

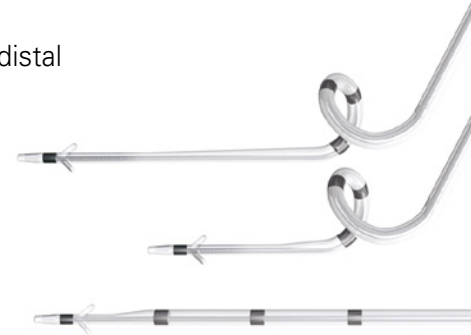
# ACUITY™ X4

## 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,<sup>1,2,3</sup> 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
- 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<sup>4</sup>
  - 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	86cm - 4674	86cm - 4677
	95cm - 4672	95cm - 4675	95cm - 4678
Electrode Spacing		<p>1 – Radiopaque Marker</p>	<p>1 – Radiopaque Marker</p>
Fixation Method	Tines	- Tines - 3D Spiral	- Tines - 3D Spiral

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### Product Specifications (continued)

<b>Compatibility</b>	IS4-LLLL
<b>Delivery Method</b>	Over the wire
<b>Recommended Guide Catheter Size</b>	0.081 in (2.06 mm) minimum inner diameter
<b>Diameter</b>	
Proximal Body	5.2F (1.7mm)
Distal Body	3.9F (1.3mm)
Distal Tip	2.6F (0.9mm)
<b>Insulation Material</b>	
External Insulation	Polyurethane and silicone
Internal Insulation	Polyurethane, silicone, ETFE
<b>Conductor Material</b>	
Coil (pin to distal electrode)	Low titanium MP35N
Cable (rings to proximal electrodes)	Low titanium MP35N with tantalum core
<b>Electrodes</b>	
Material	IROX coated platinum iridium
Tip Electrode Surface Area	4.1mm <sup>2</sup>
Proximal Electrode Surface Area	8.3mm <sup>2</sup>
<b>Steroid</b>	Dexamethasone acetate
<b>Suture Sleeve</b>	Radiopaque white silicone, three grooves
<b>Accessories included</b>	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: 359160-002 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 100042495

4 Clinical Summary: 358487-022 EN US 2016-01.

#### 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 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/LLH02 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)

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**Rhythm Management**  
300 Boston Scientific Way  
Marlborough, MA 01752-1234  
[www.bostonscientific.com](http://www.bostonscientific.com)

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

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