974 which confirm how the lead performs in an MRI environment.
- Lead Reliability: Verification was conducted to demonstrate the lead meets the Reliability requirement.
- Packaging: Verification was conducted on packaging requirements, which describe the physical packaging of the Finished Device.
- Steroid: Nonclinical design verification was conducted on chemical requirements, including those related to Steroid presence, type, and dose.
- Shelf-life/Biostability: Verification was conducted on shelf-life and biostability requirements.
- Catheter DVT: Verification was conducted on accessory compatibility requirements, including Catheters. These requirements describe the interfaces to market-released accessories.
- Sterilization: Verification was conducted to assure sterilization is conducted as per Medtronic standard.
- Biocompatibility: The Model 3930M lead has been evaluated for biological safety as guided by the applicable section of ISO 10993-1:2018/AC:2010 "Biological evaluation of medical devices – Part I: Evaluation and testing within a risk management process." Each biological endpoint applicable to a long-term implant medical device with direct contact with circulating blood has been addressed. The biological risk of the Model 3930M lead in its intended use is low and acceptable (Table 1).

Table 1: Biological Endpoint Safety Assessment Summary

Test Name	Applicable ISO Standard(s)	Result
Physical / Chemical Information	ISO 10993-1 ISO 10993-17 ISO 10993-18	Met Requirements
Cytotoxicity Test (MEM Elution)	ISO 10993-5	Non-cytotoxic

Test Name	Applicable ISO Standard(s)	Result
Maximization Sensitization Test (Guinea Pig)	ISO 10993-10	Non-sensitizer
Intracutaneous / Intradermal Test (Rabbit)	ISO 10993-23	Non-irritant
USP Material Mediated Pyrogenicity (Rabbit)	ISO 10993-11	Non-pyrogenic
Systemic Toxicity Test (Mice)	ISO 10993-11	Non-toxic
ASTM Hemolysis Study – Direct Method	ISO 10993-4	Non-hemolytic
ASTM Hemolysis Study – Extract	ISO 10993-4	Non-hemolytic
Complement Activation (SC5b-9)	ISO 10993-4	Not a complement activator
In Vivo Thrombogenicity (Canine)	ISO 10993-4	Met Requirements
Implantation Effects (Intramuscular and Subcutaneous) - 1 week, 4 weeks, 13 weeks	ISO 10993-6	Met Requirements
Bacterial Reverse Mutation Assay	ISO 10993-3	Non-mutagenic
In Vitro Mouse Lymphoma Assay	ISO 10993-3	Non-mutagenic; Non-clastogenic

A summary overview of relevant Model 3930M lead verification tests, specifications, acceptance criteria and results of associated evaluations are included in Table 2 below.

Table 2: Summary Overview of Model 3930M lead Verification Tests

Test	Test Description	Associated Specification	Acceptance Criteria	Results
Electrical Continuity	Verify the electrical continuity of each conduction path by	DC Resistance	The maximum lead DC resistance for the following conductors shall be specified for the following circuits:	Pass

Test	Test Description	Associated Specification	Acceptance Criteria	Results
	measuring the DC resistance		Low voltage circuit (Pin to Helix) High voltage circuit (R1 to Proximal Defib Coil) High voltage circuit (R1 to Distal Defib Coil)	
		Lead Intermittency	Lead intermittency shall be less than specified value.	Pass
		HIPOT (EN 45502-2-2, Clause 23.3)	Leads shall exhibit no shorting or insulation breakdown when 2000V DC is applied between conductors for a duration of 10 ± 5 seconds. The acceptable current leakage is 2 mA.	Pass
		Connector Functionality, ISO 27186 4.3.8 Current-carrying specification	The lead shall be compliant with the International Standard ISO 27186. ISO 27186 4.3.8 Current-carrying requirement: The high-voltage lead connectors shall be capable of carrying defibrillation current.	Pass
		Connector Functionality, ISO 27186 4.3.7 Dielectric Strength specification	The lead shall be compliant with the International Standard ISO 27186. ISO 27186 4.3.7 Dielectric Strength requirement: The lead connector shall provide a high-voltage electrical	Pass

Test	Test Description	Associated Specification	Acceptance Criteria	Results
			isolation between each of the lead connector contacts and between the contacts and the surrounding fluid.	
Strength of each bond	Determine the strength of each bond, joint, etc., in the lead (lower 95 percent confidence bound) as well as the composite lead strength. Leads should be subjected to a tensile test which simulates the stress it may experience during the implant procedure as well as after implant. Before pull testing, the lead should be soaked in saline for 10 days to simulate any effects of body fluids on the lead body.	Composite Tensile Integrity Test (CTIT) (EN 45502-2-2, Clause 23.3)	The lead shall meet EN 45502-2-2 clause 23.3 when subjected to tensile load of 5N.	Pass
		Connector Functionality, ISO 27186 4.3.2 tensile loads	The lead shall be compliant with the International Standard ISO 27186. ISO 27186 4.3.2 tensile loads: After tensile loading the lead shall meet the linear dimensions in figure 1 and figure 2 measured from datum A and the requirements of 4.2.1.2, 4.3.6, 4.3.7 and 4.3.8	Pass
		Composite Tensile Strength Connector Sleeve to Pin (EN 45502-1, Clause 23.3)	The lead shall remain intact under one of the following conditions: • 6.5 lb minimum force applied between the connector sleeve to connector pin under dry conditions. • 5.2 lb min force applied between the connector sleeve	Pass

Test	Test Description	Associated Specification	Acceptance Criteria	Results
			to connector pin under simulated body conditions.	
		Lead Tensile Strength	The lead shall have a minimum specified tensile strength.	
Leak-proof	For leads that are hermetically sealed at the distal end, verify that the lead is leak-proof when immersed in isotonic saline at 37ºC under physiological pressure for a minimum period of ten days.	Fluid Leakage	The lead from distal tip to connector sleeve shall be absent of fluid leakage as inspected at 7x magnification after immersion in water.	Pass
Corrosion Resistance	Document the corrosion resistance of all conductors and electrode materials in the condition of the finished lead. Address current pulsing when appropriate.	Connector Pin and Ring Corrosion	The lead connector pin and rings shall be free of discoloration at approximately 18 inches (typical) by the unaided eye (vision corrected to 20/20 (typical)) at manufacturing:	Pass
Fatigue Resistance of Conductors	Fatigue resistance of the conductor(s) should be verified. Intact leads should be used for this testing. Loading	Lead Reliability	The lead shall have a combined projected reliability for complications due to conductor fracture and insulation breach of equal to or greater than the specified	Pass

Test	Test Description	Associated Specification	Acceptance Criteria	Results
	conditions that are utilized should be able to be extrapolated to worst-case physiological conditions, i.e., ranges of motion, stresses, etc. Different areas of the lead are subjected to different stresses; this factor should be taken into consideration in the design of an appropriate test protocol. Test methods designed to accelerate fatigue of conductors should be as shown to be able to produce characteristic fracture morphologies that may have been documented previously *in vivo*.		rate. See above Validation section for further detail.	
Connector Mechanical Specification	Connectors intended to be used for joining pulse generators and leads should withstand the	Connector Functionality, ISO 27186 4.3.1 Functional dimensional check	Both initially and after soaking, the force to fully insert the lead connector into the lead connector go gauge	Pass

Test	Test Description	Associated Specification	Acceptance Criteria	Results
	mechanical forces that might occur after implantation.		shall be less than 4.5N.	
		Connector Functionality, ISO 27186 4.3.2 tensile loads	The lead shall be compliant with the International Standard ISO 27186. ISO 27186 4.3.2 tensile loads: After tensile loading the lead shall meet the specified linear dimensions and the requirements of 4.2.1.2, 4.3.6, 4.3.7 and 4.3.8.	Pass
		Connector Functionality, ISO 27186 4.3.3 Deformation due to pin contact forces	The lead shall be compliant with the International Standard ISO 27186. ISO 27186 4.3.3 Deformation due to pin contact forces: The force to withdraw the lead connector from and re-insert it into the test cavity shall not exceed 4.5N. After removal, the lead connector shall meet the contact zone diameter requirements.	Pass

Test	Test Description	Associated Specification	Acceptance Criteria	Results
		Connector Functionality, ISO 27186 4.3.4 Deformation due to ring contact forces	The lead shall be compliant with the International Standard ISO 27186. ISO 27186 4.3.4 Deformation due to ring contact forces: After application and release of the load, the lead connector shall meet the requirements of 4.2.1.5 with the exception of the surface finish requirement, the functional check of 4.3.1 and the electrical requirements of 4.3.6, 4.3.7 and 4.3.8.	Pass
Anchoring Sleeve Performance	Evaluate the performance of the anchoring sleeve packaged with the lead. Testing should assure that the lead will be held securely in place and not damage the lead body when the anchoring sleeve is sutured according to the Instruction for Use.	Anchoring Sleeve Vertical Hold	The anchoring sleeve shall remain in position when the lead is held in a vertical position prior to suturing.	Pass
		Anchoring Sleeve Breakaway Force	The anchoring sleeve shall grip the lead without damage with a specified breakaway force.	Pass
Pressure Exerted by Lead Tip	Measure the force exerted by lead tip and	Distal End Tip Stiffness/Tip Pressure	The lead shall have a tip stiffness force of less than or equal to a	Pass

Test	Test Description	Associated Specification	Acceptance Criteria	Results
	express in units of grams.		specified tip pressure for ventricular.	
In Vitro Elution Rate	Distal subassemblies containing the drug eluting component should be immersed in an appropriate physiologic solution and analyzed at periodic intervals. The amount of steroid eluted over time should be qualified.	Medtronic Steroid Specification	The lead shall meet the Global Chemical Steroid Specification which additionally includes: Description, Identity, Assay, Degradation Products, Content Uniformity, Elution, Sterility (or parametric sterility), Endotoxin, Particulate Matter, and Residual Solvents.	Pass
Shelf-life	Aged leads should be analyzed to determine whether the drug composition/quantity varies over the proposed shelf-life of the product. The performance of aged leads with respect to steroid performance should be demonstrated.	Shelf-life	The product shelf-life shall be minimally 6 months as specified.	Pass

B. Overall Summary of In Vivo Studies

Animal Studies

The following in vivo animal testing was conducted in a canine model to evaluate the performance of the Model 3930M lead.

The pathology objective is to provide gross and histopathology data with the intent to support the safety of the Model 3930M lead, as follows:

- A GLP study was performed for gross evaluations of the major organs (heart, lungs, kidneys, and liver) and body cavities to show that the test group results (Model 3930M lead) are comparable to or no worse than the results in the control group (Model 6935M ICD lead) - regarding the extent of intracardiac peri-lead thrombus and tissue capsule and occurrence of pulmonary thromboembolism.
- Thrombogenicity was evaluated as part of the GLP study to address the hemocompatibility endpoint per Thrombogenicity (In Vivo) ISO 10993-4:2017. All animal studies were conducted in accordance with 21 CFR 58 (Good Laboratory Practices).

A list and description of the animal study conducted is presented in the Table 3 below:

Table 3: Summary of Animal Studies

Study	Animal Model & Count	Duration & Major Endpoints	Endpoints Met?
Safety Study of the Model 3930M lead Model 3930M	16 Canines- Model 3930M lead 4 Canines- Sprint Quattro ICD Lead 6935M (controls for thrombogenicity)	Endpoints: Electrical performance, histopathological characteristics, and hemocompatibility per ISO 10993-1 Implant 0 wks Anesthetized monitors at 0, 2, 4, 8, and 12 wks Awake monitors at 1, 3, and 6 wks Termination and necropsy at 12 weeks	Yes

The GLP safety evaluation of the Model 3930M lead demonstrated favorable safety parameters as defined by the following:

- All animals met electrical implant criteria as documented in the instructions for use for pacing capture threshold, R-wave amplitude, and packing impedance.
- Pacing and sensing remained stable throughout the study.
- Sensing of ventricular tachycardia with subsequent defibrillation therapy met acceptance criteria at all evaluations.
- Pathological evaluations of animals raised no safety concerns.

Overall, the GLP canine study demonstrated that the electrical performance of the Model 3930M lead is within clinical limits of currently marketed ICD leads in all areas of electrical clinical performance. The canine study provided confirmatory evidence of lead electrical performance, histopathological, and stability evidence. Therefore, the study adequately represents effective performance of the Model 3930M lead.

