


ACUITY™ X4

Quadripolar LV Leads

**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.



The X4 CRT System

Designed to Help Optimize CRT-response

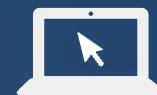
With multiple tip shapes and unique electrode configurations, ACUITY™ X4 leads are specifically designed to help you get to the optimal pacing site.

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



**Discover more
about ACUITY X4 leads.**

[BostonScientific.com/ACUITYX4](https://www.bostonscientific.com/ACUITYX4)

ACUITY™ X4

Quadripolar LV Leads

Improving Delivery & Optimizing Pacing Performance

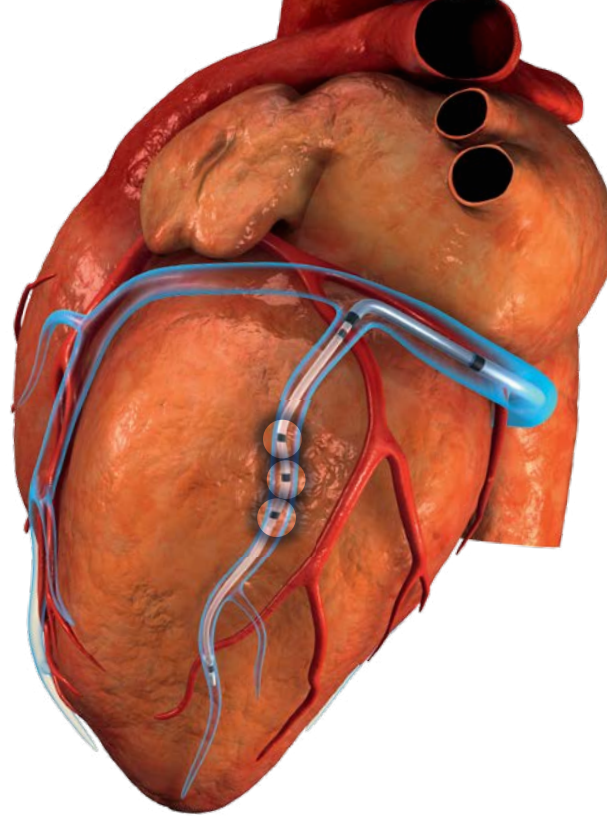
IN THE NAVIGATE X4 STUDY:

- 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*}

HALF OF ACUITY X4 SPIRAL LEADS WERE PLACED IN **6 MINUTES OR LESS**^{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.



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.

Clinically Meaningful Patient Outcomes

IN THE NAVIGATE X4 STUDY:

Shorter implant time for ACUITY X4 Spiral leads⁵ could mean reduced fluoroscopy time



ACUITY™ X4 LEADS **REQUIRED ZERO REOPERATIONS** DUE TO PACING CAPTURE OR THRESHOLDS⁵

Redefining Quadripolar Pacing to Improve CRT Response

IN THE NAVIGATE X4 STUDY:

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

77.3%⁵



Discover more about ACUITY X4 leads.

[BostonScientific.com/ACUITYX4](https://www.bostonscientific.com/ACUITYX4)

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. (Rev. A)

CRT-D Systems from Boston Scientific –DYNAGEN/INOGEN/ORIGEN

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 \leq 35% and QRS duration \geq 120 ms; or left bundle branch block (LBBB) with QRS duration \geq 130 ms, EF \leq 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

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. 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. Do not expose a patient to MRI scanning. Do not subject a patient with an implanted pulse generator and/or lead to diathermy. 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. Do not kink, twist, or braid the lead with other leads. Do not use defibrillation patch leads with the pulse generator system. Do not use this pulse generator with another pulse generator. 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 PTM feature has been triggered and the magnet response 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. 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.

PRECAUTIONS

For specific information on precautions, refer to the following sections of the product labeling: clinical considerations, sterilization and storage, implantation, device programming, hospital and medical environments, home and occupational environments, environmental and medical therapy hazards, 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.

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 A)

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](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).

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, Flanagan 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](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

All trademarks are the property of their respective owner.

**Boston
Scientific**
Advancing science for life™

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

Medical Professionals:
1.800.CARDIAC (227.3422)
Patients and Families:
1.866.484.3268

© 2016 Boston Scientific Corporation or its affiliates. All rights reserved.

CRM-373204-AB JUN2016