

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF MINNESOTA**

In Re: Medtronic, Inc., Sprint Fidelis  
Leads, Products Liability Litigation

Court File No. 08-md-1905 (RHK/JSM)

This pleading applies to:  
ALL ACTIONS

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**MASTER CONSOLIDATED COMPLAINT FOR INDIVIDUALS  
JURY DEMAND**

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**I. INTRODUCTION**

1. Plaintiffs bring this Master Consolidated Complaint for Individual Plaintiffs pursuant to PTO No. 4 for various claims against Medtronic and its affiliates related to the marketing and sale of Sprint Fidelis leads. Because the United States Food and Drug Administration (the "FDA") issued a Class I recall related to these leads, they can no longer be legally marketed in the United States and therefore any FDA approval related preemption no longer applies to Plaintiffs' claims. Pursuant to Fed. R. Civ. P. 11(b)(3), Plaintiffs' allegations have evidentiary support or will likely have evidentiary support after a reasonable opportunity for further investigation or discovery.

2. Medtronic designs, manufactures, and markets a variety of medical devices to treat heart conditions including implantable cardiac defibrillators ("ICDs"). ICDs are designed to be implanted primarily under the skin of the chest wall and wires called leads

are inserted through a major vein and attached directly to the muscle on the inside of the heart and the ICD. 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 to abort a dangerous "over-drive pace," a very rapid rhythm, or pace the heart at a normal rhythm if an irregularity is detected.

3. This Master Complaint seeks recovery for patients who have been implanted with, and suffered injury from, Sprint Fidelis Leads marketed by Medtronic under the following model numbers:

- (i) the 6949 LFJ extendable/retractable screw fixation (S) model,
- (ii) the 6948 LFH tuned fixation (T) model,
- (iii) the 6931 LFT S fixation, and,
- (iv) the 6930 LFK T fixation

(collectively "Sprint Fidelis Leads"). The Class I recall regarding the Sprint Fidelis Leads affects approximately 268,000 patients worldwide, including 172,000 Sprint Fidelis Lead implants in the United States.

4. In 2004, Medtronic introduced and marketed the Sprint Fidelis Leads to replace the Sprint Quattro Secure Lead Model 6947 ("Quattro Leads") previously marketed by Medtronic. When introducing the Sprint Fidelis, Medtronic represented that the Sprint Fidelis Leads were smaller and more effective for patients with ICDs, that "[t]he small size of the Sprint Fidelis (Fidelis is a Latin word that means 'faithful') helps improve passage into a patient's venous system for an easier implant, and minimizes venous obstruction" and that the Sprint Fidelis Leads were based on the "proven" design

of the Transvene and Quattro Leads, although it knew that it made significant changes in the design and manufacturing processes and failed to adequately advise the FDA of these significant changes. Contrary to Medtronic's representations, the Sprint Fidelis Leads are prone to an unprecedented failure rate for high voltage leads used with ICDs.

5. At all relevant times, Medtronic knew or should have known that the devices were not safe for the patients who received them because of the unacceptable failure rate. Notwithstanding, Medtronic continued to sell the leads for implantation in patients until October 15, 2007, when the Sprint Fidelis Leads were removed from the market pursuant to a recall. Plaintiffs in whom the Sprint Fidelis Leads remain implanted, not only have suffered physical injuries, they also bear an unacceptable increase in the risk of fracture, resulting in further injury and possible death.

## **II. PARTIES**

### **A. Plaintiffs**

6. Pursuant to PTO No. 4, this Master Consolidated Complaint for Individual Plaintiffs is brought on behalf of all Plaintiffs who had Sprint Fidelis Leads implanted. All Plaintiffs suffered physical injury including but not necessarily limited to death, emergency and additional surgeries to remove or replace the defective leads, unnecessary shocking, and various physical manifestations of extreme emotional distress.

### **B. Defendants**

7. Defendant Medtronic, Inc. is a Minnesota corporation, with its principal place of business at 710 Medtronic Parkway, Minneapolis, Minnesota 55432. Medtronic designs, manufactures and markets medical devices worldwide. Medtronic's Cardiac

Rhythm Disease Management Division (“CRM Division”) which is primarily responsible for Medtronic’s ICDs, and leads, including the Sprint Fidelis Leads are principally conducted out of its facilities at Cardiac Rhythm Disease Management at 7000 Central Ave., Minneapolis, Minnesota 55432.

8. Defendant Medtronic International Technology, Inc. (formerly known as Medtronic Puerto Rico, Inc.) is a Minnesota corporation, with its principal place of business at Road 149, km 56.3, Box 6001 Villalba, PR.

9. Defendant Medtronic Puerto Rico Operations Co. is a corporation existing by virtue of the laws of the Cayman Islands, with its principal place of business at Road 149, km 56.3, Box 6001 Villalba, PR.

10. Medtronic International Technology, Inc. and Medtronic Puerto Rico Operations Co. are wholly owned subsidiaries of Medtronic, Inc., which formulate, develop, manufacture and sterilize the devices at issue in this lawsuit.

11. 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 Medtronic 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**

12. The Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1332(a).

13. Venue is proper under 28 U.S.C. §§ 1391 (a) and (c). Medtronic, Inc. has its headquarters in this District and all Defendants earn substantial compensation and

profits from sales of Sprint Fidelis Leads in this District

#### IV. FACTUAL ALLEGATIONS

##### A. History Of The Heart Devices

14. In 1980, termination of human arrhythmias with ICDs was reported in the New England Journal of Medicine. Thereafter, a number of devices were designed and approved 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.

15. ICDs consist of a generator, a processor, and a lead. The lead acts 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.

16. 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

fractured wires, bending, 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.

17. ICD lead diameters are measured using the French Catheter Scale.

Medtronic's ICD leads became progressively smaller over time. The lead body for Medtronic's leads before the Sprint Fidelis Leads measured between 7.5Fr (2.5 mm) for the Transvene 6937A model and 8.6Fr (2.8 mm) for the Sprint Quattro 6947 model. Released for sale in 2004, the Sprint Fidelis Leads were considerably smaller than Medtronics' prior leads, measuring only 6.6Fr (2.1 mm) in diameter.

**B. History of The Sprint Fidelis Leads**

18. On or about April 1, 1992, Medtronic, Inc. submitted an Application for Pre-Market Approval ("PMA") to the FDA for approval to manufacture and market a lead system, known as the Medtronic Transvene Lead System. In December 1993, the FDA approved PMA (P920015) pursuant to expedited review.

19. Following approval of the original Transvene lead, Medtronic submitted dozens of supplements to the PMA (P920015), seeking FDA approval of various changes. In 1996, FDA approved lead model 6937, transvene superior vena cava lead (S005).

20. Among the PMA supplements submitted by Medtronic were approvals for lead models 6942 (S012), 6943 and 6945 (S013). In 2001, Medtronic began marketing its then-smallest defibrillation leads known as Sprint Quattro 6947, which were approved for sale pursuant to a supplement to PMA (P920015) in October 2001. In December 2001, the FDA approved a PMA supplement (S017) to market the Sprint Quattro lead

6944.

21. The Sprint Fidelis Leads were not approved under a separate PMA from the FDA. On or about November 6, 2003, Medtronic submitted a PMA supplement for the Sprint Fidelis Leads 6949 and 6931 (S029). On or about December 22, 2003, Medtronic submitted a PMA supplement for the Sprint Fidelis Leads 6948 and 6930 (S030). Both of these supplements were approved by the FDA on June 8, 2004. In its applications, Medtronic represented that the Sprint Fidelis Leads were based on Transvene and Quattro lead technology, and that the leads were intended for “long-term use” in the human body. The FDA described the changes as relating to a “polyurethane overlay.”

22. Even though the Sprint Fidelis Leads represented a distinct departure from earlier lead models, the application was based upon inadequate testing, including reliance entirely on “bench” testing, without any consideration of how the lead would actually function in the human body.

23. Based on Medtronic’s representation that the Sprint Fidelis Leads were based on the Transvene and Quattro lead technology, were substantially similar to the previously approved Transvene and Quattro leads, and were safe and effective, the FDA approved the Sprint Fidelis Lead PMA Supplements subject to certain express conditions.

24. Although Medtronic was aware that the Sprint Fidelis Leads were a significant departure from the Transvene and Quattro lead technology and that the Sprint Fidelis Leads manifested various issues that would affect their effectiveness and longevity, Medtronic, in violation of FDA regulations, withheld this information from the FDA, during the PMA supplement process. Accordingly, the issues that arose with the

Sprint Fidelis Leads became known to the medical community only after the FDA's approval of the Sprint Fidelis PMA Supplements. Such issues were only known to Medtronic and not the FDA at the time of such approval, and the FDA could not and did not approve the safety and efficacy of the Sprint Fidelis Leads with knowledge of such information.

