Clinical Investigational Plan

Reference:
SJM-CIP-CRD768

MRI Ready IDE Study

"A Clinical Evaluation of the Durata® or Optisure™ High Voltage Leads and Ellipse® VR ICD Undergoing Magnetic Resonance Imaging, an Investigational Device Exemption (IDE) Study"

Clinical Investigation Plan (CIP)

June 17, 2016

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PRINCIPAL INVESTIGATOR SIGNATURE PAGE

MRI Ready IDE study

"A Clinical Evaluation of the Durata® or Optisure™ High Voltage Leads and Ellipse VR ICD Undergoing Magnetic Resonance Imaging, an Investigational Device Exemption (IDE) Study"

Version B

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I have read and agree to adhere to the clinical investigational plan and all regulatory requirements applicable in conducting this clinical study.

Principal Investigator

Printed name: _____

Signature: _____

Date: _____

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1.0 Synopsis

	Details
Title:	A Clinical Evaluation of the Durata® or Optisure™® High Voltage (HV) Leads and Ellipse® VR ICD Undergoing Magnetic Resonance Imaging, an Investigational Device Exemption (IDE) Study
Acronym:	MRI Ready IDE Study
Purpose:	To demonstrate safety and efficacy of the Durata or Optisure high voltage lead and Ellipse VR ICD in an MRI environment.
Objectives:	Primary Objectives • Assess the safety of the right ventricular high voltage lead (Durata or Optisure lead) and Ellipse VR ICD in an MRI environment • Assess the efficacy of the right ventricular high voltage lead (Durata or Optisure lead) implanted with the Ellipse VR ICD in an MRI environment
Endpoints:	• Safety: Freedom from MRI-scan related complications* related to the Ellipse VR ICD involving the Durata or Optisure (RV) lead from MRI scan to 1 month post-MRI scan testing • Efficacy: Proportion of Durata or Optisure (RV) leads implanted with the Ellipse VR ICD with capture threshold increase of ≤ 0.5V at 0.5ms from pre-MRI scan to 1 month post-MRI scan testing • Efficacy: Proportion of Durata or Optisure (RV) leads implanted with the Ellipse VR ICD with sensing amplitude decrease of ≤ 50% from pre-MRI scan testing to 1 month post-MRI scan. *A complication is a serious adverse device effect (SADE) that requires an invasive intervention or leads to death. Note: All references to MRI scan in the protocol refer to the study MRI scan.
Design:	This clinical trial is a prospective, multi-center study designed to assess the safety and efficacy of the St. Jude Medical Durata/Optisure HV leads and Ellipse VR ICD in an MRI environment. Patients will have the Durata or Optisure HV leads implanted with a St. Jude Medical Ellipse VR ICD for at least 60 days prior to enrollment. A prospective, multi-center study design was chosen for generalizability of study results by enrolling subjects across multiple geographies and sites, with the minimum

	Details
	sample size required to demonstrate the safety and efficacy of the Durata or Optisure lead with the Ellipse ICD in an MRI environment. The total duration of the study is expected to be 1.5 to 2 years. The clinical study will be conducted in approximately 60 worldwide centers with the majority of the centers in the United States. Up to 165 subjects will be enrolled in this study in order to meet minimum target requirements for the safety endpoint (141 subjects). The PMA will be submitted to FDA when the minimal sample size for each endpoint has been met and a minimum of 25 subjects with at least one ventricular arrhythmia episode (spontaneous or induced) have been adjudicated by the Ventricular Arrhythmia Events Committee . If a minimum of 25 subjects have not experienced a ventricular arrhythmia event (spontaneous or induced) at this time, SJM will discuss progress of data collection for ventricular arrhythmia events with FDA to support the minimum requirements to support a pre-market approval (PMA) application. The data from this IDE will be used to support a marketing application for MRI labeling for SJM ICDs, CRT-Ds and CRT-Ps. Subjects will be enrolled, undergo the study MRI scans, and followed through the month following the study MRI scan. The minimum duration of each subject's participation is approximately one month from the MRI scan (1 Month Post Scan visit). Subjects that agree to participate in the MRI Ready IDE study will also be approached to enroll in a sub study of the MRI Ready IDE study which will involve induction testing that is performed after the MRI visit. The induction sub study will be conducted at all centers that are willing to participate. Ventricular tachycardia (VT) and ventricular fibrillation (VF) events will also be collected to characterize ventricular arrhythmia sensing and detection post-MRI. The device detected VT/VF events (induced or spontaneous) will be collected post MRI from a minimum of 25 subjects with at least one ventricular arrhythmia episode (spontaneous or induced) adjudicated by the Ventricular Arrhythmia Events Committee through any one of three methods: 1. Events obtained during induction testing at any time after the MRI visit, including system revision and follow up visits where induction testing was performed due to impaired R-wave sensing or other clinical reasons. 2. Events in subjects who enroll in the sub study, which will involve post MRI scan induction testing

	Details
	3. Subjects who are no
Devices used:	• Durata 7120Q , active fixation, 58/65cm length •
	It is p and sp **ICDs**

		• •
Study Population		A pat meets and th For si sub st The s an Ell exclu
Inclusion/ Exclusion Criteria		Inclus • •

Details

- Be willing to undergo an elective MRI scan without sedation

NOTE: Antianxiety agents (e.g. minor tranquilizers, etc.) may be used as long as the patient during the MRI scan

- Capture threshold is stable ≤ 2.5V @ 0.5ms
- Ventricular sensing is measurable (patient has underlying rhythm > 30bpm) and the sen
- Be able to provide informed consent for study participation (legal guardian or legally au acceptable)
- Be willing and able to comply with the prescribed follow-up tests and procedures
- Are not contraindicated for an MRI scan (per the MRI Screening Form)

Exclusion Criteria

- Have a competitor's MRI compatible endocardial lead implanted or capped
- Have another existing active implanted medical device, e.g., neurostimulator, infusion p allow the MRI scans per this protocol to be completed.
- Have a lead revision of the Durata/Optisure lead occur < 60 days of the baseline

visit

- Have other non-MRI compatible device or material implanted

NOTE: MRI compatible knee replacements, hip replacements, stents, etc. may be included a
MRI scans conducted per this protocol

NOTE: MRI compatible mechanical, prosthetic, and bioprosthetic heart valves may be inclu
allow for MRI scans conducted per this protocol

NOTE: Non-removable dental implants may be included

- Have a lead extender, adaptor, or capped/abandoned lead
- Enrolled or intend to participate in a clinical drug and/or device study (investigational de
for a device or drug or additional testing beyond standard of care procedures), which co
determined by SJM.
- Pregnant or planning to become pregnant during the duration of the subject's participati
- Have a life expectancy of less than 12 months due to any condition
- Patients with exclusion criteria required by local law (e.g., age)

Data Collection	See Study Procedures and Data Collection Table

Table 1: Study Procedures and Data Collection

Study Visit	Visit Window	Study Procedures and Data Collection
NA	***Up to or same day as Baseline***	• Screen patient for enrollment eligibility • Obtain informed consent(s) [All patients that agree to participate in the study will sign the main study consent. For sites that are participating in the sub study, subjects will be approached with the main study consent and the sub study consent]
Baseline	***The latter of :*** • 60 days after lead implant And • 60 days after most recent lead revision, if applicable	• Obtain medical and surgical history • Collect demographic information • Document indication for implant of ICD • Obtain ICD system information: model and serial number of implanted Ellipse ICD system, and if applicable, most recent lead revision information. • Complete MRI Screening Form
MRI Scan Visit	***Post Baseline (Within 30 days post baseline). The pre-MRI scan, MRI and post MRI scan procedures should occur on the same day.***	Pre-MRI Scan testing • Assess inclusion/exclusion criteria • Screen, clear and prep subject for MRI scan • Complete MRI screening form (if MRI scan visit does not occur the same day as baseline) • Complete MRI Hazard Checklist • Administer pregnancy test – can be done up to 7 days before MRI scan • Interrogate device • Perform capacitor maintenance • Obtain in-clinic Durata or Optisure lead measurements: bipolar capture, sense, pacing and HVLI impedances[1,2] • Setup and activate MRI Settings During MRI Scan • Monitor subject with ECG, pulse oximetry, and verbal communication Post-MRI scan testing • Interrogate device • Deactivate MRI Settings • Obtain in-clinic Durata or Optisure lead measurements: bipolar capture, sense, pacing and HVLI impedances [1,2] • Evaluate subject for Adverse Device Effect (ADE), Serious Adverse Device Effect (SADE), Unanticipated Adverse Device Effect (UADE) events, Unanticipated Serious Adverse Device Effect (USADE for OUS sites) and submit an AE CRF (as applicable). • Report deviations, death, screening failure/withdrawal and out of service as applicable • Submit MRI scan results, e.g. scan time, sequences used, etc. • Upload device session records through the EDC study site portal

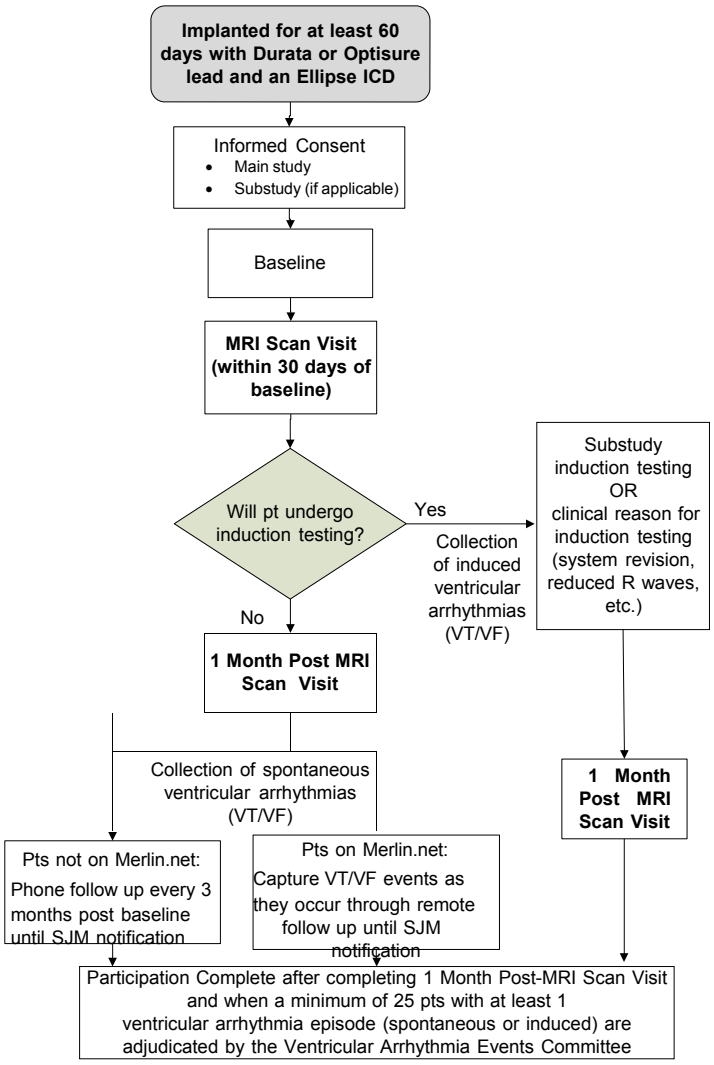
Study Visit		Visit Window	Study Procedures and Data Collection
1 Month Post MRI Scan Visit		***30 days after MRI scan (- 7/+14 days)***	• Interrogate device • Obtain in-clinic Durata or Optisure lead measurements: bipolar capture, sense, pacing and HVLI impedances [1,2] • Evaluate subject for ADE, SADE, UADE (for US sites) or USADE (for OUS sites) events and submit an AE CRF (as applicable). • Report deviations, death, withdrawal and out of service as applicable • Upload device session records through the EDC study site portal
Sub study induction testing		***Can occur any time after the MRI scan visit (Suggest that testing occurs within 30 days after MRI scan visit: - 7/+14 days)***	• Conduct induction therapy testing (e.g. DC Fibber method) • Evaluate subject for ADE, SADE, UADE (for US sites), USADE (for OUS sites) events and submit an AE CRF (as applicable). • Report deviations, death, withdrawal and out of service as applicable • Upload device session records through the EDC study site portal
Review of spontaneous VT/VF episodes (non-sub study subjects)	Subjects on Merlin.net	***Capture events as they occur any time after the 1 month post MRI scan visit***	• Merlin.net records will be reviewed by SJM for spontaneous VT/VF • Review of records will end upon notification from SJM
	Subjects not on Merlin.net	***Every 3 months post baseline ± 30 days***	• Non-Merlin.net subjects: Follow up by phone with subject and screen medical records for VT/VF since last visit. Obtain the device data related to that VT/VF episode. • Follow up phone calls will end upon notification from SJM.
System Revision (if applicable)		***Can occur any time after baseline***	• Interrogate device • Obtain applicable in-clinic lead measurements: bipolar capture[1], sense[2], pacing and HVLI impedances for cases where the lead was repositioned, or was replaced with another Durata/ Optisure lead, or where the ICD was replaced with another Ellipse ICD. • NOTE: If the device replacement/revision of the Ellipse VR device occurs post MRI visit and the Durata/Optisure lead remains in its original location, then induction testing may occur and the session records related to induction testing should be uploaded. • Evaluate subject for ADE, SADE, and UADE (for US sites) or USADE (for OUS sites) events and submit an AE CRF (as applicable). • Report deviations, death, withdrawal and out of service as applicable • Upload device session records through the EDC study site portal

Study Visit	Visit Window	Study Procedures and Data Collection
Unscheduled (if applicable)	***Any time after the MRI scan visit (where the subject is seen in clinic due to an ADE, SADE or UADE associated with the Durata or Optisure or Ellipse ICD or for follow up related to the collection of VT/VF episodes)***	• Interrogate device. • Obtain applicable in-clinic Durata or Optisure lead measurements: bipolar capture, sense, pacing and HVLI impedances[1,2] • If an unscheduled visit occurs prior to the 1 month post MRI visit, evaluate subject for ADE, SADE, and UADE (for US sites) or USADE (for OUS sites) events and submit an AE CRF (as applicable). If an unscheduled event occurs after the 1 month post MRI visit, then the AE events do not need to be submitted. • If a subject experiences reduced R waves and undergoes induction testing or undergoes induction testing for another clinical reason after the MRI visit, then an induction testing form will be submitted. • Report deviations, death, withdrawal and out of service as applicable • Upload device session records through the EDC study site portal
Non-Study MRI Scan (if applicable)	***Any time after enrollment through the conclusion of the subject's participation, excluding the MRI scan performed during the MRI scan visit.***	Perform medically required MRI scan. Where possible: Before scan • Complete MRI Hazard Checklist • Interrogate device • Perform capacitor maintenance • Obtain lead measurements: bipolar capture, sense, pacing and HVLI impedances • Enable MRI Settings During MRI Scan • Monitor subject with ECG, pulse oximetry, and verbal communication After MRI scan • Evaluate subject for adverse events • Interrogate device • Disable MRI Settings, and program device back into permanent settings • Obtain lead measurements: bipolar capture, sense, pacing and HVLI impedances • Report AEs, deviations, death, withdrawal, out of service and device deficiency information, as applicable • Document results of MRI scan, e.g. scan time, sequences used, lapses in subject monitoring, etc. • Upload device session records through the EDC study site portal

[1]Durata or Optisure lead capture thresholds are not required if a high ventricular rate is present (e.g. 110bpm). If available, sites should use the automatically obtained pacing capture threshold from the most recent archival data as a substitute for the in clinic capture threshold.

[2]Durata or Optisure lead sensing measurements are not required if the subject's intrinsic rate has been established to be at or below 30 beats per minute.

1.1 Study Flow Chart



1.2 Study Contacts

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2.0 Background and Justification for Study

Magnetic resonance imaging (MRI) is a diagnostic method to view high quality two and three dimensional images of the body.[1, 2] MRI does not use radiation, has few side effects and is very useful to view soft tissue. In 2007, an estimated 27.5 million MRI procedures were performed in the U.S. in 7,195 hospital and non-hospital sites.[3]

According to the 2005 World Survey of cardiac pacing and cardioverter defibrillators, 223,425 new pacemakers were implanted in the United States in 2005.When compared to a similar survey conducted in 2001, the 2005 survey showed an increase in the number of pacemakers and defibrillators implanted throughout the world, a trend that is likely to continue into the future.[4,5] It is estimated that 50-75% of patients with implantable cardiac devices will develop an indication for an MRI scan during the lifetime of their device.[6]

Magnetic resonance imaging systems generate three electromagnetic fields that are used to produce an image. These include a static magnetic field, a time varying gradient magnetic field, and an RF field. All three of these fields interact with implanted devices and could create hazards for the device, the patient, or both. Examples of these hazards include unwanted cardiac stimulation, heating near lead electrodes, image artifacts, and forces being applied to implanted components.[2,7,8] Due to these issues, certain currently marketed implantable cardiac device systems, including ICDs, may be contraindicated for use in an MRI environment.

Over the past 10 years, there have been numerous patients with implanted devices who successfully underwent magnetic resonance imaging.[9,10,11,12,13]

In this study, St. Jude Medical plans to investigate the Durata®/Optisure™ leads implanted with an Ellipse® VR ICD in an MRI environment.

The study intends to enroll patients indicated for or who have been implanted with a Durata or Optisure lead and an Ellipse VR ICD to evaluate the effects of an MRI scan on these devices. This evaluation will be performed in a prospective, multi-center, non-randomized, single arm clinical trial. This design was chosen to generalize the study results by enrolling subjects across multiple geographies and varying types of sites, and to allow for the smallest sample size needed to demonstrate the safety and efficacy of the Durata or Optisure lead with the Ellipse VR ICD in an MRI environment.

3.0 Risks and Benefits of the Clinical Study, including Analysis of Risks

It is estimated that 50-75% of the patients with implantable cardiac devices will develop an indication for an MRI scan during the lifetime of their device. The information gathered in

this study will add to the understanding of treatment options for patients with the Durata or Optisure lead and Ellipse ICD devices who need to have an MRI scan performed.

There are no direct benefits to the patient as a result of their participation in this study. All patients may be more closely monitored by their physician.

3.1 Description of subject population

This study intends to enroll subjects implanted with the Durata or Optisure lead and Ellipse VR ICD, as described under the Device Descriptions section of this document. This population includes males and females 18 years of age or older.

3.2 Anticipated clinical benefits

For the purposes of this study, an MRI Setting has been created, and will be enabled in the Ellipse VR ICD for the study MRI scan. The MRI Setting allows for the programming of pre-specified parameters that can be saved, and utilized for MRI scanning without the need to individually program individual parameters every time a subject needs to undergo an MRI scan; the parameters in the MRI Setting are also all individually available, programmable parameters in the Ellipse ICDs.

Additionally, the study will potentially show that MRI scans can be safely completed in subjects implanted with these leads and devices resulting in MRI conditional labeling of these systems implanted in the subjects.

3.3 Anticipated adverse events and adverse device effects

The Durata or Optisure lead and the Ellipse VR ICD are market-released devices. Risks associated with the use of the Durata or Optisure lead and the Ellipse VR ICD are anticipated to be comparable to those associated with the use of other market-released defibrillation leads, pacing leads, and ICDs. Subjects participating in this study are indicated for or implanted with an ICD as part of their standard medical management and are subject to the risks associated with these devices independent of the subject's participation in the study.

The Durata or Optisure lead and the Ellipse VR ICD are being tested in an MRI environment, and subjects participating in the study are required to undergo the study MRI scans which are investigational for the purposes of investigating the effect the scan has on the implanted ICD system. The subjects are therefore exposed to, but not limited to, an incremental risk of experiencing the events listed below.

