Ellipse™ DR

Dual-Chamber Implantable Cardioverter Defibrillator (ICD)

Merlin@home™ Transmitter Compatible

MR

Product Highlights

- MRI-ready device to allow patients to safely undergo an MRI scan when used in combination with MR Conditional leads[1,2]
- Improved shape with reduced volume and thickness
- Parylene coating for improved abrasion resistance
- DynamicTx™ Over-Current Detection Algorithm automatically changes shock configurations to ensure delivery of high voltage therapy when high current is detected
- Cold Can programmability provides an additional RV-SVC Shock Configuration to decouple the can from the shocking vector parameters in cases of lead problems
- ShockGuard™ technology with DecisionTx™ programming designed to reduce inappropriate therapy and minimise the need for programming adjustments at implant
- Low Frequency Attenuation filter designed to enhance sensing performance and may reduce the possibility of oversensing T-waves
- Sense*Ability*™ feature provides flexibility to fine-tune programming around T-wave oversensing without decreasing sensitivity
- DF4 connector designed to streamline defibrillation connections into a single terminal pin and reduce the number of set screws
- CorVue™ congestion monitoring feature monitors the intrathoracic impedance in multiple vectors for improved accuracy, and it provides the option for both patient and physician alerts
- SecureSense™ RV lead noise discrimination detects sustained and short bursts of lead noise that would otherwise go unnoticed or potentially lead to one or more inappropriate shocks
- Far Field MD™ morphology discrimination and Chamber Onset discrimination improve SVT and VT discrimination for reduced inappropriate therapies
- Antitachycardia pacing (ATP) while charging and prior to charging in the VF zone further extends the programming options for terminating tachyarrhythmias without a high-voltage shock
- ST monitoring capability provides unprecedented, continuous insight into significant ST shift events and associated ventricular arrhythmias through enhanced monitoring of iEGM and ST-segment as a diagnostic tool to help guide appropriate clinical action
- 36 J delivered energy safety shock option can provide a greater DFT safety margin
- DeFT Response™ technology offers the most noninvasive options for managing high DFTs
- QHR™† chemistry battery provides greater capacity for enhanced longevity and improved charge time performance compared to previous SVO batteries

Ordering Information

Contents: Cardiac pulse generator

Model Number	Dimensions (H x W x T, mm)	Weight (g)	Volume (cc)	Connector Defibrillation	Connector Sense/Pace
CD2377-36C	69 x 51 x 12	66	31	DF1	IS-1
CD2377-36QC*	70 x 51 x 12	68	31	DF4	IS-1; DF4

*Indicates models that are MRI Conditional[1,2]

Indications: The devices are intended to provide ventricular antitachycardia pacing and ventricular defibrillation for automated treatment of life-threatening ventricular arrhythmias.

Contraindications: Contraindications for use of the pulse generator system include ventricular tachyarrhythmias resulting from transient or correctable factors such as drug toxicity, electrolyte imbalance, or acute myocardial infarction.

Adverse Events: Implantation of the pulse generator system, like that of any other device, involves risks, some possibly life-threatening. These include but are not limited to the following: acute hemorrhage/bleeding, air emboli, arrhythmia acceleration, cardiac or venous perforation, cardiogenic shock, cyst formation, erosion, exacerbation of heart failure, extrusion, fibrotic tissue growth, fluid accumulation, hematoma formation, histotoxic reactions, infection, keloid formation, myocardial irritability, nerve damage, pneumothorax, thromboemboli, venous occlusion. Other possible adverse effects include mortality due to: component failure, device-programmer communication failure, lead abrasion, lead dislodgment or poor lead placement, lead fracture, inability to defibrillate, inhibited therapy for a ventricular tachycardia, interruption of function due to electrical or magnetic interference, shunting of energy from defibrillation paddles, system failure due to ionising radiation. Other possible adverse effects include mortality due to inappropriate delivery of therapy caused by: multiple counting of cardiac events including T waves, P waves, or supplemental pacemaker stimuli. Among the psychological effects of device implantation are imagined pulsing, dependency, fear of inappropriate pulsing, and fear of losing pulse capability.

Refer to the User's Manual for detailed indications, contraindications, warnings, precautions and potential adverse events.

†QHR is a trademark of Greatbatch Medical

ST. JUDE MEDICAL

Ellipse™ DR

Dual-Chamber Implantable Cardioverter Defibrillator (ICD)

Product Specifications

PHYSICAL SPECIFICATIONS		
Models	**CD2377-36C**	**CD2377-36QC**
Telemetry	RF	RF
Delivered/Stored Energy (J)	36/39	36/39
Volume (cc)	31	31
Weight (g)	66	68
Size (mm)	69 x 51 x 12	70 x 51 x 12
Defibrillation Lead Connections	DF1	DF4
Sense/Pace Lead Connections	IS-1	IS-1; DF4
High-Voltage Can	Electrically active titanium can	Electrically active titanium can
Coating	Parylene	Parylene
MRI Conditional	No	Yes-MRI-ready