25. Medtronic hampered the FDA's review by failing to timely, and meaningfully, report serious injuries and/or deaths that the Sprint Fidelis Leads had, or may have, caused or contributed to causing.

26. Medtronic must comply with the Food, Drug & Cosmetic Act and the Medical Devices Amendment thereto (the "Act") and applicable regulations including post-approval requirements. Among other things, Medtronic is required to continually evaluate the safety, effectiveness and reliability of Sprint Fidelis Leads and to detect, correct, report, and warn of defects in a timely manner. Medtronic failed to do so, in violation of the Medical Devices Act and regulations promulgated thereunder.

**C. Design & Manufacture Of The Sprint Fidelis Leads**

27. Medtronic's original coaxial leads passed through a 12Fr. introducer. Later generation smaller multilumen leads passed through a 10.5Fr introducer. The Sprint Quattro 6947 has an 8.2Fr. diameter that passes through a 9Fr introducer. The Sprint Fidelis Leads are 6.6Fr and pass through a 7Fr. introducer.

28. The outer core of the lead is polyurethane (80A) overlay, with an inner core, a centrally located pace-sense conduction coil, and three single and non-redundant conductor cables. One cable is a high voltage RV lead, another is the pace-sense anode

cable, and the third is the high voltage SVC coil.

29. Each of the cables is wrapped in a silicone rubber inner cover and the Sprint Fidelis Lead is encased in a polyurethane outer cover.

30. The Sprint Fidelis Lead cables are single MP35N alloy cables that are connected to Platinum-Iridium (pt/ir) anode ring electrodes or other components by direct resistance spot welding.

31. The design of the Sprint Fidelis eliminated a crimped coupler present in the previous generation of Sprint Quattro that supported the connection of the cables to the electrodes. Instead, the Sprint Fidelis Leads relied solely upon the direct resistance spot welding of two different metals to affix the lead cables.

32. The welding required to affix the Sprint Fidelis Lead cables can damage the fine, small wires in the cables. The welding techniques used were inadequate and resulted in damage to the cables in many Sprint Fidelis Leads.

33. The damage to the small wires of the Sprint Fidelis Lead cables has caused cable wire fractures near to, or at, the weld site in Sprint Fidelis Leads, particularly in areas where there is significant bending and/or flexing of the leads.

34. Medtronic knew that direct-resistance spot welding of dissimilar metals was fraught with issues of weakness and fragility, and that manufacturing of the Sprint Fidelis Leads would require, at a minimum, an enhanced level of accuracy and quality assurance to ensure adequate welding of the cables. Instead, Medtronic failed to take adequate steps to ensure the quality of the welding in the Sprint Fidelis Leads.

35. Medtronic hid the likelihood of damage to the Sprint Fidelis Leads due to

inadequate welding from the FDA and Plaintiffs.

36. Medtronic failed to recognize the deficiencies of the Sprint Fidelis Leads due to poor and inadequate quality assurance procedures, including failure of Medtronic to implement appropriate physical, manual, x-ray, microscopic and other inspections of the Sprint Fidelis Leads.

37. During the time Medtronic manufactured the Sprint Fidelis Leads at its Puerto Rican facilities, inadequate manufacturing processes were implemented that virtually ensured that all cables were damaged.

38. During the course of manufacturing the Sprint Fidelis Leads, Medtronic failed in several ways, including by:

- (a) failing to conduct adequate electrical and mechanical testing on components, subassemblies and/or finished Sprint Fidelis Leads;
- (b) failing to test an adequate number of sample devices on an ongoing basis;
- (c) failing to take adequate steps to specifically identify failure modes with clarity and suggest methods to monitor, avoid, and/or prevent further failures of the lead wires;
- (d) failing to identify and/or note the significance of any testing that resulted in failure of the Sprint Fidelis Leads;
- (e) failing to take corrective actions to eliminate or minimize further failures of the Sprint Fidelis Leads;

- (f) failing to adequately explain performance specifications for Sprint Fidelis Lead components, subassemblies, and finished leads;
- (g) failing to adequately explain or justify all test conditions and acceptance criteria for the Sprint Fidelis Leads;
- (h) failing to perform adequate testing in an environment that adequately simulated in vivo conditions;
- (i) failing to perform adequate quality assurance testing before and after sterilization as follows:
  - (1) to verify the electrical continuity of each conduction path to comply with specifications;
  - (2) to determine the strength of each bond, joint, weld, in the lead as well as the composite lead strength;
  - (3) to determine corrosion resistance of all conductors and electrodes, joints, welds or bonds; and
  - (4) to determine fatigue resistance of the conductors, lead transition zones, and other portions of the lead, including fatigue resistance with respect to physiological conditions such as ranges of motion and stresses.

39. Medtronic failed to perform adequate testing of the Sprint Fidelis Leads, including the lead connectors and connections, to ensure that the leads would withstand the mechanical forces that might occur during and after implantation.

**D. Sprint Fidelis Lead Defects Are Exposed By Physicians**

40. Upon approval of the Sprint Fidelis Leads, relying upon Medtronic's representations about the "state-of-the-art" nature and ease-of-use of the Sprint Fidelis Leads, physicians began broadly using the Sprint Fidelis Leads instead of other lead models (including the Quattro). Reports of Sprint Fidelis malfunctions soon followed. It is now apparent that a significant percentage of the Sprint Fidelis Leads have potentially fatal defects.

41. In order to track performance of the Sprint Fidelis Leads, Medtronic engaged in a post-marketing study that purported to find that 1.1% of Sprint Fidelis Leads failed within two years of implantation. That study was flawed for many reasons. Members of Medtronic's advisory committee of outside doctors recognized that the study was not sufficient to provide a conclusion about the performance of the Sprint Fidelis Leads. Medtronic nevertheless relied upon this flawed study to avoid disclosing Sprint Fidelis defects to patients and physicians.

42. The electrophysiological community began to suspect there was an endemic problem with the Sprint Fidelis Leads in around late 2006 into early 2007.

43. In January 2007, Dr. Robert G. Hauser of the Minneapolis Heart Institute ("MHI"), identified several patients who had received inappropriate shocks from Sprint Fidelis Leads. Despite the failure of Medtronic to disclose issues with the Sprint Fidelis Leads, Dr. Hauser and other physicians at MHI began noticing that their patients were complaining that they were being jolted with many unnecessary and painful shocks. When they received complaints from two such patients within two days, doctors at MHI

began to research similar incidents across their patient population. That research identified that the Sprint Fidelis Leads were a common link between the patients at MHI who had experienced inappropriate shocks. Thereafter, the doctors concluded that several of MHI's patients had suffered inappropriate shocks because of broken wires in their Sprint Fidelis Leads. Within days, the doctors notified Medtronic of their concern that the Sprint Fidelis Leads were unsafe and advised Medtronic that they therefore would stop implanting Sprint Fidelis Leads.

44. Simultaneously, Medtronic launched a \$100 million advertising campaign for its ICD products, with full knowledge and intention that the vast majority of Medtronic ICDs would be implanted with Sprint Fidelis Leads.

45. In February 2007, Dr. Hauser and several other physicians from MHI met with Medtronic Vice President Warren Watson and a Medtronic engineer, to explain that the Sprint Fidelis Leads were exhibiting serious problems.

46. Medtronic responded by defending the Sprint Fidelis Leads and blaming the doctors' implantation techniques. Medtronic claimed that the doctors' data was insufficient and also incorrectly asserted that the failure rate of Sprint Fidelis Leads was 0.15%, when the failure rate was, in fact, much higher. Moreover, even at 0.15%, the purported Sprint Fidelis Lead failure rate was three times higher than the failure rate that Medtronic acknowledged in the Quattro model.

47. Dr. Hauser advised Medtronic that he was preparing to submit a report to the Heart Rhythm Society for publication on an expedited basis to address this serious potential public health concern. Medtronic sought to persuade Dr. Hauser to withhold

publishing his data by, among other things, offering money and/or funding for research surrounding the data in order to delay Dr. Hauser's publication of the information, and took additional steps to prevent Dr. Hauser from going public with his data.

48. After receiving word of the MHI data regarding lead failures, Medtronic immediately retained physicians to refute the data generated by Dr. Hauser and MHI that was about to be published, and throughout February 2007, Medtronic took steps to undermine the credibility of Dr. Hauser's data and findings.

49. Dr. Hauser and the MHI doctors proceeded to conduct and publish a more broad study of the incidence of failures in the Sprint Fidelis Leads compared to the Sprint Quattro leads. According to the report, prepared by Dr. Hauser, et al., which was provided to Medtronic and was published in the Heart Rhythm Society Journal in the Spring of 2007, "Early Failure of Small-Diameter High-Voltage Inflammable Cardioverter-Defibrillator Lead", Heart Rhythm Society 2007.03.041 (2007) ("Early Failure"), the Sprint Fidelis Lead was much more likely to fail than the Quattro lead.

50. MHI's experience reflected that, between September 2004 and February 2007, 583 patients were implanted with Sprint Fidelis Model 6949 leads, and nine patients received other Sprint Fidelis models. During that time, six patients experienced Sprint Fidelis Model 6949 lead failures. The failed Sprint Fidelis Model 6949 leads had been implanted by various electrophysiologists, cardiologists and thoracic surgeons. The average time to failure was fourteen months (based on a range of four to twenty-three months).

51. The study compared the survival of the 583 Sprint Fidelis Model 6949

leads implanted at the MHI to the survival of 285 Sprint Quattro Model 6947 leads implanted at the MHI between November 2001 and March 2007. The difference in survival between the Sprint Fidelis Model 6949 lead and the Sprint Quattro Secure Model 6947 lead was extremely significant. The failure rate for the Sprint Fidelis Model 6949 lead was 1-2% during the first two years of implant and was ten times greater than the failure rate for the Sprint Quattro Secure Model 6947 lead.

52. Another study, conducted at Cornell University Medical Center by Sunil Mirchandani, et al., at around the same time found “(a) 17% incidence of abnormal right ventricular sensing during follow-up of patients implanted with the Medtronic Sprint Fidelis ICD lead,” necessitating “an early revision of the system in 4% of patients.”

53. Medtronic maintained that the Sprint Fidelis Lead fractures were not “statistically significant.” It issued a notice to physicians on March 21, 2007, in the form of a “Dear Doctor” letter that disclosed that “Medtronic has received reports from a limited number of implanting physicians indicating that they have experienced higher than expected conductor fracture rates in . . . Sprint Fidelis Leads.” Medtronic claimed to be investigating reports of lead failures, however, still falsely represented that the Sprint Fidelis Leads were performing consistent with, and “in line with other Medtronic leads . . . . And consistent with lead performance publicly reported by other manufacturers.”

54. This letter suggested that the Sprint Fidelis Lead fractures were the result of poor implantation techniques and stated that, “[f]or conductor fractures that occur around the suture sleeve, our preliminary investigation suggests that under certain implant techniques, the lead appears to be exposed to severe bending or kinking in the pectoral

area.” Medtronic also wrote that the fractures and failures were the result of implanter physicians being “too rough with the implant or too tight with the sutures.”

55. At no time did Medtronic warn physicians that the Sprint Fidelis Leads must be specially handled during the implantation procedure or that they could “severely bend” or “kink” if they are implanted using certain accepted implant techniques.

56. Around this time, although Medtronic still maintained that there were no issues with Sprint Fidelis Leads, other doctors began to stop implanting them. Even still, Medtronic continued to market the leads to unsuspecting physicians and patients, selling tens of thousands of units between February and October 2007.

57. In April 2007, Dr. Hauser published his data in the Journal of the Heart Rhythm Society, HEART RHYTHM, indicating that the Sprint Fidelis Leads had a higher than expected failure rate. Medtronic, through two members of its Medical Advisory Board, published criticisms of Dr. Hauser’s data.

58. Despite its efforts to refute Dr. Hauser’s findings, Medtronic in fact knew that changes were required to the Sprint Fidelis Leads. Accordingly, Medtronic submitted an application to the FDA for design and manufacturing changes to “improve the df-1 leg strength and handling characteristics of Sprint Fidelis Leads” on May 15, 2007. Just as Medtronic did with the recall of its Marquis family of ICDs with defective batteries, Medtronic made claims to the FDA of the leads’ increased robustness, but withheld all information that its leads were failing and causing public health crisis. Medtronic’s PMA Supplement was approved in July 2007, and while Medtronic may be presumed to have implemented the changes at that time, already-manufactured Sprint

Fidelis Leads were not recalled and continued to be shipped, remained in hospital inventories, and continued to be implanted.

59. On July 19, 2007, Dr. Hauser met with Medtronic officials again to urge Medtronic to stop selling the Sprint Fidelis Leads. Medtronic's Vice President for quality and regulatory affairs, Reggie Groves, declined to adopt Dr. Hauser's recommendations and, instead, referred to a Medtronic PowerPoint presentation that purported to explain that the incidence of fractures in the Sprint Fidelis Leads was "not statistically significant" (although such lead failure can lead to serious injury or death).

60. Throughout 2007, while Sprint Fidelis Leads were being implanted in patients across the United States and around the world, Medtronic was accumulating mounting and overwhelming reports that the Sprint Fidelis Leads were failing at an alarming and undisclosed rate.

61. Medtronic knew that it faced serious issues with defective Sprint Fidelis Leads. It had determined that at least five deaths since August 2006 were potentially linked to Sprint Fidelis failures and also that the Sprint Fidelis overall failure rate was at least 2.3% after 30 months on the market. That failure rate was higher than the failure rate of a Quattro model and also higher than anything Medtronic had previously disclosed.

62. On or around September 10, 2007, belatedly and in violation of Federal regulations, Medtronic filed more than 120 adverse event reports with the FDA regarding Sprint Fidelis Leads.

63. On October 7, 2007, top Medtronic executives met and decided to suspend

sales of Sprint Fidelis Leads. Following that October 7, 2007 decision, Sprint Fidelis Leads continued to be implanted in patients across the country including patients who experienced lead failures.

**E. Recall Of The Sprint Fidelis Leads**

64. Just after midnight on October 15, 2007, Medtronic announced a worldwide recall of all Sprint Fidelis Lead models. Physicians were notified to stop using the Sprint Fidelis Leads and return all remaining Sprint Fidelis Leads to Medtronic.

65. Shortly thereafter, the FDA issued a Class I Recall of the Sprint Fidelis Leads. Class I Recalls are the most serious type of medical device recall and involve situations in which there is a reasonable probability that the use of the produce will cause serious injury or death.

66. In its announcement, Medtronic advised patients with Sprint Fidelis Leads to contact their physicians immediately for reprogramming of their ICDs in order to be more sensitive to potential lead fractures, a service for which patients could be charged by their physicians.

67. In addition, physicians recommended that some patients sign up for Medtronic's monitoring system, called CareLink, in order to attempt to monitor whether fractures could appear in the leads. Patients could also be charged for this service. This system is not available to many patients who have Sprint Fidelis Leads connected to non-Medtronic ICDs.

68. Medtronic indicated that it would not compensate patients or physicians for the additional medical care required to monitor the Sprint Fidelis Leads unless a Sprint

Fidelis Lead actually fractured, in which case Medtronic would offer a new lead system plus \$800 toward unreimbursed medical expenses relating to extraction/capping surgery, which typically costs well above \$10,000. Thereafter, Medtronic extended the same offer to any patient who had a Sprint Fidelis Lead extracted due to the recall.

69. As of January 2007, approximately 144,311 Sprint Fidelis Model 6949 leads; 7,510 Model 6948 leads; 5,387 Model 6931 leads; and 236 Model 6930 Sprint Fidelis Leads had been implanted. As of October 2007, it was estimated that 257,000 of these leads remained implanted.

**F. The Sprint Fidelis Lead Defect And Failure Rates**

70. By October 2007, Medtronic was aware of at least 665 chronic fractures in returned Sprint Fidelis Leads and that they exhibited significantly reduced lead survival of no more than 97.7% at 30 months compared to Medtronic's predecessor lead, the Sprint Quattro, which had a 99.1% survival rate.

71. Medtronic was aware that the Sprint Fidelis Lead survival rate was unacceptable as compared to industry failure rates, and that failure rates of Sprint Fidelis Leads implanted in children were high, with a survival rate of no more than 98.4% at 30 months.

**G. Medical Monitoring**

72. Medtronic's safety advisory recommended (and continues to recommend) pace-sense (P/S) conductor impedance monitoring and ventricular fibrillation (VF) detection adjustments to reduce the likelihood that a patient would receive inappropriate therapies when a fracture occurred or occurs.

73. Medtronic contends that impedance monitoring may also detect a fracture of the high-voltage conductor and has recommended programming alerts to pre-empt Sprint Fidelis Lead malfunction due to fracture.

74. Presently, it is recognized that impedance monitoring for detecting impending Sprint Fidelis Lead failure and for preventing adverse clinical events such as inappropriate shocks is failing.

75. Studies that have focused on the monitoring recommendations made by Medtronic have found them to be inadequate. A recent study by doctors, including Dr. Hauser, has concluded that CareLink and the Medtronic-recommended reprogramming are not adequate to protect most patients from the adverse effects of the defective Sprint Fidelis Leads, which can include massive and painful shocks which, in and of themselves, can alter an otherwise normal heart rhythm to trigger further damage or death. *See* “Failure of impedance monitoring to prevent adverse clinical events caused by fracture of a recalled high-voltage implantable cardioverter-defibrillator lead,” Linda M. Kallinen, BS; Robert G. Hauser, MD, FHRS; Ken W. Lee, MD; Adrian K. Almquist, MD; William T. Katsiyannis, MD; Chuen Y. Tang, MD; Daniel P. Melby, MD; & Charles C. Gornick, MD (published in Heart Rhythm, June 8, 2008).

76. Plaintiffs have suffered repeated shocks and fractures, after the enhanced monitoring system was in place, and the monitoring failed. Plaintiffs suffered these shocks and fractures without any alarm sounding from this purportedly “enhanced” monitor.

77. Pace-sense conductor impedance monitoring as currently implemented does

not reliably forewarn patients of a lead malfunction. Consequently, patients who have Sprint Fidelis Leads remain at risk for additional physical injury and adverse clinical events associated with pace-sense conductor fracture.

78. Upon information and belief, an article is being published in a peer reviewed journal describing this phenomenon of inappropriate therapy and inadequacy of the Medtronic monitoring recommendations and recommending that more aggressive monitoring be considered and recommended.

79. It is believed by the medical community and the pacing community, in particular, that additional programming measures are needed to detect lead fractures before inappropriate therapy is administered and therefore Medtronic is responsible to Plaintiffs for all costs associated with medical monitoring to detect lead failure and fracture.

**H. The Regulatory Approval Process**

80. 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).

81. 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. Medtronic failed to comply with the Act and the regulations in its filing for and responses to inquiries made by the FDA as part of the PMA Supplement process.

82. A device may not be manufactured, packaged, stored, labeled, distributed, or advertised in a manner that is inconsistent with any conditions to approval specified in the PMA approval for that device. Failing to comply with the conditions submitted and approved in the PMA or PMA supplement may cause the device to be considered adulterated and/or misbranded.

**I. Federal Regulations Prescribing Requirements Which Medtronic Violated – Background**

83. Federal regulations state: “Recall classification means the numerical designation, i.e., I, II or III, assigned by the Food and Drug Administration to a particular product recall to indicate the relative degree of health hazard presented by the product being recalled.” 21 CFR §7.3 (m).

84. Pursuant to federal law, a device is deemed to be adulterated if, among other things, it fails to meet established performance standards, or if the methods, facilities or controls used for its manufacture, packing, storage or installation are not in conformity with federal requirements. See, 21. U.S.C. §351.

85. Pursuant to federal law, a device is deemed to be misbranded if, among other things, its labeling is false or misleading in any particular, or if it is dangerous to

health when used in the manner prescribed, recommended or suggested in the labeling thereof. See, 21 U.S.C. §352.

86. Pursuant to federal law, Medtronic is required to comply with FDA regulation of medical devices, including FDA requirements for records and reports, in order to prohibit introduction of medical devices that are adulterated or misbranded, and to assure the safety and effectiveness of medical devices. In particular, Medtronic was required to record and make reports if any medical device may have caused or contributed to death or serious injury, or if the device has malfunctioned in a manner likely to cause or contribute to death or serious injury.

87. Pursuant to FDA regulations, Medtronic was required to report to the FDA adverse events associated with a medical device within 30 days after it became aware that a device may have caused or contributed to death or serious injury, or that a device has malfunctioned and would be likely to cause or contribute to death or serious injury if the malfunction was to recur. Such reports must contain all information reasonably known to Medtronic, including any information that can be obtained by analysis, testing, or other evaluation of the device, and any information in the Medtronic's possession. In addition, Medtronic is responsible for conducting an investigation of each adverse event, and must evaluate the cause of the adverse event. 21 CFR §803.50.

88. Pursuant to FDA regulations, Medtronic as a manufacturer of medical devices must also describe in every individual adverse event report whether remedial action was taken in regard to the adverse event, and whether the remedial action was reported to the FDA as a removal or correction of the device. 21 CFR §803.52.

89. Pursuant to federal regulations, Medtronic must report to the FDA in 5 business days after becoming aware of any reportable MDR event or events, including a trend analysis that necessitates remedial action to prevent an unreasonable risk of substantial harm to public health. 21 CFR §803.53.

90. Pursuant to federal regulations, Medtronic must report promptly to the FDA any device corrections and removals, and maintain records of device corrections and removals. FDA regulations require submission of a written report within ten working days of any correction or removal of a device initiated by the manufacturer to reduce a risk to health posed by the device, or to remedy a violation of the Act caused by the device which may present a risk to health. The written submission must contain, among other things, a description of the event giving rise to the information reported and the corrective or removal actions taken, and any illness or injuries that have occurred with use of the device, including reference to any device report numbers. Medtronic was required to indicate the total number of devices manufactured or distributed which are subject to the correction or removal, and provide a copy of all communications regarding the correction or removal. 21 CFR §806.

91. Pursuant to federal regulations, Medtronic was required to comply with specific quality system requirements promulgated by the FDA. These regulations require Medtronic to meet design control requirements, including but not limited to conducting design validation to ensure that devices conform to defined user needs and intended uses. Further, Medtronic was required to meet quality standards in manufacture and production; to establish and maintain procedures for implementing corrective actions and

preventive actions, and investigate the cause of nonconforming product and take corrective action to prevent recurrence; to review and evaluate all complaints and determine whether an investigation is necessary; and was required to use statistical techniques where necessary to evaluate product performance. 21 CFR §820.

92. Pursuant to federal regulations, Medtronic was required to report to the FDA, through a PMA Supplement, any new indications for use of a device, labeling changes, or changes in the performance or design specifications, circuits, components, ingredients, principle of operation or physical layout of the device.

**J. Medtronic's Violations Of Medical Device Reporting Regulations and Knowledge Of Defects**

93. The federal regulations also include specific device reporting requirements for manufacturers, importers, and distributors. For example, serious injuries and/or deaths that a device has or may have caused, or contributed to, must be reported on a timely basis. Medtronic failed to meet those requirements.

94. Medtronic was acutely aware of the potentially life-threatening defects manifested in the Sprint Fidelis Leads for months, if not years, before the October 2007 recall. Medtronic, however chose not to timely issue a "firm-initiated recall," change its label to increase the warnings, and/or warn the FDA, doctors or patients of the defect.

95. Medtronic was required to timely self-report adverse events through the FDA's medical device reporting ("MDR") system. These MDR regulations are designed to assist the FDA in protecting "the public health by helping to ensure that devices are...safe and effective for their intended use." Medtronic was required to make an FDA

report “no later than 30 calendar days” after it “become[s] aware of information, from any source, that reasonably suggests that a device [it] market[s] ...has malfunctioned and this device or a similar device that [it] market[s] would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur....”

96. Further, Medtronic was required to conduct an investigation of each event involving Sprint Fidelis Leads and evaluate the cause of the event. In certain instances, such as when a reportable event necessitates remedial action to prevent an unreasonable risk of substantial harm to the public health, Medtronic was required to file a report with FDA within five days. Medtronic failed to comply with this regulation.

97. On July 3, 2007, the FDA directed a “Warning Letter” to Medtronic’s Chairman and CEO relating to Medtronic’s Neuromodulation and identifying violations of Federal Regulations which included: “[f]ailure to implement complaint handling procedures to ensure that all complaints are evaluated to determine whether the complaint represents an event that must be filed as a Medical Device report under 21 C.F.R. Part 803, as required by 21 C.F.R. 820.198(a)(3) and “[f]ailure to submit MDR reports within 30 days of receiving or otherwise becoming aware of information that reasonably suggests that a marketed device may have caused or contributed to a death or serious injury, as required by 21 C.F.R. 803.50(a)(1).” The Warning Letter confirmed that Medtronic’s procedures resulted in violations of the MDR regulations because Medtronic improperly interpreted the MDR regulations. The Warning Letter further provided, in part that the regulatory violations found by the FDA “may be symptomatic of serious underlying problems in [Medtronic’s] manufacturing and quality assurance systems.”

98. Similarly, the Warning Letter's observation of underlying problems in Medtronic's manufacturing and quality systems was correct as to the systems Medtronic implemented with respect to the Sprint Fidelis Leads, including that Medtronic also violated the MDR regulations relative to the Sprint Fidelis Leads.

99. As with its neuromuscular products Medtronic analyzed some of the leads that were returned to company and did not comply with regulations regarding analysis and reporting.

100. Medtronic's representations to physicians and the public regarding the consistent performance of Sprint Fidelis Leads were untrue in light of the reported experience with the leads, the various problems highlighted in the FDA's MAUDE database of complaints/issues reported to the FDA, and the information independently brought to Medtronic by concerned doctors regarding the dangerous propensities of the Sprint Fidelis Leads, all of which were known and/or knowable by Medtronic.

101. At all relevant times, Medtronic misrepresented the safety of the Sprint Fidelis Leads and negligently manufactured, marketed, advertised, promoted, sold, and distributed the leads as safe devices to be used together with ICDs.

102. At all relevant times, Medtronic failed to timely and adequately warn the FDA, doctors and patients of the defects inherent in the Sprint Fidelis Leads and that they were prone to cause inappropriate shocks and to fracture.

103. At all relevant times, Medtronic failed to manufacture and inspect the Sprint Fidelis Leads in a manner consistent with, and as prescribed by the FDA-approved specifications for manufacture and inspection of the Sprint Fidelis Leads.

104. At all relevant times, Medtronic failed to adhere to, and otherwise comply with FDA regulations in the manufacture, inspection, distribution, shipment, and sale of the Sprint Fidelis Leads.

**K. Medtronic's Improper Failure To Recall Sprint Fidelis Leads**

105. Under federal regulations, a recall is: "a firm's removal or correction of a marketed product that the Food and Drug Administration considers to be in violation of the laws it administers and against which the agency would initiate legal action, e.g., seizure." A recall is an effective method of removing or correcting consumer products that are in violation of laws administered by the FDA.

106. These sections also recognize that recall is an alternative to an FDA-initiated court action for removing or correcting violative, distributed products by setting forth specific recall procedures for the Food and Drug Administration to monitor recalls and assess the adequacy of a firm's efforts in recall. A company's voluntary recall of a medical device and the FDA's classification of that action as a Class I recall establish that the device violates FDA regulations.

107. In connection with the Sprint Fidelis recall, the FDA publicly stated that it considers Medtronic's action to be a product recall, as defined by FDA regulations, and on October 15, 2007, classified the recall as a Class I, potentially life threatening, recall. At all relevant times to this action, Medtronic's delayed recall of the Sprint Fidelis Leads constituted a violation of the FDA regulations.

**L. Medicare Secondary Payer Act Claims**

108. Pursuant to the MSP, Medtronic is a "primary payer" directly responsible to

Medicare for the reimbursement of health care costs resulting from the recalled Sprint Fidelis Leads. As alleged herein Medtronic has, to date, avoided these reimbursement obligations to the Medicare program. Moreover, Medtronic has effectively caused the Medicare program to pay the costs of Medtronic's obligations as warrantor of the recalled Sprint Fidelis Leads, which is an excessive burden on the Medicare program in diametric opposition to the MSP statute. Medtronic has wrongfully caused and is causing the overburdened Medicare system to absorb the substantial health care expenses associated with its recalled Sprint Fidelis Leads.

109. Congress, pursuant to 42 U.S.C. Section 1395y(b)(3)(A), has expressly authorized private parties, such as Plaintiffs, to bring a suit for damages against an entity, like Medtronic, and requires payment of all the health care costs incurred by Medicare on behalf of Plaintiffs in connection with the recalled Sprint Fidelis Leads and expressly authorizes a private action for the recovery of damages in an amount twice that of the health care costs paid by Medicare, which should have been paid by Medtronic. Plaintiffs seek the recovery of such damages in this action. Medtronic is a primary payer under MSP's first party insurer provisions. Medtronic has or will make payment of out-of-pocket expenses as part of its warranty programs. Medtronic has either knowledge or constructive knowledge that some of the recipients of such funds had received ICD-related medical treatment for which Medicare already paid. As a result, Medtronic is liable to reimburse the government pursuant to MSP.

110. Medtronic is a primary payer under MSP's third party tortfeasor insurer provisions. Medtronic carries liability insurance, or is self-insured, from which a

payment can reasonably be expected to be made.

111. Medtronic is responsible to pay double damages for every dollar expended by Medicare for costs associated with the implantation and replacement of recalled Sprint Fidelis Leads.

**M. Fraudulent Concealment**

112. Medtronic's failure to document or follow up on the known defects in Sprint Fidelis Leads, and concealment of known defects from the FDA, Plaintiffs, and the medical community constitutes fraudulent concealment that equitably tolls applicable statutes of limitation.

113. Medtronic is estopped from relying on the statute of limitations defense because Medtronic actively concealed the lead defects by, among other things, suppressing reports, failing to follow through on FDA notification requirements, and failing to disclose known defects to physicians. Instead of revealing the defects, Medtronic continued to represent the Sprint Fidelis Leads as safe for their intended use.

114. Medtronic's conduct, as described in the preceding paragraphs, amounts to conduct purposely committed, which Medtronic must have realized was dangerous, heedless and reckless, without regard to the consequences or the rights and safety of Plaintiffs.

**V. CLAIMS FOR RELIEF**

**COUNT I**

**STRICT LIABILITY – FAILURE TO WARN AND INSTRUCT**

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

116. At all relevant times hereto, Defendants were engaged in the development, testing, manufacturing, marketing and sales of Sprint Fidelis Leads. Defendants designed, manufactured, assembled and sold Sprint Fidelis Leads to medical professionals, knowing that they would then be implanted in patients with heart disease and disorders.

117. Defendants distributed and sold the Sprint Fidelis Leads in the condition in which they left their place of manufacture, in their original form of manufacture, which included the defects described herein. The Sprint Fidelis Leads were expected to and did reach Plaintiffs without substantial change or adjustment in their condition as manufactured and sold by Defendants.

118. The Sprint Fidelis Leads designed, developed, tested, manufactured, marketed and sold or otherwise placed into the stream of commerce by Defendants were in a dangerous and defective condition and posed a threat to any user or consumer of the Sprint Fidelis Leads. Plaintiffs were and are in a class of persons that Defendants should have considered to be subject to the harm caused by the defective nature of the Sprint Fidelis Leads.

119. The Sprint Fidelis Leads were implanted and used in the manner for which they were intended, that is for the detection, correction, and prevention of serious and/or life-threatening harm through surgical implantation. This use has resulted in injury to Plaintiffs.

120. Defendants knew or should have known through testing, adverse event reporting, or otherwise, that the Sprint Fidelis Leads created a high risk of bodily injury and serious harm.

121. Defendants failed to provide adequate and timely warnings or instructions regarding the Sprint Fidelis Leads and the known defects.

122. As a direct and proximate result of Defendants' wrongful conduct, Plaintiffs have sustained and will continue to sustain severe physical injuries and/or death, severe emotional distress, mental anguish, economic losses and other damages for which they are entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

## **COUNT II**

### **STRICT LIABILITY –MANUFACTURING DEFECT**

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

124. The Sprint Fidelis Leads are defectively manufactured because the foreseeable risks of mechanical malfunction and failure outweigh the benefits associated with the Sprint Fidelis Leads.

125. The Sprint Fidelis Leads were designed and/or manufactured in a manner

violative of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 321 *et seq.*, and the Medical Devices Amendment thereto (hereafter “FDCA”). The facilities or controls used by Defendants in the manufacture, packing, storage, or installation of the Sprint Fidelis Leads were not in conformity with applicable requirements of the FDCA.

126. The Sprint Fidelis Leads were expected to and did reach the Plaintiffs without substantial change or adjustment to their mechanical function upon implanting the Sprint Fidelis Leads.

127. Defendants knew or should have known of the manufacturing defects and the risk of serious bodily injury that exceeded the benefits associated with the Sprint Fidelis Leads.

128. Furthermore, the Sprint Fidelis Leads and their defects presented an unreasonably dangerous risk beyond what the ordinary consumer would reasonably expect.

129. The Sprint Fidelis Leads were defective due to inadequate warnings or instruction because Defendants knew or should have known that the Sprint Fidelis Leads created a high risk of bodily injury and serious harm. Defendants failed to adequately and timely warn consumers of this risk.

130. The Sprint Fidelis Leads are inherently dangerous for their intended use due to manufacturing defect and improper functioning. Defendants are therefore strictly liable.

