Microny™ II SR+

Single Chamber Pacemaker

Pacemakers

Product Highlights

- The Beat-by-Beat™ AutoCapture™ Pacing System is a capture verification algorithm that allows the pacemaker to deliver an output pulse 0.3 V above the measured capture threshold, thus minimizing battery drain.
- Automatic P/R Sensitivity Test suggests a programmed value for the P/R sensitivity.
- Accelerometer sensor provides reliable rate response with only one programmable parameter (Slope).
- Lead Impedance Monitoring on a beat-by-beat basis.
- Comprehensive diagnostics and management tools, including Measured Data, Rate Prediction Model, Stimulation Threshold vs. Time, Sensor Indicated Rate vs. Time and others.

Ordering Information

Contents: Cardiac pulse generator

Model Number	Dimensions (H x W x T, mm)	Weight (g)	Volume (cc)	Connector
2525T	33 x 33 x 6	12.8	5.9	IS-1 bipolar

Indications: The pulse generators are indicated for: Accepted Patient Conditions warranting chronic cardiac pacing, which include: sick sinus syndrome, chronic, symptomatic second- and third-degree AV block, recurrent Adams-Stokes syndrome, symptomatic bilateral bundle branch block when tachyarrhythmia and other causes have been ruled out.

Atrial Pacing in patients with sinus node dysfunction and normal AV and intraventricular conduction systems. Ventricular Pacing in patients with significant bradycardia and: normal sinus rhythm with only rare episodes of A-V block or sinus arrest requiring short periods of pacing support, chronic atrial fibrillation, severe physical disability.

Rate-Modulated Pacing in patients who would benefit from increased pacing rates concurrent with physical activity.

Contraindications: The pulse generators are contraindicated for: single-Chamber Ventricular Demand Pacing in patients who have demonstrated pacemaker syndrome, have retrograde VA conduction, or who suffer a drop in arterial blood pressure with the onset of ventricular pacing, single-Chamber Atrial Pacing in patients who have demonstrated compromise of AV conduction, rate-Modulated Pacing in patients who experience angina or other symptoms of myocardial dysfunction at higher sensor-driven rates, unipolar pacing in patients with an implanted cardioverter-defibrillator (ICD) since it may inhibit or trigger ICD therapy. The pulse generators are programmed to unipolar pacing and may be inappropriate for patients with an ICD.

Potential Adverse Events: Adverse events associated with the use of any pacing system include: air embolism, bleeding/hematoma, body rejection phenomena, cardiac tamponade or perforation, formation of fibrotic tissue, local tissue reaction, Inability to interrogate or program due to programmer or device malfunction, infection/erosion, interruption of desired pulse generator function due to electrical interference, either electromyogenic or electromagnetic, lead malfunction due to conductor fracture or insulation degradation, loss of capture or sensing due to lead dislodgment or reaction at the electrode/tissue interface, loss of desired pacing and/or sensing due to lead displacement, body reaction at electrode interface or lead malfunction (fracture or damage to insulation), loss of normal device function due to battery failure or component malfunction, pacemaker migration, pocket erosion or hematoma, pectoral muscle or diaphragmatic stimulation, phrenic nerve stimulation, pneumothorax/hemothorax.

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

Microny™ II SR+

Single Chamber Pacemaker

Physical Specifications	
Model	**2525T**
Dimensions (mm)	33 x 33 x 6
Weight (g)	12.8
Volume (cc)	5.9
Connector	IS-1 Bipolar
Battery Data	Lithium-iodine cell, 2.80 V/0.35 Ah

Parameter	Settings
Rate/Timing	
Mode	AOO(R); AAI(R); AAT(R); VOO(R); VVI1(R); VVT(R)
Basic Rate (ppm)	45 - 160 in steps of 5; 60[1]
Hysteresis Rate (ppm)	0, 10, 20, 30 below the basic or sensor-indicated rate; Off[1]
Refractory Period (ms)	250, 300[1], 350, 400, 450, 500, 550
Output/Sensing	
Pulse Amplitude (V)	Auto[2] 0.3 - 4.5 in steps of 0.3; 2.4[1]
Pulse Width (ms)	0.03; 0.06; 0.09; 0.12; 0.15; 0.18; 0.21; 0.24; 0.31[1]; 0.37; 0.43; 0.49; 0.58; 0.70; 0.82; 1.0
P/R Sensitivity (mV)	0.5; 0.8; 1.2; 2.0; 3.0[1]; 5.0; 7.5; 12
ER Sensitivity (mV)	1.6; 2.5; 4.0[1]; 6.0; 10.0; 15.0; 24.0
Pulse Polarity Configuration	Unipolar
Sense Polarity Configuration	Bipolar
Rate-Modulated Parameters	
VARIO	On, Off[1]
Ventricular AutoCapture™ Pacing System	On; Off[1]
Sensor	On; Off; Passive
Maximum Sensor Rate (ppm)[3]	90 - 160 in steps of 10; 130[1]
Slope[3]	1 - 16 in steps of 1; 10[1]
Reaction Time[3]	Very Fast; Fast; Medium[1]; Slow; Very Slow
Recovery Time[3]	Very Fast; Fast; Medium[1]; Slow; Very Slow
Fast Response[3]	On, Off[1]

1. Standard/Nominal settings.
2. Only with AutoCapture ON.
3. Inactive. Activate by programming the sensor ON or PASSIVE.

