UNITED STATES DISTRICT COURT FOR THE MIDDLE DISTRICT OF TENNESSEE AT NASHVILLE

WALTER GLEN GRANT and wife, PAMELA GAMBLE GRANT,	)	
Plaintiffs,	)	
	)	
vs.	)	**Case No.**
	)	**JURY DEMAND**
ST. JUDE MEDICAL, INC., and PACESETTER, D/B/A: ST. JUDE MEDICAL CARDIAC RHYTHM MANAGEMENT DIVISION,	)	
	)	
Defendants.	)	

COMPLAINT

I. INTRODUCTION

1. Plaintiffs bring this Complaint against St. Jude Medical, Inc., and Pacesetter, Inc., D/B/A: St. Jude Medical Cardiac Rhythm Management Division, (collectively referred to as "St. Jude" or "Defendants") for injuries caused by defects in the St. Jude Riata and Riata ST Leads (hereinafter referred to as "Riata Leads" or "Leads") and violation of Defendants' state-law duty of care to report known risks associated with use of the Leads. Plaintiffs allege that plaintiff, Walter Glen Grant, herein after referred to as "Glen Grant" was implanted with a defective Riata Lead and suffered injury as a result of these defects and violations, and plaintiff Pamela Grant suffered loss of consortium as a result of these defects and violations.

St. Jude manufactures a variety of medical devices to treat heart conditions including implantable cardiac defibrillators ("ICDs"). Wires called Leads, are attached

to the ICD, then inserted through a major vein and attached directly to the muscle on the inside of the heart, thereby connecting the ICD to the heart. Electrodes that sense the heart's rhythm are built into the lead wires and positioned in the heart, where they monitor the heartbeat and correct any irregular rhythms.

In 1996, St. Jude received approval to market the predecessor to the Riata and Riata ST Leads. St. Jude Medical ultimately introduced its Riata Leads into the U.S. Market beginning in 2002. These Leads were based on the original 1996 submission and numerous supplements. Approximately 227,000 Riata leads have been sold worldwide since approved for marketing. 79,000 Riata Leads are estimated to remain active and implanted in patients throughout the United States.

In December 2011, the Food and Drug Administration (FDA) issued a Class I Recall for the following Riata Lead model numbers:

Riata (8Fr): 1560, 1561, 1562, 1570, 1571, 1572, 1580, 1581, 1582, 1590, 1591, 1592; and Riata (7Fr): 7000, 7001, 7002, 7010, 7011, 7040, 7041, 7042 (collectively "Riata Leads").

II. PARTIES

A. Plaintiffs

Plaintiffs are citizens and residents of the State of Tennessee.

Plaintiff Glen Grant was implanted with a Riata Lead Model #1580/65 on June 24, 2010. On August 8, 2012, plaintiffs first learned from his physician that his Riata lead was failing. On August 21, 2012, plaintiff Glen Grant underwent invasive surgery to remove and replace the defective Riata Lead.

As a result of the defect in his Riata lead, plaintiff Glen Grant has been injured and will continue to suffer physical, emotional, economic and other damage.

Defendant

Defendant St. Jude Medical, Inc. is a Minnesota Corporation that is headquartered in St. Paul, Minnesota at One St. Jude Medical Drive, St. Paul, Minnesota, 55117.

Defendant St. Jude Medical manufactures medical devices that are sold in more than 100 countries around the world and had net sales of over $5.6 billion in 2011.

Defendant Pacesetter, Inc. ("Pacesetter") is a Delaware corporation with its principle place of business at 15900 Valley View Court, in Slymar, California. Pacesetter, doing business as St. Jude Medical Cardiac Rhythm Management Division, develops, manufactures, and distributes cardiovascular and implantable neurostimulation medical devices, including the Riata and Riata ST leads at issue here. Pacesetter operates as a wholly owned subsidiary of St. Jude Medical, Inc. Prior to 1994, Pacesetter was known as Siemens Pacesetter, Inc.

Pacesetter also holds the trademark for Riata. Specifically, on September 07, 2001, Pacesetter filed a federal trademark registration. The United States Patent Trademark Office (USPTO) issued the RIATA trademark, serial number 76310892, to Pacesetter on November 5, 2002. The correspondent listed for RIATA is Steven M. Mitchell of Pacesetter, Inc., 15900 Valley View Court, Sylmar CA 91342. The RIATA trademark is filed in the category of Medical Instrument Products. At all relevant times, each of the Defendants and their directors and officers acted within the scope of

their authority and on behalf of each other Defendant. During the relevant times, Defendants possessed a unity of interest between themselves and St. Jude Medical exercised control over its subsidiaries and affiliates. As such, each Defendant is individually, as well as jointly and severally, liable to Plaintiffs for Plaintiffs damages.

III. JURISDICTION AND VENUE

The Court has diversity jurisdiction over the parties pursuant to 28 U.S.C. § 1332 insofar as the parties are citizens of different states and the amount in controversy in this matter exceeds Seventy-Five Thousand Dollars ($75,000), exclusive of interest and costs.

