**ACCOLADE™ EL Pacing System**

**Model L321**

- Extended longevity device labeled to last up to 16.7 years
- Automatic Daily Monitoring with the LATITUDE™ NXT Patient Management System
- RightRate™ MV sensor is the only sensor clinically proven to restore chronotropic competence
- Post-Operative System Test (POST) function to facilitate patient follow-up with a fully automatic device and lead check

### Mechanical Specifications

<table>
<thead>
<tr>
<th>Model</th>
<th>Type</th>
<th>Size (cm) (W x H x D)</th>
<th>Mass (g)</th>
<th>Volume (cc)</th>
<th>Connector Type (RA RV LV)</th>
<th>C-Codes</th>
</tr>
</thead>
<tbody>
<tr>
<td>L321</td>
<td>DR</td>
<td>4.45 x 5.88 x 0.75</td>
<td>29.1</td>
<td>14.2</td>
<td>RA: IS1 – RV: IS1</td>
<td>C1785</td>
</tr>
</tbody>
</table>

### Additional Longevity Information

- Settings: pacing pulse width 0.4ms, Impedance 500Ω, LRL 60bpm, Sensor On, EGM Onset On. These calculations also assume that the pulse generator spends 6 months in Storage mode during shipping and storage, the ZIP™ telemetry use for 1 hour at implant time and for 40 minutes annually for in-clinic follow-up checks.
- The following LATITUDE usage will decrease longevity by approximately 10 months: Daily device check on, monthly full interrogations (scheduled remote follow-ups, and quarterly patient-initiated interrogations). Daily device checks and quarterly full interrogations will decrease longevity by approximately 9 months.
- Power Supply: lithium-carbon monofluoride cell; Boston Scientific; 402294.
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Pacing Therapy

| Brady Modes | Normal:DDD(R)/DDI(R)/VDD(R)/V-VI/RII/DDO-VOO-AOO-Off
| Temporary: DDD/AAI-DDI/VOO-VOO-AOO-Off
| AT/AF Management | ATR Mode Switch, Ventricular Rate Regulation (VRR), Atrial Flutter Response (AFR), Rate Smoothing
| Automaticity | Automatic Gain Control (AGC) for sensitivity
| Right Atrial Automatic Threshold (RAAT)
| Right Ventricular Automatic Capture (RVAC)
| Rate Adaptive Pacing | Accelerometer, RightRate™ (Minute Ventilation) or blended sensors with sensor trending function
| RV Pacing Reduction | AV Search +, RYTHMIQ™, AV Delay to 400 ms, Rate Hysteresis
| Rate Management | Sudden Brady Response (SBR), PMT Termination, PVARP after PVC, Dynamic PVARP
| Pace/Sense Configuration | Unipolar, Bipolar, Bipolar/Unipolar, Unipolar/Bipolar, Unipolar/Off, Bipolar/Off, Lead Safety Switch

Patient Diagnostics

| Arrhythmia Logbook | Event Summary, Stored Electrograms with Annotation Markers (Intervals and approximately 14 minutes all multi channel EGM, always with 10 seconds Onset and event storage prioritization). Implant activation of all available EGMs. On screen measurements of all stored signal, amplitudes and timing. Snapshot Function (up to 12 seconds trace of ECG/EGM display stored)
| Histograms & Counters | Ventricular Tachy Counter, Brady Counter, Histograms, Intrinsic Promotion (Rate Hysteresis % successful and AVSH+ % successful)
| Therapy/Diagnoses | Heart Rate Variability (HRV) with SDANN and ABM, Respiratory Rate Trend, Signal Artifact Monitor, AT/AF Burden, Activity Level, A & V Arrhythmias, Weight and Blood Pressure*
| Atrial Arrhythmia Report | AT/AF% and Total Time in AT/AF, AT/AF Burden Trend, RV Rate during AT/AF Trend, Pacing Percent Trend, Heart Rate Trend, Activity Level and Respiratory Rate Trends, RV Rate during AT/AF Histogram. Timeline history of interrogations, programming, and counter resets for one year. Longest AT/AF, Fastest RVs rate in AT/AF, and most recent episode.
| DAILY TREND for last 365 Days | Events, Activity Level, AT/AF Burden, Pacing Percent, Respiratory Rate, Heart Rate, SDANN, HRV Footprint, ABM, Lead Impedance and Amplitude, RAAT Trend, RVAC Trend

Implant/In-Clinic Follow-Up

| Implant Communication Mode | Programmable values: Enable use of ZIP™ telemetry (MICS) (Requires initial use of wand for device ID) or use wand for all telemetry
| Nominal: Enable use of ZIP telemetry (Requires initial use of wand for device ID)
| In-Clinic Follow-Up | Snapshot Function: 12 seconds trace of ECG/EGM display stored
| POST (Post-Operative System Test): provides an automatic device/lead check at a pre-determined time post-implant to help document proper system functionality without requiring manual system testing
| Indications-Based Programming (IBP) | Tool that provides specific programming recommendations based on the patient’s clinical needs and primary indications

Remote Follow-Up

| Remote Monitoring | This device is designed to be LATITUDE™ NXT enabled; LATITUDE NXT availability varies by region
| Thresholds | Automatic storage of last successful daily PaceSafe** threshold test for all active chambers
| Wireless | Remote follow-up for all devices (MICS)
| Patient-Triggered Monitor (PTM) | Triggers the storage of two minutes onset and one minute post – EGMs, intervals, and annotated marker data during a symptomatic episode by placing a magnet over the device

Safety Functions**

| Safety Core | Is intended to provide life-sustaining therapy if certain non-recoverable or repeat fault conditions occur. Safety Core operates independently and acts as a backup to these components
| Electrocautery Protection Mode | Provides asynchronous pacing at the programmed outputs and LRL when commanded by the programmer

**The Safety Functions do not have programmable parameters.

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Patients may develop psychological intolerance to a pulse generator system and may experience the following: Dependency; Depression; Fear of premature battery depletion; Fear of device malfunction.