Table 2: Anticipated Events and Anticipated Adverse Device Effects

Event	Mitigation
Potential MRI Related Events	
• Lead electrode heating and tissue damage resulting in loss of sensing or capture or both • Lead heating resulting in thrombus formation or embolism • Device heating resulting in tissue damage in the implant pocket or subject discomfort or both • Induced currents on leads resulting in continuous capture, VT/VF, hemodynamic collapse, or all three • Damage to the device or leads causing: a. the system to fail to detect or treat irregular heartbeats b. the system to treat the subject's condition incorrectly • Damage to the functionality or mechanical integrity of the device resulting in the inability of the device to communicate with the programmer • Movement or vibration of the device or leads • Lead dislodgment • Competitive pacing and potential for VT/VF induction due to ambulatory asynchronous pacing in MRI mode • Pulmonary Embolism	These risks are mitigated through the selection of investigators who are qualified by training and/or experience to evaluate and treat subjects implanted with an ICD system. In addition, study investigators will be trained on the study protocol to ensure the proper procedures are followed to assure subject safety during the study MRI scan. This includes continuous monitoring of the subject using pulse oximetry, ECG and verbal communication during the scan. Advanced Cardiac Life Support (ACLS) procedures will be in place to address situations where a life threatening arrhythmia and/or hemodynamic collapse occurs. The programmer will be used outside the American College of Radiology (ACR) defined Zone 4 magnet room. If the subject's hemodynamic function is compromised during the MRI scan, the MRI scan will be stopped, and proper measures will be taken to restore the subject's hemodynamic function.
Potential ICD Related Events	
• Refer to the Ellipse user's manual for a full list of potential adverse events	The Ellipse VR ICD is a market-released ICD. The adverse events associated with this ICD are the same as those associated with other market-released ICDs. These risks are mitigated through the

Event	Mitigation
	selection of investigators who are qualified by training and/or experience to evaluate and treat subjects implanted with an ICD.
Potential Lead Related Events	
• Refer to the Durata and Optisure lead user's manual for a full list of potential adverse events	The Durata and Optisure leads are market released transvenous, steroid-eluting defibrillation leads. The adverse events associated with these leads are the same as those associated with other market-released transvenous defibrillation leads. These risks are mitigated through the selection of investigators who are qualified by training and/or experience to evaluate and treat subjects implanted with an ICD system.

In addition, subjects may also experience unavoidable events related to the MRI scan. An unavoidable event is an event related to the MRI scan that is expected to occur for a projected duration in all subjects. Unavoidable events are not reportable unless the condition worsens or continues beyond the time frame listed below. Unavoidable events do not need to be reported on an adverse event form if they are resolved within the time frame specified. These events are expected to occur with any MRI scan, including the study MRI scans.

Table 3: Unavoidable events related to the MRI Scan

Event	Time Frame post – MRI scan
• Claustrophobia	• During MRI scan
• Mild diaphoresis	• During and < 1 hour post MRI scan
• Sensation of bodily warmth	• During and < 1 hour post MRI scan
• Sensation of warmth at device pocket not arising to the level of discomfort	• During and < 1 hour post MRI scan
• Hearing impairment	• < 24 hours
• Body stiffness related to immobility	• < 48 hours

3.4 Residual risks associated with the device under investigation

All risk regions were evaluated, and all the system risks were deemed acceptable. While steps have been taken to identify risks associated with the study MRI scan and participation in the study, there may be risks that are unknown at this time.

3.5 Risks associated with participation in the clinical study

Potential risks associated with the study MRI scan are the same as or comparable to those associated with MRI scans of an implanted medical device powered by a battery or other electrical source of power including, but not limited to, those listed in the Adverse Events and Adverse Device Effects section of the protocol.

Potential risks associated with the induction sub study are the same as or comparable to the risks associated with induction testing that may occur during device implant.

3.6 Possible interactions with concomitant medical treatments and/or concurrent medical interventions

Other than the study MRI scan, there are no treatments that the subject would not otherwise receive as part of the subject's medical management related to having an implanted ICD system. While an MRI scan is not part of the usual treatment regimen for subjects implanted with an ICD, it is an accepted imaging modality used in the diagnosis of diseases or other medical condition.

The MRI scanner, methods used to scan the subject (scan sequences), and monitoring procedures in and of themselves are not investigational. As such, there are no anticipated interactions with concomitant medical treatments or concurrent medical interventions associated with the study MRI scan.

The device checks at each study visit are standard of care, or involve testing of the device and lead that are normally done at a routine device check. As such, there are no anticipated interactions with concomitant medical treatments or concurrent medical interventions associated with the study visits.

3.7 Steps that will be taken to control or mitigate the risks

The risks associated with MRI scanning of subjects implanted with implantable active medical devices have been identified through clinical evaluation, including an exhaustive literature search.

Risks normally associated with ICDs and transvenous leads will be minimized in the study by selecting investigators who are experienced in treating subjects implanted with ICDs,

evaluating implanted ICD systems, and who are trained in the MRI Ready IDE Study. Subjects will be actively monitored during the study scan using verbal communication, ECG, and continuous pulse oximetry monitoring. The investigator or other ACLS-certified personnel who have been trained on the study protocol will be present during the study MRI scan to address cases of asystole or hemodynamic collapse that may occur during the study MRI scan. In addition, because the study MRI scan is not meant to be diagnostic in nature, contrast agents will not be used, thereby eliminating the risk of allergic or adverse reactions to contrast agents.

Risks will also be minimized by careful assessment of each subject prior to enrollment. After enrollment, subjects in the study will be followed as specified in this CIP to monitor the condition of the implanted system and the battery after the subject has undergone the study MRI scan.

In order to safely perform an MRI scan on a subject with the implanted study system, the physician/clinician should do the following as stated in the MRI Procedure Information for the St. Jude Medical® MR Conditional pacing system:

- Confirm that the patient has an MR Conditional System
- Confirm that no adverse conditions to MRI scanning are present (e.g. additional hardware)
- Review the potential adverse events
- Generate a report of the patient's permanently programmed parameters
- Select and Save MRI Settings
- Review the MRI Checklist and Program the MRI Settings using the Merlin® PCS
- Subject receives the MRI Scan
- Disable MRI Settings Using the Merlin® PCS

After the MRI scan and at the 1 Month Post Scan visit, the ICD will be interrogated to verify appropriate ICD function, to evaluate pacing and sensing characteristics, and to assess any adverse events.

Overall, the clinical study design, subject selection process, and procedures developed for scanning and monitoring of the subject during the MRI scan have all been designed to minimize risks to the subject.

While steps have been taken to identify and reduce or minimize risks associated with the study MRI scan and participation in the study, there may be risks that are unknown at this time due to the investigational nature of this study.

3.8 Risk-to-benefit rationale

There may be no direct clinical benefit to the subject for participating in this study; no direct therapy is being provided as part of the study procedures, i.e. the study MRI scan. However, these data will help to establish the safety and efficacy of the Durata or Optisure lead and the Ellipse VR ICD in an MRI environment, which, upon approval, will provide patients who need an ICD to have the option to be safely scanned should these patients need to undergo an MRI in the future.

4.0 Study Design

4.1 Purpose

The intent of this IDE study is to evaluate the safety and efficacy of the Durata or Optisure lead and Ellipse VR ICD that have undergone an MRI scan. The patient population under study includes patients indicated for or who have been implanted with a Durata or Optisure lead and an Ellipse VR ICD.

4.2 Study Design and Scope

The study intends to enroll patients, including Medicare beneficiaries, who have been implanted with a Durata or Optisure lead and Ellipse VR ICD to evaluate the effects of an MRI scan on the aforementioned devices. The evaluation will be performed as part of a regulated, prospective, multi-center, non-randomized, single-arm clinical trial. This design was chosen for generalizability of study results by enrolling subjects across multiple geographies and varying types of sites, with the minimum sample size required to demonstrate the safety and efficacy of the Durata or Optisure lead and the Ellipse ICD in an MRI environment.

Subjects that agree to participate in the MRI Ready IDE study will also be approached to enroll in a sub study of the MRI Ready IDE study which will involve induction testing that is performed post MRI visit.

Ventricular tachycardia (VT) and ventricular fibrillation (VF) events will also be collected to characterize ventricular arrhythmia sensing and detection post-MRI. A minimum of 25 device detected VT/VF events (induced or spontaneous) will be collected post MRI from a minimum of 25 subjects with at least one ventricular arrhythmia episode (spontaneous or induced) adjudicated by the Ventricular Arrhythmia Events Committee through any one of three methods:

1. Events obtained during induction testing at any time after the MRI visit, including system revision and follow up visits where induction testing was performed due to impaired R-wave sensing or other clinical reasons.

2. Events in subjects who enroll in the sub study, which will involve post MRI induction testing
3. Subjects who are not enrolled in the sub study will be followed via Merlin.net or phone call every 3 months post baseline visit to collect potential spontaneous VT/VF episodes after the MRI visit. The data collection effort will end upon notification from SJM.

Data collected to demonstrate safety of the Durata or Optisure lead and the Ellipse VR ICD include MRI scan related complications and deaths resulting from the study MRI scan. Data collected to demonstrate efficacy of the study devices include changes in the device's capture and sensing thresholds from the pre-MRI scan testing to 1-Month post MRI testing.

4.2.1 Number of Subjects Required to be Included in the Study

The maximum number of subjects in the study is 165. A maximum of 41 (25% of the total, if the total subjects enrolled = 165) subject enrollments will be allowed per center.

A patient will be considered enrolled in the main study after he/she signs the main study consent, meets all of the inclusion and none of the exclusion criteria verified during the pre-MRI testing, and the MRI Settings have been programmed.

4.2.2 Estimated Time Needed to Enroll Subject Population

Enrollment in this clinical study is expected to take approximately 12 months. The anticipated duration of this study is 1.5 to 2 years, depending on the rate of enrollment and regulatory timelines.

The minimum duration of each subject's participation, if he/she undergoes an MRI scan, in the study is 23 days. All subjects will have the Durata or Optisure lead implanted for at least 60 days prior to enrollment.

The following study visits will occur after enrollment:

- MRI scan/Post Scan testing
- 1 Month Post Scan visit

The MRI Scan should take place no sooner than 60 days post lead implant or lead revision procedure where the Durata or Optisure lead was implanted or repositioned. The 1 Month Post Scan visit is based on the MRI Scan Visit.

A data collection effort to collect VT/VF events will also take place. For subjects on Merlin.net, the Merlin.net records will be reviewed for spontaneous VT/ VF events. Subjects not on Merlin.net will be contacted by phone and their medical records will be screened every 3 months for VT/VF events since the last visit. The data collection effort will end upon notification from SJM.

4.3 Objectives

4.3.1 Primary Objectives

The primary objectives of this study are to assess the safety and efficacy of the Durata or Optisure lead and Ellipse VR ICD in an MRI environment.

4.4 Endpoints

4.4.1 Primary Safety Endpoint

Safety for the Ellipse VR ICD involving the Durata and Optisure leads will be evaluated in terms of:

- Freedom from MRI scan-related complications for the Ellipse VR ICD involving Durata or Optisure (RV) lead from MRI scan to 1 month post-MRI scan testing is greater than 90%

4.4.2 Primary Efficacy Endpoints

Efficacy of the Durata and Optisure leads involving the Ellipse VR ICD will be evaluated in terms of:

- Proportion of Durata or Optisure (RV) leads implanted with the Ellipse VR ICD with capture threshold increase of ≤ 0.5V at 0.5ms from pre-MRI scan to 1 month post-MRI scan testing is greater than 90%
- Proportion of Durata or Optisure (RV) leads implanted with the Ellipse VR ICD with sensing amplitude decrease of ≤ 50% from pre-MRI scan testing to 1 month post-MRI scan is greater than 87%

4.4.3 Additional Data

The following data will also be collected.

- Demographics: gender, age, ethnicity, race, cardiac disease history, arrhythmia history, indication for ICD implant, history of smoking, etc.
- Device electrical measurements at the MRI Scan Visit (before and after the scan) and at the 1 Month Post Scan Visit
- ADE, SADE, UADE/USADE
- Mortality

- Number of non-study related MRI scans
- Proportion of VT/VF episodes with significant detection delay assessed from device-detected VT/VF episodes (induced or spontaneous) with stored electrogram available
- Summarize number of subjects that returned to usual programming after the MRI scan and number of subjects, if any, experiencing delays in reprogramming

4.5 Subject Selection

A subject, who meets all of the inclusion criteria, and none of the exclusion criteria, is eligible to participate in this study.
To participate in this clinical study, the subject must meet all of the following inclusion criteria:

4.5.1 Inclusion Criteria

1. Are implanted with the Durata or Optisure lead for at least 60 days (can include patients with Durata or Optisure lead for ≥ 60 days OR patients with a new Ellipse VR ICD and/or Durata/Optisure lead implanted for at least 60 days)
2. Are implanted with an Ellipse VR ICD pectorally
3. Be willing to undergo an elective MRI scan without sedation
   NOTE: Antianxiety agents (e.g. minor tranquilizers, etc.) may be used as long as the patient can communicate with site personnel during the MRI scan
4. Capture threshold is stable at ≤ 2.5V@0.5ms
5. Ventricular sensing is measurable (patient has underlying rhythm > 30bpm) and the sensing amplitude is ≥ 4mV
6. Be able to provide informed consent for study participation (legal guardian or legally authorized representative is NOT acceptable)
7. Be willing and able to comply with the prescribed follow-up tests and procedures
8. Is not contraindicated for an MRI scan (per the MRI Screening Form)

Subjects are not eligible for clinical study participation if they meet any of the following exclusion criteria:

4.5.2 Exclusion Criteria

1. Have a competitor's MRI compatible endocardial lead implanted or capped
2. Have another existing active implanted medical device, e.g., neurostimulator, infusion pump, etc., that has MR labeling that will not allow the MRI scans per this protocol to be completed.
3. Have a lead revision of the Durata/Optisure lead occur < 60 days of the baseline visit
4. Have other non-MRI compatible device or material implanted

NOTE: MRI compatible knee replacements, hip replacements, stents, etc. may be included as long as the labeling of these devices allow MRI scans conducted per this protocol
NOTE: MRI compatible mechanical, prosthetic, and bioprosthetic heart valves may be included as long as the labeling of these devices allow for MRI scans conducted per this protocol
NOTE: Non-removable dental implants may be included

5. Have a lead extender, adaptor, or capped/abandoned lead
6. Enrolled or intend to participate in a clinical drug and/or device study (investigational device, investigational drug, new indication for a device or drug or additional testing beyond standard of care procedures), which could confound the results of this trial as determined by SJM.
7. Pregnant or planning to become pregnant during the duration of the subject's participation in the study
8. Have a life expectancy of less than 12 months due to any condition
9. Patients with exclusion criteria required by local law (e.g., age)

4.6 Subject Population

4.6.1 Patient Screening

All patients presenting at the investigational site may be screened by a member of the investigational team previously trained on the CIP and delegated to do so.

Patients who do not meet the inclusion/exclusion criteria will not be eligible to participate in this study.

Patients meeting the inclusion/exclusion criteria will be fully informed about the study and asked to review and sign informed consent. In case the subject agrees, a duly signed and dated Patient Informed Consent will be obtained.

Subjects will be approached with the main study consent at all study centers. For centers that are participating in the induction sub study, subjects will be approached with the main study consent and the sub study consent so they may make an informed decision about both the study and the sub study.

4.6.2 Point of Enrollment

Subjects are considered enrolled after the main study consent has been signed (Refer to section 4.7 for the Informed Consent Process), it has been verified during the MRI pre-scan visit that the subject meets all of the inclusion and none of the exclusion criteria, and the MRI Settings have been programmed.

4.6.3 Enrollment of Medicare Beneficiaries

This clinical study will enroll Medicare beneficiaries and therefore conforms to all standards of Medicare coverage requirements. Section 3.0 describes how all enrolled subjects, including Medicare beneficiaries, may be affected by the device under investigation. Subjects enrolled in the clinical study are expected to be consistent with the Medicare population based on age and as such the study results are expected to be generalizable to the Medicare population.

4.6.4 Vulnerable Population

This clinical study will be conducted in a vulnerable population only when the study cannot be carried out in non-vulnerable populations. At the current time, this study does not allow, and will not include vulnerable patients for enrollment into the study.

4.7 Informed Consent Process

4.7.1 General Process

Prior to enrolling in the clinical study and sub study and conducting study-specific procedures, all subjects will be consented, as required by applicable regulations and the center's IRB/EC. Informed consent must be obtained from each subject prior to any study related procedures. Each consent form must be signed and dated by the subject and by the person obtaining the consent.

In order to participate in the sub study, the subject must consent to both the main clinical study and sub study.

The principal investigator or his/her authorized designee will conduct the Informed Consent Process. This process will include a verbal discussion with the subject on all aspects of the clinical study and sub study that are relevant to the subject's decision to participate in the clinical study and sub study.

The subject shall be provided with the informed consent form that is written in a language that is understandable to the subject and has been approved by the center's IRB/EC. Failure to obtain informed consent from a subject prior to study enrollment should be reported to St. Jude Medical within 5 working days and to the reviewing center's IRB/EC/ consistent with the center's IRB/EC reporting requirements.

5.0 Devices Under Investigation

5.1 Device Descriptions

In this IDE study, patients must have the St. Jude Medical market-released Durata or Optisure high voltage leads implanted with a market released St. Jude Medical Ellipse VR ICD for at least 60 days prior to enrollment.

Table 4: Study Device

Device	Model	Type	Investigational or Market Released	Country	Description
Ellipse VR	CD1411-36QC	ICD	Market Released	US	Single chamber ICD
Ellipse VR	CD1411-36Q	ICD	Market Released	US	Single chamber ICD
Ellipse VR	CD1311-36Q	ICD	Market Released	US	Single chamber ICD
Ellipse VR	CD1377-36QC	ICD	Market Released	Outside the US	Single chamber ICD
Ellipse VR	CD1377-36Q	ICD	Market Released	Outside the US	Single chamber ICD
Durata	7120Q	Lead	Market Released	US and Outside the US	Active fixation, dual shock, 17 cm spacing, DF4 connector, 58/65cm length
Durata	7122Q	Lead	Market Released	US and Outside the US	Active fixation, single shock, DF4 connector, 58/65cm length
Optisure	LDA220Q	Lead	Market Released	US and Outside the US	Active fixation, dual shock, 17 cm spacing, DF4 connector, 58/65cm length
Optisure	LDA210Q	Lead	Market Released	US and Outside the US	Active fixation, single shock, DF4 connector, 58/65cm length

5.1.1 Ellipse ICD

The Ellipse ICD is supported by the St. Jude Medical Merlin Patient Care System (Merlin PCS) with software Model 3650, Software Model 3330 version 20.X (or higher).

The Ellipse ICD is intended to provide ventricular antitachycardia pacing and ventricular defibrillation for automated treatment of life-threatening ventricular arrhythmias.

Instructions for use, storage and handling instructions, preparation for use and any precautions can be found in the User's Manual for the Ellipse ICD.

5.1.2 Durata Lead

The Durata Models 7120Q, and 7122Q leads are market-released 7 French, transvenous, steroid eluting, bipolar, DF4 compatible (single connector with four electrical terminals), active fixation leads intended for permanent sensing and pacing of the right ventricle and the delivery of cardioversion/defibrillation therapy when used with a compatible St. Jude Medical pulse generator with a DF4-LLHH or DF4-LLHO lead receptacle designation.

Instructions for use, storage and handling instructions, preparation for use and any precautions can be found in the User's Manual for the Durata lead.

5.1.3 Optisure Lead

The Optisure Models LDA220Q and LDA210Q transvenous leads are market-released leads indicated for use with compatible pulse generators (refer to the applicable defibrillator manual for system indications). They provide pacing and sensing and deliver cardioversion/defibrillation therapy to the heart.

Instructions for use, storage and handling instructions, preparation for use and any precautions can be found in the User's Manual for the Optisure Lead.

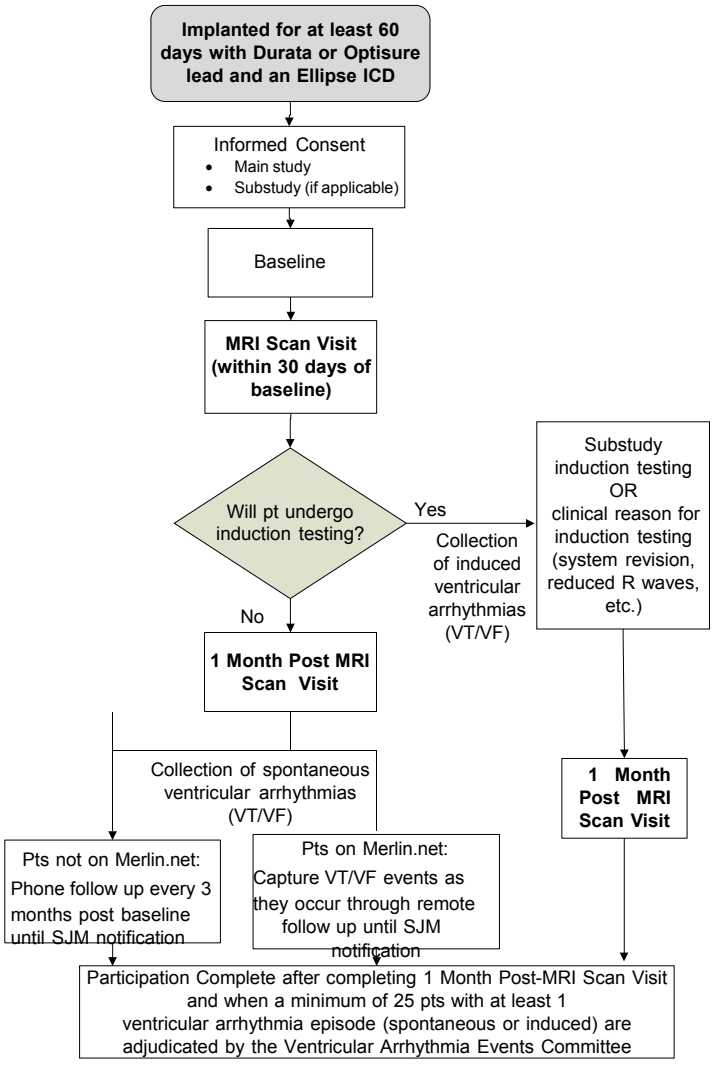
5.2 Device Handling & Storage

This study involves use of market approved products. The study procedure i.e. MRI scan, is considered investigational in nature. Physicians should consult the User's manual for device handling and storage.

