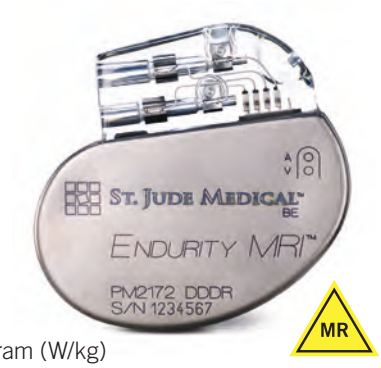
Endurity MRI™

Dual-Chamber Pacemaker



Product Highlights - Pacemaker

The Endurity MRI™ pacemaker is designed to allow patients to undergo MRI scans:

- When combined with the Tendril MRI™ LPA1200M lead, the MRI-ready device:
  - Allows full-body, MRI scans*
  - Permits a maximum whole body averaged specific absorption rate (SAR) of 4 Watts per kilogram (W/kg)
- When combined with Tendril™ 2088TC or IsoFlex™ Optim™ 1944/1948 Leads, the MRI Ready device:
  - Allows MRI scans*
  - Permits a maximum whole body averaged specific absorption rate (SAR) of 2 Watts per kilogram (W/kg)
- Physician preferred size and physiologic shape minimize pocket size
- Outstanding longevity provides 9,7 years of service life,[10] which is supported by an 8-year warranty[11]
- AutoCapture™ pacing system offers the maximum in threshold adaptability and patient safety with ventricular Beat-by-Beat™ capture confirmation. The AutoCapture pacing system automatically delivers a 5,0 V backup safety pulse when noncapture is detected, and it may be programmed to either a bipolar or unipolar configuration
- A suite of state-of-the-art features – complete automaticity (atrial and ventricular), Ventricular Intrinsic Preference (VIP™) technology, the AF Suppression™ algorithm and Sense*Ability*™ technology – is designed to deliver optimal therapy for patients at implant and throughout their lives
- The only pacemaker with programmable AT/AF alerts specifically indicated for detecting atrial tachyarrhythmias, which have been found to be associated with an increased risk of stroke in elderly, hypertensive, pacemaker patients without prior history of AF[12]
- Real-time electrogram (EGM) waveform, as well as the associated event markers that precede and follow a specific triggering event, can be programmed to automatically record up to 14 minutes of stored EGMs when encountering one or more programmable trigger options
- 6-month ERI-EOL interval
- An optional, easy-to-use hand-held device (SJM MRI Activator™ device) can be used to program the device to pre-approved MRI settings pre- and post-MRI scan, decreasing the number of workflow steps and increasing clinic efficiency

* See MRI Conditional Parameters

Ordering Information - MRI-Ready Pacing System

Model Number	Description	Dimensions (H x W x T, mm)	Weight (g)	Volume (cc)	Connector
PM2172	Endurity MRI™ Pacemaker	46 x 50 x 6	19	10,4 (± 0,5)	IS-1

Model Number	Description	Insulation	Fixation	Min. Introducer (F)	Connector	Length (cm)
LPA1200M	Tendril MRI Pacing Leads	Optim™	Ext/Ret helix	8	IS-1 bipolar	46, 52, 58
2088TC	Tendril STS Pacing Leads	Optim™	Ext/Ret helix	6	IS-1 bipolar	46, 52, 58
1944 (J-shaped)	IsoFlex Optim Pacing Leads	Optim™	Tines	7	IS-1 bipolar	46,52
1948 (Straight)	IsoFlex Optim Pacing Leads	Optim™	Tines	7	IS-1 bipolar	52, 58

Indications: Implantation is indicated in one or more of the following permanent conditions: syncope, presyncope, fatigue, disorientation due to arrhythmia/bradycardia or any combination of those symptoms. ***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 AV conduction disturbances of A-V block or sinus arrest, chronic atrial fibrillation or those conditions in which the 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: ***Dual-chamber pulse generators*** are contraindicated in patients with an implanted cardioverter-defibrillator. ***Rate-Adaptive Pacing*** may be inappropriate 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.

