

Physician's Manual

EASYTRAK® 3 IS-1

**Coronary Venous
Steroid-Eluting
Bipolar Electrode
Spiral Fixation
Pace/Sense Lead**

MODELS: 4548/4549/4550

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

EASYTRAK® 3 IS-1 Lead
Models 4548/4549/4550

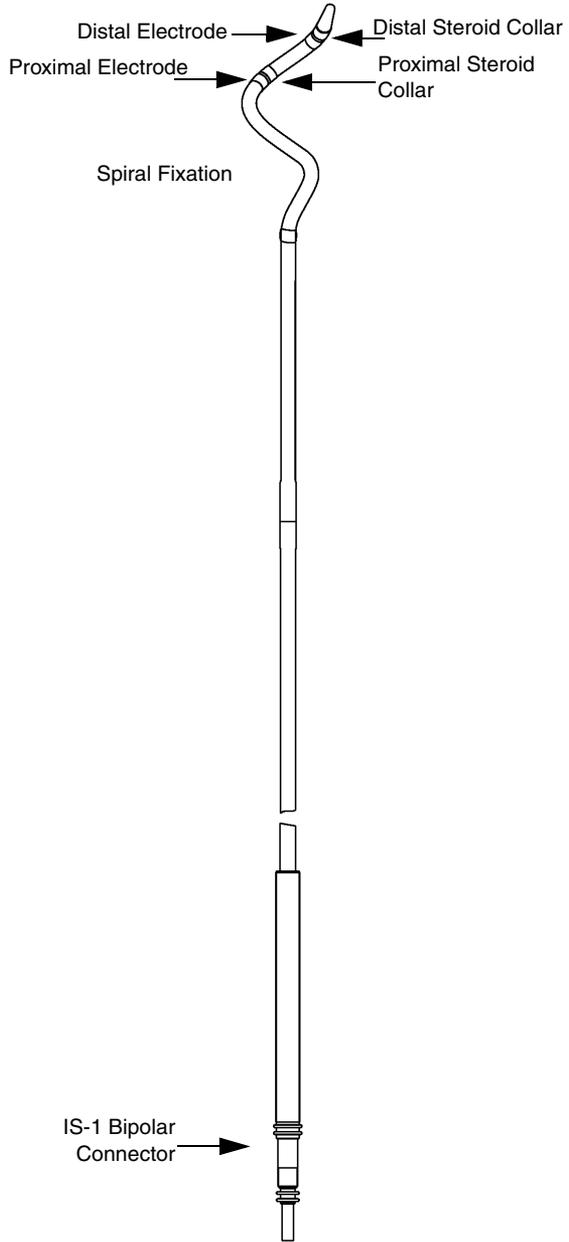


TABLE OF CONTENTS

DEVICE DESCRIPTION	1
Indications.....	1
Contraindications	1
Warnings.....	1
Precautions.....	2
Sterilization and Handling.....	3
Lead Evaluation and Implant Precautions	3
ADVERSE EVENTS	7
Observed Adverse Events	7
Potential Adverse Events.....	9
CLINICAL TRIAL	11
Study Design	11
Inclusion/Exclusion Criteria	11
Optimal Pharmacologic Therapy for Heart Failure	12
Follow-Up Schedule	13
Lead Endpoints	13
Lead Effectiveness:.....	13
Lead Safety:.....	13
Clinical Investigation	13
Lead Effectiveness	15
Lead Safety	18
Warranty	19
DEVICE FEATURES	19
Detailed Device Description.....	19
LEAD EVALUATION	20
Implant Information	20
Items Included	20
Additional Implant Tools	21
Opening Instructions.....	22
Sterilization	22
Storage	22
Surgical Preparation	22
Lead Accessories	23
Vein Pick	23
Wire Guide	23
Suture Sleeve (Attachable)	23
Handling the Lead.....	24

IMPLANTATION	24
Inserting the Lead	24
Positioning the Lead	27
Inserting the Guiding Catheter	28
Obtaining a Venogram	29
Placing the Lead.....	29
Method A.....	30
Method B.....	30
EVALUATING LEAD PERFORMANCE	32
Evaluating Lead Position	32
Repositioning the Lead.....	33
Removing the Guiding Catheter	33
Securing the Lead.....	34
Percutaneous Implant Technique	34
Venous Cut-Down Technique	35
Connection to a Pulse Generator	37
Returning Explanted Products	38
SPECIFICATIONS (NOMINAL)	39

DEVICE DESCRIPTION

Guidant EASYTRAK® 3 IS-1 coronary venous pace/sense leads, Models 4548/4549/4550, provide chronic bipolar pacing and bipolar sensing. The leads have an over-the-wire design with an IS-1¹ bipolar connector and are steroid-eluting distal to each electrode. The lead is anchored with spiral 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. The EASYTRAK 3 IS-1 lead is used in conjunction with a compatible Guidant cardiac resynchronization therapy (CRT) device.

