Boston Scientific

PHYSICIAN'S LEAD MANUAL

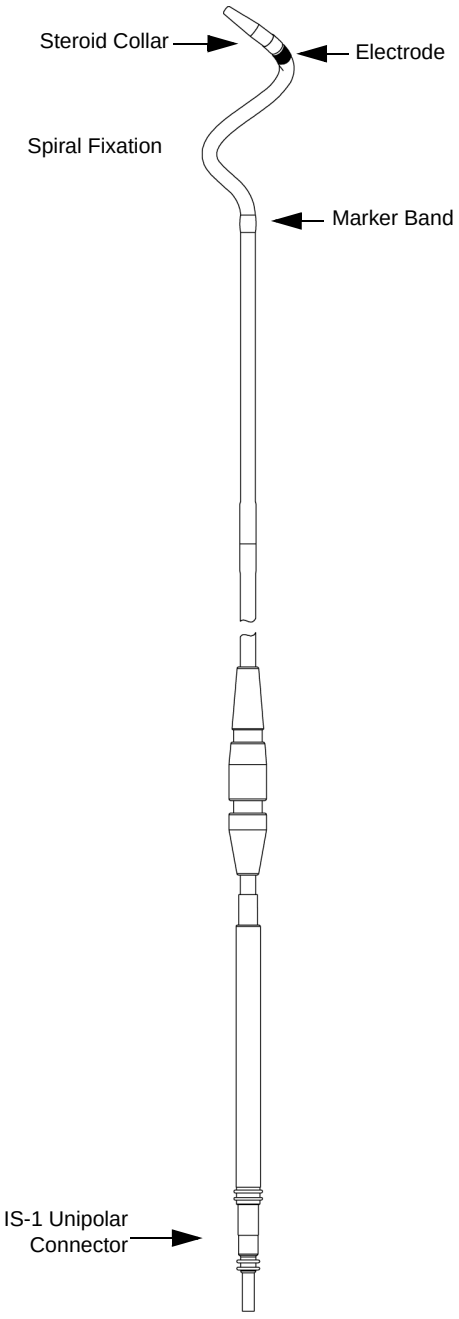
ACUITY® Spiral

Implantable Lead

Model 4591, 4592, 4593

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 Spiral Lead
Models 4591/4592/4593



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INFORMATION FOR USE

Device Description

Boston Scientific ACUITY® Spiral coronary venous pace/sense leads, Models 4591/4592/4593, provide chronic left ventricular unipolar pacing and unipolar sensing. The leads have an over-the-wire design with an IS-1[1] unipolar connector and are dexamethasone acetate-eluting distal to the electrode. The lead is anchored with spiral fixation and the electrode is 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. The ACUITY Spiral lead is used in conjunction with a compatible pulse generator.

Related Information

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.

Intended Audience

This literature is intended for use by professionals trained or experienced in device implant and/or follow-up procedures.

Indications and Usage

The ACUITY Spiral coronary venous, dexamethasone acetate-eluting, single-electrode pace/sense leads, Models 4591/4592/4593, are transvenous leads intended for chronic, left-ventricular pacing and sensing via the coronary veins when used in conjunction with a compatible pulse generator.

Contraindications

Use of the ACUITY Spiral lead is contraindicated in patients with a hypersensitivity to a maximum single dose of 0.56 mg dexamethasone acetate drug.

Warnings

In the following list of warnings, page numbers are indicated for those warnings that are specific to other areas of the manual. Refer to the indicated pages for information relevant to the warning. Failure to observe

1. IS-1 refers to the international standard ISO 5841-3:2000.

these warnings could result in incorrect lead implantation, lead damage/ dislodgment, 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 Spiral 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, dislodgment, 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.
- 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).
- **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 dislodgment (Page 25).
- **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.
- **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 36).
- **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/dislodgment, 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 at the address on the back cover of this manual (Page 24).
- **Storage temperature.** Store at 25°C (77°F). Excursions permitted between 15 - 30°C (59-86°F) [see USP Controlled Room Temperature]. Transportation spikes permitted up to 50°C (122°F).
- **Use by date.** Implant the lead on or before 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

- **Avoid using unauthorized delivery tools.** Do not use unauthorized delivery tools (e.g., stylet) to deliver the **ACUITY Spiral** lead.
- **Remove finishing wire.** The finishing wire MUST BE REMOVED before connecting the lead to the pulse generator (Page 23).
- **Vein pick.** The vein pick is not intended either for puncturing the vein or for dissecting tissue during a cutdown procedure (Page 25).
- **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 25).
- **Chronic repositioning.** Optimum threshold performance might not be achieved if the lead is chronically repositioned because the steroid can be depleted (Page 25).
- **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 25).
- **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 dislodgment 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 dislodgment 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 26).
- **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 29).
- **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 30).

- **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 literature accompanying the balloon catheter (Page 30).
- **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 32).
- **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. Follow the positioning procedures discussed (Page 32).
- **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 32).
- **Applying tools to the distal end of the lead.** Applying tools to the distal end of the lead may result in lead damage (Page 32).
- **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 34).
- **Remove the 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 34).
- **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 35).
- **Avoid too tight ligature.** When ligating the vein, avoid too tight a ligature. A tight ligature might damage the lead insulation or sever the vein. Avoid dislodging the lead tip during the stabilizing procedure (Page 36).
- **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 37).

- **Connecting the lead.** Ensure that the lead terminal of the ACUITY Spiral is connected to the LV IS-1 port of the pulse generator (Page 37).
- **Explanted leads.** Return all explanted leads to Boston Scientific (Page 37).
- **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.