Potential Adverse Events: The following are potential complications associated with the use of any pacing system: arrhythmia, heart block, thrombosis, threshold elevation, valve damage, pneumothorax, myopotential sensing, vessel damage, air embolism, body rejection phenomena, cardiac tamponade or perforation, formation of fibrotic tissue/local tissue reaction, inability to interrogate or program a device because of programmer malfunction, infection, interruption of desired device function due to electrical interference, 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, device migration, pocket erosion or hematoma, pectoral muscle stimulation, phrenic nerve or diaphragmatic stimulation. The following, in addition to the above, are potential complications associated with the use of rate-modulated pacing systems: inappropriate, rapid pacing rates due to sensor failure or to the detection of signals other than patient activity, loss of activity-response due to sensor failure, palpitations with high-rate pacing.

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

ST. JUDE MEDICAL

Endurity MRI™

Dual-Chamber Pacemaker

Product Specifications - Pacemaker

PHYSICAL SPECIFICATIONS	
Model	**PM2172**
Telemetry	Inductive
Dimensions (mm)	46 x 50 x 6
Weight (g)	19
Volume (cc)	10,4[1]
Connector	IS-1

Remote Monitoring

Compatible with Merlin@home™ Transmitter

PARAMETER	SETTINGS
Rate/Timing	
Atrial Pace Refractory (ms)	190-400 in steps of 30; 440; 470[2]
Atrial Sense Refractory (ms)	93; 125; 157; 190-400 in steps of 30; 440; 470[2]
Paced AV Delay (ms)	25; 30-200 in steps of 10; 225-300 in steps of 25; 350
Base Rate (min^{-1})	30-130 in steps of 5; 140-170 in steps of 10
Far-Field Protection Interval (ms)	16[3]
Hysteresis Rate (min^{-1})	Off; 30[4]-150 in steps of 5
Search Interval (min)	Off; 1; 5; 10; 15; 30
Cycle Count	1-16 in steps of 1
Intervention Rate (min^{-1})	Off; Same as Base Rate; 80-120 in steps of 10; Intrinsic +0; Intrinsic +10; Intrinsic +20; Intrinsic +30
Intervention Duration (min)	1-10 in 1 minute intervals
Recovery Time	Fast; Medium; Slow; Very Slow
Maximum Tracking Rate (min^{-1})	90-130 in steps of 5; 140-210 in steps of 10
Mode	AOO(R); AAI(R); AAT(R); VOO(R); VVI(R); VVT(R); VDD(R); DOO(R); DVI(R); DDI(R); DDD(R); Pacing Off
Post Ventricular Atrial Blanking (ms)	60-200 in steps of 10; 225; 250
PVARP (ms)	125-500 in steps of 25
Sensed AV Delay (ms)	25; 30-200 in steps of 10; 225-325 in steps of 25
Rest Rate (min^{-1})	Off; 30-150 in steps of 5
Rate Responsive AV Delay	Off; Low; Medium; High
Rate Responsive PVARP/VREF	Off; Low; Medium; High
Shortest AV Delay (ms)	25-50 in steps of 5; 60-120 in steps of 10
Shortest PVARP/VREF (ms)	125-475 in steps of 25
Ventricular Blanking (ms)	Auto, 12-52 in steps of 4
Ventricular Pace/Sense Refractory[5] (Fixed) (ms)	125; 160-400 in steps of 30; 440; 470; 500 [2]
Output/Sensing	
ACap™ Confirm	On; Off; Monitor
Primary Pulse Configuration	Bipolar
Backup Pulse Configuration	Bipolar
