

## Physician's Manual

### **EASYTRAK® 2 IS-1**

**Coronary Venous**

**Steroid-Eluting**

**Bipolar**

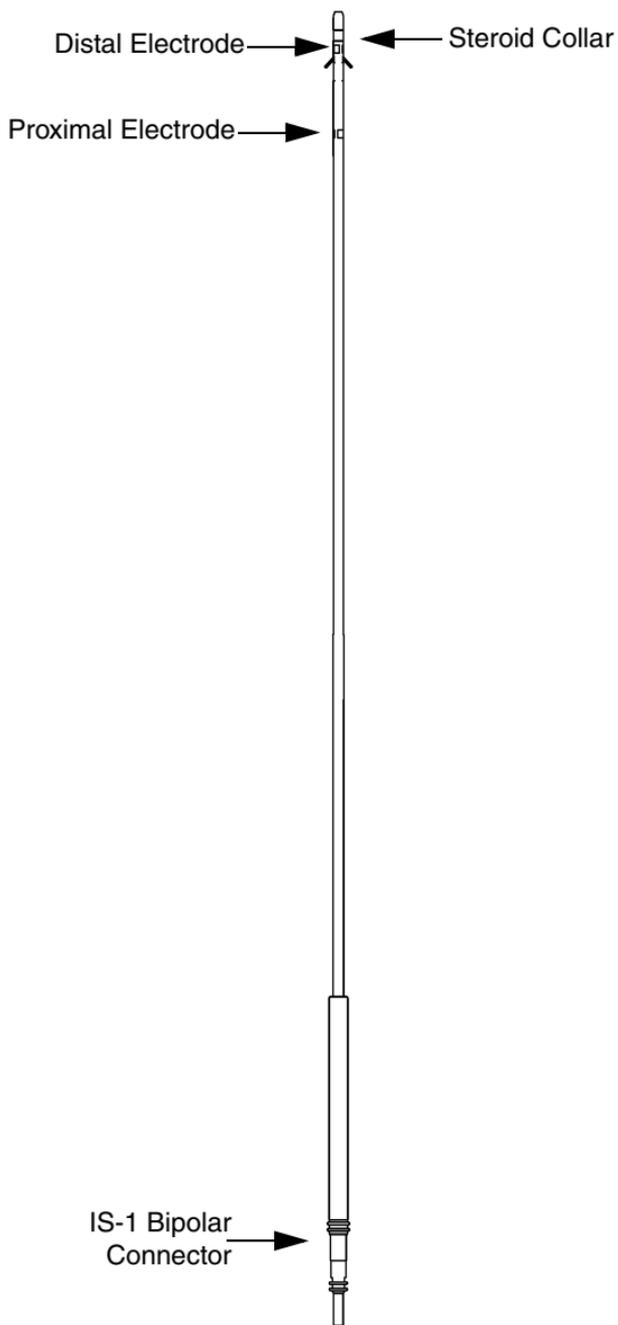
**Pace/Sense Lead**

**MODELS: 4542/4543/4544**

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<sup>®</sup> 2 IS-1 Lead  
Models 4542/4543/4544



## TABLE OF CONTENTS

<b>DEVICE DESCRIPTION</b> .....	1
Indications.....	1
Contraindications .....	1
Warnings.....	1
Precautions.....	2
Sterilization and Handling.....	2
Lead Evaluation and Implantation Precautions .....	3
<b>ADVERSE EVENTS</b> .....	6
Observed Adverse Events .....	6
Potential Adverse Events.....	9
<b>CLINICAL TRIAL</b> .....	10
Study Design .....	10
Inclusion/Exclusion Criteria .....	11
Follow-Up Schedule .....	13
Lead Endpoints .....	13
Clinical Investigation .....	13
Lead Effectiveness .....	14
Lead Safety .....	22
Warranty .....	23
<b>DEVICE FEATURES</b> .....	24
Detailed Device Description.....	24
<b>IMPLANT INFORMATION</b> .....	25
Items Included .....	25
Additional Implant Tools .....	25
Opening Instructions.....	26
Sterilization .....	26
Storage .....	26
Surgical Preparation .....	27
Lead Accessories .....	27
Vein Pick .....	27
Wire Guide .....	28
Suture Sleeve (Attachable) .....	28
Handling the Lead.....	28
<b>IMPLANTATION</b> .....	29
Inserting the Lead .....	29
Positioning the Lead .....	32
Inserting the Guiding Catheter .....	33

Obtaining a Venogram .....	33
Placing the Lead.....	34
<b>EVALUATING LEAD PERFORMANCE.....</b>	<b>35</b>
Evaluating Lead Position .....	35
Removing the Guiding Catheter .....	37
Securing the Lead.....	38
Percutaneous Implant Technique .....	38
Venous Cut-Down Technique .....	38
Connection to a Pulse Generator .....	39
Returning Explanted Products .....	40
<b>SPECIFICATIONS (NOMINAL).....</b>	<b>41</b>

## DEVICE DESCRIPTION

Guidant EASYTRAK® 2 IS-1 coronary venous pace/sense leads, Models 4542/4543/4544, provide chronic bipolar pacing and bipolar sensing. The leads have an over-the-wire design with an IS-1<sup>1</sup> bipolar connector and are steroid-eluting near the distal electrode. The lead 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 2 IS-1 lead is used in conjunction with a compatible Guidant cardiac resynchronization therapy (CRT) device.