ADVERSE EVENTS

The safety of the ACUITY Spiral lead was evaluated in 110 patients who underwent an implant procedure in the EASYTRAK 3 Downsize Clinical Study. All patients with an ACUITY Spiral lead were followed for one month.

Observed Adverse Events

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

During the one-month follow-up period, a total of 56 events were reported in 38 patients. Of these events, 24 were classified as complications, and 32 were classified as observations.

Table 1. ACUITY Spiral lead-related and procedure-related adverse events through one month. Total device months=109.

		Complications		Observations	
Adverse Event	**Number of Events (Number of Patients)**	**% of Patients (N Patients)**	**N Events/ 100 Device Month (N Events)**	**% of Patients (N Patients)**	**N Events/ 100 Device Months (N Events)**
Total Adverse Events	**56 (38)**	**19.1 (21)**	**22.0 (24)**	**22.7 (25)**	**29.4 (32)**
ACUITY Spiral Related Events (N=97)					
Dislodgment - Elevated threshold - LV	1 (1)	1.0 (1)	1.0 (1)	0.0 (0)	0.0 (0)
Elevated threshold - LV	1 (1)	0.0 (0)	0.0 (0)	1.0 (1)	1.0 (1)
Extracardiac stimulation - LV	12 (12)	1.0 (1)	1.0 (1)	11.3 (11)	11.3 (11)
LV lead slack removal	1 (1)	0.0 (0)	0.0 (0)	1.0 (1)	1.0 (1)
Subtotal ACUITY Spiral Related Events	**15 (15)**	**2.1 (2)**	**2.1 (2)**	**13.4 (13)**	**13.4 (13)**
Other EASYTRAK Family Related Events (N=9)					

Table 1. ACUITY Spiral lead-related and procedure-related adverse events through one month. Total device months=109.

		Complications		Observations	
Adverse Event	**Number of Events (Number of Patients)**	**% of Patients (N Patients)**	**N Events/ 100 Device Month (N Events)**	**% of Patients (N Patients)**	**N Events/ 100 Device Months (N Events)**
Coronary venous dissection	2 (2)	0.0 (0)	0.0 (0)	22.2 (2)	22.2 (2)
Dislodgment-Elevated threshold - LV	1 (1)	0.0 (0)	0.0 (0)	11.1 (1)	11.1 (1)
Extracardiac stimulation - LV	1 (1)	0.0 (0)	0.0 (0)	11.1 (1)	11.1 (1)
Unable to capture - LV	1 (1)	0.0 (0)	0.0 (0)	11.1 (1)	11.1 (1)
Subtotal Other EASYTRAK Family Related Events	**5 (5)**	**0.0 (0)**	**0.0 (0)**	**55.6 (5)**	**55.6 (5)**
PG Related Events (N=106)					
Elevated DFT - Defibrillation	1 (1)	0.0 (0)	0.0 (0)	0.9 (1)	0.9 (1)
Pacemaker-mediated tachycardia (PMT)	1 (1)	0.0 (0)	0.0 (0)	0.9 (1)	0.9 (1)
Subtotal PG Related Events	**2 (2)**	**0.0 (0)**	**0.0 (0)**	**1.9 (2)**	**1.8 (2)**
RV Lead Related Events (N=106)					
Dislodgment - Extracardiac stimulation - RV	1 (1)	0.9 (1)	0.9 (1)	0.0 (0)	0.0 (0)
Dislodgment - Unable to capture - RV	1 (1)	0.9 (1)	0.9 (1)	0.0 (0)	0.0 (0)
Extracardiac stimulation - RV	1 (1)	0.9 (1)	0.9 (1)	0.0 (0)	0.0 (0)
Subtotal RV Lead Related Events	**3 (2)**	**1.9 (2)**	**2.8 (3)**	**0.0 (0)**	**0.0 (0)**
Procedure Related Events (N=110)					
Hematoma - Pocket (<=30 days post-implant)	5 (4)	2.7 (3)	3.7 (4)	0.9 (1)	0.9 (1)
Loose RA set screws	1 (1)	0.9 (1)	0.9 (1)	0.0 (0)	0.0 (0)
Loose RV set screws	1 (1)	0.9 (1)	0.9 (1)	0.0 (0)	0.0 (0)

Table 1. ACUITY Spiral lead-related and procedure-related adverse events through one month. Total device months=109.

		Complications		Observations	
Adverse Event	**Number of Events (Number of Patients)**	**% of Patients (N Patients)**	**N Events/ 100 Device Month (N Events)**	**% of Patients (N Patients)**	**N Events/ 100 Device Months (N Events)**
Physical trauma	1 (1)	0.0 (0)	0.0 (0)	0.9 (1)	0.9 (1)
Pneumothorax - Procedure	2 (2)	1.8 (2)	1.8 (2)	0.0 (0)	0.0 (0)
Post-surgical infection (<= 30 days post-implant)	1 (1)	0.9 (1)	0.9 (1)	0.0 (0)	0.0 (0)
Post-surgical wound discomfort	3 (3)	0.9 (1)	0.9 (1)	1.8 (2)	1.8 (2)
Subtotal Procedure Related Events	**14 (12)**	**8.2 (9)**	**9.2 (10)**	**2.7 (3)**	**3.7 (4)**
Cardiovascular Related Events (N=110)					
Chest pain - Other	1 (1)	0.9 (1)	0.9 (1)	0.0 (0)	0.0 (0)
Dizziness	1 (1)	0.0 (0)	0.0 (0)	0.9 (1)	0.9 (1)
Dyspnea - Heart failure	1 (1)	0.9 (1)	0.9 (1)	0.0 (0)	0.0 (0)
Fatigue	1 (1)	0.0 (0)	0.0 (0)	0.9 (1)	0.9 (1)
Fatigue - Heart failure	1 (1)	0.0 (0)	0.0 (0)	0.9 (1)	0.9 (1)
Heart failure symptoms - Unspecified	1 (1)	0.9 (1)	0.9 (1)	0.0 (0)	0.0 (0)
Multi-system failure - Heart failure	2 (2)	1.8 (2)	1.8 (2)	0.0 (0)	0.0 (0)
Multiple heart failure symptoms	2 (2)	0.9 (1)	0.9 (1)	0.9 (1)	0.9 (1)
Multiple symptoms	1 (1)	0.0 (0)	0.0 (0)	0.9 (1)	0.9 (1)
Palpitations	2 (2)	0.0 (0)	0.0 (0)	1.8 (2)	1.8 (2)
Pulmonary edema - Heart failure	1 (1)	0.9 (1)	0.9 (1)	0.0 (0)	0.0 (0)
Transient ischemic attack (TIA)	1 (1)	0.0 (0)	0.0 (0)	0.9 (1)	0.9 (1)
Subtotal Cardiovascu-lar Related Events	**15 (12)**	**6.4 (7)**	**6.4 (7)**	**6.4 (7)**	**7.3 (8)**