Indications

The Guidant EASYTRAK 3 IS-1 coronary venous, steroid-eluting, dual-electrode pace/sense leads, Models 4548/4549/4550, are transvenous leads intended for chronic, left-ventricular pacing and sensing via the coronary veins when used in conjunction with a compatible Guidant cardiac resynchronization therapy (CRT) device that accepts the IS-1 connector.

Contraindications

Use of the EASYTRAK 3 IS-1 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.

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

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

EASYTRAK 3 IS-1 LEAD DEVICE DESCRIPTION

damage can result in injury to or death of the patient. (Page 21).

- When using a right ventricular (RV) pace/sense lead in conjunction with the EASYTRAK 3 IS-1 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.
- **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 24).
- 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 21).

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 and ready for use. If the container is wet, damaged, punctured, or if the seal is broken, return the lead to the nearest Guidant representative. Never attempt to resterilize the lead or accessories. Instead, return the lead to Guidant at the address on the back cover of this manual (Page 22).
- **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 Precautions

- **Vein pick.** The vein pick is not intended either for puncturing the vein or for dissecting tissue during a cutdown procedure. Page 23
- **Remove finishing wire.** The finishing wire MUST BE REMOVED before connecting the lead to the pulse generator. Page 21

*EASYTRAK 3 IS-1 LEAD
DEVICE DESCRIPTION*

- **Lead stabilizer.** 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 23
- **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 24
- **Chronic repositioning.** Optimum threshold performance might not be achieved if the lead is chronically repositioned because the steroid can be depleted. Page 24
- **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 24
- **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 25
- **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 29

- **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 29
- **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 31
- **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 previously discussed. Page 31
- **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 31
- **Applying tools to the distal end of the lead.** Applying tools to the distal end of the lead may result in lead damage. Page 31
- **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 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

*EASYTRAK 3 IS-1 LEAD
DEVICE DESCRIPTION*

- **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 37
- **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 37
- **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
- **Explanted leads.** Return all explanted leads to Guidant. Page 38
- **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.
- **Implant time.** The EASYTRAK 3 lead study data indicate that 71/74 (96%) of implants are completed within 4 hours; 73/74 (99%) are completed within 5 hours. Implants that extend beyond 5 hours are unlikely to have successful completion; the physician should consider terminating the procedure. The implant procedure may be reattempted at a later date, if feasible.

ADVERSE EVENTS

The safety of the EASYTRAK 3 lead was evaluated in 101 patients who underwent an attempted EASYTRAK 3 implant in the EASYTRAK 3 lead clinical study. All patients with an EASYTRAK 3 lead patients were followed for six-months.

Observed Adverse Events

Table 1 provides information on all lead-related and procedure-related adverse events reported from implant through the six-month follow-up visit in patients attempted or implanted with the EASYTRAK 3 lead. Those adverse events attributed to commercially available guide wires, guide catheters and diagnostic electrophysiology catheters were excluded from the EASYTRAK 3 lead-related adverse events, and were categorized as procedure-related adverse events. EASYTRAK 3 lead-related adverse events were defined as all lead-related or procedure-related adverse events attributed to the EASYTRAK 3 lead by the investigator, or when the EASYTRAK 3 lead could not be ruled out as the cause of the adverse event.

During the six-month follow-up period, a total of 47 events were reported in 37 patients. Of these events, 14 were classified as complications, and 33 were classified as observations.

**EASYTRAK 3 IS-1 LEAD
ADVERSE EVENTS**

Table 1. EASYTRAK 3 IS-1 Lead-related and Procedure-related Adverse Events Through Six Months.