## Indications

The Guidant EASYTRAK 2 IS-1 coronary venous, steroid-eluting, dual-electrode pace/sense leads, Models 4542/4543/4544, 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 2 IS-1 lead is contraindicated in patients with a hypersensitivity to a nominal single dose of 0.7 mg of dexamethasone acetate drug.

## Warnings

- **Labeling knowledge.** 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. Page 25
- When using a right ventricular (RV) pace/sense lead in conjunction with the EASYTRAK 2 IS-1 lead, it is recommended that a *polyurethane-insulated* lead be used. Failure to observe this warning could result in insulation

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

## *EASYTRAK® 2 IS-1 LEAD DEVICE DESCRIPTION*

damage of the RV lead, which can cause a 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 28
- 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. Page 26

## **Precautions**

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

### ***Sterilization and Handling***

- **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 26

- **Use before date.** Do not implant the lead after the USE BEFORE date (which appears on the lead packaging) has passed because this date reflects a validated shelf life.
- **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 the 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 Implantation Precautions***

- **Vein pick.** The vein pick is not intended either for puncturing the vein or for dissecting tissue during a cutdown procedure. Page 27
- **Remove finishing wire.** The finishing wire MUST BE REMOVED before connecting the lead to the pulse generator. Page 26
- **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 28
- **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

*EASYTRAK® 2 IS-1 LEAD  
DEVICE DESCRIPTION*

- **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 28
- **Do not insert in 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 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. Page 29
- **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 31
- **Contrast medium.** 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 vein. For further instructions, see literature accompanying the balloon catheter. Page 34

- **Guide wire prolapse.** Use fluoroscopy to verify the guide wire does not prolapse and catch on the distal tip of the lead. If this occurs, slowly extend the wire beyond the distal tip to free the guide wire and then retract it to reestablish movement of the guide wire. Page 35
- **Guide wire retraction.** If the guide wire cannot be retracted, withdraw the lead/guide wire assembly through the guiding catheter. Remove the guide wire through the distal tip of the lead and reintroduce the lead using a new guide wire. Follow the positioning procedures previously discussed. Page 35
- **Flushing a clotted lead.** Flushing a clotted lead can compromise lead integrity. If clotting is suspected, remove the lead from the body and soak the lead in heparinized saline. Insert a guide wire into the distal tip of the lead and advance the wire proximally through the terminal to clear clotting. If unsuccessful, use a new lead. Page 35
- **Applying tools to the distal end of the lead.** Applying tools to the distal end of the lead may result in lead damage. Page 35
- **Kinking 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 37
- **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 37
- **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 39
- **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 40
- **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 40

- **Explanted leads.** Return all explanted leads to Guidant. Page 40
- **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 DECREASE-HF Study data indicate that 223/233 (96%) of implants are completed within 4 hours; 230/233 (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.

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## **ADVERSE EVENTS**

The safety of the EASYTRAK 2 lead was evaluated in 244 patients who underwent an implant procedure in the Device Evaluation of CONTAK RENEWAL 2/4/4HE and EASYTRAK 2: Assessment of Safety and Effectiveness in Heart Failure (DECREASE-HF) Study. Sixty-eight 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 2 lead. Those adverse events attributed to commercially available guide wires, guide catheters and diagnostic electrophysiology catheters were excluded from the EASYTRAK 2 lead-related adverse events,

and were categorized as procedure-related adverse events. EASYTRAK 2 lead-related adverse events were defined as all lead-related or procedure-related adverse events attributed to the EASYTRAK 2 lead by the investigator, or when the EASYTRAK 2 lead could not be ruled out as the cause of the adverse event.

During the six-month follow-up period, a total of 110 events were reported in 86 patients. Of these events, 34 were classified as complications, and 76 were classified as observations.

**Table 1. EASYTRAK 2 Lead-related and Procedure-related Adverse Events Through Six Months.**

All patients implanted or attempted with an EASYTRAK 2 lead; N=244

Adverse Event	# of Events (# of pts) <sup>a</sup>	Complications		Observations	
		% Complications (Patients)	Complications per 100 Device Months (Events)	% Observations (Patients)	Observations per 100 Device Months (Events)
<b>Total Adverse Events</b>	110 (86)	12.7 (31)	3.6 (34)	23.8 (58)	8.0 (76)
<b>EASYTRAK 2 Lead Related Events</b>					
Coronary venous dissection	1 (1)	0.0 (0)	0.0 (0)	0.4 (1)	0.1 (1)
Dislodgement	22 (20)	6.6 (16)	1.9 (18)	1.6 (4)	0.4 (4)
Elevated threshold	4 (4)	0.0 (0)	0.0 (0)	1.6 (4)	0.4 (4)
Extracardiac stimulation	31 (28)	1.6 (4)	0.4 (4)	9.8 (24)	2.8 (27)
Pericardial effusion	1 (1)	0.4 (1)	0.1 (1)	0.0 (0)	0.0 (0)
Unable to capture	1 (1)	0.0 (0)	0.0 (0)	0.4 (1)	0.1 (1)
<b>Subtotal EASYTRAK 2 Lead Related Events</b>	<b>60 (50)</b>	<b>8.6 (21)</b>	<b>2.4 (23)</b>	<b>12.7 (31)</b>	<b>3.9 (37)</b>
<b>Procedure-Related Events</b>					
Adverse reaction - General	5 (5)	0.4 (1)	0.1 (1)	1.6 (4)	0.4 (4)
Coronary venous dissection	4 (4)	0.0 (0)	0.0 (0)	1.6 (4)	0.4 (4)
Physical trauma	3 (3)	0.0 (0)	0.0 (0)	1.2 (3)	0.3 (3)
Pneumothorax	3 (3)	0.8 (2)	0.2 (2)	0.4 (1)	0.1 (1)

