**ACCOLADE™ MRI Pacemakers**  
**Standard Models: L310 and L311**  
**Extended Life (EL) Model: L331**

- Use with the INGEVITY™ MRI Pacing Lead provides an ImageReady™ MR-Conditional Pacing System¹
  - Full body scan 1.5T, First level controlled operating mode (SAR 4W/Kg)
  - No MR exclusion zones, no height restriction
  - MRI Time Out Mode to return patient to original pacemaker settings after scan
- Automatic Daily Monitoring with the LATITUDE™ NXT Patient Management System, to improve clinic efficiency and provide a higher level of care for device patients²
- Available in both standard and EL models
  - Industry-leading projected longevity projected to last over 12 years with ACCOLADE MRI EL³-⁵
- Advanced diagnostic reports provide a comprehensive and proactive approach for comorbidity management
- RF telemetry for wireless transmission of information and efficiency in the operating room and follow-up setting
- PaceSafe™ RV and RA, providing dynamic adjustment of pacing outputs to ensure capture and maximize efficiency
- RightRate™ with the MV sensor, the only MV sensor clinically proven to restore chronotropic competence⁶
- RHYTHMIQ™, designed to minimize unnecessary RV pacing without clinically significant pauses, therefore reducing the risk of HF development⁷
- Enhanced features and diagnostics, including Respiratory Rate Trend, designed to provide you with greater insight into your patient’s disease progression based on the patient’s own respiration
- Post Operative System Test (POST) to facilitate patient follow-up with a fully automatic device and lead check
- EasyView™ header with port labels (on DR device) designed to make the implant experience more efficient

**Mechanical Specifications and Reimbursement Information**

<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-Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>L310</td>
<td>VR</td>
<td>4.45 x 4.81 x 0.75</td>
<td>23.6</td>
<td>13.2</td>
<td>RA/RV: IS1</td>
<td>C1786</td>
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<tr>
<td>L311</td>
<td>DR</td>
<td>4.45 x 5.02 x 0.75</td>
<td>24.8</td>
<td>13.7</td>
<td>RA: IS1 – RV: IS1</td>
<td>C1785</td>
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<tr>
<td>L331</td>
<td>DR-EL</td>
<td>4.45 x 5.88 x 0.75</td>
<td>29.1</td>
<td>15.8</td>
<td>RA: IS1 – RV: IS1</td>
<td>C1785</td>
</tr>
</tbody>
</table>

**Projected Longevity (Years)**

<table>
<thead>
<tr>
<th>Pacing</th>
<th>VR</th>
<th>DR</th>
<th>DR-EL</th>
</tr>
</thead>
<tbody>
<tr>
<td>50%</td>
<td>RA/RV 2.5V</td>
<td>10.0</td>
<td>8.8</td>
</tr>
<tr>
<td>100%</td>
<td>RA/RV 2.5V</td>
<td>9.2</td>
<td>7.6</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. For longevity calculations based on different settings please contact Boston Scientific technical services or your local representative.
- Power Supply VR and DR models: lithium-carbon monofluoride cell; Boston Scientific; 402290.
- Power Supply DR-EL: lithium-carbon monofluoride cell; Boston Scientific; 402294.
### Pacing Therapy

| Brady Modes | Normal: DDD(R)-DDI(R)-VDD(R)-VVI(R)-AAI(R)-DDO-VOO-AOO-Off  
Temporary: DDD-DDI-VDD-VVI-AAI-DOO-VOO-AOO-Off |
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>AT/AF Management</td>
<td>ATR Mode Switch, Ventricular Rate Regulation (VRR), Atrial Flutter Response (AFR), Rate Smoothing</td>
</tr>
</tbody>
</table>
| 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 (SBRI), PMT Termination, PVARP after PVC, Dynamic PVARP |
| Pace/Sense Configuration | Unipolar, Bipolar, Bipolar/Unipolar, Unipolar/Bipolar, Unipolar/Off, Bipolar/Off, Lead Safety Switch |

### ImageReady™ MR-Conditional Pacing System

| MRI Lead Selection | Pulse Generator MR-Conditional with all INGEVITY™ MRI pacing lead models |
| MRI Conditions | Full body scan at 1.5T, First Level Controlled Operating Mode (<- SAR 4w/Kg) for all INGEVITY MRI lead models¹ |
| MRI Mode | Mode: AOO, VOO, DDO, Off 
Protection Mode Time Out: Off, 12, 24, 48 hours |