All patients implanted or attempted; N=115

Adverse Event	Number of Events (# of pts) ^a	Complications		Observations	
		% 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	47 (37)	11.3 (13)	2.3 (14)	24.3 (28)	5.5 (33)
EASYTRAK 3 Lead Related Events (N = 101, Months = 567)					
Coronary Venous Spasm	1 (1)	1.0 (1)	0.2 (1)	0.0 (0)	0.0 (0)
Dislodgement	9 (8)	5.9 (6)	1.1 (6)	3.0 (3)	0.5 (3)
Elevated threshold - LV	3 (3)	0.0 (0)	0.0 (0)	3.0 (3)	0.5 (3)
Extracardiac stimulation-LV ^b	10 (10)	0.0 (0)	0.0 (0)	9.9 (10)	1.8 (10)
Oversensing - LV	1 (1)	0.0 (0)	0.0 (0)	1.0 (1)	0.2 (1)
Subtotal EASYTRAK 3 Lead Related Events	24 (20)	6.1 (7)	1.2 (7)	13.0 (15)	2.8 (17)
Procedure-Related Events (N = 115, Months = 600)					
Pneumothorax	3 (2)	0.9 (1)	0.2 (1)	1.7 (2)	0.3 (2)
Post-surgical hematoma (<=30 days post implant)	6 (6)	0.9 (1)	0.2 (1)	4.3 (5)	0.8 (5)
Other ^c	14 (12)	4.3 (5)	0.8 (5)	7.8 (9)	1.5 (9)
Subtotal Procedure Related Events	23 (19)	6.1 (7)	1.2 (7)	13.0 (15)	2.7 (16)

- The total number of patients for a given event represents the unique number of patients who experienced that event. The total may not be equal to the sum of patients with complications or observations because some patients experienced more than one event that fell into both categories.
- An additional two (2) patients were noted to have extracardiac stimulation due to the LV daily measurements feature in the pulse generator. This was remedied by reprogramming the pulse generator.
- Other procedure-related events occurred in two patients or fewer: CV perforation without tamponade (1), coronary venous occlusion (1), coronary venous dissection (2), deep vein thrombosis (1), inadvertent VT/VF (1), post-surgical infection (<=30 days post implant) (2), post-surgical wound discomfort (1), renal failure-contrast media (1), Rx reaction (2), thrombus (1), venous occlusion (1).

EASYTRAK 3 IS-1 LEAD ADVERSE EVENTS

A total of eight 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.

All patients implanted or attempted with an EASYTRAK 3 lead; N=115

Operative Relationship	Total Deaths	Cause of Death		
		Cardiac: Pump Failure	Cardiac: Other	Non-Cardiac
Peri-operative (<= 30 days)	3	1	2	0
Post-operative (> 30 days)	5	3	0	2
Total	8	4	2	2

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
- Death
- Elevated thresholds
- Erosion/extrusion
- 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

*EASYTRAK 3 IS-1 LEAD
ADVERSE EVENTS*

- 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
- 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 EASYTRAK 3 lead clinical study.

Study Design

This clinical investigation of the EASYTRAK 3 lead was a prospective, multi-center study conducted at 23 centers in the United States and was based on 115 enrolled patients. Of the patients enrolled, 101 underwent an attempted EASYTRAK 3 implant. In all patients the EASYTRAK 3 lead was connected to a CONTAK RENEWAL 3 (Model H173), cardiac resynchronization therapy defibrillator (CRT-D). Evaluation of the safety and effectiveness of the investigational lead was performed at implant, pre-discharge, one month, three months and six months post-implant and every three months thereafter.

Inclusion/Exclusion Criteria

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

- Patients who met the study indications, defined as follows: Moderate to severe heart failure (NYHA Class III/IV) including left ventricular dysfunction (EF \leq 35%) and QRS duration \geq 120 ms remaining symptomatic despite stable, optimal heart failure drug therapy
- Moderate or severe heart failure, defined as NYHA Class III/IV despite optimal pharmacological heart failure therapy, as defined below
- 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

*EASYTRAK 3 IS-1 LEAD
CLINICAL TRIAL*

Note: *Patients may or may not have had spontaneous and/or inducible life threatening ventricular arrhythmias.*

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 mechanical tricuspid heart valve

Optimal Pharmacologic Therapy for Heart Failure

All patients who participated in the study were required to be prescribed to stable optimal pharmacologic therapy for heart failure as defined below:

Beta Blockers: All patients must have been prescribed to beta blockers for at least 90 days prior to enrollment, and on a stable dose (e.g., no greater than a 50% increase or decrease in dosage) for at least 30 days prior to enrollment unless the patient was not indicated, contraindicated, intolerant or had developed a recent ICD indication that necessitated ICD therapy concurrent with the optimization of beta blocker

therapy. The choice of selective or non-selective beta blocker use was left to the investigator's discretion.

Angiotensin Converting Enzyme (ACE) Inhibitors: All patients must have been prescribed to stable ACE inhibitor therapy for at least 30 days [or angiotensin receptor blocker (ARB)] unless the patient was not indicated, contraindicated, intolerant or had developed a recent ICD indication that necessitated ICD therapy concurrent with the optimization of ACE inhibitor therapy.

