# Summary

## Original PMA P010012

CONTAK CD™ Heart Failure Device Model 1823
Programmer Software Application, Model 2848

EASYTRAK® Coronary Venous Steroid-Eluding Single Electrode
Pace/Sense Lead, Models 4510, 4511, 4512, 4513

and

Lead Accessories:

Finishing Wire, Models 6730, 6731, 6732, 6733
Suture Sleeve, Model 6741
LV™-1 Lead Cap, Model 6742
LV™-1 Lead Port Plug, Model 6743
Lead Adapter, Model 6744

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# 1 SUMMARY OF SAFETY AND EFFECTIVENESS

## 1.1 GENERAL INFORMATION

### 1.1.1 DEVICE NAME

#### 1.1.1.1 PULSE GENERATOR AND PROGRAMMER SOFTWARE

Device Generic Name: Heart Failure Device

Device Trade Name:
- CONTAK CD™, Model 1823
- Programmer Software Application, Model 2848, Versions 2.2 and 3.1

#### 1.1.1.2 LEAD AND ACCESSORIES

Device Generic Name: Implantable Coronary Venous Steroid-Eluding Pace/Sense Lead and accessories

Device Trade Name:
- EASYTRAK®, Coronary Venous Steroid-Eluding Single Electrode Pace/Sense Lead, Models 4510, 4511, 4512, 4513
- EASYTRAK Finishing Wire, Model 6730, 6731, 6732, 6733
- Lead Adapter, Model 6744
- LV-1 Lead Cap, Model 6742
- LV-1 Lead Port Plug, Model 6743
- Suture Sleeve, Model 6741

### 1.1.2 SPONSOR

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## 1.2 INDICATIONS FOR USE

The CONTAK CD heart failure device is indicated for use in the following:

- Patients who have advanced symptomatic heart failure (NYHA Class III/IV) including left ventricular dysfunction (EF ≤ 0.35) and wide QRS complex (QRS >120 ms) while on heart failure drug therapy; and

  *Note: The effects of cardiac resynchronization on advanced heart failure patients receiving sub-optimal heart failure drug therapy are not fully known. Safety and effectiveness studies have not been conducted.*

- Patients who are at high risk of sudden cardiac death due to ventricular arrhythmias. Patient populations at high risk include, but are not limited to, those with:
  - Survival of at least one episode of cardiac arrest (manifested by the loss of consciousness) due to a ventricular tachyarrhythmia.
  - Recurrent, poorly tolerated sustained ventricular tachycardia (VT).

    *NOTE: The clinical outcome of hemodynamically stable, sustained-VT patients is not fully known. Safety and effectiveness studies have not been conducted.*
  - Prior myocardial infarction, left ventricular ejection fraction of ≤35%, and a documented episode of nonsustained VT, with an inducible ventricular tachyarrhythmia. Patients suppressible with IV procainamide or an equivalent antiarrhythmic (drug) have not been studied.

## 1.3 DEVICE DESCRIPTION AND USE

### 1.3.1 CONTAK CD

The Guidant CONTAK CD heart failure device, Model 1823, is designed to provide cardiac resynchronization therapy for the treatment of heart failure (HF) by using simultaneous biventricular electrical stimulation to synchronize ventricular contractions. The device also detects and terminates ventricular tachycardia (VT) and ventricular fibrillation (VF), and provides adaptive-rate bradycardia therapy. The pulse generator, an atrial lead, and two ventricular leads connected in a parallel configuration constitute the implantable portion of the heart failure system. The device accepts one IS-1 atrial lead, one LV-1 lead—Guidant's coronary venous pace/sense lead, and one DF-1/IS-1 cardioversion/ defibrillation lead with an electrode surface area > 8mm$^2$. Guidant recommends cardioversion/defibrillation leads such as the ENDOTAK® ENDURANCE EZ® leads (Models 0154, 0155), or the ENDOTAK® DSP lead (Model 0125).

Cardioversion/defibrillation therapies include a range of low- and high-energy shocks using either a biphasic or monophasic waveform. The CONTAK CD device uses the Guidant TRIAD™ electrode system for defibrillation energy delivery. By using the metal-

lic housing of the pulse generator as an active electrode, combined with the Guidant ENDOTAK two-electrode defibrillation lead, energy is sent via a dual-current pathway from the distal shocking electrode to the proximal electrode and to the pulse generator case. The CONTAK CD device also offers a wide variety of antitachycardia pacing (ATP) schemes to terminate slower, more stable ventricular tachyarrhythmias. Bradycardia pacing with resynchronization therapy, including adaptive-rate features, is available to detect and treat bradyarrhythmias and to support the cardiac rhythm after defibrillation therapy.