**EASYTRAK® 2 IS-1 LEAD  
ADVERSE EVENTS**

**Table 1. EASYTRAK 2 Lead-related and Procedure-related Adverse Events Through Six Months.**

Post-surgical hematoma (<=30 days post implant)	10 (10)	0.8 (2)	0.2 (2)	3.3 (8)	0.8 (8)
Post-surgical infection (<=30 days post implant)	8 (8)	0.8 (2)	0.2 (2)	2.5 (6)	0.6 (6)
Post-surgical wound discomfort	3 (3)	0.0 (0)	0.0 (0)	1.2 (3)	0.3 (3)
Other <sup>b</sup>	14 (14)	1.6 (4)	0.4 (4)	4.1 (10)	1.0 (10)
<b>Subtotal Procedure Related Events</b>	<b>50 (45)</b>	<b>4.5 (11)</b>	<b>1.2 (11)</b>	<b>13.9 (34)</b>	<b>4.1 (39)</b>

- a. 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.
- b. Other procedure-related events occurred in two patients or fewer: Transient AV block (2), Adverse reaction - bradycardia (1), Adverse reaction - respiratory (2), Renal failure - contrast media (1), CV perforation without tamponade (2), myocardial perforation without tamponade (1), post-surgical pocket hemorrhage (1), chest pain (1), hemothorax (1), venous occlusion (1).

A total of twelve 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. Deaths that Occurred During the Study to Date**

All patients implanted or attempted with an EASYTRAK 2 lead; N=244

Cause of Death							
Study Period	# of Pt Deaths	Cardiac: Pump Failure	Cardiac: Ischemic	Cardiac: Unknown	Non-Cardiac	Unknown	Not Yet Classified <sup>a</sup>
Peri-operative (≤ 30 days)	3	1	1			1	
Post-operative (> 30 days)	9	3		1	1		4
Total	12	4	1	1	1	1	4

- a. Deaths not yet classified by the Events Committee were classified by the investigator as one each of cardiac arrhythmic, cardiac ischemic, non-cardiac, and unknown. The details for one recent death have not yet been received.

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

## *EASYTRAK® 2 IS-1 LEAD CLINICAL TRIAL*

- Incomplete lead connection with pulse generator
- Infection
- 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

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## **CLINICAL TRIAL**

The EASYTRAK 2 lead was evaluated in the Device Evaluation of CONTAK RENEWAL 2/4/4HE and EASYTRAK 2: Assessment of Safety and Effectiveness in Heart Failure (DECREASE-HF) Study. The following is a summary of the findings on the EASYTRAK 2 lead.

### ***Study Design***

This clinical investigation of the EASYTRAK 2 lead was a prospective, multi-center study conducted at 43 centers in the United States and was based on 245 enrolled patients. Of the patients enrolled, 244 underwent an implant procedure to receive an EASYTRAK 2 lead. In all patients the EASYTRAK 2 lead was connected to a CONTAK RENEWAL 2 (Model H155), a CONTAK RENEWAL 4 (Model H195), or a CONTAK RENEWAL 4HE (Model H199) cardiac resynchronization therapy with defibrillator (CRT-D). Evaluation of the safety and effectiveness of the investigational lead was performed at implant, pre-discharge, two-weeks post-implant and every three months thereafter.

### ***Inclusion/Exclusion Criteria***

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

- Patients who met the study indications, defined as follows: Patients who had spontaneous and/or inducible life-threatening ventricular arrhythmias and those who were at high risk for developing such arrhythmias. In addition, the study included patients with a prior myocardial infarction and an ejection fraction (EF)  $\leq$  30%  
AND  
Patients who had moderate to severe heart failure (NYHA Class III/IV) including left ventricular dysfunction (EF  $\leq$  35%) and QRS duration  $\geq$  120 ms and remained 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
- A 12-lead electrocardiogram (ECG) obtained no more than 90 days prior to enrollment documenting a sinus rate  $>$  50 bpm, QRS duration  $\geq$  150 ms, PR interval  $\leq$  320 ms measured from any two leads and a P-wave duration  $<$  150 ms measured from lead V<sub>1</sub>
- Creatinine  $\leq$  2.5 mg/dL obtained no more than 14 days prior to enrollment
- Left ventricular ejection fraction  $\leq$  35% [measured by echo, multiple gated acquisition (MUGA) scan, cardiac catheterization, etc.] no more than 14 days prior to enrollment
- Willing and capable of undergoing a device implant and participating in all testing associated with this clinical investigation
- Had a life expectancy of more than 180 days, per physician discretion
- Age 18 or above, or of legal age to give informed consent specific to state and national law