Table 1. ACUITY Spiral lead-related and procedure-related adverse events through one month. Total device months=109.

		Complications		Observations	
Adverse Event	**Number of Events (Number of Patients)**	**% of Patients (N Patients)**	**N Events/ 100 Device Month (N Events)**	**% of Patients (N Patients)**	**N Events/ 100 Device Months (N Events)**
Subtotal Non-cardio-vascular Related Events	**2 (2)**	**1.8 (2)**	**1.8 (2)**	**0.0 (0)**	**0.0 (0)**

A total of ten deaths occurred during the study as shown in Table 2, along with the cause of death as adjudicated by an independent events committee. None of the deaths were attributed to the ACUITY Spiral lead.

Table 2. Patient deaths that occurred during the study to date. All patients implanted or attempted with an ACUITY Spiral lead; N=110 (1341 total patient months).

Cause of Death	Pre-Operative	Peri-Operative	Post-Operative	Total (N=110)
Cardiac: Pump Failure	1	2	1	4
Cardiac: Unknown	0	0	1	1
Noncardiac	0	0	3	3
Unknown	0	0	2	2
Total Deaths	**1**	**2**	**7**	**10**

Potential Adverse Events

Based on the literature and on pulse generator and/or lead implant experience, the following list includes possible adverse events associated with implantation of products described in this literature:

- 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/dislodgment
- Lead fracture
- Lead insulation breakage or abrasion
- Lead tip deformation and/or breakage
- 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 ACUITY Spiral lead was evaluated in the EASYTRAK 3 Downsize Clinical Study. The following is a summary of the findings on the ACUITY Spiral lead.

Study Design

This clinical investigation of the ACUITY Spiral lead was a prospective, multi-center study conducted at 21 centers in the United States. All 110 patients enrolled underwent an implant procedure to receive an ACUITY Spiral lead.

In all patients the ACUITY Spiral lead was connected to a CONTAK RENEWAL 3 family cardiac resynchronization therapy with defibrillator (CRT-D) device or to a CONTAK RENEWAL TR family cardiac resynchronization therapy pacemaker (CRT-P) device. Evaluation of the safety and effectiveness of the investigational lead was performed at implant, pre-discharge, one-month post-implant and quarterly thereafter.

Inclusion/Exclusion Criteria

Patients who met all of the following criteria were given consideration for inclusion in this clinical investigation:

- Must be indicated for a Guidant CRT-P or CRT-D device
- Creatinine < 2.5 mg/dL obtained no more than two weeks 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 investigation center and at the intervals defined by this protocol
- Geographically stable residents who are available for follow-up

Patients who met any one of the following criteria were excluded from this clinical investigation:

- A known hypersensitivity to a nominal dose of 0.5 mg of dexamethasone acetate
- Have or had previous cardiac resynchronization therapy, a coronary venous pace/sense lead or attempted LV lead placement
- Have pre-existing cardioversion/defibrillation leads or right ventricular pacing leads other than those specified in the investigational plan (unless the investigator intends to replace them with permitted cardioversion/defibrillation leads)
- Currently requiring dialysis
- Have had a myocardial infarct, unstable angina, percutaneous coronary intervention, or coronary artery bypass graft during the preceding 30 days prior to enrollment
- Have hypertrophic obstructive cardiomyopathy or infiltrative cardiomyopathy (e.g., amyloidosis, sarcoidosis)
- Documented life expectancy of less than 6 months or expected to undergo heart transplant within 6 months
- Enrolled or participating in any concurrent study, including drug investigations, without 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; taking of patient history; obtaining informed consent.
Implant	Implantation of investigational devices and acute lead evaluation.
Pre-Discharge	Lead evaluation.
One-Month and Quarterly Visits	Physical assessment and lead evaluation.

Lead Endpoints

Lead Effectiveness:
One-month left ventricular pacing thresholds, pacing impedances, and R-wave amplitudes as measured in the tip-to-coil configuration.

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

Clinical Investigation

The objective of this investigation was to demonstrate the safety and effectiveness of the ACUITY Spiral lead. The ACUITY Spiral lead was successfully implanted in 97/109 (89.0%) patients in whom an ACUITY Spiral lead was attempted. The average procedure (skin-to-skin) time was 102 ± 45 minutes with an average fluoroscopy time of 23 ± 18 minutes. Patients were followed beyond the one-month endpoint requirement, with a mean implant duration of 13.8 ± 3.9 months (range 0.7 - 17.3 months).