The ZOOM™ Programming System, which includes the Model 2920 Programmer/ Recorder/ Monitor (PRM), the Model 2848, (Version 3.3 or higher) Software Application, the Model 6860 Magnet, and an accessory telemetry wand, constitutes the external portion of the CONTAK CD system. The external components allow interrogation and programming of the pulse generator as well as access to the device's diagnostic features. The CONTAK CD system can be programmed to provide a variety of therapy options. It also can provide noninvasive diagnostic testing and therapy history data.

The CONTAK CD can also be programmed using the Model 2901 Programmer/ Recorder/Monitor (PRM) along with the Model 2848, Version 2.2, Software Application.

### 1.3.2 CONTAK CD PULSE GENERATORS

**Design Summary:** The external case of the pulse generator is constructed of titanium with a premolded polyurethane lead connector assembly. The inner assembly (hermetically sealed in the titanium case) contains an inner structure of discrete electrical components, a hybrid assembly, batteries (two, lithium-silver vanadium oxide), two high-voltage capacitors, flex circuit/dump resistor, audible tone speaker, a telemetry coil, and x-ray ID.

The pulse generators have the following energy, approximate weight, volume, external dimensions, and connector size:

**Table 1-1: CONTAK CD, Model 1823**

| Model | Energy Stored/ (delivered) | Mass (g) | Volume (cc) | Dimensions (cm) W x H x D | Connector Size |
|---|---|---|---|---|---|
| CONTAK CD<br>Model 1823 | 31 J / (27J) | 110 | 60 | 5.9 x 7.9 x 1.6 | DF-1 Shocking ports (2 ports)<br>IS-1 Ventricular pace/sense port (1 port)<br>IS-1 Atrial pace/sense port (1 port)<br>LV-1 Left ventricular pace/sense port (1 port) |

**Therapy:** The CONTAK CD System is designed to provide therapy for patients with heart failure. The CONTAK CD device provide cardiac resynchronization therapy by providing electrical stimulation to synchronize the right and left ventricular contractions (biventricular pacing) and when needed can be programmed to provide pacing therapy to the right atrium.

The CONTAK CD has tied programmable outputs (pulse width and pulse amplitude) for the ventricular leads. The settings must be the same for both the right ventricular and left ventricular leads.

The CONTAK CD provides bipolar atrial and extended bipolar biventricular, normal and post-shock pacing in a variety of modes, including adaptive-rate modes. In addition, the CONTAK CD is able to detect and treat ventricular tachycardia and ventricular fibrillation with a combination of ATP and monophasic or biphasic cardioversion/ defibrillation shocks.

The CONTAK CD is capable of delivering two types of therapy to terminate ventricular tachycardia or fibrillation: biventricular ATP and cardioversion/defibrillation shocks. A tachyarrhythmia that falls into the programmed heart rate range (VT-1, VT, or VF) will be treated by the therapy programmed for that range. The initial therapy is invoked when the criteria for detection is satisfied to treat an arrhythmia in the selected regimen. Tachyarrhythmia therapy, that includes one or two ATP schemes and up to five shocks occurs in the right ventricle only. Defibrillation or cardioversion shocks range from 0.1 to 31 joules (J) stored energy in which only the first two shock energies in each zone are programmable. Three additional shocks are available at 31 J.

The type and polarity of the shock waveform are also programmable. If multiple therapies are required, the hierarchy of therapy is a progression from pacing to shock, with shock energies always equal to or greater than the previous shocks within the same episode.

Following shock therapy, separately programmable redetection parameters are available for a specified time period to discriminate post-shock rhythms. Should there be a need for bradycardia pacing post-therapy, pacing will be delivered as programmed.