*EASYTRAK® 2 IS-1 LEAD  
CLINICAL TRIAL*

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

- Right bundle branch block morphology (per World Health Organization Guidelines), on a 12-lead ECG obtained no more than 90 days prior to enrollment
- Had previous cardiac resynchronization therapy, a previous coronary venous lead, or met the general indications for antibradycardia pacing
- Had a neuromuscular, orthopedic, or other non-cardiac condition that prevented normal, unsupported walking
- Had an atrial tachyarrhythmia that was permanent (i.e., did not terminate spontaneously and could not be terminated with medical intervention) or persistent (i.e., could be terminated with medical intervention, but did not terminate spontaneously) within 180 days prior to enrollment
- Had a hypersensitivity to a 0.7 mg dose of dexamethasone acetate
- Had surgically uncorrected primary valvular heart disease
- Required dialysis at the time of enrollment
- Had chronic obstructive pulmonary disease (COPD), defined as  $FEV_1/FVC < 60\%$
- Had a myocardial infarct, unstable angina, percutaneous coronary intervention, or coronary artery bypass graft during the 30 days prior to enrollment
- Had hypertrophic obstructive cardiomyopathy or infiltrative cardiomyopathy (e.g., amyloidosis, sarcoidosis)
- Had a mechanical tricuspid prosthesis
- Were enrolled in any concurrent study, without Guidant written approval, that may confound the results of this study

## Follow-Up Schedule

Enrollment	Initial assessment of patient eligibility; taking of patient history; obtaining informed consent.
Implant:	Implantation of investigational devices and acute lead evaluation.
Pre-Discharge:	Lead evaluation.
Two-Week, Three-Month, Six-Month and Quarterly:	Physical assessment and lead evaluation.

## Lead Endpoints

### Lead Effectiveness:

Primary Effectiveness: Left ventricular pacing thresholds, pacing impedances, and R-wave amplitudes as measured in the Tip to Ring configuration.

Secondary Effectiveness: Left ventricular pacing thresholds, pacing impedances and R-wave amplitudes as measured in the Tip to Coil, Ring to Coil, and Ring to Tip.

### Lead Safety:

Lead-related complication-free rate over the six-month follow-up period.

## Clinical Investigation

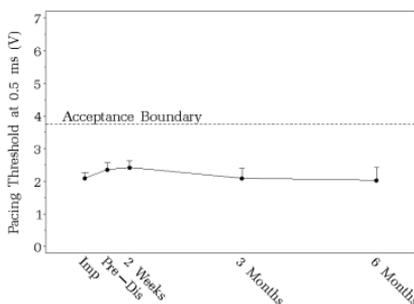
The objective of this investigation was to demonstrate the safety and effectiveness of the EASYTRAK 2 lead. The EASYTRAK 2 lead was successfully implanted in 233/244 (95.5%) patients in whom an EASYTRAK 2 lead was attempted. The average procedure (skin-to-skin) time was 124 ± 57 minutes with an average fluoroscopy time of 26 ± 23 minutes. The mean implant duration was 4.7 ± 2.9 months (range 0.1 - 11.2 months). Demographic information on all 244 patients who underwent an implant procedure for an EASYTRAK 2 lead is shown in Table 3.

**Table 3. Demographic information on all patients (N=244)**

Characteristic	Statistic	Result
Gender	Male (%)	159 (65)
	Female (%)	85 (35)
Age at Implant (years)	Mean ± SD	67 ± 10
Mean LVEF (%)	Mean ± SD	23 ± 7
Etiology of Cardiomyopathy	Ischemic(%)	151 (62)
	Non-ischemic (%)	93 (38)
NYHA Classification	III (%)	235 (96)
	IV (%)	9 (4)

### **Lead Effectiveness**

The effectiveness of the EASYTRAK 2 lead was measured by pacing thresholds, pacing impedances and sensed amplitude evaluated over a six-month period. The measurements were taken in four pacing and two sensing configurations with a CONTAK RENEWAL 2/4/4HE device. Pacing thresholds were measured at a 0.5 ms pulse width.

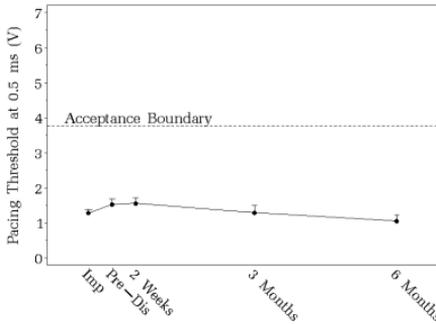


Statistic	Implant	3 Months	6 Months
N	226	102	58
Mean ± SD	2.1 ± 1.5	2.1 ± 1.9	2.0 ± 1.8
Range	0.4 – 7.5	0.2 – 7.5	0.6 – 7.5
Upper Bound	2.3	2.4	2.4

**Figure 1. Pacing thresholds in the Tip to Ring configuration.**

It was hypothesized that the upper tolerance limit of the chronic left ventricular pacing threshold of the EASYTRAK 2

lead be less than 3.75 V to ensure that an adequate safety margin exists. Chronic left ventricular pacing thresholds are within this limit.

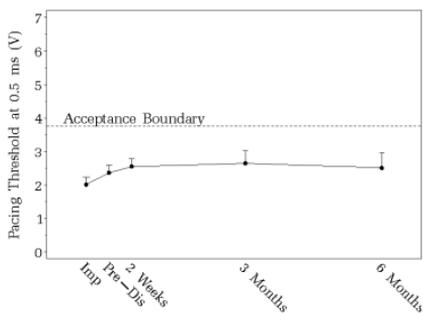


Statistic	Implant	3 Months	6 Months
N	225	101	58
Mean ± SD	1.3 ± 1.0	1.3 ± 1.3	1.1 ± 0.8
Range	0.2 – 7.5	0.2 – 7.5	0.4 – 5.0
Upper Bound	1.4	1.5	1.2

**Figure 2. Pacing thresholds in the Tip to Coil configuration.**

It was hypothesized that the upper tolerance limit of the chronic left ventricular pacing threshold of the EASYTRAK 2 lead be less than 3.75 V to ensure that an adequate safety margin exists. Chronic left ventricular pacing thresholds are within this limit.

