เครื่องช่วยการเต้นของหัวใจ ชนิดกระตุ้นหัวใจห้องล่างสองห้องพร้อมกัน
สามารถกระตุกไฟฟ้าหัวใจอัตโนมัติ

Boston Scientific
Advancing science for life™

VIGILANT™ X4 CRT-D

Model G247

- HeartLogic™ Heart Failure Diagnostic for detecting indications of worsening heart failure status.
- SmartCRT™ is Boston Scientific's approach to personalize CRT therapy by providing physicians with smart solutions to optimize where, when, and how to pace.
- EnduraLife™ Battery Technology provides more power to use more of the device, featuring up to 13.3 years projected longevity with MultiSite Pacing turned on.*
- ImageReady™ MR Conditional Systems allow patients to safely undergo 1.5T Full Body MRI scans.**

* Assumes 2.0V RA, LV-only, 2.0V LV, 700 Ω, 15% A pacing, 100% LV pacing, No LATITUDE, No Respiratory Rate Sensor, No Heart Failure Sensor Suite.
** When conditions of use are met.

HeartLogic™ Heart Failure Diagnostic | **SmartCRT**™ Technology | **ImageReady**™ MR-Conditional Systems | **EnduraLife**™ Battery Technology

Mechanical Specifications

Model	Type	Size (cm) (W x H x D)	Mass (g)	Volume (cc)	Connector Type (RA RV LV)	C-Code
G247	X4 CRT-D	5.37 x 8.18 x 0.99	73.8	32.5	RA: IS-1; RV: DF4; LV: IS4	C1882

Pulse Generator Life Expectancy Estimation (Implant to Explant) with EnduraLife Battery (All Models)

EnduraLife Battery Technology provides clinically-proven, industry-leading projected longevity.[1-16] The following tables represent sample pulse generator life expectancy estimation (implant to explant) with EnduraLife battery as provided in product labeling. For specific programmable parameter ranges, refer to product labeling at ***www.bostonscientific-elabeling.com***, or contact Boston Scientific technical services or your local representative.

Projected longevity[a]	Ventricular Chambers	RA/RV	LV	LVb[d]	500Ω with LATITUDE™[b]	700Ω with LATITUDE™[b]	700Ω no LATITUDE™, RS, or HFSS[c]
MultiSite Pacing Off							
Typical programmed setting	BiV	2.5 V	3.0 V	Off	9.7	10.5	11.3
Maximum labeled longevity	LV-Only	2.0 V / Off	2.0 V	Off	12.9	13.2	14.7
MultiSite Pacing On							
Typical programmed setting	BiV MSP	2.5 V	3.0 V	3.0 V	8.2	9.1	9.7
Maximum labeled longevity	LV-Only MSP	2.0 V / Off	2.0 V	2.0 V	11.5	12.1	13.3

- Assumes 70 PPM LRL, DDDR mode; 0.4 ms Pulse Width (RA, RV, LV); sensors On, Heart Failure Sensor Suite On.
- Projected longevity is calculated assuming 2 maximum energy charging cycles per year, including automatic capacitor re-forms and therapeutic shocks. These calculations also assume 3-channel EGM Onset is on and that the pulse generator spends 3 months in Storage mode during shipping and storage.

a. Assumes ZIP telemetry use for 2 hours at implant 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, quarterly scheduled remote follow ups, and other typical interrogations.
c. Assumes LATITUDE™ Communicator is not used, Respiratory Sensor is Off, and Heart Failure Sensor Suite is Off.
d. Applies to models with MultiSite Pacing (MSP).

Additional Longevity Information

- Boston Scientific devices have corporate warranties at 6 years in available geographies. Warranty information available at ***www.bostonscientific.com/warranty***.
- Devices use Li/MnO_2 chemistry.
- The Usable Battery Capacity is 1.9 Amp-hours (typical implant to battery capacity depleted).
- Shelf life is 2 years (before use by date).

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VIGILANT™ X4 CRT-D
Model G247

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) - MIN, MED, MAX, Atrial Flutter Response (AFR), PMT Termination, Rate Smoothing
Automaticity	PaceSafe Right Ventricular Automatic Threshold (RVAT), PaceSafe Left Ventricular Automatic Threshold (LVAT), PaceSafe Right Atrium Automatic Threshold (RAAT)
Rate Adaptive Pacing	Accelerometer with sensor trending function

Heart Failure Therapy

LV Pacing Lead Configuration	LV VectorGuide streamlines the testing required to determine the optimal LV Pacing Lead Configuration for each individual patient, using four tests: RVS-LVS Delay, LV Pace Threshold, Phrenic Nerve Stimulation (PNS), and LV Lead Impedance. Clinician can quickly evaluate multiple Quadripolar LV pacing vectors and then program the desired configuration
Heart Failure Therapy Optimization	SmartDelay™ (AV Optimization), BiV Trigger, LV Offset, LV Sensing, BiV or LV-only pacing modalities
VectorGuide	RVS-LVS sense (automatic), PNS, impedance threshold
LV Lead Options	Quadripolar LV lead
LV Pacing Vector Options	17
LV Sensing Vector Options	8 options plus OFF

Patient Diagnostics

AT/AF Diagnostics	AT/AF Burden, Daily burden, Average V-rate during ATR Mode Switch Episode
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
Daily Trends For Last 365 Days	Events, Lead impedances and amplitudes, RA Pace Threshold, RV Pace Threshold, LV Pace Threshold
Heart Failure Trends and Diagnostics	Heart Failure Management Report, Weight, Blood Pressure, Events, Activity Level, AT/AF Burden, Respiratory Rate, Heart Rate, Heart Rate Variability (SDANN), HRV Footprint, Thoracic Impedance, Night Heart Rate, Sleep Incline ***To note: Weight and Blood Pressure are only available via LATITUDE™.***

HeartLogic™ Heart Failure Diagnostic

HeartLogic™ Heart Failure Diagnostic	The HeartLogic Index and Alert are a validated diagnostic tool to detect gradual worsening of heart failure over days or weeks using multiple physiological measurements. The HeartLogic Index aggregates measurements from multiple device-based sensors (Heart Sounds, Thoracic Impedance, Respiration, and Night Heart Rate) and reflects changes over time in the patient's sensor trend data from their respective baseline values.
HeartLogic™ Heart Failure Management Report	HeartLogic™ composite index and alert, S3 Heart Sound, S1 Heart Sound, Thoracic Impedance, Respiratory Rate, Night Heart Rate, Sleep Incline, Activity Level, AT/AF Burden, V therapy, Mean Heart Rate, % LV Paced, Heart Rate Variability (SDANN), Weight, Blood Pressure ***To note: HeartLogic™ composite index and alert, heart sounds, weight, and blood pressure are only available through LATITUDE™.***

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™, RhythmID™, 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: Rhythm ID or Onset/Stability, Therapy: ATP x 2, 6 high energy shocks

MultiSite Pacing

LV Multisite Pacing (MSP)	LV MSP is intended to improve the cardiac resynchronization therapy response by delivering two LV pulses per pacing cycle. 17 vectors with 216 possible MSP configurations
SmartVector	Automatically recommends LV MSP pacing sequence, pacing vectors, and pacing characteristics (amplitude and pulse width) based on RVS-LVS delay and electrode separation distance
SmartOffset	Automatically recommends the programmed delays between the ventricular paces. Timing offsets = 0–100 ms

ImageReady™ MR Conditional System

MRI Lead Selection	RELIANCE™4-SITE defibrillation leads - active and passive fixation, single and dual coil, 59 cm, 64 cm and 70 cm INGEVITY™ and FINELINE™ II pacing leads – active and passive fixation, straight and J, 45 cm, 52 cm, 58 cm, and 59 cm ACUITY™ X4 LV Leads - straight, spiral S and spiral L, 86 cm and 95 cm
MRI Conditions	1.5T, SAR 2 W/kg
MRI Protection Mode	Asynchronous pacing during scan (DOO, VOO, and AOO) Programmable time out: Off, 3 ,6, 9, and 12 hours

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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

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)

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 designed to be LATITUDE™ enabled; LATITUDE™ 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)

References:

1. Nine independent studies confirm that CRT-Ds powered by EnduraLife Battery Technology offer industry-leading longevity.

2. Haarbo J, Hjortshoj S, Johansen J, Jorgensen O, Nielsen J, Petersen H. Device Longevity in Cardiac Resynchronization Therapy Implantable Cardioverter Defibrillators Differs Between Manufacturers. Data from the Danish ICD Registry. Presented at HRS 2014. http://ondemand.hrsonline.org/common/presentation-detail.aspx/15/35/1241/9000. Boston Scientific = 136 patients, Medtronic = 651 patients, St. Jude Medical = 1,587 patients, Biotronik = 369 patients. Time to exchange of the device because of battery depletion or device failure recorded in the Danish ICD Registry was the endpoint. The four year survival rate for devices in the Danish Registry study was 81.1% for Medtronic and 95.7% for Boston Scientific (P<0.01).

3. J. Williams, R. Stevenson. Contemporary cardiac resynchronization implantable cardioverter defibrillator battery longevity in a community hospital heart failure cohort. Presented at HFSA 2014. http://www.onlinejcf.com/article/, S1071-9164(14)00389-3/fulltext. Boston Scientific – 53 patients, Medtronic – 28 patients, St. Jude Medical – 10 patients. Four-year survival rate calculated using device replacements for battery depletion as indicated by ERI.