Venue is proper in this jurisdiction pursuant to 28 U.S.C. § 1391 (a)(2) because Defendants regularly solicited and engaged in business and other persistent courses of conduct and derived substantial revenues from goods used in the State of Tennessee. The device complained of herein was sold to and implanted in plaintiff Glen Grant in Davidson County, Nashville, Tennessee, and the plaintiffs are resident citizens of the state of Tennessee.

III. FACTUAL ALLEGATIONS

A. Brief History Of The Heart Devices

In 1980, termination of human arrhythmias with ICDs was reported in the New England Journal of Medicine. Thereafter, a number of devices were approved and manufactured to detect and treat abnormally fast and irregular heart rhythms and to provide pacing for improper heart rhythms. ICDs include pacemakers as well as defibrillators. Pacemakers are used primarily to correct slow heart rates. Defibrillators detect and correct both fast and slow heart rates. Using the pacemaker and defibrillator

function, an ICD can correct slow heart rates, pace rapid heart rates, and administer a shock to stop the heart and allow for a return to an appropriate rhythm.

Generally, leads act to conduct the electrical impulses between the heart and the ICD. Low voltage pacing therapy to treat slow heart rhythms is provided through pace-sense electrodes. High voltage shocks for defibrillation are provided through high voltage conductors. Typically, high voltage leads are inserted through a major vessel and attached directly to the muscle on the inside of the heart. Electrodes that sense the heart's rhythm are built into the lead wires and positioned in the heart, where they monitor the heartbeat and can transmit an electric shock from the ICD to abort dangerous heart rhythms or pace the heart at a normal rhythm.

Any failure that compromises the ability of the lead to conduct electrical signals will result in a failure of the ICD to perform properly. Lead failures may include externalization of the conductors, abrasion, fractured wires, insulation loss, loss of ability to capture, changes in electrical characteristics in the ventricle chamber, abnormal lead impedance, sensing failure, and changes in tissue conductor interface.

The Regulatory Approval Process Generally

A pre-market approval application ("PMA") must be submitted to the FDA for any Class III medical device. *See* 21 U.S.C. 515(b); 21 C.F.R. §814.3(e). A PMA must contain certain information which is critical to the FDA's evaluation of the safety and efficacy of the medical device at issue. A PMA and/or PMA Supplement application must provide:

a) proposed indications for use;

b) device description including the manufacturing process;

c) any marketing history;

d) summary of studies (including non-clinical laboratory studies, clinical investigations involving human subjects, and conclusions from the study that address benefit and risk considerations);

e) methods used in manufacturing the device, including compliance with current good manufacturing practices; and

f) information relevant to an evaluation of the safety and effectiveness of the device known to or that should reasonably be known to the manufacturer from any source, including commercial marketing experience.

The Regulatory Approval Process Specific to the Riata Leads

In May, 1996, the FDA approved the original PMA (P950022). From 1996 to 2002, Defendants submitted and the FDA approved 14 supplements to this original PMA. These supplements altered various aspects of the design and manufacture of the leads.

On March 11, 2002, the FDA, pursuant to St. Jude Medical's application number P950022/S014, approved the Riata Series 1500 Defibrillation Lead System. This approval applied to Riata Model Numbers 1570, 1571, 1580, and 1581.

On January 23, 2003, the FDA, pursuant to St. Jude Medical's application number P950022/S015, approved an extension of the shelf-life of the Riata Leads.

On March 25, 2003, St. Jude Medical added two new models to the Riata Series (Model No. 1572 and 1582), when the FDA approved application number P950022/S016.

On July 1, 2003, the FDA, pursuant to St. Jude Medical's application number P950022/S017, approved the addition of a fluoroscopic marker in the helix tip and the addition of new lead lengths and modifications to the suture sleeve.

On April 12, 2004, the FDA approved St. Jude Medical's application number P950022/S018, a modification to the Riata defibrillation lead family to include integrated bipolar leads (Models 1560, 1561, 1562, 1590, 1591, and 1592).

In May of 2005, a series of applications for manufacturing modifications were approved by the FDA. These requests involved "dimensional changes" to the Riata Leads, changes from welding to crimping connectors, changes from manual to automated processes, as well as changes to the order of the manufacturing steps for the crimping process, and "changes to the stylet ring and header coupling". *See*, application numbers: P950022/S020; P950022/S021; P950022/S022; P950022/S019; and P950022/S023.

On June 3, 2005, the FDA approved the addition the Riata ST Lead Models 7000, 7001, and 7002 under application number P950022/S024.

On September 13, 2005, the FDA approved, pursuant to St. Jude Medical's application number P950022/S026, the removal of 14-day hold period by instituting total and delta battery current tests.

On November 4, 2005, the FDA approved, pursuant to St. Jude Medical's application number P950022/S025, the addition of six lead models with elast-eon 2a lead body insulation materials to the Leads.