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

Table 3. Implant success rate. All patients implanted or attempted with an LV lead; N=109

Left Ventricular Lead	Number of Patients Undergoing Procedure	Number of Patients Successfully Implanted	Success Rate
ACUITY Spiral Lead success rate	109	97	89.0%
EASYTRAK[a] family success rate	109	106	97.2%

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

Lead Placement

The final implant positions of the ACUITY Spiral lead are shown in Table 4. Final lead location was documented through fluoroscopic images in Right Anterior Oblique (RAO) and Left Anterior Oblique (LAO) and Anterior/ Posterior (AP) views, as well as by X-rays in the AP view.

Table 4. ACUITY Spiral lead placement. All patients implanted with an ACUITY Spiral lead; N=97

Position from RAO View	Position from LAO View				Total
	Anterior	Lateral	Posterior	Other[a]	
Basal	1 (1.0%)	3 (3.1%)	1 (1.0%)	0 (0.0%)	5 (5.2%)
Mid	4 (4.1%)	65 (67.0%)	7 (7.2%)	2 (2.1%)	78 (80.4%)
Apical	0 (0.0%)	13 (13.4%)	1 (1.0%)	0 (0.0%)	14 (14.4%)
Total	**5 (5.2%)**	**81 (83.5%)**	**9 (9.3%)**	**2 (2.1%)**	**97 (100.0%)**

a. Other LAO positions reported Anterolateral (1) and Septal (1).

Patient Demographics

Demographic information on all 110 patients who enrolled in the clinical study is shown in Table 5.

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

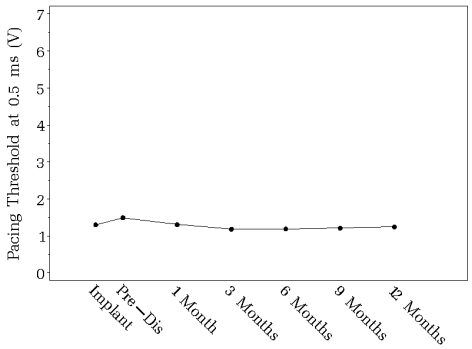
Characteristic	Measurement	Result
Age at Implant (years)	N Mean ± SD Range	110 70.1 ± 11.2 37.5 - 89.9
Gender [N (%)]	Male Female	74 (67) 36 (33)
NYHA Class [N (%)]	III IV	102 (93) 8 (7)
LVEF (%)	N Mean ± SD Range	110 23.1 ± 6.1 10.0 - 35.0
Etiology [N (%)]	Ischemic Nonischmeic	66 (60) 40 (40)

Lead Effectiveness

The effectiveness of the ACUITY Spiral lead was measured by pacing thresholds, pacing impedances and sensed amplitude evaluated over a one-month period. The measurements were taken in the tip-to-coil configuration with a CONTAK RENEWAL family device. Pacing thresholds were measured at a 0.5 ms pulse width.

Table 6. Pacing thresholds-last observation carried forward. All patients implanted with an ACUITY Spiral lead; N=97.

Measurement	Statistic	Implant	Pre-Discharge	1 Month
Pacing Threshold (V)	N	97	97	97
	Mean ± SD	1.3 ± 1.0	1.5 ± 1.3	1.3 ± 1.2
	Range	0.2 - 5.5	0.4 - 6.5	0.2 - 5.0
	Upper Bound	NA	NA	1.5



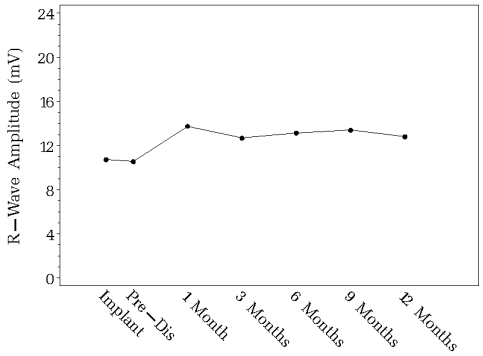
Statistic	Implant	Pre-Discharge	1 Month	3 Months	6 Months	9 Months	12 Months
N	97	96	95	89	74	66	59
Mean ± SD	1.3 ± 1.0	1.5 ± 1.3	1.3 ± 1.2	1.2 ± 1.1	1.2 ± 1.2	1.2 ± 1.2	1.2 ± 1.2
Range	0.2 - 5.5	0.4 - 6.5	0.2 -5.0	0.2 - 6.0	0.2 - 7.0	0.4 - 5.5	0.2 - 5.5

Figure 1. Mean pacing threshold with device in the Tip-to-Coil configuration. All patients implanted with an ACUITY Spiral lead; N=97.

It was hypothesized that the upper tolerance limit of the one-month left ventricular pacing threshold of the ACUITY Spiral lead be less than 2.5 V to ensure that an adequate safety margin exists. One-month left ventricular pacing thresholds are within this limit.

Table 7. Sensed amplitudes—last observation carried forward. All patients implanted with an ACUITY Spiral lead; N=97.