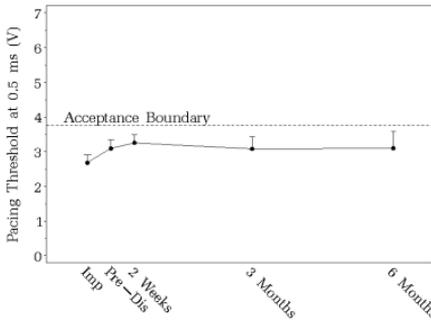
## EASYTRAK® 2 IS-1 LEAD CLINICAL TRIAL



Statistic	Implant	3 Months	6 Months
N	224	102	58
Mean ± SD	2.0 ± 2.0	2.7 ± 2.2	2.5 ± 2.0
Range	0.2 – 7.5	0.2 – 7.5	0.6 – 7.5
Upper Bound	2.2	3.0	3.0

**Figure 3. Pacing thresholds in the Ring to Coil configuration.**

It was hypothesized that the upper tolerance limit of the chronic left ventricular pacing threshold of the EASYTRAK 2 lead be less than 3.75 V to ensure that an adequate safety margin exists. Chronic left ventricular pacing thresholds are within this limit.

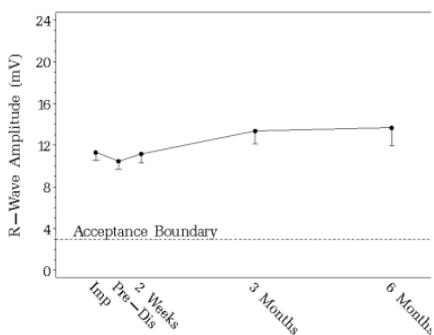


Statistic	Implant	3 Months	6 Months
N	224	102	58
Mean ± SD	2.7 ± 2.1	3.1 ± 2.1	3.1 ± 2.2
Range	0.4 – 7.5	0.2 – 7.5	0.6 – 7.5
Upper Bound	2.9	3.4	3.6

**Figure 4. Pacing thresholds in the Ring to Tip configuration.**

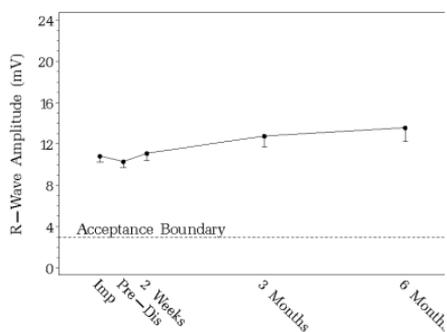
It was hypothesized that the upper tolerance limit of the chronic left ventricular pacing threshold of the EASYTRAK 2 lead be less than 3.75 V to ensure that an adequate safety margin exists. Chronic left ventricular pacing thresholds are within this limit.

## EASYTRAK® 2 IS-1 LEAD CLINICAL TRIAL



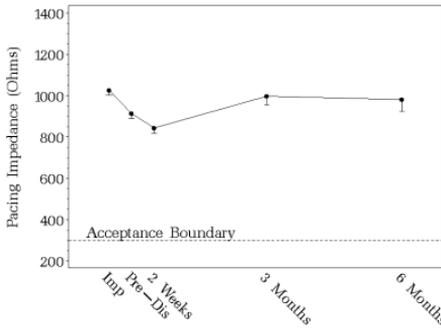
**Figure 5. Sensed R-wave amplitudes in the Tip to Ring configuration.**

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



**Figure 6. Sensed R-wave amplitude in the Tip to Coil configuration.**

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

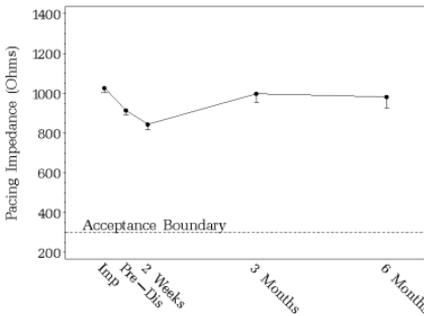


Statistic	Implant	3 Months	6 Months
N	225	101	58
Mean ± SD	1026 ± 222	998 ± 258	982 ± 253
Range	547 – 2000	549 – 2000	549 – 2000
Lower Bound	1002	955	926

**Figure 7. Pacing impedance in the Tip to Ring configuration.**

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.

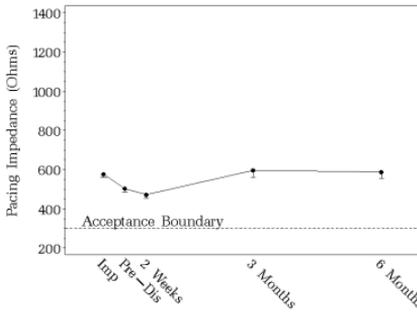
**EASYTRAK® 2 IS-1 LEAD  
CLINICAL TRIAL**



Statistic	Implant	3 Months	6 Months
N	225	101	58
Mean ± SD	578 ± 145	535 ± 136	511 ± 113
Range	336 – 1426	320 – 1081	305 – 881
Lower Bound	562	512	486

**Figure 8. Pacing Impedance in the Tip to Coil configuration.**

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.

