Quadra Allure™

Cardiac Resynchronisation Therapy Pacemaker

Cardiac Resynchronisation Therapy (CRT) Devices

Merlin@home™ Transmitter Compatible

MR

Product Highlights

- Allows patients to undergo MRI scans when used with MRI Ready leads from St. Jude Medical*
- The Quadra Allure™ CRT-P and Quartet™ quadripolar LV pacing lead feature four pacing electrodes and 14 pacing vectors to provide more options and greater control to address complications at and post implant to improve CRT response
- SyncAV™ CRT technology dynamically adjusts AV delays based on patient's intrinsic conduction to encourage patient-tailored biventricular pacing
- Elevate Response Easily with Auto VectSelect Quartet™ Test offering an efficient workflow for complete results and programming at the touch of a button
- Angled header and physiologic tear drop shape provide better lead wrap
- CorVue™ Congestion Monitoring feature monitors the intrathoracic impedance and provides the option for both patient and physician alerts
- The DirectTrend™ Report provides a summary of three month daily, one year weekly or one year daily diagnostic trends
- Better patient utilization from day one when paired with the Merlin@home™ transmitter at point of care[1]
- AT/AF alerts can be programmed to notify their clinics when a programmed AT/AF threshold or continuous episode duration has been exceeded, or when a high ventricular rate accompanies the AT/AF episode
- Exclusive AF Suppression™ algorithm is clinically proven to suppress episodes of paroxysmal and persistent AF
- AT/AF burden trend provides a graphical representation of the percentage of time in AT/AF and the number of AT/AF episodes in the previous 52 weeks
- Up to 14 minutes of stored electrograms help identify key intrinsic and pacemaker-related events and simplify the diagnosis of complex ECG rhythms associated with heart failure
- Longevity offers 8,2 years of service life supported by a six year warranty*

Ordering Information

Contents: Cardiac pulse generator.

Model Number	Dimensions (H x W x T, mm)	Weight (g)	Volume (cc)	Connector
PM3542	56 x 59 x 6	26	15	1S4-LLLL, IS-1

Indications: Implantation of a CRT-P is indicated in one or more of the following permanent conditions: syncope, presyncope, fatigue, disorientation due to arrhythmia/bradycardia, or any combinations of those symptoms. Implantation of a CRT-P is indicated for patients who would benefit from resynchronization of the right and left ventricles of have one or more conventional indications for the implantation of a pacemaker. ***Rate-Modulated Pacing*** is indicated for patients with chronotropic incompetence, and for those who would benefit from increased stimulation rates concurrent with physical activity. ***Dual-Chamber Pacing*** is indicated for those patients exhibiting: 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*** is indicated for patients with sinus node dysfunction and normal AV and intraventricular conduction systems. ***Ventricular Pacing*** is indicated for patients with significant bradycardia and normal sinus rhythm with only rare episodes of A-V block or sinus arrest, chronic atrial fibrillation, severe physical disability. ***AF Suppression™*** algorithm is indicated for suppression of paroxysmal or persistent atrial fibrillation episodes in patients with one or more of the above pacing indications.

Contraindications: Implanted Cardioverter-Defibrillator (ICD) Devices are contraindicated for patients with an implanted cardioverter-defibrillator. Rate-Adaptive Pacing may be contraindicated for patients who experience angina or other symptoms of myocardial dysfunction at higher sensor-driven rates. An appropriate Maximum Sensor Rate should be selected based on assessment of the highest stimulation rate tolerated by the patient. AF Suppression™ stimulation is not recommended in patients who cannot tolerate high atrial-rate stimulation. ***Dual-Chamber Pacing***, though not contraindicated for patients with chronic atrial flutter, chronic atrial fibrillation, or silent atria, may provide no benefit beyond that of single-chamber pacing in such patients. ***Single-Chamber Ventricular Demand Pacing*** is relatively contraindicated in patients who have demonstrated pacemaker syndrome, have retrograde VA conduction, or suffer a drop in arterial blood pressure with the onset of ventricular pacing. ***Single-Chamber Atrial Pacing*** is relatively contraindicated in patients who have demonstrated compromise of AV conduction. ***Atrial Fibrillation.*** Allure™ devices are contraindicated in patients having chronic atrial fibrillation or intermittent atrial fibrillation that does not terminate. For specific contraindications associated with individual modes, refer to the programmer's on-screen help.

Potential Adverse Events: The following are potential complications associated with the use of any pacing system: air embolism, body rejection phenomena, cardiac tamponade or perforation, hematoma, bleeding hematoma, seroma, 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 dislodgement or reaction at the electrode/tissue interface, loss of desired pacing and/or sensing due to lead displacement, body reaction at electrode interface, lead malfunction (fracture or damage to insulation), loss of normal device function due to battery depletion, component malfunction, pacemaker migration or pocket erosion, pectoral muscle or diaphragmatic stimulation, phrenic nerve stimulation, pneumothorax/hemothorax, endocarditis, excessive bleeding, induced arrhythmias or ventricular arrhythmias, myocardial irritability, pericardial effusion, pericardial rub, pulmonary edema, rise in threshold and exit block, valve damage, cardiac/coronary sinus dissection, cardiac/coronary sinus perforation, coronary sinus or cardiac vein thrombosis.

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

1. Ren X et al. Patient adherence in remote follow-up of cardiovascular implantable electronic devices. *J Am Coll Cardiol.* 2012;59:E645, doi: 10.1016/S0735-10097(12)60646-9.

*Longevity calculated based on the following settings: 2,5V @ 0,4 ms (RA/RV/LV), 500 ohms, DDD, 60 BPM, 100% Bi-V Pacing, 100% Atrial Pacing and Stored EGMS on

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Quadra Allure™

Cardiac Resynchronisation Therapy Pacemaker

Cardiac Resynchronisation Therapy (CRT) Devices

Physical Specifications

Model	PM3542
Telemetry	RF
Dimensions (mm)	56 x 59 x 6
Weight (g)	27
Volume (cc)[1]	15
Connector	IS4-LLLL, IS-1
MRI Conditional	Yes, MRI Ready