Measurement	Statistic	Implant	Pre-Discharge	1 Month
Sensed Amplitude (mV)	N	87	88	88
	Mean ± SD	10.7 ± 5.8	10.5 ± 5.3	13.5 ± 6.5
	Range	2.3 - 25.0	2.4 - 25.0	2.1 - 25.0
	Lower Bound	NA	NA	12.2



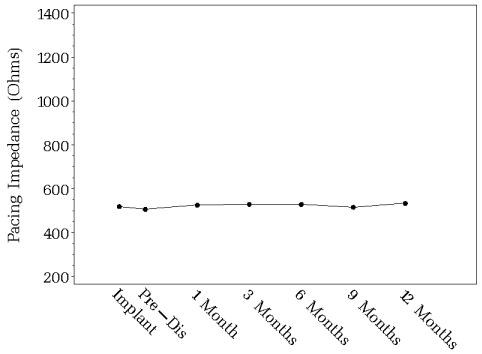
Statistic	Implant	Pre-Discharge	1 Month	3 Months	6 Months	9 Months	12 Months
N	87	87	84	83	71	61	54
Mean ± SD	10.7 ± 5.8	10.5 ± 5.3	13.8 ± 6.6	12.7 ± 6.4	13.2 ± 7.0	13.4 ± 7.0	12.8 ± 6.3
Range	2.3 - 25.0	2.4 - 25.0	2.1 - 25.0	2.3 - 25.0	2.8 - 25.0	1.9 - 25.0	0.5 - 25.0

Figure 2. Mean sensed amplitude with device in the programmed configuration. All patients implanted with an ACUITY Spiral lead; N=97.

It was hypothesized that one-month mean left ventricular R-wave amplitude be greater than 3.0 mV to ensure proper sensing. One-month left ventricular R-wave amplitudes are within this limit.

Table 8. Pacing Impedances using last observation carried forward. All patients implanted with an ACUITY Spiral lead; N=97.

Measurement	Statistic	Implant	Pre-Discharge	1 Month
Pacing Impedance (Ohms)	N	97	97	97
	Mean ± SD	519 ± 163	505 ± 156	523 ± 124
	Range	305 -1357	310 -1357	310 - 899
	Lower Bound	NA	NA	498



Statistic	Implant	Pre-Discharge	1 Month	3 Months	6 Months	9 Months	12 Months
N	97	96	95	90	74	67	61
Mean ± SD	519 ± 163	506 ± 156	525 ± 124	530 ± 142	529 ± 131	516 ± 125	533 ± 124
Range	305 - 1357	310 - 1357	310 - 899	310 - 1118	289 - 932	290 - 899	290 - 840

Figure 3. Mean pacing impedance with device in the programmed configuration. All patients implanted with an ACUITY Spiral lead; N=97.

It was hypothesized that one-month left ventricular lead impedance should be greater than 300 ohms for proper system performance. One-month left ventricular impedances are within this limit.

Lead Safety

The safety of the ACUITY Spiral lead was evaluated by the lead-related complication-free rate over the one-month follow-up period in all patients attempted or implanted with an ACUITY Spiral lead. The lower one-sided 95% confidence bound of the ACUITY Spiral lead-related complication-free rate through one-month post-implant was hypothesized to be greater than 80%.

Two patients experienced a lead-related complication within one month post-implant. One of these patients had a lead dislodgment that required a lead revision. The other patient experienced extracardiac stimulation that eventually resulted in discontinuing LV pacing. The lead-related complication-free rate at one-month was 98.2% with a lower 95% confidence bound of 96.1%. The observed one-sided lower bound of 96.1% was within the pre-specified limit, providing reasonable assurance that the ACUITY Spiral lead is safe.

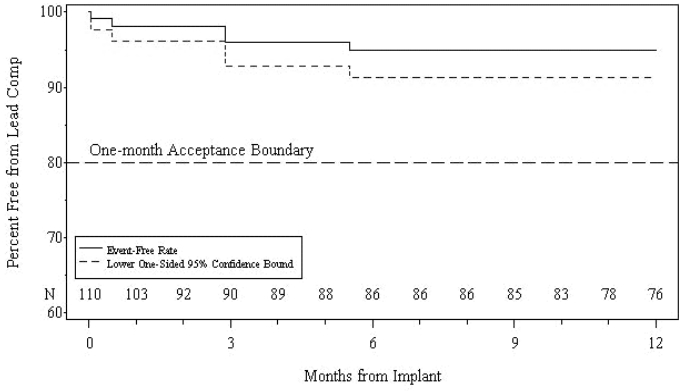
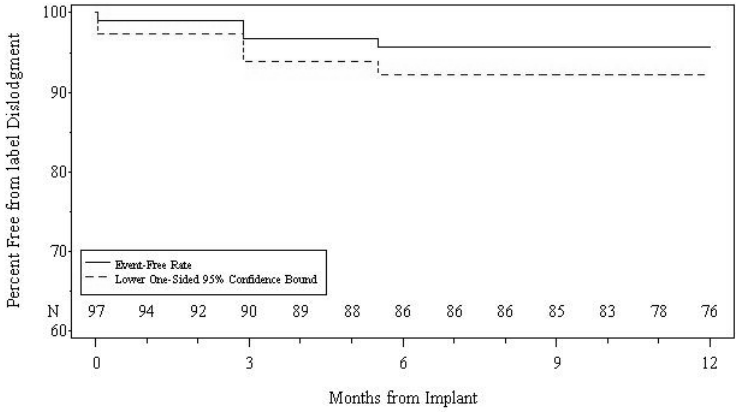


Figure 4. Time to first lead related complication through twelve-months post-implant. All patients were implanted with an ACUITY Spiral lead; N=110.

Figure 4 shows the lead-related complication-free rate through twelve months. The observed lead-related complication-free rate at the three months was 96.0% as two additional lead-related complications were discovered at the three-month follow-up. At the six-month follow-up there was an additional lead-related complication with the observed lead-related complication-free rate at 94.9% and remained steady through twelve months post-implant.

Dislodgment Rate

The dislodgment rate was calculated as the number of unique patients in whom a dislodgment occurred within the one-month follow-up period divided by the number of patients implanted with an ACUITY Spiral Lead. The one-month dislodgment rate of 1.0% (1/97) observed in the EASYTRAK 3 Downsize Lead clinical trial is lower than that observed one-month dislodgment rate in current market-approved Boston Scientific LV leads (EASYTRAK: 4.5%, EASYTRAK 2: 8.2%, EASYTRAK 3: 8.1%, ACUITY Steerable: 5.9%). Time to first dislodgment through 12 months post-implant is provided in Figure 5.