### 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 up to 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 |

### Patient Diagnostics

| 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 |

### Safety Functions²

| 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 |
Pacing Systems from Boston Scientific: ACCOLADE™, ACCOLADE™ MRI, PROponent™ MRI, PROponent™, ESSENTIO™, ESSENTIO™ MRI, ALTRUA™ 2, FORMIO™, FORMIO™ MRI, VITALIO™, VITALIO™ MRI, INGENIO™, INGENIO™ MRI, ADVANTIO™

INDICATIONS AND USAGE: Boston Scientific pacemakers are indicated for treatment of the following conditions: • Symptomatic paroxysmal or permanent second- or third-degree AV block • Sudden death syndrome in patients with implantable cardioverter-defibrillator (ICD) indications • Syncope (as described in the MRI Technical Guide) are met, MRI scanning of the patient does not meet MR Conditional requirements of the implanted system. Refer to the MRI Technical Guide for potential adverse events applicable when Conditions of Use are not met or as well, as a complete list of MRI-related Warnings and Precautions. Do not subject a patient with an implanted pulse generator and/or lead to diathermy.

For Extendable/Retractable Fixation: The safety and efficacy of this tip electrode placement in the right ventricle-above mid-atrium has not been clinically established.

Adverse Events: All trademarks are the property of their respective owners.

1. Please refer to the MRI Technical Guide: ImageReady™ MR Conditional Pacing System as the system is designated as MR Conditional in accordance with specific conditions.
2. This device is designed to be LATITUDE™ NXT enabled; LATITUDE™ NXT availability varies by region.
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Patients and Families: 1.888.494.3269

LATTITUDE™ NKT Patient Management System from Boston Scientific CRM

INDICATIONS: The LATTITUDE™ NKT Patient Management System is intended for use to remotely communicate with a compatible pulse generator from Boston Scientific implanted device and transfer data to a central database. The LATITUDE NKT System provides patient data that can be used as part of the clinical evaluation of the patient.

CONTRAINDICATIONS: The LATITUDE NKT Patient Management System is contraindicated for use with any implanted device other than a compatible Boston Scientific implanted device. Not all Boston Scientific implanted devices are compatible with the LATITUDE NKT System. For contraindications use related to the implanted device, refer to the System Guide. The LATTITUDE NKT System enables remote interrogation and therapy delivery.

PRECAUTIONS: Alerts may appear on the LATITUDE NKT website on a daily basis. Primary notification of alert conditions is through the View Patient List page on the LATITUDE NKT website. The clinician needs to log into the LATITUDE NKT website in order to receive alerts. Additional notification through email and SMS text messages is available, these reminders are dependent on external systems and may be delayed or not occur. The secondary notification feature does not eliminate or reduce the need to check the website. Implanted device data and alerts are specialty available for review on the LATITUDE NKT website within 15 minutes of a successful interrogation. However, data arrays may take significantly longer (up to 4 days) if the Communicator is unable to interrogate the implanted device or if the Communicator is unable to contact the LATITUDE NKT server to upload data, up to twice daily before the LATITUDE NKT server detects these conditions and informs the clinician that monitoring is not occurring. If both of these conditions occur at the same time, this notification is made up to twice daily for up to 30 days. Implanted device data and alert notification may be delayed or not occur at all under various conditions, which include but are not limited to the following: System limitations; the Communicator is unplugged; the Communicator is not able to connect to the LATITUDE NKT server through the configured phone system; the implanted device and the Communicator cannot establish and complete a telemetry session; the Communicator is damaged or malfunctioned; the patient is not compliant with prescribed use or is not using the LATITUDE NKT System as described in the patient manual; it subscribed to the LATITUDE Cellular Data Plan, missing two or more payments discontinues the subscription; the clinician can only identify when this is not being monitored as described above by using the leaflet. Refer to the LATITUDE NKT User’s Guide for more detailed information on the View Patient List.

ADVERSE EVENTS: None known.

The LATITUDE NKT System does not provide continuous real-time monitoring. As a remote monitoring system, the LATITUDE NKT System provides periodic patient monitoring based on clinician configured settings. There are many internal and external factors that can affect, delay, or prevent access to and delivery of implanted device, sensor, and patient information as indicated by the clinician. These factors include: implanted device clock; patient environment; cellular data service; telephone system; memory capacity; clinician environment; schedule/configuration changes; or data processing.

Refer to the product labeling for specific instructions for use. Rx only. (Rev. A)