#### IMPLANTABLE CARDIOVERTER DEFIBRILLATOR (ICD) DEVICES

# Ellipse<sup>™</sup> VR

Single-chamber Implantable Cardioverter Defibrillator (ICD)





## **Product Highlights**

- MRI Ready device has been tested for safe performance of an MRI scan using a 1,5 Tesla field-strength MRI scanner when used in combination with an MRI Conditional lead<sup>1,2</sup>
- Improved shape with reduced volume and thickness
- · Parylene coating for improved abrasion resistance
- DynamicTx<sup>™</sup> Over-current Detection Algorithm automatically changes shock configurations to ensure delivery of high voltage therapy when high current is detected
- Cold can programmability provides an additional RV-SVC shock configuration to decouple the can from the shocking vector parameters in cases of lead problems
- ShockGuard<sup>™</sup> technology with DecisionTx<sup>™</sup> programming designed to reduce inappropriate therapy and minimise the need for programming adjustments at implant
  - SecureSense™ RV lead noise discrimination algorithm detects sustained and short bursts of lead noise that would otherwise go unnoticed or potentially lead to one or more inappropriate shocks
  - Far Field MD<sup>™</sup> morphology discrimination improves SVT and VT discrimination for reduced inappropriate therapies
- Low frequency attenuation filter designed to enhance sensing performance and may reduce the possibility of oversensing T waves

- SenseAbility<sup>™</sup> sensing algorithm feature provides flexibility to fine-tune programming around T wave oversensing without decreasing sensitivity
- DF4 connector designed to streamline defibrillation connections into a single terminal pin and reduce the number of set screws
- CorVue<sup>™</sup> congestion monitoring feature monitors the intrathoracic impedance in multiple vectors for improved accuracy, and it provides the option for both patient and physician alerts
- Antitachycardia pacing (ATP) while charging and prior to charging in the VF zone further extends the programming options for terminating tachyarrhythmias without a high voltage shock
- ST monitoring capability provides unprecedented, continuous insight into significant ST shift events and associated ventricular arrhythmias through enhanced monitoring of iEGM and ST-segment as a diagnostic tool to help guide appropriate clinical action
- 36 J delivered energy safety shock option can provide a greater DFT safety margin
- DeFT Response<sup>™</sup> technology offers the most noninvasive options for managing high DFTs
- QHR<sup>†</sup> chemistry battery provides greater capacity for enhanced longevity and improved charge time performance compared to previous SVO batteries

## **Ordering Information**

Contents: Single-chamber Implantable Cardioverter Defibrillator (ICD)

MODEL NUMBER	DIMENSIONS (H × W × T, MM)	WEIGHT (G)	VOLUME (CC)	CONNECTOR DEFIBRILLATION	CONNECTOR SENSE/PACE
CD1377-36C	68 × 51 × 12	66	31	DF1	IS-1
CD1377-36QC*	66 × 51 × 12	67	30	DF4	DF4

<sup>\*</sup>Indicates models that are MRI Conditional<sup>1,2</sup>

Indications: The devices are intended to provide ventricular antitachycardia pacing and ventricular defibrillation for automated treatment of life-threatening ventricular arrhythmias. Contraindications: Contraindications for use of the implantable cardioverter defibrillator include ventricular tachyarrhythmias resulting from transient or correctable factors such as drug toxicity, electrolyte imbalance, or acute myocardial infarction.

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

### Ellipse™ VR

Single-chamber Implantable Cardioverter Defibrillator (ICD)

#### **Product Specifications**

#### PHYSICAL SPECIFICATIONS

Models	CD1377-36C	CD1377-36QC
Telemetry	RF	RF
Delivered/Stored Energy (J)	36/39	36/39
Volume (cc)	31	30
Weight (g)	66	67
Size (mm)	68 × 51 × 12	66 × 51 × 12
Defibrillation Lead	DF1	DF4
Connections		
Sense/Pace Lead Connections	IS-1	DF4
High Voltage Can	Electrically active titanium can	Electrically active titanium can
Coating	Parylene	Parylene
MRI Conditional	No	Yes-MRI Ready