For a list of potential adverse events associated with MRI scanning, refer to the MRI Technical Guide.

- Tor migration; Shunting current during defibrillation with internal or external paddles; Syncope; Tachyarrhythmias, which include acceleration of arrhythmias and early, recurrent atrial fibrillation; Thrombosis/thromboemboli; Valve damage; Vasovagal necrosis; Myocardial trauma (e.g., tissue damage, valve damage); Myopotential sensing; Oversensing/undersensing; Pacemaker-mediated tachycardia (PMT) (applies to dual-chamber devices only); Pericardial rub, effusion; Pneumothorax; Pulse generator reaction; Bleeding; Bradycardia; Cardiac tamponade; Chronic nerve damage; Component failure; Conductor coil fracture; Death; Elevated thresholds; Erosion; Excessive fibrotic tissue growth; Extracardiac stimulation (muscle/nerve stimulation); Fluid accumulation; Foreign body rejection phenomena; Formation of hematomas or seromas; Heart block; Heart failure following chronic RV apical pacing; Inability to pace; Inappropriate pacing; Intrinsic pace; Incomplete lead connection with pulse generator; Infection (including endocarditis); Lead dislodgement; Lead fracture; Lead insulation breakdown or abrasion; Lead perforation; Lead tip deformation and/or breakage; Local tissue reaction; Loss of capture; Myocardial infarction (MI); Myocardial necrosis; Myocardial trauma (e.g., tissue damage, valve damage); Myopotential sensing; Oversedensification; Pacing/mediated tachycardia (PMT) (applies to dual-chamber devices only); Pericardial rub, effusion; Pneumothorax; Pulse generator migration; Shunting current during defibrillation with internal or external paddles; Syncope; Tachyarrhythmias, which include acceleration of arrhythmias and early, recurrent atrial fibrillation; Thrombosis/thromboemboli; Valve damage; Vasovagal response; Venous occlusion; Venous trauma (e.g., perforation; desiccation; erosion); Worsening heart failure.

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1. Patients may develop psychological intolerance to a pulse generator system and may experience the following: Dependency; Depression; Fear of premature battery depletion; Fear of device malfunction.

2. For specific information on precautions, refer to the following sections of the product labeling: clinical considerations; sterilization and storage; implantation; device programming; environmental and medical therapy hazards; hospital and medical environments; home and occupational environments; follow-up testing; exploit and disposal; supplemental precautionary information. Advise patients to avoid sources of EMI. The pulse generator may inhibit pacing due to overheating, or may switch to asynchronous pacing at the programmed pacing rate or at the magent rate in the presence of EMI.

3. Refer to the MRI Technical Guide at www.bostonscientific-elabeling.com for a comprehensive list of Warnings and Precautions, and Conditions of Use that are applicable to MRI scanning of patients implanted with an ImageReady MR Conditional Pacing System.

4. These pulse generators are compatible for use with a Subcutaneous Implantable Cardioverter Defibrillator (S-ICD) when implanted with bipolar leads and programmed to a bipolar pacing configuration.

5. Based on the literature and on pulse generator and/or lead implant experience, the following alphabetical list includes the possible adverse events associated with implantation of the included devices: Air embolism; Allergic reaction; Bleeding; Bradycardia; Cardiac tamponade; Chronic nerve damage; Component failure; Conductor coil fracture; Death; Elevated thresholds; Erosion; Excessive fibrotic tissue growth; Extracardiac stimulation (muscle/nerve stimulation); Fluid accumulation; Foreign body rejection phenomena; Formation of hematomas or seromas; Heart block; Heart failure following chronic RV apical pacing; Inability to pace; Inappropriate pacing; Intrinsic pace; Incomplete lead connection with pulse generator; Infection (including endocarditis); Lead dislodgement; Lead fracture; Lead insulation breakdown or abrasion; Lead perforation; Lead tip deformation and/or breakage; Local tissue reaction; Loss of capture; Myocardial infarction (MI); Myocardial necrosis; Myocardial trauma (e.g., tissue damage, valve damage); Myopotential sensing; Oversedensification; Pacing/mediated tachycardia (PMT) (applies to dual-chamber devices only); Pericardial rub, effusion; Pneumothorax; Pulse generator migration; Shunting current during defibrillation with internal or external paddles; Syncope; Tachyarrhythmias, which include acceleration of arrhythmias and early, recurrent atrial fibrillation; Thrombosis/thromboemboli; Valve damage; Vasovagal response; Venous occlusion; Venous trauma (e.g., perforation; desiccation; erosion); Worsening heart failure.