ACUITY™ X4
Quadripolar LV Leads

Boston Scientific
Advancing science for life™

New Solutions.
Meaningful Outcomes.

The first and only LV leads uniquely designed to promote non-apical pacing options, helping physicians to pace from an optimal site for improved CRT response.

Designed to Help Optimize CRT-response

With multiple tip shapes and unique electrode configurations, ACUITY™ X4 leads are specifically designed to help you get to the optimal pacing site.

Therapy-based Vector Selection

LV Vector Guide™ helps you choose the most therapeutic vector for pacing based on RV/LV Delay.

Clinically Meaningful Difference in Longevity

The X4 CRT-D is powered by ENDURALIFE™ Battery Technology, which continues to outlast the competition.[1-4]

The X4 CRT System

Discover more about ACUITY X4 leads.

BostonScientific.com/ACUITYX4

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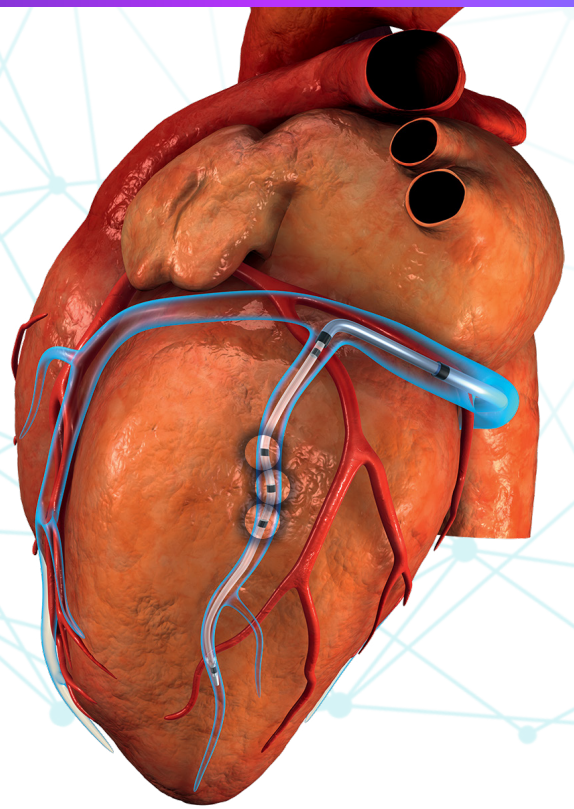
Quadripolar LV Leads



Designed to place more electrodes in mid or basal location of the left ventricle, the ACUITY X4 Spiral leads press the **proximal electrodes** against the vessel wall.

Improving Delivery & Optimizing Pacing Performance

IN THE NAVIGATE X4 STUDY:

- Dual fixation mechanisms on ACUITY X4 Spiral models led to stability rates of 99.1%[5]
- Leads experienced a 99.6% phrenic nerve stimulation complication-free rate[5*]

Clinically Meaningful Patient Outcomes

IN THE NAVIGATE X4 STUDY:

Shorter implant time for ACUITY X4 Spiral leads[5] could mean reduced fluoroscopy time

HALF OF ACUITY X4 SPIRAL LEADS WERE PLACED IN **6 MINUTES OR LESS**[5†]

ACUITY™ X4 LEADS **REQUIRED ZERO REOPERATIONS** DUE TO PACING CAPTURE OR THRESHOLDS[5]

*A PNS complication is defined as a case when a PNS occurrence was not resolvable without surgery.

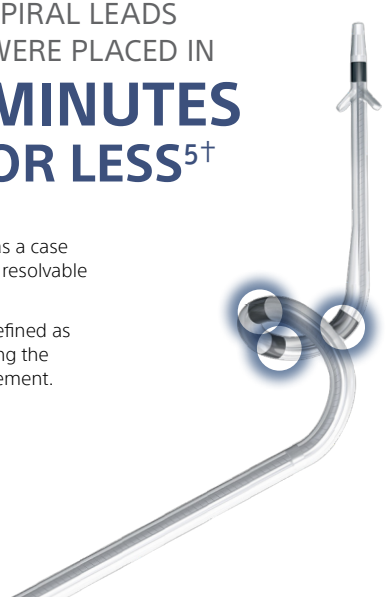
† LV lead placement time was defined as the time from the LV lead entering the catheter to the first PSA measurement.

Redefining Quadripolar Pacing to Improve CRT Response

IN THE IDE STUDY:

ACUITY X4 SPIRAL LEADS WERE PROGRAMMED WITH A **PROXIMAL ELECTRODE AS THE PACING CATHODE**

77.3%[5]



Discover more about ACUITY X4 leads.
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ACUITY X4 QUADRIPOLAR LV LEADS

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 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 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/LLHO2 and IS4-LLLL3 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 or similar monitors. 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. 92436276 (Rev. A.1)

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.

AUTOGEN™, AUTOGEN™X4, DYNAGEN™, DYNAGEN™X4, INOGEN™, INOGEN™ X4, ORIGEN™, ORIGEN™X4, INCEPTA™, ENERGEN™, PUNCTUA™. COGNIS™ 100-D CRT-D

INDICATIONS AND USAGE

These Boston Scientific Cardiac Resynchronization Therapy Defibrillators (CRT-Ds) are indicated for patients with heart failure who receive stable optimal pharmacologic therapy (OPT) for heart failure and who meet any one of the following classifications:
• Moderate to severe heart failure (NYHA Class III-IV) with EF ≤ 35% and QRS duration ≥ 120 ms; • Left bundle branch block (LBBB) with QRS duration ≥ 130 ms, EF ≤ 30%, and mild (NYHA Class II) ischemic or nonischemic heart failure or asymptomatic (NYHA Class I) ischemic heart failure

CONTRAINDICATIONS

There are no contraindications for this device.