Resynchronisation Therapy

VectSelect Quartet™ LV Pulse Configuration	Distal Tip 1–Mid 2; Distal Tip 1–Proximal 4; Distal Tip 1–RV Ring; Mid 2–Proximal 4; Mid 2–RV Ring; Mid 3–Mid 2; Mid 3–Proximal 4; Mid 3–RV Ring; Proximal 4–Mid 2; Proximal 4–RV Ring; Distal Tip 1–Can; Mid 2–Can; Mid 3–Can; Proximal 4–Can
V. Triggering options	On; Off
QuickOpt™ Timing Cycle Optimisation	Sensed/Paced AV Delay; Interventricular Paced Delay
Intraventricular pace delay	10–80 in steps of 5
RV and LV Pulse Width (ms)	0,05; 0,1–1,5 in steps of 0,1
RV and LV Pulse Amplitude (V)	0,25–4,0 in steps of 0,25; 4,5–7,5 in steps of 0,5
RV Pulse Configuration	Unipolar; Bipolar
Ventricular Sense Configuration	BV Unipolar Tip; BV Bipolar; RV Unipolar Tip; RV Bipolar; Distal Tip 1–Mid 2; Distal Tip 1–Can; and Distal Tip 1–RV Tip
First Chamber Paced	Simultaneous[2]; RV; LV
SyncAV™ CRT Delta	Off; -10 to -120 in steps of 10
Shortest AV/PV Delay (ms)	25–50 in steps of 5; 60–120 in steps of 10

Output/Sensing

Atrial ACap™ Confirm	On; Off; Monitor
Primary Pulse Confirmation	Bipolar
Backup Pulse Confirmation	Bipolar
Backup Pulse Amplitude (V)	5,0
Searchable Intervals (hrs)	8; 24
Atrial Pulse Configuration	Unipolar (tip–case); Bipolar (tip–ring)
Atrial Sense Configuration	Unipolar Tip (tip–case); Bipolar (tip–ring); Unipolar Ring (ring–case)
Atrial Sensitivity[3,4] (Fixed) (mV)	0,1–0,5 in steps of 0,1; 0,75–2,0 in steps of 0,25; 2,5–5,0 in steps of 0,5
Atrial Pulse Amplitude (V)	0,25–4,0 in steps of 0,25; 4,5–7,5 in steps of 0,5
Atrial Pulse Width (ms)	0,05; 0,1–1,5 in steps of 0,1
RVCap™ Confirm	On; Off; Monitor
Searchable Interval (hrs)	8; 24
LVCap™ Confirm	On; Off; Monitor
Searchable Interval (hrs)	8; 24
Sense*Ability*™ Technology	Off; On (Automatic Sensitivity Control adjustment for atrial and ventricular events)
A Max Sensitivity (mV)	0,2–1,0 in steps of 0,1
V Max Sensitivity (mV)	0,2–2,0 in steps of 0,1
Threshold Start	(Atrial and Ventricular Post-Sense) 50; 62,5; 75; 100% (Atrial Post-Pace) 0,2–3,0 in steps of 0,1 mV (Ventricular Post-Pace) Auto; 0,2–3,0 in steps of 0,1 mV
Decay Delay (ms)	(Atrial and Ventricular Post-Sense) 0; 30; 60; 95; 125; 160; 190; 220 (Atrial Post-Pace) 0; 30; 60; 95; 125; 160; 190; 220 (Ventricular Post-Pace) Auto; 0; 30; 60; 95; 125; 160; 190; 220
Ventricular Sensitivity (fixed) (mV)	0,5–12,5 in steps of 0,5[3,4]

Rate/Timing

Mode	AOO(R); AAI(R); AAT(R); VOO(R); VVI(R); VVT(R); DOO(R); DVI(R); DDI(R); DDT(R); DDD(R); VDD(R); Pacing Off
DDT Trigger[5]	R wave
DDT Timing[5]	DDI
Base Rate (min^{-1})	30–130 in steps of 5; 140–170 in steps of 10
Hysteresis Rate (min^{-1})	Off; 30–150 in steps of 5[6]
Search Interval (min)	Off; 1; 5; 10; 15; 30
Cycle Count	1–16
Intervention Rate (min^{-1})	Off; Same Base Rate; 80–120 in steps of 10 (Intrinsic +0; Intrinsic +10; Intrinsic +20; Intrinsic +30)
Intervention Duration (min^{-1})	1–10
Recovery Time	Fast; Medium; Slow; Very Slow
Rest Rate (min^{-1})	Off; 30–150 in steps of 5
Maximum Tracking Rate (min^{-1})	90–130 in steps of 5; 140–180 in steps of 10
Sensed AV Delay (ms)	25; 30–200 in steps of 10; 225–325 in steps of 25
Paced AV Delay (ms)	25; 30–200 in steps of 10; 225–300 in steps of 25; 350
Ventricular Pace/Sense Refractory[7] (Fixed) (ms)	125; 160–400 in steps of 30; 440; 470[8]
Atrial Pace Refractory	190–400 in steps of 30; 440; 470[8]
Atrial Sense Refractory	93; 125; 157; 190–400 in steps of 30; 440; 470[8]
PVARP (ms)	125–500 in steps of 25
Atrial Protection Interval (ms)[5]	125
Far-Field Protection Interval (ms)[5]	16

Rate-Modulated Parameters

Rate Responsive AV/PV Delay	Off; Low; Medium; High
Rate Responsive PVARP/VREF	Off; Low; Medium; High
Shortest PVARP/VREF	125–475 in steps of 25
Sensor	On; Off; Passive
Max Sensor Rate (min^{-1})	80–150 in steps of 5; 160–180 in steps of 10
Threshold	Auto (-0,5); Auto (+0,0); Auto (+0,5); Auto (+1,0); Auto (+1,5); Auto +(2,0); 1–7 in steps of 0,5
Slope	Auto (-1); Auto (+0); Auto (+1); Auto (+2); Auto (+3); 1–16
Reaction Time	Very Fast; Fast; Medium; Slow
Recovery Time	Fast; Medium; Slow; Very Slow

AF Management

AF Suppression™ Algorithm	Off; On
Lower Rate Overdrive (min^{-1})[5]	10
Upper Rate Overdrive (min^{-1})[5]	5
No. of Overdrive Pacing Cycles	15–40 in steps of 5
Rate Recovery (ms)	8; 12
Auto Mode Switch	Off; DDD(R) to DDI(R); DDD(R) to DDT(R); DDD(R) to VVI(R); DDD(R) to VVT(R); VDD(R) to VVI(R); VDD(R) to VVT(R)
AMS Base Rate (min^{-1})	40–170 in steps of 5