4. Ellis CR, Dickerman DI, Orton JM, Hassan S, Good EG, Okabe T, Andrulli JA, Quan KJ, Greenspoon AJ. Ampere Hour as a Predictor of Cardiac Resynchronization Defibrillator Pulse Generator Battery Longevity: A Multicenter Study. PACE 2016 doi: 10.1111/pace.12831 first published online 11-MAR-2016. The five major institutions performing the study include: at Vanderbilt University, Henry Ford Hospital, University of Michigan, Thomas Jefferson University, Cooper Health System, North Ohio Heart Center. Boston Scientific = 322 patients, Medtronic = 794 patients, St. Jude Medical = 186 patients. Five-year survival rate calculated using device replacements for battery depletion as indicated by ERI.

5. Landolina M, Curnis A, Morani G, Vado A, Ammendola E, D'onofrio A, Stabile G, Crosato M, Petracci B, Ceriotti C, Bontempi L, Morosato M, Ballari GP, Gasparini M. Longevity of implant Cardioverter-defibrillators for cardiacresynchronization therapy in current clinical practice: an analysis according to influencing factors, device generation, and manufacturer. Europace2015; 17:1251-58 doi:10.1093/europace/euv109. First published online: May 14, 2015. Medtronic = 532 patients, Boston Scientific = 291 patients, St. Jude Medical = 106 patients, Biotronik = 20 patients, Sorin = 69. Five year survival rate of latest marketed devices (between 2008 and 2010) calculated using device replacements for battery depletion as indicated by ERI.

6. Zanon F, Martignani C, Ammendola E, Menardi E, NarducciML, De Filippo P, Santamaria M, Campana A, Stabile G, Potenza DR, Pastore G, Iori M, La Rosa C, and Biffi M. Device Longevity in a Contemporary Cohort of ICD/CRT-D Patients Undergoing Device Replacement. Doi 10.1111/jce.12990, First published online 20-APR-2016. Comparison of device longevity by Kaplan-Meier curves of CRT-D systems extracted between March 2013 and May 2015. Medtronic = 195 patients, Boston Scientific = 157 patients, St. Jude = 72, Biotronik = 9.

7. Provided by Dr. Ernest Lau on 04/29/15 in support of Lau E, Wilson C, Ashfield K, McNair W, McEneany D, Roberts M, Large Capacity LiMnO2 Batteries Extended CRTD Longevity in Clinical Use Compared to Smaller Capacity Li/SVO Batteries Over 6 Years. Presented at HRS 2015. Medtronic = 62 patients, Boston Scientific = 27 patients, St. Jude = 68 patients. Five-year survival rate calculated using device replacements for battery depletion as indicated by ERI.

8. Von Gunten S, Schaer BA, Yap SC, Szili-Torok T, Kuhne M, Sticherling C, Osswald S, Theuns DA. Longevity of implantable cardioverter defibrillators: a comparison among manufacturers and over time. Europace. 2015 Nov 25. Epub 2015 Nov 25. Total patients = 3436.

9. Alam MB, Munir MB, Rattan R, Adelstein E, Jain S, Saba S. Battery longevity from cardiac resynchronization therapy defibrillators: differences between manufacturers and discrepancies with published product performance reports. Europace 016 doi:10.1093/europace/euw044. First published online: 22-MAR-2016. Kaplan Meier curves depicting survival of CRT devices free from battery depletion by device manufacturer. Battery Longevity in Cardiac Medtronic = 416 patients, Boston Scientific = 173 patients, St. Jude Medical = 57 patients. Previously evaluated these patients at a four-year survival rate calculated using device replacements for battery depletion as indicated by ERI. 2014 Europace (2014) 16,246-51.

10. Shabanna Din, Shabanna; Mcgee, Rao, Archana; Wright, Jay D. Longevity of implantable cardioverter defibrillators: The impact of device manufacturer and device type on device longevity were assessed. Europace. 2015 Nov 25. Epub 2015 Nov 25. Total patients = 3436. Cardiostim Abstract 2016. Total patients = 1489.

ICD Systems – RESONATE™ HF, RESONATE™ EL, PERCIVA™ HF, PERCIVA™, VIGILANT™ EL, MOMENTUM™ EL

INDICATIONS AND USAGE Boston Scientific implantable cardioverter defibrillators (ICDs) are intended to provide ventricular antitachycardia pacing (ATP) 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), electrocution, 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. 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. Do not use this pulse generator with another pulse generator. Program the pulse generator Tachy Mode(s) to Off during implant, explant, or postmortem procedures to avoid inadvertent high voltage shocks. Do not kink, twist, or braid the lead with other leads as doing so could cause lead insulation abrasion damage or conductor damage. For leads that require the use of a Connector Tool, use caution handling the lead terminal when the Connector Tool is not present on the lead. 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. Do not use atrial tracking modes in patients with chronic refractory atrial tachyarrhythmias. Tracking of atrial arrhythmias could result in ventricular tachyarrhythmias. Advise patients to 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. RESONATE HF, RESONATE, PERCIVA HF, PERCIVA, and VIGILANT devices with a DF4 right ventricular lead connection are considered MR Conditional. For these devices, 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. For potential adverse events applicable when the Conditions of Use are met or not met, refer to the MRI Technical Guide. Do not subject a patient with an implanted pulse generator and/or lead to diathermy. If desired, ensure that Patient Triggered Monitor is enabled prior to sending the patient home. Once the Patient Triggered Monitor feature has been triggered by the magnet and an EGM has been stored, or after 60 days have elapsed from the day that Store EGM was enabled, the patient should not apply the magnet.

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, and supplemental precautionary information.

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 (shocks /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 B)

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สายกระตุ้นหัวใจห้องล่างซ้าย
(Coronary sinus pacing lead)

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ACUITY™ X4

Quadripolar LV Leads

Models (Straight) 4671, 4672 (Spiral S) 4674, 4675 (Spiral L) 4677, 4678

Improving Delivery and Optimizing Pacing Performance

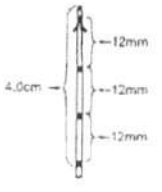
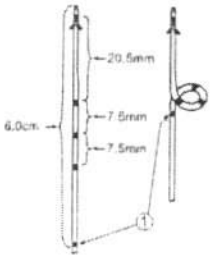
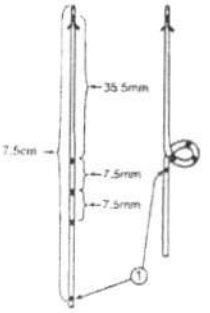
- Industry's smallest diameter,[1,2,3] atraumatic tip (2.6F) with small diameter silicone distal sections on all lead models designed to track into tortuous vasculature
- Three tip configuration designs are intended to provide choices for a variety of patient anatomies
- Inner catheter deliverable to provide additional options for lead placement
- Dual Fixation: silicone rubber tines and a distal, 3D shape on spiral models designed to provide an additional or alternative passive fixation option (5.4)
- Electrodes on the 3D spiral help overcome challenges in mid-base (proximal) ventricular regions:
  - The 3D shape presses electrodes against vessel walls, thereby improving the threshold performance of proximal electrodes[4]
  - Electrodes oriented around the circumference of the spiral increase the chances that at least one of three electrodes will be adjacent to the myocardium in any coronary vasculature location

Redefining Quadripolar Pacing to Improve CRT Response

- Only Boston Scientific offers quadripolar technology with multiple electrode configuration options to allow the lead to be fixated distally and tailor the electrode placement to the patient anatomy, which may promote basal or mid-ventricular pacing
- An industry-leading 17 pacing vectors are available when used with a Boston Scientific X4 CRT-D or X4 CRT-P
  - Using LV VectorGuide™ will streamline testing and help you quickly determine the optimal pacing configuration for each X4 CRT-D patient.

Reimbursement Information C-Code: C-1900

Product Specifications

Length/Model	86cm - 4671 95cm - 4672	86cm - 4674 95cm - 4675 (5.9)	86cm - 4677 95cm - 4678
Electrode Spacing		 1 – Radiopaque Marker	 1 – Radiopaque Marker
Fixation Method	Tines	- Tines - 3D Spiral	- Tines - 3D Spiral

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ACUITY™ X4

Quadripolar LV Leads

Models (Straight) 4671, 4672 (Spiral S) 4674, 4675 (Spiral L) 4677, 4678

Product Specifications *(continued)*

Compatibility	IS4-LLLL (5.6)
Delivery Method	Over the wire (5.4)
Recommended Guide Catheter Size	0.081 in (2.06 mm) minimum inner diameter
Diameter	
Proximal Body	5.2F (1.7mm)
Distal Body	3.9F (1.3mm) (5.3)
Distal Tip	2.6F (0.9mm)
Insulation Material	
External Insulation	Polyurethane and silicone
Internal Insulation	Polyurethane, silicone, ETFE (5.8)
Conductor Material	
Coil (pin to distal electrode)	Low titanium MP35N
Cable (rings to proximal electrodes)	Low titanium MP35N with tantalum core
Electrodes	
Material	IROX coated platinum iridium (5.7)
Tip Electrode Surface Area	4.1mm²
Proximal Electrode Surface Area	8.3mm²
Steroid	Dexamethasone acetate (5.5)
Suture Sleeve	Radiopaque white silicone, three grooves
Accessories included	Vein pick, ACUITY X4 Flushing Tool/Wire Guide, ACUITY X4 Connector Tool