WARNINGS

• 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 defibrillation patch leads with the pulse generator system, • 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 • 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. This could damage the lead terminal, possibly compromising the sealing integrity and result in loss of therapy or inappropriate therapy, such as a short within the header. • 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 contact any other portion of the IS4–LLLL 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/LLHO and IS4-LLLL lead, ensure that the leads are inserted and secured in the appropriate ports. Inserting a lead into an incorrect port will result in unanticipated device behavior (potentially leaving the patient without effective therapy). • Do not use atrial tracking modes in patients with chronic refractory atrial tachyarrhythmias. • Do not use atrial-only modes in patients with heart failure. • Left ventricular lead dislodgement to a position near the atria can result in atrial oversensing and left ventricular pacing inhibition. • Physicians should use medical discretion when implanting this device in patients who present with slow VT. Programming therapy for slow monomorphic VT may preclude CRT delivery at faster rates if these rates are in the tachyarrhythmia zones. • 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. • AUTOGEN and DYNAGEN devices except for those with an LV: LV-1 lead connection are considered MR Conditional. INOGEN and ORIGEN devices 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. Significant harm to or death of the patient and/or damage to the implanted system may result. All other devices covered by this manual are not MR conditional. Do not expose patients with non-MR Conditional devices to MRI scanning. Strong magnetic fields may damage the pulse generator and/or lead system, possibly resulting in injury to or death of the patient. • For potential adverse events applicable when the Conditions of Use are met or not met, refer to the ImageReady MR Conditional Defibrillation System 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 (PTM) is enabled prior to sending the patient home by confirming the Magnet Response is programmed to Store EGM. • 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 Magnet Response programming automatically will be set to Inhibit Therapy. When this happens, the patient should not apply the magnet because tachyarrhythmia therapy could be inhibited.

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 because EMI may cause the pulse generator to deliver inappropriate therapy or inhibit appropriate therapy. Moving away from the source of the EMI or turning off the source usually allows the pulse generator to return to normal operation.

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 • Bleeding • Bradycardia • 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) • Failure to convert an induced arrhythmia • Fluid accumulation • Foreign body rejection phenomena • Formation of hematomas or seromas • Heart block • 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 • Insulating myocardium during defibrillation with internal or external paddles • Lead dislodgment • Lead fracture • Lead insulation breakage or abrasion • Lead perforation • Lead tip deformation and/or breakage • Local tissue reaction • Loss of capture • Myocardial infarction (MI) • Myocardial necrosis • Myocardial trauma (e.g., tissue damage, valve damage) • Myopotential sensing • Oversensing/undersensing • Pacemaker-mediated tachycardia (PMT) • Pericardial rub, effusion • Pneumothorax • Pulse generator migration • Shunting current during defibrillation with internal or external paddles • Syncope • Tachyarrhythmias, which include acceleration of arrhythmias and early, recurrent atrial fibrillation • Thrombosis/thromboemboli • Valve damage • Vasovagal response • Venous occlusion • Venous trauma (e.g., perforation, dissection, erosion) • Worsening heart failure

For a list of potential adverse events associated with MRI scanning, refer to the ImageReady MR Conditional Defibrillation System MRI Technical Guide.

Patients may develop psychological intolerance to a pulse generator system and may experience the following:
• Dependency • Depression • Fear of premature battery depletion • Fear of shocking while conscious • Fear that shocking capability may be lost • Imagined shocking • Fear of device malfunction

Additionally, potential adverse events associated with the implantation of a coronary venous lead system include:
• Allergic reaction to contrast media • Breakage/failure of implant instruments • Prolonged exposure to fluoroscopic radiation • Renal failure from contrast media used to visualize coronary veins

92436228 (Rev. B.4)

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1. 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.
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, Bitronik = 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. Alam M, Munir B, Rattan R, Flanigan S, Adelstein E, Jan S, Saba S. Battery Longevity in Cardiac Resynchronization Therapy Defibrillators. 2013; Europace (2013) doi: 10.1093/europace/eut301. First published online: October 6, 2013. 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. Four-year survival rate calculated using device replacements for battery depletion as indicated by ERI.
4. Ellis C, Markus T, Dickerman D, Orton J, Hassan S, Good E, Okabe T, Greenspon A. Ampere Hour as a Predictor of CRT ICD Pulse Generator Longevity: A Multi-Center Study. Presented at HFSA 2014. http://www. onlinejcf.com/article/S1071-9164(14)00337-6/fulltext. Ampere Hour (Ah) as a Predictor of CRT ICD Pulse Generator Battery Longevity Study. The five major institutions performing the study include, at Vanderbilt University, Eastside Cardiovascular Medicine, University of Michigan, Thomas Jefferson University, Robert Wood Johnson University Hospital, Cooper Health System and North Ohio Research. Boston Scientific = 266 patients, Medtronic = 542 patients, St. Jude Medical = 149 patients. Five-year survival rate calculated using device replacements for battery depletion as indicated by ERI.
5. Clinical Summary: NAVIGATE X4 Study 358487-022 EN US 2016-01

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Cardiology
300 Boston Scientific Way
Marlborough, MA 01752-1234
www.bostonscientific.com

Medical Professionals:
1.800.CARDIAC (227.3422)
Customer Service:
1.866.484.3268

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