Stored Electrograms

Options	
Priority Options	Off; Low; High
Channel	1; 2; 3
Triggers	
Advanced Hysteresis	Off; Low; High
AMS Entry/AMS Exit/ AMS Entry and Exit	Off; Low; High
AT/AF Detection	Off; Low; High
Magnet Response	Off; Low; High
High Atrial Rate	Off; Low; High
Rate (min^{-1})	125–300 in steps of 25
No. of Consecutive Cycles	2; 3; 4; 5; 10; 15; 20
High Ventricular Rate	Off; Low; High
Rate (min^{-1})	125–300 in steps of 25
No. of Consecutive Cycles	2; 3; 4; 5; 10; 15; 20
PMT Termination	Off; Low; High
Consecutive PVCs	Off; Low; High
No. of Consecutive PVCs	2; 3; 4; 5
Noise Reversion	Off; Low; High

Other

Magnet Response	Off; Battery Test
Ventricular Intrinsic Preference, VIP™ (ms)	Off; 50–150 in steps of 25; 160–200 in steps of 10
VIP Search Interval	30 sec.; 1; 3; 5; 10; 30 min.
VIP Search Cycles	1; 2; 3
Atrial Tachycardia Detection Rate (min^{-1})	110–200 in steps of 10; 225–300 in steps of 25
Post Vent. Atrial Blanking (PVAB) (ms)	60–200 in steps of 10; 225; 250
Ventricular Safety Standby	Off; On
PVC Response	Off; Atrial Pace[8]
PMT Options	Off; Passive; Atrial Pace[8]
PMT Detection Rate (min^{-1})	90–180 in steps of 5
Lead Type	Uncoded; Unipolar; Bipolar
NIPS Options	
Stimulation Chamber	Atrial; Right Ventricular
Coupling Interval[9] (ms)	200–800 in steps of 10
S1 Count	2–25 in steps of 1
S1[10]; S2; S3 and S4 Cycle (ms)	Off; 100–800 in steps of 10 (Fixed or Adaptive)
Right Ventricular Support Rate (min^{-1})	Off; 30–95 in steps of 5
Sinus Node Recovery Delay (s)	1–5 in steps of 1
Diagnostic Trends	AT/AF Activity; Exercise; Lead Impedance; P and R Wave; A and V threshold; CorVue™ Congestion Monitoring
CorVue™ Congestion Monitoring	Off; On
CorVue Congestion Trigger	8–18 days

MRI Scan Parameters*

MRI Ready Lead Model	Magnet (Tesla)	Scanner Mode	Scan Region
Quartet™ LV Lead	1.5T	Normal Operating Mode*	Full Body
1456Q, 1457Q, 1458Q, 1458QL (86 cm)			
IsoFlex™ Lead			
1944 (46 cm, 52 cm)			
1948 (52 cm, 58 cm)			
Tendril™ STS Pacing Lead			
2088TC (46 cm, 52 cm, 58 cm)			

*As defined in IEC 60601-2-33, Normal Operating Mode corresponds to RF Power SAR: ≤2W/kg, Head SAR: ≤ 3.2 W/kg

1. ± 0.5 cc
2. LV first with 10 ms interventricular delay.
3. Sensitivity is with respect to a 20 ms haversine test signal.
4. Values 0.1–0.4 not available in a Unipolar Sense Configuration.
5. This parameter is not programmable.
6. The highest available setting for hysteresis rate is 5 min-1 below the programmed base rate.
7. In dual-chamber modes, the maximum Ventricular Refractory Period is 325 ms.
8. Programming options dependent on pacing mode.
9. During atrial NIPS in dual-chamber modes, the shortest Coupling Interval will be limited by the programmed AV/PV Delay.
10. S1 Burst Cycle is applied at the preprogrammed S1 cycle length.

Customer Support: 46-8-474-4756

Brief Summary: Prior to using these devices, please review the User's Manual for a complete listing of indications, contraindications, warnings, precautions, potential adverse events and directions for use.

SJM-QD-0816-0054(1) I Item approved for international use only. Not for distribution in Canada.

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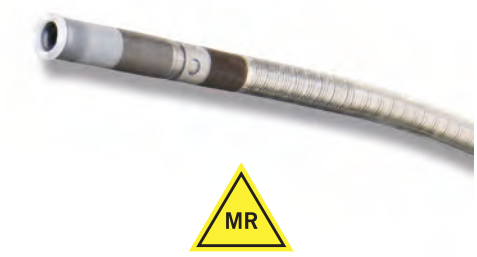
Tendril™ STS

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.

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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

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-TND-1214-0003 I This document is for International use only.

ST. JUDE MEDICAL™

Quartet™ Family

Left-Heart Leads

1458Q

1456Q

1457Q

1458QL

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 the 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 a St Jude Medical™ 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

Ordering Information

Contents: Left-heart lead

Model Number	Shape	Total Electrode Spacing (mm)	Insulation	Minimum Curve Height	Minimun 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 lead has application as part of a St. Jude Medical biventricular system.
Contraindications: The use of the Quartet 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.

Quartet™ Family

Left-Heart Lead

Physical Specifications

Models	1458Q	1456Q	1457Q	1458QL
Parameter	**Description**	**Description**	**Description**	**Description**
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™ insulation	Optim™ insulation	Optim™ insulation	Optim™ 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)

†MP35N is a trademark of SPS Technologies, Inc.

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

Rx Only

Brief Summary: Prior to using these devices, please review the User's Manual for a complete listing of indications, contraindications, warnings, precautions, potential adverse events and directions for use.

SJM-QRT-1015-0011 I Item approved for international use only.

ST. JUDE MEDICAL

CPS Direct™ Universal

Slittable Outer Guide Catheter

MODELS DS2C018, DS2C019, DS2C020, DS2C021, DS2C022, DS2C023, DS2C025, DS2C026, DS2C027, DS2C028, DS2C029

SPECIFICATIONS

- The CPS Direct Universal family of outer guide catheters is designed to facilitate left heart lead delivery. They are compatible with other products in the St. Jude Medical™ Cardiac Positioning System (CPS™) family – an inter-compatible system of tools designed to give you more control to efficiently and predictably deliver the left-heart lead to your vein of first choice.
- Enables Direct-To-Target™ delivery to the desired vein:
  - Soft, atraumatic tip with multi-durometer PEBAX™ shaft is designed to provide flexibility to allow advancement of the catheter deep into the coronary venous system.
  - CPS Direct™ Universal catheter is compatible with CPS Aim™ Universal inner catheters, designed to assist with branch vein subselection and left ventricular lead delivery , including delivery of the Quartet™ quadripolar LV lead.
- Designed to reduce procedural steps during implant:
  - Slittable hub and integrated shaft provide smooth transition during slitting of catheter.
  - U-channel valve bypass tool simplifies lead delivery.
  - Ergonomic slitter facilitates smooth slitting.
- Designed to provide reliable coronary sinus access:
  - Excellent torque transmission and soft, atraumatic tip due to braid-reinforced, multi-durometer PEBAX™* material design.
  - Unique SiteMark™ 3D markers provide fluoroscopic visibility to determine anterior/posterior location and verify torque transfer.
  - Six curve options to satisfy needs of various anatomies and different implanter techniques.
  - Compatible with CPS Aim™ Universal cannulators and CPS Luminary™ bideflectable catheter with lumen to modify shape and extend reach if necessary.
- Designed for worry-free removal:
  - Catheter design features Smooth-Slit™ braiding technology and ergonomic slitter, designed to allow effortless, best-in-class cutting, minimizing the risk of lead dislodgement upon catheter removal.

PEBAX is a trademark of Arkema Inc.

ST. JUDE MEDICAL™

PHYSICAL SPECIFICATIONS

Slittable Outer Guide Catheter

Models	CURVE SHAPE	AVAILABLE LENGTH	OVERALL LENGTH	INNER DIAMETER	OUTER DIAMETER
DS2C018	Straight	47 cm	50.6 cm	8F (2.67mm)	10F (3.34mm)
DS2C019	115°	47 cm	50.6 cm	8F (2.67mm)	10F (3.34mm)
DS2C020	135°	47 cm	50.6 cm	8F (2.67mm)	10F (3.34mm)
DS2C021	Wide	47 cm	50.6 cm	8F (2.67mm)	10F (3.34mm)
DS2C022	X-Wide	47 cm	50.6 cm	8F (2.67mm)	10F (3.34mm)
DS2C023	Right Side	47 cm	50.6 cm	8F (2.67mm)	10F (3.34mm)
DS2C025	Straight	54 cm	57.6 cm	8F (2.67mm)	10F (3.34mm)
DS2C026	115°	54 cm	57.6 cm	8F (2.67mm)	10F (3.34mm)
DS2C027	135°	54 cm	57.6 cm	8F (2.67mm)	10F (3.34mm)
DS2C028	Wide	54 cm	57.6 cm	8F (2.67mm)	10F (3.34mm)
DS2C029	X-Wide	54 cm	57.6 cm	8F (2.67mm)	10F (3.34mm)

Material	Multi-durometer PEBAX™ material reinforced with stainless steel braid wire for a kink-resistant catheter shaft and soft distal tip. Lubricious coating on inner and outer surface.
Marker	Three gold marker bands and two tungsten stripes on distal tip.

ACCESSORIES

INCLUDED	SEPARATELY AVAILABLE
Dilator	CPS™ Universal Slitter
2 Valve bypass tools	CPS Direct™ Valve Bypass Tool
	Implant Kit

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ST. JUDE MEDICAL™

CPS Aim™ Universal

Slittable Inner Catheter with Integrated Valve

MODELS DS2N026, DS2N027, DS2N028, DS2N029, DS2N030

SPECIFICATIONS

- The CPS Aim™ Universal family of inner catheters with integrated valve is designed to assist with coronary sinus cannulation, branch vein subselection and left ventricular lead delivery. The catheters are compatible with other products in the St. Jude Medical™ Cardiac Positioning System (CPS™) family–an inter-compatible system of tools designed to give you more control to deliver the left-heart lead–efficiently and predictably–to your vein of first choice.
- Three CPS Aim Universal inner catheters enable atraumatic subselection.
  - CPS Aim Universal inner catheters enable access to the vein of first choice through Direct-To-Target™ placement. The CPS Aim Universal inner catheter provides a tunnel to acute and tortuous venous anatomies for 5 F leads (including the Quartet™ lead) and guidewire.
  - The CPS Aim Universal inner catheters are easy to remove with a low slit force after Direct-To-Target™ placement.
  - Three curve shapes (acute, 90º, obtuse) with fluoroscopic visibility facilitate first-choice target vein access, even when encountering difficult angulations and tortuous anatomy.
  - The soft tip enables atraumatic subselection.
- Two CPS Aim™ cannulators assist with coronary sinus access
  - When used in conjunction with CPS Direct™ Universal outer guide catheters, CPS Aim™ Universal cannulators facilitate coronary sinus cannulation.
  - CPS Aim Universal cannulators help extend the reach and modify the shape of CPS Direct Universal outer guide catheters, helping overcome challenging anatomies.
- A combination of PEBAX™ material that becomes softer from the proximal to the distal end and increased braid wire at the distal end provide for a torqueable, kink resistant and soft-tipped subselector. The catheter has been designed to access acute and tortuous anatomies.
- The catheter body and tip are clearly seen under fluoroscopy. Fluoroscopic material in the catheter profile illuminates the catheter body. A platinum band at the tip provides a landmark to access venous anatomy.
- The CPS Aim Universal inner catheter has a low slit force to reduce the risk of lead movement when slitting the catheter. To assist in this effort, the CPS Aim Universal inner catheter has a slittable hub with a smooth hub-to-shaft transition. In addition, the braidwire and PEBAX material construction has been optimized for smooth slitting. The CPS Aim Universal slittable inner catheter has been designed to remove easily after Direct-To-Target™ placement.

ST. JUDE MEDICAL™

PHYSICAL SPECIFICATIONS

Model	DS2N026	DS2N027	DS2N028	DS2N029	DS2N030
Model Name	SUB-ACU	SUB-90	SUB-OBT	CN-CSL	CN-ALII
Curve Shape	Acute	90°	Obtuse	CSL	ALII
Available Lengths - cm (working)	59, 65	59, 65	59, 65	65	65
Overall Length - cm (respectively)	63, 69	63, 69	63, 69	69	69
Valve	Integrated				
Inner Diameter	5.87 F (1.96 mm)				
Outer Diameter	7.62 F (2.6 mm)				
Material	Multi-durometer PEBAX™ material reinforced with stainless steel braid wire for a kink-resistant catheter shaft and soft distal tip. Lubricious inner liner/outer coating.				
Marker	Platinum tip				

Accessories (available separately)

Accessory Name	CPS™ Universal Slitter (DS2A003)	CPS Direct™ Valve Bypass Tool (DS2A004)
Accessory Type	Slitter	Valve Bypass Tool

*PEBAX is a trademark of Arkema, Inc.