PARAMETER	SETTINGS
AF Management	
AF Suppression™ Pacing	On; Off
No. of Overdrive Pacing Cycles	15-40 in steps of 5
Maximum AF Suppression Rate	80-150 min^{-1}
Sensing/Detection	
Sense*Ability*™ Technology	Automatic Sensitivity Control adjustment for atrial and ventricular events
Low Frequency Attenuation	On; Off
Threshold Start	(Post-Sensed; Atrial) 50; 62,5; 75; 100%; (Post-Paced; Atrial) 0,2-3,0 mV; (Post-Sensed; Ventricular) 50; 62,5; 75; 100%; (Post-Paced; Ventricular) Auto; 0,2-3,0 mV
Decay Delay	(Post-Sense/Post-Pace; Atrial/Ventricular) 0-220
Ventricular Sense Refractory (ms)	125; 157
Detection Zones	3 zone programming - 1 zone, 2 zones or 3 zones (VT-1, VT-2, VF)
SVT Discriminators	AV Rate Branch; Arrhythmia Onset (Chamber Onset or Sudden Onset); Interval Stability; AV Association; Morphology Discrimination (Far Field MD or Original MD) with Manual (original MD only) or Automatic Template Update
Monitor Mode	Detection, discrimination and diagnostics, no therapy delivery (VT or VT-1 zone)
Discrimination modes	On; Passive; Off
SVT Threshold	150-240 min^{-1}
SVT Timeout	0,25-5 min
Reconfirmation	Continuous sensing during charging
Lead Noise Discrimination	SecureSense™ RV lead noise discrimination (On; On with Timeout; Passive; Off)
Antitachycardia Pacing Therapy	
ATP Configurations	Ramp; Burst; Scan; 1 or 2 schemes per VT zone
ATP in VF Zone	ATP While Charging; ATP Prior to Charging; Off
ATP Upper Rate Cutoff	150 - 300 min^{-1}
Burst Cycle Length	Adaptive; Readaptive or Fixed
Min. Burst Cycle Length (ms)	150-400 in increments of 5
Number of Bursts	1-15
Number of Stimuli	2-20
Add Stimuli per Burst	On; Off
ATP Pulse Amplitude (V)	7,5 Independent from Bradycardia and Post-Therapy Pacing
ATP Pulse Width (ms)	1,0 or 1,5 Independently programmable from Bradycardia and Post-Therapy Pacing
High-Voltage Therapy	
DynamicTx™ Algorithm	On; Off
DeFT Response™ Technology	Programmable pulse width for P1/P2 and tilt
High-Voltage Output Mode	Fixed Pulse Width; Fixed Tilt
Waveform	Biphasic; Monophasic
RV Polarity	Cathode (-); Anode (+)
Electrode Configuration	RV to Can; RV to SVC/Can; RV to SVC
Bradycardia Pacing	
Permanent Modes	Off; DDD(R); DDI(R); VVI(R); AAI(R)
Temporary Modes	Off; DDD; DDI; VVI; AAI; AAT; DOO; VOO; AOO
Rate-Adaptive Sensor	On; Off; Passive
Programmable Rate and Delay Parameters	Base Rate (min^{-1}); Rest Rate (min^{-1}); Maximum Tracking Rate (min^{-1}); Off; Maximum Sensor Rate (min^{-1}); Paced AV Delay (ms); Sensed AV Delay (ms); Rate Responsive AV Delay (Atrial and RV) (ms); Hysteresis Rate (min^{-1}); Rate Hysteresis with Search
Ventricular AutoCapture™ Pacing System	On; Off
ACap™ Confirm	On; Monitor; Off
QuickOpt™ Timing Cycle Optimisation	Sensed/Paced AV delay
Auto Mode Switch (AMS)	Off; DDI(R); VVI(R)
Atrial Tachycardia	
Detection Rate (min^{-1})	110-300
AMS Base Rate (min^{-1})	40; 45;...135
Auto PMT Detection/Termination	Atrial Pace on PMT; Off; Passive
Rate Responsive PVARP/VREF	Off; Low; Medium; High
Ventricular Intrinsic Preference (VIP™)	Off; On (50-200)
Post-Therapy Pacing (Independently programmable from Bradycardia and ATP)	
Post-Shock Pacing Mode	Off; AAI; VVI; DDI; DDD
Post-Shock Base Rate (min^{-1})	30-100 in increments of 5
Post-Shock Pacing Duration (min)	Off; 0,5; 1; 2,5; 5; 7,5; or 10
Device Testing/Induction Methods	
DC Fibber™ Pulse Duration (sec)	0,5-5,0
Burst Fibber Cycle Length (ms)	20-100
Noninvasive Programmed Stimulation (NIPS)	2-25 stimuli with up to three extrastimuli
Patient Notifiers	
Programmable Notifiers (On; Off)	Device at ERI; Charge Time Limit Reached; Possible HV Circuit Damage; Atrial Lead Impedance Out of Range; Ventricular Lead Impedance Out of Range; High-Voltage Lead Impedance Out of Range; AT/AF Burden; V Rate During AT/AF; % V pacing; CorVue Congestion Trigger; SecureSense – lead noise detected, non-sustained lead noise detected, ST Episodes (Type I only)
Device Parameter Reset	On
Entry into Backup VVI Mode	On
Vibration Duration (sec)	2; 4; 6; 8; 10; 12; 14; 16
Number of Vibrations per Notification	2
Number of Notifications	1-16
Time Between Notifications (hours)	10; 22
Electrograms and Diagnostics	
Stored Electrograms	Up to 45 minutes including up to one minute programmable pre-trigger data per VT/VF diagnosis/detection electrograms; triggers include diagnosis; detection; therapy; atrial episode; PMT termination; PC shock delivery; noise reversion; magnet reversion; morphology template verification; lead noise detected, non-sustained lead noise detected, NSVT/NSVF
Therapy Summary	Diagram of therapies delivered
Episodes Summary	Directory listing of up to 60 episodes with access to more details including stored electrograms
Lifetime Diagnostics	History of bradycardia events and device-initiated charging
AT/AF Burden Trend	Trend data and counts
Ventricular HV Lead Impedance Trend	Multi-Vector Trend Data
Histograms	Event Histogram; AV Interval Histogram; Mode Switch Duration Histogram; Peak Filtered Rate Histogram; Atrial Heart Rate Histogram; Ventricular Heart Rate Histogram; AT/AF Burden; Exercise and Activity Trending; V Rates during AMS; DirectTrend™ reports up to 1 year
PMT Data	Information regarding PMT detections
Real-Time Measurements (RTM)	Pacing lead impedances; high-voltage lead impedances; and signal amplitudes
ST Monitoring	ST Histogram Data; Long-term ST Deviation Trend; ST Episode Log; ST Episode Details; 24-Hour ST & HR Trend; ST EGM Baseline & Snapshots prior to ST Episode, VT/VF, Interrogation (Snapshots and 24-hour trend at time of interrogation)
CorVue™ Congestion Monitoring	On; Off
CorVue Congestion Trigger	8-18 days