The CONTAK CD also provides DDDR pacing for cardiac resynchronization and bradycardia therapies. The adaptive-rate pacing modes are intended for patients who exhibit chronotropic incompetence and who would benefit from increased pacing rates concurrent with physical activity. The Atrial Tachy Response (ATR) feature provides mode switching from DDD(R) to DDI(R) or VDI(R), and from VDD(R) to VDI(R) in the presence of detected atrial activity that exceeds the ATR trigger rate. ATR limits the time that the ventricular paced rate is at the Maximum Tracking Rate or exhibits upper-rate behavior in response to a pathological atrial arrhythmia and limits the time cardiac resynchronization therapy is inhibited due to pathological atrial tachycardia. A variety of values can be programmed.

**Sensing and Detection:** For tachycardia detection, the CONTAK CD uses composite right and left ventricular rate as the primary detection criteria. The programmable rate range is 90–250 bpm in conjunction with programmed duration (1–60 seconds). Both devices use automatic gain control circuitry (AGC) in the right atrium and in the right ventricular channels to sense tachyarrhythmias and bradyarrhythmias. AGC is also available in the left ventricular channel to sense bradycardias.

For the CONTAK CD, the maximum sensitivity to sense tachyarrhythmias and brad-yarrhythmias is 0.122-0.272 mV (atrial) and 0.113-0.286 mV (ventricular - the same in both ventricles since the two ventricular ports are electrically connected in parallel).

Each tachyarrhythmia is classified into a programmed rate zone defined by a lower heart rate boundary. The pulse generator can be programmed as a one-zone, two-zone, or a three-zone configuration. The CONTAK CD pulse generator also provides a series of detection enhancements: Onset, AFIB Rate Threshold, Stability, V Rate>A Rate, and Sustained Rate Duration (SRD).

In addition, the CONTAK CD incorporates atrial rate information, obtained from the atrial lead, into the detection enhancement features. Detection enhancements are designed to increase the specificity of the rate detection algorithm and can be used to distinguish between different types of arrhythmias in the lower zone(s) of a multi-zone configuration. The purpose of atrial rate detection is to differentiate malignant VTs from a rapid ventricular response due to atrial fibrillation. If the ventricular rhythm is unstable and the atrial rate is greater than the AFib Rate Threshold, the ventricular rhythm is declared to be atrial fibrillation. Therapy will be withheld until the atrial rate drops below the AFib Rate Threshold, the ventricular rhythm becomes stable, or the Sustained Rate Duration timer expires. When atrial fibrillation is present and the ventricular response is unstable--indicating a more benign rhythm--therapy will be withheld. If the rhythm is gradual in onset, it will be considered to be sinus tachycardia (ST). The V Rate > A Rate (ventricular rate greater than atrial rate) feature can also be programmed to bypass Onset and/or Stability as inhibitors and the device will initiate therapy in the event that the ventricular rate is greater than the atrial rate.

**Memory and Diagnostics:** The CONTAK CD provides programmed parameters as well as model number, serial number, episode count, shock lead impedance, shocks delivered and diverted, and battery status that are stored in the pulse generator's memory. Both devices also store patient information surrounding each therapy episode including: (1) the date and elapsed time; (2) attempt data that includes the number of therapy attempts; (3) shock energy level and shocking lead impedance of each attempt; (4) the detected heart rate; (5) the presence of stored electrograms; and, (6) reconfirmation results. The CONTAK CD can store therapy detail up to 69 single attempt episodes and up to 16 minutes of electrograms surrounding the most recent episodes can be stored.

The CONTAK CD provides the following diagnostic and optional features: (1) real-time electrograms and event markers that assist in evaluating system response; (2) non-invasive methods for inducing arrhythmias, including Shock on T induction; (3) automatic battery voltage evaluation every 24 hours; (4) automatic capacitor reformation every 90 days; (5) pacing lead impedance, that can be used as a relative indicator of lead status over time; (6) battery status indicator displayed as one of three level: Beginning of Life (BOL), Elective Replacement Indicator (ERI), and End of Life (EOL); (7) programmable audible tones (beeper function) that can be used to assist with system evaluation such as pulse generator battery status, capacitor charging, and ventricular rate sensing; (8) magnet control that can be programmed OFF to ensure the tachy mode will not be changed in the presence of a magnetic field, or programmed ON to allow the tachy mode of the pulse generator to be changed from OFF (inactive) or Monitor Only mode to Monitor And Therapy mode or from Monitor And Therapy to OFF mode. The magnet can also divert or inhibit therapy, and activate the beeper when Enable Magnet Use is programmed ON.