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, Six-Month and Quarterly:	Lead evaluation.

Lead Endpoints

Lead Effectiveness:

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 six-month follow-up period.

Clinical Investigation

The objective of this investigation was to demonstrate the safety and effectiveness of the EASYTRAK 3 lead.

Large branch vessels present challenges in implanting coronary venous leads for cardiac resynchronization therapy. The EASYTRAK 3 lead is secured with a spiral fixation mechanism designed to provide stability in large branch

**EASYTRAK 3 IS-1 LEAD
CLINICAL TRIAL**

vessels. This lead design is complementary to existing leads (EASYTRAK) that use a tined fixation mechanism and is intended to provide an option for patients with large branch vessels. For this clinical study physicians were encouraged, but not required, to attempt placement of the EASYTRAK 3 lead in all patients regardless of anatomy. Study sample size estimates assumed an implant success rate of 65%. Refer to Table 3 for the EASYTRAK lead family implant success rates.

Table 3. Implant Success Rate

All patients in which the LV lead placement was attempted; N=105

Left Ventricular Lead	Number of Patients Undergoing Procedure	Number of Patients Successfully Implanted	Success Rate
EASYTRAK 3 success rate	105	74	70.5
EASYTRAK family success rate	105	101	96.2

The final implant positions of the EASYTRAK 3 lead were as follows:

Table 4. EASYTRAK 3 Lead Placement

All patients implanted with an EASYTRAK 3 lead; N=74

Position from RAO View	Position from LAO View				Total
	Anterior	Lateral	Posterior	Other ^a	
Base	2 (2.7%)	5 (6.8%)	2 (2.7%)	0 (0%)	9 (12.2%)
Mid	5 (6.8%)	50 (67.6%)	5 (6.8%)	0 (0.0%)	60 (81.1%)
Apical	0 (0.0%)	2 (2.7%)	2 (2.7%)	0 (0.0%)	4 (5.4%)
Other ^a	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.4%)	1 (1.4%)
Total	7 (9.5%)	57 (77.0%)	9 (12.2%)	1 (1.4%)	74 (100.0%)

- a. Other lead position was classified by the physician as posterior-lateral.

The majority of EASYTRAK 3 leads (67.6%) were placed in a mid lateral branch. When using a tined fixation lead, placement options are sometimes limited by the need to find a small branch vein to wedge the lead. Spiral fixation with the EASYTRAK 3 lead provides an additional option to target lead placement to the physician preferred mid lateral location.

The average procedure (skin-to-skin) time was 128 ± 55 minutes with an average fluoroscopy time of 25 ± 15 minutes. The mean implant duration was 7.0 ± 1.4 months (range 0.9 - 9.4 months). Demographic information on all 115 patients who underwent an implant procedure for an EASYTRAK 3 lead is shown in Table 5.

Table 5. Demographic information on all patients (N=115)

Characteristic	Statistic	Result
Age at Implant (years)	Mean \pm SD	67.7 ± 10.7
LVEF (%)	Mean \pm SD	22.1 ± 6.1
Gender [N (%)]	Male	88 (77)
	Female	27 (23)
NYHA Classification [N (%)]	III	108 (94)
	IV	7 (6)
Etiology [N (%)]	Ischemic	81 (70)
	Non-ischemic	34 (30)

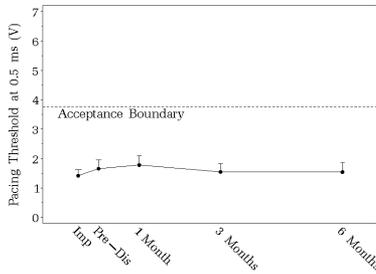
Lead Effectiveness

The effectiveness of the EASYTRAK 3 lead was measured by pacing thresholds, pacing impedances and sensed amplitude evaluated over a six-month period in the configuration selected for permanent programming. The measurements were taken with a CONTAK RENEWAL 3 H173 device. Pacing thresholds were measured at a 0.5 ms pulse width.

Table 6. Pacing Configuration selected for permanent programming.

Visit	N	Ring to Coil	Ring to Tip	Tip to Coil	Tip to Ring
Implant	74	15 (20%)	4 (5%)	47 (64%)	8 (11%)
Pre-Discharge	74	16 (22%)	4 (5%)	49 (66%)	5 (7%)
1 Month Follow-up	70	12 (17%)	6 (9%)	48 (69%)	4 (6%)
3 Month Follow-up	68	12 (18%)	6 (9%)	43 (63%)	7 (10%)
6 Month Follow-up	63	12 (19%)	5 (8%)	39 (62%)	7 (11%)

EASYTRAK 3 IS-1 LEAD CLINICAL TRIAL

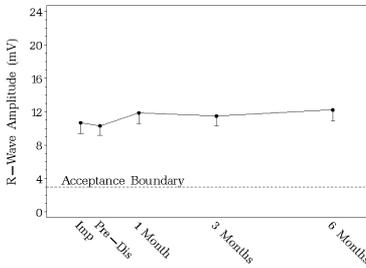


Statistic	Implant	3 Months	6 Months
N	74	66	60
Mean ± SD	1.4 ± 1.1	1.5 ± 1.4	1.5 ± 1.5
Range	0.4 - 6.5	0.4 - 6.5	0.4 - 6.5
Upper Bound	1.6	1.8	1.9

Figure 1. Pacing thresholds in the configuration selected for permanent programming.

It was hypothesized that the upper tolerance limit of the chronic left ventricular pacing threshold of the EASYTRAK 3 lead be less than 3.75 V to ensure that an adequate safety margin exists. Chronic left ventricular pacing thresholds are within this limit.

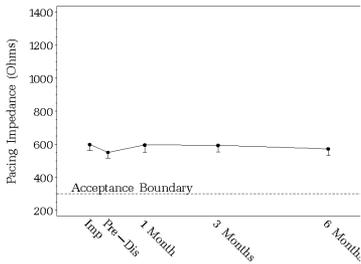
EASYTRAK 3 IS-1 LEAD
CLINICAL TRIAL



Statistic	Implant	3 Months	6 Months
N	73	64	59
Mean ± SD	10.7 ± 6.5	11.5 ± 5.6	12.2 ± 6.2
Range	2.3 - 25.0	3.3 - 25.0	3.0 - 25.0
Lower Bound	9.4	10.3	10.9

Figure 2. Sensed R-wave amplitude in the configuration selected for permanent programming.

It was hypothesized that chronic left ventricular R-wave amplitudes were greater than 3 mV to ensure proper sensing. Chronic left ventricular R-wave amplitudes are within this limit.



Statistic	Implant	3 Months	6 Months
N	74	66	60
Mean ± SD	599 ± 194	594 ± 200	573 ± 187
Range	316 - 1295	310 - 1361	322 - 1295
Lower Bound	562	553	532

Figure 3. Pacing impedance in the configuration selected for permanent programming.

EASYTRAK 3 IS-1 LEAD CLINICAL TRIAL

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

Lead Safety

The safety of the EASYTRAK 3 lead was evaluated by the lead-related complication-free rate over the six-month follow-up period in all patients attempted or implanted with an EASYTRAK 3 lead.

The lead-related complication free-rate at six months was 93.1% with a lower 95% confidence bound of 88.9%. The most common lead-related complication was lead dislodgment occurring in 6 out of 101 patients (5.9%).

Table 7. EASYTRAK 3 Lead Related Complication Free Rate at Six Months.

All patients implanted or attempted with an EASYTRAK 3 lead; N=101

Complication	Number of Events	Number of Patients	Complication Free Rate	Lower One-Sided 95% Confidence Bound
Dislodgment-Unable to capture	4	4	96.0	92.8
Dislodgment-Elevated threshold	1	1	99.0	97.4
Dislodgment-Extracardiac stimulation	1	1	99.0	97.4
Coronary Venous Spasm	1	1	99.0	97.4
Total	7	7	93.1	88.9

The lower one-sided 95% confidence bound of the EASYTRAK 3 lead-related complication-free rate through 6 months post-implant was hypothesized to be greater than 80%. The observed one-sided lower bound of 88.9% was within the pre-specified limit, providing reasonable assurance that the EASYTRAK 3 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 EASYTRAK 3 IS-1 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 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 distal electrode.
- **Ring Electrodes with IROX Coating:** The two IROX coated ring electrodes provide a pacing and sensing surface in the coronary venous system.
- **Pace/Sense Configurations:** The EASYTRAK 3 IS-1 lead offers various pace/sense configurations depending upon the programming options of a compatible Guidant CRT 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.

*EASYTRAK 3 IS-1 LEAD
LEAD EVALUATION*

- **Lead Body:** The diameter of the lead tip is 3.5F (0.045-in), (1.15-mm). The diameter of the proximal lead body is 6.0F (0.078-in), (1.98-mm). The diameter of the distal lead body is 5.7F (0.074-in), (1.88-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 resynchronization therapy (CRT) 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 EASYTRAK 3 IS-1 lead is not designed, sold, or intended for use except as indicated.