#### PARAMETER SETTINGS

Sensing/Detection	
SenseAbility™ Sensing	Automatic sensitivity control adjustment for
Algorithm Technology	ventricular events
Low Frequency Attenuation	On; Off
Threshold Start	(Post-Sensed; Ventricular) 50; 62,5; 75; 100%;
	(Post-Paced; Ventricular) Auto; 0,2-3,0 mV
Decay Delay	(Post-Sense/Post-Pace; Ventricular) 0-220
Ventricular Sense Refractory (ms)	125; 157
Detection Zones	3 zone programming - 1 zone, 2 zones or 3
	zones (VT-1, VT-2, VF)
SVT Discriminators	Sudden Onset; Interval Stability; Sinus Interval
	History; Morphology Discrimination (Far Field
	MD™ Morphology Discrimination or Original
	MD) with Manual (Original MD) or Automatic
	Template Update
Discrimination Modes	On; Passive; Off
SVT Threshold	150-240 min <sup>-1</sup>
SVT Timeout	0,25-5 min
Monitor Mode	Detection, discrimination and diagnostics, no
	therapy delivery (VT or VT-1 zone)
Reconfirmation	Continuous sensing during charging
Lead Noise Discrimination	SecureSense™ RV lead noise discrimination
	algorithm
	(On; On with Timeout; Passive; Off)

	Antitachycardia	Pacing	Therap
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Antitachycardia Pacing Therapy	
ATP Configurations	Ramp; Burst; Scan; 1 or 2 schemes per VT zone
ATP in VF Zone	ATP While Charging; ATP Prior to Charging;
	Off
ATP Upper Rate Cutoff	150-300 min <sup>-1</sup>
Burst Cycle Length	Adaptive; Readaptive or Fixed
Min. Burst Cycle Length (ms)	150-400 in increments of 5
Number of Bursts	1-15
Number of Chimaeli	2 20

Number of Stimuli 2-20 Add Stimuli per Burst On; Off ATP Pulse Amplitude (V) 7,5 Independent from Bradycardia and Post-Therapy Pacing ATP Pulse Width (ms) 1,0 or 1,5 Independently Programmable from Bradycardia and Post-Therapy Pacing

#### **High Voltage Therapy**

DynamicTx<sup>™</sup> Over-current On; Off Detection Algorithm DeFT Response™ Technology High Voltage Output Mode Programmable pulse width for P1/P2 and tilt Fixed Pulse Width; Fixed Tilt Biphasic; Monophasic Cathode (-); Anode (+) Waveform RV Polarity Electrode Configuration RV to Can; RV to SVC/Can; RV to SVC

#### Bradycardia Pacing

Permanent Modes Off; VVI(R) Temporary Modes Rate-Adaptive Sensor Off; VVI; VOO On; Off; Passive Programmable Rate Parameters

Off; Base Rate (min-1); Rest Rate (min-1); Maximum Sensor Rate (min-1): Pulse Amplitude (RV) (V); Pulse Width (RV) (ms); Hysteresis Rate (min-1); Rate Hysteresis with Search Ventricular AutoCapture

Pacing System

#### Post-Therapy Pacing (Independently Programmable from Bradycardia and ATP)

Post-Shock Pacing Mode	Off; VVI	
Post-Shock Base Rate (min-1)	30-100 in increments of 5	
Post-Shock Pacing Duration (min)	Off; 0,5; 1; 2,5; 5; 7,5; or 10	
Device Testing/Induction Methods		

DC Fibber™ Pulse Duration (sec)

Burst Fibber Cycle Length (ms) Noninvasive Programmed 20-100 2-25 stimuli with up to 3 extra stimuli

Stimulation (NIPS)

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

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‡ Indicates a third party trademark, which is property of its respective owner.