### 1.3.3 THE PROGRAMMING SYSTEM AND SOFTWARE APPLICATIONS

The commercially available Guidant ZOOM™ Programmer/Recorder/Monitor (PRM), Model 2920 PRM, and its accessories, along with the device specific Software Application provides communication between the physician and the pulse generator via radio frequency (RF) telemetry. Software Applications contain the software code specifically required to identify and interrogate the implanted pulse generator, and to program it. The Model 2848 Software Application is specific for the CONTAK CD.

The CONTAK CD can also be programmed using the Model 2901 Programmer/ Recorder/Monitor(PRM) along with the Model 2848, Version 2.2, Software Application.

### 1.3.4 EASYTRAK LEAD AND ACCESSORIES

The EASYTRAK coronary venous, steroid-eluding single electrode pace/sense leads, Models 4510/4511/4512/4513, provide chronic pacing and sensing of the left ventricle. The lead is placed by inserting it through the coronary sinus and into a branch of the cardiac veins. This lead is an over-the-wire design; the inner lumen is open to allow passage over a guide wire that facilitates placement.

The lead employs a single distally located pacing electrode. Just distal to the electrode is a drug collar constructed of silicone rubber impregnated with dexamethasone acetate, an anti-inflammatory glucocorticosteroid to reduce the local tissue inflammatory response that can cause threshold rises when a lead is implanted. The distal end of the lead also employs passive fixation tines. The very tip of the lead is constructed of soft silicone rubber.

The electrode is connected by a multifilar fatigue and corrosion resistant conductor coil to a terminal pin on the proximal end of the lead. The terminal pin is hollow to allow for insertion of the guide wire into the inner lumen of the conductor coil. The terminal pin is molded into a smooth silicone rubber, proprietary connector, (designated LV-1) for exclusive connection to a Guidant pulse generator with a compatible LV-1 lead port. The lead port in the header will house the sealing rings that will electrically insulate the terminal pin from the surrounding environment. An outer sheath of silicone rubber tubing electrically insulates the coil. Additionally, an abrasion resistant polyurethane sleeve over the silicone insulation covers all but the terminal and distal-most portion of the lead body.

The EASYTRAK Lead is used in conjunction with a compatible Guidant heart failure device (such as the CONTAK CD Model 1823 that accepts the LV-1 connector. The heart failure devices and the EASYTRAK Lead have been tested as a system. Reference Section 1.9: Summary of Pre-Clinical Studies.

The following accessories are available for use with the CONTAK CD/EASYTRAK Lead system:

- Finishing Wire, intended to hold the EASYTRAK Lead in the desired implant location while the guiding catheter is removed from the vein (Models 6730, 6731, 6732, 6733).
- Suture sleeve intended to secure and immobilize the lead (Model 6741).

- LV-1 Lead Port Plug intended to seal an unused LV-1 lead port in the header of a Guidant pulse generator with an LV-1 connector port (Model 6743)
- LV-1 Lead Cap designed to fit over the EASYTRAK LV-1 terminal (Model 6742).
- Lead Adapter is available if needed and is designed to join an IS-1 lead to the LV-1 lead port of a Guidant pulse generator with an LV-1 connector port (Model 6744).
- Implant accessory devices such as guiding catheters, balloon catheters, and guide wires that are labeled for use with the EASYTRAK Lead.

## 1.4 CONTRAINDICATIONS

The CONTAK CD heart failure device is contraindicated for use in the following:

- Patients whose ventricular tachyarrhythmias may have reversible cause, such as 1) digitalis intoxication, 2) electrolyte imbalance, 3) hypoxia, or 4) sepsis, or
- Patients whose ventricular tachyarrhythmias have a transient cause, such as 1) acute myocardial infarction, 2) electrocution, or 3) drowning.

## 1.5 WARNINGS AND PRECAUTIONS

See the labeling.