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Rx Only
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.

Thermodilution Catheter

Pulmonary Artery Monitoring Catheter and Biotray

Product	Material	Catheter Size	Lumen	Length	Balloon Volume(cc)	Thermistor Resistance (ohms)	Recommended Introducer Size	Radiopacity
THERMODILUTION CATHETER								
TD1504N	PVC	5F	4	90 cm	0.75	14K	6F	Sufficiently opaque to appear visible under conventional flouroscope illumination while in vivo
TD2504N	PU	5F	4	90 cm	0.75	14K	6F	
TD1604N	PVC	6F	4	110 cm	1.00	14K	7F	
TD2604N	PU	6F	4	110 cm	1.00	14K	7F	
TD1704N	PVC	7F	4	110 cm	1.50	14K	8F	
TD2704N	PU	7F	4	110 cm	1.50	14K	8F	
TD1755N	PVC	7.5F	5	110 cm	1.50	14K	8.5F	
TD2755N	PU	7.5F	5	110 cm	1.50	14K	8.5F	
PA MONITORING CATHETER								
TD1502N	PVC	5 Fr	2	90 cm	0.75	N/A	6F	
TD2502N	PU	5 Fr	2	90 cm	0.75	N/A	6F	
TD1602N	PVC	6 Fr	2	110 cm	1.00	N/A	7F	
TD2602N	PU	6 Fr	2	110 cm	1.00	N/A	7F	
TD1702N	PVC	7 Fr	2	110 cm	1.50	N/A	8F	
TD2702N	PU	7 Fr	2	110 cm	1.50	N/A	8F	
TD1603N	PVC	6 Fr	3	110 cm	1.00	N/A	7F	
TD2603N	PU	6 Fr	3	110 cm	1.00	N/A	7F	
TD1703N	PVC	7 Fr	3	110 cm	1.50	N/A	8F	
TD2703N	PU	7 Fr	3	110 cm	1.50	N/A	8F	

SPECIAL FEATURES

Optional Features	Suffix	Description
SAFETYWEDGE™	D	Catheter with SAFETYWEDGE™
Contamination Sleeve	X	Catheter without contamination sleeve
Non-coated tubing	N	Catheter with no coating on tubing
Stiff Body Tubing	F	Catheter with stiffer tubing

SAFETYWEDGE™ covered by U.S. Patent No. 5,007,919

1. Thomas Santora, MD; William Ganz, MD; Julian Gold, MD; Mark Wittman, MD; Beverley Leyerle, RN; H.J.C. Swan, MD, PhD; M. Michael Shabot, MD, "New method for monitoring pulmonary artery catheter location, "Critical Care Medicine". Vol. 19, No. 3, p. 422, 1991.
2. Jean-Francois Hardy, MD; Martin Morissette, MD; Jean Taillefer, MD; Rene Vauclair, MD; "Pathophysiology if Repture of the Pulmonary Artery by Pulmonary Artery Balloon-Tipped Catheters, "Anesthesia & Analgesia". Vol. 62, p. 925, 1983.

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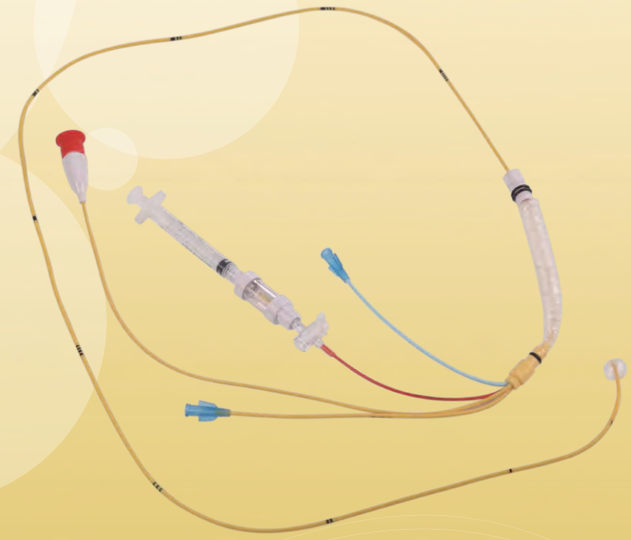
Bioptimal™

www.bioptimalg.com

Eliminating the risk of Pulmonary Artery Rupture.

Thermodilution Catheter

Pulmonary Artery Monitoring Catheter and Biotray



Bioptimal™

Thermodilution Catheter
Pulmonary Artery Monitoring Catheter and Biotray

Eliminating the risk
of Pulmonary Artery Rupture.

About SAFETYWEDGE™ Thermodilution Catheter
An unprecedented level of safety for balloon inflation.

Catheter tips often migrate to small arterial branches that are unable to safely accommodate inflated balloons.

SAFETYWEDGE™ thermodilution catheters virtually eliminate the risk of pulmonary artery rupture due to balloon overpressurization - the most serious complication associated with PA catheter monitoring.

SAFETYWEDGE™ catheters reduce the risk of this potentially dangerous situation by facilitating inflation of the SAFETYWEDGE™ device when either (1) the distal balloon encounters abnormal resistance to inflation, or (2) the pressure inside the distal balloon exceeds the normal inflation pressure.

SAFETYWEDGE™ component acts as a pressure relief valve to prevent overpressurization of the distal balloon.

This not only averts vessel rupture but balloon rupture as well, and alerts the clinician to reposition the catheter.

Features and Benefits

- **SAFETYWEDGE™**
  Exclusive Safety balloon acts as pressure relief valve to prevent overpressurization of the balloon.
- **Contamination Shield**
  Provides a protective barrier against contamination of the catheter during catheter insertion and manipulation.
- **Medication Lumen**
  Permits blood sampling, fluid and drug administration and central venous pressure monitoting *(7.5 French catheter only)*.
- **Thermistor Connector**
  Compatible with commonly used cardiac output computers, also used to monitor pulmonary artery blood temperature.
- **PA Distal Lumen**
  Allows mixed venous blood sampling, and measurements of pulmonary artery and pulmonary capillary wedge pressure.
- **Distal Balloon**
  Provides excellent symmetry and tip coverage for the safe flotation of the catheter and for pulmonary capillary wedge pressure measurements.
- **CVP Proximal or Injectate Lumen**
  Carries cardiac output injectate solution to right atrium. Accommodates blood sampling, fluid and drug administration and - when attached to a pressure transducer -monitor of right atrium pressure.