1. MRI Conditional Parameters: 1,5 Tesla, 2 W/Kg SAR
2. See MRI Procedure Information for approved MR Conditional Systems Device/Lead combinations and scan parameters

Customer Support: 46-8-474-4756

Brief Summary: Prior to using these devices, please review the Instructions for Use for a complete listing of indications, contraindications, warnings, precautions, potential adverse events and directions for use. Devices depicted may not be available in all countries. Check with your St. Jude Medical representative for product availability in your country.

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ST. JUDE MEDICAL

Durata™

Defibrillation Lead

MR

Product Highlights

- Allows patients to safely undergo an MRI scan when used in combination with an SJM MRI Ready device.[1,2]
- Optim™ insulation is a chemical co-polymer that offers superior handling and durability[3]
- Two innovative designs are intended to help prevent tissue ingrowth – flat-wire technology provides a low profile for the defibrillation coils, and silicone backfilling completely fills the shock coil space
- Redundant conductors serve as a backup system in the unlikely event of a conductor failure
- Symmetrically aligned cables within the lead body and centrally located coil provide for additional protection to the inner coil[4]
- The DF4 connector is designed to simplify implants by streamlining defibrillation connections into a single terminal pin and reducing the number of set screws

Ordering Information

Contents: Defibrillation lead

Model Number	Insulation	Fixation	Min. Introducer (F)	Shock Configuration	Sensing	Tip-to-Proximal Coil (cm)	Connector	Lengths (cm)
7120	Optim	Ext/Ret Helix	7	Dual-coil	True bipolar	17	DF1; IS-1	60; 65
7120Q	Optim	Ext/Ret Helix	7	Dual-coil	True bipolar	17	DF4	52; 58;*65*
7121	Optim	Ext/Ret Helix	7	Dual-coil	True bipolar	21	DF1; IS-1	60; 65; 75
7121Q	Optim	Ext/Ret Helix	7	Dual-coil	True bipolar	21	DF4	52; 58; 65
7122	Optim	Ext/Ret Helix	7	Single-coil	True bipolar	N/A	DF1; IS-1	60; 65; 75
7122Q	Optim	Ext/Ret Helix	7	Single-coil	True bipolar	N/A	DF4	52; 58;*65*
7170	Optim	Tines	7	Dual-coil	True bipolar	17	DF1; IS-1	60; 65; 75
7170Q	Optim	Tines	7	Dual-coil	True bipolar	17	DF4	52; 58; 65
7171	Optim	Tines	7	Dual-coil	True bipolar	21	DF1; IS-1	60; 65; 75
7171Q	Optim	Tines	7	Dual-coil	True bipolar	21	DF4	52; 58; 65
7172Q	Optim	Tines	7	Single-coil	True bipolar	N/A	DF4	52; 58; 65

*Indicates models and lead lengths that are MRI Conditional[1,2]

Indications for Use: The Durata™ transvenous leads are 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. A transvenous lead system may offer the patient the benefit of avoiding a thoracotomy for lead implantation. If the initial lead configuration is not effective, repositioning of the lead or other lead configurations should be attempted. In some patients, a nonthoracotomy lead configuration may not provide reliable conversion of arrhythmias, and the use of subcutaneous or epicardial patch defibrillation leads should be considered.

Contraindications: Contraindications for use of the Durata leads with an implantable pulse generator include ventricular tachyarrhythmias resulting from transient or reversible factors such as drug toxicity, electrolyte imbalance, or acute myocardial infarction. Transvenous lead systems are contraindicated for patients with tricuspid valvular disease or a mechanical heart valve. Durata leads are contraindicated for patients for whom a single dose of 1.0 mg of dexamethasone sodium phosphate is contraindicated. The Durata leads are contraindicated for extra firm (red color knob) stylets. The lead is not designed, sold, or intended for use other than as indicated.

1. St. Jude Medical DF1 lead connectors conform to the international connector standard ISO 11318/Amd.
2. St. Jude Medical IS-1 lead connectors conform to the international connector standard ISO 5841.
3. St. Jude Medical DF4 lead connectors conform to the international connector standard ISO 27186: 2010 (E).

Potential Complications: Possible complications of the use of transvenous lead systems include, but are not limited to, supraventricular or ventricular arrhythmias, conduction disturbances, cardiac perforation, cardiac tamponade, loss of contractility, air embolism, heart wall rupture, myocarditis, post-operative heart failure, chronic mechanical stimulation of the heart, tricuspid valve dysfunction, lead fracture necessitating surgical removal, pneumothorax, hemothorax, infection, tissue necrosis and erosion of the skin. Specific events and effects are summarised below:

WARNING: Implanted cardiac leads are subjected to a hostile environment within the body due to constant, complex flexural and torsional forces, interactions with leads and/or the pulse generator, or other forces associated with cardiac contractions and patient physical activity, posture and anatomical influences Cardiac leads' functional lifetimes can be affected by these and other factors.