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#### **Patient Notifiers**

Programmable Notifiers (On; Off)	Device at ERI; Charge Time Limit Reached;
	Possible HV Circuit Damage; Ventricular Lead
	Impedance Out of Range; High Voltage Lead
	Impedance Out of Range; %V pacing; CorVue™
	Congestion Monitoring Trigger; SecureSense
	lead noise detected, non-sustained lead noise
	detected, ST Episodes (Type I only)
Device Parameter Reset	On
Entry into Backup VVI Mode	On
Vibration Duration (sec)	2; 4; 6; 8; 10; 12; 14; 16
Number of Vibrations per	2
Notification	
Number of Notifications	1-16
Time Between Notifications (hours)	10; 22

#### **Electrograms and Diagnostics**

Stored Electrograms	Up to 45 minutes including up to one minute programmable pre-trigger data per VT/VF diagnosis/detection electrograms; triggers include: diagnosis, detection; therapy; PC shock delivery; noise reversion; magnet reversion; morphology template verification; lead noise detected; non-sustained lead noise detected; NSVT/NSVF
Therapy Summary	Diagram of therapies delivered
Episodes Summary	Directory listing of up to 60 episodes with access to more details including stored electrograms
Lifetime Diagnostics	History of bradycardia events and device- initiated charging
Ventricular HV Lead Impedance Trend	Multi-Vector Trend Data
Histograms	Event Histogram; Ventricular Heart Rate Histogram; Exercise and Activity Trending; DirectTrend™ reports up to 1 year
Real-Time Measurements (RTM)	Pacing lead impedances; high voltage lead impedances; and signal amplitudes
ST Monitoring	ST Histogram Data; Long-term ST Deviation

ST Histogram Data; Long-term ST Deviation Trend; ST Episode Log; ST Episode Details; 24-Hour ST and HR Trend; ST EGM Baseline and Snapshots prior to ST Episode; VT/VF; Interrogation (Snapshots and 24-hour trend at time of interrogation)

CorVue™ Congestion Monitoring On; Off CorVue Congestion Trigger 8-18 days

#### MRI Scan Parameters

If the implanted system is comprised of a combination of leads that have differing RF Power (SAR), scan region and/or additional considerations, use the most restrictive of each to determine the overall set of scan conditions applicable for the total system.

			SCAN	REGION
IMPLANTED ELECTRODE		RF POWER	PACING MODE	
LOW VOLTAGE LEAD MODEL	HIGH VOLTAGE LEAD MODEL	(SAR)	OFF	AOO, VOO OR DOO
Tendril MRI <sup>rss</sup> Lead LPA1200M (46, 52, 58 cm)	Durata™ Defibrillation Lead 7120Q (58, 65 cm) 7122Q (58, 65 cm) Optisure™ Lead LDA210Q (58, 65 cm) LDA220Q (58, 65 cm)	Normal	Full Body	Superior: Isocenter at or above eye leve Inferior: Isocenter at or below L2 vertebra
Tendril™ STS Pacing Lead 2088TC (46, 52 cm)	Durata <sup>™</sup> Defibrillation Lead 7120Q (58, 65 cm) 7122Q (58, 65 cm) Optisure <sup>™</sup> Lead LDA210Q (58, 65 cm) LDA220Q (58, 65 cm)	Operating Mode**	Superior: Isocenter at or above eye level Inferior: Isocenter at or below L2 vertebra	

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

1. MRI Conditional Field Strength: 1,5 Tesla.

 $2. \ See \ MRI \ procedure \ information \ for \ approved \ MR \ Conditional \ systems \ device/lead \ combinations \ and$ 



# Ellipse<sup>™</sup> DR

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- Improved shape with reduced volume and thickness
- · Parylene coating for improved abrasion resistance
- DynamicTx<sup>™</sup> Over-current Detection Algorithm automatically changes shock configurations to ensure delivery of high voltage therapy when high current is detected
- Cold can programmability provides an additional RV-SVC shock configuration to decouple the can from the shocking vector parameters in cases of lead problems
- ShockGuard™ technology with DecisionTx™ programming designed to reduce inappropriate therapy and minimise the need for programming adjustments at implant
  - SecureSense™ RV lead noise discrimination algorithm detects sustained and short bursts of lead noise that would otherwise go unnoticed or potentially lead to one or more inappropriate shocks
  - Far Field MD<sup>™</sup> morphology discrimination and chamber onset discrimination improve SVT and VT discrimination for reduced inappropriate therapies
- Low frequency attenuation filter designed to enhance sensing performance and may reduce the possibility of oversensing T waves