6.0 Procedures

6.1 Study Flow Chart

Figure 1: Study Flow Chart



6.2 Procedures

The clinical study will be conducted in accordance with the CIP. All parties participating in the conduct of the clinical study will be qualified by education, training, or experience to perform their tasks and this training will be documented appropriately.

The clinical study will not commence until St. Jude Medical receives written approval from the IRB/EC and relevant regulatory authorities and all required documents have been collected from the site(s).

All required study procedures at each specified interval are outlined in the sections below. Refer to Table 5: Study Procedures and Data Collection for an overview of the required study procedures at each interval or study visit.

Table 5: Study Procedures and Data Collection

Study Visit	Visit Window	Study Procedures and Data Collection	Forms and CRFs
NA	***Up to or same day as Baseline***	• Screen patient for enrollment eligibility • Obtain informed consent(s) [Main study consent & sub study consent, if applicable]	• Signed and Dated Patient Informed Consent Form(s)
Baseline	***The latter of :*** • ≥60 days after implant AND • ≥60 days after most recent lead revision, if applicable	• Obtain medical and surgical history • Collect demographic information • Document indication for implant of ICD • Obtain ICD system information: model and serial number of implanted Ellipse ICD system, and if applicable, most recent lead revision information. Collect demographic information • Complete MRI Screening Form	• Baseline CRF • MRI Screening Form
MRI Scan Visit	***Post Baseline (Within 30 days post baseline).*** ***The pre-MRI scan, MRI and post MRI scan procedures should occur on the same day.***	Pre-MRI scan testing • Assess inclusion/exclusion criteria • Screen, clear and prep subject for MRI scan • Complete MRI screening Form if MRI scan visit does not occur the same day as baseline) • Complete MRI Hazard Checklist • Administer pregnancy test – can be done up to 7 days before MRI scan • Interrogate device • Perform capacitor maintenance • Obtain in-clinic Durata or Optisure lead measurements: bipolar capture, sense, pacing	• MRI Hazard Checklist • Pre-MRI Scan CRF • MRI Scan CRF • MRI Survey Form *If applicable:* • MRI Screening Form • AE CRF • Deviation CRF • Death CRF • Withdrawal CRF • Product Out of Service CRF

Study Visit	Visit Window	Study Procedures and Data Collection	Forms and CRFs
		and HVLI impedances[1,2] • Set up and Activate MRI Settings During MRI Scan • Monitor subject with ECG, pulse oximetry, and verbal communication Post MRI scan testing • Interrogate device • Deactivate MRI Settings • Obtain in-clinic Durata or Optisure lead measurements: bipolar capture, sense, pacing and HVLI impedances[1,2] • Evaluate subject for ADE, SADE, UADE (for US sites) or USADE (for OUS sites) events and submit an AE CRF (as applicable). • Report deviations, death, withdrawal and out of service, as applicable • Submit MRI scan results, e.g. scan time, sequences used, etc. • Upload device session records through the EDC study site portal	
1 Month Post MRI Scan Visit	***30 days after MRI scan (-7/+14 days)***	• Interrogate device • Obtain in-clinic Durata or Optisure lead measurements: bipolar capture, sense, pacing and HVLI impedances[1,2] • Evaluate subject for ADE, SADE, UADE (for US sites) or USADE (for OUS sites) events and submit on AE CRF (as applicable). • Report deviations, death, withdrawal and out of service as applicable • Upload device session records through the EDC study site portal	• Follow Up CRF *If applicable:* • AE CRF • Deviation CRF • Death CRF • Withdrawal CRF • Product Out of Service CRF • Induction Testing CRF
Sub study induction testing	***Can occur any time after the MRI scan visit (Suggest that testing occurs within 30 days after MRI scan***	• Conduct induction therapy testing (e.g. DC Fibber method). Method of induction is physician preference.) • Evaluate subject for ADE, SADE, and UADE (for US sites) or	• Induction Testing CRF *If applicable:* • AE CRF • Deviation CRF

Study Visit		Visit Window	Study Procedures and Data Collection	Forms and CRFs
		(-7 days/+14 days)	USADE (for OUS sites) events and submit on AE or CRF (as applicable). • Report deviations, death, withdrawal and out of service as applicable • Upload device session records through the EDC study site portal	• Death CRF • Withdrawal CRF • Product Out of Service CRF
Review of spontaneous VT/VF events episodes (non-sub study subjects)	Subjects on Merlin.net	***Capture events as they occur any time after the 1 month post MRI scan visit***	• Merlin.net records will be reviewed by SJM for spontaneous VT/VF • Review of records will end upon notification from SJM	• Not applicable
	Subjects not on Merlin.net	***Every 3 months post baseline ± 30 days***	• Follow up by phone with subject and screen medical records to find out if a VT/VF arrhythmia has occurred since last visit. Obtain the device data related to that VT/VF episode. • Follow up visits will end upon notification from SJM.	• Follow Up Phone Call CRF *If applicable*: • AE CRF • Deviation CRF • Death CRF • Withdrawal CRF • Product Out of Service CRF
Unscheduled (if applicable)		***Any time after the MRI scan visit (where the subject is seen in clinic due to an ADE, SADE or UADE associated with the Durata or Optisure or Ellipse ICD or for follow up related to the collection of VT/VF episodes)***	• Interrogate device. • Obtain applicable in-clinic Durata or Optisure lead measurements: bipolar capture, sense, and pacing and HVLI impedances, [1,2] if possible • If an unscheduled visit occurs prior to the 1 month post MRI visit, evaluate ADE, SADE, UADE (for US sites) or USADE (for OUS sites) events and submit an AE CRF (as applicable). If an unscheduled event occurs after the 1 month post MRI visit, then the AE events do not need to be submitted. • If a subject experiences reduced R waves and undergoes induction testing or undergoes induction testing for another clinical reason after the MRI visit, then an induction testing form will be submitted.	• Follow Up CRF • AE CRF *If applicable:* • Deviation CRF • Death CRF • Screening Failure/Withdrawal CRF • Product Out of Service CRF • Induction Testing CRF

Study Visit	Visit Window	Study Procedures and Data Collection	Forms and CRFs
		• Report deviations, death, withdrawal and out of service, as applicable • Upload device session records through the EDC study site portal	
Non-Study MRI Scan (if applicable)	***Any time after enrollment through the conclusion of the subject's participation in the study, excluding the MRI scan performed during the MRI scan visit.***	Perform medically required MRI scan. Where possible: Before scan • Complete MRI Hazard Checklist • Interrogate device • Perform capacitor maintenance • Obtain lead measurements: bipolar capture, sense, pacing and HVLI impedances • Enable MRI Settings During MRI Scan • Monitor subject with ECG, pulse oximetry, and verbal communication After MRI scan • Evaluate subject for adverse events • Interrogate device • Disable MRI Settings, and program device back into permanent settings • Obtain lead measurements: bipolar capture, sense, pacing and HVLI impedances • Report AEs, deviations, death, withdrawal, out of service and device deficiency information, as applicable • Document results of MRI scan, e.g. scan time, sequences used, lapses in subject monitoring, etc. Upload device session records through the EDC study site portal	• Non-Study MRI Scan CRF *If applicable*: • MRI Hazard Checklist • AE CRF • Deviation CRF • Death CRF • Withdrawal CRF • Product Out of Service CRF
System Revision (if applicable)	***Can occur any time after baseline***	• Interrogate device • Obtain applicable in-clinic lead measurements: bipolar capture[1], sense[2], pacing, and HVLI impedances for cases where the lead was repositioned, or was replaced with another Durata or	• System Revision CRF *If applicable*: • AE CRF • Deviation CRF • Death CRF • Screening Failure/Withdrawal

Study Visit	Visit Window	Study Procedures and Data Collection	Forms and CRFs
		Optisure lead, or where the ICD was replaced with another Ellipse VR ICD. • NOTE: If the device replacement/revision of the Ellipse VR device occurs post MRI visit and the Durata/Optisure lead remains in its original location, then induction testing may occur and the session records related to induction testing should be uploaded. • Evaluate ADE, SADE, UADE (for US sites) or USADE (for OUS sites) events and submit an AE CRF (as applicable). • Report deviations, death, screening failure/withdrawal and out of service as applicable • Upload device session records through the EDC study site portal	CRF • Product Out of Service CRF • Induction Testing CRF

[1]Durata or Optisure lead capture thresholds are not required if a high ventricular rate (e.g. 110bpm) is present. If available, sites should use the automatically obtained pacing capture threshold from the most recent archival data as a substitute for the in clinic capture threshold.
[2]Durata or Optisure lead sensing measurements are not required if the subject's intrinsic rate has been established to be at or below 30 beats per minute.

6.3 Screening and Informed Consent

Consider all patients for participation in this study regardless of gender. Screen patients as outlined by the inclusion/exclusion criteria. Obtain informed consent from the patient. The principal investigator or delegated study personnel are responsible for screening all potential subjects to determine subject eligibility for the study.

6.4 Baseline

The baseline visit must occur the latter of:
- ≥60 days after lead implant AND
- ≥60 days after most recent lead revision, if applicable

Collect data on the subject including demographics and medical/surgical history such as gender, age, ethnicity, race, cardiac disease history, arrhythmia history, and indication for ICD implant, etc. To ensure the patient meets the requirements to undergo the study MRI

scan, use the MRI Screening Form as part of the enrollment screening. Prior lead measurements may be used to evaluate inclusion criteria at the baseline visit.

6.5 Scheduled Follow Ups

After baseline and within 30 days post baseline, subjects will be seen for an MRI Scan Visit. During the MRI Scan Visit, the pre-MRI scan testing, MRI Scan and Post-MRI scan testing should all occur on the same day. Subjects will also be seen 1 Month Post MRI Scan Visit (-7/+14 days).

All subjects will also be evaluated for spontaneous VT/VF episodes. If the patient is on Merlin.net, then Merlin.net records will be reviewed by SJM for spontaneous VT/VF. If the patient is not on Merlin.net, then the patient will be contacted by phone and/or the patient's medical records will be reviewed to find out if VT/VF has occurred since the last visit. The Merlin.net record review and phone follow up will end when SJM has collected a minimum of 25 subjects with at least one ventricular arrhythmia episode (spontaneous or induced) adjudicated by the Ventricular Arrhythmia Events Committee.
Refer to these visits in Table 5 for specific study procedures and data collection; the Baseline and MRI Scan Visit is allowed, but is not required, to be conducted on the same day.

Definition of enrollment:
The patient will be considered enrolled in the study after the main study consent is signed by the patient, it has been verified during the MRI visit that the subject meets all of the inclusion and none of the exclusion criteria, and the MRI Settings have been programmed.

6.5.1 MRI Scan Visit

IMPORTANT NOTE: Before the MRI Scan Visit, if the subject underwent a system revision since enrollment that resulted in

- implant of a lead or ICD other than the Durata or Optisure lead, or the Ellipse ICD, or
- capping/abandoning a lead
- implant of a non-MRI compatible device or material, or
- any combination above,

the subject is no longer eligible to undergo the study MRI Scan. Do not proceed with any of the tests listed for the MRI Scan Visit. The patient is a screen failure. Refer to Section 6.8 System Revisions for further details.

Otherwise, follow the procedures outlined below for the MRI Scan Visit.

6.5.1.1 Pre-Scan Testing and Device Programming

Pregnancy Testing

Administer a pregnancy test (per institutional standard) to all female subjects of childbearing potential. The pregnancy testing may be done up to 7 days before the MRI scan. Document the results of the test. If the subject is pregnant, do not proceed any further. The subject is a screen failure for the study.

Clearing the Subject for the Study Scan

In order to safely perform an MRI scan on a subject with the implanted study system, the physician/clinician should do the following as stated in the MRI Procedure Information for the St. Jude Medical® MR Conditional pacing system:

- Confirm that the patient has an MR Conditional System
- Confirm that no adverse conditions to MRI scanning are present (e.g. additional hardware)
- Review the potential adverse events
- Generate a report of the patient's permanently programmed parameters
- Select and Save MRI Settings
- Review the MRI Checklist and Program the MRI Settings using the Merlin® PCS
- Subject receives the MRI Scan
- Disable MRI Settings Using the Merlin® PCS

The radiologist or staff, a designated radiological member, must determine the subject's eligibility for an MRI scan prior to the MRI scan (per standard of practice). However, the ICD and lead (wires) contraindication item on the checklist do not apply if the subject is implanted with the St. Jude Medical Durata or Optisure lead with Ellipse VR ICD (see Table 4 for full details).

Complete MRI Screening Form again if the MRI scan visit does not occur the same day as baseline.

The study MRI Hazard Checklist may be used to document a radiologist or designated member of the radiology department has cleared the subject for an MRI scan. Alternatively, the radiology department may use its own hazard checklist in lieu of the study MRI Hazard Checklist. This documentation should be maintained with the subject's medical and/or study records.

Device Assessment and Programming

Interrogate the ICD, and obtain the following for the Durata or Optisure lead:

- In-clinic bipolar capture threshold at a pulse width of 0.5 ms. Either the manual decrement or automatic (in-clinic, programmer-based) method may be used to obtain the capture threshold. **Note: If the capture threshold is > 2.5V, then the patient does not meet inclusion criteria.**
- In-clinic bipolar sensing amplitude. Either the incremental or the automatic (in-clinic, programmer based) method may be used to obtain the sensing threshold. **Note: If the ventricular sensing is not measurable (patient has underlying rhythm < 30bpm) and the sensing amplitude is < 4mV, then the patient does not meet inclusion criteria.**
- In-clinic bipolar pacing and high voltage lead impedance

NOTE: RV capture thresholds are not required to be obtained if a high ventricular rate is present (e.g. 110bpm). If available, sites should use the automatically obtained pacing capture threshold from the most recent archival data as a substitute for the in clinic capture threshold. RV sensing measurements are not required if the subject's intrinsic rate has been established to be ≤30 beats per minute.

If the device testing results do not meet the MRI conditions for scanning per the MRI Procedure manual (also see below), or the patient's sensing threshold is not measurable or the sensing threshold is less than 4mV, the physician may choose to reschedule the subject to return for re-testing. The subject's 1 Month Post MRI Scan Visit will need to be rescheduled to correspond with the MRI Scan Visit where the MRI scan was completed.

Review the MRI checklist on the programmer. Verify the following conditions before saving the MRI Setting.

- Bipolar capture thresholds are stable at ≤2.5V@ 0.5 ms
- Bipolar pacing lead impedance is within range, i.e. ≥ 200 and ≤ 2000 ohms
- HVLI is within range, i.e. ≥20 and ≤200 ohms
- No additional hardware (adaptors, extenders, or abandoned leads)

Save the MRI Setting after the MRI Checklist has been reviewed, using the parameters listed in Table 6: MRI Parameters. Perform all other applicable tests and procedures.

Table 6: MRI Parameters

Parameters	Selectable Options	Nominal Values
MRI Mode*	VOO Pacing Off	Pacing off
MRI Base Rate	30-100 bpm, in steps of 5 bpm	n/a
MRI RV Pulse Configuration	Bipolar	n/a
MRI RV Pulse Amplitude	5.0 V, 7.5 V	n/a
MRI RV Pulse Width	1.0 msec	n/a
Tachy settings	Disabled	Disabled

***Note:** When MRI Settings are enabled, sensing is disabled. Determine whether or not the subject requires pacing support during the MRI scan. When pacing support is needed, set the MRI Mode to the asynchronous pacing mode (VOO). When pacing support is not needed, set the MRI Mode to Pacing Off.

Some subjects may be susceptible to cardiac arrhythmia induced by competitive pacing when an asynchronous MRI Mode is selected. For these subjects, it is important to select an appropriate MRI pacing rate to avoid competitive pacing and then minimize the duration of the asynchronous pacing operation.

In MR Conditional ICDs, tachytherapy is disabled when the MRI settings are programmed.

After the electrical measurements for the RV lead have been taken, capacitor maintenance has been performed, the MRI Checklist (on the programmer) verified and the MRI Setting saved, activate the MRI parameters.

Setting up Pulse Oximetry and ECG

Set up pulse oximetry and an ECG per standard of care.

Place the oximetry clip on the subject's finger or other any other appendage that results in valid pulse oximetry readings. Position MRI compatible surface electrodes on the subject to ensure the subject's heart rate can be continuously monitored during the scan. During the MRI scan, periodically record heart rate, and blood oxygen saturation levels. Visually examine the ECG during the MRI scan. Note any abnormalities observed in the cardiac rhythm (Refer to Life–threatening Ventricular Arrhythmia and Asystole Assessment below). After the MRI scan, remove the subject from the MRI field.

Definition of enrollment:

The patient will be considered enrolled in the study after the main study consent is signed by the patient, it has been verified during the MRI visit that the subject meets

all of the inclusion and none of the exclusion criteria, and the MRI Settings have been programmed.

The following documentation activities should be performed after the subject has been consented.

- Record enrollment information (name of the study, date of consent and inclusion/exclusion information) in the subject's medical and/or study records
- Complete and submit the Baseline and Pre-MRI CRFs in a timely manner (recommended within 5 days)
- Notification of enrollment to the sponsor will take place when the sponsor receives the Pre-MRI Scan CRF Form indicating that the MRI Settings has been enabled.

6.5.1.2 Data Submission

Once required testing has been performed, complete and submit the appropriate forms to St. Jude Medical. Refer to Table 5: Study Procedures and Data Collection

Upload the pre-MRI scan device session records through the EDC study portal. It is recommended that the following device printouts and measurements be maintained at the site.

- FastPath Summary
- Test Results with Freezes, Include Battery & Leads
- Wrap-up Overview with full parameters
- Device MRI summary report

6.5.2 Situations where the subject does not meet enrollment criteria

If a subject does not meet all inclusion criteria or meets any of the exclusion criteria, the subject cannot participate in the study and cannot be enrolled.

In case the subject was already consented to participate in the study, but did not meet inclusion/exclusion criteria, the following actions will be taken (Table 7). The EC/IRB and CA/FDA should be notified of deviations according to each respective entity's guidelines.

Table 7: Actions for Inclusion/Exclusion Criteria Issues that Occur Post Consent

Issues where patient was consented, but did not meet inclusion/exclusion criteria	Action
If the MRI Scan Visit has not yet taken place and the MRI Settings was not programmed	• Document consenting information (name of the study, date of consent and inclusion/exclusion) in the subject's medical and/or study records • Submit the Baseline CRF and Screening Failure CRF. The subject is a screen failure.
If the MRI Pre-Scan Visit has taken place, the MRI Settings was NOT programmed and the study MRI scan was NOT completed (e.g. Subject changed their mind about undergoing MRI scan, etc.)	• Document enrollment (name of the study, date of consent and inclusion/exclusion), MRI Scan Visit and study MRI scan information in the subject's medical and/or study records • Complete the Baseline Form • Complete the Pre-MRI Scan Form • Note that the subject did not have the MRI Settings programmed on the pre-MRI CRF. • Submit the Screening Failure CRF. The subject is a screen failure.
If the MRI Pre-Scan Visit has taken place, the MRI Settings WERE programmed but the study MRI scan was NOT completed (e.g. Subject changed their mind about undergoing MRI scan, etc.)	• Document enrollment (name of the study, date of consent and inclusion/exclusion), MRI Scan Visit and study MRI scan information in the subject's medical and/or study records • Complete the Baseline Form • Complete the Pre-MRI Scan Form • Complete deviation for inclusion/exclusion criteria not met • Complete the Withdrawal CRF. The patient is withdrawn.
If the MRI Pre-Scan Visit has taken place, the MRI Settings were programmed AND the study MRI scan has been performed	• Document enrollment (name of the study, date of consent and inclusion/exclusion), MRI Scan Visit and study MRI scan information in the subject's medical and/or study records • Complete the Baseline Form • Complete the Pre-MRI Scan Form and MRI Scan Form • Complete deviation for inclusion/exclusion not met • Continue to follow the subject through the 1 Month Post MRI Scan Visit.