Customer Support: 46-8-474-4147

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.

Integer™

Greatbatch™ Medical MyoPore® Sutureless Myocardial Pacing Lead

The MyoPore sutureless myocardial pacing lead is a permanent, sutureless, epicardial bipolar lead and available in lengths from **25 cm to 54 cm**.

Our epicardial lead technology has been on the market for **more than 25 years**, with reliable performance for the **50,000+** units sold worldwide.

DESIGN FEATURES

- Low profile construction for minimal electrode head size
- Quadrifilar inner conductor for added safety and durability
- Full 3.5 mm electrode penetration for reliable fixation, pacing and sensing
- Quadrichannel anode electrode provides increased surface area for enhanced sensing

MyoPore® Sutureless Bipolar			
Model Number	511210	511211	511212
Length	25 cm	35 cm	54 cm
Connector Type	IS-1Bi	IS-1Bi	IS-1Bi
Cathode Resistance	20 Ohms	27 Ohms	41 Ohms
Anode Resistance	38 Ohms	46 Ohms	75 Ohms
Cathode Surface Area	10 mm²	10 mm²	10 mm²
Anode Surface Area	62 mm²	62 mm²	62 mm²
Insulation	Silicone Rubber (Medical Grade)	Silicone Rubber (Medical Grade)	Silicone Rubber (Medical Grade)

The Myopore Bipolar Sutureless Myocardial Pacing Lead is indicated for use when ventricular epicardial attachment is required or when a transvenous lead cannot provide effective pacing. This type of lead is useful in situations where it is required that the potential for lead dislodgement be diminished or that pacing and/or sensing will be established subsequent to open heart surgery.

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Greatbatch™ Medical
An Integer™ brand

1002848 Rev B

Quadra Assura™

Cardiac Resynchronisation Therapy Defibrillator (CRT-D)

Merlin@home™ Transmitter Compatible

Product Highlights

- The Quadra Assura CRT-D and Quartet™ quadripolar LV pacing lead feature four pacing electrodes and 10 pacing vectors to provide more options and greater control to minimise implant complications such as diaphragmatic stimulation and high pacing thresholds
- VectSelect Quartet™ multivector testing feature offers a streamlined workflow to identify, test and program the patient's pacing vector
- DynamicTx™ Over-Current Detection Algorithm automatically changes shock configurations to ensure delivery of high voltage therapy when high current is detected
- Parylene coating for improved abrasion resistance
- 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
- 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
- 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
- Unique 40 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
- Vibratory patient notifier enables patients with hearing problems to be alerted to a low battery, lead-related complications and more
- 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
- QuickOpt™ timing cycle optimisation provides quick and effective optimisation at the push of a button

Ordering Information

Contents: Cardiac pulse generator

Model Number	Dimensions (H x W x T, mm)	Weight (g)	Volume (cc)	Connector
CD3367-40C	83 x 41 x 14	83	40	DF1, IS4, IS-1
CD3367-40QC	75 x 41 x 14	80	38	DF4, IS4, IS-1

Indications: The devices are intended to provide ventricular antitachycardia pacing and ventricular defibrillation for automated treatment of life-threatening ventricular arrhythmias. Cardiac Resynchronisation Therapy Defibrillators (CRT-Ds) are also intended to resynchronise the right and left ventricles in patients with congestive heart failure.

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

Quadra Assura™

Cardiac Resynchronisation Therapy Defibrillator (CRT-D)

Product Specifications

PHYSICAL SPECIFICATIONS

Models	CD3367-40C	CD3367-40QC
Telemetry	RF	RF
Delivered/Stored Energy (J)	40/45	40/45
Volume (cc)	40	38
Weight (g)	83	80
Size (mm)	83 x 41 x 14	75 x 41 x 14
Defibrillation Lead Connections	DF1	DF4-LLHH
LV Lead Connections	IS4-LLLL	IS4-LLLL
Sense/Pace Lead Connections	IS-1	IS-1
High-Voltage Can	Electrically active titanium can	Electrically active titanium can
Coating	Parylene	Parylene