In March of 2006, the FDA approved the following changes to the Riata Leads: 1) modifications to the Riata ST Models 7000, 7001, and 7002 active-fixation defibrillation leads to change the geometric profile of the inner coil and add white pigment to the medical adhesive used for shock coil backfill; 2) modifications to the Riata ST Models 7000, 7001, and 7002 leads to create an active-fixation integrated bipolar lead. These devices, as modified, are marketed under the trade names Riata ST Models 7010, 7011, and 7012 and are indicated for use with compatible pulse generators; and 3) modifications to the Riata ST Models 7000, 7001, and 7002 to create a passive fixation and a passive fixation integrated bipolar lead. These devices, as modified, will be marketed under the trade names Riata ST Models 7040, 7041, and 7042 (passive fixation) and Riata ST Models 7050, 7051, 7052 (passive fixation integrated bipolar) and are indicated for use with compatible pulse generators. These changes were all included in application numbers P950022/S027 and P950022/S028.

On July 7, 2006, the FDA approved, pursuant to St. Jude Medical's application number P950022/S030, an overlay over the silicone lead body of the Riata ST Leads to create the new Riata ST Optim Lead models 7020, 7021, 7022, 7030, 7031, 7070, and 7071.

In November 2006, the FDA approved St. Jude Medical's application to change the supplier for the DR-1 Boot component of its Riata Leads. (P950022/S031).

In December 2006, the FDA approved St. Jude Medical's application for a helix attachment modification for the Riata 1580, 1581 and 1582 leads as well as a crimp-weld coupling modification for the Riata and Riata ST lead families. (P950022/S032).

In February 2007, the FDA approved St. Jude Medical's application to add an automated trimming fixture to trim excess silicone adhesive on the shock electrodes during production of the Riata ST family of leads. (P950022/S033).

In March 2007, the FDA approved St. Jude Medical's application for changes to their Riata Leads: 1) Modification to the crimp slug weld tab; 2) Modification to the distal header assembly; 3) Modification to the PTFE liner in the IS-1 connector leg; 4) Removal of the PTFE liners in the two DF-1 connector legs; 5) Addition of a DF-1 plug accessory to the lead package; 6) Addition of an extra-soft stylet accessory to the lead package; 7) Minor modifications to the User Manual; and 8) Modified radius specification for the spring stopper component. (P950022/S034). The FDA also approved a change in the supplier of the front seal component (P950022/S035), added an "alternative welding process." (P950022/S036), and added alternate vendor of the molded connector boot for the manufacturer of Riata ST Leads (P950022/S037).

In June 2007, the FDA approved St. Jude Medical's application to change the suppliers of their connector rings and inner crimp sleeve components. (P950022/S038, P950022/S039, P960013/S031, and P960013/S032).

In October 2007, the FDA approved St. Jude Medical's application for an alternate supplier of ETFE coated cables. (P950022/S043).

In December 2007, the FDA approved St. Jude Medical's application to change the "shock coil backfill manufacturing process." (P950022/S046), to extend the time between plasma treatment and application of medical adhesive. (P950022/S047), and to alternate oven settings during processing of the shock coils. (P950022/S048).

In May 2008, the FDA approved St. Jude Medical's application to transition the manufacturing site located at Steri-Tech, Inc., Salinas, Puerto Rico for Ethylene Oxide sterilization of the pacemakers, ICDs and leads. (P950022/S045).

On June 9, 2008, the FDA approved St. Jude Medical's application to sterilize products for up to five cycles at the contract sterilization vendor. (P950022/S053).

In July 2008, the FDA approved St. Jude Medical's application to transition the manufacturing of the Riata Leads to a plant in Arecibo, Puerto Rico. (P950022/S051).

FDA Inspections of Defendants' Manufacturing Facilities and Processes

In 2009, the FDA conducted a For-Cause Quality Systems Inspection Technique (QSIT) of Defendants' manufacturing facility in Sylmar, California. As part of this inspection, the FDA requested a list of all Corrective and Preventative Action (CAPA) and Product Improvement Requests (PIR) opened since 2002. Defendants provided the following PIRs regarding High Voltage Leads:

- 09-005 – Helix extension retraction failure due to the spring popping out of its location and getting jammed between the header coupling and stopper
- 09-001 – Cable Fracture under Strain Relief Coil DF-1 leg
- 07-006 – Outer Coil Fractures at IS-1 Connector Ring
- 06-014 – Hypot Failures in Riata ST Leads Manufacturing
- 06-012 – Riata Coil Fracture at Inner coil Shaft
- 06-005 – Missing DF-1 Crimps in HV Lead Manufacturing
- 06-004 – Swapped DF-1 Labels in HV Lead Manufacturing
- 06-003 – Riata Lead With Incorrect Conduction Paths
- 05-016 - Riata Integrated Bipolar IS-1 Connector Dielectric Strength Improvement
- 05-009- Riata Lead Abrasion
- 04-006 – Insufficient Crimp on RV shock coil termination ring employed on the Riata Integrated Bipolar Leads seen in Manufacturing
- 04-003 - Riata Perforation

- 03-006 – Riata Lead Cable Coating Abrasion
- 02-004 – Riata, Missing Weld, DF-1 Conn. Pin.

The inspection revealed that defendants had deficiencies in the handling of complaints, making Medical Device Reporting (MDR) determinations, CAPA procedures, and receiving protocols.

The inspection also revealed that defendants failed to follow their procedure for product design developments of the Leads.

As a result of these deficiencies, the FDA issued an eight-item FDA-483 Report. An FDA Form 483 is issued to firm management at the conclusion of an inspection when an investigator(s) has observed any conditions that in their judgment may constitute violations of the Food Drug and Cosmetic Act and related Acts. FDA investigators are trained to ensure that each observation noted on the FDA Form 483 is clear, specific and significant.

Specifically, the deficiencies identified by the FDA in 2009 included the following:

a. Defendants failed to include all information that was reasonably known to the manufacturer on an MDR Report in violation of 21 CFR 803 et seq.

b. Defendants failed to timely submit MDRs to the FDA and such submissions were significantly past the mandatory reporting timeframes without written explanation in violation of 21 CFR 803 et seq.

c. Defendants failed to define the procedures for implementing corrective and preventative actions in violation of 21 CFR 820 et seq. Specifically, the Standard Operating Procedure for risk analysis failed to define the methodology for obtaining the Probability of Occurrence that is used in Risk evaluations resulting in inconsistent risk analyses.

d. Defendants failed to review their sampling methods for adequacy of their intended use in violation of 21 CFR 820 et seq. Specifically, the procedure

"Receiving Inspection Sampling Program" allowed components to be accepted without receiving inspections and review of vendor certificates (Dock to Stock method). The procedure did not have a monitoring program for receiving components that were subject to Dock to Stock methods. As of June 23, 2009, a significant number of "critical components for defibrillation leads were Dock to Stock components." Also, the sections of "Dock to Stock General Requirements" and "Dock to Stock Part Declassification" were purged without written justifications.

e. Defendants failed to perform design reviews at appropriate times in violation of 21 CFR 820 et seq. Specifically, Design Phase reviews were not conducted as required by the procedure for Global Product Development Protocol and the Product Development Plan. Additionally, team meeting minutes were not maintained as required.

f. Defendants failed to perform a complete risk analysis in violation of 21 CFR 820 et seq. Specifically, the Failure Modes Effects Criticality Analysis (FMECA) did not include all drawings and St. Jude was unable to explain why component drawings were not evaluated for failure mode, effect, and criticality analysis. The design FMECA analysis for components and top assembly drawings were part of the risk analysis for the Riata leads.

g. Defendants failed to establish procedures for the validation or verification, review, and approval of design changes before their implementation in violation of 21 CFR 820 et seq. Specifically, Defendants had no written procedure describing the review and approval process of the design verification plan and report, when design changes require a verification plan.

h. Defendants failed to resolve discrepancies noted at the completion of design verification in violation of 21 CFR 820 et seq. Specifically, the review of Quality Test Report (QTR) 1403 for Riata Series 1500 shows someone who reviewed the data sheets had made a change to the specification of DC resistance on the Qualification Test Data Sheets for Composite Lead Tensile Test, but the reason for the discrepancy and reason for the change were not discussed in the QTR or meeting minutes.

On October 17, 2012, the FDA conducted a subsequent 483-inspection of Defendants' Sylmar, California manufacturing facility and identified several deficiencies including failures regarding design verification, complaint handling, CAPA procedures, risk analyses, inspection/measuring/testing/calibration of equipment, document control, and employee training.

E. Manufacturing Defects with Regard to Riata LeadsFrom 2005-2010 St. Jude applied for over 27 manufacturing or process changes to the Riata Leads. The FDA approved these changes in a PMA and multiple supplements. Upon information and belief, Defendants failed to manufacture the Riata Leads consistent with design specifications and/or these approved changes, thereby creating a defective product.

Upon information and belief, one of these defects includes inconsistent insulation diameters surrounding the electric conductors. On information and belief, insulation diameters are required by the design specifications, the PMA and/or federal requirements to be consistent. Failure to manufacture uniform insulation diameters leads to an increased risk of abrasion at thinner insulation sites, leading to an increased risk of device failure.

A natural process of abrasion occurs *in situ* with the insulation surrounding the lead wires or electrical conductors. It is foreseeable that such abrasion will occur with the insulation surrounding the lead wires after implantation. As a result, the lead wires protrude through the insulation, causing them to be in contact with materials and fluids that can prevent the proper functioning of the ICD. This protrusion is called "externalization."

The breach of insulation and externalization of the lead wires on the Riata Leads can cause the Leads to short, and to transmit incorrect information or noise to the pacemaker/defibrillator thereby causing it to produce unnecessary and very painful shocks of electricity, or alternatively, to fail to communicate with the pacemaker/defibrillator at which point the life-saving therapies of the device are

unavailable, the latter being the circumstance suffered by plaintiff Glen Grant and complained of herein.

Further upon information and belief, St. Jude inconsistently applied a lubricious interface between the inner and outer insulation in violation of the design specifications and/or the PMA. Upon information and belief, this inconsistent application led to increased friction within the lead body, promoting abrasion and/or externalization in the instance of plaintiff Glen Grant.

Additionally, St. Jude applied and received approval for multiple changes to the cure and sterilization processes used in the manufacture of the Riata Leads. Upon information and belief, St. Jude, failed to comply with the approved methods and/or specifications of curing and sterilization during the manufacture of the Leads. Upon information and belief, failure to follow the approved cure and sterilization processes resulted in reduced tensile strength of the silicone insulation, resulting in externalization as herein described in the instance of plaintiff Glen Grant.

