Boston Scientific

PHYSICIAN'S LEAD MANUAL

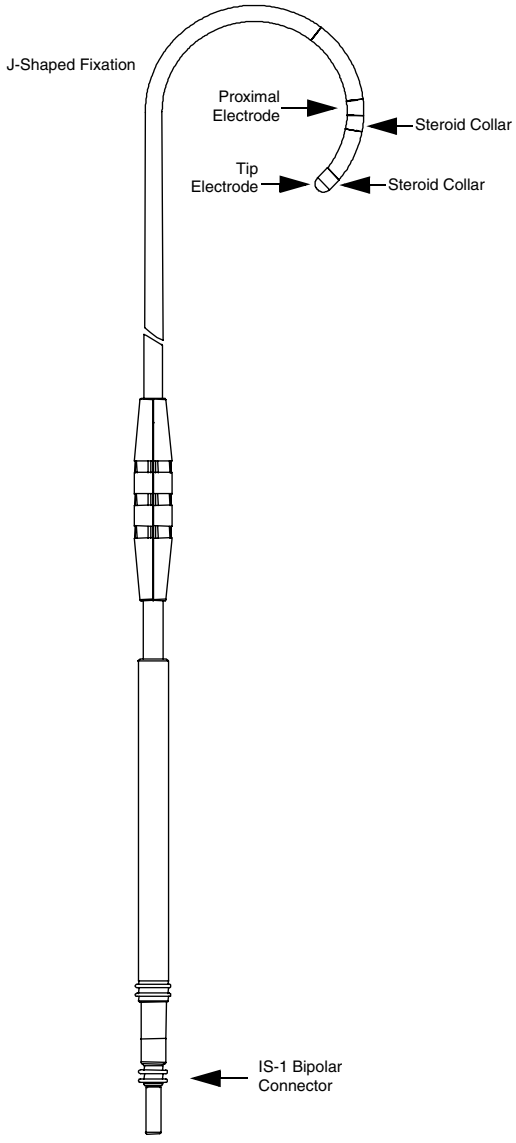
ACUITY™ Steerable

Implantable Lead

REF Reference number 4554, 4555

CAUTION: Federal law restricts this device to sale by or on the order of a physician trained or experienced in device implant and follow-up procedures.

ACUITY Steerable Lead
Models 4554/4555



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Boston Scientific Corporation acquired Guidant Corporation in April 2006. During our transition period, you may see both the Boston Scientific and Guidant names on product and patient materials. As we work through the transition, we will continue to offer doctors and their patients technologically advanced and high quality medical devices and therapies.

DEVICE DESCRIPTION

Boston Scientific ACUITY™ Steerable coronary venous pace/sense leads, Models 4554/4555, provide chronic left ventricular bipolar pacing and sensing. The leads have an over-the-wire design with an IS-1[1] bipolar connector and are steroid-eluting between the proximal and tip electrodes. The lead is anchored with J-shaped fixation and the electrodes are IROX®-coated (iridium oxide). Placement is achieved by inserting the lead through the coronary sinus and placing it into a branch of the cardiac veins using stylet or over-the-wire delivery. The ACUITY Steerable lead is used in conjunction with a compatible pulse generator.

Indications

The ACUITY Steerable IS-1 coronary venous, steroid-eluting, dual-electrode pace/sense leads are transvenous leads intended for chronic, left-ventricular pacing and sensing via the coronary veins when used in conjunction with a compatible pulse generator. Extended bipolar pacing and sensing is available using ACUITY Steerable with an RV pace/sense/defibrillation lead or a bipolar RV pace/sense lead.

Contraindications

Use of the ACUITY Steerable lead is contraindicated in patients with:

- a hypersensitivity to a nominal dose of 1.0 mg (0.5 mg per electrode) of dexamethasone acetate drug.
- mechanical tricuspid heart valves.
- obstructed or inadequate vasculature for intravenous catheterization.

1. IS-1 refers to the international standard ISO 5841.3:2000.

Warnings

In the following list of warnings, page numbers are indicated for those cautions that are specific to other areas of the manual. Refer to the indicated pages for information relevant to the caution. Failure to observe these cautions could result in incorrect lead implantation, lead damage/ dislodgement, or harm to the patient.

- **Labeling knowledge.** Read this manual thoroughly before implanting the lead to avoid damage to the system. Such damage can result in injury to or death of the patient. Page 22
- When using a right ventricular (RV) pace/sense lead in conjunction with the ACUITY Steerable lead, it is recommended that a *polyurethane-insulated* RV lead be used. Failure to observe this warning could result in insulation damage of the RV lead, which can cause periodic or continual loss of pacing, or sensing, or both.
- Lead fracture, dislodgement, abrasion, or an incomplete connection can cause a periodic or continual loss of pacing or sensing or both.
- **Battery-powered equipment.** The use of battery-powered equipment is recommended during lead implantation and testing to protect against fibrillation that might be caused by leakage currents.

  -Line-powered equipment used in the vicinity of the patient must be properly grounded.

  -The lead connector must be insulated from any leakage currents that could arise from line-powered equipment.
- **Excessive flexing.** The lead is not designed to tolerate excessive flexing, bending, tension, or injection pressure. This could cause structural weakness, conductor discontinuity, or lead dislodgement. Page 26
- When using a finishing wire accessory kit, use the corresponding finishing wire model for the lead length. If the wrong finishing wire is used, the finishing wire tip may extend out of the distal end of the lead or not stabilize the lead properly. Page 23
- When placing the lead with a stylet, use only a stylet designed for use with the ACUITY Steerable lead (see Table 12). These stylets are specifically designed to prevent the stylet from extending past the lead tip. Extending the stylet past the lead tip may cause tissue damage. Page 25 and Page 34

- **MRI exposure.** Do not expose a patient to the MRI environment. Strong electromagnetic fields in the MRI environment may interfere with the pulse generator and lead system and cause injury to the patient.
- **Diathermy exposure.** Patients with implanted leads should not receive diathermy treatment. Shortwave or microwave diathermy can cause tissue damage and injure the patient.
- **For single patient use only.** Do not reuse, reprocess, or resterilize. Reuse, reprocessing, or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness, or death. Reuse, reprocessing, or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness, or death of the patient.

Precautions

In the following list of cautions, page numbers are indicated for those cautions that are specific to other areas of the manual. Refer to the indicated pages for information relevant to the caution. Failure to observe these cautions could result in incorrect lead implantation, lead damage/dislodgement, or harm to the patient.

Sterilization and Handling

- **If package is damaged.** The lead and accessories are sterilized with ethylene oxide gas (EO) before final packaging. When they are received, they are sterile, provided the container is intact. If the packaging is wet, punctured, opened or otherwise damaged, return the device to Boston Scientific. Page 23
- **Use by date**. Implant the device system before or on the USE BY date on the package label because this date reflects a validated shelf life. For example, if the date is January 1, do not implant on or after January 2.
- **Lead compatibility.** Prior to implantation of this lead, confirm lead/pulse generator compatibility by calling Technical Services at the telephone number on the back cover of this manual.
- **Dexamethasone acetate.** It has not been determined whether the warnings, precautions, or complications usually associated with injectable dexamethasone acetate apply to the use of a low concentration, highly localized, controlled-release device. For a listing of potentially adverse effects, refer to the *Physician's Desk Reference*.

- **Defibrillating equipment.** Defibrillating equipment should be kept nearby for immediate use during the implantation procedure.

Lead Evaluation and Implant

- **Vein pick.** The vein pick is not intended either for puncturing the vein or for dissecting tissue during a cutdown procedure. Page 24
- **Remove finishing wire.** The finishing wire MUST BE REMOVED before connecting the lead to the pulse generator. Page 23
- **Suture Sleeve.** Do not suture directly over the lead body, as this may cause structural damage. Use the suture sleeve to secure the lead at the venous entry site. Page 25
- **Do not wipe or immerse the distal lead tip in fluid prior to implant.** Such treatment will reduce the amount of steroid available when the lead is implanted. Page 26
- **Chronic repositioning.** Optimum threshold performance might not be achieved if the lead is chronically repositioned because the steroid can be depleted. Page 26
- **Protect from surface contamination.** The conductor insulation is silicone rubber, which can attract particulate matter, and therefore must always be protected from surface contamination. Page 26
- **Do not insert under medial one-third region of clavicle (subclavian puncture).** When attempting to implant the lead via a subclavian puncture, do not insert the lead under the medial one-third region of the clavicle. Damage or chronic dislodgement of the lead is possible if the lead is implanted in this manner. If implantation via the subclavian vein is desired, the lead must enter the subclavian vein near the lateral border of the first rib and must avoid penetrating the subclavius muscle. It is important to observe these implant precautions to avoid clavicle/first rib damage or chronic dislodgement of the lead. It has been established in the literature that lead fracture can be caused by lead entrapment in such soft tissue structures as the subclavius muscle, costocoracoid ligament, or the costoclavicular ligament. Page 27
- **Implant risks.** Risks associated with this procedure are similar to any other catheterization procedure in the coronary sinus. Some patients can have a physical intolerance to different types of contrast agents. If this is known in advance, the physician should select an appropriate agent. Page 31
- **Contrast medium.** The type, amount, and rate of injection of the contrast medium must be determined by the physician's medical judgment regarding the adequacy of the venogram obtained. Page 31

- **Balloon catheter use.** At the physician's discretion, an occlusion balloon catheter may be used to identify the distal cardiac vein. For further instructions, see the literature accompanying the balloon catheter. Page 31
- **Bending the lead with a stylet in place.** Do not bend the lead with a stylet in place. Bending the lead could damage the conductor and insulation material. Page 34
- **Shaping the stylet.** Do not curve the stylet while it is in the lead. If a curved stylet is preferred, gently curve a straight stylet before inserting it into the lead. Page 34
- **Curving the stylet.** Do not use a sharp object to curve the distal end of the stylet. A sharp object could damage the stylet. Page 34
- **Recommended Stylets.** Using a stylet designed for use with the ACUITY Steerable lead is recommended (See Table 12 on page 25). These stylets are specifically designed to prevent the stylet from extending past the lead tip. If a stylet is used other than those listed in Table 12, verify that the stylet does not extend past the lead tip. Extending the stylet past the lead tip may cause tissue damage. Page 34
- **Guide wire prolapse.** Use fluoroscopy to verify the guide wire does not prolapse and catch on the distal tip of the lead. If this occurs, slowly extend the wire beyond the distal tip to free the guide wire and then retract it to reestablish movement of the guide wire. Page 35
- **Guide wire retraction.** If the guide wire cannot be retracted, withdraw the lead/guide wire assembly through the guiding catheter. Remove the guide wire through the distal tip of the lead and reintroduce the lead using a new guide wire. Page 35
- **Flushing a clotted lead.** Flushing a clotted lead can compromise lead integrity. If clotting is suspected, remove the lead from the body and soak the lead in heparinized saline. Insert a guide wire into either the terminal or distal tip of the lead and advance the wire to clear clotting. If unsuccessful, use a new lead. Page 36
- **Applying tools to the distal end of the lead.** Applying tools to the distal end of the lead may result in lead damage. Page 36
- **Kinking the finishing wire.** Do not kink the finishing wire in the lead. Kinking the finishing wire could lock it in the lead or damage the conductor coil. Page 42
- **Remove finishing wire.** If the finishing wire cannot be retracted from the lead, withdraw the lead and finishing wire together. Do not implant with the finishing wire inside the lead. Page 42

- **Strain relief.** When implanting the lead via a subclavian puncture, allow slack in the lead between the suture sleeve and the venous entry site. This will help minimize flexing at the suture sleeve and interaction with the clavicle/first rib region. Page 43
- **Avoid too tight ligature.** When ligating the vein, avoid too tight a ligature. A tight ligature might damage the silicone rubber insulation or sever the vein. Avoid dislodging the lead tip during the stabilizing procedure. Page 44
- **Do not kink leads.** Do not kink, twist, or braid the lead terminal with other leads, as doing so could cause lead insulation abrasion or conductor damage. Page 45
- **Do not bend the lead near the lead-header interface.** Insert the lead terminal straight into the lead port. Do not bend the lead near the lead-header interface. Improper insertion can cause insulation or connector damage. Page 45
- **Explanted leads.** Return all explanted leads to Boston Scientific. Page 45
- **Minimize dissection.** To minimize the possibility of dissection, it is recommended that a guide wire be used when advancing the guiding catheter through the venous system, right atrium, or coronary sinus.
- **Prevent renal failure.** To prevent renal failure associated with the use of contrast media, consider the patient's renal function prior to the implant procedure to determine the type, amount, and rate of injection of the contrast medium while performing a venogram.
- Tricuspid valvular disease may be exacerbated by the presence of a lead. Use medical judgement when deciding to place a lead in a patient with tricuspid valvular disease.

