DYNA\textsuperscript{TM} GEN EL (Extended Longevity) ICD

Models D150, D151, D152, and D153

- Designed to be the world’s longest lasting ICD.
- Powered by ENDURALIFE\textsuperscript{TM} Battery Technology which enables the longest projected longevities, backed by four independent studies\textsuperscript{1-4} and over six years of real-world data.\textsuperscript{5}
- The world’s thinnest ICD designed to enhance patient comfort.\textsuperscript{6}
- Includes the new EasyView\textsuperscript{TM} header with color coded lead ports, designed to improve implant efficiency.
- Offers an uncompromised set of features including:
  - An advanced system solution for patient comorbidities and HF monitoring (HF Perspectiv\textsuperscript{\texttrademark} Report, LATITUDE\textsuperscript{\texttrademark} NXT Remote Patient Management enabled with weight scale and blood pressure sensors, and Respiratory Rate Trend).
  - AcuShock\textsuperscript{\texttrademark} Advanced Technology, multiple programmable options to reduce inappropriate and unnecessary shocks, including a choice of rhythm discriminators, antitachycardia pacing (ATP) therapy in all rates zones, and advanced sensing and filtering.
  - Rhythm ID\textsuperscript{\texttrademark} with RhythmMatch\textsuperscript{\texttrademark} allows customization of Rhythm ID algorithm to reduce inappropriate shocks.
  - AV Search\textsuperscript{+} and Rythmiq\textsuperscript{TM} give clinicians options to appropriately manage RV pacing in patients with varying degrees of conduction block.
  - Wireless ECG saves time and simplifies follow-up.
  - Safety Core\textsuperscript{\texttrademark} technology is intended to provide lifesaving shock therapy and basic pacing functionality in the event of an unrecoverable fault.

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>D150</td>
<td>VR</td>
<td>5.37 x 7.36 x 0.99</td>
<td>68.9</td>
<td>29.5</td>
<td>RV:DF4</td>
<td>C1722</td>
</tr>
<tr>
<td>D151</td>
<td>VR</td>
<td>5.37 x 7.79 x 0.99</td>
<td>70.7</td>
<td>31.5</td>
<td>RV:IS-1/DF-1</td>
<td>C1722</td>
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<tr>
<td>D152</td>
<td>DR</td>
<td>5.37 x 7.68 x 0.99</td>
<td>71.4</td>
<td>31.0</td>
<td>RA:IS-1;RV:DF4</td>
<td>C1721</td>
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<tr>
<td>D153</td>
<td>DR</td>
<td>5.37 x 7.79 x 0.99</td>
<td>71.0</td>
<td>31.5</td>
<td>RA:IS-1;RV:IS-1/DF-1</td>
<td>C1721</td>
</tr>
</tbody>
</table>

Pulse Generator Projected Longevity (All Models \textsuperscript{a,b,c,d})

<table>
<thead>
<tr>
<th>Pacing</th>
<th>500\textsuperscript{\textomega}</th>
<th>700\textsuperscript{\textomega}</th>
<th>900\textsuperscript{\textomega}</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>VR</td>
<td>DR</td>
<td>VR</td>
</tr>
<tr>
<td>0%</td>
<td>11.7</td>
<td>11.2</td>
<td>11.7</td>
</tr>
<tr>
<td>15%</td>
<td>11.5</td>
<td>10.8</td>
<td>11.5</td>
</tr>
<tr>
<td>50%</td>
<td>11.0</td>
<td>10.0</td>
<td>11.1</td>
</tr>
<tr>
<td>100%</td>
<td>10.3</td>
<td>9.0</td>
<td>10.6</td>
</tr>
</tbody>
</table>

\textsuperscript{a} Assumes Zip\textsuperscript{\texttrademark} telemetry use for 1 hour at implant time and for 40 minutes annually for in-clinic follow-up checks.
\textsuperscript{b} Assumes standard use of the LATITUDE Communicator as follows: Daily Device Check on, monthly Full Interrogations (scheduled remote follow-ups, and quarterly patient interrogations).
\textsuperscript{c} Assumes 60 min \textsuperscript{\textomega} UFL ventricular and atrial settings of 2.5 V pacing pulse Amplitude and 0.4 ms pacing pulse width; RA Impedance 500\textsuperscript{\textomega}; sensors On.
\textsuperscript{d} Projected longevity is calculated assuming 3 maximum energy charging cycles per year, including automatic capacitor re-forms and therapeutic shocks. For the final year of device service, an additional 5 charging cycles are assumed to account for additional automatic capacitor re-forms as the device approaches the Explant indicator. These calculations also assume 3-channel EGM Onset is set to On, and that the pulse generator spends 6 months in Storage mode during shipping and storage.

Additional Longevity Information

- For longevity calculations based on different settings please contact Boston Scientific technical services or your local representative.
- Boston Scientific devices have corporate warranties at 10 years (VR) and 8 years (DR). See BostonScientific.com/warranty for complete warranty terms and conditions.
- Devices use Li/MnO\textsubscript{2} chemistry.
- The Usable Battery Capacity is 1.9 Amp-hours for the EL ICD (typical implant to battery capacity depleted).
- Shelf life is 2 years (before use by).

