ESSENTIO™ EL Pacing System
Model L121

- Industry-leading longevity projected to last over 12 years\(^1\)-\(^3\)
- Automatic Daily Monitoring with the LATITUDE™ NXT Patient Management System, to improve clinic efficiency and provide a higher level of care for device patients
- 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 competence\(^4\)
- AV Search +, designed to minimize unnecessary RV pacing without clinically significant pauses, therefore reducing the risk of HF development
- Enhanced features and diagnostics designed to provide you with greater insight into your patient’s disease progression
- Post Operative System Test (POST) to facilitate patient follow-up with a fully automatic device and lead check
- EASYVIEW™ header with port labels designed to make the implant experience more efficient

### Mechanical Specifications

<table>
<thead>
<tr>
<th>Model</th>
<th>Type</th>
<th>Size (cm) ((W \times H \times 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>L121</td>
<td>DR</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

<table>
<thead>
<tr>
<th>Pacing</th>
<th>Years</th>
</tr>
</thead>
<tbody>
<tr>
<td>50%</td>
<td></td>
</tr>
<tr>
<td>100%</td>
<td></td>
</tr>
</tbody>
</table>

#### Additional Longevity Information

- Settings: pacing pulse width 0.4ms, Impedance 500\(\Omega\), 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: lithium-carbon monofluoride cell; Boston Scientific; 402294.
Pacing Therapy

Brady Modes
- Normal/DDDR/DDIR/DDDR/VVIR/AAIR/DDD-VOO-AOO-Off
- Temporary: DDD-DDDR-VVI-AAI-DDD-VOO-AOO-Off

AT/AF Management
- ATR Mode Switch, 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 +, AV Delay to 400 ms, Rate Hysteresis

Rate Management
- Sudden Brady Response (SBR), PMT Termination, VPARP after PVC, Dynamic PVARP

Pace/Sense Configuration
- Unipolar, Bipolar, Unipolar/Bipolar, 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 multichannel EGMs, 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 IRate Hysteresis % successful and AVS+ % successful

Diagnostics
- AT/AF Burden, A & V Arrhythmias

DAILY TREND for last 365 Days
- Events, AT/AF Burden, Heart Rate, 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 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

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 Triggers
- Monitor (PTM)

Electrocutaure Protection Mode
- 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

Pacing Systems from Boston Scientific – ACCOLADE and ESSENTIO™ EL Pacing System

Model L121

Rhythm Management
300 Boston Scientific Way
Marlborough, MA 01752-1234
www.bostonscientific.com

Medical Professionals:
1.800.CARDIAC (227.3422)

Patients and Families:
1.866.484.3268

© 2015 Boston Scientific Corporation or its affiliates. All rights reserved.

All trademarks are the property of their respective owners.

INDICATIONS AND USAGE
Boston Scientific pacemakers are indicated for treatment of the following conditions: • Symptomatic paroxysmal or permanent second or thirddegree AV block • Symptomatic bifurcated bundle branch block • Symptomatic paroxysmal or transient sinus node dysfunction with or without associated AV conduction disorders i.e., sinus bradycardia, sinus arrest, sinoatrial [SA] block • Bradycardia-tachycardia syndrome, to prevent symptomatic bradycardia or in forms of symptomatic tachyarrhythmia • Neurovascular (vascular-wall) syndrome or hyperesinophilia-cardiac syndrome

CONTRAINDICATIONS:
These Boston Scientific pacemakers are contraindicated for patients who have a separate implanted cardioverter defibrillator (ICD) with transvenous leads. Use of certain pacing modes and/or features available in these Boston Scientific pacemakers is contraindicated for the following patients under the circumstances listed: • Unipolar pacing or use of the LV Sensor with a Subcutaneous Implantable Cardioverter Defibrillator (ICD) – because it may cause inappropriate therapy or inhibition of appropriate ICD therapy. • Minute Ventilation in patients with both unipolar atrial and ventricular leads in single-chamber atrial or features available in these Boston Scientific pacemakers is contraindicated for the following patients under the circumstances listed: • Unipolar pacing or use of the MV Sensor with a Subcutaneous Implantable Cardioverter Defibrillator (ICD) – because it may cause inappropriate therapy or inhibition of appropriate ICD therapy.

WARNINGs:
Read this manual thoroughly before implantation to avoid damage to the pulse generator and/or lead. Such damage can result in patient injury or death. For single patient use only. Do not reuse, reprocess, or resterilize. Always have external defibrillation equipment available during implant and electrophysiological testing. Using more pulse generators could cause pulse generator interaction, resulting in patient injury or a lack of therapy delivery. In response to applicable nonrarefied or repeated burst conditions, the pulse generator will switch in sequence to Safety Core operation. Do not limit, twist, or load the lead with other leads. Do not use atrial tracking modes in patients with chronic refractory atrial tachyarrhythmia. Lead Safety Switch should be programmed Off for patients with an ICD. Unipolar pacing due to Lead Safety Switch is contraindicated for patients with an ICD. Unipolar pacing due to RA myocardial involvement should not be programmed for patients with an ICD. If programmed to a fixed atrial Sensitivity value of 0.15 mV or a fixed sensitivity value of 2.0 mV or less in a unipolar lead configuration in any chamber, the pulse generator may be more susceptible to electromagnetic interference. Advise patients to seek medical guidance before entering environments that could inadvertently affect the operation of the active implantable medical device. Do not expose patient to MRI scanning. Do not subject an implantable pulse generator and/or lead to delamination, silica dust, etc.

PRECAUTIONS:
For specific information on precautionary measures, 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, explant and disposal; supplemental precautionary information. Advise patients to avoid sources of EMI. The pulse generator may inhibit pacing due to oversensing, or may switch to asynchronous pacing at the programmed pacing rate or at the magnet rate in the presence of EMI. These pulse generators are compatible for use with a Subcutaneous Implantable Cardioverter Defibrillator (ICD) when implanted with bipolar leads and programmed to a bipolar pacing configuration.

POTENTIAL ADVERSE EVENTS:
Potential adverse events include, but are not limited to the following: allergic/physical/physiologic reaction, death, erosion/migration, fibrillation or other arrhythmias, lead or accessory lead breakage, structural failure, or pump mechanical failure; hospital and medical environments; home and occupational environments; follow-up testing; explant and disposal; supplemental precautionary information. Advise patients to avoid sources of EMI. These pulse generators are compatible for use with a Subcutaneous Implantable Cardioverter Defibrillator (ICD) when implanted with bipolar leads and programmed to a bipolar pacing configuration.