	Start of Interval (Months from Implant)												
Statistic	**0**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**
Number at Risk at Start of Interval	97	94	92	90	89	88	86	86	86	85	83	78	76
Number of Events in Interval	1	0	2	0	0	1	0	0	0	0	0	0	0
Number Censored in Interval	2	2	0	1	1	1	0	0	1	2	5	2	76
% Freedom from Event	100.0	99.0	99.0	96.8	96.8	96.8	95.7	95.7	95.7	95.7	95.7	95.7	95.7

Figure 5. Time to first dislodgment. All patients implanted with an ACUITY Spiral lead; N=97.

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 Spiral lead include the following:

- **Over-The-Wire Lead Design:** The lead design consists of an open-lumen conductor coil that tracks over a 0.014-in (0.36-mm) diameter guide wire.
- **Steroid:** The silicone rubber collar near the electrode contains a nominal dose of 0.45 mg dexamethasone acetate. The excipient is liquid silicone rubber (biomedical grade). Upon exposure to body fluids, the steroid elutes from the lead to help reduce tissue inflammation response at the distal electrode.

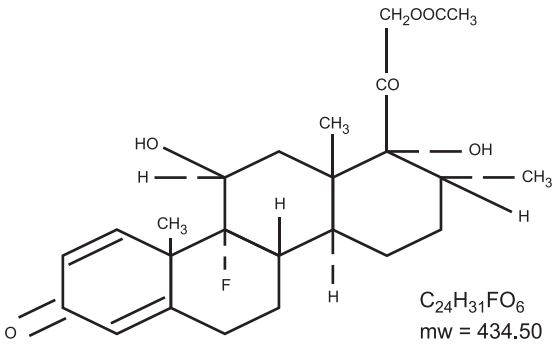


Figure 6. Structure of Dexamethasone Acetate

- **Ring Electrode with IROX Coating:** The IROX coated ring electrode provides a pacing and sensing surface in the coronary venous system.
- **Pace/Sense Configurations:** The ACUITY Spiral lead offers various pace/sense configurations depending upon the programming options of a compatible device. Refer to the pulse generator manual for instructions.
- **Distal Tip:** The distal tip is protected by silicone rubber. This protection allows for atraumatic lead advancement through the coronary venous system.
- **Spiral Fixation:** The distal portion of the lead provides fixation after guide wire removal. The lead is anchored in position by removing the

guide wire and allowing the distal tip to assume a spiral shape that lodges in the coronary venous system.

- **Lead Body:** The diameter of the distal lead body (working profile) is 4.1F (1.37-mm), (0.054-in). The diameter of the proximal lead body is 4.5F (1.5-mm), (0.059-in). The lead body consists of a single conductor coil that provides one pathway. The conductor coil is sheathed in silicone rubber tubing, which is subsequently sheathed in polyurethane tubing.
- **IS-1 Unipolar 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 Spiral lead is not designed, sold, or intended for use except as indicated.

Items Included

Items packaged include the following:

- (1) ACUITY Spiral Lead
- (1) Wire Guide
- (1) Vein Pick
- 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:

- Outer guiding catheter: An 8F removable outer guiding catheter with a minimum inner diameter of 2.21-mm (0.087-in) or greater, 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, 0.81–0.97-mm (0.032–0.038-in) diameter (optional), that is intended for use in the coronary venous vasculature
    - Inner guiding catheter, 6F removable inner guiding catheter (optional) with a minimum inner diameter of 1.73-mm (0.068-in), that is intended for accessing the coronary venous system
    - Deflectable tip mapping catheter, 6F (2-mm) (0.078-in) diameter (optional), that is intended for use in the coronary sinus ostium
- Guide wire, 0.36-mm (0.014-in) 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. See Table 9 for the available finishing wires to be used with ACUITY Spiral.

Table 9. Available Finishing Wires for use with ACUITY Spiral

Finishing Wire	Finishing Wire Model Numbers and Lengths
FINISHING WIRE Universal	6004 (80 cm)
	6005 (90 cm)
	6007 (100 cm)
FINISHING WIRE SUPPORTRAK	6667 (80 cm)
	6668 (90 cm)
	6669 (100 cm)

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

- Standard occlusion balloon, 6F (2-mm) (0.078-in) 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 at the address on the back cover of this manual.

Storage

Store at 25°C (77°F). Excursions permitted between 15 - 30°C (59-86°F) [see USP Controlled Room Temperature]. Transportation spikes permitted up to 50°C (122°F).

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	**4591**	**4592**	**4593**
Length	**80 cm**	**90 cm**	**100 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 in the lead tray 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.

Wire Guide

The wire guide is intended to ease insertion of a guide wire into the lumen at the terminal of the lead (Figure 7).

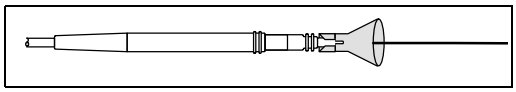


Figure 7. Using the wire guide.

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.

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 dislodgment.

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 dislodgment 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 dislodgment 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]

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] It is recommended to introduce the lead into the subclavian vein near the lateral border of the first rib.

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.
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.

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 8, identify points St (sternal angle) and Cp (coracoid process).