X. SUMMARY OF PRIMARY CLINICAL STUDY

The applicant performed a clinical study to establish a reasonable assurance of safety and effectiveness with the Model 3930M lead 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 in the United States (US)/Canada, Asia Pacific (APAC), Greater China and Europe, Middle East and Africa (EMEA) regions under IDE #G210150. Data from this clinical study were the basis for the PMA approval decision. A summary of the clinical study is presented below.

A. Study Design

Patients were treated between June 21, 2021 and November 14, 2022. The database for this PMA reflected data collected through November 09, 2023 and included 657 patients. There were 47 investigational sites.

The study was a prospective, uncontrolled, multi-center, single-arm, nonrandomized pivotal clinical study. The study had a Bayesian adaptive design, and the number of enrolled subjects in the study was allowed to vary from 500-900 subjects depending on the number of lead fractures observed during the study and on the number of implants as specified in the adaptive design decision rules. The maximum number of subjects enrolled at each site was capped at 50, which is 10% of the minimum number of enrollments (500).

Adult subjects (≥18 years of age), who were indicated for a de novo implantation of a single or dual chamber ICD system or CRT-D system according to the current ACC/AHA/HRS or ESC guidelines and met all inclusion and none of the exclusion criteria, were eligible for enrollment and implant with the Model 3930M lead.

There were two primary objectives for this study (safety and effectiveness). The primary safety objective sample size requirement of 500 subjects refers to subjects who undergo an implant attempt of the Model 3930M lead, while sample size for the primary effectiveness objective was at least 95 subjects, who completed the implant defibrillation testing protocol. All subjects undergoing an implant attempt of the Model 3930M lead were included in the secondary safety objective to estimate fracture-free rate.

The LEADR study design was adaptive with regard to both sample size and follow-up duration. It featured two decision points based on the observed number of fractures in the study. Based on the study decision rules, the initial sample size was 500 subjects with an implant attempt but could have been increased to 800 subjects with an implant attempt, depending on the number of study lead fractures observed. To further account for subjects who enrolled in the study but exit prior to an implant attempt, the protocol allowed for enrollment up to 900 subjects.

All subjects who signed an informed consent were defined as the 'All Enrolled' cohort. All subjects with an implant attempt of the Model 3930M lead were included in the primary analysis for the primary safety and secondary safety objectives. The primary effectiveness objective included a subset (≥95) of enrolled subjects who completed the defibrillation protocol at implant. Subjects who did not complete the defibrillation protocol due to an insufficient number of episodes being inducible were excluded from the analysis.

The sponsor consulted with the Steering Committee before and during the study.

A Clinical Events Committee (CEC) consisting of physicians independent of the study reviews and adjudicates at a minimum of all system- and procedure-related adverse events (AEs) as classified by the investigator or Medtronic, AEs associated with lead system events, and all death events (AEs with fatal outcomes) for their relationship to components of the system (including the Model 3930M lead) and/or procedure. The CEC also provides adjudication of the death classification for all death events.

A Data Monitoring Committee (DMC) consisting of physicians independent of the study was responsible for safeguarding the scientific integrity of the study. The DMC periodically reviewed the total incidence of AEs, followed trends of these events in the study and made recommendations to Medtronic and/or the Steering Committee regarding study conduct and subject safety.

An Episode Review Committee (ERC) consisting of physicians independent of the study evaluated device-treated ventricular episodes and adjudicated true rhythm and success of therapy (shocks and anti-tachycardia pacing (ATP)). Medtronic experts, who served as advisors to expedite the adjudication process but did not adjudicate episodes, also participated as ERC members.

1. Clinical Inclusion and Exclusion Criteria

   Enrollment in the LEADR study was limited to adult patients > 18 years of age who met the following inclusion criteria:

- Subject meets current clinical practice guidelines for ICD or Cardiac Resynchronization Therapy – Defibrillator (CRT-D) implantation and will undergo one of the following:
    - de novo Medtronic CRT-D system implant
    - de novo Medtronic ICD system implant (single or dual chamber)
- Subject has, per local law and requirements, the minimum age for autonomously signing an Informed Consent Form
- Subject is willing to undergo implant defibrillation testing if requested
- Subject is geographically stable and willing and able to complete the study procedures and visits for the duration of the follow-up

Patients were <u>not</u> permitted to enroll in the LEADR study if they met any of the following exclusion criteria:

- Subject is unwilling or unable to personally provide Informed Consent
- Subject has contraindications for standard RV transvenous lead placement (e.g., mechanical right heart valve)
- Subject is contraindicated for ≤1 mg dexamethasone acetate
- Subject has a life expectancy of less than 12 months
- Subject is unable to undergo defibrillation testing (only a subset (≥95) of enrolled subjects undergoing implant of the Model 3930M lead are required to undergo defibrillation testing) due to physician judgement or medical conditions such as
    - Pre-existing or suspected pneumothorax during implant
    - Current intracardiac left atrial or left ventricular (LV) thrombus
    - Severe aortic stenosis
    - Severe proximal three-vessel or left main coronary artery disease without revascularization
    - Unstable angina
    - Ejection Fraction less than 25%
    - Recent stroke or transient ischemic attack (within the last 6 months)
    - Known inadequate external defibrillation
    - Any other known medical condition not listed that precludes their participation in the opinion of the investigator
- Subject is enrolled or planning to enroll in a concurrent clinical study that may confound the results of this study, without documented pre-approval from a Medtronic study manager
- Subject with any exclusion criteria as required by local law (e.g., age or other)
- Pregnant women or breastfeeding women, or women of childbearing potential and

who are not on a reliable form of birth regulation method or abstinence

- Subject with an existing pacemaker (including transcatheter pacing system), ICD, or CRT device or leads
- Subject with any evidence of active infection or undergoing treatment for an infection
- Recent (or planned) cardiac surgery or stenting less than 1 month before implant
- End stage renal disease
- Subjects with New York Heart Association (NYHA) IV classification
- Subjects with a transplanted heart
- Subjects with a history of extracted leads
- Subjects with Left Ventricular Assist Device

2. Follow-up Schedule

All patients were scheduled to return for follow-up examinations at 3, 6, 12, and 18 months postoperatively and every 6 months thereafter until study closure.

Preoperatively, patients were assessed at baseline, implant, discharge. Postoperatively, the objective parameters postoperatively measured during the study in listed in Table 4 below. Adverse events and complications were recorded at all visits.

Table 4: Schedule of Study Events

Study Procedure	Enrollment / Baseline	Implant	PHD	3/6/12/18 Months (in office)	Long-term (post 18 months, remote or in office)	Un-scheduled	System Modification	Study Exit
Informed Consent	X							
Inclusion/Exclusion Assessment	X							
Physical Exam, Demographics, Cardiovascular Medical History, Surgical History	X							
Physician Lead and Catheter Handling Assessment		X					X[3]	
System and procedure information		X					X	
Sensing, Impedance & Pacing Tests		X	X	X	X	X[1]	X	
Defibrillation Testing		X[2]						
Fluoroscopy of final lead position (LAO)		X					X[3]	
Chest Radiographs (AP/PA & Lateral)			X				X[3]	
Save-to-media/Save Session files		X	X	X	X	X	X	X
Medications		X						

Adverse Events (AEs; including AEs with fatal outcome), Device Deficiencies, Study Deviations, Lead and Systems Alerts, Lead Systems Events	As they occur

1 Optional
2 Required for a minimum of 95 subjects.
3 Only required in case of replacement of the Model 3930M lead.
Note: In-person visits could be replaced by other options as per required per local regulations in the case of e.g., a pandemic.

The key timepoints are shown below in Section X (D) Safety and Effectiveness Results.

3. Clinical Endpoints

The primary safety objective was to demonstrate the freedom from major complications related to the Model 3930M lead at 6 months post-implant exceeds a pre-specified threshold of 90%. The objective will be met if the two-sided 95% lower credible bound for the 6-month Model 3930M lead-related major complication-free rate exceeds the pre-specified threshold of 90%.

The endpoint was defined as a subject's first occurrence of a major complication related to the Model 3930M lead, as determined by an independent CEC, that occurs on or prior to 6 months (182 days) post implant.

For an adverse event (AE) to meet the endpoint, the event must have occurred within 182 days (inclusive) of the Model 3930M lead implant and be adjudicated by the CEC as being a major complication related (causal relationship) to the Model 3930M lead.

Major complications are those complications resulting in:

- Death
- Lead Fracture
- Hospitalization (in-patient)
- Prolongation of an existing hospitalization by at least 48 hours
- System Revision (reposition, replacement, explant)

The secondary safety objective was to estimate the fracture-free rate of the Model 3930M lead throughout the study duration.

The primary effectiveness objective was to demonstrate the percentage of subjects successfully defibrillated at implant with the Model 3930M lead exceeds the pre-specified threshold of 88%. The objective will be met if the two-sided 95% lower credible bound for the percentage of subjects successfully defibrillated exceeds the pre-specified threshold of 88%. The endpoint, defibrillation testing success, was defined as:

- One induced shockable ventricular arrhythmia (SSVA) episode successfully terminated with a 18J shock, or

- 2 consecutive SSVA episodes successfully terminated with 25J shocks

B. Accountability of PMA Cohort

At the time of database lock, of 675 patients enrolled in the PMA study, 657 (97.3%) patients are available for analysis at the completion of the study.

The subject disposition is presented in Figure 2, where completed visits, missed visits, and attrition due to exit and deaths up to the 12-month visit are indicated.

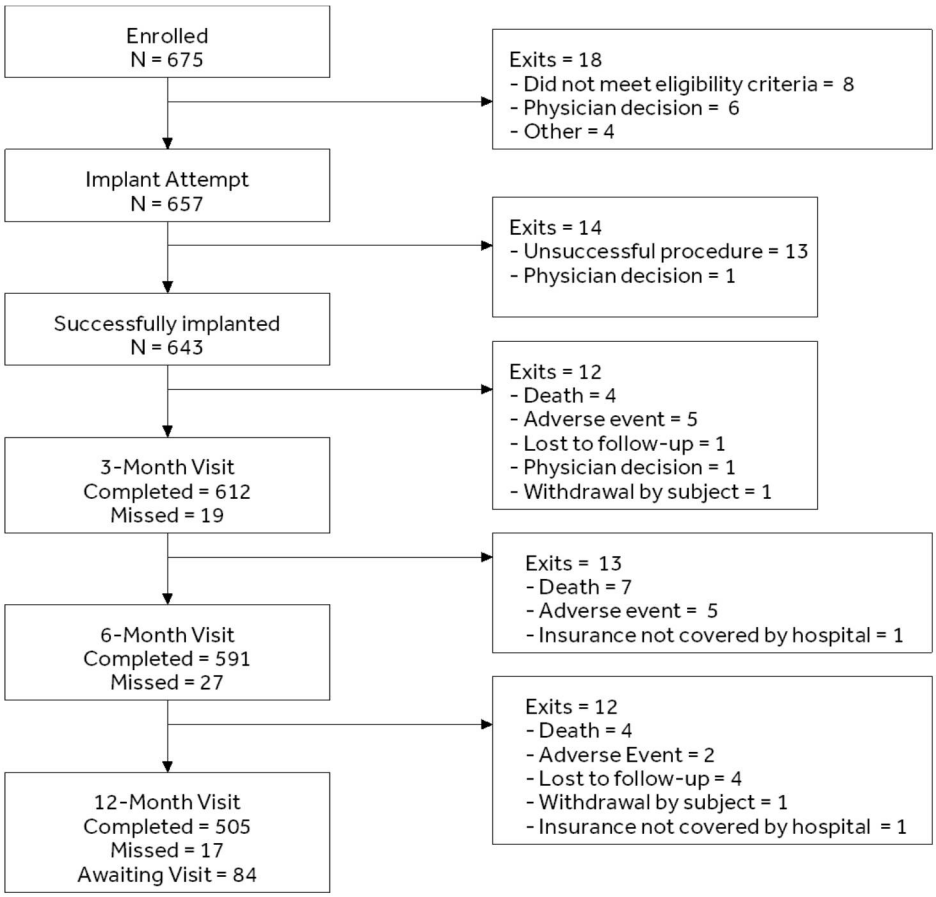

Figure 2: Subject Flowchart LEADR Study

C. Study Population Demographics and Baseline Parameters

The demographics of the study population are typical for a pivotal study performed in the US.