## 1.6 POSSIBLE ADVERSE EVENTS

- Acceleration of arrhythmias
- Air embolism
- Allergic reaction
- Bleeding
- Chronic nerve damage
- Death
- Elevated pacing thresholds
- Erosion
- Excessive fibrotic tissue growth
- Extracardiac stimulation
- Extrusion
- Fluid accumulation
- Formation of hematomas or cysts
- Inappropriate shocks
- Infection
- Keloid formation
- Lead abrasion
- Lead discontinuity

- Lead migration/dislodgment
- Local tissue reaction
- Muscle and nerve stimulation
- Myocardial damage/irritability
- Myopotential sensing
- Oversensing/undersensing
- Pacemaker mediated tachycardia
- Pneumothorax
- Potential mortality due to inability to defibrillate or pace
- Prolonged exposure to fluoroscopic radiation
- Renal failure from contrast media used to visualize coronary veins
- Shunting current or insulating myocardium during defibrilla tion with internal or external paddles
- Thromboemboli
- Venous occlusion
- Venous or cardiac perforation

Patients susceptible to frequent shocks despite antiarrhythmic medical management may develop psychologic intolerance to an implantable system that may include the following:

- Dependency
- Depression
- Fear of premature battery depletion
- Fear of shocking while conscious
- Fear that shocking capability may be lost
- Imagined shocking

## 1.7 ALTERNATE PRACTICES AND PROCEDURES

Patients with heart failure are routinely treated with medications. Additional medical treatments include, but are not limited to, exercise and nutrition programs. Alternative therapies for the treatment of ventricular arrhythmias, as deemed appropriate by the physician based upon electrophysiological (EP) testing and other diagnostic evaluation include antiarrhythmic medication; electrical ablation; cardiac surgery; and electronic devices including pacemaker and other commercially available implantable cardioverter defibrillator (ICD) systems, or a combination thereof.

## 1.8 MARKETING HISTORY

The CONTAK CD heart failure device, and the EASYTRAK Lead and accessories, are currently legally marketed in the following countries: Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Israel, Italy, Lebanon, Malta, Netherlands,

Norway, Portugal, Spain, Sweden, Switzerland, Turkey, United Kingdom, Argentina, Australia, Brazil, Canada, Chile, Hong Kong, India, New Zealand, Singapore, Uruguay, and Venezuela. The CONTAK CD System has been marketed in the European Economic Area since November 1999. The system has not been removed from any of these countries for any reasons related to the safety and effectiveness of the device.

## 1.9 SUMMARY OF PRE-CLINICAL STUDIES

Laboratory studies for the CONTAK CD/EASYTRAK System consisted of bench testing (i.e., components, assemblies, device system/software tests), biocompatibility evaluation, and animal studies. These studies were designed to show that the heart failure device systems will function safely per the design intent.

### 1.9.1 PULSE GENERATOR AND SOFTWARE: DESIGN VERIFICATION TESTING

Design verification testing (DVT) was done to demonstrate that all device level requirements were met. The design verification of the CONTAK CD pulse generator and software applications are described in the following paragraphs:

***Battery Capacity Test:***

A Battery Capacity Test was performed for the CONTAK CD device to establish the usable capacity of the cell (battery) and the reserve capacity between ERI (Elective Replacement Indicator) and EOL (End Of Life) when used with the pulse generator's electronics.

***Electromagnetic Compatibility (EMC) Evaluation:***

The CONTAK CD device was evaluated to ensure that the devices operate safely in the presence of commonly encountered electromagnetic interference (EMI).

***Electronic Design Verification Test:*** The CONTAK CD device was tested to verify that pulse generator (PG) electronics met the device specifications.

***Mechanical Design Verification Test:*** The CONTAK CD pulse generator and assemblies were subjected to mechanical tests to verify that the devices met the mechanical design specifications.

***Pulse Generator Software Design Verification Test:*** Design verification testing (DVT) of the software incorporated in the pulse generators was conducted to verify the proper operation and interaction of the various tasks to be executed by the software (according to the test requirements specification) and to ensure proper function, timing, and data exchange.

***Programmer Software Application Design Verification Test:*** Design verification testing (DVT) of the Programmer Software Application (the PRM Software) was conducted with a Heart Failure Device (or simulator) and a Model 2920 PRM (Programmer, Recorder, Monitor) with the Model 2909 Multiple Application Utility (MAU), and the Model 2848 Software Application.

### 1.9.2 EASYTRAK LEAD: DESIGN VERIFICATION TESTING

Design Verification Testing was performed to evaluate the electrical and mechanical integrity of the EASYTRAK Lead and to ensure conformance to the device specification.

### 1.9.3 SYSTEM: DESIGN VALIDATION TESTING

Design validation testing was done to demonstrate that the CONTAK CD System conforms to user needs and intended use. Design validation testing included: System Features Tests, Simulated Use Test, and Animal Studies.