Refer to the defibrillator manual for additional complications and precautions specific to the pulse generator.

ST. JUDE MEDICAL

Durata™

Defibrillation Lead

Product Specifications

PHYSICAL SPECIFICATIONS

True Bipolar, Active-Fixation Defibrillation Leads

Models	7120	7120Q	7121	7121Q	7122	7122Q
Fixation	Ext/Ret Helix	Ext/Ret Helix	Ext/Ret Helix	Ext/Ret Helix	Ext/Ret Helix	Ext/Ret Helix
Shock Configuration	Dual-Coil	Dual-Coil	Dual-Coil	Dual-Coil	Single-Coil	Single-Coil
Sensing Configuration	True Bipolar	True Bipolar	True Bipolar	True Bipolar	True Bipolar	True Bipolar
Min. Size Introducer	7 F	7 F	7 F	7 F	7 F	7 F
Lengths (cm)	60; 65	52; 58; 65	60; 65; 75	52; 58; 65	60; 65; 75	52; 58; 65
Connector	DF1; IS-1	DF4	DF1; IS-1	DF4	DF1; IS-1	DF4
Body Diameter	6,8 F	6,8 F	6,8 F	6,8 F	6,8 F	6,8 F
Tip-to-Anode Spacing	11 mm	11 mm	11 mm	11 mm	11 mm	11 mm
Tip-to-Proximal Coil	17 cm	17 cm	21 cm	21 cm	N/A	N/A
Tip Electrode Area	6 mm^2	6 mm^2	6 mm^2	6 mm^2	6 mm^2	6 mm^2
Steroid Plug	Yes	Yes	Yes	Yes	Yes	Yes
Distal Shock Coil Area	367 mm^2	367 mm^2	367 mm^2	367 mm^2	367 mm^2	367 mm^2
Proximal Shock Coil Area	588 mm^2	588 mm^2	588 mm^2	588 mm^2	N/A	N/A
MRI Conditional	No	Yes, MRI-ready (lengths: 58 and 65 cm)	No	No	No	Yes, MRI-ready (lengths: 58 and 65 cm)

True Bipolar, Passive-Fixation Defibrillation Leads

Models	7170	7170Q	7171	7171Q	7172Q
Fixation	Tines	Tines	Tines	Tines	Tines
Shock Configuration	Dual-Coil	Dual-Coil	Dual-Coil	Dual-Coil	Single-Coil
Sensing Configuration	True Bipolar	True Bipolar	True Bipolar	True Bipolar	True Bipolar
Min. Size Introducer	7 F	7 F	7 F	7 F	7 F
Lengths (cm)	60; 65; 75	52; 58; 65	60; 65; 75	52; 58; 65	52; 58; 65
Connector	DF1; IS-1	DF4	DF1; IS-1	DF4	DF4
Body Diameter	6,8 F	6,8 F	6,8 F	6,8 F	6,8 F
Tip-to-Anode Spacing	11 mm	11 mm	11 mm	11 mm	11 mm
Tip-to-Proximal Coil	17 cm	17 cm	21 cm	21 cm	N/A
Tip Electrode Area	3.5 mm^2	3.5 mm^2	3.5 mm^2	3.5 mm^2	3.5 mm^2
Steroid Plug	Yes	Yes	Yes	Yes	Yes
Distal Shock Coil Area	367 mm^2	367 mm^2	367 mm^2	367 mm^2	367 mm^2
Proximal Shock Coil Area	588 mm^2	588 mm^2	588 mm^2	588 mm^2	N/A
MRI Conditional	No	No	No	No	No

1. MRI Conditional Parameters: 1,5 Tesla, 2 W/Kg SAR
2. See MRI Procedure Information for approved MR Conditional Systems Device/Lead combinations and scan parameters
3. Jenney C, Tan J, Karicherla A, Burke J, Helland J. A New Insulation Material for Cardiac Leads with Potential for Improved Performance, Heart Rhythm, 2, S318-S319 (2005).
4. St. Jude Medical Engineering Report: Tension and Cable Shortening Comparison. Report 60032635

Customer Support: 46-8-474-4756

Brief Summary: Prior to using these devices, please review the Instructions for Use for a complete listing of indications, contraindications, warnings, precautions, potential adverse events and directions for use. Devices depicted may not be available in all countries. Check with your St. Jude Medical representative for product availability in your country.

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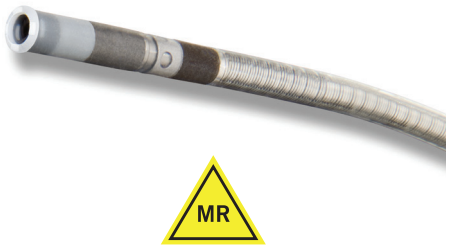
ST. JUDE MEDICAL

Tendril™ STS

Pacing Lead



Product Highlights - Pacing Lead

- The Tendril STS lead allows patients to undergo MRI scans when used in conjunction with a MRI Ready pacemaker from St. Jude Medical
  - Allows MRI scans (See Parameter Settings for scan exclusion zone)
  - Permits a maximum whole body averaged specific absorption rate (SAR) of 2 watts per kilogram (W/kg)
- Soft silicone tip offers more compliance and less tip pressure at the lead tip-endocardium interface
- Small diameter lead offers improved ease of venous passage, reduced risk of venous thrombosis or rib-clavicle crush and ability to accommodate additional leads more easily
- Optim™ lead insulation—a chemical co-polymer that blends the best features of polyurethane and silicone for improved handling and increased durability
- Titanium nitride (TiN) fractal coating on the tip and ring electrodes is designed to promote precise sensing and to provide improved contact with the myocardium
- Lubricious Fast-Pass™ coating facilitates lead insertion through the introducer and veins to ease implantation
- Fits through a 6 F introducer

Ordering Information - MRI-Ready Pacing System

Model Number	Description	Insulation	Fixation	Min. Introducer (F)	Connector	Length (cm)
2088TC	Tendril™ STS Pacing Lead	Optim™	Ext/Ret helix	6	IS-1 bipolar	46*; 52*; 58*; 65; 100

* Indicates lead lengths that are MRI conditional with a scan exclusion zone.

