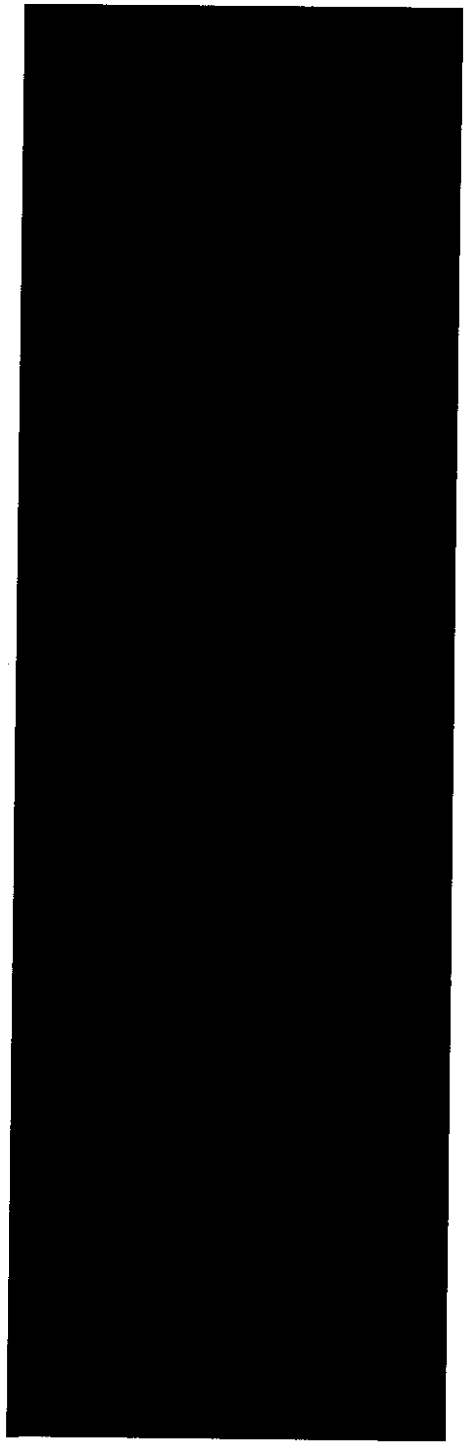


ACUITY™ Steerable

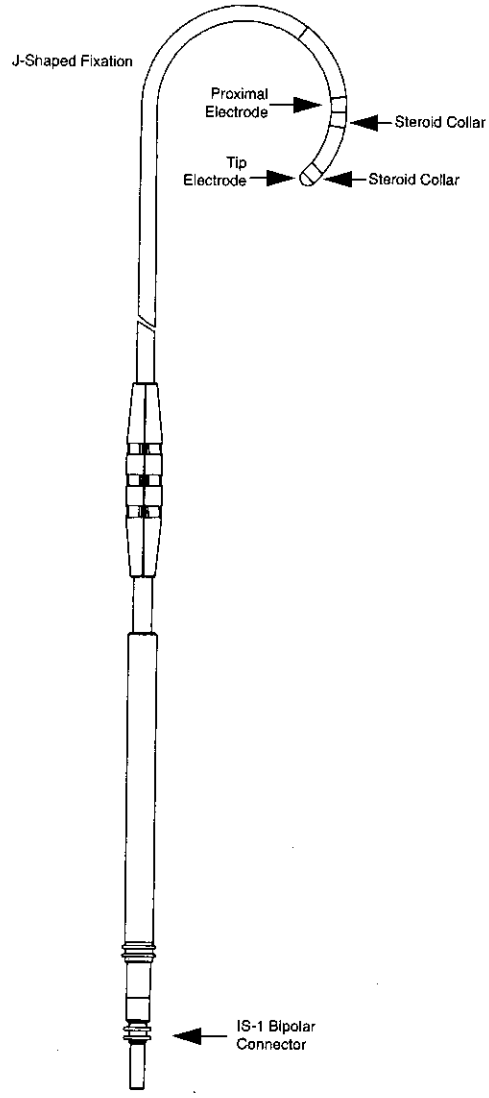
Stylet/Over-the-Wire
Steroid-Eluting
Coronary Venous
Bipolar
Pace/Sense Lead

MODELS: 4554/4555/4556

RESTRICTED DEVICE: Federal law (USA) restricts the sale, distribution, or use of this device to, by, or on the lawful order of a physician.

GUIDANT

ACUITY Steerable Lead
Models 4554/4555/4556



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DEVICE DESCRIPTION

Guidant ACUITY™ Steerable coronary venous pace/sense leads, Models 4554/4555/4556, 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 Guidant 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 24
- 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 28
- 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 25

- 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 27 and Page 36
- **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.