Accessories

ACUITY X4 Connector Tool (Model 4625)

The Connector Tool can be attached to a lead with or without a guidewire inserted and performs the following functions when attached to the lead:

- Protects the lead terminal during the implant procedure when determining lead electrical performance
- Provides a safe and secure connection between PSA patient cables and the lead terminal

ACUITY X4 Flushing Tool/Wire Guide (Model 4604)

The flushing tool/wire guide performs the following functions when attached to the lead:

- Provides compatibility with luer lock and luer slip tip syringes for flushing the lead
- Provides a wire guide to ease insertion of a guide wire

1 ACUITY™ X4 Physician's Lead Manual 359180-002 EN US 2015-07
2 ATTAIN™ PERFORMA™ 4298 Technical Manual M948374A001, ATTAIN™ PERFORMA™ STRAIGHT 4398 Technical Manual M948374A001, ATTAIN™ PERFORMA™ S 4598 Technical Manual M950705A001
3 Quartet™ Users Manual 100047495
4 Clinical Summary 359849-022 EN US 2016-01

(5.1)

ACUITY X4 Brief Summary

Indications This Boston Scientific lead is indicated for use as follows: Intended for chronic, left ventricular pacing and sensing via the coronary venous system when used in conjunction with a compatible pulse generator. The Boston Scientific ACUITY X4 lead is a steroid eluting (dexamethasone acetate) IS4 quadripolar lead.

Contraindications Use of this Boston Scientific lead is contraindicated for the following patients: Patients with a hypersensitivity to a maximum single dose of 0.54 mg dexamethasone acetate.

Warnings 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. Ensure that an external defibrillator and medical personnel skilled in CPR are present during post-implant device testing should the patient require external rescue. When using a right ventricular (RV) pace/sense lead in conjunction with this left coronary venous pace/sense lead, it is recommended that a polyurethane insulated lead be used. 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 bend the lead with other leads as doing so could cause lead insulation abrasion damage or conductor damage. Use caution handling the lead terminal when the Connector Tool is not present on the lead. 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 lead terminal, other than the terminal pin, even when the lead cap is in place. When implanting a system which uses both a DF4-LLHH/LHO2 and IS4-LLL3 lead, ensure that the leads are inserted and secured in the appropriate ports. Only use the Connector Tool for electrical connections to pacing system analyzers of similar make and model. Take care to obtain appropriate electrode position. 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 may cause fibrillation, burning of the myocardium, and irreversible damage to the pulse generator because of induced currents.

Precautions Refer to the lead product labeling for cautions specific to clinical considerations, sterilization and storage, handling, implanting, hospital and medical environments, and testing the lead. Failure to observe these cautions could result in incorrect lead implantation, lead damage and/or harm to the patient.

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.

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

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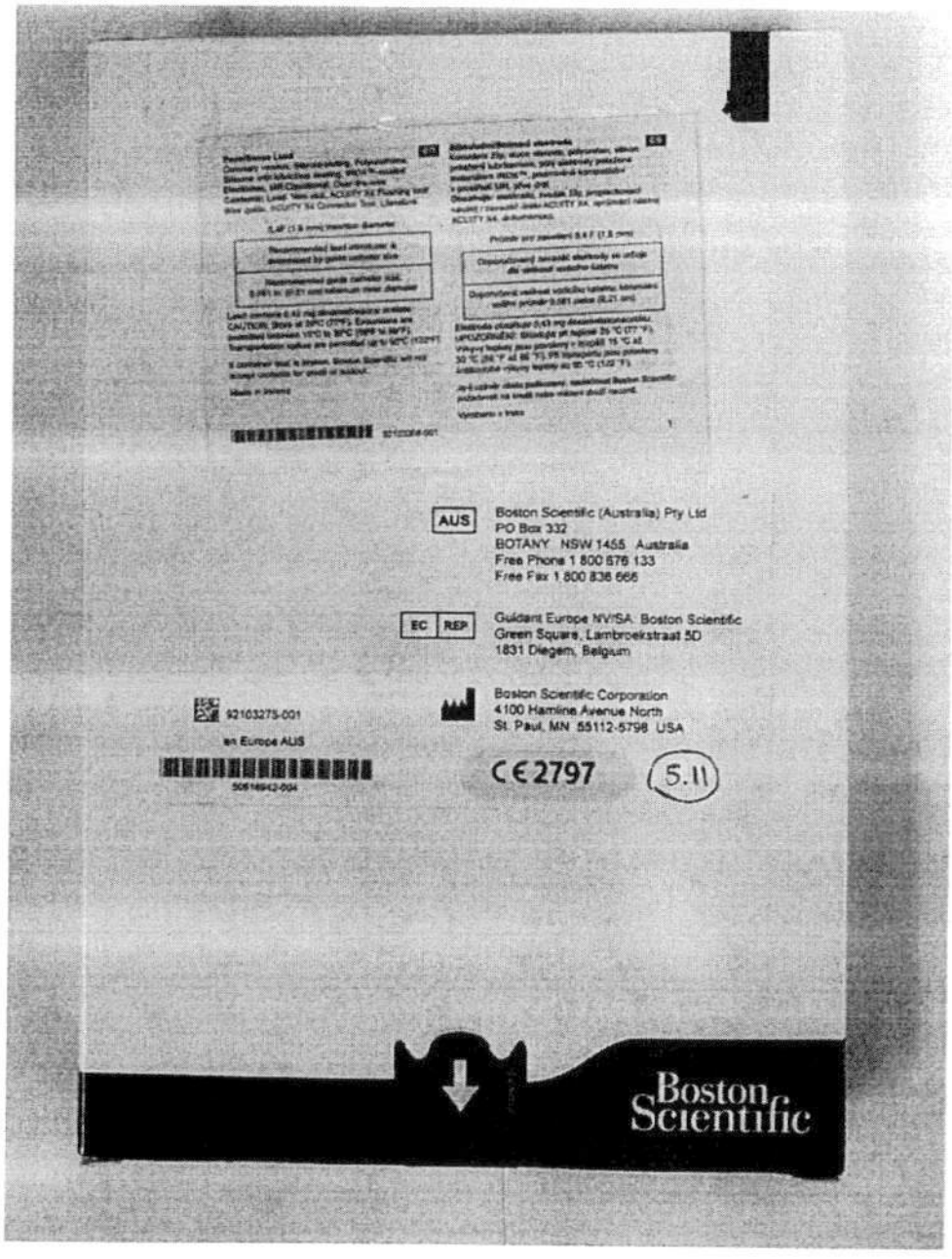

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แบบ บ.น.ท 1

รับรองบางส่วน
หนังสือรับรองประกอบการนำเข้าเครื่องมือแพทย์
สำนักงานคณะกรรมการอาหารและยา
กระทรวงสาธารณสุข

หนังสือเลขที่ IRL 6306382

2 กรกฎาคม 2563

ได้พิจารณาหนังสือรับรองการขาย/หนังสือรับรองการขายและหนังสือรับรองระบบคุณภาพการผลิตแล้ว ถูกต้องตามประกาศกระทรวงสาธารณสุข (ฉบับที่ 34) พ.ศ. 2549 แห่งพระราชบัญญัติเครื่องมือแพทย์ พ.ศ. 2531

ชื่อผู้นำเข้า : **บริษัท บอสตัน ไซเอนทิฟิค(ประเทศไทย) จำกัด**

ชื่อผู้ผลิต : BOSTON SCIENTIFIC LIMITED (IRELAND)

หนังสือฉบับนี้ใช้ประกอบกับ ☑ หนังสือรับรองการขายเลขที่ CFS010325

ประเทศ Ireland

☑ หนังสือรับรองระบบคุณภาพการผลิตเลขที่ MD 607739

สามารถใช้ประกอบการนำเข้าเครื่องมือแพทย์จนถึงวันที่ 13 กันยายน 2567

สำนักงานคณะกรรมการอาหารและยา

กระทรวงสาธารณสุข

ผู้อนุญาต

เงื่อนไข

1.เมื่อปรากฏว่าประเทศผู้ผลิตหรือประเทศเจ้าของผลิตภัณฑ์ห้ามขาย หรือมีการยกเลิกการรับรองระบบคุณภาพการผลิตของเครื่องมือแพทย์รายการใดตามที่ระบุไว้ในหนังสือรับรองฉบับนี้ให้ถือว่าการรับรองเครื่องมือแพทย์ดังกล่าวเป็นอันยกเลิก

2. ห้ามนำเลขที่หนังสือไปประกาศโฆษณา

3. ห้ามโฆษณาว่าได้ผ่านการรับรองจากสำนักงานคณะกรรมการอาหารและยา

4. ห้ามโฆษณาเครื่องมือแพทย์ก่อนได้รับความเห็นชอบจากสำนักงานคณะกรรมการอาหารและยา

5. สำนักงานคณะกรรมการอาหารและยา ขอสงวนสิทธิ์ที่จะยกเลิก/เพิกถอนหนังสือรับรองประกอบการนำเข้าเครื่องมือแพทย์ฉบับนี้ หากผู้นำเข้าไม่ดำเนินการให้เป็นไปตามกฎกระทรวงกำหนดหลักเกณฑ์วิธีการ และเงื่อนไข การจดทะเบียนสถานประกอบการนำเข้าเครื่องมือแพทย์ที่ออกตามพระราชบัญญัติเครื่องมือแพทย์ พ.ศ. 2551 เมื่อกฎกระทรวงดังกล่าวมีผลบังคับใช้แล้ว