Model Number	Description	Dimensions (H x W x T, mm)	Weight (g)	Volume (cc)	Connector
PM1140	Endurity™ Core Pacemaker	41 x 50 x 6	19	9,7 (± 0,5)	IS-1
PM2140	Endurity Core Pacemaker	46 x 50 x 6	19	10,4 (± 0,5)	IS-1
PM1152	Endurity Core Pacemaker	41 x 50 x 6	19	9,7 (± 0,5)	IS-1
PM2152	Endurity Core Pacemaker	46 x 50 x 6	19	10,4 (± 0,5)	IS-1
PM1162	Endurity Pacemaker	41 x 50 x 6	19	9,7 (±0,5)	IS-1
PM2162	Endurity Pacemaker	46 x 50 x 6	19	10,4 (± 0,5)	IS-1
PM1172	Endurity MRI™ Pacemaker	41 x 50 x 6	19	9,7 (± 0,5)	IS-1
PM2172	Endurity MRI Pacemaker	46 x 50 x 6	19	10,4 (± 0,5)	IS-1
PM1272	Assurity MRI™ Pacemaker	47 x 50 x 6	20	10,4 (±0,5)	IS-1
PM2272	Assurity MRI Pacemaker	47 x 50 x 6	20	10,4 (±0,5)	IS-1

Indications: Tendril™ STS lead is designed for permanent sensing and pacing in either the right atrium or the right ventricle, in combination with a compatible device. Active leads such as the Tendril STS lead may be indicated for patients where permanent fixation of passive leads is suspected to be unstable.

In atrial applications, the use of screw-in leads such as Tendril STS lead may be indicated in the presence of an abnormal, surgically altered or excised atrial appendage.

Contraindications: Tendril STS lead is contraindicated: in the presence of tricuspid atresia, for patients with mechanical tricuspid valves, in patients who are expected to be hypersensitive to a single dose of one milligram of dexamethasone sodium phosphate.

Adverse Events: Potential complications associated with the use of Tendril STS lead are the same as with the use of other active fixation leads and include: cardiac tamponade, diaphragmatic stimulation, embolism, excessive bleeding, induced ventricular ectopy, infection, loss of pacing and/or sensing due to dislodgment or mechanical malfunction of the pacing lead, phrenic nerve stimulation, thrombosis. Complications reported with direct subclavian venipuncture include pneumothorax, hemothorax, laceration of the subclavian artery, arteriovenous fistula, neural damage, thoracic duct injury, cannulation of other vessels, massive hemorrhage and, rarely, death.

Refer to the User's Manual for detailed indications, contraindications, warnings, precautions and potential adverse events.

ST. JUDE MEDICAL

Tendril™ STS

Pacing Lead

Product Specifications - Pacing Leads

PHYSICAL SPECIFICATIONS

Model	2088TC
Minimum Introducer Size	6 F
Type of Lead	Active-fixation, bipolar, steroid-eluting, endocardial, pacing lead
Lead Connector	IS-1 bipolar
Lead Lengths	46; 52; 58; 65; 100 cm
Fixation Mechanism	Extendable/Retractable helix
Typical Number of Rotations for Helix Extension	6-11 (straight stylet)
Lead Body Diameter	1,9 mm (max)
Tip-to-Ring Spacing	10 mm
Lead Tip Electrode (Cathode)	Active titanium-nitride-coated Pt/Ir helix (2,0 mm extension)
Tip Electrode Surface Area	6,9 mm^2
Ring Electrode (Anode)	Titanium-nitride-coated Pt/Ir
Ring Electrode Surface Area	16 mm^2
Mapping	Capable with titanium-nitride-coated Pt/Ir helix
Steroid	< 1 mg dexamethasone sodium phosphate
Inner Conductor/Outer Conductor	MP35N™* coil
Inner Insulation	Silicone rubber
Outer Insulation	Optim™ lead insulation
Lead Body Coating	Fast-Pass™ coating

In Pack

Straight stylets	1 x-soft in lead; 1 x-soft; 1 soft
J-curved stylets	2 soft
Helix extension/retraction clip-on tools	2 clip-on tools

Accessory Kits

Available Separately	Model Number	Compatible Lengths	Description
Stylet Kit	DSO6002 with appropriate length designation	46; 52; 58; 65; 100 cm	1 fixation tool; 1 clip-on tool; 1 J-shaped soft; 1 x-soft; 1 soft; 1 firm; 1 x-firm
	DSO6003 with appropriate length designation	46; 52; 58; 65; 100 cm	1 clip-on tool; 1 J-shaped soft; 1 x-soft; 1 soft; 1 firm; 1 x-firm
Locator™ Plus Deflectable Stylet	1281 with appropriate length designation	46; 52; 58; 65 cm	Disposable implant tool to facilitate precise lead positioning and manipulation with one hand
	1292 with appropriate length designation	46; 52; 58; 65 cm	

MRI Conditional Parameters

Magnet strength: 1.5 Tesla
SAR: ≤ 2 W/kg
Scan region: Isocenter must be inferior to L4 or 10 cm superior to C1

*MP35N is a trademark of SPS Technologies, Inc.