Backup Pulse Amplitude (V)	5,0
Search Interval (hours)	8; 24
A or V Pulse Amplitude (V)	0,25-4,0 in steps of 0,25; 4,5-7,5 in steps of 0,5
A or V Pulse Width (ms)	0,05; 0,1-1,5 in steps of 0,1
A or V Pulse Configuration	Unipolar (tip-case); Bipolar (tip-ring)
A or V Sense Configuration	Unipolar Tip (tip-case); Bipolar (tip-ring); Unipolar Ring (ring-case)
Ventricular AutoCapture™ Pacing System	On; Off
Primary Pulse Configuration	Unipolar; Bipolar
Backup Pulse Configuration	Unipolar; Bipolar
Backup Pulse Amplitude (V)	5,0[3]
Search Interval (hours)	8; 24
AutoCapture Paced/Sensed AV Delay (ms)	50/25; 100/70; 120/100
Atrial Sensitivity (mV)	0,1-0,4[6] in steps of 0,1; 0,5; 0,75-2,0 in steps of 0,25; 2,5-4,0 in steps of 0,5; 5,0[7]
Ventricular Sensitivity (mV)	0,5-5,0 in steps of 0,5; 6-10 in steps of 1,0; 12,5[7]
SenseAbility™ 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
Rate-Modulated Parameters	
Maximum Sensor Rate (min^{-1})	80-150 in steps of 5; 160-180 in steps of 10
Reaction Time	Very Fast; Fast; Medium; Slow
Recovery Time	Fast; Medium; Slow; Very Slow
Sensor	On; Off; Passive
Slope	Auto (-1); Auto (+0); Auto (+1); Auto (+2); Auto (+3); 1-16 in steps of 1
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
AF Management	
AF Suppression™ Algorithm	Off; On
Lower Rate Overdrive (min^{-1})	10[3]
Upper Rate Overdrive (min^{-1})	5[3]
No. of Overdrive Pacing Cycles	15-40 in steps of 5
Rate Recovery (ms)	8; 12[3]
Maximum AF Suppression Rate (min^{-1})	80-200 in steps of 10; 225-300 in steps of 25
Atrial Tachycardia Detection Rate (min^{-1})	110-200 in steps of 10; 225-300 in steps of 25
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	
A and V Lead Monitoring	Monitor; Auto Polarity Switch
A and V Low Impedance Limit (Ω)	100-500 in steps of 25
A and V High Impedance Limit (Ω)	750-2500 in steps of 250; 3000
Lead Type	Uncoded; Unipolar; Bipolar
Magnet Response	Off; Battery Test
Negative AV Hysteresis Search (ms)	Off; -10 to -120 in steps of 10
NIPS Options	
Stimulation Chamber	Atrial; Ventricular
Coupling Interval (ms)	100-800 in steps of 10[8]
S1 Count	2-25 in steps of 1
SI[9]; S2; S3 and S4 Cycle (ms)	Off; 100-800 in steps of 10 (Fixed or Adaptive)
Ventricular Support Rate (min^{-1})	Off; 30-95 in steps of 5
Sinus Node Recovery Delay (sec)	1; 2; 3; 4; 5
PMT Options	Off; Passive; Atrial Pace[2]
PMT Detection Rate (min^{-1})	90-180 in steps of 5
PVC Response	Off; Atrial Pace[2]
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
Ventricular Safety Standby	Off; On
Diagnostic Trends	AT/AF Activity; Exercise; Lead Impedance; P and R Wave; A and V Threshold
MRI Settings	
MRI Mode	AOO; VOO; DOO; Pacing Off
MRI Base Rate	30-120 bpm in steps of 5 bpm
MRI Paced AV Delay	25 ms; 30-120 ms in steps of 10 ms
MRI Atrial Pulse Configuration	Bipolar
MRI Atrial Pulse Amplitude	5,0 V; 7,5 V
MRI Atrial Pulse Width	1,0 ms
MRI RV Pulse Configuration	Bipolar
MRI RV Pulse Amplitude	5,0 V; 7,5 V
MRI RV Pulse Width	1,0 ms