6.5.2.1 The MRI Scan

After confirmation by the electrophysiologist or device specialist that all pre-MRI system checks (mentioned above) have been met, subjects will have their MRI scan completed by a radiology staff member. Note: If the patient does not pass the Pre-MRI scan System Check specified above, then the patient should not undergo an MRI scan. The patient can be rescheduled to come back to repeat the Pre-MRI scan System Check testing within the visit window.

Protocol required MRI scan sequences for each subject undergoing an MRI scan are described in detail in Appendix E. It is recommended that the MRI scan be set up on the MRI scanner in advance of the first subject scheduled for a study scan to ensure the scan has been appropriately programmed, and to provide adequate time to address any questions or issues that may arise.

Subjects will undergo two different scans for the study, both of which will expose the ICD to extreme scanning conditions: (1) a thoracic scan that is RF intensive, and (2) a head scan that is gradient intensive. The thoracic scan should be set up to last about 6 minutes and 15 seconds, and the head scan should be set to get as close as possible to 5 minutes without being under 5 minutes. The thoracic scan will need to be repeated 4 times to ensure the subject is scanned approximately 25 minutes. Further details about the set-up, programming and ways to adjust the parameters for MRI scans can be found in Appendix E.

The subject may be in the bore or near the vicinity of the magnet for approximately 60 minutes. The actual amount of time the subject will be scanned is about 30 minutes: 25 minutes for the thoracic scan, and 5 minutes for the head scan.

These two MRI scans are not intended to be diagnostic in nature and therefore the administration of contrast fluids or sedation, or the application of water and fat saturation techniques are not permitted.

Consult the “MRI Ready Systems Manual. MRI Procedure Information for the St. Jude Medical™ MR Conditional System” for guidelines and `precautions related to conducting an MRI scan with the implanted study ICD system.

NOTE: The non-clinical study MRI scan in this study is being performed to demonstrate safety and MRI compatibility of the Durata or Optisure lead and Ellipse ICD for an MRI scan, and is not meant to be diagnostic in nature. The MRI scan will not be read by the radiologist.

If subject movement causes distortion on the MRI, do not repeat the MRI scan.

Cardiac Monitoring

During the entire MRI scan, the subject's cardiac function must be monitored using pulse oximetry and an ECG by an MRI Ready IDE study trained electrophysiologist, cardiologist, or Advanced Cardiac Life Support (ACLS) trained personnel capable of delivering external cardiac pacing defibrillation and advanced cardiac life support. Verbal communication with the subject must also take place to assess and/or confirm any clinically significant changes noted in the subject's oxygen saturation or heart rate, as well as any clinically significant complaints not obvious with pulse oximetry. Record these changes and complaints during the MRI scan.

ACLS procedures must be in place to address situations where a life threatening arrhythmia and/or hemodynamic collapse occurs. The programmer must be used outside the American College of Radiology (ACR) defined Zone 4 magnet room. If the subject's hemodynamic function is compromised during the MRI scan, discontinue the MRI procedure and take proper measures to restore the subject's hemodynamic function.

Life–threatening Ventricular Arrhythmia and Asystole Assessment

Monitoring of spontaneous ventricular arrhythmias and asystole must be conducted via an ECG and pulse oximetry during the MRI scans. Any sustained ventricular arrhythmias or asystole (see definition below) must be documented on an Adverse Event form. Non-sustained ventricular tachycardias (NSVT) or premature ventricular contractions (PVCs) do not need to be reported as an adverse event. However, if an arrhythmia reproducibly occurs (occurring more than once during the study scan) while the subject is actively being scanned, report the event on an Adverse Event form.

Definitions:

- *Sustained Ventricular Arrhythmia:* Heart Rate >150bpm for > 30 seconds with depolarization originating in the ventricles
- *Asystole:* A standstill > 6 seconds in electrical activity of the heart (i.e., no heart rate for 6 seconds or more)

Handling of Subjects Unable to Tolerate an MR Scan

In cases where the scan cannot be tolerated by the subject, remove the subject from the scanner. Assess the subject for possible adverse events, and treat the subject's reported symptoms according to your institution's standard of practice. Document the reason for the intolerance. At a minimum, information related to the sequence used to perform the scan, the length of time the subject was scanned, and the whole body SAR level reached should be collected and submitted to St. Jude Medical. A repeat scan is not required to be completed. The subject is not withdrawn from the

study. The subject should be scheduled to return for their 1 month post MRI scan visit.

6.5.2.2 Post-Scan Testing

Device Assessment and Programming

Following the MRI Scan, remove the subject from the MRI bore. Interrogate the ICD. Disable the MRI Settings. **Note: MRI settings must be disabled to ensure that tachyarrhythmia therapy is turned back on.** Obtain the following for the Durata or Optisure lead:

- In-clinic bipolar capture threshold at a pulse width of 0.5 ms. Either the manual decrement or automatic (in-clinic, programmer-based) method may be used to obtain the capture threshold. `
- In-clinic bipolar sensing amplitude. Either the incremental or the automatic (in-clinic, programmer based) method may be used to obtain the sensing threshold.
- In clinic bipolar lead impedance
- In-clinic HVLI impedance

NOTE: RV capture thresholds are not required to be obtained if a high ventricular rate is present. If available, sites should use the automatically obtained pacing capture threshold from the most recent archival data as a substitute for the in clinic capture threshold. RV sensing measurements are not required if the subject's intrinsic rate is established to be ≤30 beats per minute.

Reporting of MRI Scan-Related Adverse Device Effects

An ADE or SADE related to the following should be reported as soon as possible, but no later than 10 working days, to St. Jude Medical: clotting, pulmonary embolism, or heating of the device pocket during the MRI scan. These events are likely to be associated with symptoms occurring during or immediately following the MRI scan and may manifest as chest pain, shortness of breath, or changes in vital signs during or immediately following the MRI scan.

To ensure all ADEs or SADEs related to or caused by the MRI scan are appropriately captured, before starting the scan, verbally instruct the subject to report symptoms of chest pain, shortness of breath or pocket discomfort that he/she experiences while being scanned or immediately after exiting the scanner. Note changes in vital signs such as changes in heart rate, room air blood oxygen saturation, and/or respiration rate that occur during the MRI scan that may suggest an ADE or SADE has occurred due to clotting, pulmonary embolus or related to lead tip or device pocket heating.

If symptoms during or immediately after the MRI scan suggest that an ADE or SADE has occurred due to clotting, pulmonary embolus or related to lead tip or device pocket heating, test to assess possible causes. Diagnostic testing may be performed in any order deemed appropriate by the investigator; if any test was not performed, provide medical justification for not performing that test:

(1) A 12-lead EKG
(2) A 2-view chest X-ray (PA and Lateral).
(3) Room air blood oxygen saturation
(4) A transthoracic echocardiogram.

If the subject reports pocket discomfort, ask the subject for additional descriptive information and determine if the pocket is discolored or warm to the touch. EKG, chest x-ray, room air blood oxygen saturation, or transthoracic echocardiogram testing are not required to be performed for symptoms related to device pocket heating.

Sites should report an ADE or SADE if the subject experiences a significant rise in pacing threshold (1.25V @0.5ms or greater) from pre-MRI scan to one month post-MRI scan.

6.5.2.3 Data Submission

Once required testing has been performed, complete and submit the appropriate forms to St. Jude Medical. Refer to Table 5: Study Procedures and Data Collection

Export the study MRI scan onto a CD, or other form of electronic media in DICOM format, and send to St. Jude Medical. Upload post MRI scan device session records through the EDC study portal. It is recommended that the following device printouts and measurements be maintained at the site.

- FastPath Summary
- Test Results with Freezes, Include Battery & Leads
- Wrap-up Overview with full parameters
- Upload device session record

6.5.3 One (1) Month Post Scan Visit

6.5.3.1 Testing

Interrogate the ICD and obtain electrical measurements for the Durata or Optisure lead.

- In-clinic bipolar capture threshold at a pulse width of 0.5 ms. Either the manual decrement or automatic (in-clinic, programmer based) method may be used to obtain the capture threshold. If a significant rise in pacing threshold (1.25V @0.5ms or greater) from pre-MRI scan to one month post MRI scan has occurred, then complete an AE form.
- In-clinic bipolar sensing amplitude. Either the incremental or the automatic (in-clinic, programmer based) method may be used to obtain the sensing threshold.
- In-clinic Bipolar lead pacing impedance
- In-clinic HVLI impedance

Evaluate the subject for ADE, SADE, and UADE (for US sites) or USADE (for OUS sites) and submit an AE CRF CRF if applicable. Note if any spontaneous VT/VF episodes occurred on the Follow up CRF.

NOTE: RV capture thresholds are not required to be obtained if a high ventricular rate (e.g. 110bpm) is present. If available, sites should use the automatically obtained pacing capture threshold from the most recent archival data as a substitute for the in clinic capture threshold. RV sensing measurements are not required if the subject's intrinsic rate is established to be ≤30 beats per minute.

6.5.3.2 Data Submission

Once required testing has been performed, complete and submit the appropriate forms to St. Jude Medical. Refer to Table 5: Study Procedures and Data Collection
It is recommended that the following device printouts and measurements be maintained at the site.

- FastPath Summary
- Test Results with Freezes, Include Battery & Leads
- Wrap-up Overview with full parameters
- Upload device session record

6.6 VT/VF Data Collection Effort

6.6.1 Induction Testing

6.6.1.1 Sub Study Induction Testing

Subjects that will participate in the induction testing sub study signed the consent for this sub study prior to or during the baseline visit of the MRI Ready IDE study. For sub study subjects, suggest that testing occurs within 30 days after MRI scan visit (-7/+14 days).

Conduct induction testing. The method of induction is physician preference

Evaluate subject for ADE, SADE, and UADE (for US sites) or USADE (for OUS sites) events and submit on AE CRF (as applicable). Report deviations, death, withdrawal, and out of service as applicable

Upload the device session records from the induction therapy testing.

6.6.1.1.1 Data Submission

Once required testing has been performed, complete and submit the appropriate forms to St. Jude Medical. Refer to Table 5: Study Procedures and Data Collection

6.6.1.2 Induction testing for clinical reasons

If a subject experiences reduced R waves or has other clinical needs for induction testing during a follow up visit after the MRI, then the physician may decide if the subject would benefit from induction testing.

A single induction test may be completed. The method of induction is physician preference.

Evaluate subject for ADE, SADE, and UADE (for US sites) or USADE (for OUS sites) events and submit on AE CRF (as applicable). Report deviations, death, withdrawal, and out of service as applicable

Upload the device session records from the induction therapy testing.

6.6.1.2.1 Data Submission

Once required testing has been performed, complete and submit the appropriate forms to St. Jude Medical. Refer to Table 5: Study Procedures and Data Collection.

6.6.2 Non-sub study subjects: Review of spontaneous VT/VF episodes

All enrolled subjects that are not enrolled in the sub study will also be followed via Merlin.net to capture events as they occur any time after the 1 month post MRI scan visit or phone call every 3 months post baseline for subjects that are not on Merlin.net to collect potential spontaneous VT/VF episodes that occur after the MRI visit.

If the subject is on Merlin.net and experienced a VT/VF episode, then the episodes will be collected by SJM from session records at the 1 month post MRI visit and from Merlin.net as they occur any time after the 1 month post MRI scan.

If the subject is not on Merlin.net, then the site will contact the subject by phone every 3 months post baseline ± 30 days to find out if the subject has experienced a VT/VF tachyarrhythmia. If the subject has experienced a VT/VF tachyarrhythmia, then the subject will be asked to visit the clinic so that the session records may be obtained.

The review of Merlin.net records and/or follow up phone calls to subjects will end when SJM has collected a minimum of 25 subjects with at least one ventricular arrhythmia episode (spontaneous or induced) adjudicated by the Ventricular Arrhythmia Events Committee or until notification from SJM.

6.6.2.1 Data Submission

Once required testing has been performed, complete and submit the appropriate forms to St. Jude Medical. Refer to Table 5.

If an ADE, SADE, and UADE (for US sites) or USADE (for OUS sites) events has occurred, submit an AE CRF (as applicable). Report withdrawal and out of service as applicable. Upload device session records through the EDC study site portal (as applicable).

6.7 Complete System Explants

If the subject has the entire Ellipse VR ICD system removed at any time during the study, and the subject will not receive a replacement Ellipse ICD system, follow the subject for 30 days, and withdraw the subject from the study. Complete a Product Out of Service CRF and submit through EDC. A System Revision CRF is not required to be submitted.

6.8 System Revisions

In cases where only the device pocket is revised (leads are not repositioned, leads have not been disconnected from the ICD), a System Revision CRF is not required to be submitted. A System Revision CRF should be completed for all other types of revisions such as pulse generator replacement, lead replacement and lead repositioning. The subject's follow up schedule is not affected in any way.

6.8.1 Revisions Before the MRI Scan

A system revision is defined as a replacement of or repositioning of one or more components of the study ICD system (Durata or Optisure lead, Ellipse VR ICD) that occurs after the subject has been consented into the study. Because all components of the study ICD system are market-released, all procedures related to the revision should be performed according to standard of care. The revision may be performed by either a study investigator or other clinician qualified to perform such procedures.

Any explanted devices or leads (including damaged leads, lead segments and lead fragments) should be returned to St. Jude Medical promptly for analysis. Document any change to the status of the lead and device (e.g. capped, removed) on the Product Out of Service CRF.

Refer to Table 5: Study Procedures and Data Collection to determine which case report forms need to be completed and submitted.

Refer to Table 8: System Revision Scenarios Prior to MRI Scan below to determine what actions need to be performed.

Table 8: System Revision Scenarios Prior to MRI Scan

System Revisions that occur prior to MRI Scan	Action	Data Submission
Revisions where the Ellipse ICD system is still implanted: • Durata or Optisure lead or the Ellipse ICD is repositioned or replaced, AND • The Ellipse AND Durata or Optisure lead are still implanted, AND • No other non-MRI compatible material has been implanted	**Obtain (if possible):** o In-clinic bipolar capture threshold at a pulse width of 0.5 ms for the applicable lead(s). Either the manual decrement or automatic (in-clinic, programmer based) method may be used to obtain the capture threshold. o In-clinic bipolar sensing amplitude for the applicable lead(s). Either the incremental or the automatic (in-clinic, programmer based) method may be used to obtain the sensing threshold. o In clinic Bipolar lead pacing impedance for the applicable lead o In clinic HVLI impedance for the applicable lead o Retain the subject in the study. If the MRI scan visit has not occurred yet, then wait at least 60 days from the successful revision before completing the MRI scan visit. If the MRI scan visit has occurred, then follow the subject through the 1 Month Post Scan visit.	Complete and submit the appropriate forms to St. Jude Medical. Refer to Table 5: Study Procedures and Data Collection. It is recommended that the following device printouts and measurements be maintained at the site. o FastPath Summary o Test Results with Freezes, Include Battery & Leads o Wrap-up Overview with full parameters
Revisions where the Ellipse ICD system is not retained and the MRI Settings have not been	The patient is a screen failure.	Document consenting information (name of the study, date of consent and inclusion/exclusion) in the subject's medical and/or study records. Submit the Baseline CRF and Screening Failure

programmed • Durata or Optisure or the Ellipse ICD was explanted but was not replaced with another Durata or Optisure or the Ellipse ICD, and/or • A non-MRI compatible material(s) or device(s) was implanted		CRF. Submit Deviation, Product Out of Service, or Death CRFs if applicable. It is recommended that the following device printouts and measurements be maintained at the site. o FastPath Summary o Test Results with Freezes, Include Battery & Leads o Wrap-up Overview with full parameters
Revisions where the Ellipse ICD system is not retained and the MRI Settings were programmed • Durata or Optisure or the Ellipse ICD was explanted but was not replaced with another Durata or Optisure or the Ellipse ICD, and/or • A non-MRI compatible material(s) or device(s) was implanted	The patient will be withdrawn from the study.	Document consenting information (name of the study, date of consent and inclusion/exclusion) in the subject's medical and/or study records. Submit the Baseline CRF, Pre-MRI CRF, and Withdrawal CRF. Submit Deviation, Product Out of Service, or Death CRFs if applicable. It is recommended that the following device printouts and measurements be maintained at the site. o FastPath Summary o Test Results with Freezes, Include Battery & Leads o Wrap-up Overview with full parameters

6.8.2 Revisions After the MRI scan

All subjects are enrolled in the study once the subject signs the main study consent, meets all of the inclusion criteria and none of the exclusion criteria, and the MRI Settings are enabled. If a system revision occurs after the MRI scan, then the subject will remain in the study until the subject completes the **1 Month Post Scan visit.**

Any explanted devices or leads (including damaged leads, lead segments and lead fragments) should be returned to St. Jude Medical promptly for analysis. Document any change to the status of the lead and device (e.g. capped, removed) on the Product Out of Service CRF.

Refer to Table 9: System Revision Scenarios After MRI Scan below to determine what actions need to be performed.

Note: If a system revision occurs after the MRI scan visit, sites are encouraged to complete induction testing on the new Ellipse VR ICD during the procedure to assist in the collection of VT/VF episodes. Sites will be notified when a minimum of 25 subjects with at least one ventricular arrhythmia episode (spontaneous or induced) adjudicated by the Ventricular Arrhythmia Events Committee have been collected..

Table 9: System Revision Scenarios After MRI Scan

System Revisions that occur after the MRI Scan	Action	Data Submission
Revisions where the Ellipse ICD system is still implanted • The Ellipse and Durata or Optisure lead are still implanted, BUT • A non-MRI compatible material(s) or device(s) has been implanted OR Revisions where the Ellipse ICD system is still implanted • Durata or Optisure lead or the Ellipse ICD is repositioned or replaced, AND • The Ellipse AND Durata or Optisure lead are still implanted, AND	**Obtain (if possible):** • In-clinic bipolar capture threshold at a pulse width of 0.5 ms for the applicable lead(s). Either the manual decrement or automatic (in-clinic, programmer based) method may be used to obtain the capture threshold. • In-clinic bipolar sensing amplitude for the applicable lead(s). Either the incremental or the automatic (in-clinic, programmer based) method may be used to obtain the sensing threshold. • In clinic bipolar lead pacing impedance for the applicable lead(s) • In clinic HVLI impedance for the applicable lead • **Note**: If an enrolled patient	Once required testing has been performed, complete and submit the appropriate forms to St. Jude Medical. Refer Table 5: Study Procedures and Data Collection

• No other non-MRI compatible material has been implanted	undergoes a revision of the Ellipse VR device after the MRI visit and the Durata/Optisure lead remains in its original location, then induction testing could be performed during the system revision on the new Ellipse VR ICD. • Continue to follow the patient until the subject completes the 1 Month Post scan visit.	
Revisions where the Durata/Optisure lead is not retained • Durata or Optisure lead is replaced with another lead, AND • The Ellipse VR ICD is still implanted, AND • A non-MRI compatible material(s) or device(s) has been implanted	Follow the subject for 30 days post system revision and then withdraw the subject from the study.	Document consenting information (name of the study, date of consent and inclusion/exclusion) in the subject's medical and/or study records. Submit the Baseline CRF, and Pre-MRI CRF, MRI CRF, System Revision CRF and Withdrawal CRF. Submit Deviation, Product Out of Service, Adverse Event or Death CRFs if applicable. It is recommended that the following device printouts and measurements be maintained at the site. o FastPath Summary o Test Results with Freezes, Include Battery & Leads o Wrap-up Overview with full parameters
Revisions where the Ellipse ICD is not retained • Ellipse VR ICD is replaced with another Ellipse VR ICD, AND • Durata or Optisure lead is still implanted, AND • A non-MRI compatible material(s) or device(s) has been implanted	Continue to follow the subject until the subject completes the 1 Month Post scan visit.	Once required testing has been performed, complete and submit the appropriate forms to St. Jude Medical. Refer Table 5: Study Procedures and Data Collection

6.9 Unscheduled Follow Up

An unscheduled visit is defined as a visit that occurs after the MRI Scan Visit where the subject is seen in clinic due to an ADE, SADE or UADE associated with the Durata or Optisure or Ellipse ICD or for follow up related to the collection of VT/VF episodes. Where possible, perform a device interrogation for the applicable lead(s) to obtain:

- In-clinic bipolar capture threshold at a pulse width of 0.5 ms.
- In-clinic bipolar sensing amplitude. Either the incremental or the automatic (in-clinic, programmer based) method may be used to measure the sensing threshold.
- In-clinic Bipolar lead impedance
- In-clinic HVLI lead impedance

6.9.1 Data Submission

Once testing has been performed, complete and submit the appropriate forms to St. Jude Medical. Refer Table 5: Study Procedures and Data Collection.
It is recommended that the following device printouts and measurements be maintained at the site.