ADVERSE EVENTS

The safety of the ACUITY Steerable lead was evaluated in 110 patients who underwent an implant procedure for the ACUITY Steerable lead in the ACUITY Steerable lead clinical study. All patients with an ACUITY Steerable lead were followed for three months.

Observed Adverse Events

Table 1 provides information on all lead-related and procedure-related adverse events reported from implant through the three-month follow-up visit in patients attempted or implanted with the ACUITY Steerable lead. Those adverse events attributed to commercially available guide wires, guide catheters and diagnostic electrophysiology catheters were excluded from the ACUITY Steerable lead-related adverse events, and were categorized as procedure-related adverse events. ACUITY Steerable lead-related adverse events were defined as all lead-related or procedure-related adverse events attributed to the ACUITY Steerable lead by the investigator, or when the ACUITY Steerable lead could not be ruled out as the cause of the adverse event.

During the three-month follow-up period, a total of 103 events were reported in 61 patients. Of these events, 37 were classified as complications, and 66 were classified as observations.

Table 1. ACUITY Steerable lead-related and procedure-related adverse events through three months. All patients implanted or attempted; N=110, 313 total device months.[a]

		Complications		Observations	
Adverse Event	**Number of Events (Number of Patients)**	**% of Patients (N Patients)**	**N Events/ 100 Device Months (N Events)**	**% of Patients (N Patients)**	**N Events/ 100 Device Months (N Events)**
Total Adverse Events	**103 (61)**	**27.3 (30)**	**11.8 (37)**	**40.0 (44)**	**21.1 (66)**
ACUITY Steerable Related Events (N=101)					
Coronary venous dissection	1 (1)	0.0 (0)	0.0 (0)	1.0 (1)	0.3 (1)
Dislodgment - Elevated threshold - LV	2 (2)	2.0 (2)	0.7 (2)	0.0 (0)	0.0 (0)
Dislodgment - Extracardiac stimulation - LV	4 (4)	2.0 (2)	0.7 (2)	2.0 (2)	0.7 (2)
Dislodgment - Multiple signs - LV	2 (2)	2.0 (2)	0.7 (2)	0.0 (0)	0.0 (0)
Dislodgment - No reported signs - LV	1 (1)	1.0 (1)	0.3 (1)	0.0 (0)	0.0 (0)
Dislodgment - Unable to capture - LV	2 (2)	2.0 (2)	0.7 (2)	0.0 (0)	0.0 (0)
Elevated threshold - LV	2 (2)	0.0 (0)	0.0 (0)	2.0 (2)	0.7 (2)
Extracardiac stimulation - LV	16 (15)	1.0 (1)	0.3 (1)	13.9 (14)	5.1 (15)
Subtotal ACUITY Steerable Related Events	**30 (27)**	**8.9 (9)**	**3.4 (10)**	**18.8 (19)**	**6.8 (20)**
PG Related Events (N=106)					
Elevated DFT - Defibrillation	1 (1)	0.0 (0)	0.0 (0)	0.9 (1)	0.3 (1)
Extracardiac stimulation - Daily impedance testing	2 (2)	0.0 (0)	0.0 (0)	1.9 (2)	0.6 (2)
Hematoma - Pocket (> 30 days post-implant)	1 (1)	0.0 (0)	0.0 (0)	0.9 (1)	0.3 (1)
Migration	1 (1)	0.0 (0)	0.0 (0)	0.9 (1)	0.3 (1)
Pacemaker-mediated tachycardia (PMT)	2 (2)	0.0 (0)	0.0 (0)	1.9 (2)	0.6 (2)
Psychological effect due to device therapy	1 (1)	0.0 (0)	0.0 (0)	0.9 (1)	0.3 (1)
Subtotal PG Related Events	**8 (7)**	**0.0 (0)**	**0.0 (0)**	**6.6 (7)**	**2.6 (8)**
RA Lead Related Events (N=106)					

Table 1. ACUITY Steerable lead-related and procedure-related adverse events through three months. All patients implanted or attempted; N=110, 313 total device months.[a]

Dislodgment - Unable to capture - RA	2 (2)	1.9 (2)	0.6 (2)	0.0 (0)	0.0 (0)
Elevated threshold - RA	1 (1)	0.0 (0)	0.0 (0)	0.9 (1)	0.3 (1)
Oversensing - RA	2 (1)	0.0 (0)	0.0 (0)	0.9 (1)	0.6 (2)
Unable to capture - RA	1 (1)	0.9 (1)	0.3 (1)	0.0 (0)	0.0 (0)
Subtotal RA Lead Related Events	**6 (4)**	**2.8 (3)**	**1.0 (3)**	**0.9 (1)**	**1.0 (3)**
RV Lead Related Events (N=106)					
Dislodgment - Elevated threshold - RV	1 (1)	0.9 (1)	0.3 (1)	0.0 (0)	0.0 (0)
Elevated threshold - RV	1 (1)	0.9 (1)	0.3 (1)	0.0 (0)	0.0 (0)
Subtotal RV Lead Related Events	**2 (2)**	**1.9 (2)**	**0.6 (2)**	**0.0 (0)**	**0.0 (0)**
Procedure Related Events (N=110)					
Adverse reaction - Hypotension	2 (2)	0.9 (1)	0.3 (1)	0.9 (1)	0.3 (1)
Chest pain	1 (1)	0.9 (1)	0.3 (1)	0.0 (0)	0.0 (0)
Hematoma - Pocket (<=30 days post-implant)	6 (6)	0.9 (1)	0.3 (1)	4.5 (5)	1.6 (5)
LV Lead Insulation Damaged During Procedure	1 (1)	0 (0)	0 (0)	0.9 (1)	0.3 (1)
Post-surgical wound discomfort	1 (1)	0 (0)	0 (0)	0.9 (1)	0.3 (1)
Psychological effect due to recall	2 (2)	0 (0)	0 (0)	1.8 (2)	0.6 (2)
Thrombus	1 (1)	0.9 (1)	0.3 (1)	0 (0)	0 (0)
Subtotal Procedure Related Events	**14 (12)**	**3.6 (4)**	**1.3 (4)**	**8.2 (9)**	**3.2 (10)**
Protocol Testing Related Events (N=110)					
Extracardiac stimulation - LV	2 (2)	0 (0)	0 (0)	1.8 (2)	0.6 (2)
Subtotal Protocol Testing Related Events	**2 (2)**	**0 (0)**	**0 (0)**	**1.8 (2)**	**0.6 (2)**
Cardiovascular Related Events (N=110)					
Atrial fibrillation (AF)	4 (3)	0.9 (1)	0.3 (1)	1.8 (2)	1.0 (3)
Cerebrovascular accident (CVA)	1 (1)	0.0 (0)	0.0 (0)	0.9 (1)	0.3 (1)
Chest pain - Heart failure	2 (1)	0.0 (0)	0.0 (0)	0.9 (1)	0.6 (2)

Table 1. ACUITY Steerable lead-related and procedure-related adverse events through three months. All patients implanted or attempted; N=110, 313 total device months.[a]

Chest pain - Ischemic	2 (2)	0.9 (1)	0.3 (1)	0.9 (1)	0.3 (1)
Chest pain - Other	1 (1)	0.0 (0)	0.0 (0)	0.9 (1)	0.3 (1)
Chronotropic incompetence	1 (1)	0.0 (0)	0.0 (0)	0.9 (1)	0.3 (1)
Dizziness	1 (1)	0.0 (0)	0.0 (0)	0.9 (1)	0.3 (1)
Dizziness - Heart failure	1 (1)	0.0 (0)	0.0 (0)	0.9 (1)	0.3 (1)
Dyspnea - Heart failure	2 (2)	1.8 (2)	0.6 (2)	0.0 (0)	0.0 (0)
Hypotension - Heart failure	1 (1)	0.0 (0)	0.0 (0)	0.9 (1)	0.3 (1)
Multi-system failure - Heart failure	1 (1)	0.9 (1)	0.3 (1)	0.0 (0)	0.0 (0)
Multiple heart failure symptoms	9 (8)	5.5 (6)	1.9 (6)	2.7 (3)	1.0 (3)
Multiple symptoms	2 (2)	0.9 (1)	0.3 (1)	0.9 (1)	0.3 (1)
Myocardial infarction	1 (1)	0.9 (1)	0.3 (1)	0.0 (0)	0.0 (0)
Other SVT (AVRT, AVNRT, EAT etc.)	2 (2)	0.0 (0)	0.0 (0)	1.8 (2)	0.6 (2)
Sinus tachycardia	1 (1)	0.0 (0)	0.0 (0)	0.9 (1)	0.3 (1)
Ventricular fibrillation (VF)	1 (1)	0.0 (0)	0.0 (0)	0.9 (1)	0.3 (1)
Subtotal Cardiovascular Related Events	**33 (26)**	**10.9 (12)**	**4.2 (13)**	**13.6 (15)**	**6.4 (20)**
Subtotal Non-cardiovascular Related Events	**8 (7)**	**3.6 (4)**	**1.6 (5)**	**2.7 (3)**	**1.0 (3)**

a. For additional adverse event data collected after the 3-month endpoint of the clinical study, please refer to the Appendix (Page 49).

A total of 4 deaths occurred during the study periods as shown in Table 2, along with the cause of death as adjudicated by an independent events committee.

Table 2. Patient deaths that occurred during the study.

Cause of Death	Implants (N=106)	Attempts (N=4)	Total (N=110)
Cardiac: Pump Failure	1	0	1
Cardiac: Unknown	1	0	1
Not Yet Classified[a]	2	0	2
Total Deaths	**4**	**0**	**4**

a. Deaths not yet classified by the events committee have been classified by the investigator as Cardiac: Unknown and Cardiac: Pump Failure.

Potential Adverse Events

Based on the literature and lead implant experience, the following alphabetical list includes possible adverse events associated with implantation of an implantable cardioverter defibrillator and/or pacemaker lead system:

- Acceleration of arrhythmias
- Adverse reaction to procedure (e.g., bradycardia, general, respiratory, hypotension)
- Air embolism
- Allergic reaction
- Bleeding
- Cardiac tamponade
- Chronic nerve damage
- Conductor coil fracture
- Coronary venous spasm
- Death
- Elevated thresholds
- Erosion/extrusion
- Extracardiac stimulation (e.g., phrenic, diaphragm, chest wall)
- Fibrotic tissue formation (e.g., keloid formation)
- Fluid accumulation
- Formation of hematomas or cysts
- Heart block
- Inappropriate therapy (e.g., shocks, ATP, pacing)
- Incomplete lead connection with pulse generator
- Infection
- Lead displacement/dislodgement
- Lead fracture
- Lead insulation breakage or abrasion
- Lead tip deformation and/or breakage

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- Local tissue reaction
- Muscle and nerve stimulation
- Myocardial trauma (e.g., cardiac perforation, irritability, injury)
- Myopotential sensing
- Oversensing/undersensing
- Pacemaker-mediated tachycardia
- Pericardial rub, effusion
- Pneumothorax/hemothorax
- Random component failures
- Shunting current or insulating myocardium during defibrillation with internal or external paddles
- Thrombosis/thromboemboli
- Valve damage
- Venous occlusion
- Venous trauma (e.g., perforation, dissection, erosion)

In addition to the implantation of an implantable cardioverter defibrillator and/or pacemaker lead system, possible adverse events associated with implantation of a coronary venous lead system are listed below in alphabetical order:

- Allergic reaction to contrast media
- Breakage/failure of implant tools
- Coronary venous occlusion
- Coronary venous trauma (e.g., perforation, dissection, erosion)
- Prolonged exposure to fluoroscopic radiation
- Renal failure from contrast media used to visualize coronary veins

CLINICAL TRIAL

The following is a summary of the findings on the ACUITY Steerable lead clinical study.

Study Design

This clinical investigation of the ACUITY Steerable lead was a prospective, multi-center study conducted at 26 centers in the United States from March 23, 2005 through September 1, 2005, and was based on 110 enrolled patients. Of the 110 patients enrolled, 101 patients were successfully implanted with the ACUITY Steerable lead.

In all patients implanted with the ACUITY Steerable lead, the lead was connected to a CONTAK RENEWAL® 3 or CONTAK RENEWAL 3 HE, cardiac resynchronization therapy defibrillator (CRT-D) or to a CONTAK RENEWAL TR cardiac resynchronization therapy pacemaker (CRT-P). Evaluation of the investigational lead was performed at implant, pre-discharge, one month, three months and quarterly thereafter.

Inclusion/Exclusion Criteria

Patients enrolled in the clinical investigation were required to meet the following inclusion criteria:

- Must receive a commercially available Guidant CRT-P or CRT-D device
- Creatinine < 2.5 mg/dL obtained no more than 14 days prior to enrollment
- Age 18 or above, or of legal age to give informed consent specific to state and national law
- Willing and capable of providing informed consent, undergoing a device implant, participating in all testing associated with this clinical investigation at an approved clinical investigational center and at the intervals defined by this protocol
- Geographically stable residents who are available for follow-up

Patients were excluded from the investigation if they met any of the following criteria:

- A known hypersensitivity to a 1.0 mg (0.5 mg per electrode) dose of dexamethasone acetate
- Previous cardiac resynchronization therapy, a coronary venous pace/sense lead or attempted LV lead placement
- Pre-existing cardioversion/defibrillation leads other than those specified in this investigational plan (unless the investigator intends to replace them with permitted cardioversion/defibrillation leads)
- Required dialysis at the time of enrollment
- A myocardial infarct, unstable angina, percutaneous coronary intervention, or coronary artery bypass graft during the preceding 30 days prior to enrollment
- Hypertrophic obstructive cardiomyopathy or infiltrative cardiomyopathy (e.g., amyloidosis, sarcoidosis)
- A documented life expectancy of less than 6 months or expected to undergo heart transplant within 6 months
- Enrolled in any concurrent study, without prior Guidant written approval, that may confound the results of this study
- Have a pre-existing unipolar pacemaker that will not be explanted/abandoned
- Have a mechanical tricuspid heart valve
- Women who are pregnant or plan to become pregnant

Note: *Women of childbearing potential must have had a negative pregnancy test within seven days of enrollment.*

Follow-up Schedule

Enrollment:	Initial assessment of patient eligibility and informed consent.
Implant:	Implantation of investigational devices and acute lead evaluation.
Pre-Discharge, One-month, Three-Month and Quarterly:	Lead evaluation.

Lead Endpoints

Lead Effectiveness:
Three-month left ventricular pacing thresholds, pacing impedances, and R-wave amplitudes as measured in the configuration selected for permanent programming.

Lead Safety:
Lead-related complication-free rate over the three-month follow-up period.

Clinical Investigation

The objective of this investigation was to demonstrate the safety and effectiveness of the ACUITY Steerable lead.

Implant Rate
Table 3 shows the ACUITY Steerable lead implant success rates.

Table 3. Implant success rate. All patients implanted or attempted with an LV lead; N=110

Left Ventricular Lead	Number of Patients Undergoing Procedure	Number of Patients Successfully Implanted	Success Rate
ACUITY Steerable lead success rate	110	101	91.8%
EASYTRAK[a] family success rate	110	106	96.3%

a. The EASYTRAK family implant success included patients who received any lead in the EASYTRAK family (EASYTRAK, EASYTRAK 2, EASYTRAK 3 and ACUITY Steerable).

Lead Placement

The final implant positions of the ACUITY Steerable lead are shown in Table 4.

Table 4. ACUITY Steerable lead placement. All patients implanted; N=101

Position from RAO View	Position from LAO View				Total
	Anterior	Lateral	Posterior	Other[a]	
Basal	1 (1.0%)	9 (8.9%)	1 (1.0%)	1 (1.0%)	12 (11.9%)
Mid	2 (2.0%)	74 (73.3%)	5 (5.0%)	2 (2.0%)	83 (82.2%)
Apical	0 (0.0%)	3 (3.0%)	1 (1.0%)	1 (1.0%)	5 (5.0%)
Other[a]	0 (0.0%)	0 (0.0%)	1 (1.0%)	0 (0.0%)	1 (1.0%)
Total	**3 (3.0%)**	**86 (85.1%)**	**8 (7.9%)**	**4 (4.0%)**	**101 (100.0%)**

a. Other RAO position reported as posterior/lateral (1); other LAO positions reported as posterior/lateral (3) and lateral/apical (1).

Patient Demographics

Demographic information on all 110 patients who underwent an implant procedure for an ACUITY Steerable lead is shown in Table 5. The mean age of patients enrolled in the ACUITY Steerable lead investigation was 68.0 ± 11.6 years. The clinical study consisted of 72 males and 38 females.

Table 5. Demographic information on all patients enrolled (N=110).

Characteristic	Measurement	Result
Age at Implant (years)	N Mean ± SD Range	110 68.0 ± 11.6 28.7-84.9
Gender [N (%)]	Male Female	72 (65) 38 (35)
NYHA Class [N (%)]	II III IV	1 (1) 98 (89) 11 (10)
LVEF (%)	N Mean ± SD Range	110 23.5 ± 7.0 10.0-40.0
Etiology [N (%)]	Ischemic Nonischmedic	70 (64) 40 (36)

Lead Effectiveness

The effectiveness of the ACUITY Steerable lead was measured by pacing thresholds, pacing impedances and sensed amplitude evaluated over a three-month period in the configuration selected for permanent programming. The measurements were taken with a Guidant CRT-D or CRT-P device and the pacing thresholds were measured at a 0.5 ms pulse width. Table 6 shows the distribution of pacing configurations selected at each visit.

Table 6. Programmed pacing configuration at each visit. All patients implanted; N=101

Polarity	Pacing Configuration	Implant (N=100)	Pre-Discharge (N=99)	1 Month (N=95)	3 Months (N=95)
Bipolar	Ring>>Tip	2 (2%)	2 (2%)	4 (4%)	5 (5%)
	Tip>>Ring	38 (38%)	38 (38%)	34 (36%)	36 (38%)
Extended Bipolar	Ring>>Coil	19 (19%)	15 (15%)	15 (16%)	13 (14%)
	Tip>>Coil	39 (39%)	41 (41%)	39 (41%)	38 (40%)
	Tip>>RV Ring	1 (1%)	1 (1%)	1 (1%)	2 (2%)
Unipolar	Tip>>Can	1 (1%)	2 (2%)	2 (2%)	1 (1%)

Figure 1 and Table 7 show left ventricular pacing threshold in the configuration selected for permanent programming.

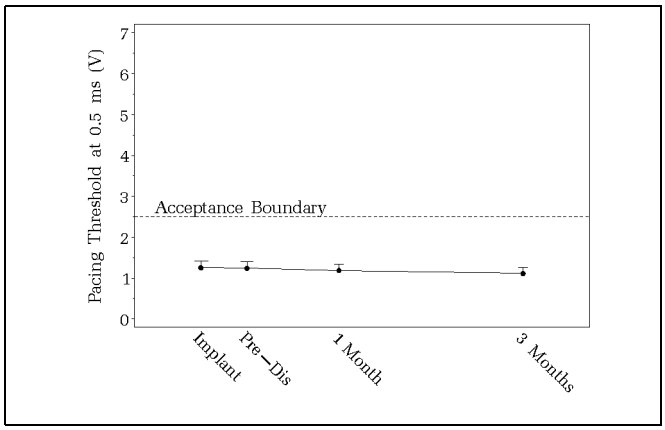


Figure 1. ACUITY Steerable lead pacing thresholds with device in the programmed configuration. All patients implanted; N=101 (Mean, 95% confidence bound).

The three-month mean pacing threshold was 1.1 ± 0.9 V, with an upper bound of 1.3 V. At all follow-up time points, the mean pacing thresholds were within the pre-specified performance limit.

Table 7. ACUITY Steerable lead pacing thresholds with device in the programmed configuration. All patients implanted; N=101

Measurement	Statistic	Implant	Pre-Discharge	1 Month	3 Months
Pacing Threshold (V)	N	98	95	90	90
	Mean ± SD	1.3 ± 1.0	1.2 ± 0.9	1.2 ± 0.9	1.1 ± 0.9
	Median	0.8	0.8	1.0	0.8
	Range	0.2 - 5.0	0.4 - 5.0	0.2 - 5.5	0.4 - 5.0
	Upper Bound	1.4	1.4	1.3	1.3

It was hypothesized that the upper bound of the three-month left ventricular pacing threshold of the ACUITY Steerable lead be less than 2.5 V to ensure that an adequate safety margin existed. Left ventricular pacing thresholds are within this limit.

Figure 2 and Table 8 show sensed R-wave amplitude in the configuration selected for permanent programming.