Of 675 enrolled subjects, 663 subjects had a completed baseline case report form (CRF). All 12 subjects with no baseline CRF exited without an implant attempt. All 657 subjects with an implant attempt, i.e., an implant of the study lead was attempted, had a baseline CRF completed.

Among the 657 subjects who underwent implant attempt, 73.8% were male, the average age was 61.8 ± 13.0 years with a minimum of 19 years, and the average body mass index (BMI) was 28.5 ± 6.4 kg/m2 (655 of 657 subjects had measurement available). NYHA classification was performed in 561 of 657 subjects. 17.1% of subjects were known to be NYHA Class I, 59.5% NYHA Class II and 23.4% NYHA Class III. None of the subjects had NYHA class IV which was an exclusion criterion for the study.

There were 97 subjects included in the defibrillation testing main analysis cohort. All 97 subjects had a completed baseline CRF. Among these 97 subjects, the majority were male (79.4%), the average age was 62.7 ± 13.5 years with a minimum age of 29, and the average BMI was 28.5 ±6.8 kg/m2. 83 of 97 subjects had NYHA classification completed and most of these subjects were NYHA Class II (65.1%).

There were several primary indications for device implant. The most common indications for the 657 subjects who underwent an implant attempt were "Subject has nonischemic dilated cardiomyopathy and has an LVEF less than or equal to 35% and is in NYHA functional Class II or III" (26.5%), followed by "Subject has LVEF less than or equal to 35% due to prior myocardial infarction and is at least 40 days post-myocardial infarction and is in NYHA functional Class II or III" (23.6%). These were also the most common indications for subjects in the defibrillation testing main analysis cohort. 25.8% had a primary implant indication of "Subject has nonischemic dilated cardiomyopathy and has an LVEF less than or equal to 35% and is in NYHA functional Class II or III' and 22.7% had the indication of "Subject has LVEF less than or equal to 35% due to prior myocardial infarction and is at least 40 days post- myocardial infarction and is in NYHA functional Class II or III."

Baseline characteristics are summarized in Table 5- Table 14.

Table 5: Subject Demographics

Subject Characteristics	Enrolled (N = 675)	Implant Attempted (N = 657)	Successfully Implanted (N = 643)	Defibrillation Testing Main Analysis Cohort (N = 97)
Sex (N,%)*				
Male	489 (72.4%)	485 (73.8%)	476 (74.0%)	77 (79.4%)
Female	174 (25.8%)	172 (26.2%)	167 (26.0%)	20 (20.6%)
Age (years)**				
Mean ± Standard Deviation	61.9 ± 13.0	61.8 ± 13.0	61.9 ± 12.9	62.7 ± 13.5
Median	64.0	64.0	64.0	65.0
25th Percentile - 75th Percentile	55 - 71	55 - 71	55 - 71	55 - 74
Minimum - Maximum	19 - 92	19 - 92	19 - 92	29 - 85
Number of Subjects with Measure Available (N, %)	663 (98.2%)	657 (100.0%)	643 (100.0%)	97 (100.0%)
Ethnicity (N, %)***	**264**	**261**	**255**	**34**
Hispanic or Latino	22 (8.3%)	22 (8.4%)	22 (8.6%)	2 (5.9%)
Not Hispanic or Latino	234 (88.6%)	232 (88.9%)	226 (88.6%)	32 (94.1%)
Not Reported	3 (1.1%)	3 (1.1%)	3 (1.2%)	0 (0.0%)
Unknown	5 (1.9%)	4 (1.5%)	4 (1.6%)	0 (0.0%)

Race (N, %)**,*****	**354**	**351**	**345**	**71**
American Indian or Alaska Native	1 (0.3%)	1 (0.3%)	1 (0.3%)	0 (0.0%)
Asian	39 (11.0%)	39 (11.1%)	39 (11.3%)	11 (15.5%)
Black or African American	54 (15.3%)	53 (15.1%)	53 (15.4%)	10 (14.1%)
Native Hawaiian or Other Pacific Islander	2 (0.6%)	2 (0.6%)	2 (0.6%)	1 (1.4%)
White	241 (68.1%)	240 (68.4%)	234 (67.8%)	47 (66.2%)
Not reported	5 (1.4%)	5 (1.4%)	5 (1.4%)	1 (1.4%)
Unknown	11 (3.1%)	10 (2.8%)	10 (2.9%)	1 (1.4%)
Other	3 (0.8%)	3 (0.9%)	3 (0.9%)	1 (1.4%)

* Categories do not sum up to 100% due to uncompleted baseline CRFs
**Only the birth year was reported for 6 subjects because the site is unable to provide full date of birth as this is considered identifiable information. The birth date was imputed as "1 July + reported year" to determine subject's age at time of enrollment for these 6 subjects.
***Ethnicity is only collected in US
****Race is only collected in US, Japan, and Australia
***** Multiple response options may be selected.

Table 6: Physical Exam Results

Subject Characteristics	**Enrolled (N = 675)**	**Implant Attempted (N = 657)**	**Successfully Implanted (N = 643)**	**Defibrillation Testing Main Analysis Cohort (N = 97)**
Height (cm)				
Mean ± Standard Deviation	171.2 ± 10.6	171.3 ± 10.5	171.4 ± 10.4	170.0 ± 10.4
Median	171.0	172.0	172.0	170.0
25th Percentile - 75th Percentile	165 - 179	165 - 179	165 - 179	165 - 177
Minimum - Maximum	138 - 203	138 - 203	138 - 203	144 - 194
Number of Subjects with Measure Available (N, %)	661 (97.9%)	655 (99.7%)	641 (99.7%)	97 (100.0%)
Weight (kg)				
Mean ± Standard Deviation	84.1 ± 22.2	84.1 ± 22.3	84.1 ± 22.3	82.6 ± 21.5
Median	81.0	81.0	81.0	78.0
25th Percentile - 75th Percentile	68 - 96	68 - 96	68 - 96	69 - 95
Minimum - Maximum	33 - 191	33 - 191	33 - 191	33 - 165
Number of Subjects with Measure Available (N, %)	661 (97.9%)	655 (99.7%)	641 (99.7%)	97 (100.0%)
BMI (kg/m²)				
Mean ± Standard Deviation	28.5 ± 6.3	28.5 ± 6.4	28.5 ± 6.4	28.5 ± 6.8
Median	27.4	27.4	27.4	27.0
25th Percentile - 75th Percentile	24 - 32	24 - 32	24 - 32	24 - 32
Minimum - Maximum	15 - 52	15 - 52	15 - 52	15 - 50
Number of Subjects with Measure Available (N, %)	661 (97.9%)	655 (99.7%)	641 (99.7%)	97 (100.0%)

Table 7: Cardiac Disease Classification Characteristics

Subject Characteristics	Enrolled (N = 675)	Implant Attempted (N = 657)	Successfully Implanted (N = 643)	Defibrillation Testing Main Analysis Cohort (N = 97)
Was the New York Heart Association (NYHA) Classification performed? *				
Yes	563 (84.9%)	561 (85.4%)	548 (85.2%)	83 (85.6%)
No	40 (6.0%)	37 (5.6%)	37 (5.8%)	3 (3.1%)
Not Applicable	60 (9.0%)	59 (9.0%)	58 (9.0%)	11 (11.3%)
New York Heart Association Classification (N, %)	**563**	**561**	**548**	**83**
Class I	97 (17.2%)	96 (17.1%)	95 (17.3%)	17 (20.5%)
Class II	334 (59.3%)	334 (59.5%)	327 (59.7%)	54 (65.1%)
Class III	132 (23.4%)	131 (23.4%)	126 (23.0%)	12 (14.5%)
Class IV	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
NYHA Classification Not Available	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)

* Categories do not sum up to 100% due to uncompleted baseline CRFs

Table 8: Primary Indication for Implant

Subject Characteristics (N, %) *	Enrolled (N = 675)	Implant Attempted (N = 657)	Successfully Implanted (N = 643)	Defibrillation Testing Main Analysis Cohort (N = 97)

Subject is survivor of cardiac arrest due to ventricular fibrillation or hemodynamically unstable sustained VT excluding any completely reversible causes	61 (9.0%)	59 (9.0%)	59 (9.2%)	10 (10.3%)
Subject has structural heart disease and spontaneous sustained VT, whether hemodynamically stable or unstable	35 (5.2%)	35 (5.3%)	35 (5.4%)	9 (9.3%)
Subject has syncope of undetermined origin with clinically relevant, hemodynamically significant sustained VT or ventricular fibrillation induced at electrophysiological study	5 (0.7%)	5 (0.8%)	5 (0.8%)	1 (1.0%)
Subject has LVEF less than or equal to 35% due to prior myocardial infarction and is at least 40 days post-myocardial infarction and is in NYHA functional Class II or III	155 (23.0%)	155 (23.6%)	150 (23.3%)	22 (22.7%)
Subject has nonischemic dilated cardiomyopathy and has an LVEF less than or equal to 35% and is in NYHA functional Class II or III	174 (25.8%)	174 (26.5%)	169 (26.3%)	25 (25.8%)
Subject has LV dysfunction due to prior myocardial infarction and is at least 40 days post-myocardial infarction, has an LVEF less than or equal to 30%, and is in NYHA functional Class I	15 (2.2%)	14 (2.1%)	14 (2.2%)	4 (4.1%)
Subject has nonsustained VT due to prior myocardial infarction, LVEF less than 40%, and inducible ventricular fibrillation or sustained VT at electrophysiological study	6 (0.9%)	6 (0.9%)	6 (0.9%)	0 (0.0%)
Subject has documented hemodynamically unstable VT and/or VT with syncope and EF equal to or less than 40%	11 (1.6%)	11 (1.7%)	11 (1.7%)	1 (1.0%)
Pediatric/congenital subject is survivor of cardiac arrest after evaluation to define the cause of the event and to exclude any reversible causes	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Subject has symptomatic sustained VT in association with congenital heart disease and has undergone hemodynamic and electrophysiological evaluation	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Subject has unexplained syncope, significant LV dysfunction, and nonischemic dilated cardiomyopathy	7 (1.0%)	7 (1.1%)	7 (1.1%)	2 (2.1%)

Subject Characteristics (N, %) *	**Enrolled (N = 675)**	**Implant Attempted (N = 657)**	**Successfully Implanted (N = 643)**	**Defibrillation Testing Main Analysis Cohort (N = 97)**

Subject has sustained VT and normal or near normal ventricular function	15 (2.2%)	15 (2.3%)	14 (2.2%)	2 (2.1%)
Subject has hypertrophic cardiomyopathy and has 1 or more major risk factors for SCD	52 (7.7%)	52 (7.9%)	51 (7.9%)	5 (5.2%)
Subject has arrhythmogenic right ventricular dysplasia / cardiomyopathy and has 1 or more risk factor for SCD	7 (1.0%)	7 (1.1%)	7 (1.1%)	0 (0.0%)
Subject has long-QT syndrome and is experiencing syncope and/or VT while receiving beta blockers	1 (0.1%)	1 (0.2%)	1 (0.2%)	0 (0.0%)
Subject is nonhospitalized and awaiting transplantation	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Subject has Brugada syndrome and has had syncope	3 (0.4%)	3 (0.5%)	3 (0.5%)	0 (0.0%)
Subject has Brugada syndrome and has documented VT that has not resulted in cardiac arrest	3 (0.4%)	3 (0.5%)	3 (0.5%)	3 (3.1%)
Subject has catecholaminergic polymorphic VT and has syncope and/or documented sustained VT while receiving beta blockers	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Subject has cardiac sarcoidosis, giant cell myocarditis, or Chagas disease	15 (2.2%)	15 (2.3%)	14 (2.2%)	3 (3.1%)
Subject has congenital heart disease with recurrent syncope of undetermined origin in the presence of either ventricular dysfunction or inducible ventricular arrhythmias at EP study	1 (0.1%)	1 (0.2%)	1 (0.2%)	0 (0.0%)
Subject has nonischemic heart disease and has an LVEF of less than or equal to 35% and is in NYHA functional Class I	8 (1.2%)	8 (1.2%)	8 (1.2%)	0 (0.0%)
Subject has long-QT syndrome and risk factors for SCD	1 (0.1%)	1 (0.2%)	1 (0.2%)	0 (0.0%)
Subject has syncope and advanced structural heart disease, and thorough invasive and noninvasive investigations have failed to define a cause	4 (0.6%)	4 (0.6%)	4 (0.6%)	0 (0.0%)
Subject has familial cardiomyopathy associated with sudden death	5 (0.7%)	5 (0.8%)	5 (0.8%)	1 (1.0%)
Subject has LV noncompaction	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Subject has recurrent syncope associated with complex congenital heart disease and advanced systemic ventricular dysfunction for which invasive and noninvasive investigations have not defined a cause	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Other	79 (11.7%)	76 (11.6%)	75 (11.7%)	9 (9.3%)