Items Included

Items packaged include the following:

- (1) EASYTRAK 3 IS-1 Lead
- (2) Suture Sleeves
- (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 Guidant CRT device physician's manual and instructions for use on any implant accessories or tools.

Additional Implant Tools

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

- Removable guiding catheter, 8F or larger, minimum 0.087-in (2.2-mm) inside diameter, that is intended for accessing the coronary venous system
 - Tools for advancing the guiding catheter to the right atrium and cannulating the coronary sinus:
 - Guide wire, 0.032–0.038-in (0.81–0.97-mm) diameter (optional), that is intended for use in the coronary venous vasculature
 - Guiding catheter, 6F (0.078-in), (2-mm), (optional), that is intended for accessing the coronary venous system
 - Deflectable tip mapping catheter, 6F (0.078-in), (2-mm) (optional), that is intended for use in the coronary sinus ostium
- Guide wire, 0.014-in (0.36-mm) diameter, that is intended for use in the coronary venous system
- Finishing wire, designed to stabilize the positioned lead in the venous system during guiding catheter removal

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

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

- Standard occlusion balloon, 6F (0.078-in), (2-mm), (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: Guidant sterilizes the lead and accessories with ethylene oxide gas (EO) before final packaging. When they are received, they are sterile and ready for use. If the container is wet, damaged, punctured, or if the seal is broken, return the lead to the nearest Guidant representative. Never attempt to resterilize the lead or accessories. Instead, return the lead to Guidant at the address on the back cover of this manual.

Storage

Recommended storage temperature range is 20°C to 25°C. Avoid temperatures above 50°C.

Surgical Preparation

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

Nominal lengths of the leads are as follows:

Model	4548	4549	4550
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 Guidant as accessory items:

Vein Pick

The vein pick is a sterile, disposable, nontoxic, nonpyrogenic, 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 4)

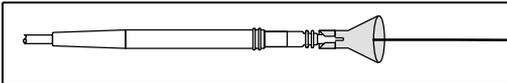


Figure 4. Using the wire guide.

Suture Sleeve (Attachable)

The attachable 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 Guidant 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 Guidant recommends introducing the lead into the subclavian vein near the lateral border of the first rib.

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

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

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.

**EASYTRAK 3 IS-1 LEAD
IMPLANTATION**

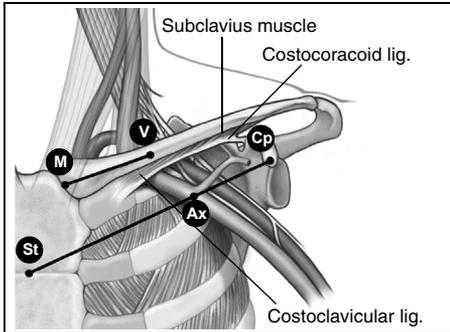


Figure 5. Landmarks identify the entry point for a percutaneous subclavian venipuncture.

2. Visually draw a line between St and Cp, and divide the segment into thirds. The needle should pierce the skin at the junction of the middle and lateral thirds, directly above the axillary vein (point Ax).
3. Place an index finger on the clavicle at the junction of the medial and middle thirds (point V), beneath which point the subclavian vein should be located.
4. Press a thumb against the index finger and project one or two centimeters below the clavicle to shield the subclavius muscle from the needle (when hypertrophy of the pectoralis muscle is apparent, the thumb should project about two centimeters below the clavicle because the subclavius muscle should be hypertrophied as well) (Figure 6).

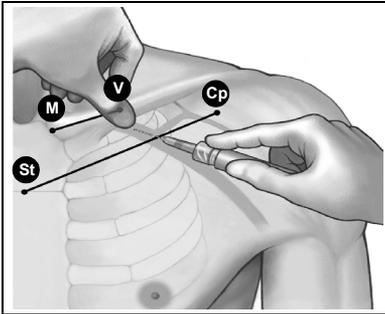


Figure 6. Location of thumb and needle entry.

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

Positioning the Lead

Positioning the lead includes the following steps:

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

Referring to Figure 7, the lead is introduced into the coronary venous system through the ostium of the coronary sinus and advanced into its tributaries. The coronary sinus and its tributaries include the great cardiac vein, middle cardiac vein, left posterior vein, and left marginal vein. All cardiac veins are potential sites for implantation of the EASYTRAK 3 IS-1 lead. Variability in patient anatomy may preclude placement in one or more of the suggested sites.

EASYTRAK 3 IS-1 LEAD IMPLANTATION

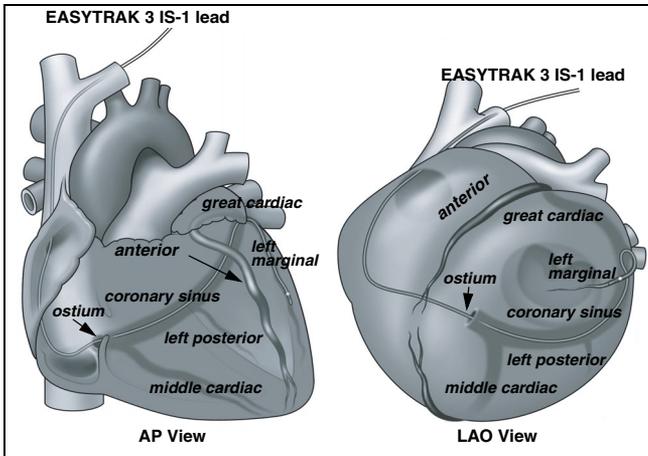


Figure 7. Anterior Posterior (AP) and Lateral Anterior Oblique (LAO) View of the Coronary Venous System.

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

Inserting the Guiding Catheter

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

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

Obtaining a Venogram

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

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

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

CAUTIONS:

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

Placing the Lead

The following section describes two preferred methods for the EASYTRAK 3 IS-1 lead placement 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 EASYTRAK 3 IS-1 lead during the placement of other leads.*

EASYTRAK 3 IS-1 LEAD IMPLANTATION

- *Guidant recommends flushing 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, Guidant recommends flushing 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 floppy tip of the 0.014-in (0.36-mm) 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 0.014-in (0.36-mm) 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. See Figure 8 and Figure 9 for pacing system analyzer connections. Threshold measurements can be taken immediately after the lead is positioned and the spiral fixation is engaged.

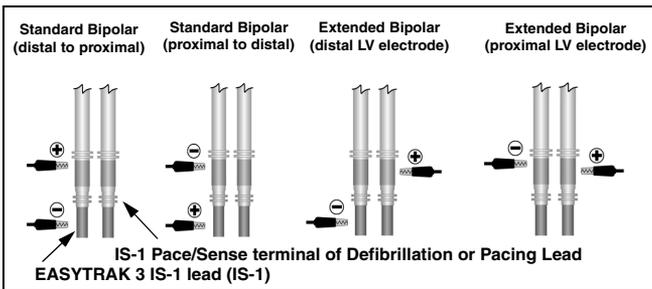


Figure 8. Pacing system analyzer connections to the EASYTRAK 3 IS-1 lead terminal for LV pacing.

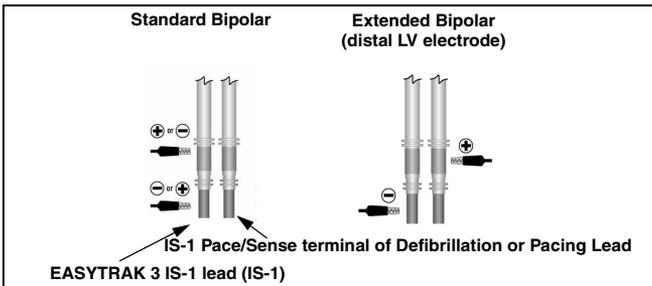


Figure 9. Pacing system analyzer connections to the EASYTRAK 3 IS-1 lead terminal for LV sensing.

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

EASYTRAK 3 IS-1 LEAD EVALUATING LEAD PERFORMANCE

0.5 ms pulse width), R-wave amplitude, and pacing impedance, using recommended values in Table 8.

Table 8. Recommended Threshold and Sensing Measurements

Ventricular Data	
Voltage threshold ^a	≤ 3.0 V
R-wave amplitude	≥ 5.0 mV
Lead Impedance	300-1200 Ω

a. Pulse width setting 0.5 ms.

Note: *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 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.

Note: *Under fluoroscopy confirm that the marker band, proximal to the spiral fixation, remains within the branch vein.*

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

EASYTRAK 3 IS-1 LEAD EVALUATING LEAD PERFORMANCE

instructions for use. Using fluoroscopy, verify that the position of the lead tip does not change during the removal of the guiding catheter. Hold the proximal end of the lead near the venous entry site, disconnect the finishing wire from the terminal pin and withdraw the finishing wire from the lead. Verify under fluoroscopy that the lead has not moved.