Correct catheter position, with SAFETYWEDGE™ device in READY mode.

Catheter tip migration into small PA branch, SAFETYWEDGE™ device activated upon attempt to inflate distal balloon.

SAFETYWEDGE™ Thermodilution Catheter with the Biotray
Reducing the Serious Risk of Pulmonary Artery Rupture.

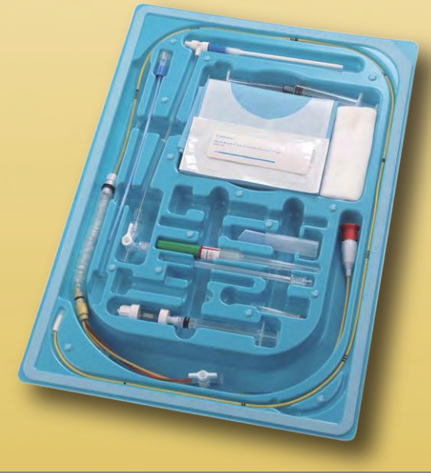
The BioTray contains all the necessary supplies used with the SAFETYWEDGE™ thermodilution catheter.
Value added benefits:

- Elimination of the sheath-catheter size compatible issue
- Ease of use
- Convenience
- Easier inventory control
- Elimination of nursing cover as the tray can be opened in a sterile area
- All components matched by BIOPTIMAL for optimum compatibility

Contents of the Biotray

Features high quality products at lower costs, saves time and reduces supply inventories.

- One Thermodilution Catheter / PA Monitoring Catheter
- Contamination Shield
- SAFETYWEDGE™ Balloon Device
- Venous Introducer with Dilator
- Guidewire (0.035")
- Needle 18G x 2 1/2"
- Needle 18G x 2 1/2" OTN Catheter
- Paper Towel 17 x 22"
- Gauze Swab
- Syringe Luer Slip 5cc
- Scalpel #11 Short
- Needle 25G
- Needle 22G
- Drape Minor Proc. Fen 22 x 22"
- Syringe
- Suture, Silk

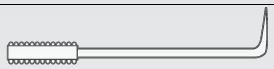
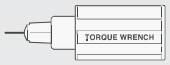
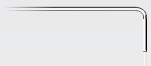
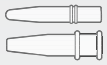
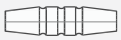
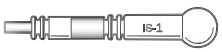


Advantage of PU catheter

- Polyurethane performs better against thrombosis, eliminating the need for Heparin coating.
- Polyurethane is tough, biocompatible, and hemocompatible. Polyurethane also outperforms many other materials in flexibility, tear resistance and abrasion resistance.
  Polyurethane is stiff when insert the catheter however after it goes into vein and contacts blood it will become soft which can reduce the risk of damage and injury to the vein wall.
- The use of Polyurethane in Bioptimal's thermodilution catheters eliminates the problems associated with other materials such as PVC, where the dangers of leachable plasticizers has become a concern.
- Polyurethane is radiopaque material which can be detected clearly to ensure correct placement of the catheter.

Total Package, Total Solution
Enjoy the benefits of the **SAFETYWEDGE™** thermodilution catheter in a convenient, fully accessorised all-in one tray.

Bioptimal™

Model Number	Receptacle (for adapting from)
AC-0160	Test Magnet 90 gauss at 1"
60007717-001	Vein Pick 
442-2	Torque Wrench (#2) 
437-246	Set of “L” Hex Wrenches (#2, #4, #6) 
4033A	DF4/IS-1/DF-1 Lead Terminal Cap 
6201	FasTac™ Flex Epicardial Lead Implant Tool
4080	Lead Removal Tool
DS0A001	Suture Sleeve (radiopaque 7.0 F) 
AC-0130	Silicone Oil
424	Medical Adhesive
FL-1056	Lead Flushing Tool
4071	Torque Tool and Tip Introducer
AC-IP-2	IS-1 Port Plug
AC-DP-3	DF-1 Port Plug 
AC-IS4PP	IS4/DF4 Port Plug
4078G	Custom Floppy Firm Guidewire, Straight, 5 cm Floppy Tip, 180 cm, 0.014", PTFE Coated
EX3151	IS4/DF4 Connector Sleeve

FasTac is a trademark of Greatbatch Medical.

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-CAG-0915-0036 I Item approved for international use only.

ST. JUDE MEDICAL

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

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-099

Product Service

EU Technical Documentation Assessment Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapter II
(Implantable Class IIb Devices and Class III Devices)

No. G70 014607 0258 Rev. 00

Manufacturer:

Abbott Medical
15900 Valley View Court
Sylmar CA 91342
USA

SRN Manufacturer - US-MF-000010383

Authorized Representative:

Abbott Medical
The Corporate Village, Da Vincilaan 11 Box F1, 1935 Zaventem, BELGIUM

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has drawn up and presented a Technical Documentation according to Annex II and III of the Regulation (EU) 2017/745 on medical devices. Details on devices covered by the Technical Documentation are described on the following page(s)
The Report referenced below summarises the result of the assessment and includes reference to relevant CS, harmonized standards and test reports. The technical documentation assessment included an assessment of the clinical evaluation assessment.
The conformity assessment has been carried out according to Annex IX chapter II of this regulation with a positive result.
Changes to the approved device, where such changes could affect the safety and performance of the device or the conditions prescribed for use of the device, shall require approval from the notified body TÜV SÜD Product Service GmbH.
In order to place the devices on the market with CE-marking, an EU Quality Management System Certificate pursuant to Annex IX chapters I and III is necessary in addition to this EU Technical Documentation Assessment Certificate. All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see:
www.tuvsud.com/ps-cert?q=cert:G70 014607 0258 Rev. 00

Report No.: 713261279

Valid from: 2023-09-18
Valid until: 2028-09-17

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2023-09-18

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123
TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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TÜV SÜD Product Service

EU Technical Documentation Assessment Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapter II
(Implantable Class IIb Devices and Class III Devices)

No. G70 014607 0258 Rev. 00

Classification:	Class III
Device Group:	J01010101 - IMPLANTABLE SINGLE CHAMBER PACEMAKERS (SC)
Basic UDI-DI:	5415067LVD0001JX
Intended Purpose:	The Abbott pacemakers are implantable pulse generators that, when used in combination with compatible pacing leads, are intended to detect and treat chronic symptomatic bradyarrhythmia and various atrioventricular conduction abnormalities by providing sensing and pacing in the right ventricle and/or right atrium.
Device(s):	Endurity™ Core PM1140