PARAMETER	SETTINGS
Biventricular Pacing	
VectSelect Quartet™ LV	Distal Tip 1 - Mid 2, Distal Tip 1 - Proximal 4, Distal Tip 1 - RV Coil; Pulse Configuration Mid 2 - Proximal 4; Mid 2 - RV Coil; Mid 3 - Mid 2; Mid 3 - Proximal 4; Mid 3 - RV Coil; Proximal 4 - Mid 2; Proximal 4 - RV Coil
V. Triggering	On; Off
QuickOpt™ Timing Cycle Optimisation	Sensed/paced AV delay, interventricular pace delay
V-V Timing	Simultaneous*; RV First; LV First
Interventricular Pace Delay (ms)	RV First 10-80 / LV First 15-80 in increments of 5
Ventricular Sensing	RV only (not programmable)
Ventricular Pacing Chamber	RV only; biventricular
Negative AV Hysteresis/Search (ms)	Off; -10 to -120
Shortest AV Delay (ms)	25-120
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
Sense Filter	(Post-Sensed; Atrial) 50; 62,5; 75; 100%; (Post-Paced; Atrial) 0,2-3,0 mV; Threshold Start (Post-Sensed; Ventricular) 50; 62,5; 75; 100%; (Post-Paced; Ventricular) Auto; 0,2-3,0 mV
Decay Delay	(Post-Sensed/Post-Paced; 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/Stimuli	1-15 with 2-20 Stimuli
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); DDT(R); DDI(R); VVT(R); VVI(R); AAI(R)
Temporary Modes	Off; DDD; DDT; DDI; VVT; VVI; AAI; AAT; DOO; VOO; AOO
Rate-Adaptive Sensor	On; Off; Passive
Programmable Rate and Delay Parameters	Off; Base Rate (min^{-1}); Rest Rate (min^{-1}); Maximum Tracking Rate (min^{-1}); Maximum Sensor Rate (min^{-1}); Paced AV Delay (ms); Sensed AV Delay (ms); Rate Responsive AV Delay; Hysteresis Rate (min^{-1}); Rate Hysteresis with Search
BiVCap™ Confirm; LVCap™ Confirm; RVCap™ Confirm	Setup; On; Monitor; Off
ACap™ Confirm	Setup; On; Monitor; Off
QuickOpt™ Timing Cycle Optimisation	Interventricular Pace Delay
Auto Mode Switch (AMS)	Off; DDI(R); DDT(R); VVI(R); VVT(R)
Atrial Tachycardia Detection Rate (min^{-1})	110-300
AMS Base Rate (min^{-1})	40; 45; ... 135
Auto PMT Detection/Termination	Atrial Pace; 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; or 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 3 extrastimuli
Patient Notifiers	
Programmable Notifiers (On; Off)	Device at ERI; Charge Time Limit Reached; Possible HV Circuit Damage; Atrial Lead Impedance Out of Range; RV Lead Impedance Out of Range; LV Lead Impedance Out of Range; High-Voltage Lead Impedance Out of Range; AT/AF Burden; V Rate During AT/AF; AT/AF Episode Duration; % V Pacing; CorVue™ Congestion Trigger, SecureSense — lead noise detected, non-sustained lead noise detected
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 1 minute programmable pre-trigger data per VT/VF diagnosis; detection; electrograms; triggers include diagnosis; 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
CorVue™ Congestion Monitoring	On; Off
CorVue Congestion Trigger	8-18 days

* LV first with 10 ms interventricular delay

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.

Item GMCRM1074EN

GMCRM1074EN

ST. JUDE MEDICAL™

Quadra Assura MP™

Cardiac Resynchronisation Therapy Defibrillator (CRT-D)

Merlin@home™ Transmitter Compatible

Product Highlights

- MultiPoint™ pacing delivers multiple LV pacing pulses per cardiac cycle and is designed to improve hemodynamic and clinical response
- The Quadra Assura MP CRT-D and Quartet™ quadripolar LV pacing lead feature four pacing electrodes and 10 pacing vectors to provide more options and greater control to minimise implant complications such as diaphragmatic stimulation and high pacing thresholds
- VectSelect Quartet™ multivector testing feature offers a streamlined workflow to identify, test and program the patient's pacing vector
- 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
- 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
- Low Frequency Attenuation filter designed to enhance sensing performance and may reduce the possibility of oversensing T-waves
- Sense*Ability*™ feature provides the 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
- Unique 40 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
- Vibratory patient notifier enables patients with hearing problems to be alerted to a low battery, lead-related complications and more
- 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
- QuickOpt™ timing cycle optimisation provides quick and effective optimisation at the push of a button

Ordering Information

Contents: Cardiac pulse generator

Model Number	Dimensions (H x W x T, mm)	Weight (g)	Volume (cc)	Connector
CD3371-40C	83 x 41 x 14	83	40	DF1, IS4, IS-1
CD3371-40QC	75 x 41 x 14	80	38	DF4, IS4, IS-1

Indications: The devices are intended to provide ventricular antitachycardia pacing and ventricular defibrillation for automated treatment of life-threatening ventricular arrhythmias. Cardiac Resynchronisation Therapy Defibrillators (CRT-Ds) are also intended to resynchronise the right and left ventricles in patients with congestive heart failure.