Finally, St. Jude applied and received approval for numerous modifications to the welding and crimping procedures in the manufacture of the Riata Leads. Upon information and belief, a controlled, uniform degree of force was required when applying the crimp. Upon information and belief, failure to crimp with a controlled, uniform, degree of force, resulted in insecure crimps over the length of the Lead.

Failure of the Riata leads was apparently unrelated to patient age or sex, ICD indication, the primary heart disease, left ventricular ejection fraction, or lead tip

position, suggesting that manufacturing problems are responsible for the failure of the devices.

G. Recall Of The Riata Leads

On December 15, 2010, St. Jude Medical published a "Dear Doctor" letter regarding its Riata Leads. In the 2010 letter, St. Jude indicated that issues with defects in the insulation have been identified in the Riata Lead Models 1560, 1561, 1562, 1570, 1571, 1572, 1580, 1581, 1582, 1590, 1591, 1592, 7000, 7001, 7002, 7010, 7011, 7040, 7041, and 7042.

Specifically, St. Jude states that "the Riata and Riata ST Family of Silicone Leads have exhibited an insulation abrasion rate of 0.47% over nine years of use." Additionally, St. Jude noted that the silicone used on these leads was "vulnerable to abrasion."

In the 2010 Dear Doctor Letter, St. Jude indicated that Lead insulation abrasion had been associated with:

a) Oversensing (leading to inhibition of pacing or inappropriate high voltage therapy);

b) Undersensing;

c) Loss of capture;

d) Changes in pacing and/or high voltage lead impedances; and

e) Inability to deliver high voltage therapy

Despite the dangers associated with these leads, St. Jude did not initiate a voluntary recall of the leads at that time. Rather, St. Jude simply noted that it was "phasing-out" all Riata Lead models by the end of 2010.

On November 28, 2011, St. Jude Medical published a second Dear Doctor letter relating to the same set of Riata Lead Models as the 2010 Dear Doctor letter.

The November 28, 2011 Letter updated the previously published failure rates for the Riata Leads, indicating that it had increased to 0.63% from its 2010 rate of 0.47%. Again, despite the dangers associated with these leads, St. Jude did not initiate a voluntary recall.

On December 21, 2011, the FDA reclassified St. Jude's Dear Doctor advisories to a Class I Recall.

A Class I Recall is the most serious level of recall and is defined as: a situation in which there is a reasonable probability that the use of or exposure to a violative product will cause serious adverse health consequences or death.

Specifically, the FDA indicated that the reason for the recall was that "failures associated with lead insulation abrasion on the St. Jude Medical Riata and Riata ST Silicone Endocardial Defibrillation Leads may cause the conductors to become externalized. If this occurs, this product may cause serious adverse health causes, including death."

Physicians Expose the Riata Lead Defects

Beginning in September 2011, Dr. Robert Hauser of the Minneapolis Heart Institute Foundation (MHI), began researching the FDA's MAUDE database for reported deaths related to the St. Jude Riata Leads. In a manuscript sent to the *Heart Rhythm* Journal in March 2012, Dr. Hauser detailed his research and conclusions comparing the failure rates of the St. Jude Riata Leads to the reported failure rates of a competitor's

leads. Hauser et al. *Deaths caused by the failure of Riata and Riata ST implantable cardioverter-defibrillator leads*. HEART RHYTHM 2012 Aug;9(8):1227-35.

In his manuscript, Dr. Hauser indicated that the reports showed that 31% of the deaths involving the Riata Leads were lead-related whereas, 8% of the deaths involving the competitor's lead were found to be lead-related. *Id.* It is important to note that adverse events are often under-reported. *Id.*

Additionally, Dr. Hauser noted that "Abnormal high voltage impedances were the hallmark of catastrophic Riata and Riata ST lead Failure, often resulting in failure to defibrillate." *Id.* Finally, Dr. Hauser concludes that the Riata Leads are prone to high-voltage failures that have resulted in multiple deaths. *Id.*

On March 8, 2012, Dr. Hauser's article entitled "Here we Go Again – Another Failure in Postmarketing Device Surveillance" was published in the New England Journal of Medicine. This article exposed the increased harm in failing to have an accurate, active post-market reporting mechanism for medical devices and advocated for greater research and review of medical device failures in order to better protect patients. Robert G. Hauser, *Here We Go Again – Another Failure in Postmarketing Device Surveillance*, 366 NEW ENG. J. MED. 873, 873-75 (2012).

St. Jude Medical reacted to Dr. Hauser's article in what industry analysts have described as a "rare," "unprecedented," and "confounding" manner by demanding that the New England Journal of Medicine retract Dr. Hauser's article. *See* Barry Meier and Katie Thomas, *At St. Jude, Firing Back at Critics*, N.Y. TIMES, Apr. 11, 2012, at B1; Susan Kelly and Debra Sherman, *Analysis: Heart device troubles cloud St. Jude's*

outlook, Reuters.com, Apr. 13, 2012, http://www.reuters.com/ article/2012/04/13/us-stjude-idUSBRE83C0ME20120413.