หมายเหตุเพิ่มเติม

ข้อมูลที่ผู้ประกอบการบันทึกเข้ามาทั้งหมดถือเป็นความรับผิดชอบของผู้ประกอบการ

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รายการนำเข้าผลิตภัณฑ์เครื่องมือแพทย์ ตามหนังสือรับรองเลขที่ IRL 6306382

วันที่อนุมัติ 2/7/2563 วันที่หมดอายุ 13/9/2567

Owner	manucd	gmpno	catno	offname	pdtname	desc	pageno	umdn	gmdn	RefItemNo
47929	47931	MD 607739	4555	ACUITY Steerable Implantable Lead	ACUITY Steerable Implantable Lead	ACUITY Steerable Implantable Lead	4	11458	35223	6347931000077
47929	47931	MD 607739	4671	ACUITY X4 Straight Implantable Lead	ACUITY X4 Straight Implantable Lead	ACUITY X4 Straight Implantable Lead	4	11458	35223	6347931000078
47929	47931	MD 607739	4672	ACUITY X4 Straight Implantable Lead	ACUITY X4 Straight Implantable Lead	ACUITY X4 Straight Implantable Lead	4	11458	35223	6347931000079
47929	47931	MD 607739	4674	ACUITY X4 Spiral S Implantable Lead	ACUITY X4 Spiral S Implantable Lead	ACUITY X4 Spiral S Implantable Lead	4	11458	35223	6347931000080
47929	47931	MD 607739	4675	ACUITY X4 Spiral S Implantable Lead	ACUITY X4 Spiral S Implantable Lead	ACUITY X4 Spiral S Implantable Lead	4	11458	35223	6347931000081
47929	47931	MD 607739	4677	ACUITY X4 Spiral L Implantable Lead	ACUITY X4 Spiral L Implantable Lead	ACUITY X4 Spiral L Implantable Lead	4	11458	35223	6347931000082
47929	47931	MD 607739	4678	ACUITY X4 Spiral L Implantable Lead	ACUITY X4 Spiral L Implantable Lead	ACUITY X4 Spiral L Implantable Lead	4	11458	35223	6347931000083
47929	47931	MD 607739	7731	INGEVITY MRI Implantable Lead	INGEVITY MRI Implantable Lead	INGEVITY MRI Implantable Lead	4	11458	35223	6347931000084
47929	47931	MD 607739	7732	INGEVITY MRI Implantable Lead	INGEVITY MRI Implantable Lead	INGEVITY MRI Implantable Lead	4	11458	35223	6347931000085
47929	47931	MD 607739	7735	INGEVITY MRI Implantable Lead	INGEVITY MRI Implantable Lead	INGEVITY MRI Implantable Lead	4	11458	35223	6347931000086
47929	47931	MD 607739	7736	INGEVITY MRI Implantable Lead	INGEVITY MRI Implantable Lead	INGEVITY MRI Implantable Lead	4	11458	35223	6347931000087
47929	47931	MD 607739	7740	INGEVITY MRI Implantable Lead	INGEVITY MRI Implantable Lead	INGEVITY MRI Implantable Lead	4	11458	35223	6347931000088
47929	47931	MD 607739	7741	INGEVITY MRI Implantable Lead	INGEVITY MRI Implantable Lead	INGEVITY MRI Implantable Lead	4	11458	35223	6347931000089

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สายกระตุกไฟฟ้าหัวใจอัตโนมัติ
(Implantable Cardioverter Defibrillator lead)

Boston Scientific
Advancing science for life™

RELIANCE 4-FRONT™

Pace/Sense and Defibrillation Lead

RELIANCE 4-FRONT, Single-coil
RELIANCE 4-FRONT, Dual-coil

The RELIANCE 4-FRONT Leads are 7.3F (2.4 mm), steroid-eluting, endocardial cardioversion/defibrillation and pace/sense leads (4.1) available in extendable/retractable models as well as in passive fixation models. These leads utilize the DF4 connector and incorporate the IROX™ (iridium oxide) coating on the tip electrode. The silicone lead body has a lubricious coating, and the electrode coils are silicone-backfilled.

Lead Specifications (4.3)

Product	Dual-coil Active	Dual-coil Passive	Single-coil Active	Single-coil Passive
Model/Length	0675 59 cm 0676 64 cm 0653 70 cm	0665 59 cm 0636 64 cm 0651 70 cm	0672 59 cm (4.5) 0673 64 cm 0652 70 cm	0662 59 cm 0663 64 cm 0650 70 cm
Terminal Sizes	DF4-LLHH	DF4-LLHH	DF4-LLHO (4.6)	DF4-LLHO
PG Compatibility	RELIANCE 4-FRONT Leads with the DF4-LLHH / LLHO label are compatible with a device containing a DF4-LLHH port			
Lead Introducer without Guide Wire	8F (2.7 mm)	8F (2.7 mm)	8F (2.7 mm) (4.7)	8F (2.7 mm)
Lead Introducer with Guide Wire	10.5F (3.5 mm)	10.5F (3.5 mm)	10.5F (3.5 mm)	10.5F (3.5 mm)
Isodiametric Lead Body Diameter	7.3F (2.4 mm)	7.3F (2.4 mm)	7.3F (2.4 mm) (4.5)	7.3F (2.4 mm)
Rotations Expected to Extend/Retract Helix*	11	N/A	11	N/A
Tip/Helix Electrode Surface Area (mm^2)	5.7	3.5	5.7	3.5
Proximal Coil Active Electrode Surface Area (mm^2)	660	660	N/A	N/A
Distal Coil Active Electrode Surface Area (mm^2)	450	450	450	450
Tip to Proximal Coil Electrode Length (mm)	180	180	N/A	N/A
Tip to Distal Coil Electrode Length (mm)	12	12	12	12
Lead Body Insulation Material	Layer of silicone, layer of polyurethane (for the first ~ 12 cm) and then the silicone trilumen			
Terminal Pin Material	MP35N nickel-cobalt alloy			
Pace/Sense Conductor Material	Low titanium, MP35N nickel-cobalt alloy, PTFE sleeve			
Terminal Ring Material	MP35N nickel-cobalt alloy			
Shocking Conductor Material	1X19 Low titanium MP35N nickel-cobalt alloy, silver-core, drawn filled tube, ETFE coated			
Tip Electrode Material	IROX coated platinum/iridium			
Coil Electrode Material	Platinum clad tantalum clad titanium with silicone backfill			
Steroid Material	Approximately 0.96 mg dexamethasone acetate nominally (4.4)			

*Use the fluoroscopy markers for verification of full helix extension/retraction.

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Features

Limited Lifetime Lead Warranty available: For full terms and conditions, please visit www.BostonScientific.com/warranty.

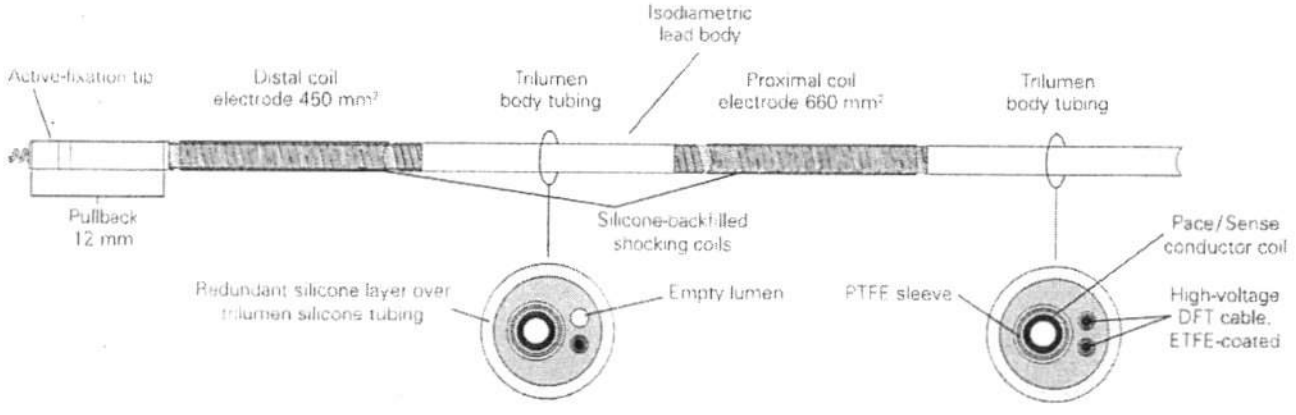
Terminal configuration: The RELIANCE 4-FRONT™ Lead is DF4-LLHH for dual-coil leads and DF4-LLHO for single-coil leads. This suffix provides functional identifications of conductors.

4.3

L = Low Voltage
H = High Voltage
O = Inactive Ring Contact (Single-Coil Leads Only)

4.2

Rings 1 and 2 are electrically connected within the terminal for integrated bipolar pacing/sensing. Cable conductors are utilized for both shock coils. Ring 2 is connected to the distal shock coil, and ring 3 connects to the proximal coil.