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

Quadra Assura MP™

Cardiac Resynchronisation Therapy Defibrillator (CRT-D)

Product Specifications

PHYSICAL SPECIFICATIONS		
Models	**CD3371-40C**	**CD3371-40QC**
Telemetry	RF	RF
Delivered/Stored Energy (J)	40/45	40/45
Volume (cc)	40	38
Weight (g)	83	80
Size (mm)	83 x 41 x 14	75 x 41 x 14
Defibrillation Lead Connections	DF1	DF4-LLHH
LV Lead Connections	IS4-LLLL	IS4-LLLL
Sense/Pace Lead Connections	IS-1	IS-1
High-Voltage Can	Electrically active titanium can	Electrically active titanium can
Coating	Parylene	Parylene

PARAMETER	SETTINGS
Biventricular Pacing	
VectSelect Quartet™	Distal Tip 1 - Mid 2, Distal Tip 1 - Proximal 4, Distal Tip 1 - RV Coil; Pulse Configuration Mid 2 - Proximal 4; Mid 2 - RV Coil; Mid 3 - Mid 2; Mid 3 -Proximal 4; Mid 3 - RV Coil; Proximal 4 - Mid 2; Proximal 4 - RV Coil
MultiPoint Pacing	LV1; LV2
Delay MultiPoint Pacing	Delay 1: 5; 10; …80 ms Delay 2: 5; 10; … 50 ms
V. Triggering	On; Off
QuickOpt™ Timing	
Cycle Optimisation	Sensed/paced AV delay, interventricular pace delay
V-V Timing	Simultaneous*; RV First; LV First
Interventricular Pace Delay (ms)	RV First 10-80 / LV First 15-80 in increments of 5
Ventricular Sensing	RV only (not programmable)
Ventricular Pacing Chamber	RV only; biventricular
Negative AV Hysteresis/Search (ms)	Off; -10 to -120
Shortest AV Delay (ms)	25-120
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/Stimuli	1-15 with 2-20 Stimuli
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); DDT(R); DDI(R); VVT(R); VVI(R); AAI(R)
Temporary Modes	Off; DDD; DDT; DDI; VVT; VVI; AAI; AAT; DOO; VOO; AOO;
Rate-Adaptive Sensor	On, Off, Passive
Programmable Rate and Delay Parameters	Off; Base Rate (min^{-1}); Rest Rate (min^{-1}); Maximum Tracking Rate (min^{-1}); Maximum Sensor Rate (min^{-1}); Paced AV Delay (ms); Sensed AV Delay (ms); Rate Responsive AV Delay; Hysteresis Rate (min^{-1}); Rate Hysteresis with Search
BiVCap™ Confirm; LVCap™ Confirm; RVCap™ Confirm	Setup; On; Monitor; Off
ACap™ Confirm	On; Monitor; Off
QuickOpt™ Timing Cycle Optimisation	Interventricular Pace Delay
Auto Mode Switch (AMS)	Off; DDI(R); DDT(R); VVI(R); VVT(R)
Atrial Tachycardia Detection Rate (min^{-1})	110-300
AMS Base Rate (min^{-1})	40; 45; ... 135
Auto PMT Detection/Termination	Atrial Pace; 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; or 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; RV Lead Impedance Out of Range; LV Lead Impedance Out of Range; High-Voltage Lead Impedance Out of Range; AT/AF Burden; V Rate During AT/AF; AT/AF Episode Duration; % V pacing; CorVue Congestion Trigger; SecureSense — lead noise detected, non-sustained lead noise detected
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 1 minute programmable pre-trigger data per VT/VF diagnosis; detection; electrograms; triggers include diagnosis; 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
CorVue™ Congestion Monitoring	On; Off
CorVue Congestion Trigger	8-18 days

* LV first with 10 ms interventricular delay

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.

Item GMCRM1076EN

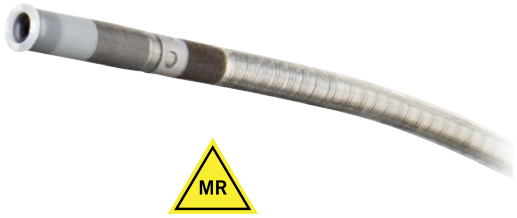
GMCRM1076EN

ST. JUDE MEDICAL

PACING LEADS

Tendril™ STS

Pacing Lead



Product Highlights - Pacing Leads

- The Tendril™ STS lead allows patients to undergo 1.5 T or 3 T MRI scans when used in conjunction with an MRI Ready device from Abbott*
- 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

MODEL NUMBER	DESCRIPTION	INSULATION	FIXATION	MIN. INTRODUCER (F)	CONNECTOR	LENGTH (CM)
2088TC	Tendril™ STS Pacing Leads	Optim™	Ext/Ret helix	6	IS-1 bipolar	46**; 52**; 58**; 65; 100

*See MRI conditional parameters.
**Indicates lead lengths that are MRI conditional.