- FastPath Summary
- Test Results with Freezes, Include Battery & Leads
- Wrap-up Overview with full parameters

6.10 Non-Study MRI Scans

A non-study MRI scan is defined as an MRI scan occurring at any time following enrollment up to the conclusion of the subject's participation in the study, excluding the MRI scan performed during the MRI Scan Visit. Non-study MRI scans should be performed per each center's standard of care.

For non-study MRI scans performed at the study center, the same safety data collection and safety precautions outlined at the MRI Scan Visit should be followed. However, if procedures or data are not followed or collected as presented on the non-study MRI Case report form during a non-study MRI scan, it will not be considered a protocol deviation.

MRI Scan Analysis
The MRI scan should be reviewed for obvious abnormalities by a radiologist, and reported to the subject's physician (per standard of care by the facility performing the MRI scan).

The following data should be collected, and reported to St. Jude Medical for non-study MRI scans.

- Date of scan
- Type of scan performed
- Documentation of any Adverse Device Effects
- Device diagnostics, if available
- MRI Scan report, if available
- Fast Path Summary, if available

6.10.1 Data Submission

If the subject undergoes a non-study MRI scan at any time during the study, complete and submit the appropriate forms to St. Jude Medical.

Upload device session records, if applicable and available, through the EDC study site portal. Device session records may also be sent to St. Jude Medical CRMD, Sylmar, CA.

It is recommended that the following forms, device printouts and measurements be maintained at the site.

- MRI Hazard Checklist
- FastPath Summary
- Test Results with Large Freezes, Include Battery & Leads
- Wrap-up Overview with full parameters

6.11 Description of Activities performed by Sponsor Representatives

Trained sponsor personnel may perform certain activities to ensure compliance to the clinical investigational plan and may provide technical expertise. Sponsor field clinical engineers may perform the following activities:

- Interrogation of and testing the implanted ICD system at any study visit (scheduled or unscheduled): capture, sense, pacing and HVLI measurements,
- Verifying MRI scan parameters on the programmer at the MRI Scan Visit or Non-Study MRI visit,
- Programming of the ICD per protocol, and/or as directed by the investigator/designee.

While sponsor representatives may perform these activities, the principal investigator remains responsible for ensuring all study data is collected as required per protocol. Deviations resulting from failure to comply with protocol requirements will be reported through completion of a Deviation CRF.

6.12 Subject study completion

The minimum duration of each subject's participation is approximately one month from the MRI scan (1 Month Post Scan visit). The VT/VF data collection effort will continue until a minimum of 25 subjects with at least one VT/VF episode (spontaneous or induced) has been adjudicated by the Ventricular Arrhythmia Events Committee. SJM will notify sites when the VT/VF data collection effort has ended. When the subject's participation in the clinical study has been completed the subject will return to standard medical care as per physician's recommendation.

6.13 Any Known or Foreseeable Factors that May Compromise the Outcome of the Clinical Study or the Interpretation of the Results

All foreseeable factors that may compromise the outcome have been taken into account by the clinical study design and well defined subject selection criteria.

6.14 Description of the Methods that will be used to Address Potentially Confounding Factors in the Clinical Study Design

The efficacy endpoints are change in bipolar ventricular capture and sensing threshold from pre-MRI scan to 1 Month Post Scan for the RV high voltage lead implanted with the Ellipse VR ICD. Each subject therefore acts as his/her own control. Therefore, there is no concern for confounding factors for the efficacy endpoint.

6.15 Criteria and Procedures for Subject Withdrawal or Screen Failure

Subjects must be informed about their right to withdraw from the study at any time and for any reason without sanction, penalty or loss of benefits to which the subject is otherwise entitled and withdrawal from the study will not jeopardize their future medical care or relationship with the investigator. Subjects will be asked to specify the reason for the termination, but have the right not to answer.

The investigator may decide to withdraw a subject from the study at any time with reasonable rationale. The subject's future care will not be influenced by a decision, voluntary or otherwise, to withdraw from the study. All reasonable efforts should be made to retain the subject in the clinical study until completion of the study.

Reasons for subject's withdrawal include, but are not limited to:

- Subject refuses to continue participating in the study
- Subject is deceased (cause must be documented)
- Subject's non-compliance

- Subject's participation is terminated by the PI or investigator, although the subject consented, since participation is no longer medically appropriate
- Subject is 'lost to follow up': Subject does not adhere to the scheduled follow up visits but has not explicitly requested to be withdrawn from the clinical study. (This does not apply to missed visits). Site personnel should at all times make all reasonable efforts to locate and communicate with the subject in order to achieve subject compliance to the scheduled follow up visits:
    1. A subject will be considered 'Lost to Follow Up' after a minimum of 2 phone calls of a physician or delegate at the investigational site to the subject or contact. These 2 phone calls need to be documented in the subject's hospital records.
    2. If these attempts are unsuccessful, a certified letter should be sent to the subject's last known address or general practitioner (GP) and a copy of this letter should be maintained in the subject's hospital records.

If a subject withdraws from the clinical study, the site will record the subject's reasons for withdrawal, on a Withdrawal CRF.

When subject withdrawal from the clinical study is due to an adverse event the subject will be followed until resolution of that adverse event or determination that the subject's condition is stable. The status of the subject's condition should be documented at the time of withdrawal.

Screening Failure: A subject may also become a screen failure based if the subject's participation ended prior to enrollment in the study. Refer to section 6.5.2 Situations where the subject does not meet enrollment criteria and 6.8.1 Revisions Before the MRI Scan. Complete a Screening Failure CRF for screen failure subjects and note that the subject is a screen failure.

7.0 Compliance to the CIP

7.1 Statements of Compliance

The study will be performed in accordance with the most current versions of the World Medical Association (WMA) Declaration of Helsinki, ISO14155 and any regional and/or national regulations and will be compliant to this International Standard and any regional and national regulations, as appropriate.

The investigator will not start enrolling subjects or requesting informed consent from any subject prior to obtaining IRB/EC approval and Competent Authority approval, if applicable, and authorization from the sponsor in writing for the study.

In case additional requirements are imposed by the IRB/EC or Competent Authority, those requirements will be followed, if appropriate. If any action is taken by an IRB/EC, and regulatory requirements with respect to the study, that information will be forwarded to St. Jude Medical.

As sponsor, St. Jude Medical has taken up general liability insurance in accordance with the requirements of the applicable local laws. Appropriate country representative will be utilized to understand the requirements for the type of insurance that will be provided for subjects, such information will be incorporated into the informed consent, as applicable

If required, additional subject coverage or a study specific insurance will be provided by the Sponsor as well.

7.2 Adherence to the Clinical Investigation Plan (Protocol Deviations)

A deviation is defined as an event where the clinical investigator, site personnel, sponsor or sponsor representative did not conduct the clinical study according to the Clinical Investigational Plan, IRB/EC requirements or the Investigator Agreement. The investigator is not allowed to deviate from the CIP, except as specified under emergency circumstances.

In some cases, failure to comply with the CIP may be considered failure to protect the rights, safety and well-being of subjects, since the non-compliance exposes subjects to unreasonable risks. For example, failure to adhere to the inclusion/exclusion criteria: these criteria are specifically defined by the Sponsor to exclude subjects for whom the device is not beneficial and the use involves unreasonable risks. This may be considered failure to protect the rights, safety and well-being of the enrolled subject. Similarly, failure to perform safety assessments intended to detect adverse events may be considered failure to protect the rights, safety and well-being of the enrolled subject. Investigators should seek minimization of such risks by adhering to the CIP.

Simultaneously, in the event that adhering to the CIP exposes the subject to unreasonable risks, the investigator is also required to protect the rights, safety and well-being of the subject by intentionally deviating from the requirements of the CIP, so that subjects are not exposed to unreasonable risks.

It is the responsibility of the investigator to provide adequate medical care to a subject enrolled in a study.

Regulations require that the PI maintain accurate, complete, and current records, including documents showing the date of and reason for every deviation from the Clinical Investigational Plan. Relevant information for each deviation will be documented on a Deviation Case Report Form. The site will submit the CRF to St. Jude Medical.

Regulations require Investigators obtain approval from St. Jude Medical and the IRB/EC [as required] before initiating changes in or deviations from the protocol, except when necessary to protect the life or physical well-being of a subject in an emergency. Under emergency circumstances, deviations from the CIP to protect the rights, safety and well-being of human subjects may proceed without prior approval of the sponsor and the EC. Such deviations shall be documented and reported to the sponsor and the EC as soon as possible, but no later than 5 working days.

Prior approval must be requested when the PI anticipates, contemplates, or makes a conscious decision to depart from the CIP, except when unforeseen circumstances are beyond the investigator's control (e.g. a subject who fails to attend a scheduled follow-up visit, a subject is too ill to perform a CIP-required test, etc.). All deviations, including those beyond the investigator's control, must be reported on a CRF.

To obtain approval, the Principal Investigator may call or email and discuss the potential deviation with St. Jude Medical or designee prior to initiating any changes.

All deviations must be reported to appropriate regulatory authorities in specified timelines (if appropriate).

Investigator will notify St. Jude Medical and the reviewing IRB/EC within 5 working days of:

- Any deviation to protect the life or physical well-being of a subject in an emergency
- Any failure to obtain informed consent

Investigators or the designee must notify St. Jude Medical, Inc. as soon as possible and complete the Deviation CRF.

The Investigator is required to adhere to local regulatory requirements for reporting deviations to IRB/EC.

7.3 Repeated and Serious Non-compliance

In the event of repeated non-compliance or a one-time serious non-compliance, as determined by the Sponsor, a Clinical Research Associate or clinical representative will attempt to secure compliance by one or more of the following actions:

- Visiting the investigator
- Contacting the investigator by telephone
- Contacting the investigator in writing

- Retraining of the investigator

If an investigator is found to be repeatedly non-compliant with the signed agreement, the CIP or any other conditions of the clinical study, the Sponsor will either secure compliance or, at its sole discretion, terminate the investigator's participation in the clinical study.

8.0 Adverse Device Effect

8.1 Definitions

8.1.1 Medical Device

Any instrument, apparatus, implement, machine, appliance, implant, software, material or other similar or related article

(a) Intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific purpose(s) of

- Diagnosis, prevention, monitoring, treatments or alleviation of disease,
- Diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury,
- Investigation, replacement, modification, or support of the anatomy or of a physiological process,
- Supporting or sustaining life,
- Control of conception,
- Disinfection of medical devices and

(b) Which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its intended function by such means

8.1.2 Adverse Device Effect (ADE)

An adverse device effect is an adverse event related to the use of an investigational medical device.

This definition includes adverse events resulting from insufficient or inadequate instructions for use, deployment, implantation, installation, or operation, or any malfunction of the investigational medical device.

This definition includes any event resulting from the use, error, or from intentional misuse of the investigational medical device.

8.1.3 Serious Adverse Device Effect (SADE)

Adverse device effect that has resulted in any of the consequences characteristic of a serious adverse event:

- Death
- A serious deterioration in the health of the subject, that either resulted in:
  - A life-threatening illness or injury OR
  - A permanent impairment to a body structure or a body function OR
  - An in-patient or prolonged hospitalization OR
  - A medical or surgical intervention to prevent life-threatening illness or injury or permanent impairment to a body structure or a body
- Fetal distress, fetal death or a congenital abnormality or birth defect

A planned hospitalization for a pre-existing condition, or a procedure required by the CIP is not considered a serious adverse event.

8.1.3.1 Unanticipated Adverse Device Effect (UADE)

As defined in 21 CFR §812.3, unanticipated adverse device effects (UADE) are defined as any serious adverse effect on health or safety or any life-threatening problem or death caused by, or associated with, a device, if that effect, problem, or death was not previously identified in nature, severity, or degree of incidence in the clinical investigational plan or application (including a supplementary plan or application), or any other unanticipated serious problem associated with a device that relates to the rights, safety, or welfare of subjects.

If an unanticipated adverse device effect occurs, the investigator must notify St. Jude Medical and the IRB/MEC immediately, but no later than 10 working days of the investigator's knowledge of the event, as required by 21 CFR §812.150. St. Jude Medical will take any steps necessary to investigate the event, and will be responsible for notifying FDA and all other participating IRBs/MECs and investigators.

8.1.3.2 Unanticipated Serious Adverse Device Effect (USADE)

A serious adverse device effect which by its nature, incidence, severity or outcome has not been identified in the current version of the risk analysis report.

8.1.4 Reporting of MRI Scan-Related Adverse Device Effects

An ADE or SADE related to the following should be reported as soon as possible, but no later than 10 working days, to St. Jude Medical: clotting, pulmonary embolism, or

heating of the device pocket during the MRI scan. These events are likely to be associated with symptoms occurring during or immediately following the MRI scan and may manifest as chest pain, shortness of breath, or changes in vital signs during or immediately following the MRI scan. To ensure all ADEs or SADEs related to or caused by the MRI scan are appropriately captured, follow the instructions in section 6.5.2.2 above.

8.1.5 Complication

A complication is defined as an SADE that requires an invasive intervention or leads to death.

8.1.6 MRI scan related complication

A complication is deemed to be MRI related if it is caused by or related to the interaction between the RV high voltage lead, Ellipse VR ICD and the MRI system that occurs during the MRI scan and includes the time the subject is within the 5 Gauss line of the MRI system, or up through the subject's 1 month post MRI scan follow up visit. The MRI scan related complications will be based on the CEC adjudication data.

8.2 Procedure for assessing, recording and reporting adverse device effects, serious adverse device effects and UADEs (for US sites) and USADEs (for OUS sites):

Safety surveillance within this study and the safety reporting, both performed by the investigator, starts as soon as the subject is enrolled in the study. Enrollment occurs after the subject signs the main study consent, meets all of the inclusion and none of the exclusion criteria verified during the pre-MRI testing, and the MRI Settings have been programmed. . The safety surveillance and the safety reporting will continue until the last investigational visit has been performed, the subject is deceased, the subject/investigator concludes his participation into the study or the subject/investigator withdraws the subject from the study, except as otherwise specified in the CIP.

Once the patient completes the pre-MRI visit testing and the MRI Settings have been programmed according to the protocol, all adverse device effects (whether serious or not-serious) UADEs and USADEs will be collected and reported to the Sponsor on an Adverse Event case report form through the EDC system.

8.2.1 Criteria and guidelines for non-reportable events

Except as otherwise noted in the CIP, the following events are not reportable to the sponsor:

- Events not related to the procedure to remove, replace or reposition the study lead or ICD.
- Unavoidable events, as listed in Table 3: Unavoidable events related to the MRI Scan that resolve within the timeframes specified

8.2.2 Criteria and guidelines for reportable events

Records relating to the subject's subsequent medical course must be maintained and submitted (as applicable) to the Sponsor until the event has subsided or, in case of permanent impairment, until the event stabilizes and the overall clinical outcome has been ascertained. Adverse events will be monitored until they are adequately resolved. The status of the subject's condition should be documented at each visit.

The investigator will report the event to the IRB/EC per their reporting requirements.

Reportable events to sponsor are considered:

- ADEs, SADEs, and UADEs (for US sites) and USADEs (for OUS sites) caused by or associated with the study MRI scan (except unavoidable events related to the MRI scan)
- Unavoidable ADEs whose conditions worsen or continue beyond the time frame listed in the Unavoidable events tables.
- All ADEs, SADEs and UADEs(for US sites)/USADEs (for OUS sites) that are not associated with the MRI scan

All above events will be reported to the Sponsor, as soon as possible, but no later than 72 hours of first learning of the event. A list of foreseeable adverse events and anticipated adverse device effects include, but are not limited to, those listed in Table 2: Anticipated Events and Anticipated Adverse Device Effects. Refer to section 3.3 for full details.

The Sponsor will ensure that all adverse events are reported to the relevant authorities as per regulations. The description of the adverse event, date of the adverse event, treatment and resolution of the reportable adverse events will be reported, as applicable, to the relevant authorities per regulations. Additional information may be requested, when required, by the Sponsor in order to support the reporting of AE CRFs to regulatory authorities.

The investigator must notify the IRB, if appropriate, in accordance with national and local laws and regulations, of the AE CRFs reported to the Sponsor.

8.2.3 Preliminary Safety Report

A preliminary report of all adverse event data will be sent to FDA by the Sponsor after the first 20 subjects complete their one month post MRI scan visit. In addition, the Sponsor will also report to the FDA if five or more subjects experience a worsening of pacing capture threshold, as defined by the primary endpoint.

8.3 Subject Death

8.3.1 Procedure for recording and reporting subject death

All subject deaths are to be documented and reported to the sponsor within 72 hours after becoming aware of the event.

The Clinical Events Committee (CEC) (see section 14.1) reviewing adverse device effects noted in sections 8.1.2-8.1.6for the study will also review and classify all potential subject deaths. All subject deaths that occur during this investigation must be reported to St. Jude Medical as soon as possible. Notification of death should include a detailed statement of the pertinent events and be signed by the investigator in addition to the appropriate case report forms (Death CRF, Withdrawal CRF, and Product Out of Service CRF). It is the investigator's responsibility to notify the IRB per the IRB policy. Details of death and the following information, if available, should be provided in a letter to St. Jude Medical by the investigator summarizing the subject's course since enrollment in the study:

- Date and time of death
- Place death occurred (e.g. hospital, nursing home, subject's home)
- If death was witnessed
- Identification of the rhythm at the time of death, if known (include any available documentation)
- Cause of death
- Any other circumstances surrounding the death
- Approximate time interval to death from the initiating event.
- Autopsy report (if performed)
- Whether it was device and/or procedure related
- Whether it was related to the study
- Device configuration at the time of death

If any of the above information is not available, provide an explanation in the death narrative of what attempts (and how many) were made to obtain the information, and the outcome of those attempts. At a minimum, two (2) phone calls should be placed, followed by a certified letter, to the subject's next of kin. Provide clinical notes and

witness statements. If possible, interrogate the ICD. Retrieve and print all episode diagnostics, IEGMs, and programmed parameters.

Every attempt should be made to explant the ICD and/or leads intact. Any explanted devices or leads should be returned to St. Jude Medical for analysis promptly. In the event that the device is not explanted, the above procedure must be followed to retrieve the data. The reason the ICD and/or lead(s) are not being returned to St. Jude Medical must be stated clearly on the case report form.

8.4 Complaint

A complaint is defined as an inadequacy of a medical device with respect to its identity, quality, durability, reliability, safety or performance. Complaints may be submitted from the time of consent through the end of the study.

If a complaint involves an adverse device effect category or death as described in the protocol (section 8.1-8.3), then the investigator shall notify the Sponsor by completing the adverse event or death case report form as applicable and must provide the Sponsor with all necessary documentation needed.

If the complaint does not involve a reportable adverse event per protocol the investigator should notify the SJM Product Surveillance Department through one of the methods listed below as soon as possible after becoming aware of a complaint.

Email address: SVcomplaints@sjm.com
Toll Free: 800-722-3774
Direct US:818-364-1506

Complaints will be collected and reported by St. Jude Medical according to our product reporting process.

9.0 Data Management

Overall, the Sponsor will be responsible for the data handling. The sponsor and/or its affiliates will be responsible for compiling and submitting all required reports to governmental agencies.

Data will be analyzed by the Sponsor and may be transferred to the Sponsor's locations outside of the US and/or any other worldwide regulatory authority in support of a market-approval application.

St. Jude Medical respects and protects personally identifiable information that we collect or maintain. As part of our commitment, St. Jude Medical is certified in the U.S. - European Union Framework and U.S. – Swiss Safe Harbor Framework Agreements regarding human resources and subject clinical trial personal information. The privacy of each subject and confidentiality of his/her information will be preserved in reports and when publishing any data. Confidentiality of data will be observed by all parties involved at all times throughout the clinical study. All data will be secured against unauthorized access.

An electronic data capture (EDC) system will be used to collect data and store data specified in the CIP. This data collection includes all data points found on the electronic case report forms (eCRFs) for the study. The EDC system may also be used to upload source documents related, but not limited to AE CRFs and deaths.

The Principal Investigator or institution will provide direct access to source data during and after the clinical study for monitoring, audits, IRB/EC review and regulatory authority inspections. As required, the Principal Investigator or institution will obtain permission for direct access to source documents from the subject, hospital administration and national regulatory authorities before starting the clinical study.

9.1 Data Management Plan

A detailed Data Management Plan (DMP) will be established to ensure consistency of data collection. This document will include procedures used for data review, database cleaning, and issuing and resolving data queries. If appropriate, the DMP may be updated throughout the study duration. All revisions will be tracked and document controlled.