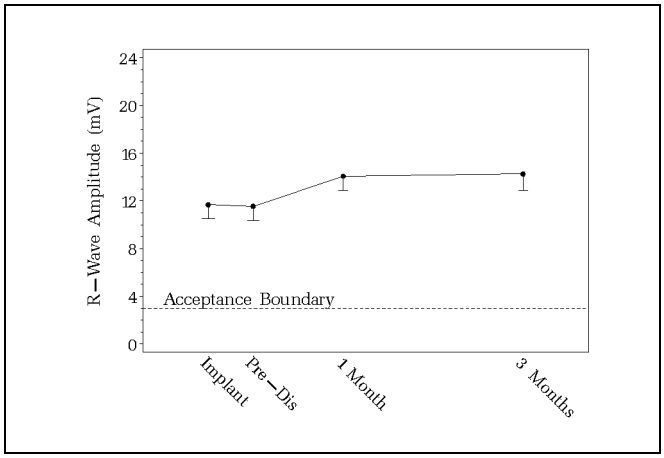


Figure 2. ACUITY Steerable lead sensed amplitudes with device in the programmed configuration. All patients implanted; N=101 (Mean, 95% confidence bound)

The three-month mean sensed amplitude was 14.3 ± 7.4 mV, with a lower bound of 12.9 mV. At all follow-up time points, the mean sensed amplitudes were within the pre-specified performance limit.

Table 8. ACUITY Steerable lead sensed amplitudes with device in the programmed configuration. All patients implanted; N=101

Measurement	Statistic	Implant	Pre-Discharge	1 Month	3 Months
Sensed Amplitude (mV)	N	88	86	83	80
	Mean ± SD	11.7 ± 6.6	11.6 ± 6.7	14.1 ± 6.7	14.3 ± 7.4
	Median	10.4	10.3	13.1	12.9
	Range	1.8 - 25.0	2.6 - 25.0	3.4 - 25.0	2.5 - 25.0
	Lower Bound	10.5	10.4	12.9	12.9

It was hypothesized that the lower bound of the three-month left ventricular R-wave amplitude is greater than 3 mV; the R-wave amplitudes are within this limit.

Figure 3 and Table 9 show left ventricular pacing impedances with device in the programmed configuration.

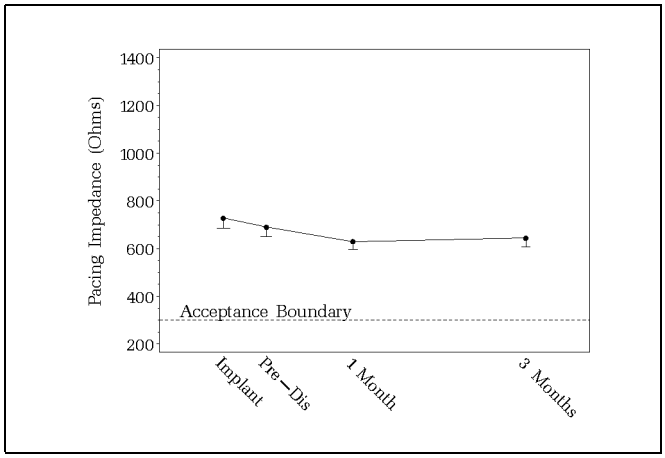


Figure 3. ACUITY Steerable lead pacing impedances with device in programmed configuration. All patients implanted; N=101 (Mean, 95% confidence bound)

The three-month mean pacing impedance was 644 ± 207 ohms, with a lower bound of 608 ohms. At all follow-up time points, the mean pacing impedances were within the pre-specified performance limit.

Table 9. ACUITY Steerable lead pacing impedances with device in programmed configuration. All patients implanted; N=101

Measurement	Statistic	Implant	Pre-Discharge	1 Month	3 Months
Pacing Impedance (Ohms)	N	98	96	91	90
	Mean ± SD	729 ± 249	692 ± 229	633 ± 193	644 ± 207
	Median	717	644	608	635
	Range	346 -1738	352 -1320	327 - 1284	293 - 1223
	Lower Bound	687	653	600	608

It was hypothesized that the lower bound of the three-month left ventricular lead impedance should be greater than 300 ohms for proper system performance. Left ventricular lead impedances were greater than 300 ohms.

Lead Safety

The safety of the ACUITY Steerable lead was evaluated by the lead-related complication-free rate over the three-month follow-up period in all patients attempted or implanted with an ACUITY Steerable lead. Table 10 shows the lead-related complication free-rate at three months.

Table 10. ACUITY Steerable lead related complication free rates at three months. All patients implanted or attempted with an ACUITY Steerable lead; N=110

Complication	Number of Events	Number of Patients	Complication Free Rate	Lower One-Sided 95% Confidence Bound
Dislodgment - Elevated threshold - LV	2	2	98.2	94.4
Dislodgment - Extracardiac stimulation - LV	2	2	98.2	94.4
Dislodgment - Multiple signs - LV	2	2	98.2	94.4
Dislodgment - No reported signs - LV	1	1	99.1	95.8
Dislodgment - Unable to capture - LV	2	2	98.2	94.4
Extracardiac stimulation - LV	1	1	99.1	95.8
Total	**10**	**9**	**91.8**	**86.2**

The lower one-sided 95% confidence bound of the ACUITY Steerable lead-related complication-free rate through three-months post-implant was hypothesized to be greater than 80%. The observed one-sided lower bound of 86.2% was within the pre-specified limit, providing reasonable assurance that the ACUITY Steerable lead is safe.

Warranty

See the enclosed Lead Information card for warranty. For additional copies, please contact Boston Scientific at the address on the back cover.

Refer to the Contraindications, Warnings, Precautions, and Adverse Events sections of this manual for information concerning the performance of this device.

DEVICE FEATURES

Detailed Device Description

Features of the ACUITY Steerable lead include the following:

- **Stylet/Over-The-Wire Lead Design:** The lead design consists of an open-lumen conductor coil to enable lead delivery using a stylet. This design also enables lead delivery using the Over-the-Wire technique and will track over a guide wire up to 0.016-in (0.41 mm) in diameter.
- **Steroid:** The silicone rubber collars near each electrode each contain a nominal dose of 0.5 mg (1.0 mg total) dexamethasone acetate. Upon exposure to body fluids, the steroid elutes from the lead to help reduce tissue inflammation response at the electrodes.
- **Ring and Tip Electrodes with IROX Coating:** The IROX coated ring and tip electrodes provide a pacing and sensing surface in the coronary venous system.
- **Pace/Sense Configurations:** The ACUITY Steerable lead offers various pace/sense configurations depending upon the programming options of a compatible device. Refer to the pulse generator manual for instructions.
- **J-Shaped Fixation:** The distal portion of the lead provides fixation after guide wire or stylet removal. The lead is anchored in position by removing the guide wire or stylet and allowing the distal tip to assume a J shape that lodges in the coronary venous system.
- **Lead Body:** The diameter of the lead tip is 5.4F (0.070 in) (1.78 mm). The diameter of the proximal lead body is 6.0F (0.078 in) (1.98 mm).The lead body consists of coaxial coils that provide two conductive pathways. The inner conductor coil is sheathed in silicone rubber tubing. The outer conductor filars are individually sheathed in Ethylene Tetrafluoroethylene (ETFE) insulation. The distal lead body is silicone tubing. The proximal lead body is polyurethane tubing.
- **IS-1 Bipolar Connector:** The industry standard connector can be used in conjunction with a compatible cardiac device that accepts the IS-1 connector.

LEAD EVALUATION

Implant Information

Proper surgical procedures and techniques are the responsibility of the medical professional. The described implant procedures are furnished for informational purposes only. Each physician must apply the information in these instructions according to professional medical training and experience.

The ACUITY Steerable lead is not designed, sold, or intended for use except as indicated.

Items Included

Items packaged include the following:

- (1) ACUITY Steerable Lead
- (1) Stylet/Wire Guide
- (1) Vein Pick
- (2) Standard Delivery Stylets (STD)
- (1) Packaging Stylet
- Literature Packet

WARNING: Instructions in the lead manual should be used in conjunction with other resource material, including the applicable pulse generator physician's manual and instructions for use on any implant accessories or tools.

Additional Implant Tools

The following is a list of devices used for implanting the lead, but not packaged with the lead:

- Removable guiding catheter, 8F or larger, minimum 0.087-in (2.2-mm) inside diameter, that is intended for accessing the coronary venous system
  - Tools for advancing the guiding catheter to the right atrium and cannulating the coronary sinus:
    - Guide wire, 0.032–0.038-in (0.81–0.97-mm) diameter (optional), that is intended for use in the coronary venous vasculature
    - Guiding catheter, 6F (0.078-in) (2-mm) diameter (optional), that is intended for accessing the coronary venous system
    - Deflectable tip mapping catheter, 6F (0.078-in) (2-mm) diameter (optional), that is intended for use in the coronary sinus ostium

- Guide wire, up to 0.016-in (0.41-mm) diameter, that is intended for use in the coronary venous system
- Finishing wire, designed to stabilize the positioned lead in the venous system during guiding catheter removal

WARNING: When using a finishing wire accessory kit, use the corresponding finishing wire model for the lead length. If the wrong length finishing wire is used, the finishing wire tip may extend out of the distal end of the lead or not stabilize the lead properly.

CAUTION: The finishing wire MUST BE REMOVED before connecting the lead to the pulse generator.

- Standard occlusion balloon, 6F (0.078-in) (2-mm) diameter (optional), that is used to obtain venograms by occluding the coronary sinus
- Implant accessories

Opening Instructions

The outer package and sterile tray should be opened under clean conditions. To ensure sterility, the sealed inner sterile tray must be opened using accepted aseptic technique by scrubbed, masked personnel. The sterile tray is opened by peeling back the cover.

Sterilization

CAUTION: The lead and accessories are sterilized with ethylene oxide gas (EO) before final packaging. When they are received, they are sterile, provided the container is intact. If the packaging is wet, punctured, opened or otherwise damaged, return the device to Boston Scientific.

Storage

Recommended storage temperature range is 0°C to 50°C.

Surgical Preparation

Instrumentation for heart monitoring, imaging (fluoroscopy), external defibrillation, and pacing threshold and sensitivity measurements should be available during implantation. The sterile field should be large enough to accommodate the use of the guide wires. Sterile duplicates of all implantable items should also be available for use if accidental damage or contamination occurs. Always isolate the patient from potentially hazardous leakage current when using electrical instrumentation.

Nominal lengths of the leads are as follows:

Model	4554	4555
Length	80 cm	90 cm

Selection of the lead length appropriate to the patient's cardiac anatomy is a matter of medical judgment.

Lead Accessories

The following items are packaged with the lead and are also available from Boston Scientific as accessory items:

Vein Pick

The vein pick is a sterile, disposable, nontoxic, plastic device designed to assist with placement of the guiding catheter into the vein.

To use the vein pick during a cutdown procedure, isolate and open the selected vein using an appropriate instrument. Introduce the point of the vein pick via this incision into the lumen of the vein. With the point of the vein pick facing in the direction of the desired guiding catheter passage, gently raise and tilt the pick. Pass the guiding catheter under the vein pick and into the vein.

CAUTION: The vein pick is not intended either for puncturing the vein or for dissecting tissue during a cutdown procedure.

Stylet/Wire Guide

The stylet/wire guide is intended to ease insertion of a guide wire or stylet into the lumen at the terminal of the lead (Figure 4)

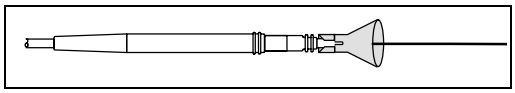


Figure 4. Using the stylet/ wire guide.