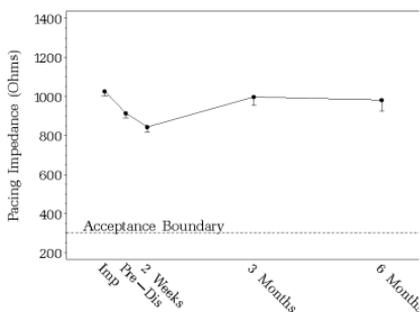


Statistic	Implant	3 Months	6 Months
N	224	102	58
Mean ± SD	577 ± 148	597 ± 206	588 ± 142
Range	320 – 2000	293 – 2000	293 – 941
Lower Bound	560	563	556

**Figure 9. Pacing Impedance in the Ring to Coil configuration.**

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.

## EASYTRAK® 2 IS-1 LEAD CLINICAL TRIAL



Statistic	Implant	3 Months	6 Months
N	224	102	58
Mean ± SD	1042 ± 223	992 ± 274	974 ± 256
Range	547 – 2000	400 – 2000	549 – 2000
Lower Bound	1018	947	918

**Figure 10. Pacing impedance in the Ring to Tip configuration.**

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 2 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 2 lead.

The lead-related complication free-rate at six months was 91.4% with a lower 95% confidence bound of 88.4%. The most common lead-related complication was lead dislodgment occurring in 16 out of 244 patients (6.6%).

**Table 4. EASYTRAK 2 Lead Related Complication Free Rate at Six Months.**

All patients implanted or attempted with an EASYTRAK 2 lead; N=244

Complication	Number of Events	Number of Patients	Complication Free Rate	Lower One-Sided 95% Confidence Bound
Dislodgment-Unable to capture	10	8	96.7	94.8
Dislodgment-Elevated threshold	6	6	97.5	95.9
Dislodgment-Extracardiac stimulation	2	2	99.2	98.2
Extracardiac stimulation	4	4	98.4	97.0
Pericardial effusion	1	1	99.6	98.9
<b>Total</b>	<b>23</b>	<b>21</b>	<b>91.4</b>	<b>88.4</b>

Of the 21 patients with an EASYTRAK 2 lead-related complication:

- 18 were successfully corrected with one surgical intervention,
- One patient cancelled the procedure and no further intervention has taken place, and
- Two patients had two lead dislodgments and required a second surgical intervention to replace or reposition the lead.

The lower one-sided 95% confidence bound of the EASYTRAK 2 lead-related complication-free rate through 6 months post-implant was hypothesized to be greater than 80%. The observed one-sided lower bound of 88.4% was within the pre-specified limit, providing reasonable assurance that the EASYTRAK 2 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 2 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 collar between the lead tip and distal electrode contains a nominal dose of 0.7 mg dexamethasone acetate. Upon exposure to body fluids, the steroid elutes from the lead to help reduce tissue inflammation response at the distal electrode.
- **Slotted-Ring Electrodes with IROX Coating:** The two slotted-ring electrodes provide a pacing and sensing surface in the coronary venous system. The IROX coating creates a larger surface area for sensing while maintaining a smaller electrode diameter for pacing, which reduces polarization potentials.
- **Pace/Sense Configurations:** The EASYTRAK 2 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 molded silicone rubber. This protection allows for lead advancement through the coronary venous system.
- **Tined Fixation:** Two silicone tines provide passive fixation of the lead after surgical placement.
- **Lead Body:** The distal portion of the lead body is 5.4F in diameter and consists of a coradial (corrosion-resistant, multifilar) coil that provides two conductive pathways. The conductor filars are individually sheathed in Ethylene Tetrafluoroethylene (ETFE) insulation and the conductor coil is sheathed in silicone insulation. In addition, the silicone rubber is covered with a polyurethane protective sleeve.

- **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.

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## 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 2 IS-1 lead is not designed, sold, or intended for use except as indicated.

### Items Included

Items packaged include the following:

- (1) EASYTRAK 2 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
  - Guide wire, 0.032–0.038-in (0.81–0.97-mm) diameter (optional), that is intended for use in the coronary venous vasculature

## *EASYTRAK® 2 IS-1 LEAD IMPLANT INFORMATION*

- Deflectable tip mapping catheter, 6F (optional), that is intended for use in the coronary sinus ostium
- Guide wire, 0.014-in (0.36-mm) diameter, and torque device 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 (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:

<b>Model</b>	4542	4543	4544
<b>Length</b>	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 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 open lumen at the terminal of the lead (Figure 11).

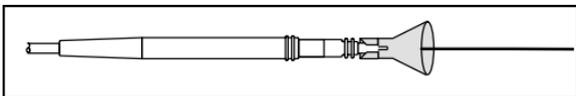


Figure 11. Using the wire guide.

## 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.<sup>2</sup>

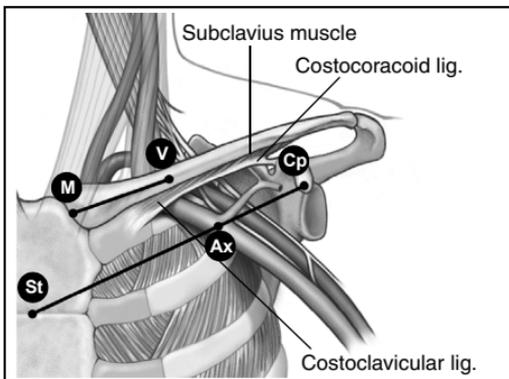
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2. Magney JE, et al. Anatomical mechanisms explaining damage to pacemaker leads, defibrillator leads, and failure of central venous catheters adjacent to the sternoclavicular joint. *PACE*. 1993;16:445-457.