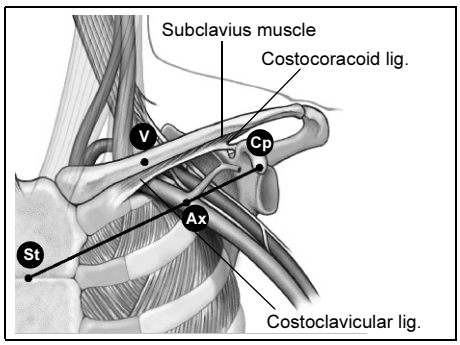


Figure 8. Landmarks identify the entry point for a percutaneous subclavian venipuncture.

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 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 9).

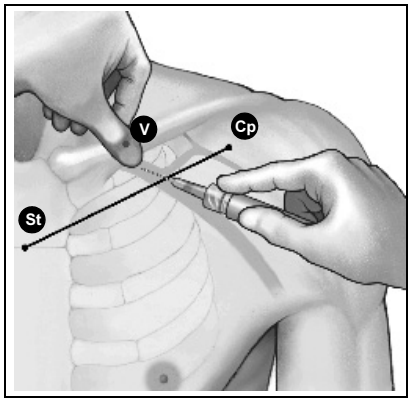


Figure 9. Location of thumb and needle entry.

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 by advancing the lead over a guide wire.

Referring to Figure 10, 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 Spiral lead. Variability in patient anatomy may preclude placement in one or more of the suggested sites.

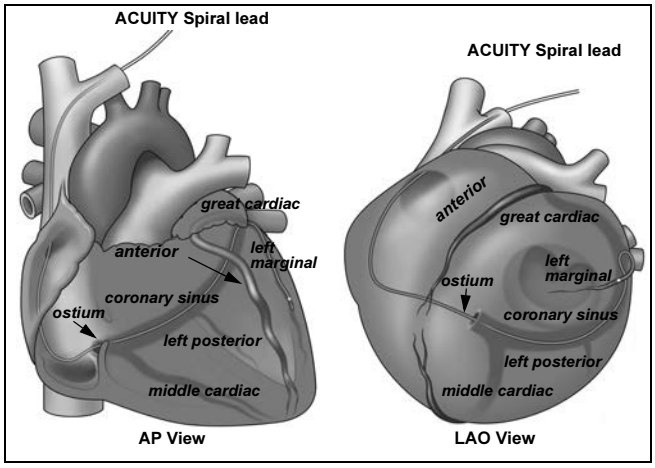


Figure 10. Anterior Posterior (AP) and Lateral Anterior Oblique (LAO) View of the Coronary Venous System.

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 judgment to determine the best lead implant site.*

Inserting the Guiding Catheter

Recommended methods for finding the coronary ostium include but are not limited to the following: **a)** placing a guide wire 0.81–0.97 mm (0.032–0.038-in) diameter in the ostium first and then following the guide wire with the guiding catheter or **b)** inserting a 6F (2 mm) (0.078-in) diameter (or smaller) fixed curve or deflectable tip mapping catheter through the guiding catheter and then into the ostium.

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.

Inserting the Lead Into the Guiding Catheter

The ACUITY Spiral lead can be delivered through the guiding catheter used to cannulate the coronary sinus after the venogram has been obtained. Alternatively, the ACUITY Spiral lead can be delivered through a secondary inner catheter that has been introduced through the cannulation catheter for the purpose of sub-selecting a branch vein.

Note: *The inner catheter must be removable over the lead and must have a minimum inner diameter of 0.068 in (1.73 mm)*.

Placing the Lead

The following section describes two preferred methods for the ACUITY Spiral lead placement over 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 Spiral lead during the placement of other leads.*
- *It is recommended to flush the guide wire's protective hoop and the inner lumen of the guide catheter with heparinized saline* ***before and during*** *guide wire use.*
- *To prevent blood from clotting in the lead, it is recommended to flush the inner lumen of the lead with heparinized saline* ***before and during*** *use.*

- *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 spiral fixation to varying degrees. Guide wires with more distal support will provide the greatest amount of spiral straightening.*
- *Under fluoroscopy confirm that the marker band, proximal to the spiral fixation, remains within the branch vein.*

Method A

1. Insert the 0.36-mm (0.014-in) diameter guide wire 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 helix 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 0.36-mm (0.014-in) diameter guide wire 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 spiral fixation 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 spiral 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.

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 into the pacing lead so the spiral 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 10.

Table 10. Recommended Threshold and Sensing Measurements

Ventricular Data	
Voltage threshold[a]	< 2.5 V
R-wave amplitude	> 5.0 mV
Lead Impedance	300-2000 Ω

a. Pulse width setting 0.5 ms.

See Figure 11 and Figure 12 for pacing system analyzer connections. Threshold measurements can be taken immediately after the lead is positioned and the spiral fixation is engaged.

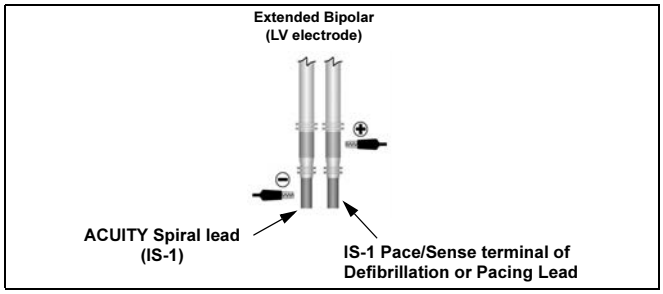


Figure 11. LV Pacing/Sensing Bipolar: Pacing system analyzer connections.