In May 2012, Dr. Hauser published additional findings regarding the Riata Lead insulation defects in the Heart Rhythm Journal. Hauser, R.G., McGriff, D., Retel, L.K., Riata *Implantable Cardioverter-Defibrillator Lead Failure: Analysis of Explanted Leads with a Unique Insulation Defect* (May 2012).

In 2012, the FDA ordered Defendants to collect clinical data related to the potential for premature insulation failure in Riata and Riata ST Leads. The FDA also required Defendants to conduct three-year post market surveillance studies, or Section 522 studies, to address concerns related to premature insulation failure and to address important questions related to follow-up of affected patients.

In January 2013, a study published in the Heart Rhythm Journal indicated that Defendants had recently advised that the rate of cable externalization was 24% in the Riata 8fr Leads and 9% in the Riata ST 7fr Lead – despite previous reports that such rates were only .63%. The article also stated that a number of studies have confirmed that Riata Leads fail more often than other brands.

V. CLAIMS FOR RELIEF

COUNT I
STRICT LIABILITY –MANUFACTURING DEFECT

Plaintiffs hereby incorporate by reference all preceding paragraphs as if fully set forth herein.

Upon information and belief, the Riata Leads possess a manufacturing defect because the actual manufacture of the Riata Leads differs from the specifications set forth in the PMA and/or the conditions for approval.

This manufacturing defect renders the Riata Lead unreasonably dangerous for its intended use and plaintiffs could not have anticipated the danger the defect in this product created.

This manufacturing defect was present in the Riata Lead received by plaintiff Glen Grant when it left St. Jude's control. Specifically, the insulation failed resulting in "externalization", causing a mass (blood clot) and internal infection, as well as misfiring of the implant, and/or the failure of the lead to communicate with plaintiff's defibrillator, resulting in a life threatening event.

The Riata Leads were expected to and did reach plaintiff Glen Grant without substantial change or adjustment to their mechanical function upon implanting the Riata Leads.

As a direct and proximate result of the manufacturing defect, plaintiff Glen Grant has sustained and will continue to sustain severe physical injuries and/or death, severe emotional distress, mental anguish, economic losses, and other damages for which he is entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

COUNT II
NEGLIGENCE IN MANUFACTURING

Plaintiffs hereby incorporate by reference all preceding paragraphs as if fully set forth herein.

Defendants have a duty to manufacture the Riata Leads consistent with the specifications, the PMA and/or conditions of approval. Defendants breached this duty.

As a direct and proximate result of St. Jude's failure to manufacture the Riata Leads consistent with the specifications, PMA, and/or conditions of approval, plaintiff Glen Grant has sustained and will continue to sustain severe physical injuries and/or death, severe emotional distress, mental anguish, economic losses, and other damages for which he is entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

COUNT III
NEGLIGENCE PER SE

Plaintiffs hereby incorporate by reference all preceding paragraphs as if fully set forth herein.

Federal Regulations impose standards of care on St. Jude Medical related to the manufacture, marketing, and sale of the Riata Leads.

Plaintiffs allege the Federal Regulations define the standard of care, and thus, St. Jude's duties are contained in, but not limited to, the following: 21 CFR 803.10; 21 CFR 803.50; 21 CFR 803.52; 21 CFR 803.53; 21 CFR 803.56; 21 CFR 806; 21 CFR 814.1; 21 CFR 814.3; 21 CFR 814.9; 21 CFR 814.20; 21 CFR 814.37; 21 CFR 814.39; 21 CFR

814.80; 21 CFR 814.82; 21 CFR 814.84; 21 CFR 820.5; 21 CFR 820.20; 21 CFR 820.22; 21 CFR 820.25; 21 CFR 820.70.

Plaintiff Glen Grant is within the class of persons the statutes and regulations protect and plaintiff's injuries are the type of harm these statutes and regulations are to prevent.

Upon information and belief the Conditions of Approval for the Riata Leads incorporate these statutes and regulations. Failure to comply with the Conditions of Approval invalidates the approval order. *See* 21 CFR 814.82(c). St. Jude failed to comply with the Conditions of Approval and Federal Regulations.

As a direct and proximate result of St. Jude's failure to comply with the PMA and conditions of approval for manufacturing the Riata Leads, plaintiff Glen Grant has sustained and will continue to sustain severe physical injuries and/or death, severe emotional distress, mental anguish, economic losses and other damages for which he is entitled to compensatory and other damages and in an amount to be proven at trial.

COUNT IV
NEGLIGENCE RES IPSA LOQUITUR

Plaintiffs hereby incorporate by reference all preceding paragraphs as if fully set forth herein.

The manufacturing defects found in the Riata Leads can only occur while the devices are under the control of Defendant.

Plaintiff Glen Grant's injury was of a kind that, in the ordinary course of events, would not have happened if defendant had manufactured the Riata Leads consistent with the specifications, PMA, and/or Conditions for Approval.

Defendant was responsible for the manufacturing defect that was the direct cause of plaintiff's injury.

The manufacturing defect that caused the injury was not due to the actions of plaintiff Glen Grant or any third person.