Longevity projections as provided in the product labeling. Specific programmable parameter ranges available in product labeling. Product labeling available at BostonScientific.com/ifu.
Pacing Therapy

Brady Modes: Normal: DDD(R), DDI(R), VDD(R), VVI(R), AAI(R), Off Temporay: DDI, DOO, VDD, VVI, VOO, AAI, AOO, Off

AT/AF Management: ATR Mode Switch, Ventricular Rate Regulation (VRR), Atrial Flutter Response (AFR), PMT Termination, Rate Smoothing

Rate Adaptive Pacing: Accelerometer with sensor trending function

RV Pacing Reduction: A/V Search+, Rythmos®, A/ V Delays to 400 ms, Rate Hysteresis

Patient Diagnostics

Arrhythmia Logbook: Events summary, Stored Electromgrams with Annotated Markers, (intervals and approximately 17 minutes of multi-channel EGM, always with 10 seconds Onset and event storage prioritization).

Implant activation of all available EGMs. On screen measurement of all stored signal amplitudes and timing

Heart Rate Variability (HRV): SDANN and HRV Footprint (24 hour heart rate collection period)

Daily Trends For Last 365 Days: Events, Activity Level, Atrial Burden, Respiratory Rate, Heart Rate, SDANN, HRV Footprint, Autonomic Balance Monitor (ABM), Lead impedances and amplitudes

AT/AF Diagnostics: % Atrial Burden, Daily burden, Average V-rate during ATR Mode Switch Episode

Heart Failure Therapy/ Diagnostics: HF Perspectives® Report, Respiratory Rate Trend, Weight, Blood Pressure, Heart Rates, HRV Footprint, SDANN, Autonomic Balance Monitor (ABM), Atrial Arrhythmia Burden, Activity Level, A & V Arrhythmias, Pacing Parameters

Histograms & Counters: Tachy Events and Brady Counters

Device Testing/Induction Methods

Induction Methods: Vfib Induction, Shock on T Induction, Programmed Electrical Stimulation (PES), 50 Hz/Manual Burst Pacing

Commanded Therapy Methods: Commanded Shock, Commanded ATP

Tachycardia Therapy

Sensing/Detection: Zones VF only, or VF and VT or VF, VT, VT-1. Lowest Zone can be Monitor Only

Shock Reduction and Appropriate Therapy: AuoShock™ Advanced Technology including Onset/Stability™, Rhythm ID™ with RhythmMatch™, Dynamic Noise Algorithm (DNA) for sensing, Automatic Gain Control (AGC) with programmable sensing floor, Narrow Band Pass Filter

Antitachycardia Therapy: Quick Convert™ in VF Zone. Two programmable ATP schemes in both VT and VT-1 zones. Burst, Ramp, Scan, Ramp-Scan

Shock Energy: 41 J stored, 35 J delivered. First two shocks in each zone programmable. VT-1 has 5 shocks, VT has 6 shocks and VF has 8 shocks. Reverse Last Shock Polarity in zone. Programmable RV Coil to RA Coil and Can (TRIAL), RV Coil to Can, RV Coil to RA Coil (COLD CAN)

Nominals: VF Zone (200 min⁻¹)–Detection: Rate and Duration Therapy: Quick Convert, 8 high energy shocks VT Zone (160 min⁻¹)–Detection: RhythmID or OBDE, Therapy: ATP x 2, 6 high energy shocks

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

Nominals: Enable use of Zip telemetry (Requires initial use of wand for device ID)

In clinic Follow-Up: Wireless ECG

Remote Follow Up

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

Beeper Feature (Patient Alerts): Beep During Capacitor Charge, Beep when Expiration is Indicated, Beep when Lead Impedance measurement (Shock or Pace) is Out-of-Range

Magnet Feature: Magnet Response (Off, Store EGM, Inhibit Therapy)

Remote Monitoring: This device is LATITUDE™ enabled

Wireless: Remote follow-up for all devices (MICS)

ICD Systems from Boston Scientific –

DYNAHEN™ EL (Extended Longevity) ICD, DYNAHEN™ MINI ICD, INOGEN™ EL ICD, INOGEN™ MINI ICD, ORIGEN™ EL ICD, ORIGEN™ MINI ICD

Indications and Use: Boston Scientific implantable cardioverter defibrillators (ICDs) are intended to provide ventricular antitachycardia/cardioversion (ATV) and ventricular defibrillation for automated treatment of life-threatening ventricular arrhythmias.

Contraindications: Use of these Boston Scientific pulse generators are contraindicated for the following patients: whose ventricular tachyarrhythmias may have reversible cause, such as: digitalis intoxication, electrolyte imbalance, hypoxia, sepsis, or patients whose ventricular tachyarrhythmias have a transient cause, such as: acute myocardial infarction (MI), electocution, drowning; or patients who have a unipolar pacemaker.

Warnings: Read this manual thoroughly before implantation to avoid damage to the pulse generator and/or lead. For single patient use only. Do not reuse, reprocess, or resterilize.

Program the pulse generator Tachy Modes to Off during implant, explant, or postmortem procedures to avoid inadvertent high voltage shocks. Always have external defibrillation equipment available during implant and electrophysiological testing. Ensure that an external defibrillator and medical personnel skilled in CPR are present during post-implant device testing should the patient require emergency rescue. Patients should seek medical guidance before entering environments that could adversely affect the operation of the active implantable medical device, including areas protected by a warning notice that prevents entry by patients who have a pulse generator. Do not expose a patient to MRI scanning.

Device Performance: The pulse generator is designed to provide 8 seconds of amplification, isprogrammable. VT-1 has 5 shocks, VT has 6 shocks and VF has 8 shocks. Reverse Last Shock Polarity in zone. Programmable RV Coil to RA Coil and Can (TRIAL), RV Coil to Can, RV Coil to RA Coil (COLD CAN)

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