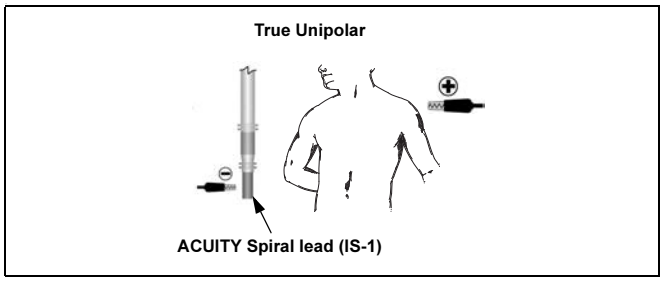


Figure 12. LV Pacing/Sensing Unipolar: Pacing system analyzer connections.

Note: *The guide wire must be withdrawn so the spiral 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.

Notes:

- *Under fluoroscopy confirm that the marker band, proximal to the spiral fixation, remains within the branch vein.*
- *While pulling out the lead, keep the wire in place so that the bias shape is not damaged.*

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 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.

Note: *Catheter removal with the ACUITY Spiral lead has been evaluated using the ACUITY Universal Cutter (Model 7060).*

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

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 13).
2. Using both 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.

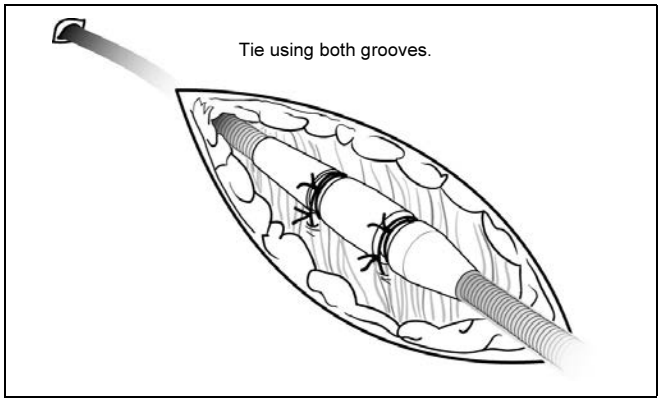


Figure 13. Using the sleeve with the percutaneous implant technique.

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.

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 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 14).

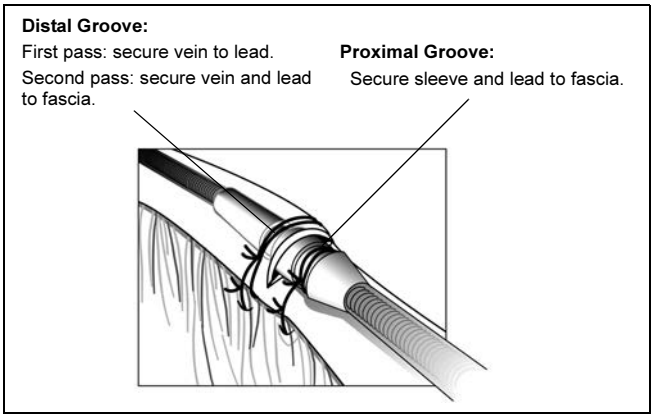


Figure 14. Using the sleeve with the venous cutdown technique.

2. Using the proximal groove, 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.
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 lead 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.

WARNING: Do not kink, twist, or braid the lead terminal with other leads,

as doing so could cause lead insulation abrasion or conductor damage.

CAUTIONS:

- 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.
- Ensure that the lead terminal of ACUITY Spiral is connected to the LV IS-1 port of the pulse generator.

Notes:

- *If a lubricant is needed when connecting the lead to the pulse generator, 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.*

Symbols on Packaging

The following symbols may be used on leads packaging and labeling (Table 11).

Table 11. Symbols on packaging

Symbol	Definition
	Opening instructions
	Do not reuse
	Consult instructions for use
	Sterilized using ethylene oxide
	Use by
	Date of manufacture
	Lot number
	Serial number
	Manufacturer
	Do not resterilize
	Do not use if package is damaged

SPECIFICATIONS (Nominal)

Model and Length	4591 - 80 cm 4592 - 90 cm 4593 - 100 cm
Terminal compatibility	IS-1
Electrode configuration	Unipolar (single)
Compatibility	Pulse generators that accept IS-1 connectors
Insertion Diameter	1.60 mm
Recommended introducer size	Determined by guiding catheter size.
Recommended guiding catheter size	Outer catheter (cannulation catheter): 8F, with an inner diameter of 0.087 in (2.21 mm) or greater
	Inner catheter (branch sub-selection catheter): 6F, with an inner diameter of 0.068 in (1.73 mm) or greater
Steroid	0.45 mg dexamethasone acetate
Conductors:	
Type	Quadfilar
Material	MP35N® with Tantalum Core
Electrode:	
Surface area	5.2 mm^2
Material	Platinum iridium substrate
Coating	IROX (iridium oxide) coating
Lead Body:	
Proximal body diameter	4.5F (1.5 mm)
Distal body (working profile) diameter	4.1F (1.37 mm)
Inside diameter	0.022 in (0.56 mm)
Tip diameter	2.6F (0.86 mm)
Insulation material	Silicone rubber, polyurethane 55D
Protective sleeve material	Polyurethane 55D
Terminal pin and ring material	Titanium
Fixation mechanism	3 dimensional spiral

ACUITY SPIRAL LEAD
SPECIFICATIONS (NOMINAL)

Location of Marker Band	41 mm from the distal tip
Maximum lead conductor resistance (ohms) from terminal pin to distal electrode	4591 - 71 Ω 4592 - 77 Ω 4593 - 82 Ω
CENELEC pacing impedance test result[a]	600 Ω
CENELEC sensing impedance test result[a]	765 Ω

a. The CENELEC pacing and sensing impedance test provides a standardized way to compare the performance of lead designs. Boston Scientific does not believe the test result necessarily reflects clinical performance. See Table 10 on page 32 for the recommended pacing impedance range at implant.

ACUITY SPIRAL LEAD
SPECIFICATIONS (NOMINAL)

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