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.
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
**ACUITY™ X4**
Quadripolar LV Leads

**Improving Delivery & Optimizing Pacing Performance**

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

IN THE NAVIGATE X4 STUDY:
- Dual fixation mechanisms on ACUITY X4 Spiral models led to stability rates of 99.1%.
- Leads experienced a 99.6% phrenic nerve stimulation complication-free rate.

**Clinically Meaningful Patient Outcomes**

IN THE NAVIGATE X4 STUDY:
- Shorter implant time for ACUITY X4 Spiral leads could mean reduced fluoroscopy time.
- ACUITY™ X4 LEADS REQUIRED ZERO REOPERATIONS DUE TO PACING CAPTURE OR THRESHOLDS.

**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%
ACUITY X4 Quadriolar 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 quadriolar 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. Advise patients to seek medical guidance before entering environments that could adversely affect 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. When 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-LLLH leads, 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-LLLLH/ LLLH02 and IS4-LLLLL 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 skin, 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, infection-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 ≤ 35% and QRS duration ≥ 120 ms; or left bundle branch block (LBBB) with QRS duration ≥ 130 ms, EF ≥ 50%, 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 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. When 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-LLLH leads, 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-LLLH lead terminal, other than the terminal pin, even when the lead cap is in place. When implanting a system which uses both a DF4-LLLLH/ LLLH02 and IS4-LLLLL 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 skin, and irreversible damage to the pulse generator because of induced currents.

PRECAUTIONS

Refer to the 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, infection-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)


2. Haerbo J, Hjortshøj 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).


4. Ellis C, Markus T, Dickerman D, Orton J, Hassan S, Good E, Okabe T, Greenspoon A, Ampere Hour (AH) as a Predictor of CRT ICD Pulse Generator Longevity: A Multi-Center Study. Presented at HFA 2014. http://www.onlinejif.com/article/S1071-9164(14)00337-8/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.