CRF data will be captured in a validated electronic database management Oracle Clinical system hosted by St. Jude Medical. Only authorized site personnel will be permitted to enter the data through the electronic data capture (EDC) system deployed by St. Jude Medical. An electronic audit trail will be used to track any subsequent changes of the entered data.

9.2 Document and Data Control

9.2.1 Traceability of documents and data

The investigator will ensure accuracy, completeness, legibility and timeliness of the data reported to the sponsor on the CRFs and in all required reports.

9.2.2 Recording Data

Source documents will be created and maintained by the investigational site team throughout the clinical study.

The data reported on the CRFs will be derived from, and be consistent with, these source documents, and any discrepancies will be explained in writing.

All data reported for the study must be substantiated with source documentation in the subject's medical records, clinic records or other forms of documentation provided by or approved by Sponsor.

The CRFs will be validated (eCRF) by the authorized site personnel. .

10.0 Monitoring

It is the responsibility of St. Jude Medical as the sponsor of the study to ensure the study is conducted, recorded, and reported according to the approved protocol, subsequent amendment(s), applicable regulations, and guidance documents. Monitoring will be conducted according to the St. Jude Medical Clinical Monitoring standard operating procedure.

Prior to beginning the study, St. Jude Medical will contact the investigator or designee to discuss the study and data requirements. A St. Jude Medical monitor will periodically review the subject records and associated source documents.

The investigator shall make subject and study records available to the clinical monitor for monitoring.

11.0 Regulatory Inspections

The investigator and/or delegate should contact St. Jude Medical immediately upon notification of a governmental agency inspection at the site. A clinical monitor or designee will assist the investigator and/or delegate in preparing for the audit.

An investigator who has authority to grant access will permit authorized governmental agency employees, at reasonable times and in reasonable manner, to enter and inspect any establishment where devices are held (including any establishment where devices are used or where records or results are kept).

An investigator, or any person acting on behalf of such a person with respect to the study, will permit authorized governmental agency employees, at reasonable times and in reasonable manner, to inspect and copy all records relating to the study.

An investigator will permit authorized governmental agency employees to inspect and copy records that identify subjects, upon notice that governmental agency has reason to suspect that adequate informed consent was not obtained, or that reports required to be submitted by

the investigator, to the Sponsor or IRB/EC have not been submitted or are incomplete, inaccurate, false or misleading.

12.0 Statistical considerations

The following section presents statistical considerations for the study. Additional details on statistical analyses are maintained in a separate Statistical Analysis Plan (SAP).

12.1 Statistical design, hypotheses, method and analytical procedures

Note: In the statistical section below, all references to MRI are referring to the study MRI scan.

12.1.1 Primary Safety endpoint

The primary safety endpoint #1 is: Freedom from MRI scan-related complications related to the Ellipse VR ICD involving Durata or Optisure (RV) lead from MRI scan to 1 month post MRI scan testing.

Hypothesis
The hypothesis is formally expressed as:

H_0: $p_S \leq 90\%$
H_a: $p_S > 90\%$

where p_S is the freedom from MRI scan-related complications(s) for the Durata or Optisure RV lead from MRI scan to 1 month after the MRI scan.

Analysis
The primary analysis will be conducted on subjects who meet all of the following criteria:

- Implanted with St. Jude Medical Durata or Optisure (RV) Lead
- Sign informed consent
- Meet the MRI Conditions of Use
- Undergo a Study MRI scan
- Have 1 month post-MRI scan visit or have MRI-scan related complication(s) for the Ellipse VR ICD involving Durata or Optisure RV lead before the 1 month post MRI visit

The hypothesis will be tested at the 2.5% significance level. The null hypothesis will be rejected if the 97.5% lower confidence bound for p_S is greater than 90%. The 97.5% lower confidence bound will be calculated by the exact (Clopper-Pearson) method for binomial probabilities.

12.1.2 Primary Efficacy Endpoint #1 (Change in Capture Threshold for Durata and Optisure (RV) Leads)

The primary efficacy endpoint #1 is the proportion of Durata or Optisure (RV) leads implanted with the Ellipse VR ICD with capture threshold increase of ≤ 0.5V at 0.5ms from pre-MRI scan to 1 month post-MRI scan testing.

Hypothesis
Success is defined as ventricular capture threshold increase of ≤ 0.5V at 0.5ms for the Durata or Optisure (RV) lead from pre-MRI scan testing to 1 month post-MRI scan.

The hypothesis is formally expressed as:

H_0: $p_{E1} \leq 90\%$
H_a: $p_{E1} > 90\%$

where p_{E1} is the probability of success.

Analysis
The primary analysis will be conducted on subjects who meet all of the following criteria:

- Implanted with the Durata or Optisure RV lead and Ellipse VR ICD
- Sign Informed consent
- Meet the MRI Conditions of Use
- Undergo a Study MRI scan
- Have MRI visit data for right ventricular capture threshold
- Have 1 month post-MRI scan visit data for RV capture threshold
- Have not undergone any VR ICD lead repositioning or replacement since the MRI scan up to 1 month post-MRI scan

The hypothesis will be tested at the 2.5% significance level. The null hypothesis will be rejected if the 97.5% lower confidence bound for pE1 is greater than 90%. The 97.5% lower confidence bound will be calculated by the exact (Clopper-Pearson) method for binomial probabilities

12.1.3 Primary Efficacy Endpoint #2 (Change in Sensing Threshold for Durata and Optisure (RV) leads)

The primary efficacy endpoint #2 is the proportion of Durata or Optisure (RV) leads implanted with the Ellipse VR ICD with sensing amplitude decrease of ≤ 50% from pre-MRI scan testing to 1 month post-MRI scan.

Hypothesis
Success is defined as ventricular sensing amplitude decrease of ≤ 50% from pre-MRI scan testing to 1 month post-MRI scan. The hypothesis is formally expressed as:

H_0: $p_{E2} \leq 87\%$
H_a: $p_{E2} > 87\%$

where p_{E2} is the probability of success.

Analysis
The primary analysis will be conducted on subjects who meet all of the following criteria:

- Implanted with the Durata or Optisure RV lead and Ellipse VR ICD
- Sign informed consent
- Meet the MRI Conditions of Use
- Undergo a Study MRI scan
- Have MRI visit data for RV sensing threshold
- Have 1 month post-MRI scan visit data for RV sensing threshold
- Have not undergone any VR ICD lead repositioning or replacement since the MRI scan up to 1 month post-MRI scan
- Have an intrinsic heart rate ≥ 30 beats per minute at the time of ventricular capture threshold measurements

The null hypothesis will be tested at the 2.5% significance level. The null hypothesis will be rejected if the 97.5% lower confidence bound for p_{E2} is greater than 87%. The 97.5% lower confidence bound will be calculated by the exact (Clopper-Pearson) method for binomial probabilities.

12.2 Sample size

12.2.1 Sample size for primary safety endpoint

In the St. Jude Medical Accent MRI pacemaker IDE study, the results of which were submitted in PMA 60067410/A, and another manufacturer's study involving an MRI conditional pacemaker, the complication-free rate was observed to be 100%.[16,14] Therefore, the sample size is calculated under the conservative assumption of

complication-free rate of 97%. Under this assumption, a sample size of 141 subjects will provide 90% power to reject the null hypothesis at a 2.5% significance level. The sample size was calculated using the exact binomial method in SAS® v9.4.

12.2.2 Sample size for primary efficacy endpoint #1 (Change in capture threshold for Durata or Optisure (RV) lead

In the St. Jude Medical Accent MRI pacemaker IDE study, the results of which were submitted in PMA 60067410/A, the proportion of leads with an increase in threshold ≤0.5 volts from pre-MRI scan testing to 1-Month after the MRI scan was 100%.[1,2]. Therefore, the sample size is calculated under the conservative assumption of 98% for the endpoint. Under this assumption, a sample size of 85 subjects will provide 80% power to reject the null hypothesis at a 2.5% significance level. The sample size was calculated using the exact binomial method in SAS® v9.4.

12.2.3 Sample size for primary efficacy endpoint #2 (Change in sensing threshold in Durata or Optisure (RV) lead)

In the St. Jude Medical Accent MRI pacemaker IDE study, the results of which were submitted in PMA 60067410/A, the proportion of leads with 'ventricular sensing amplitude decrease of ≤ 50% from pre-MRI scan testing to 1-Month after the MRI scan,' was approximately 97%. Therefore, the sample size is calculated under the conservative assumption of 95% success rate for the ventricular sensing threshold endpoint. Under this assumption, a sample size of 118 subjects will provide 80% power to reject the null hypothesis at a 2.5% significance level. The sample size was calculated using the exact binomial method in SAS® v9.4.

12.2.4 Overall Sample Size

Up to 165 subjects will be enrolled in this study in order to meet minimum target requirements for primary safety endpoint #1. The sample size estimate of 165 subjects is based on 15% attrition rate. (141/0.85=165).

12.2.5 Analysis

The dataset will be frozen for analysis when 141 subjects have completed the 1 month post MRI visit and a minimum of 25 subjects with at least one ventricular arrhythmia event (spontaneous or induced) are adjudicated by the Ventricular Arrhythmia Events Committee. If a minimum of 25 subjects have not experienced a ventricular arrhythmia event (spontaneous or induced) at this time, SJM will discuss progress of data collection for ventricular arrhythmia events with FDA to support the minimum requirements to support a pre-market approval (PMA) application.

12.3 Pass/fail criteria to be applied to the results of the clinical study

The study will be considered successful if the primary safety and two primary efficacy endpoints are met.

12.4 The provision for an interim analysis

There are no planned interim analyses for the study

12.5 Criteria for the termination of the clinical study on statistical grounds

There is no planned termination for the study based on statistical grounds.

12.6 Procedures for reporting any deviation(s) from the original statistical plan

Refer to the statistical analysis plan for this study.

12.7 The specification of subgroups for analysis

Refer to the statistical analysis plan for this study.

12.8 Procedures that take into account all the data

Refer to the statistical analysis plan for this study.

12.9 The treatment of missing, unused or spurious data, including drop-outs and withdrawals

Refer to the statistical analysis plan for this study.

12.10 The exclusion of particular information for the testing of the hypothesis, if relevant

Refer to the statistical analysis plan for this study.

12.11 In multi-center studies, the minimum and maximum number of subjects to be included for each center

A minimum of 1 subject and a maximum of 41 subjects may be included at each center participating in the study.

13.0 Document Retention

St. Jude Medical and the Principal Investigators will maintain the clinical study documents as required by St. Jude Medical, Inc. and applicable regulatory requirements. They will take measures to prevent accidental or premature destruction of these documents. The Principal Investigator or St. Jude Medical may transfer custody of records to another person/party and document the transfer at the investigational site or at St. Jude Medical's facility.

These documents must be retained by the investigational site for a period of 2 years after clinical study conclusion and made available for monitoring or auditing by St. Jude Medical's representative or representatives of the FDA and other applicable regulatory agencies. The Principal Investigator must ensure the availability of source documents from which the information on the case report forms was derived.

14.0 Study Committee

14.1 Clinical Events Committee (CEC)/Ventricular Arrhythmia Event Review Committee (VAC)

The CEC is responsible for providing an independent review and adjudication of CIP pre-defined clinical events. The CEC will consist of at least 3 members. The CEC will be comprised of independent and unblinded physicians that are not investigators, DSMB members or steering committee members in the trial. St. Jude Medical will appoint members of the CEC and the chairperson. St. Jude Medical may facilitate the CEC meeting, but will not be voting members.

Reportable events to be collected under this protocol will be adverse device effects outlined in sections 8.1.2-8.1.6. The CEC will base their final adjudication on the information provided on the case report forms, medical records, and their clinical knowledge and experience. The CEC will also review and classify all subject deaths under this protocol. The primary function, responsibilities and membership of the CEC will be described in detail in a CEC charter .

The Ventricular Arrhythmia Event Review Committee (VAC) will review all device detected VT and VF episodes with a stored electrogram available and non-sustained VT/VF episodes of at least 16 beats. The members of the CEC will also be members on the VAC.

VT/VF episodes with at least 4 intervals ≥ 300ms, with 1 interval ≥ 600 ms, or with the pre-detection time lasting more than 10 seconds, will be evaluated by the VAC for ventricular arrhythmia undersensing and amount of detection delay. A clinically significant detection delay is defined as ≥ 5 seconds.

14.2 Data Safety Monitoring Board (DSMB)

The DSMB is an independent committee responsible for monitoring study conduct, progress, and reviewing accumulated data to inform the sponsor of any circumstances that might compromise subject safety or data integrity. The DSMB will recommend at the end of each meeting whether to continue, modify or terminate the study. Membership will not include steering committee members, CEC members or site investigators for the study under review.

The primary function, responsibilities and membership of the DSMB will be described in detail in a DSMB charter.

14.3 Steering Committee

The Steering Committee will be used to advise the sponsor during a clinical study, such as in the development of the study CIP, during the conduct of the study, during data analysis and/or presentation/publication of the study results.

15.0 Investigation Suspension or Termination

15.1 Premature termination of the whole clinical study or of the clinical study in one or more investigational sites.

The Sponsor reserves the right to stop the study at any stage, with appropriate written notice to the investigator.

Possible reasons for early termination of the study by the sponsor, either at local, national or international level, may include, but are not limited to:

- The device/therapy fails to perform as intended
- Occurrence of UADE which cannot be prevented in future cases
- Sponsor's decision
- Request from Regulatory bodies
- Request of Ethics Committee(s)
- Concern for subject safety and welfare
- Failure to secure subject Informed Consent prior to any investigational activity
- Failure to report unanticipated adverse device effects within 72 hours to St. Jude Medical and the EC
- Repeated non-compliance with this CIP or the Clinical Trial Agreement
- Inability to successfully implement this CIP
- Violation of the Declaration of Helsinki 2008 (refer to Appendix C)

- Violation of applicable national or local laws and regulations
- Falsification of data, or any other breach of ethics or scientific principles
- Loss of or unaccounted use of investigational device inventory

The study will be terminated according to applicable regulations.

The investigator may also discontinue participation in the clinical study with appropriate written notice to the Sponsor.

Should either of these events occur, the investigator will return all documents to the sponsor; provide a written statement as to why the premature termination has taken place and notify the IRB/EC and/or the Competent Authority (if applicable). Follow-up for all enrolled subjects will be as per CIP requirements.

A Principal Investigator, IRB/EC or regulatory authority may suspend or prematurely terminate participation in a clinical study at the investigational sites for which they are responsible.

If suspicion of an unacceptable risk to subjects arises during the clinical study or when so instructed by the IRB/EC or regulatory authority, St. Jude Medical may suspend the clinical study as appropriate while the risk is assessed. St. Jude Medical will terminate the clinical study if an unacceptable risk is confirmed.

St. Jude Medical will consider terminating or suspending the participation of a particular investigational site or investigator in the clinical study if monitoring or auditing identifies serious or repeated deviations on the part of an investigator.

If suspension or premature termination occurs, the terminating party will justify its decision in writing and promptly inform the other parties with whom they are in direct communication. The Principal Investigator and St. Jude Medical will keep each other informed of any communication received from IRB/EC or regulatory authority.

If for any reason St. Jude Medical suspends or prematurely terminates the study at an individual investigational site, St. Jude Medical will inform the responsible regulatory authority, as appropriate, and ensure that the IRB/EC are notified, either by the Principal Investigator or by St. Jude Medical. If the suspension or premature termination was in the interest of safety, St. Jude Medical will inform all other Principal Investigators.

If suspension or premature termination occurs, St. Jude Medical will remain responsible for providing resources to fulfill the obligations from the CIP and existing agreements for following up the subjects enrolled in the clinical study, and the Principal Investigator or

authorized designee will promptly inform the enrolled subjects at his/her investigational site, if appropriate.

15.2 Resuming the study after temporary suspension

When St. Jude Medical concludes an analysis of the reasons for the suspension, implements the necessary corrective actions, and decides to lift the temporary suspension, St. Jude Medical will inform the Principal Investigators, IRB/EC, or regulatory authority, where appropriate, of the rationale, providing them with the relevant data supporting this decision.

Concurrence will be obtained before the clinical study resumes from the IRB/EC or regulatory authority where appropriate.

If subjects have been informed of the suspension, the Principal Investigator or authorized designee will inform them of the reasons for resumption.

15.3 Study Conclusion

The study will be concluded when:

- All sites are closed AND
- The Final report generated by St. Jude Medical has been provided to sites or St. Jude Medical has provided formal documentation of study closure

16.0 Publication Policy

The results of the clinical study will be submitted, whether positive or negative for publication.

A 'Publication Agreement' will be signed between the Principal Investigator and the Sponsor either as a separate Publication Agreement or within the Clinical Trial Agreement.

For more information on publication guidelines, please refer to the International Committee of Medical Journal Editors (ICMJE) on www.icmje.org.

Upon receiving IDE approval from the FDA, this clinical study will be registered on ClinicalTrials.gov. A full report of the pre-specified outcomes, including any negative outcomes, will be made public through the ClinicalTrials.gov website according to the requirements of Section 801 of the FDA Amendments Act. If this clinical study is terminated early, the Sponsor will make every effort to accelerate the release of the pre-specified outcomes through the ClinicalTrials.gov website.

17.0 Bibliography

A literature search was conducted to obtain information relevant to implanted active medical devices, including ICDs, and MRI scanning to characterize and understand the effects of MRI scanning on ICDs. A list of the bibliographic references pertaining to this study can be found in the References section of this document.

Appendix A: Abbreviations

Abbreviation	Term
ADE	Adverse Device Effect
AE	Adverse Event
ANZ	Australia – New Zealand
ASADE	Anticipated Serious Adverse Device Effect
CA	Competent Authority
CCI	Clinical Coordination Investigator
CEC	Clinical Events Committee
CIP	Clinical Investigational Plan
CRF	Case Report Form
CPRB	Clinical Project Review Board
DMP	Data Management Plan
DSMB	Data Safety Monitoring Board
EC	Ethics Committee
ECG	Electrocardiogram
eCRF	Electronic Case Report Form
EDC	Electronic Data Capture
EMEA	Europe, Middle East, Africa
GP	General Practitioner
IB	Investigator Brochure
ICMJE	International Committee of Medical Journal Editors
IRB	Institutional Review Board
ISB	Investigator Site Binder
ISO	International Organization for Standardization
MP	Monitoring Plan
NA	Not Applicable
OUS	Outside the United States
PI	Principal Investigator
POA	Power of Attorney
RDC	Remote Data Capture
SADE	Serious Adverse Device Effect
SAE	Serious Adverse Event
SC	Steering Committee
SJM	St. Jude Medical
USADE	Unanticipated Serious Adverse Device Effect
WMA	World Medical Association

Appendix B: CIP Revision History

Revision History

Amendment Number	Version	Date	Rationale	Details
Not Applicable	A	06Nov2015	First release of CIP.	First document controlled version of protocol submitted to FDA 14Nov2015.
Not Applicable	B	11Jan2016	Protocol revised based on feedback from FDA	• Usage of registered trademark and unregistered trademark symbols revised for applicable devices • Modified the synopsis and protocol to indicate that the PMA will be submitted to FDA when both the minimum sample size for each endpoint has been met and a minimum of 25 subjects with at least one ventricular arrhythmia episode has been adjudicated by the Ventricular Arrhythmia Events Committee. • Added note to synopsis stating that all references to MRI scan in the protocol refer to the study MRI scan • Clarified that ventricular events consist of Ventricular tachycardia (VT) and Ventricular Fibrillation (VF). • Added wording that VT/VF events will include follow up visits where R-wave sensing is impaired. • Added additional data to be collected in Section 4.4.3 to include the number of subjects that returned to usual programming after the MRI scan and the number of subjects, if any, experiencing delays in reprogramming • Added wording within the Study Procedures and Data Collection table to clarify that among sites participating in the sub study, subjects will be approached with both the main study and sub study consents. • Added MRI Survey Form and Induction Testing Form to Table 5. • Removed “if MRI scan visit does not

Amendment Number	Version	Date	Rationale	Details
				occur the same day as baseline" when referring to the Hazard checklist required as part of Pre-MRI Scan testing. • Added a Non-study MRI Scan form (if applicable) to account for medically required MRI scans. • Added wording for sites to use the automatically obtained pacing capture threshold from most recent archival data as a substitute for the in-clinic threshold, if a high ventricular rate was present during in-clinic interrogation. • Updated Study Flow Chart • Clarified Subject Inclusion criteria #1 to reinforce that eligible patients can include those with the Durata/Optisure lead ≥ 60 days • Added wording within the VT/VF Data Collection Effort section to indicate that if a subject consented in the main study has impaired R wave sensing after the MRI scan visit or other clinical reason for induction testing, then the physician may choose to complete induction testing for that subject. • Within Pre-scan device assessment, removed typo regarding Bipolar lead impedance. • Added wording to clarify when the MRI Parameters table should be used. • Added wording and updated the definition of a reproducibly occurring arrhythmia in MRI Scan section 6.5.2.1. • Added wording in Scheduled Follow Up section to clarify that all subjects will be evaluated for spontaneous VT/VF episodes. • Added wording in Scheduled Follow Ups section to clarify that a minimum of 25 subjects with at least one VT/VF

Amendment Number	Version	Date	Rationale	Details
				episode will be adjudicated by the Ventricular Arrhythmia Events Committee. • Added a note in the Post-Scan Testing section to reinforce that MRI settings must be disabled to ensure that tachyarrhythmia therapy is turned back on. • Added Section 6.10 for Non-study MRI scans • Added wording in Section 6.12 to clarify the duration of sub study data collection. • Added Section 8.2.3 to include a Preliminary Report after the first 20 subjects complete the one month post MRI scan visit and/or if at least 5 subjects experience a worsening of pacing capture threshold, defined by the primary endpoint. • Added note in section 12 specifying that references to MRI refer to the study MRI scan. • Added Section 12.2.5 for Analysis • Added wording to include a combined committee (Clinical Events Committee/Ventricular Arrhythmia Event Review Committee) to review adverse device effects, deaths and ventricular arrhythmia events. • Revised Appendix F: MRI Screening Form to update the numbering of the questions and addition of the subject ID example. • Added site name, subject ID, and date of completion to Appendix G: MRI Hazard Checklist. • Modified Appendix I: Sample Informed Consent & Sub study consent.