- SenseAbility<sup>™</sup> sensing algorithm feature provides flexibility to fine-tune programming around T wave oversensing without decreasing sensitivity
- DF4 connector designed to streamline defibrillation connections into a single terminal pin and reduce the number of set screws
- CorVue<sup>™</sup> congestion monitoring feature monitors the intrathoracic impedance in multiple vectors for improved accuracy, and it provides the option for both patient and physician alerts
- Antitachycardia pacing (ATP) while charging and prior to charging in the VF zone further extends the programming options for terminating tachyarrhythmias without a high voltage shock
- ST monitoring capability provides unprecedented, continuous insight into significant ST shift events and associated ventricular arrhythmias through enhanced monitoring of iEGM and ST segment as a diagnostic tool to help guide appropriate clinical action
- 36 J delivered energy safety shock option can provide a greater DFT safety margin
- DeFT Response<sup>™</sup> technology offers the most noninvasive options for managing high DFTs
- QHR<sup>†</sup> chemistry battery provides greater capacity for enhanced longevity and improved charge time performance compared to previous SVO batteries

## Ordering Information

Contents: Dual-chamber Implantable Cardioverter Defibrillator (ICD)

MODEL NUMBER	DIMENSIONS (H × W × T, MM)	WEIGHT (G)	VOLUME (CC)	CONNECTOR DEFIBRILLATION	CONNECTOR SENSE/PACE
CD2377-36C	69 × 51 × 12	66	31	DF1	IS-1
CD2377-36QC*	70 × 51 × 12	68	31	DF4	IS-1; DF4

<sup>\*</sup>Indicates models that are MR Conditional1,2

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

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

Adverse Events: Implantation of the implantable cardioverter defibrillator, like that of any other device, involves risks, some possibly life-threatening. These include but are not limited to the following: acute hemorrhage/bleeding, air emboli, arrhythmia acceleration, cardiac or venous perforation, cardiogenic shock, cyst formation, erosion, exacerbation of heart failure, extrusion, fibrotic tissue growth, fluid accumulation, hematoma formation,

histotoxic reactions, infection, keloid formation, myocardial irritability, nerve damage, pneumothorax, thromboemboli, venous occlusion. Other possible adverse effects include mortality due to: component failure, device-programmer communication failure, lead abrasion, lead dislodgment or poor lead placement, lead fracture, inability to defibrillate, inhibited therapy for a ventricular tachycardia, interruption of function due to electrical or magnetic interference, shunting of energy from defibrillation paddles, system failure due to ionising radiation. Other possible adverse effects include mortality due to inappropriate delivery of therapy caused by: multiple counting of cardiac events including Twaves, P waves, or supplemental pacemaker stimuli. Among the psychological effects of device implantation are imagined pulsing, dependency, fear of inappropriate pulsing, and fear of losing pulse capability.

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

### Ellipse™ DR

Dual-chamber Implantable Cardioverter Defibrillator (ICD)

#### **Product Specifications**

#### PHYSICAL SPECIFICATIONS

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

Automatic sensitivity control adjustment for atrial and ventricular events On; Off

(Post-Sensed; Atrial) 50; 62,5; 75; 100%; (Post-Paced; Atrial) 0,2–3,0 mV; (Post-Sensed; Ventricular) 50; 62,5; 75; 100%; (Post-Paced; Ventricular) Auto; 0,2–3,0 mV

Continuous sensing during charging SecureSense<sup>®</sup> RV lead noise discrimination algorithm (On; On with Timeout; Passive; Off)

7,5 Independent from Bradycardia and Post-Therapy Pacing 1,0 or 1,5 Independently Programmable from Bradycardia and Post-Therapy Pacing