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.

Tendril™ STS

Pacing Lead

Product Specifications

PHYSICAL SPECIFICATIONS

Models	2088TC
Minimum Introducer Size	6 F
Type of Lead	Active-fixation, steroid-eluting, endocardial, straight 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-shaped stylets	2 soft
Helix extension/retraction clip-on tools	2 clip-on tools

Accessory Kits Available Separately	Model Number	Compatible Lenghts	Description
Stylet Kit	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 cm	Disposable implant tool to facilitate precise lead positioning and manipulation with one hand
	1292 with appropriate length designation	46; 52; 58 cm	

MRI Conditional Parameters

MRI scan parameters vary depending on the MRI Ready device used. Consult the MRI Ready System Manual for specific product combinations and associated MRI scan parameters.

MP35N is a trademark of SPS Technologies, LLC

MR

*See MRI conditional parameters.

**Indicates lead lengths that are MRI conditional.

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.

26022-SJM-TND-0914-0002(7) | Item approved for international use only.

Abbott

PACING LEADS

OptiSense™

Pacing Lead

Product Highlights

- OptiSense™ pacing lead technology offers optimal tip-to-ring spacing for more precise atrial sensing without inappropriately sensing extra-atrial signals:
  - Unique 1,1 mm tip-to-ring spacing enables sensing of even the finest atrial arrhythmia signals (standard atrial leads typically have a tip-to-ring spacing of 10 mm or more)
  - Accurate atrial sensing enables appropriate atrial diagnostics and therapies
- Less far-field R-wave interference with innovative far-field signal reduction technology
- Optim™ lead insulation — a chemical copolymer that blends the best features of polyurethane and silicone for improved handling and increased durability
- Thin lead body diameter of 5,8 F can be inserted using a 7 F introducer
- Steroid elution and titanium nitride fractal coating on electrodes for low thresholds
- Includes three different J-shaped stylets providing options for different patient anatomies and handling preferences

Ordering Information

Contents: Cardiac Pacing Lead

MODEL NUMBER	INSULATION	FIXATION	MINIMUM INTRODUCER (F)	CONNECTOR	LENGTHS (CM)
1999	Optim	Ext/Ret helix	7	IS-1 bipolar	40; 46; 52

Indications: The OptiSense™ lead is designed for permanent sensing and pacing in the atrium with a compatible pulse generator. An active lead, such as the OptiSense™ lead, may be indicated for patients where permanent fixation of passive leads is suspected to be unstable. In atrial applications, the use of a screw-in lead, such as the OptiSense™ lead, may be indicated in the presence of an abnormal, surgically altered or excised atrial appendage.

Contraindications: The OptiSense™ 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 OptiSense™ leads 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.

OptiSense™
Pacing Lead

Product Specifications

PHYSICAL SPECIFICATIONS

Model	1999
Minimum Introducer Size	7 F
Type of Lead	Active-fixation; bipolar; steroid-eluting; endocardial: atrial pacing lead
Lead Connector	IS-1 bipolar
Lead Lengths	40; 46; 52 cm
Fixation Mechanism	Extendable/retractable helix
Lead Body Diameter	0,076"/1,9 mm (5,8 F)
Tip-to-ring Spacing	1,1 mm
Lead Tip Electrode (Cathode)	Active titanium-nitride-coated Pt/Ir helix (1,8 mm extension)
Tip Electrode Surface Area	6,4 mm^2
Ring Electrode (Anode)	Titanium-nitride-coated titanium ring
Ring Electrode Surface Area	17 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	1 standard; 1 wide; 1 narrow
Helix Extension/ Retraction Clip-on Tools	2 clip-on tools

ACCESSORY KITS

Available Separately	Model Number	Compatible Lengths	Description
Stylet Kit	DS06000 with appropriate length designation	52 cm	1 fixation tool; 1 clip-on tool; 1 standard J shape; 1 wide J shape; 1 narrow J shape
	DS06001 with appropriate length designation	46; 52 cm	1 clip-on tool; 1 standard J shape; 1 wide J shape; 1 narrow J shape
	DSO6002 with appropriate length designation	46; 52 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	40; 46; 52 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 cm	Disposable implant tool that facilitates precise lead positioning and allows manipulation with one hand
	1292 with appropriate length designation	52 cm	

LIMITED LIFETIME WARRANTY

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

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St. Jude Medical is now Abbott.

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.

28817-SJM-CAG-1115-0058(1) | Information contained herein intended for audiences from outside the United States only.