Appendix C: Declaration of Helsinki

The most current version of the document will be followed.

Appendix D: Report of Prior Investigations

The report of prior investigations is kept under separate cover and is available upon request.

The purpose of the IB/RPI is to provide the Principal Investigator with sufficient safety or performance data from pre-clinical studies or clinical studies to justify human exposure to the investigational device specified in the CIP.

The IB/RPI will be updated throughout the course of the clinical study as significant new information becomes available (e.g. a significant change in risk, etc.)

The Principal Investigators will acknowledge the receipt of the IB and all subsequent amendments, and will keep all information confidential.

Appendix E: MRI Scan Guidelines

Instructions and guidelines for performing MRI scans for the MRI Ready IDE Study are kept under separate cover, and will be provided to study centers by St. Jude Medical.

Appendix F: MRI Screening Form

MRI Screening Form

Site Name:_____Site Subject ID: _____
(E.g. US1234-0567)

Questions to ask Subject / Assess Subject for:	YES	NO
General Enrollment Screening		
A YES must be answered for questions 1-9 for the subject to be considered for enrollment.		
1. Do you have an Ellipse VR ICD implanted in your chest?		
2. Do you have a Durata or Optisure lead implanted for at least 60 days?		
3. Are you willing to undergo an MRI scan without sedation? (ensure subject is not claustrophobic)? Note: Antianxiety agents (e.g. minor tranquilizers,, etc.) may be used as long as the patient can communicate with site personnel during the MRI scan		
4. Is the subject's capture threshold $\leq$ 2.5V @0.5ms		
5. Can the subject's ventricular sensing threshold be measured (patient has underlying rhythm > 30bpm)?		
6. Is the subject's ventricular sensing threshold $\geq$ 4mV?		
7. Can you provide consent to participate in the study on your own? That is, can you sign and date a consent form on your own? You cannot use a legally authorized representative (LAR).		
8. Are you able to come in to the clinic or office for an MRI scan, and can you come back for follow up visits as needed?		
9. Are you able to fit in the MRI bore without any part of your body coming into contact with the magnet façade inside the MRI bore?		
A NO must be answered for questions 10-19 for the subject to be considered for enrollment.		
10. Do you have a non-St. Jude Medical lead in your body?		
11. Do you have an existing active implanted medical device (e.g. neurostimulator, infusion pump, etc.), that has MR labeling that will not allow the MRI scans per this protocol to be completed in your body?		
12. Has your ICD lead been revised < 60 days prior to the baseline visit?		
13. Do you have anything implanted that is metallic (wires, devices, clips, staples, rods, pins, screws, plates, dentures, braces, etc.) that would prevent you from getting an MRI scan? NOTE: MRI compatible knee replacements, hip replacements, stents, etc. may be included as long as the labeling of these devices allow MRI scans conducted per this protocol NOTE: MRI compatible mechanical, prosthetic, and bioprosthetic heart valves may be included as long as the labeling of these devices allow for MRI scans conducted per this protocol NOTE: Non-removable dental implants may be included		

Questions to ask Subject / Assess Subject for:	YES	NO
14. Do you have a lead extender or adaptor implanted?		
15. Does the subject have a capped or abandoned lead?		
16. Are you participating in any other studies that include investigational products or drugs, or require you to receive medical or surgical treatment that is not part of your normal and usual medical treatment?		
17. Are you pregnant or are you planning on getting pregnant while participating in this study?		
18. Is the subject expected to live less than 12 months from now?		
19. Are there any local laws or regulations that would exclude this subject from participating in this study, e.g. age limits >18 years?		
MRI Scan Medical History		
A NO must be answered for questions 20-31 for the subject to be considered for enrollment, unless otherwise clarified that subject remains eligible for the study MRI scan.		
20. Have you ever had an MRI examination before and had a problem?		
21. If YES, please describe:		
22. If YES, does problem disqualify subject from participating? Explain:		
23. Have you ever had a surgical operation or procedure of any kind?		
24. If YES, list all prior surgeries and dates (if known):		
25. Did surgery result in any material or devices that is metallic (wires, devices, clips, staples, rods, pins, screws, plates, dentures, braces, etc.)		
26. List all metallic materials or devices: include MFG and model		
27. Does the implanted metallic material or device prevent the subject from undergoing the study MRI scan, e.g. materials or devices MRI are NOT compatible at ≥2 W/kg?		
28. Have you ever been injured by a metal or foreign object (e.g., bullet, BB, shrapnel, lamp, rod, welding supplies) or have metal in your eyes?		
29. If YES, do you still have the metal or object in you?		

Questions to ask Subject / Assess Subject for:	YES	NO
30. Do you have any drug allergies that would prevent you from getting the study MRI scan, e.g. valium or similar? Food and other allergies do not apply.		
31. If YES, please list drugs		

Complete this form for each subject at the baseline visit. Complete the MRI Screening Form again at the MRI scan visit does not occur the same day as baseline. This form may be used to supplement medical records to support subject's eligibility for enrollment and ability to undergo a study MRI scan at the time of enrollment. If YES has been answered to any of the questions above, has it been verified that the subject is currently eligible for enrollment and an MRI scan according to the protocol requirements?

☐ Yes, the subject **IS** eligible for a study MRI scan(s).

☐ The subject **is NOT** eligible for a study MRI scan(s).

Do not enroll subject into study.

Study Personnel Completing Form:

Print Name:_____ Signature:_____ Date:_____

Appendix G: MRI Hazard Checklist

MRI Hazard Checklist

Site Name:_____Site Subject ID: _____
(E.g. US1234-0567)

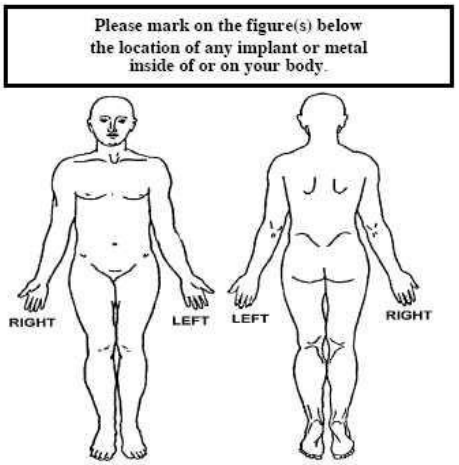
Date of Form Completion: _____

☐ ***Check this box if a site specific checklist was used. Remainder of form does not need to be completed. The standard form used by the MRI department at the site may be used in lieu of completing this form. If one is used, provide a copy to Cardiology for maintenance in the study records. Include the subject ID and Date that form was completed.***

The following may be harmful to the subject during the study MRI scan or may interfere with the MRI examination. Please mark on the drawings provided the location of any metal inside the subject's body or site of surgical operation.

A Yes or No must be provided for every item. Please indicate if the subject has any of the following. If Yes is checked, provide MFG and model for the device or material implanted.

YES NO
_____Any type of electronic, mechanical or magnetic implant
_____Cardiac pacemaker
_____Aneurysm clip(s)
_____Implantable cardiac defibrillator (Ellipse ICD specified in the MRI Ready IDE CIP is OK)
_____Neurostimulator
_____Biostimulator (Type_____)
_____Any type of internal electrode(s) or wire(s) (Durata and Optisure, lead specified in MRI Ready IDE CIP is OK)
_____Cochlear implant
_____Hearing aid
_____Implanted drug pump (e.g. insulin, Baclofen, chemotherapy, pain medication)
_____Halo vest
_____Spinal fixation device
_____Spinal fusion procedure
_____Any type of coil, filter, or stent (Type_____)
_____Any type of metal object (e.g., shrapnel, bullet, BB)
_____Artificial heart valve
_____Penile implant
_____Artificial eye
_____Eyelid spring
_____Any type of implant held in place by a magnet (Type_____)
_____Any type of surgical clip or staple
_____Any I.V. access port (e.g. Broviac, Port-a-Cath, Hickman, Picc line)
_____Medication patch (e.g., Nitroglycerine, nicotine)
_____Shunt
_____Artificial limb or joint (What and where_____)
_____Tissue expander (e.g., breast)
_____Removable dentures, false teeth or partial plate
_____Diaphragm, IUD, Pessary (Type_____)
_____Surgical mesh (Location_____)
_____Body piercing (Location_____)
_____Wig, hair implants
_____Tattoos or tattooed eyeliner
_____Radiation seeds (e.g., cancer treatment)
_____Any implanted items (e.g., pins, rods, screws, nails, plates, wires)



_____Any hair accessories (e.g., bobby pins, barrettes, clips)
_____Jewelry
_____Any other type of implanted item (Type_____)

Instructions for patients

1. You are urged to use the ear plugs or headphones that we supply for use during your MRI examination since some patients may find the noise levels unacceptable and the noise levels may affect your hearing.
2. Remove all jewelry (e.g., necklaces, pins, rings).
3. Remove all hair pins, bobby pins, rings).
4. Remove all dentures, false teeth, partial dental plates.
5. Remove all hearing aids.
6. Remove eyeglasses.
7. Remove your watch, pager, cell phone, credit and bank cards, and all other cards with a magnetic strip.
8. Remove body piercing objects.
9. Use gown, if provided, or remove all clothing with metal fasteners, zippers.

Subject attests that the above information is correct to the best of subject's knowledge. Subject has read or has had contents read to subject, understands the entire contents of this form, and had the opportunity to ask questions regarding the information on this form.

Subject signature_____

Hazard Checklist for Radiology Personnel

The following items are not permitted to be used during the study MRI scan.

- *Endotracheal tube*
- *Swan-Ganz catheter*
- *Extraventricular device*
- *Arterial line transducer*
- *Foley catheter with temperature sensor and/or metal clip*
- *Rectal probe*
- *Esophageal probe*
- *Tracheotomy tube*
- *Guidewires*

Radiology Personnel Completing Checklist

- Print Name:_____Signature_____Date:_____

Appendix H: List of Clinical Investigation Sites and IRB/EC

A list of Clinical Investigational sites and IRB/EC is kept under a separate cover and is available upon request.

Appendix I: Sample Informed Consent & Sub study consent

STUDY TITLE AND NUMBER A Clinical Evaluation of the Durata® or Optisure™ High Voltage Leads and Ellipse® VR ICD Undergoing Magnetic Resonance Imaging, an Investigational Device Exemption (MRI Ready IDE) Study

SPONSOR St. Jude Medical, Inc. (SJM)

PRINCIPAL INVESTIGATOR

SITE NAME

Introduction

You are being asked to take part in this research study evaluating the Durata or Optisure High Voltage Leads implanted with the Ellipse ICD in an MRI environment because you currently have an Ellipse ICD and Durata or Optisure high voltage lead implanted and may be willing to undergo an MRI scan.

This form explains why this research is being done and what your role will be if you decide to participate. This form also talks about the possible risks that may happen if you take part in this study. This study is sponsored by St. Jude Medical. This company manufactures medical devices intended to treat various medical conditions.

Please read this form, and ask your study doctor any questions you may have about the study so that your questions may be answered before you decide if you want to take part in the study. Please take your time and talk about this information with your family, friends, or family doctor.

This consent form may contain some words that you do not understand. It is important that you understand what is in this form. It will explain the different activities you will be asked to do or participate if you take part in the research study and what the risks might be; whether or not you do take part is entirely your choice. Please ask the study doctor or the study staff to explain any words or information that you do not understand.

If you decide you want to take part in the research project, you will be asked to sign the consent section before any study-related activities are performed. By signing it you are telling us that you:

- Understand what you have read

- Consent to take part in the research project
- Consent to have the tests and treatments that are described
- Consent to the use of your personal and health information as described.

Taking part in this study is entirely voluntary. If you don't wish to take part, you don't have to. You will receive the best possible care whether or not you take part in the study. Refusing participation will not involve any penalty or loss of benefit. If you decide to take part in this study, you must sign your name at the end of this form. No research activity can be performed until you sign this form.

What is the purpose of this study?

The purpose of this study is to demonstrate the safety and effectiveness of the Durata or Optisure high voltage lead with the Ellipse ICD in an MRI environment. In order to evaluate the safety and effectiveness of your devices in an MRI environment, you will be asked to undergo an MRI scan.

Please note: The MRI is not meant to be diagnostic in nature. There are no guarantees that results will be provided to you, nor will these results be provided to your physician(s) for review.

What is the device being tested?

The Durata and Optisure high voltage leads and Ellipse ICD have been approved for use by the Food and Drug Administration (FDA) and TUV are commercially available. This IDE study is testing the ability for the Durata or Optisure high voltage lead and Ellipse ICD (this is referred to as the ICD system) to safely undergo an MRI scan.

What will be requested from you if you take part in this study?

This research study includes a screening/qualification phase to determine if you are a good candidate for the study. Your doctor or other study personnel will ask you medically related questions, such as whether or not you've had any MRI scans in the past, and whether you have been implanted with a Durata or Optisure high voltage lead and Ellipse ICD for at least 60 days. Other questions you may be asked include:

- Age
- Gender
- Past medical history
- Past surgical history

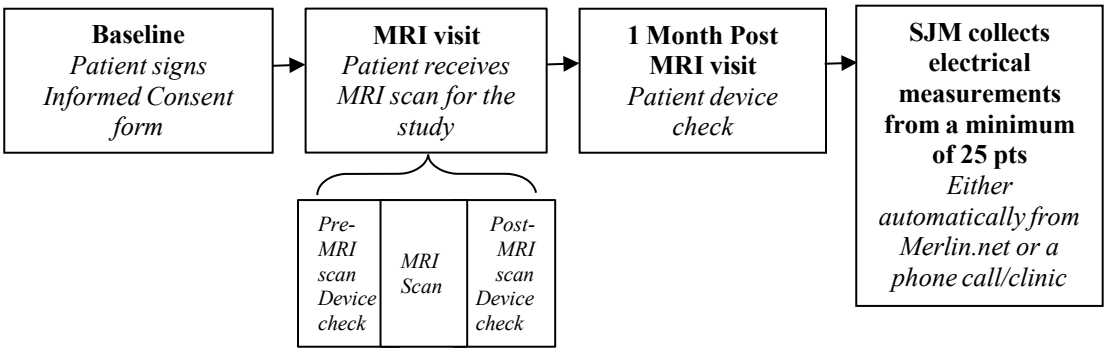
- Whether you have any type of permanent implants (for example, staples, wires, pins, rods, screws, plates, cardiac stents, insulin pumps, meshes, dentures, braces, etc.) that are metallic
- Whether you've had any accidents or been injured by metallic objects

In order to participate in this study, you must meet all the inclusion criteria and none of the exclusion criteria to safely undergo an MRI scan for this study. Based on your answers and your medical history, your doctor will decide if you qualify to take part in the MRI Ready IDE Study. If you do not qualify for the study, your participation will end.

If your doctor determines that you qualify, and you decide to take part in this study, the procedure(s) described below will be performed. Your doctor may decide that you do not need an MRI scan and not taking part in this study would be better for you.

There may be a representative from the sponsor at your study visits and the representative may carry out some of the study procedures. The study doctor may direct a representative from the sponsor to collect information from your implanted device. At the study doctor's direction, the sponsor representative may also program your device or run tests to see if your device is working as expected. The sponsor's representative will work under the direction of your study doctor or other care provider.

The figure below describes the research activities involved in this trial. These visits are experimental and would not occur if you do not choose to participate in this trial:



You will be required to have your implanted lead(s) and ICD tested in the same way as a regular device check-up. These device tests will be done at the following visits:

- MRI Scan Visit
- 1 Month Post MRI Scan Visit

- Collection of additional electrical measurements – SJM may automatically collect electrical measurements (remote follow up) from Merlin.net after the 1 month post MRI scan visit. If you are not on Merlin.net, then you may be called by the site every 3 months to check on the status of your device. When SJM has collected electrical measurements from a minimum of 25 patients, then the remote follow up/phone calls will end for all patients.

You may also need to return for additional visits not listed above if your lead(s) and/or ICD need to be repositioned or replaced. Your study doctor or study personnel will work with you to schedule those extra visits if they are needed.

The section below describes the procedures that will occur.

1. MRI Scan Visit

Before the MRI Scan:

- A pregnancy test will be given (for women of child bearing age). If you are pregnant, you will be withdrawn from the study.
- Before the actual MRI scan, your ICD device will be tested using a programmer in the same way as at a regular clinical check-up. You should not feel any discomfort during this procedure. The following information will be collected.
  a. Capture threshold (how much energy it takes to make your heart beat)
  b. Sensing threshold (how well your ICD can sense your heart beat)
  c. Pacing impedance of your implanted lead
  d. High voltage lead impedance of your implanted lead
- A member of your study doctor's staff or the radiological team will ask you a series of questions (MRI Screening Form and MRI Hazard Checklist) to make sure you meet the safety requirement to receive the MRI scan.
- You may be asked to undress, and put on a gown for the MRI scan.
- You may be asked to come back another day if your test results do not meet the criteria for you to be scanned. The MRI Scan Visit will be repeated if this happens.

During the MRI Scan:

- Once you are cleared to have an MRI scan, you will be placed on a padded table and positioned for your exam. Electrodes (sticky pads) will be placed on your chest, and the electrodes will be connected to an electrocardiogram machine (ECG). The ECG allows the MRI staff to monitor your heart rhythm during the exam.
- A pulse oximeter will be placed on your finger tip. The pulse oximeter is a painless finger clip used to measure the amount of oxygen in your body. This allows the doctor to see how much oxygen content is in your blood during the MRI.

- A soft padded coil may be placed at the area where the pictures will be taken. Another coil may be placed on or behind your head.
- The table on which you are lying will be moved to the center of the MRI magnet, which looks like a short narrow tube. Even though the tube is open, some people feel confined in small places. If this bothers you, please notify the MRI staff.
- During the exam, you will be monitored. The MRI staff is able to see and hear you. You will be able to hear the MRI staff, too.
- When MRI pictures are taken, radio signals and magnetic fields are used to generate an image. When this happens, it is normal for the MRI machine to make loud, banging, and clicking noises. You may be asked to wear earplugs or headphones for your comfort during the exam.
- You may feel warm during the scan. This is expected. If you feel discomfort or have pain in the area where your ICD is implanted, please let your study doctor or other study staff know.
- When the MRI exam is finished, you will be taken out of the MRI magnet and the pulse oximeter and ECG electrodes will be removed.

After the MRI Scan:

- After you have your scan, your device will be tested using a programmer. Your device settings may be adjusted if changes occurred during the MRI. This device testing is done the same way as at a regular clinical check-up. You should not feel any discomfort while your device is being tested. The following information will be collected.
    a. Capture threshold (how much energy it takes to make your heart beat)
    b. Sensing threshold (how well your ICD can sense your heart beat)
    c. Pacing impedance of your implanted lead
    d. High voltage lead impedance of your implanted lead

2. 1 Month Post MRI Visit

- A sponsor representative may also program your device or collect information from your device under a physician's supervision.
- Your ICD device will be tested using a programmer in the same way as at a regular clinical check-up. You should not feel any discomfort during this procedure. The following information will be collected.
    a. Capture threshold (how much energy it takes to make your heart beat)
    b. Sensing threshold (how well your ICD can sense your heart beat)
    c. Pacing impedance of your implanted lead
    d. High voltage lead impedance of your implanted lead

3. Non-Study MRI Scans (if applicable)

Should you need a MRI scan performed for specific medical reasons after the study MRI scan visit was performed until the completion of your participation in the study, then the procedures listed in the MRI scan visit above may also occur during the non-study MRI scan.