MRI Conditional Parameters

Lead	Lead Lengths	Scan Exclusion Zone
Tendril MRI LPA1200M Lead	46, 52, 58 cm	No scan exclusion zone
Tendril 2088TC Lead	46, 52, 58 cm	Isocenter must be inferior to L4 or 10 cm superior to C1
IsoFlex 1944 Lead	46, 52 cm	Isocenter must be inferior to L4 or superior to C1
IsoFlex1948 Lead	52, 58 cm	Isocenter must be inferior to L4 or superior to C1

Lead	Lead Lengths	Magnet	SAR	
Tendril MRI LPA1200M Lead	46, 52, 58 cm	1.5T	≤ 4 W/kg	MR 1.5T SAR 4
Tendril 2088TC Lead	46, 52, 58 cm	1.5T	≤ 2 W/kg	MR 1.5T SAR 2
IsoFlex 1944 Lead	46, 52 cm	1.5T	≤ 2 W/kg	
IsoFlex 1948 Lead	52, 58 cm	1.5T	≤ 2 W/kg	

1. ± 0,5 cc
2. Programming options dependent on pacing mode.
3. This parameter is not programmable.
4. The highest available setting for hysteresis rate will be 5 min^{-1} below the programmed base rate.
5. In dual-chamber modes, the maximum ventricular refractory period is 325 ms.
6. Values 0,1-0,4 not available in a unipolar sense configuration.
7. Sensitivity is with respect to a 20 ms haversine test signal.
8. During atrial NIPS in dual-chamber modes, the shortest Coupling Interval will be limited by the programmed AV/PV delay.
9. S1 Burst Cycle is applied at the preprogrammed S1 cycle length.
10. A,V = 2,5 V @ 0,4 ms; 500 ohms; 100% DDD pacing @ 60 bpm; AutoCapture™ Pacing System OFF; SEGMs ON
11. Terms and conditions apply; refer to the warranty for details.
12. Healey JS, Connolly SJ, Gold MR, et al. on behalf of the ASSERT investigators. Sub-clinical atrial fibrillation and the risk of stroke: ASymptomatic atrial fibrillation and Stroke Evaluation in pacemaker patients and the AF Reduction atrial pacing Trial (ASSERT). N Engl J Med 2012; 366:120 –129.

Customer Support: 46-8-474-4756

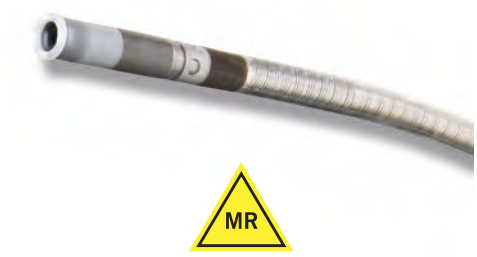
Brief Summary: Prior to using these devices, please review the Instructions for Use for a complete listing of indications, contraindications, warnings, precautions, potential adverse events and directions for use. Devices depicted may not be available in all countries. Check with your St. Jude Medical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

SJM-END-0814-0003(3) I This document is approved for international use only.

ST. JUDE MEDICAL™

Tendril™ STS

Pacing Lead



Product Highlights - Pacing Lead

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

Ordering Information - MRI-Ready Pacing System

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

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

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

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

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

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

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

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

ST. JUDE MEDICAL

Tendril™ STS

Pacing Lead

Product Specifications - Pacing Leads

PHYSICAL SPECIFICATIONS

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

In Pack

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

Accessory Kits

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

MRI Conditional Parameters

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

*MP35N is a trademark of SPS Technologies, Inc.

Customer Support: 46-8-474-4756

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™

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

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

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

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

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

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®

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

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:	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

.

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.

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

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

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

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

The signature is applied on page 1

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

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

TÜV®

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. Bratului 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.