131. As a direct and proximate result of Defendants’ wrongful conduct, Plaintiffs have sustained and will continue to sustain severe physical injuries and/or

death, severe emotional distress, mental anguish, economic losses and other damages for which they are entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

**COUNT III**

**NEGLIGENCE**

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

133. At all relevant times, Defendants had a duty and continue to owe a duty to Plaintiffs to provide a safely manufactured product, to notify the FDA of flaws, and to warn the FDA and Plaintiffs of the defective nature of Sprint Fidelis Leads. Defendants breached their duty of reasonable care to Plaintiffs by incorporating a defect into the manufacture of the Sprint Fidelis Leads, thereby causing Plaintiffs' injuries.

134. Defendants breached their duty of reasonable care to Plaintiffs by manufacturing and assembling the Sprint Fidelis Leads in such a manner that they were prone to fray and/or fracture and fail to operate and malfunction and expose Plaintiffs to life-threatening physical trauma.

135. Defendants breached their duty of reasonable care to Plaintiffs by failing to promptly and adequately notify the FDA and warn, and instruct Plaintiffs, the medical community, and the public at the earliest possible date of known defects in the Sprint Fidelis Leads.

136. Defendants breached their duty of reasonable care to Plaintiffs by failing to exercise due care under the circumstances.

137. As a direct and proximate result of Defendants' wrongful conduct, Plaintiffs have sustained and will continue to sustain severe physical injuries and/or death, severe emotional distress, mental anguish, economic losses and other damages for which they are entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

**COUNT IV**

**NEGLIGENCE PER SE**

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

139. Defendants have an obligation not to violate the law in the manufacture, design, testing, assembly, inspection, labeling, packaging, supplying, marketing, selling, advertising, preparing for use, warning of the risks and dangers of the Sprint Fidelis Leads, and otherwise distributing the Sprint Fidelis Leads.

140. Defendants' acts constitute an adulteration, misbranding, or both, as defined by the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §§ 331(a) and 333(a)(2), and constitute a breach of duty subjecting Defendants to civil liability for all damages arising there from, under theories of negligence per se.

141. Plaintiffs, as purchasers of Sprint Fidelis Leads, are within the class of persons the statutes and regulations (described above) are designed to protect and Plaintiffs' injuries are the type of harm these statutes and regulations are designed to prevent.

142. As a direct and proximate result of Defendants' wrongful conduct,

Plaintiffs have sustained and will continue to sustain severe physical injuries and/or death, severe emotional distress, mental anguish, economic losses and other damages for which they are entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

## COUNT V

### BREACH OF IMPLIED WARRANTY

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

144. Defendants impliedly warranted that their Sprint Fidelis Leads, which Defendants designed, manufactured, assembled, promoted and sold to Plaintiffs, were merchantable and fit and safe for ordinary use.

145. Defendants further impliedly warranted that their Sprint Fidelis Leads, which Defendants designed, manufactured, assembled, promoted and sold to Plaintiffs, were fit for the particular purposes for which they were sold, including to provide prophylactic treatment of patients with prior myocardial infarction and a limited ejection fraction, patients who have had spontaneous and/or inducible life-threatening ventricular arrhythmias, and patients who are at high risk for developing such arrhythmias.

146. Contrary to these implied warranties, Sprint Fidelis Leads were defective, unmerchantable, and unfit for their ordinary use when sold, and unfit for the particular purpose for which they were sold.

147. As a direct and proximate result of Defendants' wrongful conduct, Plaintiffs have sustained and will continue to sustain severe physical injuries and/or

death, severe emotional distress, mental anguish, economic losses and other damages for which they are entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

## COUNT VI

### BREACH OF EXPRESS WARRANTY

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

149. Defendants expressly warranted to Plaintiffs by and through Defendants and/or their authorized agents or sales representatives, in publications, package inserts, the internet, and other communications intended for physicians, medical patients, and the general public, that the Sprint Fidelis Leads were safe, effective, fit and proper for their intended use.

150. In allowing the implantation of the Sprint Fidelis Leads, Plaintiffs and their physicians relied on the skill, judgment, representations, and express warranties of Defendants. These warranties and representations were false in that the Sprint Fidelis Leads were not safe and were unfit for the uses for which they were intended.

151. Through sale of the Sprint Fidelis Leads, Defendants are merchants pursuant to Section 2-314 of the Uniform Commercial Code.

152. Defendants breached their warranty of the mechanical soundness of the Sprint Fidelis Leads by continuing sales and marketing campaigns highlighting the safety of its product, while it knew of the defects and risk of product failure.

153. As a direct and proximate result of Defendants' wrongful conduct,

Plaintiffs have sustained and will continue to sustain severe physical injuries and/or death, loss of companionship and society, severe emotional distress, mental anguish, economic losses and other damages for which they are entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

**COUNT VII**

**NEGLIGENT MISREPRESENTATION**

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

155. At the time Defendants manufactured, designed, marketed, sold and distributed the Sprint Fidelis Leads for use by Plaintiffs, Defendants knew or should have known of the use for which the Sprint Fidelis Leads were intended and the serious risks and dangers associated with such use of these Sprint Fidelis Leads.

156. Defendants owed a duty to treating physicians and ultimate end users of the Sprint Fidelis Leads, including Plaintiffs, to accurately and truthfully represent the risks of the Sprint Fidelis Leads. Defendants breached that duty by misrepresenting and/or failing to adequately warn Plaintiffs, the medical community and public about the risks of the Sprint Fidelis Leads, which Defendants knew or in the exercise of diligence should have known

157. As a direct and proximate result of Defendants' wrongful conduct, Plaintiffs have sustained and will continue to sustain severe physical injuries and/or death, severe emotional distress, mental anguish, economic losses and other damages for which they are entitled to compensatory and equitable damages and declaratory relief in

an amount to be proven at trial.

### **COUNT VIII**

#### **INTENTIONAL MISREPRESENTATION**

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

159. Defendants, having undertaken to prepare, design, research, develop, manufacture, inspect, label, market, promote and sell the Sprint Fidelis Leads, owed a duty to provide accurate and complete information regarding the Sprint Fidelis Leads.

160. Defendants' advertising program and promotional items, by containing affirmative misrepresentations and omissions, falsely and deceptively sought to create the image and impression that the Sprint Fidelis Leads were safe for human use, had no unacceptable side effects and would not interfere with daily life.

161. Defendants purposefully concealed, failed to disclose, misstated, downplayed and understated the health hazards and risks associated with the use of the Sprint Fidelis Leads. Defendants, through promotional practices as well as the publication of medical literature, deceived potential treating physicians, Plaintiffs and the public. Defendants falsely and deceptively kept relevant information from potential treating physicians, the FDA and the general public, including Plaintiffs, regarding the safety of the Sprint Fidelis Leads.

162. Defendants expressly denied that the Sprint Fidelis Leads created an increased risk of injury and took affirmative steps to prevent the discovery and dissemination of any evidence on the increased likelihood of injury from the Sprint

**Fidelis Leads.**

163. Defendants did not accurately report the results of adverse events by fraudulently and intentionally withholding information from the FDA, physicians, and the public, the truth regarding Sprint Fidelis Lead failures for months, if not years, all the while undertaking a major advertising campaign to sell products including the Sprint Fidelis Leads. Defendants received reports of the Sprint Fidelis defects from various sources, including Dr. Hauser, and intentionally withheld this information, while continuing to sell the Sprint Fidelis Leads for implantation in individuals such as Plaintiffs.

164. Further, even as Defendants disclosed some information regarding the Sprint Fidelis defects, the disclosures were incomplete and misleading.

165. Defendants effectively deceived and misled the scientific and medical communities regarding the risks and benefits of the Sprint Fidelis Leads. The truth did not begin to emerge until, at the earliest, March 2007, when Medtronic issued a "Dear Doctor" letter to physicians that suggested that Sprint Fidelis defects were arising because of the manner in which the leads were being implanted. This letter was inadequate to fully inform physicians, patients, and the public of the true defects in the Sprint Fidelis Leads. Even after the letter, Defendants' sales representatives continued to assure physicians that Sprint Fidelis Leads were adequate and reliable for the purpose intended and continued to sell Sprint Fidelis Leads.

166. Through the materials they disseminated, Defendants falsely and deceptively misrepresented or omitted a number of material facts regarding the Sprint

**Fidelis Leads.**

167. Defendants possessed evidence demonstrating the Sprint Fidelis Leads cause serious adverse side effects. Nevertheless, Defendants continued to market the Sprint Fidelis Leads by providing false and misleading information with regard to their safety to Plaintiffs and Plaintiffs' treating physicians.

