Boston Scientific
Advancing science for life™

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 System[1]
  - 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 orginal 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 patients[2]
- Available in both standard and EL models
  - Industry-leading projected longevity projected to last over 12 years with ACCOLADE MRI EL[3-5]
- 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 competence[6]
- RHYTHMIQ™, designed to minimize unnecessary RV pacing without clinically significant pauses, therefore reducing the risk of HF development[7]
- 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

Model	Type	Size (cm) (W x H x D)	Mass (g)	Volume (cc)	Connector Type (RA RV LV)	C-Code
L310	VR	4.45 x 4.81 x 0.75	23.6	13.2	RA/RV: IS1	C1786
L311	DR	4.45 x 5.02 x 0.75	24.8	13.7	RA: IS1 – RV: IS1	C1785
L331	DR-EL	4.45 x 5.88 x 0.75	29.1	15.8	RA: IS1 - RV: IS1	C1785

Projected Longevity (Years)

Pacing		VR	DR	DR-EL
50%	RA/RV 2.5V	10.0	8.8	14.0
100%	RA/RV 2.5V	9.2	7.6	12.1

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 monoflouride cell; Boston Scientific; 402294.

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Pacing Therapy

Brady Modes	Normal:DDD(R)-DDI(R)-VDD(R)-VVI(R)-AAI(R)-DOO-VOO-AOO-Off Temporary: DDD-DDI-VDD-VVI-AAI-DOO-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/Diagnostics	Heart Rate Variability (HRV) with SDANN and ABM, Respiratory Rate Trend, AT/AF Burden, Activity Level, A & V Arrhythmias, Weight and Blood Pressure[8]
Atrial Arrythmia 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

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 models[1]
MRI Mode	Pacing Mode: AOO, VOO, DOO, 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

Safety Functions[9]

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™, PROPONENT™ MRI, 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 bloc• 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 the 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 withk

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. Unless all of the MRI Conditions of Use are met, MRI scanning of the patient does not meet MR Conditional requirements for the implanted system, and significant harm to or death of the patient and/or damage to the implanted system may result. Do not subject a patient with an implanted pulse generator and/or lead to 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.

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

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

Pacing Systems from Boston Scientific – INGEVITY™ MRI Extendable/Retractable Fixation and Tined Fixation

INDICATIONS: INGEVITY™ MRI Leads are intended for chronic pacing and sensing in the right atrium (only preformed atrial J with the Tined Fixation) and/or right ventricle (only straight with the tined fixation) when used with a compatible pulse generator.

CONTRAINDICATIONS: Use of these leads are contraindicated in: patients with a hypersensitivity to a nominal single dose dexamethasone acetate: 0.61 mg for Tined Fixation, 0.91 mg for Extendable Retractable Fixation; and patients with mechanical tricuspid heart valves.

WARNINGS: Refer to the product labeling before implanting the lead to avoid damage to the pulse generator and/or lead. For single patient use only. Do not reuse, reprocess, or resterilize. Always have external defibrillation equipment available during implant and electrophysiologic testing. Ensure that an external defibrillator and medical personnel skilled in CPR are present during post-implant device testing should the patient require external rescue. Lead fracture, dislodgment, abrasion, or an incomplete connection can cause a periodic or continual loss of pacing or sensing or both. Although pliable, the lead is not designed to tolerate excessive flexing, bending, or tension. Do not kink, twist, or braid the lead with other leads. Implant of the system cannot be performed in an MRI site Zone III (and higher). Take care to obtain appropriate electrode position. Failure to do so may result in suboptimal lead measurements. Unless all of the MRI Conditions of Use (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 met or not met, 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 the tip electrode placement in the right ventricle above midseptum has not been clinically established.

PRECAUTIONS: Refer to the implant product labeling for cautions specific to clinical considerations, sterilization and storage, handling, implantation, hospital and medical environments, and follow up testing of the lead. Failure to observe these cautions could result in incorrect lead implantation, lead damage/dislodgment, or harm to the patient. Prior to implantation of this lead, confirm lead/pulse generator compatibility. Lead fracture, dislodgment, abrasion, or an incomplete connection can cause a periodic or continual loss of pacing or sensing or both. Defibrillation equipment should be kept nearby during the implant procedure. Optimum threshold performance might not be achieved if the lead is chronically repositioned because the steroid can be depleted.