(Post-Sense/Post-Pace; Atrial/Ventricular) 0-220

AE Monogomont	

AF Suppression™ Pacing On; Off No. of Overdrive Pacing Cycles 15-40 in steps of 5 Maximum AF Suppression Rate 15-40 in steps of 5

Sensing/Detection

SenseAbility™ Sensing Algorithm Technology Low Frequency Attenuation Threshold Start

Decay Delay

Ventricular Sense Refractory (ms) Detection Zones

SVT Discriminators

 $\begin{array}{l} 125;157\\ 3 \ zone\ programming-1\ zone, 2\ zones\ or\ 3\ zones\\ (VT-1,VT-2,VF)\\ AV\ Rate\ Branch;\ Arrhythmia\ Onset\ (Chamber\ Onset\ or\ Sudden\ Onset);\ Interval\ Stability;\ AV\ Association;\ Morphology\ Discrimination\ (Far\ Field\ MD^m\ Morphology\ Discrimination\ or\ Original\ MD)\ with\ Manual\ (original\ MD\ only)\ or\ Automatic\ Template\ Update\ Detection,\ discrimination\ and\ diagnostics,\ no\ therapy\ delivery\ (VT\ or\ VT-1\ zone)\ On;\ Passive;\ Off\ 150-240\ min^3\\ \end{array}$ Monitor Mode Discrimination Modes SVT Threshold 150-240 min-1 SVT Timeout

Reconfirmation Lead Noise Discrimination

Antitachycardia Pacing Therapy ATP Configurations Ramp; Burst; Scan; 1 or 2 schemes per VT zone

1-15

2-20

On; Off

On: Off

ATP in VF Zone ATP Upper Rate Cutoff ATP While Charging; ATP Prior to Charging; Off 150-300 min<sup>-1</sup> Burst Cycle Length Adaptive; Readaptive or Fixed 150-400 in increments of 5

Min. Burst Cycle Length (ms) Number of Bursts Number of Stimuli Add Stimuli per Burst

ATP Pulse Amplitude (V)

ATP Pulse Width (ms)

High Voltage Therapy DvnamicTx™ Over-current

Detection Algorithm DeFT Response™ Technology High Voltage Output Mode Waveform RV Polarity

Electrode Configuration Bradycardia Pacing

Permanent Modes

Temporary Modes Rate-Adaptive Sensor Programmable Rate and Delay Parameters

Ventricular AutoCapture<sup>™</sup> Pacing System
ACap™ Confirm Feature
QuickOpt™ Timing Cycle
Optimisation

Auto Mode Switch (AMS) Atrial Tachycardia Detection Rate (min<sup>-1</sup>) AMS Base Rate (min<sup>-1</sup>) Auto PMT Detection/Termination

Rate Responsive PVARP/VREF Ventricular Intrinsic Preference (VIP™)  $\begin{aligned} & \text{Off; DDD(R); DDI(R); VVI(R); AAI(R)} \\ & \text{Off; DDD; DDI; VVI; AAI; AAT; DOO; VOO; AOO} \end{aligned}$ 

RV to Can; RV to SVC/Can; RV to SVC

Fixed Pulse Width; Fixed Tilt Biphasic; Monophasic

Cathode (-); Anode (+)

On; Off; Passive Base Rate (min<sup>-1</sup>); Rest Rate (min<sup>-1</sup>); Maximum

Programmable pulse width for P1/P2 and tilt

Base Rate (min '); Rest Rate (min '); Maximum Tracking Rate (min'); Off; Maximum Sensor Rate (min'); Paced AV Delay (ms); Sensed AV Delay (ms); Rate Responsive AV Delay (Atrial and RV) (ms); Hysteresis Rate (min'); Rate Hysteresis with Search On; Off

On; Monitor; Off Sensed/Paced AV delay Off; DDI(R); VVI(R)

110-300

40; 45;...135 Atrial Pace on PMT: Off: Passive Off; Low; Medium; High Off; On (50-200)

Post-Therapy Pacing (Independently Programmable from Bradycardia and ATP)