Allow extra slack in the lead in the atrium for a strain relief to reduce the chance of 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. An attachable suture sleeve is provided for this purpose.

Percutaneous Implant Technique

1. Place the suture sleeve over the lead body. Slide the suture sleeve deep into the tissue (Figure 10).
2. Using both grooves, ligate the suture sleeve to the lead.
3. Next, secure the sleeve and lead to the fascia.

EASYTRAK 3 IS-1 LEAD EVALUATING LEAD PERFORMANCE

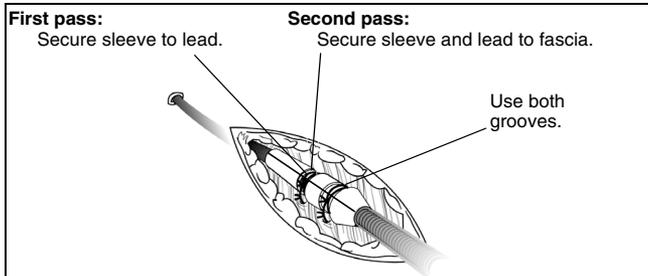


Figure 10. Using the sleeve with the percutaneous implant technique.

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

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

Venous Cut-Down Technique

1. Place the suture sleeve over the lead body. Slide the suture sleeve into the vein past the distal pre-formed 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 11).

**EASYTRAK 3 IS-1 LEAD
EVALUATING LEAD PERFORMANCE**

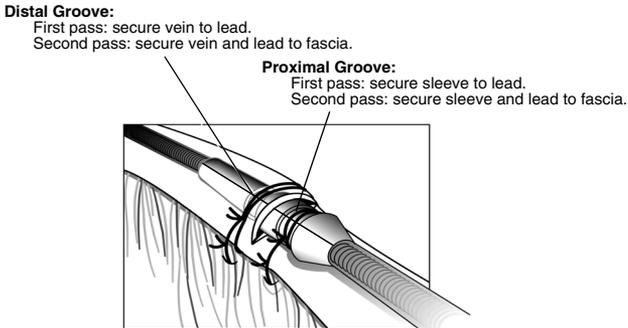


Figure 11. Using the sleeve with the venous cutdown technique.

2. Using the proximal pre-formed groove, secure the sleeve to the lead. Using the same groove, secure the sleeve and lead to the adjacent 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 silicone rubber insulation or sever the vein. Avoid dislodging the lead tip during the stabilizing procedure.

Connection to a Pulse Generator

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

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

CAUTIONS:

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

Notes:

- *Guidant suggests using sterile water if a lubricant is needed when connecting the lead to the pulse generator.*
- *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

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

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

*EASYTRAK 3 IS-1 LEAD
SPECIFICATIONS (NOMINAL)*

SPECIFICATIONS (Nominal)

Model and Length	4548 - 80 cm 4549 - 90 cm 4550 - 100 cm
Terminal compatibility	IS-1
Electrode configuration	Bipolar (Dual)
Compatibility	Pulse generators that accept IS-1 connectors
Insertion Diameter	2.16 mm
Recommended introducer size	Determined by guiding catheter size.
Recommended guiding catheter size	8F (2.6 mm) (inner diameter 2.2 mm)
Steroid	0.5 mg per collar (1.0 mg total) dexamethasone acetate
Conductors:	
Type	Co-Axial design, quadfilar (inner), trifilar (outer)
Material	MP35N with Tantalum core (inner) Platinum clad tantalum with ETFE coating (outer)
Electrode:	
Distal surface area	8.5 mm ²
Proximal surface area	9.0 mm ²
Distance between electrodes	11 mm
Material	Platinum iridium substrate
Coating	IROX (iridium oxide) coating
Lead Body:	
Proximal body diameter	6.0F (1.98 mm)
Distal body diameter	5.7F (1.88 mm)
Inside diameter	0.022 in (0.56 mm)
Tip diameter	3.5F (1.15 mm)
Insulation material	Silicone rubber, ETFE, and polyurethane 55D
Protective sleeve material	Polyurethane 55D
Terminal pin and ring material	Titanium

*EASYTRAK 3 IS-1 LEAD
SPECIFICATIONS (NOMINAL)*

Fixation mechanism	3 dimensional spiral
Maximum lead conductor resistance (ohms) from terminal pin to distal electrode	4548 - 33 Ω 4549 - 38 Ω 4550 - 42 Ω
Maximum lead conductor resistance (ohms) from terminal ring to proximal electrode	4548 - 45 Ω 4549 - 51 Ω 4550 - 57 Ω

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