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Isodiametric lead body: The isodiametric lead body contains one conductor for pacing/sensing. For defibrillation, the lead has two conductors in dual-coil models and one for the single-coil models leaving one lumen empty in single-coil models. The conductors are insulated in separate lumens within the silicone rubber lead body. A second layer of silicone covers the lead body, providing additional insulation and a uniform body diameter. RELIANCE 4-FRONT™ has a 7.3F (2.4 mm) lead body which fits through an 8F (2.7 mm) non-hemostatic introducer when not retaining a guide wire.

Insulation:

- **Silicone construction:** Silicone has been used in Boston Scientific leads for nearly 4 decades.
- **Polyurethane sleeve:** The first 12 cm of the lead distal to the terminal boot incorporates a polyurethane sleeve underneath the outer silicone rubber insulation for enhanced abrasion resistance within the pocket.
- **Lubricious coating:** The RELIANCE 4-FRONT Lead family utilizes a proprietary coating that makes the silicone lead surface more lubricious. This reduces both the static and dynamic coefficients of friction, making the lead surface feel and handle like polyurethane while providing the time-tested reliability of silicone.

Backfilled coils: The silicone backfill enhances the lead's extractability by preventing fibrotic tissue from forming around and between the individual coil filars.

IROX™ coating: RELIANCE 4-FRONT features an IROX (iridium oxide) coated pace/sense cathode electrode, which may improve pacing performance. Lower and more predictable pacing thresholds may increase the longevity of the pulse generator.

Steroid distal tip: The tip electrode contains a nominal dose of steroid that elutes upon exposure to body fluids. The steroid suppresses the inflammatory response believed to cause threshold rises typically associated with implanted pacing electrodes. Lower thresholds are desirable because they can increase pacing safety margins and reduce pacing energy requirements, potentially increasing pulse generator longevity.

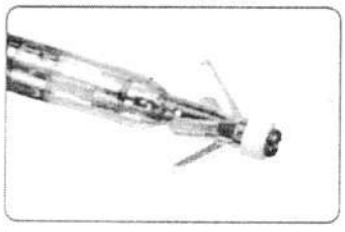
4.4

Pullback: Pullback is the distance the defibrillation electrode is removed from the lead tip, a critical factor in helping to direct energy deep into the ventricular apex. Standard for multiple generations of Boston Scientific defibrillation leads, the 12 mm RELIANCE 4-FRONT pullback design is important for low defibrillation thresholds, while optimizing sensing characteristics.

Radiopaque suture sleeve: The radiopaque suture sleeve is visible under fluoroscopy and is used to secure and protect the lead at the venous entry site after lead placement. The window feature is designed to aid compression of the sleeve onto the lead during suturing.

Passive-Fixation Features

Design: Leveraged from successful FINELINE™ II family. 12 mm Tip to RV Coil spacing is identical to RELIANCE. Incorporates a flexible neck region and IROX coating for improved pacing performance.

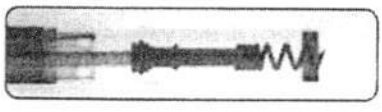


Active-Fixation Features

Terminal pin-driven extendable/retractable fixation helix: Rotating the knob of the EZ-4™ Connector tool rotates the terminal pin which extends/retracts the helix. The IROX coated platinum-iridium helix anchors the pacing electrode to the endocardial surface without support of trabecular structures, offering various lead placement possibilities for the tip electrode in the right ventricle.

Fluoroscopic markers: The RELIANCE 4-FRONT active fixation model incorporates a radiographic marker system to enable clear visualization of the helix position under fluoroscopy.

Fully retracted



Fully extended

Mapping: The RELIANCE 4-FRONT tip and helix design allows mapping even with the helix fully retracted. Helix is flush to prevent snagging while enabling mapping.

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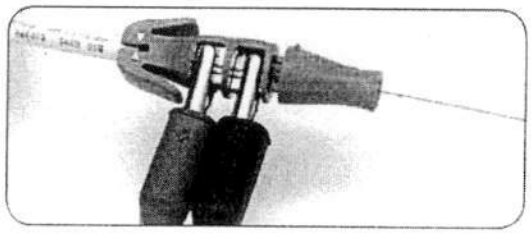
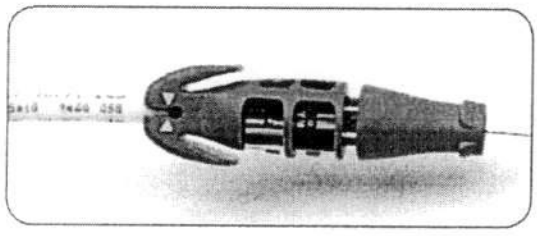
EZ-4™ Connector Tool





When connected to the lead, the EZ-4 Connector Tool performs the following functions.

1. Protects the lead terminal during the implant procedure.
2. Provides a safe and secure connection between the pacing system analyzer (PSA) patient cables and the lead terminal.
3. Guides the stylet into the lead through the stylet funnel.
4. For leads with an extendable/retractable helix, rotates the terminal pin clockwise or counterclockwise to extend or retract the helix.
   The EZ-4 Connector Tool is intended to be left on the lead for the duration of the implant, until the lead terminal is inserted into the header.

RELIANCE 4-FRONT™ Pace/Sense and Defibrillation Lead

Indications and Usage This Boston Scientific lead is indicated for use as follows:
• Intended for pacing, rate-sensing, and delivery of cardioversion and defibrillation shocks when used with a compatible pulse generator.

4.1

Contraindications Use of this Boston Scientific lead is contraindicated for the following patients:
• Patients who have a unipolar pacemaker
• Patients with a hypersensitivity to a maximum single dose of 1.1 mg dexamethasone acetate
• Patients with mechanical tricuspid heart valves

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. Always have external defibrillation equipment available during implant and electrophysiologic testing. Do not use any component of the lead system to assist in delivery of external-source rescue shocks or extensive tissue damage could occur. 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. The lead is not designed to tolerate excessive flexing, bending, or tension. Do not kink, twist, or braid the lead with other leads as doing so could cause lead insulation abrasion damage or conductor damage. Use caution handling the lead terminal when the Connector Tool is not present on the lead. Do not contact any other portion of the lead terminal, other than the terminal pin, even when the lead cap is in place. Implant of the system cannot be performed in an MRI site Zone III (and higher). In order to deliver defibrillation therapy, the single-coil models must be implanted with an additional defibrillation electrode. For DF4-LLHH or DF4-LLHO leads, only use the Connector Tool for electrical connections to pacing system analyzers or similar monitors. Take care to obtain appropriate electrode position. When connecting the lead to the pulse generator, it is very important that proper connections are made. 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 for the implanted system, and significant harm to or death of the patient and/or damage to the implanted system may result. Refer to the MRI Technical Guide for potential adverse events applicable when Conditions of Use are met or not met, as well as for a complete list of MRI-related Warnings and Precautions. Do not subject a patient with an implanted pulse generator and/or lead to diathermy.

Extendable/Retractable Models The safety and efficacy of the tip electrode placement in the right ventricle above midseptum has not been clinically established. Use fluoroscopy to verify that the lead tip is directed toward the apex when implanted.

Precautions For specific information on precautions, refer to the following sections of the product labeling: clinical considerations, sterilization and storage, handling, implantation, hospital and medical environments, follow-up testing.

Potential Adverse Events Based on the literature and on pulse generator and/or lead implant experience, the following alphabetical list includes the possible adverse events associated with implantation of products described in this literature:
• Air embolism • Allergic reaction • Arterial damage with subsequent stenosis • Bleeding • Bradycardia • Breakage/failure of the implant instruments • Cardiac perforation • Cardiac tamponade • Chronic nerve damage • Component failure • Conductor coil fracture • Death • Electrolyte imbalance/dehydration • Elevated thresholds • Erosion • Excessive fibrotic tissue growth • Extracardiac stimulation (muscle/nerve stimulation) • Fluid accumulation • Foreign body rejection phenomena • Formation of hematomas or seromas • Heart block • Hemorrhage • Hemothorax • Inability to defibrillate or pace • Inappropriate therapy (e.g., shocks and antitachycardia pacing [ATP] where applicable, pacing) • Incisional pain • Incomplete lead connection with pulse generator • Infection including endocarditis • Lead dislodgment • Lead fracture • Lead insulation breakage or abrasion • Lead tip deformation and/or breakage • Local tissue reaction • Low amplitude VF signals • Malignancy or skin burn due to fluoroscopic radiation • Myocardial trauma (e.g., irritability, injury, tissue damage) • Myopotential sensing • Oversensing/undersensing • Pericardial rub, effusion • Pneumothorax • Post-shock rhythm disturbances • Pulse generator and/or lead migration • Shunting current during defibrillation with internal or external paddles • Syncope • Tachyarrhythmias, which include acceleration of arrhythmias and early, recurrent atrial fibrillation • Thrombosis/thromboembolism • Valve damage • Vasovagal response • Venous occlusion • Venous trauma (e.g., perforation, dissection, erosion) For a list of potential adverse events associated with MRI scanning, refer to the ImageReady MR Conditional Defibrillation System MRI Technical Guide.

Refer to the product labeling for specific indications, contraindications, warnings/precautions and adverse events.
Rx only. Version 1. 046774 AF

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www.bostonscientific.com

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IFM-553413-AA

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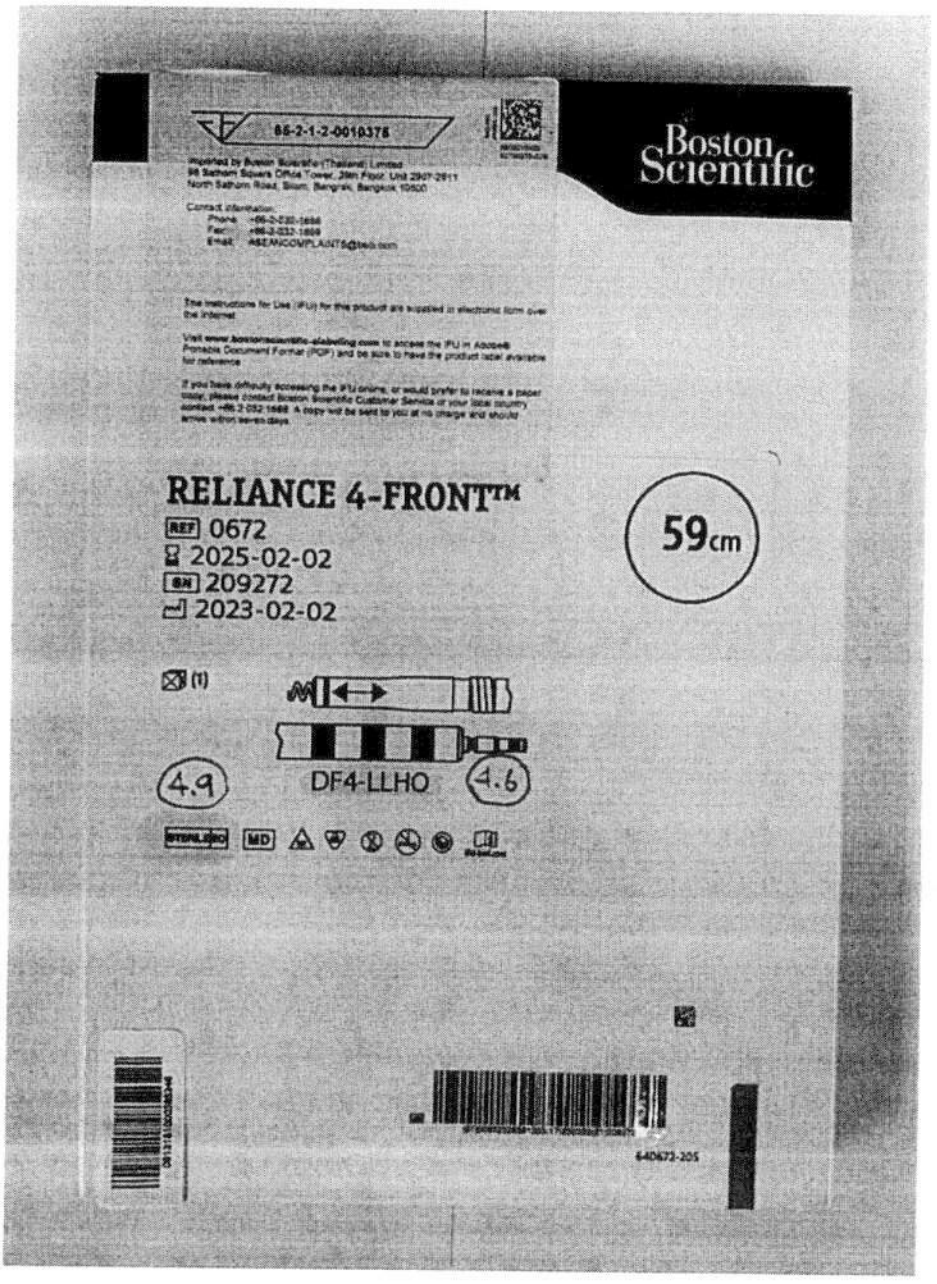

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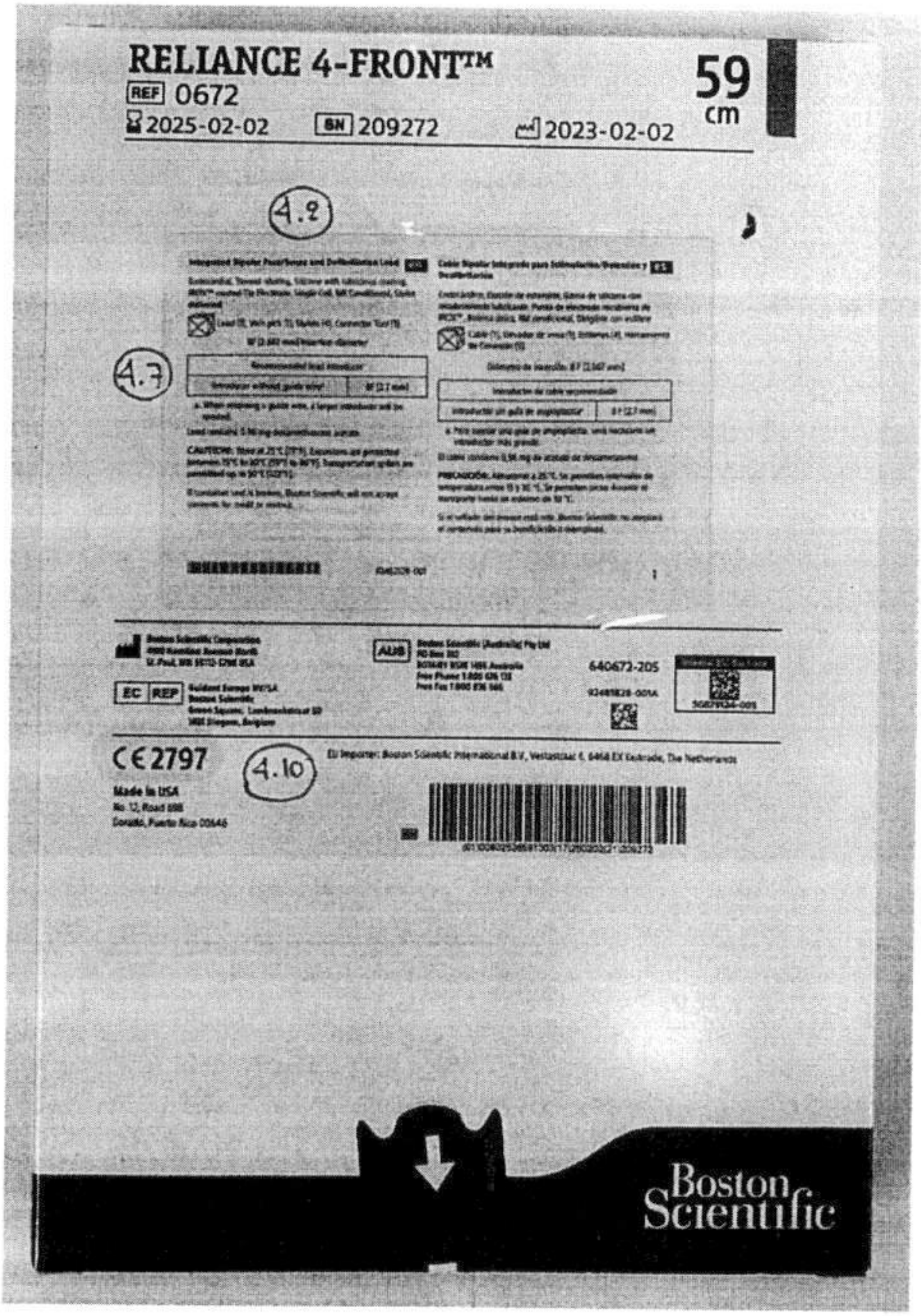

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แบบ บ.น.ท 1

รับรองบางส่วน
หนังสือรับรองประกอบการนำเข้าเครื่องมือแพทย์
สำนักงานคณะกรรมการอาหารและยา
กระทรวงสาธารณสุข

หนังสือเลขที่ IRL 6306382

2 กรกฎาคม 2563

ได้พิจารณาหนังสือรับรองการขาย/หนังสือรับรองการขายและหนังสือรับรองระบบคุณภาพการผลิตแล้ว ถูกต้องตามประกาศกระทรวงสาธารณสุข (ฉบับที่ 34) พ.ศ. 2549 แห่งพระราชบัญญัติเครื่องมือแพทย์ พ.ศ. 2531

ชื่อผู้นำเข้า : บริษัท บอสตัน ไซเอนทิฟิค(ประเทศไทย) จำกัด

ชื่อผู้ผลิต : BOSTON SCIENTIFIC LIMITED (IRELAND)

หนังสือฉบับนี้ใช้ประกอบกับ ☑ หนังสือรับรองการขายเลขที่ CFS010325

ประเทศ Ireland

☑ หนังสือรับรองระบบคุณภาพการผลิตเลขที่ MD 607739

สามารถใช้ประกอบการนำเข้าเครื่องมือแพทย์จนถึงวันที่ 13 กันยายน 2567

สำนักงานคณะกรรมการอาหารและยา

กระทรวงสาธารณสุข

ผู้อนุญาต

เงื่อนไข

1.เมื่อปรากฏว่าประเทศผู้ผลิตหรือประเทศเจ้าของผลิตภัณฑ์ห้ามขาย หรือมีการยกเลิกการรับรองระบบคุณภาพการผลิตของเครื่องมือแพทย์รายการใดตามที่ระบุไว้ในหนังสือรับรองฉบับนี้ให้ถือว่าการรับรองเครื่องมือแพทย์ดังกล่าวเป็นอันยกเลิก

2. ห้ามนำเลขที่หนังสือไปประกาศโฆษณา

3. ห้ามโฆษณาว่าได้ผ่านการรับรองจากสำนักงานคณะกรรมการอาหารและยา

4. ห้ามโฆษณาเครื่องมือแพทย์ก่อนได้รับความเห็นชอบจากสำนักงานคณะกรรมการอาหารและยา

5. สำนักงานคณะกรรมการอาหารและยา ขอสงวนสิทธิ์ที่จะยกเลิก/เพิกถอนหนังสือรับรองประกอบการนำเข้าเครื่องมือแพทย์ฉบับนี้ หากผู้นำเข้าไม่ดำเนินการให้เป็นไปตามกฎกระทรวงกำหนดหลักเกณฑ์วิธีการ และเงื่อนไข การจดทะเบียนสถานประกอบการนำเข้าเครื่องมือแพทย์ที่ออกตามพระราชบัญญัติเครื่องมือแพทย์ พ.ศ. 2551 เมื่อกฎกระทรวงดังกล่าวมีผลบังคับใช้แล้ว

หมายเหตุเพิ่มเติม

ข้อมูลที่ผู้ประกอบการบันทึกเข้ามาทั้งหมดถือเป็นความรับผิดชอบของผู้ประกอบการ

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สำนักงานคณะกรรมการอาหารและยา กองควบคุมเครื่องมือแพทย์

รายการนำเข้าผลิตภัณฑ์เครื่องมือแพทย์ ตามหนังสือรับรองเลขที่ IRL 6306382

วันที่อนุมัติ 2/7/2563 วันที่หมดอายุ 13/9/2567

Owner	manucd	gmpno	catno	offname	pdtname	desc	pageno	umdn	gmdn	RefItemNo
47929	47931	MD 607739	0295	ENDOTAK RELIANCE G / SG 4-SITE	ENDOTAK RELIANCE G / SG 4-SITE	ENDOTAK RELIANCE G / SG 4-SITE	2	11458	35223	6347931000034
47929	47931	MD 607739	0296	ENDOTAK RELIANCE G / SG 4-SITE	ENDOTAK RELIANCE G / SG 4-SITE	ENDOTAK RELIANCE G / SG 4-SITE	2	11458	35223	6347931000035
47929	47931	MD 607739	0672	RELIANCE 4-FRONT Implantable Lead	RELIANCE 4-FRONT Implantable Lead	RELIANCE 4-FRONT Implantable Lead	2	11458	35223	6347931000036
47929	47931	MD 607739	0673	RELIANCE 4-FRONT Implantable Lead	RELIANCE 4-FRONT Implantable Lead	RELIANCE 4-FRONT Implantable Lead	2	11458	35223	6347931000037
47929	47931	MD 607739	0652	RELIANCE 4-FRONT Implantable Lead	RELIANCE 4-FRONT Implantable Lead	RELIANCE 4-FRONT Implantable Lead	2	11458	35223	6347931000038
47929	47931	MD 607739	0675	RELIANCE 4-FRONT Implantable Lead	RELIANCE 4-FRONT Implantable Lead	RELIANCE 4-FRONT Implantable Lead	3	11458	35223	6347931000039
47929	47931	MD 607739	0676	RELIANCE 4-FRONT Implantable Lead	RELIANCE 4-FRONT Implantable Lead	RELIANCE 4-FRONT Implantable Lead	3	11458	35223	6347931000040
47929	47931	MD 607739	0692	RELIANCE 4-FRONT Implantable Lead	RELIANCE 4-FRONT Implantable Lead	RELIANCE 4-FRONT Implantable Lead	3	11458	35223	6347931000041
47929	47931	MD 607739	0693	RELIANCE 4-FRONT Implantable Lead	RELIANCE 4-FRONT Implantable Lead	RELIANCE 4-FRONT Implantable Lead	3	11458	35223	6347931000042
47929	47931	MD 607739	0657	RELIANCE 4-FRONT Implantable Lead	RELIANCE 4-FRONT Implantable Lead	RELIANCE 4-FRONT Implantable Lead	3	11458	35223	6347931000043
47929	47931	MD 607739	0695	RELIANCE 4-FRONT Implantable Lead	RELIANCE 4-FRONT Implantable Lead	RELIANCE 4-FRONT Implantable Lead	3	11458	35223	6347931000044
47929	47931	MD 607739	0696	RELIANCE 4-FRONT Implantable Lead	RELIANCE 4-FRONT Implantable Lead	RELIANCE 4-FRONT Implantable Lead	3	11458	35223	6347931000045

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สายกระตุ้นหัวใจชนิดถาวร (Pacemaker lead)

Boston Scientific
Advancing science for life™

INGEVITY™+ Pacing Lead

Active Fixation Models: 7840, 7841, 7842

(3.3)

The INGEVITY+ pacing leads are 6F (2.0 mm) steroid-eluting, endocardial pace/sense leads designed for permanent implantation for either atrial or ventricular applications. (3.2)

INGEVITY+ is built on the proven INGEVITY platform, with nearly 700,000 INGEVITY leads sold worldwide with a 99.2% reliability at 7 years.[1]

INGEVITY+ is specifically designed with three layers of insulation between conductors and a polyurethane lead body. The tri-filar inner coil design provides consistent, low, and repeatable turn counts when extending and retracting the helix[2].

These leads utilize an IS-1 bipolar connector. The tip features a flexible neck design and incorporates an IROX™ (iridium oxide) coating on the tip electrode.

Lead Specifications and Reimbursement Information

Product	INGEVITY+ Pacing Lead
Model/Length	7840 / 45 cm 7841 / 52 cm 7842 / 59 cm } (3.5)
Type	Bipolar Atrial / Ventricular Straight
Connector	IS-1 BI (3.3) , (3.4)
Compatibility	Pulse generators with an IS-1 port, which accepts an IS-1 terminal
MRI Conditions of Use*	ImageReady™ MR-Conditional System when used with an MR-Conditional pulse generator - Full body scan 1.5T and 3T (3.7)
Introducer without guide wire	6F (2.0 mm) (3.6)
Introducer with guide wire	9F (3.0 mm)
Fixation	Extendable/retractable helix
Expected number of rotations to fully extend/retract the helix**	6 ± 2 turns with straight stylet 7 ± 3 turns with J stylet
Recommended maximum number of turns to extend/retract the helix**	30
Nominal fixation helix penetration depth	1.8 mm

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Q3 2019 Boston Scientific Corporation Product Performance Report
Internal data on file
* Refer to the MRI Technical Guide for a complete list of cardiology and radiology conditions of use.
** Use fluoroscopy markers for verification of full extension/ retraction of the helix. The number of turns to extend or retract the helix may vary based on patient anatomy and implant conditions.

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INGEVITY™+ Pacing Lead

Active Fixation Models: 7840, 7841, 7842

Lead Specifications and Reimbursement Information *(continued)*

Product	INGEVITY+ Pacing Lead
Nominal Electrode:	
Fixation helix surface area	4.5 mm²
Distance between electrodes	10.7 mm
Anode electrode surface area	20 mm²
Nominal Diameter:	
Insertion	2.0 mm (6 F)
Anode electrode	2.0 mm
Lead body	1.9 mm
Fixation helix	1.2 mm
Material:	
External insulation	Polyurethane (55 D)
Internal insulation	Silicone rubber
Terminal ring contact	316 L stainless steel
IS-1 terminal pin contact	316L stainless steel
Tip electrode	IROX™ (iridium oxide) coated Pt-Ir
Anode electrode	IROX (iridium oxide) coated Pt-Ir
Conductor Type	Tri-filar inner coil of MP35N™ and single-filar outer coil of MP35N with a silver core.[1]
Steroid	0.91 mg dexamethasone acetate (3.1)
Radiopaque Markers	Pt-Ir
Suture Sleeve	Radiopaque white silicone rubber
C-code	1898

[1]MP35N is a trademark of SPS Technologies, Inc.