Suture Sleeve

The suture sleeve is an adjustable, tubular reinforcement positioned over the outer lead insulation. It is designed to secure and protect the lead at the venous entry site after lead placement. Using a suture sleeve reduces the possibility of structural damage caused by suturing directly over the lead body.

CAUTION: Do not suture directly over the lead body, as this may cause structural damage. Use the suture sleeve to secure the lead at the venous entry site.

Stylets

A stylet aids in positioning the lead tip in the coronary veins. Standard stylets are packaged with each lead. Soft stylets are available as accessory items only. The stylets can be pre-shaped and then inserted into the terminal pin of the lead to provide shape to the lead. The stylet length is imprinted on the color-coded cap of the knob (Table 11). The stylet stiffness is imprinted on the color-coded body of the knob. See “Placing the Lead With a Stylet” on page 33 for more information.

CAUTION: Using a stylet designed for use with the ACUITY Steerable lead is recommended (See Table 12). These stylets are specifically designed to prevent the stylet from extending past the lead tip. If a stylet is used other than those listed in Table 12, verify that the stylet does not extend past the lead tip. Extending the stylet past the lead tip may cause tissue damage.

Table 11. Stylets

	Stylet Length (cm)	Knob Color	Cap Color
Straight	80	Green = Soft or White = Standard	White
	90		Red

Table 12. ACUITY Steerable Lead Model and Corresponding Lead Stylet Model

ACUITY Steerable Lead Model	Lead Stylet Model
4554 (80 cm)	6690 (80 cm), soft[a]
	6490 (80 cm), std
4555 (90 cm)	6691 (90 cm), soft[a]
	6491 (90 cm), std

a. Available as accessory item only.

Packaging Stylet

A packaging stylet is preinserted in the packaged lead and is used to maintain the lead's J-shape at the distal end. The packaging stylet must be removed from the lead prior to implant.

Handling the Lead

Observe the following when handling the lead:

WARNING: The lead is not designed to tolerate excessive flexing, bending, tension, or injection pressure. This could cause structural weakness, conductor discontinuity, or lead dislodgement.

CAUTIONS:

- **Do not wipe or immerse the distal lead tip in fluid prior to implant.** Such treatment will reduce the amount of steroid available when the lead is implanted.
- Optimum threshold performance might not be achieved if the lead is chronically repositioned because the steroid can be depleted.
- The conductor insulation is silicone rubber, which can attract particulate matter, and therefore must always be protected from surface contamination.

IMPLANTATION

Inserting the Lead

The lead may be inserted using one of the following two methods:

Via cutdown through the left or right cephalic vein.

Only one incision over the deltopectoral groove is required to insert the guiding catheter through the cephalic vein. The endocardial lead is inserted into the right or left cephalic vein in the deltopectoral groove.

The vein pick packaged with this lead can be used during a cutdown procedure to aid insertion of the guiding catheter into the vein. Before inserting the guiding catheter, see the section, “Lead Accessories” for instructions on using the vein pick.

Percutaneously or via cutdown through the subclavian vein or internal jugular vein—typically the left subclavian or right internal jugular vein.

A subclavian introducer set is available from Boston Scientific for use during percutaneous lead insertion.

CAUTION: When attempting to implant the lead via a subclavian puncture, do not insert the lead under the medial one-third region of the clavicle. Damage or chronic dislodgement to the lead is possible if the lead is implanted in this manner. If implantation via the subclavian vein is desired, the lead must enter the subclavian vein near the lateral border of the first rib and must avoid penetrating the subclavius muscle. It is important to observe these implant precautions to avoid clavicle/first rib damage or chronic dislodgement to the lead. It has been established in the literature that lead fracture can be caused by lead entrapment in such soft tissue structures as the subclavius muscle, costocoracoid ligament, or the costoclavicular ligament.[2]

2. Magney JE, et al. Anatomical mechanisms explaining damage to pacemaker leads, defibrillator leads, and failure of central venous catheters adjacent to the sternoclavicular joint. PACE. 1993;16:445-457.

Leads placed by percutaneous subclavian venipuncture should enter the subclavian vein, where it passes over the first rib (rather than more medially), to avoid entrapment by the subclavius muscle or ligamentous structures associated with the narrow costoclavicular region.[3] Introducing the lead into the subclavian vein near the lateral border of the first rib is recommended.

The syringe should be positioned directly above and parallel to the axillary vein to reduce the chance that the needle will contact the axillary or subclavian arteries or the brachial plexus. Use of fluoroscopy is helpful in locating the first rib and in guiding the needle. The steps below explain how to identify the skin entry point and define the course of the needle toward the subclavian vein where it crosses the first rib.

1. Referring to Figure 5, identify points St (sternal angle) and Cp (coracoid process).

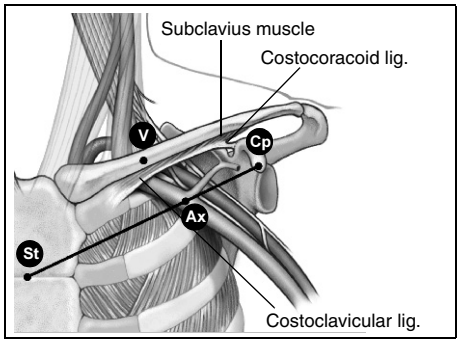


Figure 5. Landmarks identify the entry point for a percutaneous subclavian venipuncture.

2. Visually draw a line between St and Cp, and divide the segment into thirds. The needle should pierce the skin at the junction of the middle and lateral thirds, directly above the axillary vein (point Ax).
3. Place an index finger on the clavicle at the junction of the medial and middle thirds (point V), beneath which point the subclavian vein should be located.
4. Press a thumb against the index finger and project one or two centimeters below the clavicle to shield the subclavius muscle from the

3. Magney JE, et al. A new approach to percutaneous subclavian venipuncture to avoid lead fracture or central venous catheter occlusion. PACE. 1993;16:2133-2142.

needle (when hypertrophy of the pectoralis muscle is apparent, the thumb should project about two centimeters below the clavicle because the subclavius muscle should be hypertrophied as well) (Figure 6).

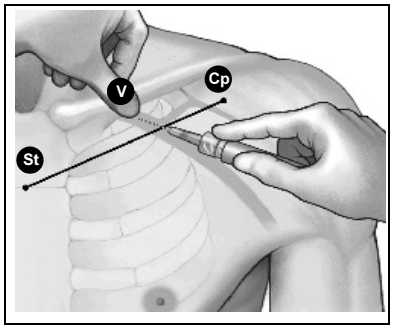


Figure 6. Location of thumb and needle entry.

5. Feel with the thumb the pressure from the passage of the needle through the superficial fascia; direct the needle deep into the tissues toward the subclavian vein and the underlying first rib. Fluoroscopic guidance will reduce the chance that the needle would pass below the first rib and into the lung.

Positioning the Lead

Positioning the lead includes the following steps:

1. ***Insert a guiding catheter*** into the ostium of the coronary sinus to provide a path for lead placement.
2. ***Obtain a venogram*** to visualize the coronary venous system.
3. ***Place the lead*** through the guiding catheter in the coronary venous system using a stylet or by advancing the lead over a guide wire.

Referring to Figure 7, the lead is introduced into the coronary venous system through the ostium of the coronary sinus and advanced into its tributaries. The coronary sinus and its tributaries include the great cardiac vein, middle cardiac vein, left posterior vein, and left marginal vein. All cardiac veins are potential sites for implantation of the ACUITY Steerable lead. Variability in patient anatomy may preclude placement in one or more of the suggested sites.

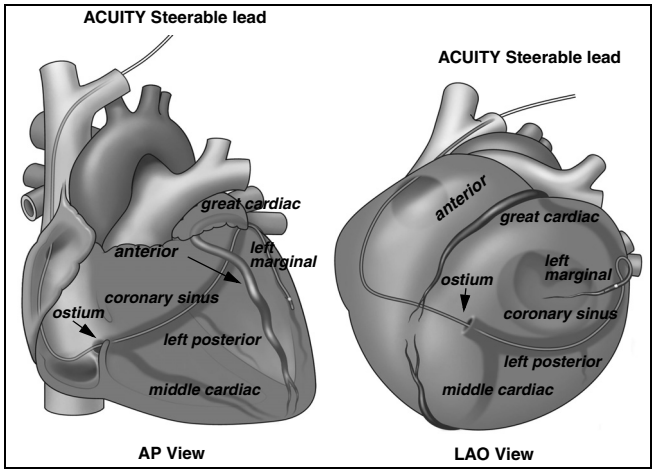


Figure 7. Anterior Posterior (AP) and Lateral Anterior Oblique (LAO) View of the Coronary Venous System.

Note: *It is recommended that a venogram be performed to determine the patient's cardiac anatomy. Any preexisting condition of the patient, e.g., coronary stent or coronary artery bypass graft (CABG), should be taken into consideration while using proper medical judgement to determine the best lead implant site.*

Inserting the Guiding Catheter

Recommended methods for inserting the guiding catheter into the coronary sinus include, but are not limited to, the following: **a)** directly access the coronary sinus ostium with the curve of the guiding catheter alone **b)** advance a 0.032"- 0.038" guide wire through the guiding catheter and extend it into the ostium of the coronary sinus and then follow with the guiding catheter **c)** insert a 6F fixed shape catheter or a deflecting mapping catheter through the guiding catheter and extend it into the ostium of the coronary sinus and then follow with the guiding catheter.

Note: *Prior to inserting the lead into the guiding catheter, the inner tool must be removed.*

Obtaining a Venogram

CAUTION: Risks associated with this procedure are similar to any other catheterization procedure in the coronary sinus. Some patients can have a physical intolerance to different types of contrast agents. If this is known in advance, the physician should select an appropriate agent.

Once the guiding catheter is in place and while under fluoroscopy, inject a small amount of contrast medium into the coronary sinus to confirm proper placement of the guiding catheter tip in the coronary sinus. The contrast agent will flow out of the coronary sinus.

Once the position is confirmed, use a minimum amount of contrast to identify the coronary sinus branch vein. Save the acquired venogram for future reference of the venous anatomy.

CAUTIONS:

- The type, amount, and rate of injection of the contrast medium must be determined by the physician's medical judgment regarding the adequacy of the venogram obtained.
- At the physician's discretion, an occlusion balloon catheter may be used to identify the distal cardiac veins. For further instructions, see literature accompanying the balloon catheter.

Placing the Lead

The ACUITY Steerable lead can be placed using a stylet or a guide wire. Review the venogram to determine the appropriate placement method.

Note: *A packaging stylet is inserted in the packaged lead to maintain the lead's J-shape at the distal end.The packaging stylet must be removed from the lead prior to implant.*

Using either a stylet or a guide wire can result in success when delivering the ACUITY Steerable lead in simple, compound, or complex anatomy. Simple anatomy is less tortuous and generally less narrow (Figure 8).

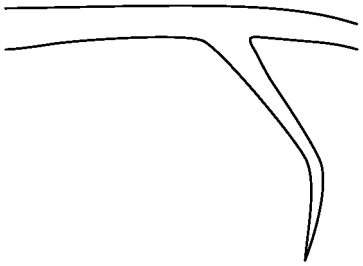


Figure 8. Simple anatomy.

Compound anatomy may have some tortuosity at the ostium of the branch vessel or further distal within the branch (Figure 9).