* Categories do not sum up to 100% due to uncompleted baseline CRFs

Table 9: Left Ventricular Ejection Fraction

Testing Results	Enrolled (N = 675)	Implant Attempted (N = 657)	Successfully Implanted (N = 643)	Defibrillation Testing Main Analysis Cohort (N = 97)

LV Ejection Fraction (%)				
Mean ± Standard Deviation	35.3 ± 14.1	35.2 ± 14.1	35.3 ± 14.1	38.0 ± 13.5
Median	30.6	30.6	30.9	33.0
25th Percentile - 75th Percentile	25 - 40	25 - 40	25 - 40	28 - 48
Minimum - Maximum	10 - 84	10 - 84	10 - 84	25 - 70
Number of Subjects with Measure Available (N, %)	638 (94.5%)	632 (96.2%)	618 (96.1%)	96 (99.0%)

Table 10: Cardiovascular History

Subject Characteristics (N, %)	**Enrolled (N = 675)**	**Implant Attempted (N = 657)**	**Successfully Implanted (N = 643)**	**Defibrillation Testing Main Analysis Cohort (N = 97)**
None of the following	**7 (1.0%)**	**7 (1.1%)**	**7 (1.1%)**	**1 (1.0%)**
Cardiac Arrest	70 (10.4%)	68 (10.4%)	68 (10.6%)	12 (12.4%)
Cardiomyopathy*	**542 (80.3%)**	**540 (82.2%)**	**528 (82.1%)**	**78 (80.4%)**
Ischemic	266 (39.4%)	265 (40.3%)	261 (40.6%)	42 (43.3%)
Non-ischemic	229 (33.9%)	228 (34.7%)	222 (34.5%)	31 (32.0%)
Hypertrophic	67 (9.9%)	67 (10.2%)	65 (10.1%)	9 (9.3%)
Congestive Heart Failure	297 (44.0%)	294 (44.7%)	288 (44.8%)	47 (48.5%)
Coronary Artery Disease	317 (47.0%)	314 (47.8%)	311 (48.4%)	48 (49.5%)
Hypertension	415 (61.5%)	411 (62.6%)	404 (62.8%)	63 (64.9%)
Hypotension	23 (3.4%)	23 (3.5%)	22 (3.4%)	6 (6.2%)
Idiopathic Structural Heart Disease	15 (2.2%)	15 (2.3%)	15 (2.3%)	5 (5.2%)
Left Ventricular Hypertrophy	77 (11.4%)	77 (11.7%)	73 (11.4%)	9 (9.3%)
Myocardial Infarction	233 (34.5%)	229 (34.9%)	224 (34.8%)	41 (42.3%)
Arrhythmogenic RV Dysplasia	8 (1.2%)	8 (1.2%)	8 (1.2%)	0 (0.0%)
Brugada Syndrome	8 (1.2%)	8 (1.2%)	8 (1.2%)	3 (3.1%)
Long Q/T Syndrome	9 (1.3%)	9 (1.4%)	9 (1.4%)	0 (0.0%)
Primary / idiopathic electrical disease, unknown type	3 (0.4%)	3 (0.5%)	3 (0.5%)	1 (1.0%)
Primary / idiopathic electrical disease, other	7 (1.0%)	7 (1.1%)	6 (0.9%)	0 (0.0%)
Stroke*	**53 (7.9%)**	**53 (8.1%)**	**52 (8.1%)**	**6 (6.2%)**
Stroke, ischemic	48 (7.1%)	48 (7.3%)	48 (7.5%)	6 (6.2%)
Stroke, hemorrhagic	5 (0.7%)	5 (0.8%)	4 (0.6%)	0 (0.0%)
Syncope*	**96 (14.2%)**	**95 (14.5%)**	**89 (13.8%)**	**9 (9.3%)**
Due To Arrhythmia	50 (7.4%)	50 (7.6%)	44 (6.8%)	6 (6.2%)
Due To No Arrhythmia Causes	10 (1.5%)	9 (1.4%)	9 (1.4%)	1 (1.0%)
Unexplained / Unknown	37 (5.5%)	37 (5.6%)	37 (5.8%)	2 (2.1%)
Thromboembolism	33 (4.9%)	32 (4.9%)	31 (4.8%)	6 (6.2%)
Transient Ischemic Attack	11 (1.6%)	11 (1.7%)	11 (1.7%)	2 (2.1%)
Vascular Disease, e.g. Peripheral Artery Disease, Aortic Plaque	52 (7.7%)	52 (7.9%)	52 (8.1%)	7 (7.2%)

*Multiple response options may be selected.

Table 11: Cardiovascular Surgical History

Subject Characteristics (N, %)	Enrolled (N = 675)	Implant Attempted (N = 657)	Successfully Implanted (N = 643)	Defibrillation Testing Main Analysis Cohort (N = 97)
None of the following	**377 (55.9%)**	**373 (56.8%)**	**361 (56.1%)**	**50 (51.5%)**
Ablation*	**23 (3.4%)**	**23 (3.5%)**	**23 (3.6%)**	**4 (4.1%)**
AV Node	8 (1.2%)	8 (1.2%)	8 (1.2%)	1 (1.0%)
HIS Bundle	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
VT	15 (2.2%)	15 (2.3%)	15 (2.3%)	3 (3.1%)
Cardiac Transplant	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Coronary Artery Bypass Graft (CABG)	81 (12.0%)	80 (12.2%)	79 (12.3%)	16 (16.5%)
Coronary Artery Intervention*	**220 (32.6%)**	**219 (33.3%)**	**217 (33.7%)**	**33 (34.0%)**
Balloon Angioplasty	59 (8.7%)	58 (8.8%)	57 (8.9%)	6 (6.2%)
Stent	186 (27.6%)	185 (28.2%)	183 (28.5%)	31 (32.0%)
Other	30 (4.4%)	30 (4.6%)	30 (4.7%)	3 (3.1%)
Previous ICM device	8 (1.2%)	8 (1.2%)	8 (1.2%)	2 (2.1%)

*Multiple response options may be selected.

Table 12: Sinus Node Dysfunction or Supraventricular Tachycardia History

Subject Characteristics (N, %)	Enrolled (N = 675)	Implant Attempted (N = 657)	Successfully Implanted (N = 643)	Defibrillation Testing Main Analysis Cohort (N = 97)
None of the following	**394 (58.4%)**	**390 (59.4%)**	**380 (59.1%)**	**57 (58.8%)**
Sinus Node Dysfunction*	**116 (17.2%)**	**116 (17.7%)**	**114 (17.7%)**	**17 (17.5%)**
Bradycardia-tachycardia Syndrome	8 (1.2%)	8 (1.2%)	8 (1.2%)	3 (3.1%)
Chronotropic Incompetence	6 (0.9%)	6 (0.9%)	6 (0.9%)	0 (0.0%)
Sinus Arrest / Pause / Exit Block	9 (1.3%)	9 (1.4%)	9 (1.4%)	0 (0.0%)
Sinus Bradycardia	88 (13.0%)	88 (13.4%)	87 (13.5%)	15 (15.5%)
Sinus Tachycardia	22 (3.3%)	22 (3.3%)	21 (3.3%)	0 (0.0%)
Supraventricular Tachycardia*	**197 (29.2%)**	**195 (29.7%)**	**193 (30.0%)**	**32 (33.0%)**
Atrial Fibrillation*	**171 (25.3%)**	**169 (25.7%)**	**167 (26.0%)**	**29 (29.9%)**
Paroxysmal	110 (16.3%)	109 (16.6%)	108 (16.8%)	20 (20.6%)
Persistent	35 (5.2%)	34 (5.2%)	34 (5.3%)	5 (5.2%)
Long-standing Persistent	9 (1.3%)	9 (1.4%)	8 (1.2%)	2 (2.1%)
Permanent	21 (3.1%)	21 (3.2%)	21 (3.3%)	2 (2.1%)
Atrial Flutter	44 (6.5%)	44 (6.7%)	44 (6.8%)	9 (9.3%)
Atrial Tachycardia	27 (4.0%)	27 (4.1%)	27 (4.2%)	2 (2.1%)

*Multiple response options may be selected.

Table 13: Ventricular Arrhythmia, AV Junctional Arrhythmia or Block History

Subject Characteristics (N, %)	Enrolled (N = 675)	Implant Attempted (N = 657)	Successfully Implanted (N = 643)	Defibrillation Testing Main Analysis Cohort (N = 97)
None of the following	**210 (31.1%)**	**208 (31.7%)**	**203 (31.6%)**	**38 (39.2%)**
Ventricular Arrhythmias*	**326 (48.3%)**	**323 (49.2%)**	**318 (49.5%)**	**41 (42.3%)**
Premature Ventricular Complexes	157 (23.3%)	157 (23.9%)	154 (24.0%)	16 (16.5%)
Torsades De Pointes	5 (0.7%)	5 (0.8%)	5 (0.8%)	0 (0.0%)
Ventricular Fibrillation	44 (6.5%)	42 (6.4%)	42 (6.5%)	9 (9.3%)
Ventricular Flutter	3 (0.4%)	3 (0.5%)	3 (0.5%)	0 (0.0%)
Ventricular Tachycardia*	**238 (35.3%)**	**237 (36.1%)**	**233 (36.2%)**	**32 (33.0%)**
Ventricular Tachycardia, Non-sustained	172 (25.5%)	171 (26.0%)	168 (26.1%)	25 (25.8%)
Ventricular Tachycardia, Sustained Monomorphic	45 (6.7%)	45 (6.8%)	44 (6.8%)	8 (8.2%)
Ventricular Tachycardia, Sustained Polymorphic	7 (1.0%)	7 (1.1%)	7 (1.1%)	0 (0.0%)
Ventricular Tachycardia, Sustained Unknown Morphology	27 (4.0%)	27 (4.1%)	27 (4.2%)	3 (3.1%)
AV Junctional Arrhythmias and Blocks*	**80 (11.9%)**	**79 (12.0%)**	**76 (11.8%)**	**6 (6.2%)**
1st Degree AV Block	**62 (9.2%)**	**61 (9.3%)**	**59 (9.2%)**	**6 (6.2%)**
2nd Degree AV Block	14 (2.1%)	14 (2.1%)	13 (2.0%)	0 (0.0%)
3rd Degree AV Block	17 (2.5%)	16 (2.4%)	16 (2.5%)	0 (0.0%)
Bundle Branch Blocks*	**215 (31.9%)**	**215 (32.7%)**	**211 (32.8%)**	**31 (32.0%)**
Left Bundle Branch Block	130 (19.3%)	130 (19.8%)	128 (19.9%)	15 (15.5%)
Intraventricular Conduction Delay	35 (5.2%)	35 (5.3%)	35 (5.4%)	3 (3.1%)
Right Bundle Branch Block	71 (10.5%)	71 (10.8%)	69 (10.7%)	14 (14.4%)

*Multiple response options may be selected.

Table 14: Other Medical History

Subject Characteristics (N, %)	Enrolled (N = 675)	Implant Attempted (N = 657)	Successfully Implanted (N = 643)	Defibrillation Testing Main Analysis Cohort (N = 97)
None of the following	**305 (45.2%)**	**302 (46.0%)**	**297 (46.2%)**	**52 (53.6%)**
COVID-19 (Confirmed by PCR or antibody)	86 (12.7%)	86 (13.1%)	82 (12.8%)	7 (7.2%)
Chronic Obstructive Pulmonary Disease (COPD)	44 (6.5%)	44 (6.7%)	44 (6.8%)	9 (9.3%)
Diabetes*	**256 (37.9%)**	**253 (38.5%)**	**248 (38.6%)**	**34 (35.1%)**
Insulin Dependent	55 (8.1%)	54 (8.2%)	53 (8.2%)	10 (10.3%)

Subject Characteristics (N, %)	Enrolled (N = 675)	Implant Attempted (N = 657)	Successfully Implanted (N = 643)	Defibrillation Testing Main Analysis Cohort (N = 97)
Non-insulin Dependent	202 (29.9%)	200 (30.4%)	196 (30.5%)	24 (24.7%)
Renal Dysfunction	107 (15.9%)	105 (16.0%)	101 (15.7%)	11 (11.3%)

*Multiple response options may be selected.

D. Safety and Effectiveness Results

1. Safety Results

1.1 Primary Safety Objective Results

Of the 657 subjects undergoing an implant attempt, 25 subjects had a total of 25 adverse events (AEs) causally related to the Model 3930M lead. Of these, 20 events in 20 subjects were adjudicated as major complications by the CEC, of which 19 events in 19 subjects occurred within 182 days (6 months) and 19 events in 19 subjects occurred within 365 days (12 months) post-implant; the remaining 1 occurred after the 12-month follow-up.

The Kaplan-Meier estimated freedom from Model 3930M lead-related major complication rate at 6 months (182 days) and 12 months (365 days) was 97.1%, with a two-sided 95% confidence interval of 95.4% - 98.1% and at 12 months (Table 12). At time of this analysis, 6-month follow-up windows are closed for all subjects, and 12- month follow-up visits are ongoing; 522 subjects have had the opportunity to have a 12- month follow-up visit. 492 subjects have completed their 18-month follow-up visit. Figure 2 displays the Kaplan-Meier curve for freedom from Model 3930M lead-related major complications through 12 months. The Kaplan-Meier curve shows that the event rate is highest within the first days or month after implant and tends to decrease with a lower rate after the first days or month.

Table 15: Model 3930M lead-Related Major Complication-Free Rate at 6 and 12 Months

Time Point	Number of Subjects with Implant Attempt	Number of Subjects with Events	Major Complication Free Rate (Kaplan Meier Estimate)	95% Confidence Interval
6 Months	657	19	97.1%	95.4% - 98.1%
12 Months	657	19	97.1%	95.4% - 98.1%

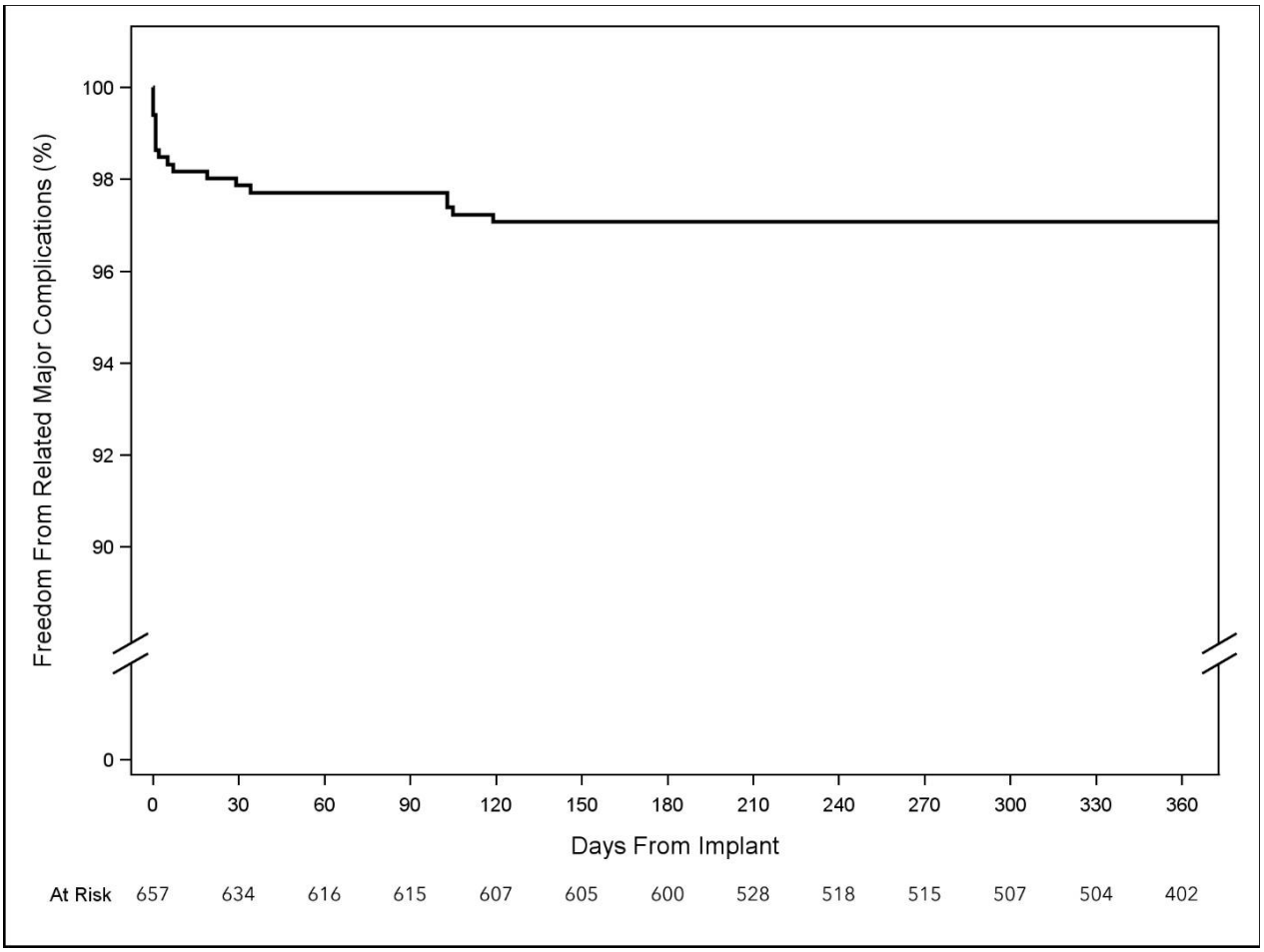

Figure 3: Kaplan-Meier Curve for Freedom from Model 3930M lead-Related Major Complications up to 12 Months

Bayesian analysis methods were used to estimate the Model 3930M lead- related major complication free rate at 6 months as 96.7% (posterior mean). The lower bound of the two-sided 95% credible interval is above the performance criterion of 90% (Table 13) and hence the primary safety objective was met. Given the collected data and the prespecified Bayesian prior distribution, the Bayesian posterior probability that the Model 3930M lead-related major complication free rate exceeds the performance goal of 90% is >99.9%. The Kaplan-Meier event rate at 6 month differs from the Bayesian analysis results (posterior mean of 96.7%) since the Kaplan-Meier estimate is based on different methodology than the Bayesian methodology which incorporated a skeptical prior.

Table 16: Results of the Primary Safety Objective

Number of Subjects with Implant Attempt	Number of Subjects with Events	Major Complication Free Rate at 6 Months (Posterior Mean)	95% Credible Interval	Posterior Probability Major Complication Free Rate > 90%
657	19	96.7%	95.2% - 98%	>99.9%

1.2 Secondary Safety Objective Results

The secondary safety objective was evaluated with Bayesian methodology that combined clinical and simulated virtual patient data to provide a more precise estimate of the fracture-free rate than the clinical study alone. At each desired time point (6-, and 12- months), two-sided 95% credible intervals for the Model 3930M lead fracture-free rates were generated using a combination of clinical and virtual patient data derived from engineering models. The engineering model incorporates *in-vivo* use conditions (i.e. *in-vivo* curvature) and in-vitro fatigue strength testing (i.e. cyclic use conditions) to determine expected fracture-free survival of the Model 3930M lead over time. Specifically, lead bending data (i.e. "curvature") were obtained during calibrated biplane fluoroscopy sessions in a subset of LEADR patients that performed several arm movements. A distribution for the number of arm movements was based on data collected from healthy non-LEADR trial volunteers across a variety of age groups. Finally, lead fatigue strength was measured during in-vitro testing and used to derive the number of bending cycles required to cause conductor fracture.

The fracture-free rate at 6-months and 12-months are provided in Table 17 for clinical data only and clinical plus virtual patient data.

There were 657 subjects with implant attempt included in the analysis. There were no Model 3930M lead fractures reported during a mean follow-up period of 12.7 ± 4.8 months. No adverse events were assessed by the CEC to be Model 3930M lead fracture-related. Using clinical data only with a non-informative Bayesian prior, this resulted in a 6-month fracture-free survival rate of 99.99% (posterior mean) and 12-month fracture-free survival rate of 99.98%.

The survival outcomes from the virtual patient engineering model were used to elicit an informative Bayesian prior distribution to be used in the LEADR fracture-free analysis. A discounting approach was used to down-weigh the influence of the model based on the agreement between the fracture rate observed in the clinical data and the fracture rate observed from the engineering model. The simulated patients contributed a weight equivalent to approximately 242 additional patients.

Analysis of the combined clinical and virtual patient data resulted in a 6-month fracture-free survival rate of 99.99% (posterior mean) and 12-month fracture-free survival rate of 99.97%. The estimate from the engineering model is more conservative than the estimate from the clinical data only. Thus, the credible intervals are slightly wider and posterior means are slightly lower after incorporating the virtual patient data. It can be seen that there is a high fracture-free rate for the Model 3930M lead based on analysis of the clinical data only as well as of the clinical and virtual patients data.

Table 17: Results of the Secondary Safety Objective

Time Point	Data Cohort	Fracture Free Rate (Posterior Mean)	95% Credible Interval
6-month	Clinical Data Only	99.99%	99.91% - 100%
	Clinical + Virtual Patient Data	99.99%	99.9% - 100%
12-month	Clinical Data Only	99.98%	99.83% - 100%
	Clinical + Virtual Patient Data	99.97%	99.79% - 100%

1.3 Adverse effects that occurred in the PMA clinical study:

AEs in this study were coded using MedDRA (Medical Dictionary for Regulatory Activities) which is organized with a five-level hierarchy. The highest or broadest level is System Organ Class (SOC), further divided into High-Level Group Terms (HLGT), High-Level Terms (HLT), Preferred Terms (PT), and finally into the most granular Lowest Level Terms (LLT). MedDRA Preferred Term were used to summarize AEs.

There were 1425 AEs reported in 425 enrolled subjects. No AEs were experienced by enrolled subjects who did not undergo a study lead implant attempt, resulting in the same total of 1425 AEs from 425 subjects who had an implant attempt. The most common AE was 'Ventricular Tachycardia' with 183 events in 93 subjects, of which 70 events from 38 subjects were serious. Of the 1425 total AEs reported, most occurred post-procedure (1404), but 7 AEs happened pre-procedure and 14 AEs happened during the procedure.

Among all AEs, no reported events, reviewed individually or in aggregate, were considered to be unexpected serious adverse device effects (USADEs) or unexpected adverse device effects (UADEs). 610 events were serious, 118 events were indicated to be related to the procedure (73 causal relationship and 45 possible to implant or system modification), 133 events were related to the system (79 causal relationship and 54 possible to ICD/CRT-D and/or RA, RV, and/or LV leads), and 14 events were indicated to be related to the accessory (4 causal relationship or 10 possible to implant tool, programmer or catheter). There were 58 events related to the RV lead (25 causal relationship and 33 possible to RV lead) and there were no events adjudicated to be related to RV lead fracture. Of note, one of the 33 events with possible relationship to the RV lead was related to a commercially available RV lead (Medtronic Sprint Quattro TM) and not the Model 3930M lead.