Customer Support: 46-8-474-4756

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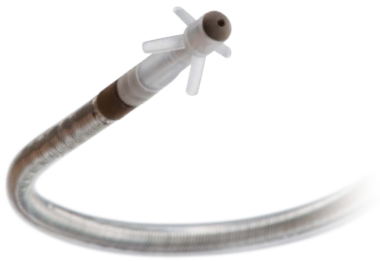
ST. JUDE MEDICAL™

IsoFlex™ Optim™

Pacing Lead



Product Highlights - Pacing Leads

- The IsoFlex Optim lead allows patients to undergo an MRI scan when used in conjunction with a MRI Ready pacemaker from St. Jude Medical*
- Straight or J-shaped lead is available in multiple lengths to accommodate varying needs and patient anatomies
- Optim™ lead insulation—a chemical co-polymer that blends the best features of polyurethane and silicone—provides improved handling and increased durability
- Symmetrical lead body with coaxial multifilar coils for reliability
- Steroid-eluting tip for reduced inflammation at the lead-tissue interface and low pacing thresholds
- Small tip surface area for higher impedance levels and optimal device longevity
- Titanium nitride (TiN) coated tip and ring electrode for low polarization values and compatibility with the AutoCapture™ pacing system algorithm
- Radiopaque suture sleeve for visibility under fluoroscopy to simplify invasive procedures

*See MRI Conditional Parameters

Ordering Information - MRI-Ready Pacing System

Model Number	Description	Insulation	Fixation	Min. Introducer (F)	Connector	Length (cm)
1944 (J-Shaped)	IsoFlex™ Optim™ Pacing Lead	Optim™	Tines	7	IS-1 bipolar	46*; 52*
1948 (Straight)	IsoFlex Optim Pacing Lead	Optim	Tines	7	IS-1 bipolar	46; 52*; 58*

* Indicates lead lengths that are MRI conditional with a scan exclusion zone.

Model Number	Description	Dimensions (H x W x T, mm)	Weight (g)	Volume (cc)	Connector
PM1140	Endurity™ Core Pacemaker	41 x 50 x 6	19	9,7 (± 0,5)	IS-1
PM2140	Endurity Core Pacemaker	46 x 50 x 6	19	10,4 (± 0,5)	IS-1
PM1152	Endurity Core Pacemaker	41 x 50 x 6	19	9,7 (± 0,5)	IS-1
PM2152	Endurity Core Pacemaker	46 x 50 x 6	19	10,4 (± 0,5)	IS-1
PM1162	Endurity Pacemaker	41 x 50 x 6	19	9,7 (± 0,5)	IS-1
PM2162	Endurity Pacemaker	46 x 50 x 6	19	10,4 (± 0,5)	IS-1
PM1172	Endurity MRI™ Pacemaker	41 x 50 x 6	19	9,7 (± 0,5)	IS-1
PM2172	Endurity MRI Pacemaker	46 x 50 x 6	19	10,4 (± 0,5)	IS-1
PM1272	Assurity MRI™ Pacemaker	47 x 50 x 6	20	10,4 (± 0,5)	IS-1
PM2272	Assurity MRI Pacemaker	47 x 50 x 6	20	10,4 (± 0,5)	IS-1

Indications: IsoFlex™ Optim™ Model 1948 leads are 7F, steroid eluting (DXA), passive fixation (tined) straight body leads designed for use with compatible pulse generators to provide permanent pacing and sensing in either the right atrium or right ventricle. IsoFlex Optim Model 1944 leads are 7F, steroid eluting (DXA), passive fixation (tined) J-shaped leads designed for use with compatible pulse generators to provide permanent pacing and sensing in the right atrium.

Contraindications: The use of IsoFlex™ Optim™ leads is contraindicated in patients who are expected to be hypersensitive to a single dose of 1.0 milligram of dexamethasone sodium phosphate

The use of the Model 1948 is also contraindicated in the presence of tricuspid atresia and in patients with mechanical tricuspid valves.

Adverse Events: Potential complications associated with the use of the IsoFlex Optim family of leads are the same as with the use of any lead and include:

Cardiac perforation, Cardiac tamponade, damage to vessels, embolism, excessive bleeding, induced atrial or ventricular arrhythmias, infection, loss of pacing and or sensing due to dislodgment or mechanical malfunction of the lead, phrenic nerve stimulation, tissue necrosis, thrombosis, valve damage. Phrenic nerve or direct diaphragmatic stimulation may also be a result of lead position. Complications reported with direct subclavian venipuncture include pneumothorax, hemothorax, laceration of the subclavian artery, arteriovenous fistula, neural damage, thoracic duct injury, cannulation of other vessels, massive hemorrhage and, rarely, death.