Your study participation may end following the successful completion of the 1 month post MRI visit. If further electrical measurements are needed from your device, then SJM may automatically collect electrical measurements (remote follow up) from Merlin.net after the 1 month post MRI scan visit. If you are not on Merlin.net, then you may be called by the site every 3 months and asked questions about your health history from the time of your baseline visit. The phone call will last approximately 15 minutes. The phone calls will occur until SJM receives electrical measurements from a minimum of 25 enrolled study participants.

How long will the study last?

If you agree to take part in the study, your involvement will last approximately 6 months. You will be asked to return to the clinic 2-3 times. Your MRI scan visit may take up to three hours to complete and your one month post MRI scan visit will take approximately 30 minutes. If you are asked to receive the 3 month follow up phone calls, then these calls will take approximately 15 minutes as well.

Up to 165 people will take part in this research at approximately 60 sites worldwide, with a majority of the centers located within the United States.

What are the possible risks and discomforts?

There are risks, discomforts, and inconveniences associated with any research study to you (or to an embryo, unborn child or nursing infant if you become pregnant). These deserve careful thought.

While in the study, you will receive an MRI scan. The risks and adverse effects of the MRI scan are listed below but they will vary from person to person. You should talk with the study doctor if you have any questions.

Risks associated with MRI scans of patients with Cardiac Devices:

a) **Potential MRI Scan Adverse Events:**

- Claustrophobia (fear of enclosed spaces)
- Mild diaphoresis (sweating)
- Hearing impairment (difficulty hearing)
- Sensation of bodily warmth
- Sensation of warmth at device pocket not arising to the level of discomfort

- Body stiffness related to immobility

There will be emergency personnel and equipment on hand for your safety. Please tell the study doctor, nurse or technician if you experience any unusual sensations or discomfort during the scan.

b) **Potential ICD System Adverse Events:**

- Lead electrode heating and tissue (heart muscle) damage, resulting in loss of sensing or capture or both: A portion of the lead may heat up causing damage to the heart muscle resulting in the loss of some of the device's electrical functions.
- Lead heating resulting in a blood clot or blockage of a blood vessel
- Device heating resulting in tissue damage in the implant pocket or patient discomfort or both
- Induced currents on leads resulting in continuous capture (continuous pacing of the heart), VT/VF (abnormal beating of the lower heart chambers), hemodynamic collapse (blood circulation failure), or all three
- Damage to the device or leads causing:
  - the system to fail to detect or treat irregular heartbeats
  - the system to treat the patient's condition incorrectly
- Damage to the functionality or mechanical integrity of the device resulting in the inability of the device to communicate with the programmer
- Movement or vibration of the device or leads
- Lead dislodgment (lead comes loose from the heart)
- When the ICD is in MRI mode, it paces independent of the natural heart rhythm. This pacing may happen at the same time of a natural heart beat and may cause VT/VF (abnormal beating of the lower heart chambers).
- Syncope (fainting) due to loss of pacing if no pacing support is programmed with MRI settings
- Pulmonary embolism (blockage of the lung's blood vessel)
- Death due to untreated spontaneous arrhythmia because tachyarrhythmia therapy is disabled when MRI settings are programmed

These risks would also apply if you undergo a non-study MRI scan.

There may be other risks or discomforts to you (or to an embryo, unborn child or nursing infant if you become pregnant) that are not known at this time. If important information is learned during the course of this research study, your doctor will be notified by St. Jude

Medical. Your doctor will discuss with you important new information that is learned during the course of this study that may affect your condition or willingness to continue to take part in this research study.

What are the risks for women of childbearing age?

If you are a woman who is able to become pregnant, it is expected that you will use an effective method of birth control to prevent exposing a fetus to a potentially dangerous agent with unknown risk. If you are pregnant or currently breast feeding, you may not participate in this study. You understand that if you are pregnant, if you become pregnant, or if you are breast-feeding during this study, you or your child may be exposed to an unknown risk.

If you are pregnant or plan to become pregnant in the next 2 months, you should discuss your participation with your study doctor. Patients who become pregnant while taking part in the study should contact the study doctor right away.

What are the possible benefits to you or others?

If you decide to take part in this study, you may benefit from the ability to safely undergo MRI scans with an implanted Durata or Optisure lead and Ellipse ICD, but there is no guarantee that this will happen. The information gathered in this study will add to the understanding of treatment options for patients with this ICD system who need to have an MRI scan performed.

If you do not want to take part in this study, what other options are available to you?

Your study doctor will discuss other options available to you, such as your choice not to take part in this study.

If you choose to take part in this study, what are the costs?

For all patients enrolled in the study, the cost of the MRI scan performed at the MRI visit, and the cost of the device check performed at the 1 Month Post MRI visit will be covered through the study.

However, you and your insurance provider are responsible for all Routine Costs associated with this study. Routine Costs are costs that are covered by Medicare/Country specific insurance system in connection with studies such as this one, even if Medicare/Country specific insurance system is not your insurance provider. Generally, Routine Costs include items and services required to insert a study device into your body; items or services reasonably necessary to treat complications that may result from this study; and items and services that would typically be provided to you even if there were no clinical trial. Routine Costs typically do not include the

study device (although some exceptions exist) and items and services provided only to collect data for the study.

All Routine Costs will be billed to your insurance provider, but there is no guarantee that your insurance provider will cover all Routine Costs. Even where such insurance coverage is provided, you may still have to pay some costs such as copayments, coinsurance, or deductibles for the covered items or services. You should contact your insurance provider to discuss its coverage policy for items or services provided during a research study.

You should also contact your insurance provider to discuss the coverage options available following completion of the study. Because the treatment being investigated is not currently approved, insurance may not pay for clinic visits or device-related surgery once you have exited the study. Where post-trial insurance coverage is not available, you might have expenses as a result of being in this study even after the study has been completed. Ask your study doctor to discuss the coverage options available. Otherwise, you might have unexpected expenses from being in this study.

Will you receive payment for taking part in this study?
You will receive a payment of $100 for the MRI scan visit to help cover the costs of travel, time, meals, and parking related to your participation in the research study.

What if the device needs to be removed?

In the event your ICD system or any part has to be removed, it will be returned to St. Jude Medical for analysis. Should you withdraw from this study and choose to have your ICD system or any part of it removed, the cost will be your responsibility.

In the event of your death, your implanted ICD system may be removed and returned to St. Jude Medical for analysis. The study doctor will get your family's approval prior to removing the device.

What if you are injured because of this study?

If you suffer any injuries, illnesses, or complications as a direct result of participation in this study, conducted in accordance with the study protocol, treatment for that injury including surgery, first aid, and emergency care will be available as needed. The hospital or clinic where you receive treatment will bill your insurance provider for Routine Costs (as defined in the section above entitled "If you choose to take part in this study, what are the costs?"), although you may have to pay some costs such as copayments, coinsurance, or deductibles for the covered items or services.

The Sponsor will pay for all non-Routine Costs associated with reasonable and necessary treatment of injuries, undesirable side effects, or adverse reactions directly resulting from

participation in this study, so long as you followed all study instructions. The Sponsor will not cover the cost of injuries resulting from participation in the study to the extent that they are caused by your failure, or that of the hospital or study doctor, to follow study instructions or other negligence, the natural progression of an underlying condition (whether diagnosed or not) or pre-existing condition, or events that would have been expected using currently approved therapies for your condition.

However, signing this consent form in no way limits your legal rights against the Sponsor, investigators, or anyone else, and you do not release the study doctors or participating institutions from their legal and professional responsibilities.

During the study, if you experience any injuries, illnesses, or complications from taking part in this study, please contact Dr._____ at___-___-____.

What are your rights if you decide to take part in this study?

Your signature on this consent form means that you have received information about this research study and that you agree to be a part of the study.

You may stop taking part in the study at any time without penalty or loss of benefits to which you are otherwise entitled. If you wish to stop taking part in this research study for any reason, you should contact Dr._____at____-___-_____.

If you do withdraw your consent during the study, the study doctor and relevant study staff will not collect additional personal information from you, although personal information already collected will be retained to ensure that the results of the research project can be measured properly and to comply with the law. You should be aware that data collected by the sponsor up to the time you withdraw will be part of the study results.

Your study doctor or designee will discuss with you what follow-up is required if you decide to withdraw, or are withdrawn from the study before the study is finished.

Your doctor or the sponsor of the study (St. Jude Medical, Inc.) may also stop your participation in the study at any time, without your consent, for any reason.

How will your information be kept confidential?

If you decide to take part in this study, your medical records and personal information will be kept confidential to the extent allowed by federal, state, and local law. A special code (number combination) will be used to identify your personal health information. However, information from the study may be exported to countries where different data protection laws apply, including the United States (US). The data protection laws in other countries may be less strict than those of your country.

If you decide to participate in the study, the study sponsor and others who work with the study, such as the study staff and Institutional Review Board (IRB) / Ethics Committee (EC) will see health information about you. The IRB/EC is a group of people who perform independent review of research as required by laws governing this type of research.

U.S. Food and Drug Administration (FDA), relevant international regulatory authority and/or national competent authority or other regulatory agencies, EC/IRB and sponsor's representative may inspect and copy your medical records.

The information collected about you may be used in several ways. Information about you and your health that might identify you may be given to others to carry out the research study. Your study doctor may use some of the information in making decisions about your care.

The sponsor may use the information in any of the following ways:

- To analyze and make conclusions about the results of the study,
- In documents sent to the government agencies throughout the world including the U.S. Food and Drug Administration (FDA) to request approval to market the Durata® or Optisure™ lead and Ellipse® ICD as MR Conditional,
- For reporting undesirable events to the FDA and other government health agencies,
- To provide overall study results to other study doctors, including in publications,
- To conduct new medical research, to reanalyze the study results in the future or to combine your information with information from other studies,
- To develop new medical products and procedures, and other product-development related activities.

Your name will not be provided for publications in medical journals. While using the information in these ways, the sponsor may give study data to its affiliated companies in the U.S. or other countries. The sponsor may also share the information with its business partners or companies it hires to provide study-related services. Information received during the study will not be used for any mailing lists or sold to anyone for marketing purposes.

Your permission for the use, retention, and sharing of your identifiable health information will expire when FDA/regulatory body approval of the study is obtained. At that time the research information not already in your medical record will not be given to the sponsor.

A description of this clinical study will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search the Web site at any time. Please note information may not be available on ClinicalTrials.gov until the study is completed and the device is marketed.

Who can you contact for study information?

If you have any questions about the study or taking part in this study, please contact Dr. _____ at___-___-_____.

In addition, if you have any concerns, complaints or questions about your rights as a research patient or an injury that you believe is a research-related, please contact:

Name of person at IRB/EC:
Title of person at IRB/EC:
IRB/EC phone number:
IRB/EC email, if known:

Consent and authorization for participation in this study

Taking part in this study is entirely voluntary. You are making a decision on whether or not to take part in the research study. Your signature indicates that you have read the information in this form and have decided to take part in the research study. You will be given a signed copy of this form to keep.

I have read all of the above information in this consent and authorization form. I have had the opportunity to ask questions and have received answers concerning areas I did not understand.

I willingly give my consent to participate in this study and to comply with the procedures related to it.

I confirm that my relevant anonymized personal data collected during the study will be used in the analysis and communicated in publications.

I understand that I am free to refuse to participate in the proposed study, without giving any reason and without my medical care or legal rights being affected.

I understand that I am free to withdraw from the proposed study at any time, without giving any reason, without my medical care or legal rights being affected.

I give my permission to representatives from the sponsor, the IRB/EC and the regulatory authorities to access my medical records.

I understand that my personal physician will be informed of my participation in this research study.

Name of Participant (please print) _____

Signature_____Date _____

Name of Person Obtaining Consent (please print) _____

Signature_____Date _____

If participant is unable to read:
I have attended the entire informed consent discussion. I attest that the information in the consent form and any other written information was accurately explained to, and apparently understood by the patient. Informed consent was freely given by the patient.

Impartial Witness Name (please print) _____

Signature_____Date _____

Patient Informed Consent Addendum: Sub Study

A CLINICAL EVALUATION OF THE DURATA® OR OPTISURE™ HIGH VOLTAGE LEADS AND ELLIPSE VR ICD UNDERGOING MAGNETIC RESONANCE IMAGING, AN INVESTIGATIONAL DEVICE EXEMPTION (MRI READY IDE) STUDY

Introduction

You were asked to and agreed to participate in the MRI Ready IDE research study because you have an implanted Durata® or Optisure™ high voltage lead and Ellipse® ICD and were willing to undergo an MRI scan.

You are being asked to take part in this research sub study evaluating the ability of your implantable cardioverter-defibrillator (ICD) to shock your heart out of an abnormal heart rhythm.

This consent addendum explains why this research sub study is being done and what your role will be if you decide to participate. This form also talks about the possible risks that may happen if you take part in this study. The study is sponsored by St. Jude Medical. This company manufactures medical devices intended to treat various medical conditions. ***Please refer to your main consent form for other information such as your rights as a study participant.***

Please read this form, and ask your study doctor any questions you may have about the research study so that your questions may be answered before you decide if you want to take part in the study. Please take your time and talk about this information with your family, friends, or family doctor.

Taking part in this research study is entirely voluntary. If you don't wish to take part, you don't have to. You will receive the best possible care whether or not you take part in the study. Refusing participation will not involve any penalty or loss of benefit. You may stop taking part in the study at any time without penalty or loss of benefits to which you are otherwise entitled. Your study doctor or designee will discuss with you what follow-up is required if you decide to withdraw, or are withdrawn from the study before the study is finished. If you decide to take part in this study, you must sign your name at the end of this form. No research study activity can be performed until you sign this form.

Purpose

The purpose of this research sub study is to test your ICD's ability to deliver appropriate shock to treat ventricular fibrillation after undergoing an MRI scan.

What is being tested?

Your ICD treats abnormally fast heart rates. Ventricular fibrillation (VF) and ventricular tachycardia (VT) are types of fast irregular rhythm that begins in the lower chambers (ventricles) of the heart. In VT, the heart beats fast, but it beats at a regular rate. If VT is not treated, it can lead to VF which is when the heart beats fast and irregular. In VF, the heart beats too rapidly and cannot deliver oxygen-rich blood to vital organs. If the supply of oxygen-rich blood is reduced, loss of consciousness and death may occur unless the blood supply is restored.

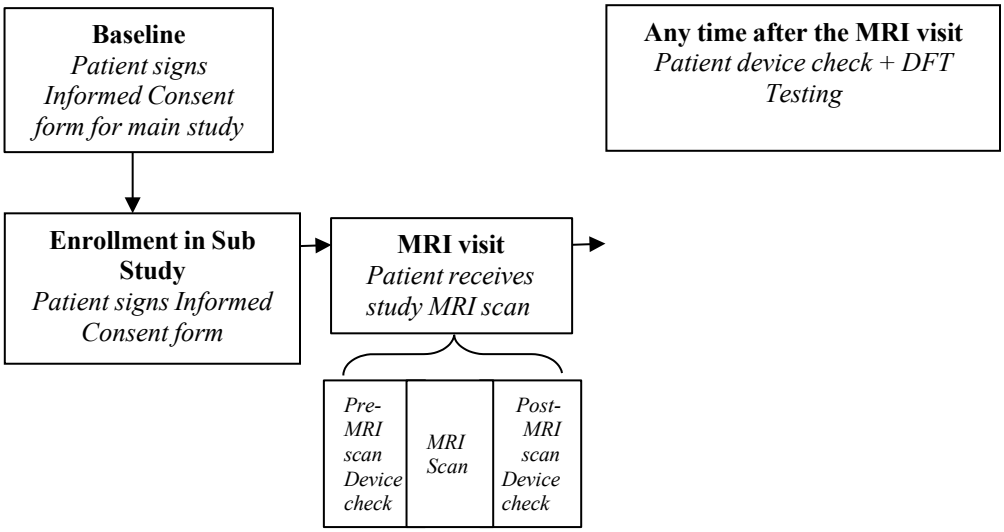
Treating the heart with appropriate electrical pulses often can restore a normal heart rhythm. To treat VT or VF, the ICD delivers a high energy electrical pulse, which is known as a defibrillation shock. Defibrillate means to return your unnatural twitching of the heart muscle to a correct rhythm. An electrical pulse or shock delivered from the ICD through leads (thin insulated wires) to the heart can stop the fast heart rhythm and restore normal function.

What will be requested from you if you take part in this research study?

The section below describes the procedures that will occur. All patients who agree to take part in this sub study will undergo defibrillation threshold (DFT) testing. During this procedure, your study doctor will stimulate your heart to VF and then shock it back to normal rhythm with your ICD.

You will be anesthetized in the hospital and your heart will be induced to VF or VT (your doctor will decide which method is best) and shocked to see whether the shock delivered to the heart will stop an abnormally fast heart rate. Two external defibrillating pads may be placed on your body during testing for backup defibrillation. After all of the testing is complete and the ICD device is determined to be in good working order, your ICD device will be programmed as needed.

The DFT testing will occur in the hospital after the MRI visit. The figure below describes the research activities involved in this sub study, in relation to your existing participation in the MRI Ready IDE trial. These visits are experimental and would not occur if you do not choose to participate in this trial:



How long will the study last?

If you agree to take part in the research study, your involvement will be approximately a minimum of 2 hours**.** You will not be asked to return to the hospital unless your physician requires it.

Up to 25 people will take part in this research study at about 40 sites.

What are the possible discomforts and risks?

Additional risks to you are associated with having an increased number of ventricular tachycardia and ventricular fibrillation episodes. The risks could be a failure to stop the arrhythmia and risks associated with a longer procedure time.

Your doctor will review the risks related to DFT testing. These risks include but are not limited to:

- An increased number of fast heart beats and irregular heartbeats during the induction testing. There could be a failure to stop the irregular heartbeat during the induction testing.
- Discomfort during the procedure
- Need for an outside shock to restart the heart during the induction testing in rare instances
- Stroke in very rare instances
- Death in very rare instances

There may be other risks to you that are not known at this time.

If you are pregnant or currently breast feeding, you may not participate in this sub study. You understand that if you are pregnant, if you become pregnant, or if you are breast-feeding during this study, you or your child may be exposed to an unknown risk. If you are pregnant or plan to become pregnant in the next 2 months, you should discuss your participation with your study doctor. Patients who become pregnant while taking part in the study should contact the study doctor right away.

If you do not want to take part in this portion of the study, what other options are available to you?

Your doctor will discuss other options available to you, including not participating in this sub study.

If you choose to take part in this study, what are the costs?

The cost of the DFT testing performed after the MRI scan visit will be covered by St Jude Medical.

Will you receive payment for taking part in this study?

You will receive a payment of $250 for the DFT testing to help cover the costs of travel, time, meals, and parking related to your participation in the research study.

This research study is being sponsored and funded in the United States, by St Jude Medical. St Jude Medical may benefit financially from this research study if, for example, the project assists St Jude Medical to obtain approval for a new device.

In addition, if knowledge acquired through this research study leads to discoveries that are of commercial value to St Jude Medical, the study doctors or their institutions, there will be no financial benefit to you or your family from these discoveries.

[Name of institution] will be compensated by St Jude Medical for undertaking this research study. No member of the research study team will receive a personal financial benefit from your involvement in this research study (other than their ordinary wages).

What are the possible benefits to you or to others?

The information gathered in this study will add to the understanding of treatment options for patients with your implanted device system who have had or need to have an MRI scan performed.

The sponsor of this study is paying for cost of data capture and items that are not deemed standard of care/routine care in the study. St. Jude Medical will pay the study center where the study is being conducted.

Signature

You are making a decision on whether or not to take part in this sub study. Your signature indicates that you have read the information in this form and have decided to take part in the sub study of the MRI Ready IDE trial. You will be given a signed copy of this form to keep.

_____ Printed Name of Patient	
_____ Signature of Patient	_____ Date
_____ Print Name of Person Obtaining Consent	
_____ Signature of Person Obtaining Consent	_____ Date

If participant is unable to read:
I have attended the entire informed consent discussion. I attest that the information in the consent form and any other written information was accurately explained to, and apparently understood by the patient. Informed consent was freely given by the patient.

Impartial Witness Name
(please print) _____

Signature_____Date _____

Appendix J: Product Labeling

The product labeling for the investigational device, instructions for use and packaging are kept under a separate cover, and will be provided to FDA in the IDE application.

Appendix K: Case Report Forms

The case report forms for the study are kept under a separate cover, and are available upon request.

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