168. Defendants engaged in all the acts and omissions described above with the intent that Plaintiffs' physicians and Plaintiffs would rely on the misrepresentation, deception and concealment in deciding to use Defendants' Sprint Fidelis Leads.

169. Plaintiffs and Plaintiffs' treating physicians justifiably relied to their detriment on Defendants' intentional and fraudulent misrepresentations as set out above. This reliance proximately caused the injuries as damages detailed herein.

170. As a direct and proximate result of Defendants' wrongful conduct, Plaintiffs have sustained and will continue to sustain severe physical injuries and/or death, loss of companionship and society, severe emotional distress, mental anguish, economic losses and other damages for which they are entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

**COUNT IX**

**FRAUD**

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

172. At all relevant times during the course of dealing between Defendants and Plaintiffs, Defendants misrepresented, omitted, and suppressed that the Sprint Fidelis

Leads were not safe or effective for their intended use.

173. In representations to Plaintiffs, Defendants fraudulently concealed the following material information:

- (a) that for several years, Defendants knew or had reason to know, of problems with their Sprint Fidelis Leads; and
- (b) that Sprint Fidelis Leads were defective, and that they were prone to fray or fracture, failed to operate and/or malfunctioned, and caused injuries and deaths.

174. Defendants also fraudulently concealed information regarding the Sprint Fidelis Lead defects from the FDA, preventing the FDA from performing its regulatory function.

175. Defendants were under a duty to disclose to Plaintiffs, the medical community, and public, the defective nature of the Sprint Fidelis Leads, and had full access to material facts concerning the defective nature of the Sprint Fidelis Leads and the propensity of the Sprint Fidelis Leads to fray and/or fracture, and hence, cause injuries to the patients who had the Sprint Fidelis Leads implanted in them.

176. Defendants intentionally, knowingly, and/or recklessly misrepresented that the Sprint Fidelis Leads were safe and effective for their intended use even though Defendants knew as early as 2004 that fractures in the Sprint Fidelis Leads had occurred.

177. Defendants' misrepresentations, concealment, suppression and omissions were made purposefully, willfully, wantonly, uniformly, deliberately or recklessly to Plaintiff, the medical community, and the public, to induce the purchase and use of

Defendants' Sprint Fidelis Leads over other leads available on the market and to induce patients to agree to have the Sprint Fidelis Leads implanted into their bodies. Plaintiffs reasonably relied upon the misrepresentations and omissions made by the Defendants about the Sprint Fidelis Leads when agreeing to purchase and/or have the Sprint Fidelis Leads implanted into their bodies.

178. Defendants knew that Plaintiffs had no way to determine that the Defendants' representations about the Sprint Fidelis Leads were false and misleading, and that they included material omissions.

179. As a direct and proximate result of Defendants' wrongful conduct, Plaintiffs have sustained and will continue to sustain severe physical injuries and/or death, severe emotional distress, mental anguish, economic losses and other damages for which they are entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

### **COUNT X**

#### **CONSTRUCTIVE FRAUD**

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

181. At the time Defendants' sold the Sprint Fidelis Leads to Plaintiffs, Defendants were in a unique position of knowledge concerning the safety and effectiveness of the devices, which knowledge was not possessed by Plaintiffs or their physicians, and Defendants thereby held a position of superiority over Plaintiffs.

182. Through their unique knowledge and expertise regarding the defective

nature of the Sprint Fidelis Leads, and through their statements to physicians and their patients in advertisements, promotional materials, and other communications, Defendants professed to Plaintiffs that they had knowledge of the truth of the representation that the Sprint Fidelis Leads were safe and effective for their intended use and were not defective.

183. Defendants' representations to Plaintiffs, the medical community, and public were unqualified statements made to induce Plaintiffs to purchase the Sprint Fidelis Leads, and Plaintiffs relied upon the statements when purchasing the devices and having them implanted in their bodies.

184. Defendants took unconscionable advantage of their dominant position of knowledge with regard to Plaintiffs and engaged in constructive fraud in their relationship with Plaintiffs. Plaintiffs reasonably relied on Defendants' representations.

185. As a direct and proximate result of Defendants' wrongful conduct, Plaintiffs have sustained and will continue to sustain severe physical injuries and/or death, severe emotional distress, mental anguish, economic losses and other damages for which they are entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

#### **COUNT XI**

#### **VIOLATION OF MINNESOTA FALSE STATEMENTS IN ADVERTISING ACT**

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

187. Defendants produced and published advertisements and deceptive and misleading statements of the soundness and mechanical reliability of the Sprint Fidelis

Leads after learning of their inherent defects with the intent to sell the Sprint Fidelis Leads.

188. Defendants concealed their deceptive practices in order to increase the sale of and profit from the Sprint Fidelis Leads.

189. Defendants violated the Minnesota False Statements in Advertising Act, Minn. Stat. § 325F.67 et seq., when they failed to comply with FDA requirements and when they failed to adequately warn consumers and the medical community of the safety risks associated with the Sprint Fidelis Leads.

190. Defendants violated Minn. Stat. § 325F.67 by intending to sell and create customer demand for the Sprint Fidelis Leads by using deceptive or untrue statements of fact about the Sprint Fidelis Leads' mechanical soundness and the reliability of the leads through promotional materials, including but not limited to, Defendants' website and medical brochures distributed to patients and physicians.

191. As a direct result of Defendants' deceptive, unfair, unconscionable, and fraudulent conduct and violation of Minn. Stat. § 325F.67 et seq., Plaintiffs were injured in that they paid substantial sums for the Sprint Fidelis Leads and for the costs of replacing the Sprint Fidelis Leads that they would not have paid had Defendants not engaged in unfair and deceptive conduct.

192. The Minnesota False Statement in Advertising Act applies to Plaintiffs' transactions with Defendants because Defendants deceptive scheme was carried out in Minnesota and affected Plaintiffs implanted with the defective Sprint Fidelis Leads.

193. As a direct and proximate result of Defendants' wrongful conduct,

Plaintiffs have also sustained and will continue to sustain severe physical injuries and/or death, loss of companionship and society, severe emotional distress, mental anguish, economic losses and other damages for which they are entitled to statutory, compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

## **COUNT XII**

### **VIOLATION OF THE MINNESOTA DECEPTIVE TRADE PRACTICE ACT**

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

195. Defendants applied advertising and marketing campaigns representing the Sprint Fidelis Leads as mechanically sound and medically safe, while Defendants knew of the defects in the Sprint Fidelis Leads. Defendants continued these campaigns of deception until 2007, when the Sprint Fidelis Leads were recalled.

196. Defendants knew or should have known of the defective nature of the Sprint Fidelis Leads but denied public access to the information, to avoid corporate responsibility. Defendants knew the Plaintiffs and their physicians were at a disadvantage in accessing information involving the safety of the Sprint Fidelis Leads.

197. Defendants concealed the defects of the Sprint Fidelis Leads for the purposes of higher profits and increased sales.

198. Defendants have violated Minn. Stat. §325D.44. The violations include the following:

- (a) Defendants violated Minn. Stat. §325D.44 (5) by representing the Sprint Fidelis Leads as having characteristics, uses, and benefits of a

safe and mechanically sound device while knowing the statements were false and the Sprint Fidelis Leads contained inherent defects, including manufacturing defects;

- (b) Defendants violated Minn. Stat. § 325D.44 (7) by representing the Sprint Fidelis Leads as a non-defective medical product of a particular standard, quality, or grade while knowing the statements were false and the Sprint Fidelis Leads contained inherent defects, including manufacturing defects;
- (c) Defendants violated Minn. Stat. § 325D.44 (9) by advertising, marketing, and selling the Sprint Fidelis Leads as medically reliable and without a known design defect while knowing those claims were false and without any medical support; and
- (d) Defendants violated Minn. Stat. § 325D.44 (13) by creating a likelihood of confusion about the efficacy and mechanical soundness of the Sprint Fidelis Leads, comparing the Sprint Fidelis Leads with other non-defective products.

199. The Minnesota statutes prohibiting unfair and deceptive trade practices apply because Defendants' deceptive scheme was carried out in Minnesota and affected Plaintiffs who were implanted with the Sprint Fidelis Leads containing the known defects.

200. As a direct and proximate result of Defendants' wrongful conduct, Plaintiffs have sustained and will continue to sustain severe physical injuries and/or

death, loss of companionship and society, severe emotional distress, mental anguish, economic losses and other damages for which they are entitled to statutory, compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

**COUNT XIII**

**VIOLATION OF THE MINNESOTA PREVENTION OF CONSUMER FRAUD**

**ACT**

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

202. Defendants intentionally concealed their design and manufacturing defects and failed to disclose the defects for the purpose of continuing to sell and distribute the Sprint Fidelis Leads.