Twenty-four subject deaths have been reported. Of the 24 deaths, 13 were non-cardiac deaths, 6 were non-sudden cardiac deaths, 2 were sudden cardiac death, and 3 were adjudicated as unknown classification. No deaths were adjudicated to have a causal relationship to the Model 3930M lead. However, the CEC determined that three deaths (sepsis, death of unknown cause due to insufficient information, and

sudden cardiac death due to ventricular fibrillation in a patient with multiple myeloma) have a possible relationship to all components of the system, including the Model 3930M lead.

Table 18: Overall Summary of Adverse Events

Adverse Event Classification	Enrolled (N = 675)	Implant Attempted (N = 657)	Successfully Implanted (N = 643)
What is the relative time from the procedure			
Pre-procedure	7 (6, 0.9%)	7 (6, 0.9%)	7 (6, 0.9%)
During procedure	14 (14, 2.1%)	14 (14, 2.1%)	14 (14, 2.2%)
Post-procedure	1404 (418, 61.9%)	1404 (418, 63.6%)	1397 (414, 64.4%)
Serious (N, %)*			
Yes	610 (270, 40.0%)	610 (270, 41.1%)	607 (267, 41.5%)
No	815 (309, 45.8%)	815 (309, 47.0%)	811 (306, 47.6%)
Unanticipated Serious Adverse Device Effect (USADE) or Unanticipated Adverse Device Effect (UADE) (Medtronic)**			
Yes	0 (0, 0.0%)	0 (0, 0.0%)	0 (0, 0.0%)
No	1425 (425, 63.0%)	1425 (425, 64.7%)	1418 (421, 65.5%)
Procedure Relatedness (N, %)***			
Causal Relationship	73 (65, 9.6%)	73 (65, 9.9%)	72 (64, 10.0%)
Possible	45 (41, 6.1%)	45 (41, 6.2%)	44 (40, 6.2%)
Not Related	1307 (392, 58.1%)	1307 (392, 59.7%)	1302 (389, 60.5%)
Identify the Procedure (N, %)			
Implant	114 (100, 14.8%)	114 (100, 15.2%)	112 (98, 15.2%)
System Modification	4 (3, 0.4%)	4 (3, 0.5%)	4 (3, 0.5%)
System Relatedness (N, %)***			
Causal Relationship	79 (67, 9.9%)	79 (67, 10.2%)	77 (65, 10.1%)
Possible	54 (47, 7.0%)	54 (47, 7.2%)	53 (46, 7.2%)
Not Related	1292 (395, 58.5%)	1292 (395, 60.1%)	1288 (392, 61.0%)
ICD/CRT-D Relatedness (N, %)***			
Causal Relationship	41 (33, 4.9%)	41 (33, 5.0%)	40 (32, 5.0%)
Possible	23 (22, 3.3%)	23 (22, 3.3%)	22 (21, 3.3%)
Not Related	1361 (417, 61.8%)	1361 (417, 63.5%)	1356 (413, 64.2%)
RV Lead Relatedness (N, %)***			
Causal Relationship	25 (25, 3.7%)	25 (25, 3.8%)	25 (25, 3.9%)
Possible	33 (31, 4.6%)	33 (31, 4.7%)	32 (30, 4.7%)
Not Related	1367 (405, 60.0%)	1367 (405, 61.6%)	1361 (401, 62.4%)
RA Lead Relatedness (N, %)***			
Causal Relationship	10 (10, 1.5%)	10 (10, 1.5%)	10 (10, 1.6%)
Possible	31 (29, 4.3%)	31 (29, 4.4%)	31 (29, 4.5%)
Not Related	1384 (416, 61.6%)	1384 (416, 63.3%)	1377 (412, 64.1%)
LV Lead Relatedness (N, %)***			
Causal Relationship	9 (8, 1.2%)	9 (8, 1.2%)	8 (7, 1.1%)
Possible	13 (11, 1.6%)	13 (11, 1.7%)	13 (11, 1.7%)
Not Related	1403 (417, 61.8%)	1403 (417, 63.5%)	1397 (414, 64.4%)
RV Lead Fracture Relatedness (N, %)****			

Causal Relationship	0 (0, 0.0%)	0 (0, 0.0%)	0 (0, 0.0%)

Adverse Event Classification	Enrolled (N = 675)	Implant Attempted (N = 657)	Successfully Implanted (N = 643)
Possible	0 (0, 0.0%)	0 (0, 0.0%)	0 (0, 0.0%)
Not Related	304 (214, 31.7%)	304 (214, 32.6%)	298 (210, 32.7%)
Accessory Relatedness* **			
Causal Relationship	4 (4, 0.6%)	4 (4, 0.6%)	4 (4, 0.6%)
Possible	10 (10, 1.5%)	10 (10, 1.5%)	10 (10, 1.6%)
Not Related	1411 (419, 62.1%)	1411 (419, 63.8%)	1404 (415, 64.5%)
Implant Tool Relatedness (N, %)* **			
Causal Relationship	3 (3, 0.4%)	3 (3, 0.5%)	3 (3, 0.5%)
Possible	2 (2, 0.3%)	2 (2, 0.3%)	2 (2, 0.3%)
Not Related	1420 (422, 62.5%)	1420 (422, 64.2%)	1413 (418, 65.0%)
Programmer Relatedness (N, %)* **			
Causal Relationship	0 (0, 0.0%)	0 (0, 0.0%)	0 (0, 0.0%)
Possible	0 (0, 0.0%)	0 (0, 0.0%)	0 (0, 0.0%)
Not Related	1425 (425, 63.0%)	1425 (425, 64.7%)	1418 (421, 65.5%)
Catheter Relatedness (N, %)* **			
Causal Relationship	1 (1, 0.1%)	1 (1, 0.2%)	1 (1, 0.2%)
Possible	9 (9, 1.3%)	9 (9, 1.4%)	9 (9, 1.4%)
Not Related	1415 (422, 62.5%)	1415 (422, 64.2%)	1408 (418, 65.0%)
Total Adverse Events	**1425 (425, 63.0%)**	**1425 (425, 64.7%)**	**1418 (421, 65.5%)**

*AE seriousness by investigator
**U(S)ADE determined by Medtronic
***AE relatedness per CEC adjudication if event required adjudication by CEC; otherwise investigator determination was used; categories of AE relatedness were not mutually exclusive
****RV lead fracture relatedness is only adjudicated by the CEC. Hence, the responses do not sum up to the number of adverse events.

Table 16 provides a summary of all AEs that were adjudicated as system and procedure-, system- (i.e., system only), or procedure- (i.e., procedure only) related. There were 175 AEs (89 serious, 86 non-serious) experienced by 139 subjects with an implant attempt, that were adjudicated as causal or possible related to the system and/or procedure. The most common preferred terms were lead dislodgement (22 events in 20 subjects) and device inappropriate shock delivery (22 events in 18 subjects).

Table 19: System and/or Procedure-related Events by Key Term

	Number of Events (Number, % of Subjects)			
	Implant Attempted (N = 657)		Successfully Implanted (N = 643)	
Adverse Event MedDRA Preferred Term	**Events**	**Serious Events**	**Total Events**	**Serious Events**
Acute kidney injury	1 (1, 0.2%)	1 (1, 0.2%)	1 (1, 0.2%)	1 (1, 0.2%)
Acute respiratory failure	1 (1, 0.2%)	1 (1, 0.2%)	1 (1, 0.2%)	1 (1, 0.2%)
Anemia macrocytic	1 (1, 0.2%)	1 (1, 0.2%)	1 (1, 0.2%)	1 (1, 0.2%)
Anxiety	2 (2, 0.3%)	1 (1, 0.2%)	2 (2, 0.3%)	1 (1, 0.2%)
Arrhythmia supraventricular	1 (1, 0.2%)	1 (1, 0.2%)	1 (1, 0.2%)	1 (1, 0.2%)
Arthralgia	2 (2, 0.3%)	0 (0, 0.0%)	2 (2, 0.3%)	0 (0, 0.0%)
Atrial fibrillation	9 (9, 1.4%)	1 (1, 0.2%)	9 (9, 1.4%)	1 (1, 0.2%)

Atrioventricular block	1 (1, 0.2%)	1 (1, 0.2%)	1 (1, 0.2%)	1 (1, 0.2%)
Atrioventricular block complete	1 (1, 0.2%)	0 (0, 0.0%)	1 (1, 0.2%)	0 (0, 0.0%)
Cardiac perforation[a]	4 (4, 0.6%)	4 (4, 0.6%)	4 (4, 0.6%)	4 (4, 0.6%)

	Number of Events (Number, % of Subjects)			
	Implant Attempted (N = 657)		Successfully Implanted (N = 643)	
Adverse Event MedDRA Preferred Term	**Events**	**Serious Events**	**Total Events**	**Serious Events**
Cardiac tamponade[b]	2 (2, 0.3%)	2 (2, 0.3%)	2 (2, 0.3%)	2 (2, 0.3%)
Cardiogenic shock	1 (1, 0.2%)	1 (1, 0.2%)	1 (1, 0.2%)	1 (1, 0.2%)
Cerebrovascular accident	1 (1, 0.2%)	1 (1, 0.2%)	1 (1, 0.2%)	1 (1, 0.2%)
Chest discomfort	1 (1, 0.2%)	0 (0, 0.0%)	1 (1, 0.2%)	0 (0, 0.0%)
Chest pain	2 (2, 0.3%)	1 (1, 0.2%)	2 (2, 0.3%)	1 (1, 0.2%)
Death[c]	1 (1, 0.2%)	1 (1, 0.2%)	1 (1, 0.2%)	1 (1, 0.2%)
Deep vein thrombosis	4 (4, 0.6%)	1 (1, 0.2%)	4 (4, 0.6%)	1 (1, 0.2%)
Device capturing issue	1 (1, 0.2%)	1 (1, 0.2%)	1 (1, 0.2%)	1 (1, 0.2%)
Device connection issue	1 (1, 0.2%)	1 (1, 0.2%)	1 (1, 0.2%)	1 (1, 0.2%)
Device dislocation	2 (2, 0.3%)	1 (1, 0.2%)	2 (2, 0.3%)	1 (1, 0.2%)
Device inappropriate shock delivery	22 (18, 2.7%)	14 (13, 2.0%)	22 (18, 2.8%)	14 (13, 2.0%)
Device pacing issue	11 (9, 1.4%)	0 (0, 0.0%)	11 (9, 1.4%)	0 (0, 0.0%)
Device stimulation issue	5 (5, 0.8%)	2 (2, 0.3%)	4 (4, 0.6%)	2 (2, 0.3%)
Embolism venous	1 (1, 0.2%)	1 (1, 0.2%)	1 (1, 0.2%)	1 (1, 0.2%)
Endocarditis	1 (1, 0.2%)	1 (1, 0.2%)	1 (1, 0.2%)	1 (1, 0.2%)
Hypotension	1 (1, 0.2%)	1 (1, 0.2%)	1 (1, 0.2%)	1 (1, 0.2%)
Implant site dehiscence	1 (1, 0.2%)	1 (1, 0.2%)	1 (1, 0.2%)	1 (1, 0.2%)
Implant site hematoma	8 (8, 1.2%)	1 (1, 0.2%)	8 (8, 1.2%)	1 (1, 0.2%)
Implant site hemorrhage	1 (1, 0.2%)	0 (0, 0.0%)	1 (1, 0.2%)	0 (0, 0.0%)
Implant site pain	6 (6, 0.9%)	0 (0, 0.0%)	6 (6, 0.9%)	0 (0, 0.0%)
Implant site swelling	1 (1, 0.2%)	0 (0, 0.0%)	0 (0, 0.0%)	0 (0, 0.0%)
Infection	1 (1, 0.2%)	0 (0, 0.0%)	1 (1, 0.2%)	0 (0, 0.0%)
Lead dislodgement[d]	22 (20, 3.0%)	21 (20, 3.0%)	22 (20, 3.1%)	21 (20, 3.1%)
Medical device site hematoma	1 (1, 0.2%)	0 (0, 0.0%)	1 (1, 0.2%)	0 (0, 0.0%)
Medical device site infection	1 (1, 0.2%)	0 (0, 0.0%)	1 (1, 0.2%)	0 (0, 0.0%)
Medical device site necrosis	1 (1, 0.2%)	0 (0, 0.0%)	1 (1, 0.2%)	0 (0, 0.0%)
Medical device site pain	3 (3, 0.5%)	0 (0, 0.0%)	3 (3, 0.5%)	0 (0, 0.0%)
Medical device site swelling	1 (1, 0.2%)	0 (0, 0.0%)	1 (1, 0.2%)	0 (0, 0.0%)
Neck pain	1 (1, 0.2%)	0 (0, 0.0%)	1 (1, 0.2%)	0 (0, 0.0%)
Needle issue	1 (1, 0.2%)	0 (0, 0.0%)	1 (1, 0.2%)	0 (0, 0.0%)
Nerve compression	1 (1, 0.2%)	0 (0, 0.0%)	1 (1, 0.2%)	0 (0, 0.0%)
Oedema peripheral	1 (1, 0.2%)	0 (0, 0.0%)	1 (1, 0.2%)	0 (0, 0.0%)
Oversensing	7 (7, 1.1%)	7 (7, 1.1%)	6 (6, 0.9%)	6 (6, 0.9%)
Pacemaker generated arrhythmia	1 (1, 0.2%)	0 (0, 0.0%)	1 (1, 0.2%)	0 (0, 0.0%)
Pain in extremity	1 (1, 0.2%)	0 (0, 0.0%)	1 (1, 0.2%)	0 (0, 0.0%)
Palpitations	2 (2, 0.3%)	0 (0, 0.0%)	2 (2, 0.3%)	0 (0, 0.0%)
Paresthesia	1 (1, 0.2%)	1 (1, 0.2%)	1 (1, 0.2%)	1 (1, 0.2%)
Periarthritis	3 (3, 0.5%)	0 (0, 0.0%)	3 (3, 0.5%)	0 (0, 0.0%)
Pericardial effusion[e]	4 (4, 0.6%)	3 (3, 0.5%)	4 (4, 0.6%)	3 (3, 0.5%)
Pericardial hemorrhage[f]	1 (1, 0.2%)	1 (1, 0.2%)	1 (1, 0.2%)	1 (1, 0.2%)
Pericarditis	2 (2, 0.3%)	0 (0, 0.0%)	2 (2, 0.3%)	0 (0, 0.0%)
Phantom shocks	1 (1, 0.2%)	0 (0, 0.0%)	1 (1, 0.2%)	0 (0, 0.0%)
Pleural effusion	1 (1, 0.2%)	0 (0, 0.0%)	1 (1, 0.2%)	0 (0, 0.0%)
Pneumothorax	4 (4, 0.6%)	2 (2, 0.3%)	4 (4, 0.6%)	2 (2, 0.3%)
Pyrexia	4 (4, 0.6%)	3 (3, 0.5%)	4 (4, 0.6%)	3 (3, 0.5%)
Sepsis	1 (1, 0.2%)	1 (1, 0.2%)	1 (1, 0.2%)	1 (1, 0.2%)