Abbott

DEFIBRILLATION LEADS

Durata™

Defibrillation Lead

MR

Product Highlights

- Allows patients to safely undergo an MRI scan when used in combination with an Abbott MRI Ready device.*,†
- Optim™ lead insulation is a chemical copolymer that offers superior handling and durability.[1]
- 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.[2]
- 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

REORDER NUMBER	INSULATION	FIXATION	MINIMUM INTRODUCER (F)	SHOCK CONFIGURATION	SENSING	TIP-TO-PROXIMAL COIL (CM)	CONNECTOR§	LENGTH (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

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.

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.

Durata™

Defibrillation Lead

Product 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)
MRI Whole-body SAR	N/A	2 W/kg	N/A	N/A	N/A	58 cm = 2 W/kg 65 cm = 1.6 W/kg

TRUE BIPOLAR, PASSIVE-FIXATION DEFIBRILLATION LEADS

Models	**7170**	**7170Q**	**7171**	**7171Q**	**7171Q**
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
MRI Whole-body SAR	N/A	N/A	N/A	N/A	N/A

*MRI Conditional Field Strength, 1,5 Tesla.
†See MRI Procedure Information for approved MR Conditional Systems Device/Lead combinations and scan parameters
§Abbott DF1 lead connectors conform to the international connector standard ISO 11318/Amd. Abbott IS-1 lead connectors conform to the international connector standard ISO 5841. Abbott DF4 lead connectors conform to the international connector standard ISO 27186: 2010 (E).
+Indicates lead lengths that are MRI Conditional.*,†

1. Jenney C, Tan J, Karicherla A, Burke J, Helland J. A New Insulation Material for Cardiac Leads with Potential for Improved Performance. *Heart Rhythm*. 2005;2:S318-S319.
2. Abbott. Engineering Report: Tension and Cable Shortening Comparison. Report 60032635.

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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.

28818-SJM-DUR-1114-0001(2) | Information contained herein intended for audiences from outside the United States only.

Abbott

LEFT-HEART LEADS

Quartet™ Family

Left-heart Leads

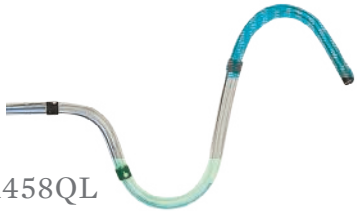
Product Highlights

- Proven Quartet™ LV lead performance with the most Quadripolar lead options to match a patient's anatomy
- The Quartet™ Family of LV leads offers more distal shape options including the Large-S, Small-S and Double Bend and more total electrode spacing options including 40, 47 and 60 mm
- Allows patients to safely undergo an MRI scan when used in combination with an Abbott MRI Ready device[1,2]
- Four pacing electrodes to provide more options and greater control in pacing vector selection
- Superb deliverability with exceptional stability and performance
- Low profile—4,7 F lead body; 4,0 F lead tip
- Optim™ lead insulation—a chemical co-polymer that blends the best features of polyurethane and silicone for improved handling and increased durability
- Steerable tip—distal tip angle can be controlled to maneuver through venous anatomy
- Flexible lead body—narrow ring electrodes provide lead tip flexibility
- Allows Direct-To-Target™ delivery placement through CPS Aim™ SL slittable inner catheter to deliver leads to small, acute venous anatomies that may have been unreachable in the past
- Compatible with over-the-wire or stylet approaches

1458Q

1456Q

1457Q



1458QL

Ordering Information

Contents: Left-heart Lead

MODEL NUMBER	SHAPE	TT	INSULATION	MINIMUM CURVE HEIGHT	MINIMUM INTRODUCER (F)	CONNECTOR	LENGTHS (CM)
1458Q	Large-S	47	Optim™	16	5	IS4-LLLL	75; 86*; 92
1456Q	Small-S	40	Optim™	8	5	IS4-LLLL	75; 86*
1457Q	Double Bend	47	Optim™	16	5	IS4-LLLL	75; 86*
1458QL	Large-S	60	Optim™	16	5	IS4-LLLL	75; 86*

*Indicates models that are MRI conditional.[1,2]

Indications and Usage: The Quartet LV lead has application as part of an Abbott biventricular system.

Contraindications: The use of the Quartet LV lead is contraindicated in patients who:

- Are expected to be hypersensitive to a single dose of 1,0 mg of dexamethasone sodium phosphate.
- Are unable to undergo an emergency thoracotomy procedure.
- Have coronary venous vasculature that is inadequate for lead placement, as indicated by venogram.