IsoFlex™ Optim™

Pacing Lead

Product Specifications - Pacing Leads

PHYSICAL SPECIFICATIONS

Model	1944	1948
Minimum Introducer Size	7 F	7 F
Type of Lead	bipolar, passive fixation lead	bipolar, passive fixation lead
Lead Connector	IS-1 bipolar	IS-1 bipolar
Lead Lengths	46; 52 cm	46; 52; 58 cm
Fixation Mechanism	tines	tines
Tip-to-ring Spacing	10 mm	10 mm
Lead Tip Electrode (Cathode)	Semi spherical shape, steroid coating	Semi spherical shape, steroid coating
Tip Electrode Surface Area	3,5 mm^2	
Ring Electrode (Anode)	Platinum-iridium, coated with titanium nitride	3,5 mm^2
Ring Electrode Surface Area	16 mm^2	16 mm^2
Steroid	< 1 mg dexamethasone sodium phosphate in silicone matrix	< 1 mg dexamethasone sodium phosphate in silicone matrix
Inner Insulation	Silicone rubber	Silicone rubber
Outer Insulation	Optim™ lead insulation	Optim™ lead insulation
Lead Body Coating	Fast-Pass™ coating	Fast-Pass™ coating

In Pack

Straight Stylets	1 soft in lead; 1 soft; 2 firm

Accessory Kits

Available Separately	Model Number	Compatible Lengths	Description
Stylet Kit	4064	46; 52, 58 cm	X-Firm Stylets (2)
Stylet Kit	4062	46; 52, 58 cm	Firm Stylets (2)
Stylet Kit	4060	46; 52, 58 cm	Soft Stylets (2)

Limited Lifetime Warranty

Terms and conditions apply; refer to the warranty for details.

MRI Conditional Parameters

Magnet strength: 1.5 Tesla
SAR: ≤ 2 W/kg
Scan region: Isocenter must be inferior to L4 or superior to C1

Customer Support: 46-8-474-4756

Brief Summary: Prior to using these devices, please review the Instructions for Use for a complete listing of indications, contraindications, warnings, precautions, potential adverse events and directions for use. Devices depicted may not be available in all countries. Check with your St. Jude Medical representative for product availability in your country.

SJM-IFX-1214-0002 I This document is approved for International use only.

ST. JUDE MEDICAL

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Product Service

EC Certificate

EC Design-Examination Certificate

Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD), Annex 2 (4)
(Other devices than custom made or intended for clinical investigation)

No. I7 17 07 14607 216

Manufacturer:

St. Jude Medical
Cardiac Rhythm Management
Division
15900 Valley View Court
Sylmar, CA 91342
USA

EC-Representative:

St. Jude Medical
Coordination Center BVBA
The Corporate Village
Da Vincilaan 11 Box F1
1935 Zaventem
BELGIUM

Product: **Implantable Cardioverter / Defibrillators**

The Certification Body of TÜV SÜD Product Service GmbH declares that a design examination has been carried out on the respective devices in accordance with AIMDD Annex 2 (4). This design of the devices conforms to the requirements of this Directive. For marketing of these devices an additional Annex 2 certificate is mandatory. See also notes overleaf.

Report no.: 713106728

Valid from: 2017-09-26
Valid until: 2022-09-25

Date, 2017-09-25

Stefan Preiß

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

A1 / 07.17

TÜV SÜD Product Service GmbH · Zertifizierstelle · Ridlerstraße 65 · 80339 München · Germany

TÜV®

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Product Service

EC Certificate
EC Design-Examination Certificate

Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD), Annex 2 (4)
(Other devices than custom made or intended for clinical investigation)

No. I7 17 07 14607 216

Model(s): **see attachment**

Parameters: ./.

Facility(ies):

St. Jude Medical Cardiac Rhythm Management Division
15900 Valley View Court, Sylmar, CA 91342, USA

St. Jude Medical Puerto Rico LLC
Lot A Interior - #2 Rd Km. 67.5, Santana Industrial Park, Arecibo
PR 00612, USA

St. Jude Medical Operations (M) Sdn.Bhd.
Plot 102, Lebuhraya Kampung Jawa, Bayan Lepas Industrial
Zone, 11900 Penang, MALAYSIA

St. Jude Medical Coordination Center BVBA
European Distribution Center, BruCargo 831, 1931 BruCargo,
BELGIUM

Design Facility(ies):

St. Jude Medical Cardiac Rhythm Management Division
15900 Valley View Court, Sylmar, CA 91342, USA

Product Service

Attachment for Certificate no I7 17 07 14607 216
dated 2017-09-25

Product: **Implantable Cardioverter / Defibrillators**

Test Report No.: 71362982

Model:	**Model No:**
Fortify™ VR	CD1233-40, CD1233-40Q
Fortify™ DR	CD2233-40, CD2233-40Q
Unify™	CD3235-40, CD3235-40Q

Test Report No.: 71376924

Unify Quadra™	CD3251-40, CD3251-40Q

Test Report No.: 713000600 / 713000540

Ellipse™ VR	CD1275-36, CD1275-36Q,
Ellipse™ DR	CD2275-36, CD2275-36Q,

Test Report No.: 713015987_1

Quadra Assura™	CD3367-40, CD3367-40C
Quadra Assura MP™	CD3371-40, CD3371-40C
Unify Assura™	CD3361-40, CD3361-40C CD3361-40Q, CD3361-40QC
Fortify Assura™ DR	CD2359-40, CD2359-40C
Fortify Assura™ VR	CD1359-40, CD1359-40C
Ellipse™ DR	CD2377-36, CD2377-36C
Ellipse™ VR	CD1377-36, CD1377-36C

TÜV SÜD Product Service GmbH · Zertifizierstelle · Ridlerstraße 65 · 80339 München · Germany

TÜV®

Product Service

Attachment for Certificate no I7 17 07 14607 216
dated 2017-09-25

Test Report No.: 713015987_1 / 713057341

Model:	**Model No:**	**Variants:**
Ellipse™ VR	CD1377-36Q, CD1377-36QC	MR Conditional
Ellipse™ DR	CD2377-36Q, CD2377-36QC	MR Conditional

Test Report No.: 713015987_1 / 713060615

Fortify Assura™ VR	CD1359-40Q, CD1359-40QC	MR Conditional
Fortify Assura™ DR	CD2359-40Q, CD2359-40QC	MR Conditional