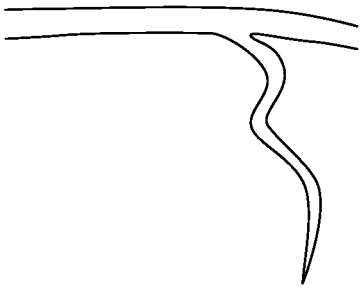


Figure 9. Compound anatomy.

Complex anatomy may be both tortuous and narrow in width (Figure 10).

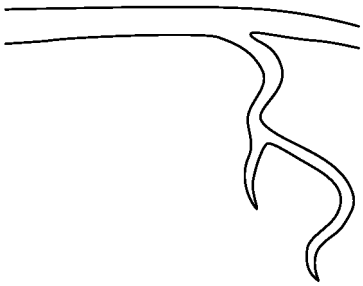


Figure 10. Complex tortuous anatomy.

Physician preference and comfort are the most important factors to consider

when determining whether to start with a stylet or a guide wire. During the clinical trial, physicians were successful using stylet, guide wire, or both to successfully deliver the ACUITY Steerable lead.

Placing the Lead With a Stylet

Notes:

- *To optimize insertion into the lead, do not allow body fluids to come in contact with the stylet. If body fluids come in contact with the stylet, use a new stylet.*
- *The stylets can be pre-shaped and then inserted into the terminal pin of the lead to provide shape to the lead.*
- *The physician should consider the venous anatomy of the patient when selecting the appropriate stylet for lead delivery. Standard stylets will provide a greater amount of straightening to the J-shaped fixation than the soft stylets.*
- *The guiding catheter serves as a conduit for the delivery of implantable coronary venous leads and can help protect the ACUITY Steerable lead during the placement of other leads.*
- *Flushing the inner lumen of the guide catheter with heparinized saline **before and during** stylet use is recommended.*
- *To prevent blood from clotting in the lead, carefully flushing the inner lumen of the lead with heparinized saline **before and during** use is recommended.*
- *Position the guide catheter tip as close as possible to the origin of the target branch vein.*

Remove and discard the packaging stylet that is inserted in the distal tip of the lead.

1. Select a standard or soft stylet (see Table 11 on page 25 for additional information on selecting a stylet). Insert the distal end of the stylet into the terminal pin. Advance the stylet until it stops at the distal tip. The stylet should not protrude from the tip.
2. Insert the lead/stylet assembly into the guiding catheter. Under fluoroscopy, advance the lead/stylet assembly to the desired lead position.
3. When the lead is in the desired target branch vein, advance the lead to the desired location within the branch vein. Remove the stylet while applying gentle forward pressure on the lead until the J-shaped fixation engages.

CAUTIONS:

- Do not bend the lead with a stylet in place. Bending the lead could damage the conductor and insulation material.
- Do not curve the stylet while it is in the lead. If a curved stylet is preferred, gently curve a straight stylet before inserting it into the lead.
- Do not use a sharp object to curve the distal end of the stylet. Using a sharp object may damage the stylet.
- Using a stylet designed for use with the ACUITY Steerable lead is recommended (See Table 12 on page 25). These stylets are specifically designed to prevent the stylet from extending past the lead tip. If a stylet is used other than those listed in Table 12, verify that the stylet does not extend past the lead tip. Extending the stylet past the lead tip may cause tissue damage.

Placing the Lead With a Guide Wire

The following section describes two preferred methods for ACUITY Steerable lead placement with a guide wire after the guiding catheter has been positioned in the coronary sinus and a venogram has been obtained.

Notes:

- *The guiding catheter serves as a conduit for the delivery of implantable coronary venous leads and can help protect the ACUITY Steerable lead during the placement of other leads.*
- *Flushing the guide wire's protective hoop and the inner lumen of the guide catheter with heparinized saline* ***before and during*** *guide wire use is recommended.*
- *To prevent blood from clotting in the lead, carefully flushing the inner lumen of the lead with heparinized saline* ***before and during*** *use is recommended.*
- *Position the guide catheter tip as close as possible to the origin of the target branch vein.*
- *The physician should consider the venous anatomy of the patient when selecting the appropriate guide wire for lead delivery. Guide wires with varying distal stiffness will straighten the J-shaped fixation to varying degrees. Guide wires with more distal support will provide the greatest amount of straightening.*

Remove and discard the packaging stylet that is inserted in the distal tip of the lead.

Method A

1. Insert the floppy tip of the guide wire (up to 0.016-in (0.41-mm) in diameter) into the guiding catheter and advance the tip of the wire through the coronary sinus to the desired position within the venous system.
2. Insert the proximal end of the guide wire into the distal opening of the lead. While inserting the guide wire, carefully straighten the J-shape to prevent perforating the lead or damaging the conductor coil.
3. While holding the guide wire in place, advance the lead over the wire to the desired lead position.

Method B

1. Insert the floppy tip of the guide wire (up to 0.016-in (0.41-mm) in diameter) into the terminal pin of the lead. Extend at least 3 cm of the guide wire beyond the distal tip of the lead to ensure the guide wire slides easily through the lumen and to straighten the J-shape of the lead.
2. Insert the lead/guide wire assembly into the guiding catheter. Under fluoroscopy, advance the lead until the tip of the lead is even with, but does not extend beyond the tip of the guide catheter. Advance the guide wire through the coronary sinus to the desired position within the venous system.
3. While holding the guide wire in place, advance the lead over the wire to the desired lead position.

When the lead is in the desired target branch vein, advance the lead to a distal location within that branch. Remove the guide wire while applying gentle forward pressure on the lead until the J-shaped fixation engages.

CAUTIONS:

- Use fluoroscopy to verify the guide wire does not prolapse and catch on the distal tip of the lead. If this occurs, slowly extend the wire beyond the distal tip to free the guide wire and then retract it to reestablish movement of the guide wire.
- If the guide wire cannot be retracted, withdraw the lead/guide wire assembly through the guiding catheter. Remove the guide wire through the distal tip of the lead and reintroduce the lead using a new guide wire. Follow the positioning procedures previously discussed.

- Flushing a clotted lead can compromise lead integrity. If clotting is suspected, remove the lead from the body and soak the lead in heparinized saline. Insert a guide wire into either the terminal or distal tip of the lead and advance the wire to clear clotting. If unsuccessful, use a new lead.
- Applying tools to the distal end of the lead may result in lead damage.

General lead placement methods

Lead Tip Orientation

- To reorient the tip to a more favorable position, torque the lead body near the hemostasis valve while the lead is in motion. The lead is more responsive to torquing of the lead body while it is in motion forward or backward.
- To ensure best lead push, the stylet should be fully engaged or seated in the lead tip to minimize tip prolapse during forward motion (unless trying to deflect the tip with a stylet).

If upon exiting the guiding sheath the tip of the ACUITY Steerable lead is pointing superior, the lead tip can be torqued to point inferior for better branch vein sub-selection (Figure 11).

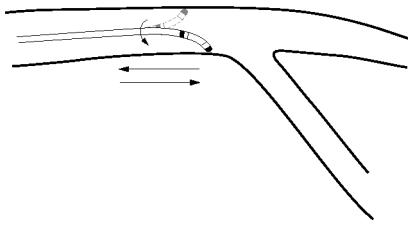


Figure 11. Lead tip orientation for vein selection.

Advance or Push Method

1. Advance the lead, pre-straightened with a stylet, to the junction of the branch vein (Figure 12).
2. Use the canted shape of the straightened lead to catch the ostium of the target branch (Figure 12).

3. Retract the stylet to allow the lead tip to deflect into the target branch (Figure 12).
4. Advance the lead further into the branch vein, using the stylet as necessary (Figure 12).

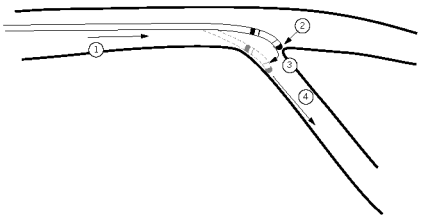


Figure 12. Lead placement using the Advance or Push Method.

Retract or Pull Method with a Stylet

1. Advance the lead, pre-straightened with a stylet fully inserted, past the junction of the branch vein (Figure 13).
2. Retract the stylet and "drag" the lead backwards to allow it to deflect into the target branch (Figure 13).
3. Advance the lead further into the branch vein, using the stylet as necessary (Figure 13).

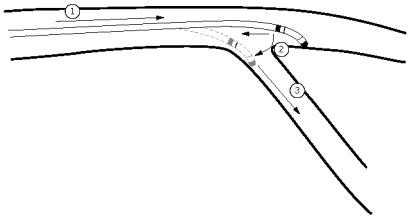


Figure 13. Lead placement using the Retract or Pull Method with a stylet.

Retract or Pull Method with a Guide Wire

1. Advance the lead, pre-straightened with a guide wire extending ahead of the lead, past the junction of the branch vein (Figure 14).

2. Retract the guide wire to allow the lead to reform its curve (Figure 14).
3. "Drag" the lead backwards to allow it to deflect into the target branch (Figure 14).
4. Advance the lead further into the branch vein, using the guide wire as necessary (Figure 14).

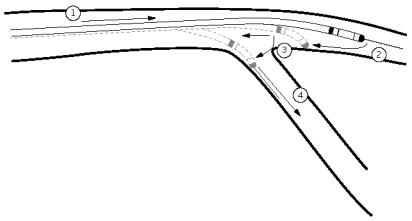


Figure 14. Lead placement using the Retract or Pull Method with a guide wire.

Using a Stylet followed by a Guide Wire within a Branch Vein

1. Advance the lead through the major branch vein by adjusting the position of the stylet as necessary (Figure 15).

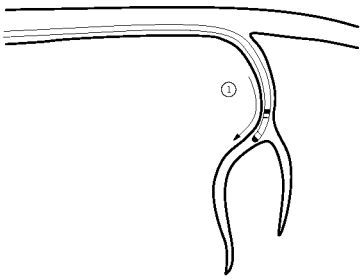


Figure 15. The lead being advanced through the major branch vein.

2. To access the side branch retract the lead proximal to the vein bifurcation and replace the stylet with a guide wire. Direct the guide wire into the side branch (Figure 16).
3. Advance enough wire ahead of the lead to anchor the wire in the side branch and to prevent the lead from reforming its J shape (Figure 16).
4. Track the lead over the wire into the side branch (Figure 16).

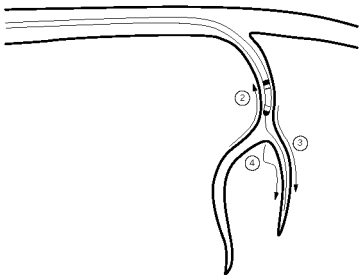


Figure 16. Using a stylet followed by a guide wire within a branch vein.

Using a Guide Wire within a Branch Vein

1. Advance the lead through the major branch vein using the shape of the lead alone or by tracking over a guide wire extended ahead of the lead (Figure 17).

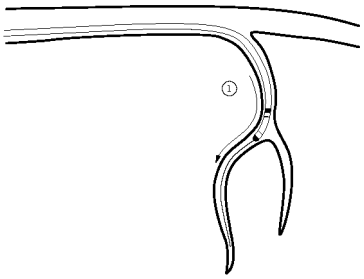


Figure 17. Using a guide wire within a branch vein.