As a direct and proximate result of defendants' negligence, plaintiff Glen Grant was injured as described herein.

COUNT V

Plaintiffs hereby incorporate by reference all preceding paragraphs as if fully set forth herein.

Plaintiff Pamela Grant claims loss of the companionship, company and enjoyment of the company of her husband as a result of the negligent acts of the defendants and seeks compensatory damages as a result thereof.

PRAYER FOR RELIEF

WHEREFORE, plaintiffs pray for judgment against defendants as follows:

A. Economic and non-economic damages in an amount as provided by law and to be supported by the evidence at trial;

B. For plaintiffs compensatory damages according to proof;

C. For declaratory judgment that defendants are liable to plaintiff Glen Grant for all evaluative, monitoring, diagnostic, preventative, and corrective medical, surgical, and incidental expenses, costs, and losses caused by defendants' wrongdoing;

D. For disgorgement of profits;

E. For an award of attorneys' fees and costs;

F. For prejudgment interest and the costs of suit; and

G. For such other and further relief as this Court may deem just and proper.

DEMAND FOR JURY TRIAL

Plaintiffs hereby demand a trial by jury as to all claims in this action.

Dated: August 6, 2013.

Respectfully submitted,

/s/ Russell L. Leonard

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JS 44 (Rev. 12/07)

CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. (SEE INSTRUCTIONS ON THE REVERSE OF THE FORM.)

I. (a) PLAINTIFFS

Walter Glen Grant and wife, Pamela Gamble Grant

(b) County of Residence of First Listed Plaintiff Franklin
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorney's (Firm Name, Address, and Telephone Number)

Russell L. Leonard & Janet M. Songer 315 North High Street, Winchester, TN 37398 (931) 962-0447

DEFENDANTS

St. Jude Medical, Inc. and Pacesetter d/b/a St. Jude Medical Cardiac Rhythm Management Division

County of Residence of First Listed Defendant
(IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE LAND INVOLVED.

Attorneys (If Known)

II. BASIS OF JURISDICTION (Place an "X" in One Box Only)

- ☐ 1 U.S. Government Plaintiff
- ☐ 3 Federal Question (U.S. Government Not a Party)
- ☐ 2 U.S. Government Defendant
- ☒ 4 Diversity (Indicate Citizenship of Parties in Item III)

III. CITIZENSHIP OF PRINCIPAL PARTIES (Place an "X" in One Box for Plaintiff and One Box for Defendant)
(For Diversity Cases Only)

	PTF	DEF		PTF	DEF
Citizen of This State	☒ 1	☐ 1	Incorporated or Principal Place of Business In This State	☐ 4	☐ 4
Citizen of Another State	☐ 2	☐ 2	Incorporated and Principal Place of Business In Another State	☐ 5	☒ 5
Citizen or Subject of a Foreign Country	☐ 3	☐ 3	Foreign Nation	☐ 6	☐ 6

IV. NATURE OF SUIT (Place an "X" in One Box Only)

CONTRACT
- ☐ 110 Insurance
- ☐ 120 Marine
- ☐ 130 Miller Act
- ☐ 140 Negotiable Instrument
- ☐ 150 Recovery of Overpayment & Enforcement of Judgment
- ☐ 151 Medicare Act
- ☐ 152 Recovery of Defaulted Student Loans (Excl. Veterans)
- ☐ 153 Recovery of Overpayment of Veteran's Benefits
- ☐ 160 Stockholders' Suits
- ☐ 190 Other Contract
- ☐ 195 Contract Product Liability
- ☐ 196 Franchise

REAL PROPERTY
- ☐ 210 Land Condemnation
- ☐ 220 Foreclosure
- ☐ 230 Rent Lease & Ejectment
- ☐ 240 Torts to Land
- ☐ 245 Tort Product Liability
- ☐ 290 All Other Real Property

TORTS

PERSONAL INJURY
- ☐ 310 Airplane
- ☐ 315 Airplane Product Liability
- ☐ 320 Assault, Libel & Slander
- ☐ 330 Federal Employers' Liability
- ☐ 340 Marine
- ☐ 345 Marine Product Liability
- ☐ 350 Motor Vehicle
- ☐ 355 Motor Vehicle Product Liability
- ☐ 360 Other Personal Injury

PERSONAL INJURY
- ☐ 362 Personal Injury - Med. Malpractice
- ☒ 365 Personal Injury - Product Liability
- ☐ 368 Asbestos Personal Injury Product Liability

PERSONAL PROPERTY
- ☐ 370 Other Fraud
- ☐ 371 Truth in Lending
- ☐ 380 Other Personal Property Damage
- ☐ 385 Property Damage Product Liability

CIVIL RIGHTS
- ☐ 441 Voting
- ☐ 442 Employment
- ☐ 443 Housing/ Accommodations
- ☐ 444 Welfare
- ☐ 445 Amer. w/Disabilities - Employment
- ☐ 446 Amer. w/Disabilities - Other
- ☐ 440 Other Civil Rights

PRISONER PETITIONS
- ☐ 510 Motions to Vacate Sentence

Habeas Corpus:
- ☐ 530 General
- ☐ 535 Death Penalty
- ☐ 540 Mandamus & Other
- ☐ 550 Civil Rights
- ☐ 555 Prison Condition