For Extendable/Retractable Fixation: Avoid creating sharp bends while extending or retracting the helix. Sharp bends can increase the risk of breaking the conductor coil or fixation mechanism during helix extension or retraction. Do not rotate the terminal pin clockwise or counterclockwise more than the recommended maximum number of turns indicated in the specifications. Continuing to rotate the terminal pin once the helix is fully extended or retracted (as indicated by fluoroscopy) can damage the lead, cause a conductor coil break during fixation, cause lead dislodgment, tissue trauma, and/or cause acute pacing threshold to rise.

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. In rare cases severe complications or device failures can occur.

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

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

LATITUDE™ NXT Patient Management System from Boston Scientific CRM

INDICATIONS: The LATITUDE™ NXT Patient Management System is intended for use to remotely communicate with a compatible pulse generator from Boston Scientific CRM and transfer data to a central database. The LATITUDE

NXT System provides patient data that can be used as part of the clinical evaluation of the patient.

CONTRAINDICATIONS: The LATITUDE NXT 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 NXT System. For contraindications for use related to the implanted device, refer to the System Guide for the Boston Scientific implanted device being interrogated.

PRECAUTIONS: Alerts may appear on the LATITUDE NXT website on a daily basis. Primary notification of alert conditions is through the View Patient List page on the LATITUDE NXT website. The clinician needs to log onto the LATITUDE NXT website in order to receive alerts. Although secondary 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 typically available for review on the LATITUDE NXT website within 15 minutes of a successful interrogation. However, data uploads may take significantly longer (up to 14 days). If the Communicator is unable to interrogate the implanted device or if the Communicator is unable to contact the LATITUDE NXT server to upload data, up to two weeks may elapse before the LATITUDE NXT server detects these conditions and informs the clinic user that monitoring is not occurring. If both of these conditions occur at the same time, this notification could take up to 28 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 NXT server through the configured phone system; the implanted device and the Communicator cannot establish and complete a telemetry session; the Communicator is damaged or malfunctions; the patient is not compliant with prescribed use or is not using the LATITUDE NXT System as described in the patient manual; if subscribed to the LATITUDE Cellular Data Plan, missing two or more payments discontinues the subscription; the clinic user can identify any patients that are not being monitored as described above by using the Not Monitored filter on the View Patient List.

ADVERSE EVENTS: None known.

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

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

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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.
3. Boston Scientific ACCOLADE Pacemaker Physician's Technical Manual 359246-001 EN US 2014-05.
4. Medtronic Advisa DR MRI SureScan A2DR01 Clinician Manual. M950432A001E 2013-11-15.
5. St. Jude Medical Accent MRI Pacemaker Rep to Clinician PPT. httpprofessional-intl.sjm.com~mediaproproductscrma-faccent-mri-pacemakermrireptoclinician_ppt_final_1020.ashx. Accessed 1/10/14.
6. Chronotropic competence is defined by the Model of the Cardiac Chronotropic Response to Exercise. Wilkoff B, Corey J, Blackburn G. A mathematical model of the cardiac chronotropic response to exercise. Journal of Electrophysiology. 1989;3:176–180. Refer to the Physician's System Guide for more information on adaptive-rate therapy. Additional clinical performance was assessed using INSIGNIA™ Ultra clinical data with the AutoLifestyle™ feature programmed On. Boston Scientific. Data on file. ALTRUA™ Pacemaker System Guide. 2008;1:20–25.monthly Full Interrogations (scheduled remote follow ups, and quarterly patient-interrogations).
7. Boston Scientific Clinical Summary Ivory Study 358487-019 EN US 2012-10
8. Weight and Blood Pressure are only available via LATITUDE NXT.
9. The Safety Functions do not have programmable parameters.