Boston Scientific
Advancing science for life™

DYNAGEN™ MINI ICD

Models D020, D021, D022, and D023

- The world's smallest and thinnest high-energy ICD designed to enhance patient comfort.[1]
- Includes the new EasyView™ 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™ report, LATITUDE™ NXT Remote Patient Management enabled with Respiratory Rate Trend).
  - AcuShock™ 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™ with RHYTHMMATCH™ feature to allow customization of RHYTHM ID algorithm to reduce inappropriate shocks.
  - AV Search+ and RYTHMIQ™ which gives clinicians options to appropriately manage RV pacing in patients with varying degrees of conduction block.
  - Wireless ECG to save time and simplify follow-up.
  - Safety Core™ technology intended to provide lifesaving shock therapy and basic pacing functionality in the event of an unrecoverable fault.

Mechanical Specifications and Reimbursement Information

Model	Type	Size (cm) (W x H x D)	Mass (g)	Volume (cc)	Connector Type (RA RV LV)	
D020	VR	5.23 x 6.71 x 0.99	60.0	26.5	RV:DF4	1722
D021	VR	5.23 x 7.14 x 0.99	61.9	28.5	RV:IS-1/DF–1	1722
D022	DR	5.23 x 7.03 x 0.99	62.5	28.0	RA:IS-1;RV:DF4	1721
D023	DR	5.23 x 7.14 x 0.99	62.3	28.5	RA:IS-1;RV:IS-1/DF–1	1721

Pulse Generator Projected Longevity (All DYNAGEN MINI ICD Models [a,b,c,d])

	Longevity (years) at 500Ω, 700Ω, and 900Ω Pacing Impedance (RV)					
	500Ω		700Ω		900Ω	
Pacing	VR	DR	VR	DR	VR	DR
0%	5.5	5.3	5.5	5.3	5.5	5.3
15%	5.4	5.1	5.4	5.1	5.5	5.1
50%	5.2	4.7	5.3	4.7	5.3	4.8
100%	4.9	4.2	5.0	4.3	5.1	4.4

a Assumes ZIP™ telemetry use for 1 hour at implant time and for 40 minutes annually for in-clinic follow-up checks.
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).
c Assumes 60 bpm LRL, ventricular and atrial settings of 2.5 V pacing pulse Amplitude and 0.4 ms pacing pulse width; RA Impedance 500 ; sensors On.
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 a limited product warranty of 5 years (VR and DR). See BostonScientific.com/warranty for complete warranty terms and conditions.
- Devices use Li/MnO_2 battery chemistry.
- The usable battery capacity is 1.0 Amp-hours for the MINI ICD (typical implant to battery capacity depleted).
- Shelf life is 2 years (before use by date).

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

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Pacing Therapy

Brady Modes	Normal: DDD(R), DDI(R), VDD(R), VVI(R), AAI(R), Off Temporary: DDD, 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	AV Search+, RYTHMIQ™, AV Delays to 400 ms, Rate Hystersis

Patient Diagnostics

Arrhythmia Logbook	Events summary, Stored Electrograms 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
Histograms & Counters	Tachy Events and Brady Counters
Heart Rate Variability (HRV)	SDANN and HRV Footprint (24 hour heart rate collection period)
Daily Trends For Last 365 Days	HF Perspectiv™ report, Events, Activity Level, Atrial Burden, Respiratory Rate, Heart Rate, SDANN, HRV Footprint, Autonomic Balance Monitor (ABM), Lead impedances and amplitudes ***To note: Automatic activation of all available daily trends at implant.***
AT/AF Diagnostics	% Atrial Burden, Daily burden, Average V-rate during ATR Mode Switch Episode
Heart Failure Therapy/ Diagnostics	HF Perspectiv™ report, Respiratory Rate Trend, Heart Rates, HRV Footprint, SDANN, Autonomic Balance Monitor (ABM), Atrial Arrhythmia Burden, Activity Level, A & V Arrhythmias, Pacing Histograms

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

Tachyarrhythmia 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	AcuShock™ 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 Pacing Therapy (ATP) Termination	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 (TRIAD), RV Coil to Can, RV Coil to RA Coil (COLD CAN)
Nominals	VF Zone (200 bpm)–Detection: Rate and Duration, Therapy: Quick Convert, 8 high energy shocks VT Zone (160 bpm)–Detection: RhythmID or Onset/Stability, 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 Nominal: 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 Explant 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)

[1] Boston Scientific Implantable Cardioverter Defibrillator Physician's Technical Manual 359050-003 EN US 2014-01. Biotronik Ilesto 5/7 Technical Manual 404843 Revision G (2014-10-15). Medtronic Evera™ XT VR DVBB2D4 Device Manual. St. Jude Medical High Voltage Devices User's Manual April 2013.

ICD Systems from Boston Scientific – PUNCTUA™, ENERGEN™, and INCEPTA™

ICD INDICATIONS AND USAGE
PUNCTUA™, ENERGEN™, and INCEPTA™ ICDs are intended to provide ventricular antitachycardia pacing and ventricular defibrillation for automated treatment of life-threatening ventricular arrhythmias.

CONTRAINDICATIONS
Use of these ICD systems are contraindicated in: Patients whose ventricular tachyarrhythmias may have reversible cause, such as 1) digitalis intoxication, 2) electrolyte imbalance, 3) hypoxia, or 4) sepsis, or whose ventricular tachyarrhythmias have a transient cause, such as 1) acute myocardial infarction, 2) electrocution, or 3) drowning. Patients who have a unipolar pacemaker.

WARNINGS
Read the product labeling thoroughly before implanting the pulse generator to avoid damage to the ICD system. For single patient use only. Do not reuse, reprocess, or resterilize. Program the pulse generator ventricular Tachy Mode to Off during implant, explant or post-mortem procedures. Always have external defibrillator protection available during implant and electrophysiologic testing. Ensure that an external defibrillator and medical personnel skilled in cardiopulmonary resuscitation (CPR) are present during post-implant device testing. 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. Do not subject a patient with an implanted pulse generator to diathermy. Do not use atrial tracking modes in patients with chronic refractory atrial tachyarrhythmias. Do not use this pulse generator with another pulse generator. Do not kink, twist or braid lead with other leads. For Patient Triggered Monitor (PTM) feature, make sure the feature is enabled prior to sending the patient home with a magnet. Once the PTM feature has been triggered and the magnet response programming is set to inhibit therapy, the patient should not reapply the magnet.

For DF4-LLHH or DF4-LLHO leads, use caution handling the lead terminal when the Connector Tool is not present on the lead and do not directly contact the lead terminal with any surgical instruments or electrical connections such as PSA (alligator) clips, ECG connections, forceps, hemostats, and clamps. Do not contact any other portion of the
DF4-LLHH or DF4-LLHO lead terminal, other than the terminal pin even when the lead cap is in place.

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 electromagnetic interference (EMI).

POTENTIAL ADVERSE EVENTS
Potential adverse events from implantation of the ICD system 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 (shocks/pacing/sensing), infection, procedure related, psychologic intolerance to an ICD system – patients susceptible to frequent shocks despite antiarrhythmic medical management/imagined shocking, and component failure. 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. C)

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