2. To access the side branch retract the lead and guide wire proximal to the vein bifurcation and direct the guide wire into the side branch (Figure 18).
3. Advance enough wire ahead of the lead to anchor the wire in the side branch to prevent the lead from reforming its J shape (Figure 18).
4. Track the lead over the wire into the side branch (Figure 18).

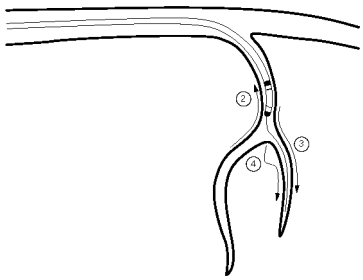


Figure 18. Using a guide wire within a branch vein.

EVALUATING LEAD PERFORMANCE

Evaluating Lead Position

Verify electrical performance of the lead using a pacing system analyzer or similar monitor before attaching the lead to the pulse generator. Once the lead is placed in the desired location, withdraw the guide wire tip or stylet tip approximately 4 cm into the pacing lead so the J-shaped fixation is engaged. Perform the measurements for voltage threshold (at 0.5 ms pulse width), R-wave amplitude, and pacing impedance, using recommended values in Table 13.

Table 13. Recommended Threshold and Sensing Measurements

Voltage threshold[a]	≤ 3.0 V
R-wave amplitude	≥ 5.0 mV
Lead Impedance	300-2000 Ω

a. Pulse width setting 0.5 ms.

See Figure 19, Figure 20, and Figure 21 for pacing system analyzer connections. Threshold measurements can be taken immediately after the lead is positioned and the J-shaped fixation is engaged.

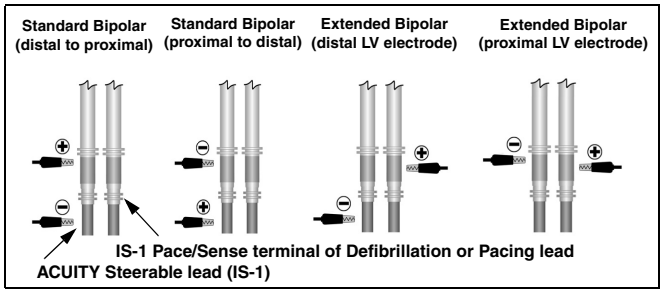


Figure 19. LV Pacing Bipolar: Pacing system analyzer connections.

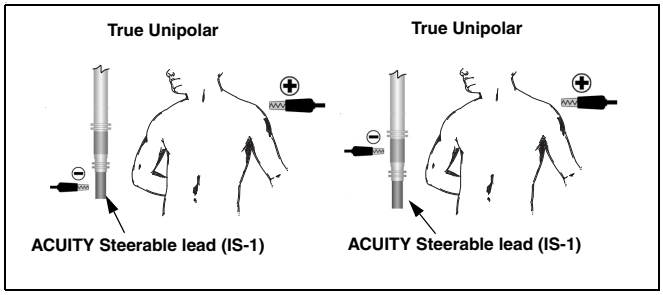


Figure 20. LV Pacing Unipolar: Pacing system analyzer connections.

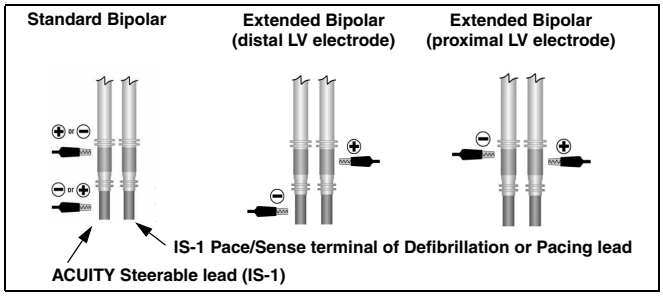


Figure 21. LV Sensing: Pacing system analyzer connections.

Note: *The guide wire or stylet must be withdrawn so the J-shaped fixation is engaged when performing lead evaluation.*

Perform the lead evaluation process:

1. Take measurements using one or more of the pacing and/or sensing configurations allowed by the pulse generator.
2. If satisfactory measurements free of extra cardiac stimulation are not achieved in any available configuration, reposition the lead.

Repositioning the Lead

Recommended methods for repositioning the lead include:

1. Reposition the lead to a more proximal location within the branch vein. Repeat the lead evaluation process.
2. Reposition the lead to a new branch vein if measurements from method one are unsatisfactory.

Removing the Guiding Catheter

Once the lead is positioned, remove the guide wire or stylet from the lead. Next, remove the finishing wire from its packaging and insert it into the lead according to the manufacturer's instructions.

Peel away the introducer sheath, if used. While holding the lead and finishing wire in place, remove the guiding catheter using the method described in the guiding catheter instructions for use. Using fluoroscopy, verify that the position of the lead tip does not change during the removal of the guiding catheter. Hold the proximal end of the lead near the venous entry site, disconnect the finishing wire from the terminal pin and withdraw the finishing wire from the lead. Verify under fluoroscopy that the lead has not moved.

Allow extra slack in the lead in the atrium for a strain relief to reduce the chance of dislodgement.

CAUTIONS:

- Do not kink the finishing wire in the lead. Kinking the finishing wire could lock it in the lead or damage the conductor coil.
- If the finishing wire cannot be retracted from the lead, withdraw the lead and finishing wire together. Do not implant with the finishing wire inside the lead.

Securing the Lead

After the lead is satisfactorily positioned, use the following steps to secure the lead to the vein to achieve permanent hemostasis and lead stabilization. Suture sleeve tie-down techniques can vary with the lead insertion technique used. A suture sleeve is provided for this purpose.

Percutaneous Implant Technique

1. Peel back the introducer sheath and slide the suture sleeve deep into the tissue (Figure 22).
2. Using the grooves, ligate the suture sleeve and the lead to the fascia. For additional stability, the sleeve may be secured to the lead first before securing the sleeve to the fascia.
3. The multiple grooves provide options for tie-down sites. At a minimum, two of the three grooves should be used for ligation.

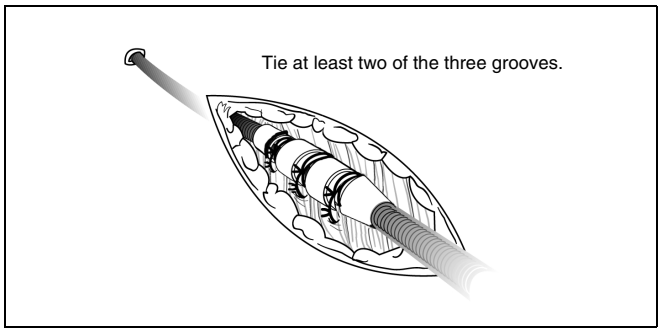


Figure 22. Using the sleeve with the percutaneous implant technique.

4. Check the suture sleeve after tie-down to demonstrate stability and lack of slippage by grasping the suture sleeve with fingers and trying to move the lead in either direction.

CAUTION: When implanting the lead via a subclavian puncture, allow slack in the lead between the suture sleeve and the venous entry site. This will help minimize flexing at the suture sleeve and interaction with the clavicle/first rib region.

Venous Cutdown Technique

1. Slide the suture sleeve into the vein past the most distal groove. Ligate the vein around the suture sleeve to obtain hemostasis. Next, using the same groove, secure the lead and vein to the adjacent fascia (Figure 23).

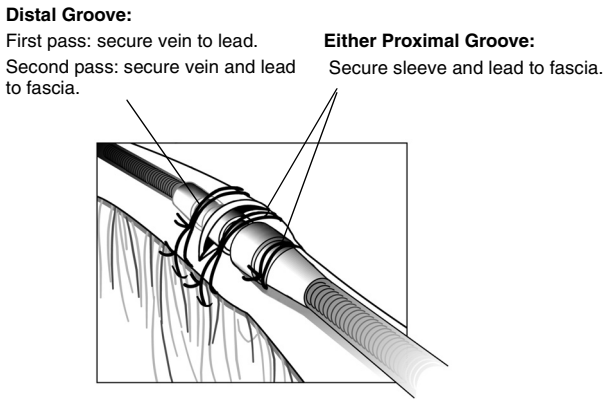


Figure 23. Using the sleeve with the venous cutdown technique.

2. Using one of the proximal grooves, secure the sleeve and the lead to the adjacent fascia. For additional stability, the sleeve may be secured to the lead first before securing the sleeve to the fascia. The other groove may be used as an additional tie-down site.
3. Check the suture sleeve after tie-down to demonstrate stability and lack of slippage by grasping the suture sleeve with fingers and trying to move the lead in either direction.

Note: *If venous entry is made using a Guidant lead introducer, ligate the lead to the adjacent fascia using the suture sleeve to prevent lead movement.*

CAUTION: When ligating the vein, avoid too tight a ligature. A tight ligature might damage the silicone rubber insulation or sever the vein. Avoid dislodging the lead tip during the stabilizing procedure.

Connection to a Pulse Generator

Remove the finishing wire from the lead before connecting the lead to the pulse generator. A finishing wire left in the lead could cause (1) lead perforation or (2) myocardial or coronary venous perforation.

When the lead is secured at the venous entry site, reverify position and threshold measurements and then connect the lead to the pulse generator using the procedure described in the applicable pulse generator physician's manual.

CAUTIONS:

- Do not kink, twist, or braid the lead terminal with other leads, as doing so could cause lead insulation abrasion or conductor damage.
- Insert the lead terminal straight into the lead port. Do not bend the lead near the lead-header interface. Improper insertion can cause insulation or connector damage.

Notes:

- *If a lubricant is needed when connecting the lead to the pulse generator, using sterile water is suggested.*
- *If the lead terminal will not be connected to a pulse generator at the time of lead implantation, the lead connector must be capped before closing the pocket incision. The IS-1 lead cap is designed specifically for this purpose. Place a suture around the lead cap to keep it in place.*

Giving consideration to patient anatomy and pulse generator size and motion, gently coil any excess lead and place adjacent to the pulse generator. It is important to place the lead into the pocket in a manner that minimizes lead tension, twisting, sharp angles, and/or pressure.

Returning Explanted Products

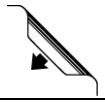
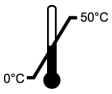
CAUTION: Return all explanted leads to Boston Scientific.

Examination of explanted leads can provide information for continued improvement in system reliability. Use a Boston Scientific Returned Product Kit to properly package the lead and complete an Observation/ Complication/Out-of-Service Report form. Send the form and kit to Boston Scientific at the address on the back of this manual.

Note: *Disposal of explanted devices is subject to local, state, and federal regulations. Contact your sales representative or call the telephone number on the back of the manual for a Returned Product Kit.*

Graphical Symbols

Table 14. Definition of Graphical Symbols.