Staphylococcal sepsis	1 (1, 0.2%)	1 (1, 0.2%)	1 (1, 0.2%)	1 (1, 0.2%)
Subclavian vein thrombosis	1 (1, 0.2%)	1 (1, 0.2%)	1 (1, 0.2%)	1 (1, 0.2%)
Suture related complication	1 (1, 0.2%)	0 (0, 0.0%)	1 (1, 0.2%)	0 (0, 0.0%)
Twiddler's syndrome	1 (1, 0.2%)	1 (1, 0.2%)	1 (1, 0.2%)	1 (1, 0.2%)

Adverse Event MedDRA Preferred Term	**Number of Events (Number, % of Subjects)**			
	Implant Attempted (N = 657)		**Successfully Implanted (N = 643)**	
	Events	**Serious Events**	**Total Events**	**Serious Events**
Undersensing	1 (1, 0.2%)	0 (0, 0.0%)	1 (1, 0.2%)	0 (0, 0.0%)
Venous thrombosis	1 (1, 0.2%)	0 (0, 0.0%)	1 (1, 0.2%)	0 (0, 0.0%)
Ventricular fibrillation	1 (1, 0.2%)	1 (1, 0.2%)	1 (1, 0.2%)	1 (1, 0.2%)
Ventricular tachycardia	4 (4, 0.6%)	4 (4, 0.6%)	4 (4, 0.6%)	4 (4, 0.6%)
Total Adverse Events	**175 (139, 21.2%)**	**89 (79, 12.0%)**	**172 (137, 21.3%)**	**88 (78, 12.1%)**

a: 2 of the cardiac perforation events were causal related to the RV lead (Model 3930M lead) and treated with pericardial drainage/pericardiocentesis. One event possible related to the RV lead was treated with an RV lead replacement.
b: One of the cardiac tamponade events was possible related to the RV lead (Model 3930M lead), RA lead, LV lead, and catheter; the other event was causal related to the implant tool.
c: There was a lack of information available (e.g., product return analysis, autopsy, etc.) to determine cause of death for one subject despite all reasonable attempts by the sites and sponsor to obtain further information, resulting in an AE MedDRA Preferred Term of "death." While there was no evidence of system involvement the CEC took a conservative position and adjudicated the event to have a possible relationship to the system due to lack of information.
d: 11 of lead dislodgement events were causal to the RV lead (Model 3930M lead), 6 causal to RA lead, 1 possible to RA lead, and 3 causal to the LV lead. An additional lead dislodgement (not considered a system-related event but was procedure related) was for dislodgement of a conduction system pacing lead and adjudicated by CEC to not be related to any components of the system. The percentage of subjects with RV lead dislodgement within subjects with implant attempt was 1.7%.
e: All 4 pericardial effusion events were possible related to the RV lead (Model 3930M lead); 3 occurred within 20 days of implant, while one event occurred 181 days post-implant. 3 events resolved after pericardial drainage/pericardiocentesis (2) or with medication alone (1). No actions were taken for one event, once confirmed by echocardiogram to not be hemodynamically significant.
f: One pericardial hemorrhage event was reported on the day of implant and was adjudicated as possible related to the RV lead (Model 3930M lead), RA lead, LV lead, and catheter.

2. Effectiveness Results

Defibrillation testing was initiated in 123 subjects and completed per protocol in 119 subjects among 657 subjects with an implant attempt (Figure 4).

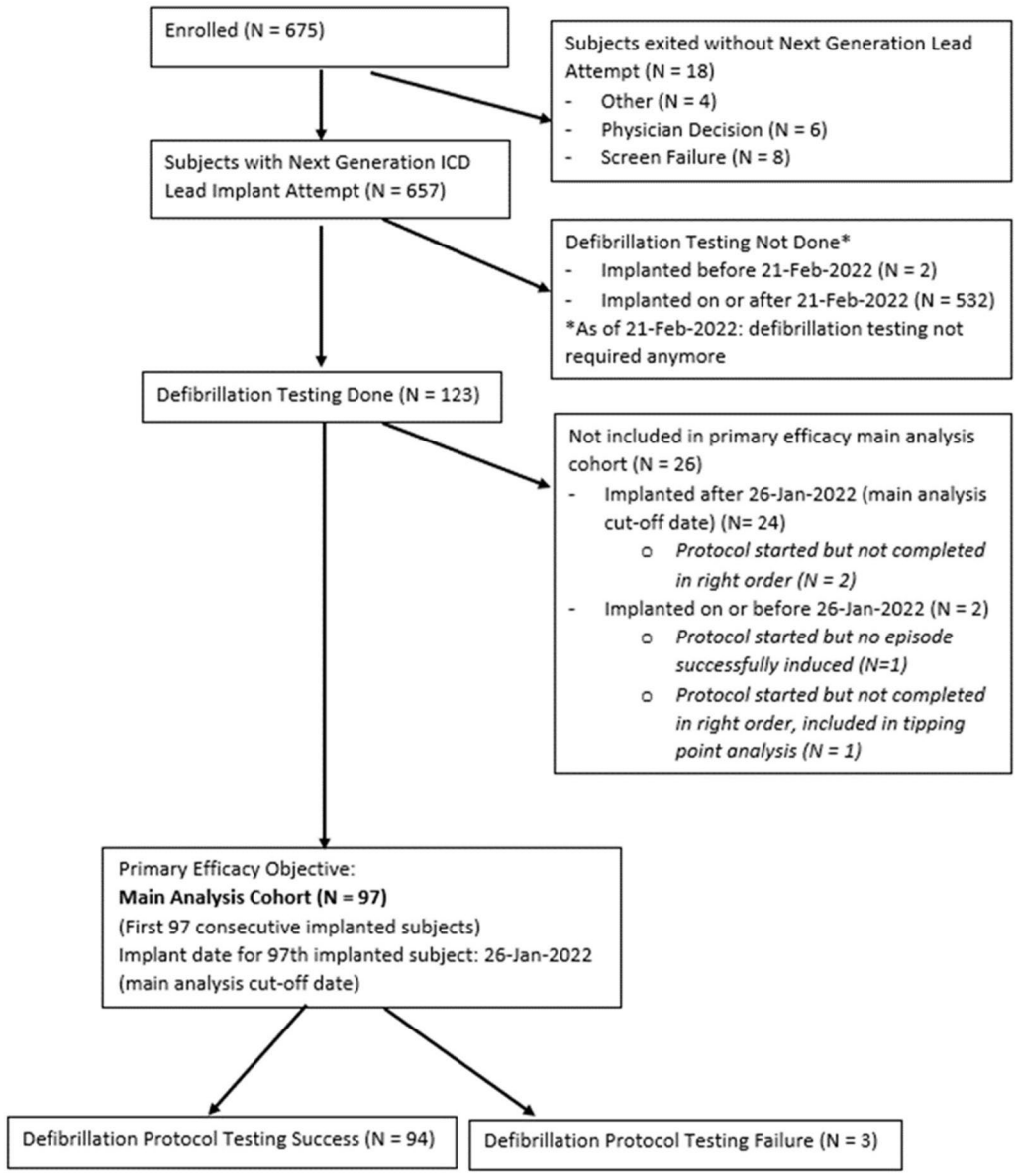

Figure 4: Subject Flowchart LEADR Study Primary Effectiveness **Objective**

A supplemental analysis was completed on all subjects completing the defibrillation testing protocol to determine the overall defibrillation effectiveness at implantation. Because the defibrillation protocol was started but not completed correctly in the right order as was required per the defibrillation protocol or no episode was successfully induced in four subjects of 123 subjects starting the defibrillation protocol (Figure 4), 119 subjects were included in this supplemental analysis. Of these 119 protocols available for this analysis, 116 defibrillation protocols were successful providing an observed success rate of 97.5% (116/119). Of the 116 subjects, 82.8% (96/116) of patients were successfully defibrillated with a single 18-J shock and 17.2% (20/116) with 2 consecutive shocks at 25 J (Defibrillation Testing Success at 18J Shock or 25J Shocks). Of the 3 subjects with

unsuccessful defibrillation testing, 2 remained in the study after successful conversion of at least 1 episode using 25J and 1 exited and received a non-study lead.

Table 20: Defibrillation Protocol – Analysis Results for Full Cohort

	Number of Subjects	Defibrillation Success (Observed Rate)
Defibrillation Success Rate	119	97.5% (116/119)

The main analysis cohort for the analysis of the primary effectiveness objective was pre- specified to be performed on the first 95 consecutive implanted subjects who completed defibrillation testing, hence a cut-off date for inclusion in the main defibrillation analysis of 26-Jan-2022. In 4 subjects, the defibrillation protocol was started but not completed correctly in the right order as was required per the defibrillation protocol and/or subjects were implanted after the cut-off date for inclusion in the defibrillation main analysis.

There were three subjects who completed implant on 26-Jan-2022. All of these subjects are included in the main analysis, resulting in a cohort of 97 subjects for the main analysis. The flowchart above in Figure 3 presents an overview of how the sample size of at least 95 subjects for the main analysis for the defibrillation objective was reached.

Of these 97 protocols available for the main, i.e., primary, analysis, 94 defibrillation protocols were successful providing a posterior mean of 95.8% with a 95% credible interval ranging from 91.0% to 98.8% (Table 18). Since the lower bound of the two-sided 95% credible interval is greater than the performance goal of 88%, the primary effectiveness objective is met. Given the collected data and the prespecified Bayesian prior distribution, the Bayesian posterior probability that the defibrillation success rate is higher than 88% is 99.8%.