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

- **For single use only-do not resterilize leads.** Do not resterilize the lead or the accessories packaged with it because Guidant cannot ensure that resterilization is effective. Do not reuse.
- **If package is damaged.** Guidant sterilizes the lead and accessories 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 Guidant. Page 25
- **Use before date.** Implant the lead before the USE BEFORE 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 1.

- **Lead compatibility.** Prior to implantation of this lead, confirm lead/pulse generator compatibility by calling Guidant 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 26
- **Remove finishing wire.** The finishing wire MUST BE REMOVED before connecting the lead to the pulse generator. 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 27
- **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 28
- **Chronic repositioning.** Optimum threshold performance might not be achieved if the lead is chronically repositioned because the steroid can be depleted. Page 28
- **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 29
- **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 29

- **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 33
- **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 33
- **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 33
- **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 36
- **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 36
- **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 37
- **Recommended Stylets.** Guidant recommends using a stylet designed for use with the ACUITY Steerable lead (See Table 12 on page 28). 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 37

- **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 38
- **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 39
- **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 39
- **Applying tools to the distal end of the lead.** Applying tools to the distal end of the lead may result in lead damage. Page 39
- **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 46
- **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 46
- **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 47
- **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 48

- **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 49
- **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 49
- **Explanted leads.** Return all explanted leads to Guidant. Page 50
- **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)**

ACUITY STEERABLE LEAD
ADVERSE EVENTS

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]

RA Lead Related Events (N=106)					
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)**	**6.2 (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)

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]

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)
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 53).

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
- 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.

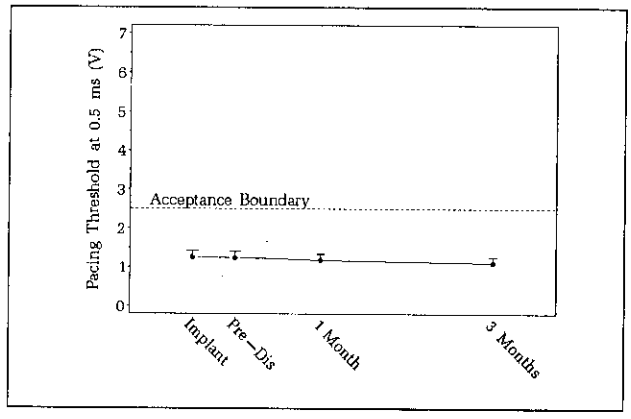

Figure 1. ACUITY Steerable lead pacing thresholds with device in the programmed configuration. All patients implanted; N=101 (Mean, 95% confidence bound).

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.

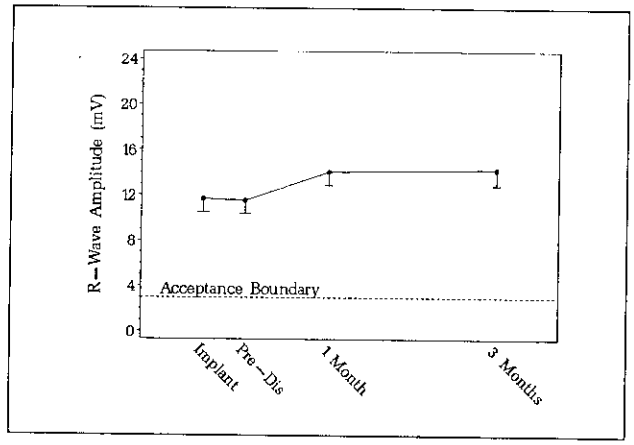

Figure 2. ACUITY Steerable lead sensed amplitudes with device in the programmed configuration. All patients implanted; N=101 (Mean, 95% confidence bound)

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.

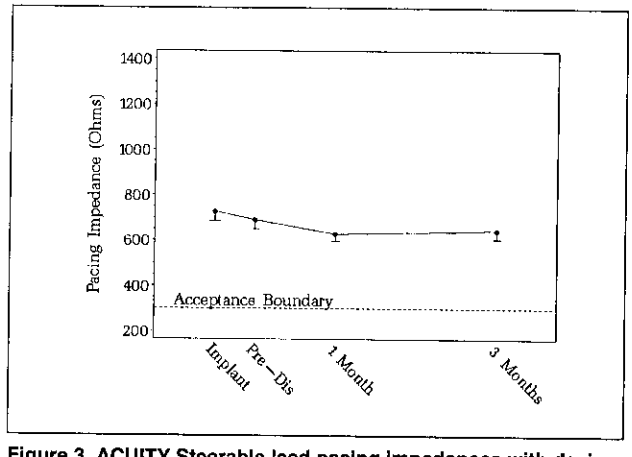

Figure 3. ACUITY Steerable lead pacing impedances with device in programmed configuration. All patients implanted; N=101 (Mean, 95% confidence bound)

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 Guidant Corporation 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: