

ACCOLADE™ Pacemakers



Mechanical Specifications

| | Extended Life (EL) | Single Chamber | Dual Chamber |
|----------------------------|--------------------|----------------|--------------------|
| Model | L321 | L300 | L301 |
| Type | DR | SR | DR |
| Size (cm) W | 4.45 | 4.45 | 4.45 |
| H | 5.88 | 4.81 | 5.02 |
| D | 0.75 | 0.75 | 0.75 |
| Mass (g) | 29.1 | 23.6 | 24.8 |
| Volume (cc) | 15.8 | 13.2 | 13.7 |
| Connector Type (RA RV LV) | RA: IS1 RV: IS1 | RA/RV: IS1 | RA: IS1 RV: IS1 |
| C-Code | C1785 | C1786 | C1785 |
| Projected Longevity (yrs)* | 12.1 | 9.2 | 7.6 |

*100% pacing, RA/RV 2.5V, 500

Sources

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AUTOMATIC Assurance

Automatic Daily Monitoring

Providing wireless remote monitoring for improved patient compliance

Actionable Data

Providing a comprehensive view of AT/AF and HF status that can enable earlier intervention

Leader in Longevity

Extended Longevity (EL) batteries provide the industry's longest projected battery life at over 12 years⁹⁻¹¹

Pacing Systems from Boston Scientific: ACCOLADE™, ESSENTIO™, VITALIO™, INGENIO™, 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, symptomatic bilateral 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 some forms of symptomatic tachyarrhythmias, neurovascular (vaso-vagal) syndromes or hypersensitive carotid sinus syndromes. Adaptive-rate pacing is indicated for patients exhibiting chronotropic incompetence and who may benefit from increased pacing rates concurrent with increases in minute ventilation and/or level of physical activity. Dual-chamber and atrial tracking modes are also indicated for patients who may benefit from maintenance of AV synchrony. Dual chamber modes are specifically indicated for treatment of the following: Conduction disorders that require restoration of AV synchrony, including varying degrees of AV block, VVI intolerance (i.e., pacemaker syndrome) in the presence of persistent sinus rhythm, low cardiac output or congestive heart failure secondary to bradycardia.

CONTRAINDICATIONS: These Boston Scientific pacemakers are contraindicated in 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 MV Sensor with a Subcutaneous Implantable Cardioverter Defibrillator (S-ICD) because it may cause inappropriate therapy or inhibition of appropriate S-ICD therapy, Minute Ventilation in patients with both unipolar atrial and ventricular leads, single-chamber atrial pacing in patients with impaired AV nodal conduction, atrial tracking modes for patients with chronic refractory atrial tachyarrhythmias (atrial fibrillation or flutter), which might trigger ventricular pacing, dual-chamber and single-chamber atrial pacing in patients with chronic refractory atrial tachyarrhythmias, asynchronous pacing in the presence (or likelihood) of competition between paced and intrinsic rhythms.

WARNINGS: General: 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 electrophysiologic testing. Using multiple pulse generators could cause pulse generator interaction, resulting in patient injury or a lack of therapy delivery. In response to applicable nonrecoverable or repeat fault conditions, the pulse generator will switch irreversibly to Safety Core operation. Do not kink, twist, or braid the lead with other leads. Do not use atrial tracking modes in patients with chronic refractory atrial tachyarrhythmias. 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 RAAT is contraindicated and should be programmed off 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 adversely affect the operation of the active implantable medical device. Do not expose a patient to MRI scanning. Do not subject a patient with an implanted pulse generator and/or lead to diathermy since diathermy.

PRECAUTIONS: 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; 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 (S-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 breakage (fracture/insulation/lead tip), hematoma/seroma, inappropriate or inability to provide therapy (pacing/sensing), infection, procedure related, and component failure. Patients may develop psychological intolerance to a pulse generator system and may experience fear of shocking, fear of device failure, or imagined shocking. In rare cases severe complications or device failures can occur.

Refer to the product labeling for specific indications, contraindications, warnings/precautions and adverse events. Rx only. (Rev. A)

Boston Scientific

Advancing science for life™

Cardiac Rhythm Management

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Patients and Families:
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Boston Scientific
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ACCOLADE™ Pacemakers

AUTOMATIC Assurance



Automatic Daily Monitoring

Improving Patient Compliance

Wireless, hands-free remote monitoring with LATITUDE™ NXT can increase your confidence in patient compliance

Automatic and Customizable Alerts

Atrial arrhythmia burden

>0, 0.5, 1, 3, 6, 12, 18, 24 hours*

RV pacing percentage

>10, 20, 30, 40, 50

Weight gain over time

1-10 lbs in 1-7 days

Automatic Device Interrogation

- Interrogate the patient's device on a schedule set by your clinic
- No patient interaction required



* Within a 24 hour period

Actionable Data

Enabling Earlier Intervention

Providing a comprehensive view of your patient's AT/AF and HF status to monitor disease progression

The New Atrial Arrhythmia Report

- Assess AT/AF status and treatment efficacy
- Determine length and burden of episodes
- Correlate patient symptoms to rates

HF PERSPECTIV™ System

Respiratory Rate Trend (RRT)

Measure and track your patient's respiration

Heart Rate Variability (HRV) Platform

Can be used as a marker of disease progression¹⁻⁶

SDANN & HRV Footprint

Daily and weekly trends that allow for earlier intervention and prevention of HF hospitalizations⁷

Autonomic Balance Monitor

In combination with HRV measurement, shows evolution of HF status and effectiveness of treatment (Rx or CRT)⁸

Heart Rate Trend

Shows long-term maximum, minimum and average heart rate

Leader in Longevity

Longest Projected Longevity

The ACCOLADE Extended Longevity (EL) batteries provide the industry's greatest battery capacity at 1.6 Amp hours with the longest projected longevity⁹⁻¹¹



Efficient Circuitry

+ Greatest Battery Capacity

Industry Leading Projected Longevity

* Model L321 ACCOLADE EL devices

New Efficiencies

New Features that Support Improved Efficiencies

The ACCOLADE Pacing System provides new features that are designed to increase efficiencies during implant and follow-up

Snapshot Capability

Review real-time EGM/ECG data and pacing threshold test results

Post-Operative System Test (POST)

Improve workflow with an automatic system evaluation after implant

- Lead impedances
- Intrinsic amplitudes
- Capture thresholds

EasyView™ Header with Port Labels

Aids with quick and easy identification of the appropriate port and verification of full lead insertion