Table 21: Results of the Primary Effectiveness Objective

	Number of Subjects	Defibrillation Success Rate (Posterior Mean)	95% Credible Interval	Posterior Probability of Defibrillation Success Rate > 88%
Defibrillation Success Rate	97	95.8%	91% - 98.8%	99.8%

3. Subgroup Analyses

The primary effectiveness objective analysis was done on the main analysis cohort of 97 subjects and a supplemental analysis was done on all patients with completed defibrillation testing (119 subjects). For results see primary effectiveness objective results section above.

4. Pediatric Extrapolation

Medtronic has thoroughly evaluated this cohort with multiple sources of Real-World Evidence (RWE) for similar defibrillation lead models in the adolescent pediatric population. A review of RWE provided evidence of expected performance similarity of the Model 3930M lead in the adolescent pediatric population to that of the adult patient ICD/CRT-D populations. This analysis supports the inclusion of adolescent pediatric patients as an indicated patient for the Model 3930M lead upon approval for market release. The inclusion criteria of the adolescent pediatric cohort in this analysis defined the adolescent pediatric patient to be between the age of ≥12 and <22 years old, who are at least 30kg, and whose cardiac anatomy is conducive to RV coil placement, consistent with Model 3930M lead indications for use.

In addition, in this premarket application, existing LEADR clinical data was leveraged to support the reasonable assurance of safety and effectiveness of the proposed device in the pediatric sub-population of adolescent patients. For details about the leverage data, refer to Section X (D) Safety and Effectiveness Results.

XI. FINANCIAL DISCLOSURE

The Financial Disclosure by Clinical Investigators regulation (21 CFR 54) requires applicants who submit a marketing application to include certain information concerning the compensation to, and financial interests and arrangement of, any clinical investigator conducting clinical studies covered by the regulation. The pivotal clinical study included 208 investigators of which one was a full-time employee of the sponsor (however, employment by sponsor began after last day as an electrophysiologist at a participating study site), and eleven had disclosable financial interests/arrangements as defined in 21 CFR 54.2(a), (b), (c) and (f) and described below:

- Significant payment of other sorts, such as a grant to fund ongoing research, compensation in the form of equipment, retainer for ongoing consultation, or honoraria: 10 of 208 investigators
- Significant equity interest held by spouse of investigator in sponsor of covered study: 1 of 208 investigators

The applicant has adequately disclosed the financial interest/arrangements with clinical investigators. Statistical analyses were conducted by FDA to determine whether the financial interests/arrangements had any impact on the clinical study outcome. The information provided does not raise any questions about the reliability of the data.

XII. PANEL MEETING RECOMMENDATION AND FDA'S POST-PANEL ACTION

In accordance with the provisions of section 515(c)(3) of the act as amended by the Safe Medical Devices Act of 1990, this PMA was not referred to the Circulatory System

Devices Panel, an FDA advisory committee, for review and recommendation because the information in the PMA substantially duplicates information previously reviewed by this panel.

XIII. CONCLUSIONS DRAWN FROM PRECLINICAL AND CLINICAL STUDIES

A. Effectiveness Conclusions

The LEADR clinical trial was a prospective, multi-center, single-arm, nonrandomized, Bayesian, adaptive study design that assessed the effectiveness of the Model 3930M lead 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. Defibrillation testing was initiated in 123 subjects and completed per protocol in 119 subjects among 657 subjects with an implant attempt but reported in 97 consecutive patients as the main analysis cohort. 24 of the 26 patients not included in this cohort were mainly implanted after the main analysis cutoff date. Defibrillation testing was successful in 94/97 patients (95.8%, 95% credible interval 91 – 98.8%) compared with a performance goal of 88%. Including all 119 patients, ICD testing was successful in 116/119 (97.5%).

Results from ancillary objectives evaluating electrical lead measurements, which included pacing capture threshold, R-wave sensing amplitude, and pacing impedance were characterized through the 12-month follow-up and provide supplemental support of the Model 3930M lead performance and reliability. The mean pacing capture threshold was 0.6 ± 0.26 V (0.4 ms pulse width) at implant and remained stable throughout follow-up. Mean R-wave amplitude was 10.2 ± 4.8 mV at implant and remained stable throughout follow-up. The mean pacing impedance was 635.1 ± 175 Ω at implant, 394.4 ± 64.5 U at 3-month follow-up, and was chronically stable thereafter.

B. Safety Conclusions

The risks of the device are based on nonclinical laboratory and animal studies as well as data collected in a clinical study conducted to support PMA approval as described above. The known or probable risks that are more than minimal include AEs related to the device itself, AEs related to the use of the device or the procedure to use the device, in particular, long-term issues such as the development of exit block and lead fracture. Despite these risks, the primary safety endpoint (freedom from lead-related complications) at 6 months met the performance goal. The rate was 97.1% with a 95% CL of 95.4 – 98.1%. No complications occurred between 6 and 12 months, using frequentist methodology. Using Bayesian methodology, the Bayesian posterior probability that the Model 3930M lead-related major complication free rate of 96.7% exceeds the performance goal of 90% is >99.9%, with 95% credible interval of 95.2 – 98%. The secondary safety endpoint, the fracture-free rate at 12 months, also met the performance goal of 95%, and no fractures were observed.

C. Benefit-Risk Determination

The probable benefit of the device is also based on data collected in a clinical study conducted to support PMA approval as described above. The probable benefit is the availability of a small diameter lead with both pacing and defibrillator performance that are at least as reliable as currently available leads.

The probable risks of the device are also based on data collected in a clinical study conducted to support PMA approval as described above. The known or probable risks that are more than minimal include AEs related to the device itself, AEs related to the use of the device or the procedure to use the device, in particular, long-term issues such as the development of exit block and lead fracture.

Additional factors to be considered in determining probable risks and benefits for the Model 3930M lead device included the uncertainty of long-term lead performance as the follow-up interval is shorter than the expected lifespan of the device. Additionally, subjects under the age of 22 years old were not included in the pivotal trial to support an indication for pediatric adolescent population. To further characterize long-term performance of the OmniaSecure defibrillation lead, Medtronic will perform a post approval study using their Product Surveillance Registry (PSR). Enrollment will include adolescent pediatric patients as a subpopulation for subgroup analysis.

This submission either did not include specific information on patient perspectives or the information did not serve as part of the basis of the decision to approve or deny the PMA for this device.

In conclusion, given the available information above, the data support that 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, the probable benefits of the Model 3930M lead outweigh the probable risks.

D. Overall Conclusions

The data in this application support the reasonable assurance of safety and effectiveness of this device when used in accordance with the indications for use. The probable benefits outweigh the probable risks. The pivotal trial demonstrated that lead performance is acceptable and compares favorably with currently available single coil and dual coil defibrillator leads. The subject lead provides a smaller diameter alternative to currently available defibrillator leads and has a low fracture rate. The LEADR clinical study has demonstrated the safety, effectiveness, and reliability of the Model 3930M lead through a global prospective trial by passing its pre-specified primary objectives.

XIV. CDRH DECISION

CDRH issued an approval order on 04/22/2025. The final clinical conditions of approval cited in the approval order are described below.

The OmniaSecure PAS is a post-market approval registry and will be conducted within the Medtronic Product Surveillance Registry (PSR) platform. Registry data will be collected from patients both US and OUS dependent on timing of market approval and actual product use. The purpose of this study is to characterize the long-term safety and estimate the lead-related complication-free survival of the Model 3930M lead. Patients enrolled and successfully implanted with a Model 3930M lead will be followed for at least five (5) years. The target enrollment is up to 2000 patients from approximately 250 US and OUS sites. The number of contributing sites will depend on market approval across geographies and actual volume of product use following market approval. This study will also include enrollment of 125 adolescent patients at five (5) pediatric cardiology sites and existing PSR sites where IRB approval for pediatric enrollment is present. The pediatric enrollment number may be reevaluated in the future, if needed. Follow-up clinical data will be collected and provided to Food and Drug Administration (FDA) every six (6) months for two (2) years and annually thereafter. If there are delays in enrollment, quarterly enrollment status reports will be submitted every three (3) months in addition to the periodic PAS Progress Reports until FDA provides notice to discontinue quarterly reporting. The study duration is estimated to be seven (7) years. The study will submit a final PAS report to the FDA when approximately 500 patients have completed five (5) years of follow-up. The final PAS report will be submitted no more than six (6) months from the database freeze inclusive of 500 patients completing five (5) years of follow-up, i.e. study completion.

The primary objective of the PAS will be the following:

1. Estimate Model 3930M lead-related complication-free survival through five (5) years post implant. For an adverse event to meet the endpoint, defined as a first occurrence of a complication related to the Model 3930M lead of an enrolled patient as determined by the CEC, the event must have occurred within five (5) years post-lead implant and be adjudicated by the CEC as being a complication related to the lead.
    a. The following complications will be included in the analysis:
        i. Failure to capture
        ii. Failure to sense/undersensing
        iii. Oversensing
        iv. Elevated threshold
        v. Abnormal pacing/defibrillation impedance
        vi. Lead insulation breach
        vii. Lead conductor fracture
        viii. Extracardiac Stimulation
        ix. Lead migration/dislodgement
        x. Cardiac perforation
        xi. Lead structural failure

xii. Erosion/extrusion
xiii. Infection
xiv. Transvenous lead-related thrombosis

Ancillary objectives will include the following:

1. Summarize patient demographics
2. Summarize Model 3930M lead-related adverse events
3. Summarize patient deaths
4. Summarize all OmniaSecure system modifications
5. Summarize OmniaSecure Lead electrical performance

Case Report Forms and remote device data will also include the following information at implant and each follow-up visit, and effort should be made to collect data on as many patients as possible:

1. Pacing capture threshold
2. Pacing impedance
3. R-wave sensing amplitude
4. Defibrillation impedance

A progress report must be submitted every six (6) months for this PAS for the first two (2) years and annually thereafter. In addition, the results from any surveillance should be included in the labeling as these data become available. Any updated labeling must be submitted to FDA in the form of a PMA Supplement.

The applicant's manufacturing facilities have been inspected and found to be in compliance with the device Quality System (QS) regulation (21 CFR 820).

XV. APPROVAL SPECIFICATIONS

Directions for use: See device labeling.

Hazards to Health from Use of the Device: See Indications, Contraindications, Warnings, Precautions, and Adverse Events in the device labeling.

Post-approval Requirements and Restrictions: See approval order.

XVI. REFERENCES

1. Biventricular Pacing for Atrioventricular Block and Systolic Dysfunction. Curtis AB, Worley SJ, Adamson PB, Bhung ES, Nizazi I, Sherfesee L, Shinn T, Sutton MSJ. 17, 2013, New England Journal of Medicine, Vol. 368, pp. 1585-1593.

2. Randomized trial of cardiac resynchronization in mildly symptomatic heart failure patients and in asymptomatic patients with left ventricular dysfunction and previous heart failure symptoms. Linde C, Abraham WT, Gold MR, Sutton MSJ, Ghio S, Daubert C. 23, Dec 2, 2008, Journal of American College of Cardiology, Vol. 52, pp. 1834-1843.

3. Full-Body MRI in Patients With an Implantable Cardioverter-Defibrillator: Primary Results of a Randomized Study. Gold MR, Sommer T, Schwitter J, Fagih AA, Albert T, Merkely B, Peterson M, Ciuffo A, Lee S, Landborg L, Cerkvenik J, Kanal E, Evera MRI Study Investigators. 24, Jun 23, 2015, Journal of American College of Cardiology, Vol. 65, pp. 2581-2588.

4. Low inappropriate shock rates in patients with single- and dual/triple-chamber implantable cardioverter-defibrillators using a novel suite of detection algorithms: PainFree SST trial primary results. Auricchio A, Schloss EJ, Kurita T, Meijer A, Gerritse B, Zweibel S, ALSmadi FM, Leng CT, Sterns LD, PainFree SST Investigators. 5, May 2015, Heart Rhythm, Vol. 12.

5. Safety, efficacy, and reliability evaluation of a novel small-diameter defibrillation lead: Global LEADR pivotal trial results. Crossley GH, Sanders P, Hansky B, De Filippo P, Shah M, Shoda M, et al. 17, May 2024, Heart Rhythm. Vol. 12, pp. 1917-1922.