Post-Shock Pacing Mode Off; AAI; VVI; DDI; DDD Post-Shock Base Rate (min-1) 30-100 in increments of 5 Post-Shock Pacing Duration (min) Off; 0,5; 1; 2,5; 5; 7,5; or 10

Device Testing/Induction Methods

DC Fibber™ Pulse Duration (sec) 0.5-5.0 Burst Fibber Cycle Length (ms) 20-100

Noninvasive Programmed 2-25 stimuli with up to three extra stimuli Stimulation (NIPS)

Patient Notifiers

Programmable Notifiers

Device at ERI; Charge Time Limit Reached; Possible HV Circuit Damage; Atrial Lead Impedance Out of Range; Ventricular Lead Impedance Out of Range; (On: Off) High Voltage Lead Impedance Out of Range; AT/AF Burden; V Rate During AT/AF; % V pacing; CorVue Congestion Trigger; SecureSense - lead noise detected; non-sustained lead noise detected;

ST Episodes (Type I only) On

Entry into Backup VVI Mode On 2; 4; 6; 8; 10; 12; 14; 16 Vibration Duration (sec) Number of Vibrations per

Notification Number of Notifications 1-16 10; 22

Time Between Notifications (hours)

**Electrograms and Diagnostics** 

Device Parameter Reset

Up to 25 minutes including up to one minute programmable pre-trigger data per VT/VF diagnosis/ detection electrograms; triggers include diagnosis; detection; therapy; atrial episode; PMT termination; PC shock delivery; noise reversion; magnet reversion; morphology template verification; lead noise detected; Stored Electrograms

non-sustained lead noise detected; NSVT/NSVF Diagram of therapies delivered Therapy Summary Directory listing of up to 60 episodes with access to more details including stored electrograms History of bradycardia events and device-initiated Episodes Summary Lifetime Diagnostics

charging Trend data and counts AT/AF Burden Trend Ventricular HV Lead Multi-Vector Trend Data Impedance Trend

Event Histogram; AV Interval Histogram; Mode Histograms Switch Duration Histogram; Peak Filtered Rate
Histogram; Atrial Heart Rate Histogram; Ventricular
Heart Rate Histogram; AT/AF Burden; Exercise and
Activity Trending; V Rates during AMS; DirectTrend<sup>™</sup>
reports up to 1 year
Information regarding PMT detections

PMT Data Real-Time Measurements

Information regarding FM1 detections
Pacing lead impedances; high voltage lead
impedances; and signal amplitudes
ST Histogram Data; Long-term ST Deviation Trend;
ST Episode Log; ST Episode Details; 24-Hour ST and
HR Trend; ST EGM Baseline and Snapshots prior to
ST Episode; VT/VF; Interrogation (Snapshots and 24-hour trend at time of interrogation)

CorVue<sup>™</sup> Congestion Monitoring On; Off CorVue Congestion Trigger 8-18 days

#### MRI Scan Parameters

ST Monitoring

If the implanted system is comprised of a combination of leads that have differing RF Power (SAR), scan region and/or additional considerations, use the most restrictive of each to determine the overall set of scan conditions applicable for the total system

LEAD MODEL	LEAD LENGTHS	RF POWER (SAR)	SCAN REGION
Tendril MRI™ Lead LPA1200M	46, 52, 58 cm	Normal Operating Mode**	Full Body
Tendril™ STS Pacing Lead 2088TC	46, 52 cm		
IsoFlex™ Optim™ Pacing Leads 1944	46, 52 cm		
Durata™ Defibrillation Lead 7120Q, 7122Q	58, 65 cm		
Optisure™ Lead LDA210Q, LDA220Q	58, 65 cm		

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

- 1. MRI Conditional Field Strength: 1.5 Tesla.
- 2. See MRI-Ready Systems Manual for approved MR Conditional systems device/lead combinations and

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Brief Summary: Prior to using these devices, please review the Instructions for Use for a complete listing of indications, contraindications, warnings, precautions, potential adverse events and directions for us

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