FORFEITURE/PENALTY
- ☐ 610 Agriculture
- ☐ 620 Other Food & Drug
- ☐ 625 Drug Related Seizure of Property 21 USC 881
- ☐ 630 Liquor Laws
- ☐ 640 R.R. & Truck
- ☐ 650 Airline Regs.
- ☐ 660 Occupational Safety/Health
- ☐ 690 Other

LABOR
- ☐ 710 Fair Labor Standards Act
- ☐ 720 Labor/Mgmt. Relations
- ☐ 730 Labor/Mgmt.Reporting & Disclosure Act
- ☐ 740 Railway Labor Act
- ☐ 790 Other Labor Litigation
- ☐ 791 Empl. Ret. Inc. Security Act

IMMIGRATION
- ☐ 462 Naturalization Application
- ☐ 463 Habeas Corpus - Alien Detainee
- ☐ 465 Other Immigration Actions

BANKRUPTCY
- ☐ 422 Appeal 28 USC 158
- ☐ 423 Withdrawal 28 USC 157

PROPERTY RIGHTS
- ☐ 820 Copyrights
- ☐ 830 Patent
- ☐ 840 Trademark

SOCIAL SECURITY
- ☐ 861 HIA (1395ff)
- ☐ 862 Black Lung (923)
- ☐ 863 DIWC/DIWW (405(g))
- ☐ 864 SSID Title XVI
- ☐ 865 RSI (405(g))

FEDERAL TAX SUITS
- ☐ 870 Taxes (U.S. Plaintiff or Defendant)
- ☐ 871 IRS—Third Party 26 USC 7609

OTHER STATUTES
- ☐ 400 State Reapportionment
- ☐ 410 Antitrust
- ☐ 430 Banks and Banking
- ☐ 450 Commerce
- ☐ 460 Deportation
- ☐ 470 Racketeer Influenced and Corrupt Organizations
- ☐ 480 Consumer Credit
- ☐ 490 Cable/Sat TV
- ☐ 810 Selective Service
- ☐ 850 Securities/Commodities/ Exchange
- ☐ 875 Customer Challenge 12 USC 3410
- ☐ 890 Other Statutory Actions
- ☐ 891 Agricultural Acts
- ☐ 892 Economic Stabilization Act
- ☐ 893 Environmental Matters
- ☐ 894 Energy Allocation Act
- ☐ 895 Freedom of Information Act
- ☐ 900Appeal of Fee Determination Under Equal Access to Justice
- ☐ 950 Constitutionality of State Statutes

V. ORIGIN (Place an "X" in One Box Only)

☒ 1 Original Proceeding ☐ 2 Removed from State Court ☐ 3 Remanded from Appellate Court ☐ 4 Reinstated or Reopened ☐ 5 Transferred from another district (specify) ☐ 6 Multidistrict Litigation ☐ 7 Appeal to District Judge from Magistrate Judgment

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing (**Do not cite jurisdictional statutes unless diversity**):
28 U.S.C. Section 1332

Brief description of cause:
Manufacturing defects in the St. Jude Riata and Riata ST Leads

VII. REQUESTED IN COMPLAINT:

☐ CHECK IF THIS IS A **CLASS ACTION** UNDER F.R.C.P. 23

DEMAND $

CHECK YES only if demanded in complaint:
JURY DEMAND: ☒ Yes ☐ No

VIII. RELATED CASE(S) IF ANY (See instructions): JUDGE _____ DOCKET NUMBER _____

DATE
08/06/2013

SIGNATURE OF ATTORNEY OF RECORD
s/Russell L. Leonard

FOR OFFICE USE ONLY

RECEIPT # _____ AMOUNT _____ APPLYING IFP _____ JUDGE _____ MAG. JUDGE _____

AO 440 (Rev. 12/09) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

Middle District of Tennessee

Walter Glen Grant and wife, Pamela Gamble Grant

Plaintiff

v.

St. Jude Medical, Inc., & Pacesetter d/b/a St. Jude Medical Cardiac Rhythm Management Division

Defendant

Civil Action No. 3-13 0782

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* Pacesetter d/b/a St. Jude Medical Cardiac Rhythm Management Division
CT Corporation System
o/b/o Pacesetter, Inc.
818 West Seventh Street
Los Angeles, CA 90017

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are:

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

KEITH THROCKMORTON

CLERK OF COURT

AUG 07 2013

Date: _____

_____
Signature of Clerk or Deputy Clerk

AO 440 (Rev. 12/09) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

Middle District of Tennessee

Walter Glen Grant and wife, Pamela Gamble Grant

Plaintiff

v.

St. Jude Medical, Inc., & Pacesetter d/b/a St. Jude Medical Cardiac Rhythm Management Division

Defendant

Civil Action No. 3-13 0782

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* St. Jude Medical, Inc.
CT Corporation System
800 South Gay Street, Suite 2021
Knoxville, TN 37929-9710

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are:

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

KEITH THROCKMORTON
CLERK OF COURT

AUG 07 2013

Date: _____

_____
Signature of Clerk or Deputy Clerk