### 1.9.4 SAFETY AND RISK ANALYSIS TESTING

The safety and risk analysis testing of the CONTAK CD System was conducted to identify potential hazards and their causes, and to take appropriate actions to minimize patient and user risk.

### 1.9.5 BIOCOMPATIBILITY EVALUATION

The biocompatibility of the tissue contacting materials used in the CONTAK CD pulse generator, EASYTRAK Lead and lead accessories was established.

### 1.9.6 ANIMAL STUDIES

The following animal studies were done in compliance with Good Laboratory Practice (GLP) regulations (21 CFR § 58).

#### 1.9.6.1 CONTAK CD/EASYTRAK SYSTEM: ANIMAL STUDIES

Guidant conducted an animal study with the CONTAK CD/EASYTRAK Lead System in an in-vivo canine model to demonstrate that the system meets user needs and intended uses.

#### 1.9.6.2 EASYTRAK LEAD: ANIMAL STUDIES

Guidant conducted a series of animal studies to verify that the EASYTRAK lead is safe for chronic implantation.

## 1.10 CLINICAL STUDY

### 1.10.1 OVERVIEW

The purpose of the study was to demonstrate that cardiac resynchronization therapy (CRT) slowed the progression of heart failure. The study was also designed to demonstrate safe and effective performance of the EASYTRAK® coronary venous pace/sense lead. A total of 581 patients were enrolled at 48 investigational centers in the United States from February 3, 1998, through December 8, 2000. Of these, 501 patients received an investigational system, 14 patients were withdrawn prior to surgery, and 66 patients were unable to have an investigational device placed.

### 1.10.2 PATIENTS STUDIED

At the time of implant, patients who received the investigational system (84% male) had a mean age of 66 ± 10 years (range: 26 – 86 years) and a mean left ventricular ejection fraction (LVEF) of 21 ± 7% (range: 5 – 35%). Electrocardiography showed mean QRS duration of 158 ± 26 ms (range: 120 – 264 ms) with intraventricular conduction delay patterns of left bundle branch block (57%), right bundle branch block (13%), and nonspecific (30%). Heart failure status was characterized as NYHA II (33%), III (58%), and IV (9%) and 69% of patients had ischemic etiology. Preimplant heart failure medications included ACE inhibitors or angiotensin receptor blockers (87%), diuretics (85%), digoxin (68%), and beta blockers (47%). All patients met conventional indications for an implantable cardioverter defibrillator (ICD) implant.

### 1.10.3 OBJECTIVE

The primary therapy endpoint was the progression of heart failure, defined as the composite of all-cause mortality, heart failure hospitalization, and tachyarrhythmias requiring device therapy. Safety was assessed by severe device-related adverse events and operative mortality. Secondary therapy endpoints included functional status and quality of life. Secondary device endpoints included VF detection time and ATP conversion efficacy. The primary lead endpoints were chronic left ventricular pacing threshold, biventricular sensing, and biventricular lead impedance. Secondary lead endpoints included implant success rate.

### 1.10.4 STUDY DESIGN

Patients were randomized on a 1:1 basis to either the investigational group [CRT + ICD + drugs, referred to as the "CRT" cohort] or to the control group [ICD + drugs, referred to as the "No CRT" cohort]. The study began with a crossover phase with 3-month follow-up and was changed to a parallel design with 6-month follow-up. The data from the first three months of the crossover phase were pooled with data obtained from the parallel phase.

### 1.10.5 METHODS AND STATISTICS

The sample size and statistical power consideration was calculated to enable comparison of the CRT and No CRT cohorts to detect a 25% reduction in heart failure progression with 80% power at a 0.05 level of significance. Enrollment and follow-up of 308 patients with 6-month data was required. The crossover phase (3-month follow-up) enrolled 248 patients and the parallel phase (6-month follow-up) enrolled 348 patients. Randomization per cohort of those patients who were implanted with the device was 248 patients to CRT and 253 patients to No CRT.

For assessing the therapy, n = 501 will be used based on patients who received the investigational system. For assessing safety, n = 567 will be used based on patients who underwent a surgical procedure for implant of the investigational system.

For assessing the EASYTRAK lead performance and lead safety, n = 448 will be used based on patients who received the EASYTRAK lead. For assessing procedure safety, n = 517 will be used based on patients who underwent a surgical procedure for implant of the EASYTRAK lead.

### 1.10.6 RESULTS

See the Clinical Summary section of the panel information posting.