Symbol	Definition
	Opening instructions
	Do not reuse
	Consult instructions for use
	Temperature limitation
	Sterilized using ethylene oxide
	Reference number
	Use by
	Date of manufacture
	Lot number
	Serial number
	Manufacturer

SPECIFICATIONS (NOMINAL)

Model and Length	4554 - 80 cm 4555 - 90 cm
Terminal compatibility	IS-1
Electrode configuration	Bipolar (Dual)
Compatibility	Pulse generators that accept IS-1 connectors
Insertion Diameter	2.16 mm
Recommended introducer size	Determined by guiding catheter size.
Recommended guiding catheter size	8F (2.6 mm) (inner diameter 2.2 mm)
Steroid	0.5 mg per collar (1.0 mg total) dexamethasone acetate
Conductors:	
Type	Co-Axial design, quadfilar (inner), trifilar (outer)
Material	MP35N with Tantalum core (inner) Platinum clad tantalum with ETFE coating (outer)
Electrode:	
Distal surface area	7.8 mm^2
Proximal surface area	9.0 mm^2
Distance between electrodes	8 mm
Material	Platinum iridium substrate
Coating	IROX (iridium oxide) coating
Lead Body:	
Proximal body diameter	6F (1.98 mm)
Inside diameter	0.022 in (0.56 mm)
Tip diameter	5.4F (1.78 mm)
Insulation material	Silicone rubber, ETFE, and polyurethane 55D
Protective sleeve material	Polyurethane 55D
Terminal pin and ring material	Titanium
Fixation mechanism	2 dimensional J-shape

ACUITY STEERABLE LEAD
SPECIFICATIONS (NOMINAL)

Maximum lead conductor resistance (ohms) from terminal pin to distal electrode	4554 - 72 Ω 4555 - 77 Ω
Maximum lead conductor resistance (ohms) from terminal ring to proximal electrode	4554 - 86 Ω 4555 - 94 Ω

APPENDIX

Table 15. ACUITY Steerable lead-related and procedure-related adverse events including all adverse events reported through March 21, 2006. All patients implanted or attempted; N=110, 984 total device months.

		Complications		Observations	
Adverse Event	**Number of Events (Number of Patients)**	**% of Patients (N Patients)**	**N Events/ 100 Device Months (N Events)**	**% of Patients (N Patients)**	**N Events/ 100 Device Months (N Events)**
Total Adverse Events	**157 (65)**	**34.5 (38)**	**6.6 (65)**	**44.5 (49)**	**9.3 (92)**
ACUITY Steerable Related Events (N=101)					
Coronary venous dissection	1 (1)	0.0 (0)	0.0 (0)	1.0 (1)	0.1 (1)
Dislodgment - Elevated threshold - LV	2 (2)	2.0 (2)	0.2 (2)	0.0 (0)	0.0 (0)
Dislodgment - Extracardiac stimulation - LV	4 (4)	2.0 (2)	0.2 (2)	2.0 (2)	0.2 (2)
Dislodgment - Multiple signs - LV	2 (2)	2.0 (2)	0.2 (2)	0.0 (0)	0.0 (0)
Dislodgment - No reported signs - LV	2 (2)	2.0 (2)	0.2 (2)	0.0 (0)	0.0 (0)
Dislodgment - Unable to capture - LV	2 (2)	2.0 (2)	0.2 (2)	0.0 (0)	0.0 (0)
Elevated threshold - LV	2 (2)	0.0 (0)	0.0 (0)	2.0 (2)	0.2 (2)
Extracardiac stimulation - LV	19 (17)	1.0 (1)	0.1 (1)	15.8 (16)	1.9 (18)
Subtotal ACUITY Steerable Related Events	**34 (29)**	**9.9 (10)**	**1.1 (11)**	**19.8 (20)**	**2.4 (23)**
PG Related Events (N=106)					
Elevated DFT - Defibrillation	2 (2)	0.9 (1)	0.1 (1)	0.9 (1)	0.1 (1)
Extracardiac stimulation - Daily impedance testing	3 (3)	0.0 (0)	0.0 (0)	2.8 (3)	0.3 (3)
Hematoma - Pocket (> 30 days post-implant)	1 (1)	0.0 (0)	0.0 (0)	0.9 (1)	0.1 (1)
Infection (> 30 days post-implant)	1 (1)	0.9 (1)	0.1 (1)	0.0 (0)	0.0 (0)
Migration	1 (1)	0.0 (0)	0.0 (0)	0.9 (1)	0.1 (1)
Pacemaker-mediated tachycardia (PMT)	3 (3)	0.0 (0)	0.0 (0)	2.8 (3)	0.3 (3)

Table 15. ACUITY Steerable lead-related and procedure-related adverse events including all adverse events reported through March 21, 2006. All patients implanted or attempted; N=110, 984 total device months.

Psychological effect due to device therapy	1 (1)	0.0 (0)	0.0 (0)	0.9 (1)	0.1 (1)
Subtotal PG Related Events	**12 (9)**	**0.9 (1)**	**0.2 (2)**	**7.5 (8)**	**1.0 (10)**
RA Lead Related Events (N=106)					
Dislodgment - Unable to capture - RA	2 (2)	1.9 (2)	0.2 (2)	0.0 (0)	0.0 (0)
Elevated threshold - RA	1 (1)	0.0 (0)	0.0 (0)	0.9 (1)	0.1 (1)
Oversensing - RA	2 (1)	0.0 (0)	0.0 (0)	0.9 (1)	0.2 (2)
Unable to capture - RA	1 (1)	0.9 (1)	0.1 (1)	0.0 (0)	0.0 (0)
Subtotal RA Lead Related Events	**6 (4)**	**2.8 (3)**	**0.3 (3)**	**0.9 (1)**	**0.3 (3)**
RV Lead Related Events (N=106)					
Dislodgment - Elevated threshold - RV	1 (1)	0.9 (1)	0.1 (1)	0.0 (0)	0.0 (0)
Elevated threshold - RV	1 (1)	0.9 (1)	0.1 (1)	0.0 (0)	0.0 (0)
Subtotal RV Lead Related Events	**2 (2)**	**1.9 (2)**	**0.2 (2)**	**0.0 (0)**	**0.0 (0)**
Procedure Related Events (N=110)					
Adverse reaction - General	1 (1)	0.0 (0)	0.0 (0)	0.9 (1)	0.1 (1)
Adverse reaction - Hypotension	2 (2)	0.9 (1)	0.1 (1)	0.9 (1)	0.1 (1)
Chest pain	1 (1)	0.9 (1)	0.1 (1)	0.0 (0)	0.0 (0)
Hematoma - Pocket (<=30 days post-implant)	6 (6)	0.9 (1)	0.1 (1)	4.5 (5)	0.5 (5)
Inappropriate VF sensing - Noise	1 (1)	0.0 (0)	0.0 (0)	0.9 (1)	0.1 (1)
LV Lead Insulation Damaged	1 (1)	0.9 (1)	0.1 (1)	0.0 (0)	0.0 (0)
LV Lead Insulation Damaged During Procedure	1 (1)	0.0 (0)	0.0 (0)	0.9 (1)	0.1 (1)
Post-surgical wound discomfort	1 (1)	0 (0)	0 (0)	0.9 (1)	0.1 (1)
Psychological effect due to recall	2 (2)	0 (0)	0 (0)	1.8 (2)	0.2 (2)
RV and LV leads transposed on header	1 (1)	0.9 (1)	0.1 (1)	0.0 (0)	0.0 (0)
Thrombus	1 (1)	0.9 (1)	0.1 (1)	0 (0)	0 (0)

Table 15. ACUITY Steerable lead-related and procedure-related adverse events including all adverse events reported through March 21, 2006. All patients implanted or attempted; N=110, 984 total device months.

Subtotal Procedure Related Events	**18 (16)**	**5.5 (6)**	**0.6 (6)**	**10.0 (11)**	**1.2 (12)**
Protocol Testing Related Events (N=110)					
Extracardiac stimulation - LV	3 (2)	0.0 (0)	0.0 (0)	1.8 (2)	0.3 (3)
Subtotal Protocol Testing Related Events	**3 (2)**	**0.0 (0)**	**0.0 (0)**	**1.8 (2)**	**0.3 (3)**
Cardiovascular Related Events (N=110)					
Atrial fibrillation (AF)	5 (4)	0.9 (1)	0.1 (1)	2.7 (3)	0.4 (4)
Atrial flutter	1 (1)	0.0 (0)	0.0 (0)	0.9 (1)	0.1 (1)
Cerebrovascular accident (CVA)	1 (1)	0.0 (0)	0.0 (0)	0.9 (1)	0.1 (1)
Chest pain - Heart failure	3 (2)	0.0 (0)	0.0 (0)	1.8 (2)	0.3 (2)
Chest pain - Ischemic	4 (3)	0.9 (1)	0.1 (1)	1.8 (2)	0.3 (3)
Chest pain - Other	1 (1)	0.0 (0)	0.0 (0)	0.9 (1)	0.1 (1)
Chronotropic incompetence	1 (1)	0.0 (0)	0.0 (0)	0.9 (1)	0.1 (1)
Dizziness	1 (1)	0.0 (0)	0.0 (0)	0.9 (1)	0.1 (1)
Dizziness - Heart failure	1 (1)	0.0 (0)	0.0 (0)	0.9 (1)	0.1 (1)
Dyspnea - Heart failure	4 (4)	2.7 (3)	0.3 (3)	0.9 (1)	0.1 (1)
Gastrointestinal - Heart failure	1 (1)	0.9 (1)	0.1 (1)	0.0 (0)	0.0 (0)
Hypotension - Heart failure	2 (2)	0.0 (0)	0.0 (0)	1.8 (2)	0.2 (2)
Multi-system failure - Heart failure	3 (3)	2.7 (3)	0.3 (3)	0.0 (0)	0.0 (0)
Multiple heart failure symptoms	16 (14)	10.0 (11)	1.2 (12)	3.6 (4)	0.4 (4)
Multiple symptoms	2 (2)	0.9 (1)	0.1 (1)	0.9 (1)	0.1 (1)
Myocardial infarction	2 (2)	1.8 (2)	0.2 (2)	0.0 (0)	0.0 (0)
Nonsustained ventricular tachycardia (NSVT)	1 (1)	0.0 (0)	0.0 (0)	0.9 (1)	0.1 (1)
Other SVT (AVRT, AVNRT, EAT etc.)	2 (2)	0.0 (0)	0.0 (0)	1.8 (2)	0.2 (2)
Peripheral edema - Heart failure	1 (1)	0.9 (1)	0.1 (1)	0.0 (0)	0.0 (0)
Prophylactic treatment	1 (1)	0.9 (1)	0.1 (1)	0.0 (0)	0.0 (0)
Pulmonary embolism (PE)	1 (1)	0.9 (1)	0.1(1)	0.0 (0)	0.0 (0)

Table 15. ACUITY Steerable lead-related and procedure-related adverse events including all adverse events reported through March 21, 2006. All patients implanted or attempted; N=110, 984 total device months.

Renal insufficiency - Heart failure	2 (2)	0.9 (1)	0.1 (1)	0.9 (1)	0.1 (1)
Sinus tachycardia	1 (1)	0.0 (0)	0.0 (0)	0.9 (1)	0.1 (1)
Syncope	3 (2)	0.0 (0)	0.0 (0)	1.8 (2)	0.3 (3)
Ventricular fibrillation (VF)	1 (1)	0.0 (0)	0.0 (0)	0.9 (1)	0.1 (1)
Ventricular tachycardia (VT)	2 (2)	0.9 (1)	0.1 (1)	0.9 (1)	0.1 (1)
Subtotal Cardiovascular Related Events	**63 (36)**	**17.3 (19)**	**2.9 (29)**	**20.9 (23)**	**3.5 (34)**
Subtotal Non-cardiovascular Related Events	**19 (11)**	**6.4 (7)**	**1.2 (12)**	**4.5 (5)**	**0.7 (7)**

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