Test Report No.: 713015987_1 / 713068024

Quadra Assura™	CD3367-40Q, CD3367-40QC	MR Conditional
Quadra Assura MP™	CD3371-40Q, CD3371-40QC	MR Conditional

Munich, MHS-CRT, 2017-09-25

Stefan Preiß
Certification Medical Technology

TÜV SÜD Product Service GmbH · Zertifizierstelle · Ridlerstraße 65 · 80339 München · Germany

SJM Declaration of Conformity
Implantable Cardioverter/Defibrillators

St. Jude Medical (SJM) hereby declares that the following SJM facilities and products conform to the applicable provisions of Annex 2 of the European Union's Active Implantable Medical Devices Directive, AIMDD, 90/385/EEC. All supporting documentation is retained under the premises of SJM. We declare no application has been lodged with any other notified body for the same products. This declaration is issued under the sole responsibility of the manufacturer. This declaration supersedes any declaration issued previously for the same product(s).

Manufacturer Address:	*St. Jude Medical Cardiac Rhythm Management Division* *15900 Valley View Court* *Sylmar, CA 91342, USA*
European Representative:	St. Jude Medical Coordination Center BVBA The Corporate Village Da Vincilaan 11 Box F1 1935 Zaventem, Belgium
Product Type:	Implantable Cardioverter/Defibrillators
Product Name(s):	See Attachment
Model Number(s):	*See Attachment*
Classification:	AIMD
GMDN Code(s):	*See Attachment*
Original CE Mark Date:	*See Attachment*
Certificate No. and expiration date:	EC Certification No: I7 17 07 14607 216 Expiration Date: 2022-09-25 FQA Certificate No: I1 16 12 14607 211 Expiration Date: 2021-07-25 ISO13485 Certificate No: Q1N 17 09 14607 217 Expiration Date: 2020-10-31

Signature:

Kathy Berg
Manager Regulatory Affairs

07Nov2017
Issue Date

SJM Declaration of Conformity
Implantable Cardioverter/Defibrillators

Applicable Quality System Standards:	Fulfills the requirements of Annex 2 of the European Union's Active Medical Devices Directive, AIMDD, 90/385/EEC/corresponding national legislation Fulfills applicable requirements including CE marking and the Essential Requirements of AIMDD, 90/385/EEC/corresponding national legislation
Notified Body:	TÜV SÜD Product Service GmbH Zertifizierstelle Ridlerstraße 65, 80339, Münich, Germany
Notified Body Number:	0123
Manufacturing Facilities:	*St. Jude Medical Cardiac Rhythm Management Division 15900 Valley View Court Sylmar, CA 91342, USA* *St. Jude Medical Puerto Rico LLC Lot A Interior - #2 Rd Km. 67.5, Santana Industrial Park, Arecibo PR 00162, USA* *St. Jude Medical Operations (M) Sdn.Bhd Plot 102, Lebuhraya Kampung Jawa, Bayan Lepas Industrial Zone, 11900 Penang, MALAYSIA*

Signature:

Kathy Berg
Manager Regulatory Affairs

07 Nov 2017
Issue Date

SJM Declaration of Conformity
Implantable Cardioverter/Defibrillators
ATTACHMENT TO DECLARATION OF CONFORMITY

The following product(s) is/are approved under EC-Certificate number **I7 17 07 14607 216.**

Product Name	Model No.	GMDN Code	First Date of CE Marking
Fortify™ VR	CD1233-40, CD1233-40Q	35852	2010-1-29
Fortify™ DR	CD2233-40, CD2233-40Q	37265	2010-1-29
Unify™	CD3235-40, CD3235-40Q	47270	2010-1-29
Unify Quadra™	CD3251-40, CD3251-40Q	47270	2011-3-15
Ellipse™ VR	CD1275-36, CD1275-36Q	35852	2012-2-3
Ellipse™ DR	CD2275-36, CD2275-36Q	37265	2012-2-3
Quadra Assura™ IS-1/DF-1	CD3367-40, CD3367-40C	47270	2012-12-18
Quadra Assura MP™ IS-1/DF-1	CD3371-40, CD3371-40C	47270	2012-12-18
Unify Assura™ IS-1/DF-1	CD3361-40, CD3361-40C CD3361-40Q, CD3361-40QC	47270	2012-12-18
Fortify Assura™ DR IS-1/DF-1	CD2359-40, CD2359-40C	37265	2012-12-18
Fortify Assura™ VR IS-1/DF-1	CD1359-40, CD1359-40C	35852	2012-12-18
Ellipse™ DR IS-1/DF-1	CD2377-36, CD2377-36C	37265	2012-12-18
Ellipse™ VR IS-1/DF-1	CD1377-36, CD1377-36C	35852	2012-12-18
Ellipse™ VR DF-4	CD1377-36Q, CD1377-36QC MR Conditional	35852	2015-05-11
Ellipse™ DR DF-4	CD2377-36Q, CD2377-36QC MR Conditional	37265	2015-05-11
Fortify Assura™ VR DF-4	CD1359-40Q, CD1359-40QC MR Conditional	35852	2015-7-14
Fortify Assura™ DR DF-4	CD2359-40Q, CD2359-40QC MR Conditional	37265	2015-7-14
Quadra Assura™ DF4	CD3367-40Q, CD3367-40QC MR Conditional	47270	2015-10-13
Quadra Assura MP™ DF-4	CD3371-40Q, CD3371-40QC MR Conditional	47270	2015-10-13

Signature:

Kathy Berg

Kathy Berg
Manager Regulatory Affairs

07Nov2017
Issue Date