Physical Specifications

PARAMETER	DESCRIPTION	DESCRIPTION	DESCRIPTION	DESCRIPTION
Models	**1458Q**	**1456Q**	**1457Q**	**1458QL**
Connector	IS4-LLLL	IS4-LLLL	IS4-LLLL	IS4-LLLL
Lead Length	75; 86; 92 cm	75; 86 cm	75; 86 cm	75; 86 cm
Maximum Lead Size	5,1 F (1,70 mm/0,067″) at the ring electrode	5,1 F (1,70 mm/0,067″) at the ring electrode	5,1 F (1,70 mm/0,067″) at the ring electrode	5,1 F (1,70 mm/0,067″) at the ring electrode
Lead Body Size	4,7 F (1,57 mm/0,062″)	4,7 F (1,57 mm/0,062″)	4,7 F (1,57 mm/0,062″)	4,7 F (1,57 mm/0,062″)
Tip Electrode Size	4,0 F (1,3 mm/0,052″)	4,0 F (1,3 mm/0,052″)	4,0 F (1,3 mm/0,052″)	4,0 F (1,3 mm/0,052″)
LV Lead Delivery System Introducer Size	Minimum 5 F ID	Minimum 5 F ID	Minimum 5 F ID	Minimum 5 F ID
Minimum Curve Height	16 mm	8 mm	16 mm	16 mm
Tip Electrode	Pt/Ir; TiN coated; ring-shaped; two grooves	Pt/Ir; TiN coated; ring-shaped; two grooves	Pt/Ir; TiN coated; ring-shaped; two grooves	Pt/Ir; TiN coated; ring-shaped; two grooves
Steroid	Dexamethasone sodium phosphate	Dexamethasone sodium phosphate	Dexamethasone sodium phosphate	Dexamethasone sodium phosphate
Tip Electrode Surface Area	4,9 mm^2	4,9 mm^2	4,9 mm^2	4,9 mm^2
Ring Electrode Surface Area	7,4 mm^2	7,4 mm^2	7,4 mm^2	7,4 mm^2
Electrode Spacing				
Distal Tip 1 – Mid 2	20 mm	20 mm	20 mm	20 mm
Distal Tip 1 – Mid 3	30 mm	30 mm	30 mm	47 mm
Distal Tip 1 – Proximal 4	47 mm	40 mm	47 mm	60 mm
Lead Body Insulation	Optim™ lead insulation	Optim™ lead insulation	Optim™ lead insulation	Optim™ lead insulation
Lead Body Coating	Fast-Pass™ coating	Fast-Pass™ coating	Fast-Pass™ coating	Fast-Pass™ coating
Conductors				
Distal (coil)	MP35N‡ LT	MP35N‡ LT	MP35N‡ LT	MP35N‡ LT
Proximal (cables)	ETFE; MP35N LT	ETFE; MP35N LT	ETFE; MP35N LT	ETFE; MP35N LT
Suture Sleeve	Attached	Attached	Attached	Attached
MRI Conditional	Yes, MRI Ready (length: 86 cm)	Yes, MRI Ready (length: 86 cm)	Yes, MRI Ready (length: 86 cm)	Yes, MRI Ready (length: 86 cm)

1. MRI conditional parameters: 1,5 Tesla, 2 W/Kg SAR.
2. See MRI Ready Systems Manual for approved MR conditional systems device/lead combinations and scan parameters.

Customer Support: 46-8-474-4756

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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.

28905-SJM-QRT-1015-0011(3)
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Abbott

ACCESSORIES — CRT LEADS DELIVERY TOOLS

CPS Direct™ SL II

Slittable Outer Guide Catheter

Product Highlights

- Integrated hub and hemostasis valve
- Increased curve retention and optimized catheter body structure for improved kink resistance
- Soft tip to lessen risk of traumatic insertion

Ordering Information

Contents: Dilator and Two Valve Bypass Tools

MODEL NUMBER	CURVE SHAPE	AVAILABLE LENGTH (CM)	OVERALL LENGTH (CM)	INNER DIAMETER (F/MM)	OUTER DIAMETER (F/MM)
DS2C001	Straight	47	50,7	7/2,44	9/3,00
DS2C002	115º	47	50,7	7/2,44	9/3,00
DS2C003	135º	47	50,7	7/2,44	9/3,00
DS2C004	Wide	47	50,7	7/2,44	9/3,00
DS2C005	X-Wide	47	50,7	7/2,44	9/3,00
DS2C006	Right Side	47	50,7	7/2,44	9/3,00
DS2C011	Straight	54	57,7	7/2,44	9/3,00
DS2C012	115º	54	57,7	7/2,44	9/3,00
DS2C013	135º	54	57,7	7/2,44	9/3,00
DS2C014	Wide	54	57,7	7/2,44	9/3,00
DS2C015	X-Wide	54	57,7	7/2,44	9/3,00

Straight 115º 135º Wide Extra Wide Right Side

Separately Available Accessories

MODEL NUMBER	NAME	TYPE
DS2A003	CPS™ Universal Slitter	Slitter
DS2A004	CPS Direct™ SL Valve Bypass Tool	Valve bypass tool

Customer Support: 46-8-474-4756
Abbott
The Corporate Village, Da Vincilaan 11 Box F1, 1935 Zaventem, Belgium, Tel: +32 2 774 68 11
SJM.com
St. Jude Medical is now Abbott.