## EASYTRAK® 2 IS-1 LEAD IMPLANTATION

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.<sup>3</sup> 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 12, identify points St (sternal angle) and Cp (coracoid process).



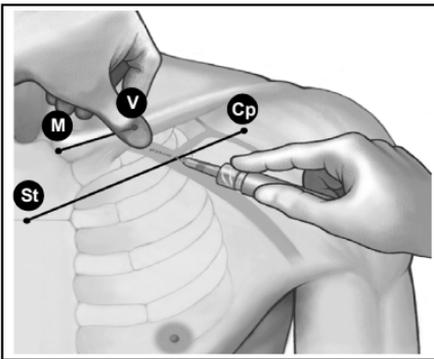
**Figure 12. Landmarks identify the entry point for a percutaneous subclavian venipuncture.**

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).

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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.

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 13).



**Figure 13. 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.

**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.

## 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 14, 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 2 IS-1 lead. Variability in patient anatomy may preclude placement in one or more of the suggested sites.

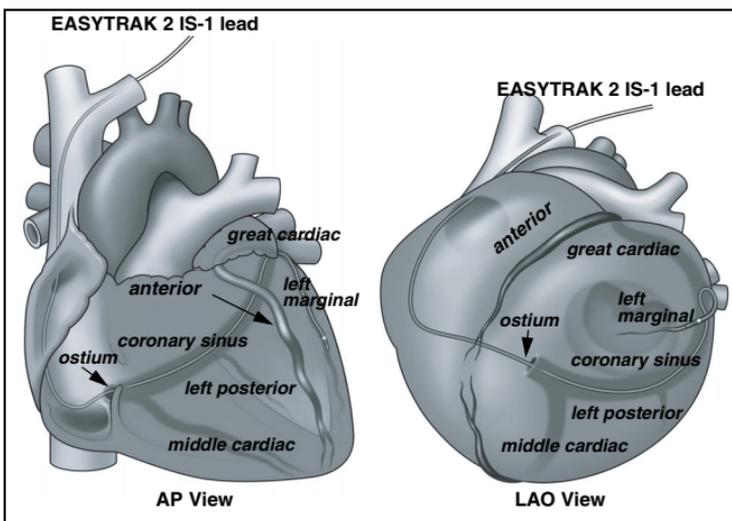


Figure 14. Anterior Posterior (AP) and Lateral Anterior Oblique (LAO) View of the Coronary Venous System.

**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 6 F (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.

## EASYTRAK® 2 IS-1 LEAD IMPLANTATION

- At the physician's discretion, an occlusion balloon catheter may be used to identify the distal vein. For further instructions, see literature accompanying the balloon catheter.

### **Placing the Lead**

The following section describes two preferred methods for the EASYTRAK 2 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 helps to advance the lead into the venous system and can help protect the EASYTRAK 2 IS-1 lead during the placement of other leads.*
- *Guidant recommends flushing the guide wire's protective hoop and the inner lumen of the guiding 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.*

#### **Method A**

1. Insert 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 holding the guide wire in place, advance the lead over the wire to the desired lead position.

#### **Method B**

1. Insert the 0.014-in (0.36-mm) diameter guide wire into the lead. Extend less than 2 cm of the guide wire beyond the distal tip of the lead to ensure the guide wire slides easily through the lumen. Retract the guide wire fully into the lead tip prior to introduction into the guiding catheter.

2. Insert the lead/guide wire assembly into the guiding catheter. Under fluoroscopy, verify the tip of the lead has emerged from the guiding 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.

**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 the distal tip of the lead and advance the wire proximally through the terminal to clear clotting. If unsuccessful, use a new lead.
- Applying tools to the distal end of the lead may result in lead damage.

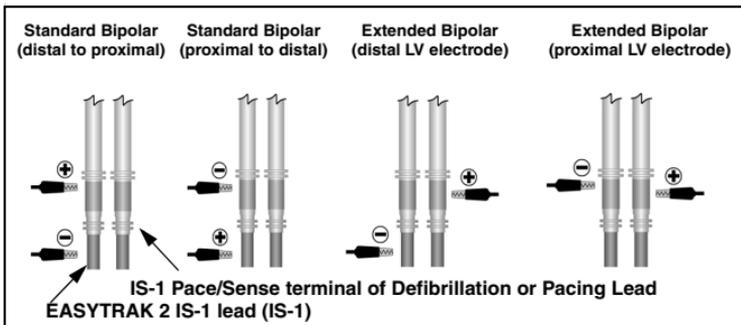
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## **EVALUATING LEAD PERFORMANCE**

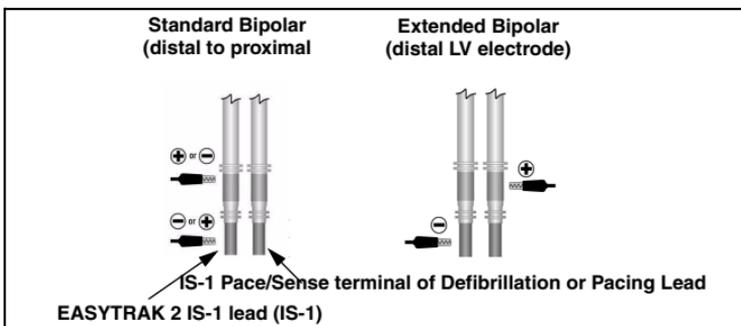
### **Evaluating Lead Position**

Verify electrical performance of the lead using a pacing system analyzer or similar monitor before attaching the lead to the pulse generator. See Figure 15 and Figure 16 for pacing system analyzer connections. Threshold measurements can be taken immediately after the lead is positioned.