Classification:	Class III
Device Group:	J01010102 - IMPLANTABLE SINGLE CHAMBER PACEMAKERS WITH SENSOR (SR)
Basic UDI-DI:	5415067LVD0001JX
Intended Purpose:	The Abbott pacemakers are implantable pulse generators that, when used in combination with compatible pacing leads, are intended to detect and treat chronic symptomatic bradyarrhythmia and various atrioventricular conduction abnormalities by providing sensing and pacing in the right ventricle and/or right atrium.
Device(s):	Endurity™ Core PM1152 Endurity™ PM1162 Endurity MRI™ PM1172 Assurity MRI™ PM1272 Zenex MRI™ PM1282 Zenus MRI™ PM1182

Classification:	Class III
Device Group:	J01010301 - IMPLANTABLE DUAL CHAMBER PACEMAKERS (DC)
Basic UDI-DI:	5415067LVD0001JX
Intended Purpose:	The Abbott pacemakers are implantable pulse generators that, when used in combination with compatible pacing leads, are intended to detect and treat chronic symptomatic bradyarrhythmia and various atrioventricular conduction abnormalities by providing sensing and pacing in the right ventricle and/or right atrium.
Device(s):	Endurity™ Core PM2140

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EU Technical Documentation Assessment Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapter II
(Implantable Class IIb Devices and Class III Devices)

No. G70 014607 0258 Rev. 00

Classification:	Class III
Device Group:	J01010302 - IMPLANTABLE DUAL CHAMBER PACEMAKERS WITH SENSOR (DR)
Basic UDI-DI:	5415067LVD0001JX
Intended Purpose:	The Abbott pacemakers are implantable pulse generators that, when used in combination with compatible pacing leads, are intended to detect and treat chronic symptomatic bradyarrhythmia and various atrioventricular conduction abnormalities by providing sensing and pacing in the right ventricle and/or right atrium.
Device(s):	Endurity™ Core PM2152 Endurity™ PM2162 Endurity MRI™ PM2172 Assurity MRI™ PM2272 Zenex MRI™ PM2282 Zenus MRI™ PM2182

Classification:	Class III
Device Group:	J01010401 - IMPLANTABLE TRIPLE CHAMBER PACEMAKERS FOR CARDIAC RESYNCHRONIZATION (TR)
Basic UDI-DI:	5415067LVD0002JZ
Intended Purpose:	The CRT-P devices when used in combination with compatible pacing leads, are intended to detect and treat chronic symptomatic bradyarrhythmia and various atrioventricular conduction abnormalities by providing sensing and pacing in the ventricle(s) and/or right atrium. The CRT-P devices are intended to resynchronize the right and left ventricles via biventricular pacing.
Device(s):	Allure™ RF PM3222 Quadra Allure™ PM3542 Quadra Allure MP™ PM3562 Quadra Allure MP™ RF PM3262

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The validity of this certificate depends on conditions and/or is limited to the following:	./.

Revision History:

Rev.	Dated	Report	Description
00	2023-09-18	713261279	Initial issuance

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123
TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany
TÜV®

Abbott Medical
15900 Valley View Court,
Sylmar, CA 91342 USA
Tel: +1 818 3662 6822
Fax: +1 818 364 5814

00114571 Rev. A

Declaration of Conformity

Manufacturer:	Abbott Medical
Manufacturer SRN:	US-MF-000010383
Address:	15900 Valley View Court Sylmar, California 91342 United States of America
Manufacturing Site(s):	Abbott Medical 15900 Valley View Court Sylmar, California 91342 United States of America Abbott Medical Lot A Interior - #2 Rd Km. 67.5 Santana Industrial Park, Arecibo PR United States of America Abbott Medical Plot 102, Lebuhraya Kampung Jawa, Bayan Lepas Industrial Zone 11900 Penang Malaysia
European Authorized Representative:	Abbott Medical The Corporate Village Da Vincilaan 11 Box F1 1935 Zaventem, Belgium
European Authorized Representative SRN:	BE-AR-000008744

This declaration of conformity is issued under the sole responsibility of the manufacturer.

Product Trade Name(s):	See attached Product List
Model Number(s):	See attached Product List
Intended Purpose:	The Abbott pacemakers are implantable pulse generators that, when used in combination with compatible pacing leads, are intended to detect and treat

Signature: C Canan Colleen Canan Divisional Vice President Regulatory Affairs	October 12, 2023 Issue Date On behalf of Abbott Medical, signed at Sylmar, CA.

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MDR Declaration of Conformity

	chronic symptomatic bradyarrhythmia and various atrioventricular conduction abnormalities by providing sensing and pacing in the right ventricle and/or right atrium. The CRT-P devices when used in combination with compatible pacing leads, are intended to detect and treat chronic symptomatic bradyarrhythmia and various atrioventricular conduction abnormalities by providing sensing and pacing in the ventricles and/or right atrium. The CRT-P devices are intended to resynchronize the right and left ventricles via biventricular pacing. The torque driver is intended to secure lead connectors and port plugs within the device header.
Risk Classification:	**Class III** as per EU MDR 2017/745 per Annex VIII
Risk Classification Rationale:	Annex VIII, Rule 8, 6th Indent
EMDN Code(s):	See attached Product list.
GMDN Code:	See attached Product list.
Basic UDI-DI:	Implantable Single and Dual Chamber Pacemakers: 5415067LVD0001JX Implantable Triple Chamber Pacemakers (CRT-P): 5415067LVD0002JZ

The products described in this declaration are in conformity with all applicable EU harmonized legislation, including:

- Regulation (EU) 2017/745, and the applicable *General Safety & Performance Requirements* in Annex 1

Common Specifications Applied:	Not Applicable. No common specifications are available for this type of device
Notified Body:	TÜV SÜD Product Service GmbH Ridlerstraße 65 80339 Munich Germany ID Number: 0123
Supporting Certificate(s):	Technical Documentation Assessment Certificate Number: G70 014607 0258 Rev. 00 Expiration Date: 2028-09-17

The signature is applied on page 1

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00114571 Rev. A

MDR Declaration of Conformity

	EU Quality Management System Certificate: G12 014607 0255 Rev. 05 Expiration Date: 2027-08-14
Original CE Mark Date:	See attached Product List.
Conformity Assessment:	EU MDR 2017/745, Annex IX

The products in the attached Declaration of Conformity Product List are approved under EC Certificate G70 014607 0258 Rev. 00.