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.

28047-SJM-CPS-1115-0005(2) | Item approved for international use only.

Abbott

ACCESSORIES — CRT LEADS DELIVERY TOOLS

CPS Direct™ PL

Peelable Outer Guide Catheter

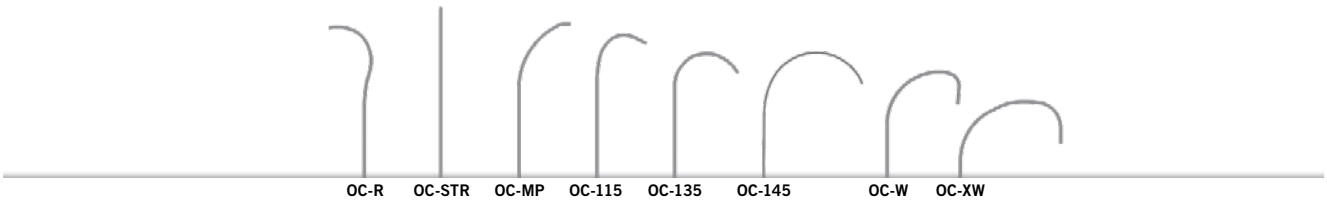
Product Highlights

- Unique SiteMark™ tungsten marker stripes provide superior fluoroscopic visibility to verify torque transfer
- Compatible with CPS Aim™ inner catheter and CPS Luminary™ bideflectable catheter with lumen to modify shape and extend reach if necessary
- EvenPeel™ stripes provide more smooth and reliable peeling for worry-free sheath removal

Ordering Information

Contents: Sheath with hemostasis valve attached, dilator and 2 valve bypass tools

MODEL NUMBER	CURVE SHAPE	AVAILABLE LENGTH (CM)	OVERALL LENGTH (CM)	INNER DIAMETER (F/MM)	OUTER DIAMETER (F/MM)
410210	Straight (OC-STR)	47	50,7	7/2,44	9/3,00
410211	Multipurpose (OC-MP)	47	50,7	7/2,44	9/3,00
410212	115° (OC-115)	47	50,7	7/2,44	9/3,00
410213	135° (OC-135)	47	50,7	7/2,44	9/3,00
410214	Wide (OC-W)	47	50,7	7/2,44	9/3,00
410215	Extra Wide (OC-XW)	47	50,7	7/2,44	9/3,00
410216	Right Sided (OC-R)	47	50,7	7/2,44	9/3,00
410224	145° (OC-145)	47	50,7	7/2,44	9/3,00
410217	Straight (OC-STR)	54	57,7	7/2,44	9/3,00
410218	Multipurpose (OC-MP)	54	57,7	7/2,44	9/3,00
410219	115° (OC-115)	54	57,7	7/2,44	9/3,00
410220	135° (OC-135)	54	57,7	7/2,44	9/3,00
410221	Wide (OC-W)	54	57,7	7/2,44	9/3,00
410222	Extra Wide (OC-XW)	54	57,7	7/2,44	9/3,00
410223	Right Sided (OC-R)	54	57,7	7/2,44	9/3,00
410225	145° (OC-145)	54	57,7	7/2,44	9/3,00



Separately Available Accessories

MODEL NUMBER	NAME	TYPE
410194	CPS Direct™ PL Valve Bypass Tool (Pack of 2)	Valve bypass tool
410195	CPS Direct™ PL Inner Catheter SafeSheath™ Sealing Adapter	Self-sealing valve
410190	CPS™ Implant Kit (Includes Needle, Syringe and 0,035″ Guidewire)	Implant Kit

Abbott
The Corporate Village
Da Vincilaan 11 Box F1
1935 Zaventem, Belgium
Tel: +32 2 774 68 11
SJM.com
St. Jude Medical is now Abbott.

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.

28810-SJM-CPS-1115-0004(1)

Information contained herein intended for audiences from outside the United States only.

Abbott

Special CRT Accessories

ARROW INTERNATIONAL

AI-07125 6 Fr. 60 cm Balloon Wedge Pressure Catheter	One: Wedge Catheter: 6 Fr. 2-Lumen, 60 cm One: Syringe: 1.10 cc Control Stroke
AI-07126 6 Fr. 110 cm Balloon Wedge Pressure Catheter	One: Wedge Catheter: 6 Fr. 2-Lumen, 110 cm One: Syringe: 1.10 cc Control Stroke

Pressure Products

PLS-09	Pacing Lead Stabilizer for lead size 1.4 - 2.7 mm/ 4.3 – 8.0 Fr.