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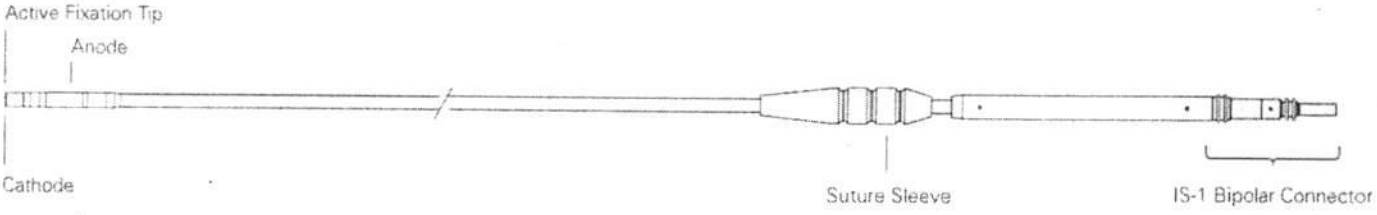
INGEVITY™ + Pacing Lead

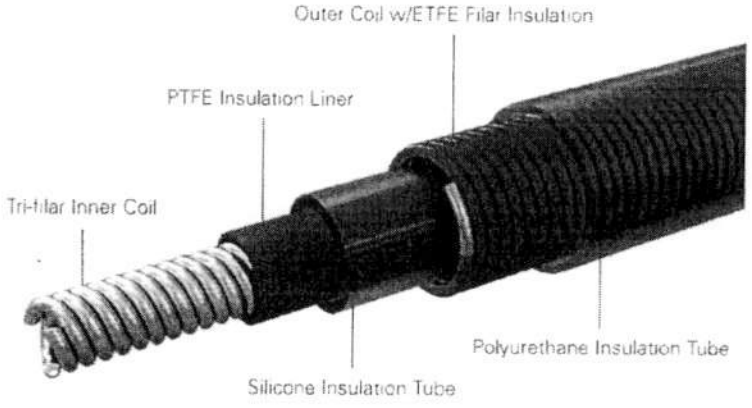
Active Fixation Models: 7840, 7841, 7842

Features

Lifetime Warranty: The INGEVITY+ pacing lead family is backed with a lifetime warranty.*

Lead Body Design: The isodiametric lead body consists of a coaxial design that includes a tri-filar inner coil and a single-filar outer coil. Both the inner and outer coils are designed for MR Conditional use in the MRI environment and provide robust flexural fatigue performance. In addition, the tri-filar inner coil provides consistent helix deployment performance. The conductors are separated by both a silicone rubber and Polytetrafluoroethylene (PTFE) lining. The outer coil is covered in Ethylene tetrafluoroethylene (ETFE) for extra insulation protection. The entire lead body is encompassed in a polyurethane outer insulation.





IROX™-coated Electrodes: The electrodes are coated with IROX to increase the microscopic surface area.

Steroid-eluting: Upon exposure to body fluids, the steroid elutes from the lead to help reduce tissue inflammation response at the distal electrode. The steroid suppresses the inflammatory response believed to cause threshold rises typically associated with implanted pacing electrodes.

(3.1)

Radiopaque Suture Sleeve: The radiopaque suture sleeve is visible under fluoroscopy and is used to secure, immobilize, and protect the lead at the venous entry site after lead placement. The window feature is designed to aid compression of the sleeve onto the lead during suturing.

*Limited lifetime warranty. For a full and complete description of the INGEVITY™+ warranty, please review the warranty card included with the product labeling.

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INGEVITY™ + and INGEVITY™ MRI Extendable/Retractable Fixation and Tined Fixation Pacing Leads

INDICATIONS

This Boston Scientific lead is indicated for use as follows: (3.2)

- Intended for chronic pacing and sensing in the right atrium and/or right ventricle when used with a compatible pulse generator (INGEVITY+ and INGEVITY MRI extendable/retractable fixation)
- Intended for chronic pacing and sensing in the right atrium (Preformed Atrial J) or right ventricle (Straight) when used with a compatible pulse generator (INGEVITY MRI tined fixation)

CONTRAINDICATIONS

Use of these leads are contraindicated for the following patients:

- Patients with a hypersensitivity to a nominal single dose of 0.91mg dexamethasone acetate (for INGEVITY+ and INGEVITY MRI extendable retractable fixation)
- Patients with a hypersensitivity to a nominal single dose of 0.61mg dexamethasone (for INGEVITY MRI tined fixation)
- Patients with mechanical tricuspid heart valves

WARNINGS

Read the 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. 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 torsion. 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 for 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 INGEVITY+ and INGEVITY MRI extendable/retractable fixation: The safety and efficacy of this tip electrode placement in the right ventricle above the septum has not been clinically established.

PRECAUTIONS

For specific information on precautions, refer to the following sections of the product labeling: clinical considerations, sterilization and storage, handling, implantation, hospital and medical environments, and follow-up testing.

POTENTIAL ADVERSE EVENTS

Based on the literature and on pulse generator and/or lead implant experience, the following alphabetical list includes the possible adverse events associated with implantation of products described in this literature: Air embolism; Allergic reaction; Arterial damage with subsequent stenosis; Bleeding; Bradycardia; Breakage/failure of the implant instruments; Cardiac perforation; Cardiac tamponade; Chronic nerve damage; Component failure; Conductor coil fracture; Death; Electrolyte unbalance/dehydration; Elevated thresholds; Erosion; Excessive fibrotic tissue growth; Extracardiac stimulation (muscle/nerve stimulation); Fluid accumulation; Foreign body rejection phenomena; Formation of hematomas or seromas; Heart block; Hemorrhage; Hemothorax; Inability to pace; Inappropriate therapy (e.g., shocks and antitachycardia pacing [ATP] where applicable, pacing); Incisional pain; Incomplete lead connection with pulse generator; Infection including endocarditis; Lead dislodgment; Lead fracture; Lead insulation breakage or abrasion; Lead tip deformation and/or breakage; Malignancy or skin burn due to fluoroscopic radiation; Myocardial trauma (e.g., tissue damage, valve damage); Myopotential sensing; Oversensing/undersensing; Pericardial rub; effusion; Pneumothorax; Pulse generator and/or lead migration; Syncope; Tachyarrhythmias, which include acceleration of arrhythmias and early recurrent atrial fibrillation; Thrombosis/thromboembolic; Valve damage; Vasovagal response; Venous occlusion; Venous trauma (e.g., perforation, dissection, erosion).

For a list of potential adverse events associated with MRI scanning, refer to the ImageReady™ MR Conditional Pacing System or Defibrillation System MRI Technical Guide.
92436280 (Rev B)

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician. Rx only. Prior to use, please see the complete "Directions for Use" for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator's Instructions.

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CRM-699008-AA

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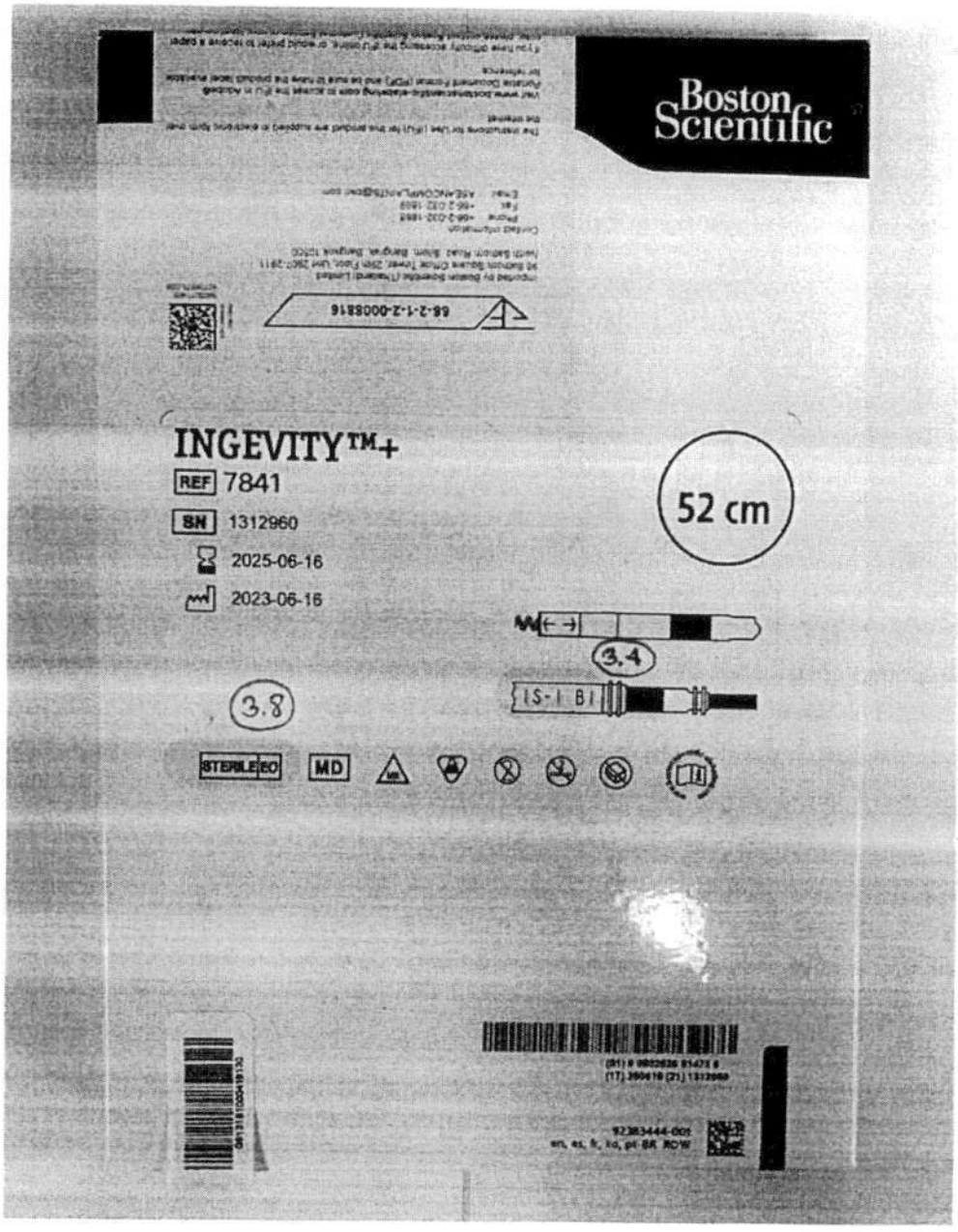

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