Declaration of Conformity Product List

Model No.	Product Trade Name	Original CE Mark Date	EMDN Code	GMDN Code	Basic UDI-DI
PM1140	Endurity™ Core	2015-07-24	J01010101	47267	5415067LVD0001JX
PM1152	Endurity™ Core		J01010101	47267	5415067LVD0001JX
PM2140	Endurity™ Core		J01010301	47265	5415067LVD0001JX
PM2152	Endurity™ Core		J01010301	47265	5415067LVD0001JX
PM1162	Endurity™	2014-12-18	J01010101	47267	5415067LVD0001JX
PM2162	Endurity™		J01010301	47265	5415067LVD0001JX
PM1172	Endurity MRI™		J01010101	47267	5415067LVD0001JX
PM2172	Endurity MRI™		J01010301	47265	5415067LVD0001JX
PM1272	Assurity MRI™		J01010101	47267	5415067LVD0001JX
PM2272	Assurity MRI™		J01010301	47265	5415067LVD0001JX
PM2282	Zenex MRI™	2018-10-12	J01010301	47265	5415067LVD0001JX
PM1282	Zenex MRI™		J01010101	47267	5415067LVD0001JX
PM2182	Zenus MRI™		J01010301	47265	5415067LVD0001JX
PM1182	Zenus MRI™		J01010101	47267	5415067LVD0001JX
PM3222	Allure™ RF	2013-03-07	J01010401	47263	5415067LVD0002JZ
PM3542	Quadra Allure™	2016-10-21	J01010401	47263	5415067LVD0002JZ
PM3262	Quadra Allure MP™	2013-03-07	J01010401	47263	5415067LVD0002JZ
PM3562	Quadra Allure MP™	2016-10-21	J01010401	47263	5415067LVD0002JZ

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

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

TÜV SÜD Product Service

Certificate

No. Q5 014607 0231 Rev. 03

Holder of Certificate: **Abbott Medical**
15900 Valley View Court
Sylmar CA 91342
USA

Certification Mark:

Scope of Certificate: **Design and Development, Production and Distribution of Implantable Pulse Generators and Implantable Cardioverter Defibrillators, Implantable Leads for AIMDs, Programmers for AIMDs, Application Software (external), Cardiac Rhythm Management Device Accessories (adapters, stylets, guidewires, tools, etc.)**

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q5 014607 0231 Rev. 03

Report No.: 713237689

Valid from: 2022-08-12
Valid until: 2025-03-31

Date, 2022-08-12

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

TÜV SÜD
Product Service

Certificate

No. Q5 014607 0231 Rev. 03

Applied Standard(s):

EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

Facility(ies):

Abbott Medical
15900 Valley View Court, Sylmar CA 91342, USA

Design and Development, Production and Distribution of Implantable Pulse Generators and Implantable Cardioverter Defibrillators, Implantable Monitoring and Recording Systems, Implantable Leads for AIMDs, Programmers for AIMDs, Application Software (external), Cardiac Rhythm Management Device, Accessories (adapters, stylets, guidewires, tools, etc)

Abbott Medical
645 Almanor Avenue, Sunnyvale CA 94085, USA

Design and Development of Implantable Pulse Generators and Implantable Cardioverter Defibrillators, Implantable Monitoring and Recording Systems, Implantable Leads for AIMDs, Programmers for AIMDs, Application Software (external), Cardiac Rhythm Management Device Accessories (adapters, stylets, guidewires, tools, etc.); and returned product analysis of Implantable Cardioverter Defibrillators, Implantable Monitoring and Recording Systems and Cardiac Rhythm Management Device Accessories

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

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CERTIFICATE

This is to certify that

SANTE INTERNATIONAL S.A.

Str. Mantuleasa nr. 33, Sector 2
023961 Bucuresti
Romania

has implemented and maintains a **Quality Management System**.

Scope:
Import, trade and storage of medical and laboratory equipment, disinfectants, laboratory reagents, cardiovascular surgery devices, service for medical and laboratory equipment. Consulting for state and private medical units.

Through an audit, documented in a report, it was verified that the management system fulfills the requirements of the following standard:

ISO 9001 : 2015

Certificate registration no.	497269 QM15
Valid from	2021-06-16
Valid until	2024-06-15
Date of certification	2021-06-16

DQS GmbH

Markus Bleher
Managing Director

Accredited Body: DQS GmbH, August-Schanz-Straße 21, 60433 Frankfurt am Main, Germany
Administrative Office: DQS Romania, Str. Barbatului nr. 11, 020565 Bucharest - Romania

Annex to certificate
Registration No. 497269 QM15

SANTE INTERNATIONAL S.A.

Str. Mantuleasa nr. 33, Sector 2
023961 Bucuresti
Romania

Location	Scope
075906 **Sante International SA** **Sos. Mihai Bravu nr. 7, bl. P37-P37A, sector 2** **021303 Bucuresti** **Romania**	Import, trade and storage of medical and laboratory equipment, disinfectants, laboratory reagents, cardiovascular surgery devices. Consulting for state and private medical units.
497270 **Sante International SA** **Str. Pupitrului, nr. 81, sect. 3** **033036 Bucuresti** **Romania**	Storage of medical and laboratory equipment, disinfectants, laboratory reagents,cardiovascular surgery devices, service for medical and laboratory equipment. Consulting for state and private medical units.
31050285 **Sante International SA** **Calea Ghirodei, nr. 36** **300327 Timisoara** **Romania**	Trade of medical and laboratory equipment, disinfectants, laboratory reagents, cardiovascular surgery devices, service for medical and laboratory equipment. Consulting for state and private medical units.
31050284 **Sante International SA** **Calea Dorobantilor, nr. 111** **400609 Cluj-Napoca** **Romania**	Trade of medical and laboratory equipment, disinfectants, laboratory reagents, cardiovascular surgery devices, service for medical and laboratory equipment. Consulting for state and private medical units.
31050283 **Sante International SA** **Str. Lascar Catargi, nr. 37** **700107 Iasi** **Romania**	Trade of medical and laboratory equipment, disinfectants, laboratory reagents, cardiovascular surgery devices, service for medical and laboratory equipment. Consulting for state and private medical units.

This annex (edition:2021-06-16) is only valid in connection with the above-mentioned certificate.