**EASYTRAK® 2 IS-1 LEAD**  
**EVALUATING LEAD PERFORMANCE**



**Figure 15. Pacing system analyzer connections to the EASYTRAK 2 IS-1 lead terminal for LV pacing.**



**Figure 16. Pacing system analyzer connections to the EASYTRAK 2 IS-1 lead terminal for LV sensing.**

Once the lead is placed in the desired location, partially withdraw the guide wire tip into the pacing lead so it does not extend beyond the lead tip. Perform the measurements for voltage threshold (at 0.5 ms pulse width), R-wave amplitude, and pacing impedance, using recommended values in Table 5.

**Table 5. Recommended Threshold and Sensing Measurements**

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

a. Pulse width setting 0.5 ms.

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.

## **Removing the Guiding Catheter**

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

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

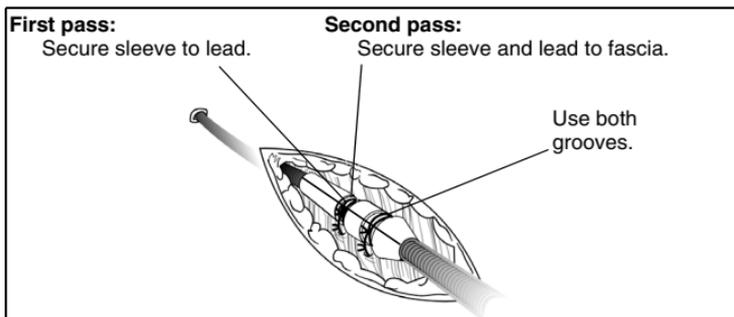
- Do not kink the finishing wire in the lead. Kinking the finishing wire could lock it in the lead or damage the conductor coil.
- If the finishing wire cannot be retracted from the lead, withdraw the lead and finishing wire together. Do not implant with the finishing wire inside the lead.

## 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 17).
2. Using both grooves, ligate the suture sleeve to the lead.
3. Next, secure the sleeve and lead to the fascia.



**Figure 17. 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.

### 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 18).

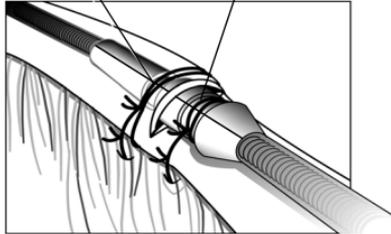
## EASYTRAK® 2 IS-1 LEAD EVALUATING LEAD PERFORMANCE

### Distal Groove:

First pass: secure vein to lead.  
Second pass: secure vein and lead to fascia.

### Proximal Groove:

First pass: secure sleeve to lead.  
Second pass: secure sleeve and lead to fascia.



**Figure 18. 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.

## EASYTRAK® 2 IS-1 LEAD EVALUATING LEAD PERFORMANCE

### **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.

**CAUTION:** Return all explanted leads to Guidant.

**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® 2 IS-1 LEAD  
SPECIFICATIONS (NOMINAL)*

## SPECIFICATIONS (NOMINAL)

Model	4542/4543/4544
Length	4542 - 80 cm 4543 - 90 cm 4544 - 100 cm
Terminal compatibility	IS-1 Bipolar
Electrode configuration	Bipolar (Dual)
Compatibility	Pulse generators that accept IS-1 Bipolar connectors
Insertion diameter	0.078" (1.98 mm)
Recommended introducer size	Determined by guiding catheter size
Steroid	0.7 mg dexamethasone acetate
Conductors:	
Conductor type	Coradial, two conductor pathways, multifilar coil
Conductor material	Platinum clad tantalum
Electrode:	
Distal electrode surface area	4.0 mm <sup>2</sup>
Proximal electrode surface area	4.2 mm <sup>2</sup>
Distance between electrodes	11 mm
Electrode material	Platinum iridium, IROX (iridium oxide)
Lead Body:	
Lead body diameter	1.78 mm (5.4F)
Lead body insulation material	Silicone rubber and ETFE
Lead body protective sleeve material	Polyurethane
Terminal pin and ring material	Titanium
Tines:	
Number of tines	2
Angle of tine projection	45 degrees
Angle of tine separation	180 degrees
Tine material	Silicone rubber

*EASYTRAK® 2 IS-1 LEAD  
SPECIFICATIONS (NOMINAL)*

Maximum lead conductor resistance (ohms) from terminal pin to distal electrode	4542 - 20 $\Omega$ 4543 - 22 $\Omega$ 4544 - 25 $\Omega$
Maximum lead conductor resistance (ohms) from terminal ring to proximal electrode	4542 - 38 $\Omega$ 4543 - 43 $\Omega$ 4544 - 48 $\Omega$



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**24-Hour Consultation**

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