203. Defendants represented that the Sprint Fidelis Leads were safe and effective and intended that Plaintiffs and their physicians rely on those representations when deciding if Defendants' Sprint Fidelis Leads were optimal for meeting the Plaintiffs' needs.

204. Through these misleading and deceptive statements and false promises, Defendants violated Minn. Stat. § 325F.69.

205. The Minnesota statutes prohibiting consumer fraud apply to all of Defendants' transactions with Plaintiffs implanted with the Sprint Fidelis Leads because Defendants' deceptive scheme was carried out in Minnesota and affected Plaintiffs implanted with defective Sprint Fidelis Leads.

206. As a direct and proximate result of Defendants' wrongful conduct,

Plaintiffs have sustained and will continue to sustain severe physical injuries and/or death, severe emotional distress, mental anguish, economic losses and other damages for which they are entitled to statutory, compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

**COUNT XIV**

**VIOLATION OF THE SENIOR CITIZEN AND HANDICAPPED PERSON**

**CONSUMER FRAUD ACT, MINNESOTA STATUTE 325F.71**

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

208. Pursuant to Minn. Stat. § 325F.71(2), this Count applies to Plaintiffs who are Senior Citizens or Handicapped, as defined within the statute.

209. Minnesota Statute 325F.71 (2) incorporates the afore-referenced Minnesota Statutes 325D.43 to 325D.48 regarding deceptive trade practices, 325F.67 regarding false advertising and 325F.68-70 regarding consumer fraud and provides special remedies if violations of those statutes are directed against Senior Citizens or handicapped people, including priority of restitution 325F.71(3) and the recovery of “damages, including costs of investigation and reasonable attorney’s fees” and to “other equitable relief as determined by the Court.” 325F.71(4).

210. The affirmative misrepresentations and the pattern of omissions by Defendants described above, violated Minnesota Statute 325F.44, Subd. 1, (5) because, through those affirmative misrepresentations and the pattern of omissions, Defendants represented that the Sprint Fidelis Leads had “characteristics, ingredients, uses [and/or]

benefits . . . that they do not have...,” a per se violation of Minnesota Statute 325F.71.

211. The affirmative misrepresentations and the pattern of omissions by Defendants described above, violated Minnesota Statute 325F.44, Subd. 1, (6).

212. The affirmative misrepresentations and the pattern of omissions by Defendant described above, violated Minnesota Statute 325F.44, Subd. 1, (7) because, through those affirmative misrepresentations and the pattern of omissions, Defendants represented that the Sprint Fidelis Leads were of a “particular standard, quality or grade...,” when they were, in fact, of a much lower standard, quality or grade, a per se violation of Minnesota Statute 325F.71.

213. The affirmative misrepresentations and the pattern of omissions by Defendants in their Annual Reports, advertising literature, press releases and other public statements, constitutes false advertising as prohibited by Minnesota Statute 325F.67, a per se violation of Minnesota Statute 325F.71.

214. The conduct, affirmative misrepresentations and the pattern of omissions by Defendant described above constitutes a “fraud, false pretense, false promise, misrepresentation, misleading statement or deceptive practice, with the intent that others rely thereon in connection with the sale of ... [the Sprint Fidelis Leads],” in violation of Minnesota Statute 325F.69, Subd. 1, a per se violation of Minnesota Statute 325F.71.

215. Pursuant to Minnesota Statute 325F.71 Subd. 4, Plaintiffs are entitled to recover all damages arising out of Defendants’ violation of Minnesota Statute 325F.44, Subd. 1, (5), (6) and/or (7); Minnesota Statute 325F.67 and/or Minnesota Statute 325F.69, Subd. 1.

216. As a direct and proximate result of Defendants' wrongful conduct, Plaintiffs have sustained and will continue to sustain severe physical injuries and/or death, loss of consortium, severe emotional distress, mental anguish, economic losses and other damages for which they are entitled to statutory, compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

217. In addition, Plaintiffs are entitled to recover costs of investigation and reasonable attorney's fees pursuant to Minnesota Statute 325F.71, Subd. 4 and Plaintiffs respectfully request that the Court give priority to the remedy of "restitution" pursuant to Minnesota Statute 325F.71, Subd. 3.

#### **COUNT XV**

#### **NEGLIGENT INFLICTION OF EMOTIONAL DISTRESS**

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

219. Defendants carelessly and negligently manufactured, marketed and sold the Sprint Fidelis Leads to Plaintiffs, carelessly and negligently concealed the Sprint Fidelis defects from Plaintiffs, and carelessly and negligently misrepresented the quality, safety and usefulness of the Sprint Fidelis Leads.

220. Plaintiffs were directly involved in and directly impacted by Defendants' carelessness and negligence, in that Plaintiffs have sustained and will continue to sustain severe physical injuries and/or death, economic losses, and other damages as a direct result of the decision to purchase, use and have implanted in their bodies a defective and dangerous products manufactured, sold and distributed by Defendants.

221. As a direct and proximate result of Defendants' wrongful conduct, Plaintiffs have sustained and will continue to sustain severe physical injuries and/or death, severe emotional distress, mental anguish, economic losses and other damages for which they are entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

## COUNT XVI

### LOSS OF CONSORTIUM

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

223. At all relevant times hereto, the Plaintiffs had spouses (hereafter referred to as "Spouse Plaintiffs") and/or family members (hereafter referred to as "Family Member Plaintiffs") who have suffered injuries and losses as a result of Plaintiffs' injuries.

224. For the reasons set forth herein, Spouse Plaintiffs and/or Family Member Plaintiffs have necessarily paid and have become liable to pay for medical aid, treatment, monitoring, medications, and other expenditures and will necessarily incur further expenses of a similar nature in the future as a proximate result of Defendants' misconduct.

225. For the reasons set forth herein, Spouse Plaintiffs and/or Family Member Plaintiffs have suffered and will continue to suffer the loss of their loved one's support, companionship, services, society, love and affection.

226. For all Spouse Plaintiffs, Plaintiff alleges his/her marital relationship has been impaired and depreciated, and the marital association between husband and wife has

been altered.

227. Spouse Plaintiffs and/or Family Member Plaintiffs have suffered great emotional pain and mental anguish.

228. As a direct and proximate result of Defendants' wrongful conduct, Spouse Plaintiffs and/or Family Member Plaintiffs have sustained and will continue to sustain severe physical injuries, severe emotional distress, economic losses and other damages for which they are entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial. Defendants are liable to Spouse Plaintiffs and/or Family Member Plaintiffs jointly and severally for all general, special and equitable relief to which Spouse Plaintiffs and/or Family Member Plaintiffs are entitled by law.

## **COUNT XVII**

### **WRONGFUL DEATH**

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

230. Decedent Plaintiffs died as a direct and proximate result of defects in Defendants' Sprint Fidelis Leads and are survived by various family members, named and unnamed.

231. Defendants' wrongful conduct has proximately caused Decedent Plaintiffs' heirs to suffer the loss of Decedents' companionship, services, society, marital association, love and consortium.

232. Plaintiff is the next of kin, statutory heir, and survivor of Decedent, and brings herein this wrongful death claim pursuant to Minn. Stat. §573.02 for all damages

and claims authorized therein. Plaintiff has been duly appointed as the Trustee for the heirs and next of kin.

**COUNT XVIII**

**SURVIVAL ACTION**

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

234. As a direct and proximate result of the conduct of Defendants outlined above, Decedent Plaintiffs suffered bodily injury and resulting pain and suffering, disability, disfigurement, mental anguish, loss of capacity of the enjoyment of life, shortened life expectancy, and expenses of hospitalization, medical and nursing care and treatment, monitoring, and loss of earnings as well as loss of ability to earn money and other economic damages prior to Decedent Plaintiffs' death.

235. Plaintiff is the next of kin, statutory heir, and survivor of Decedent, and brings herein this survival claims pursuant to Minn. Stat. §573.02 for all damages and claims authorized therein. Plaintiff has been duly appointed as the Trustee for the heirs and next of kin.

**COUNT XIX**

**MEDICAL MONITORING**

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

237. Through the unlawful conduct set forth in the preceding paragraphs, Plaintiffs have been implanted with a device which tends to fracture, and otherwise

malfunction. These defects have potentially fatal consequences for many patients who rely upon the presence of the leads connected to the ICDs to regulate their cardiac rhythms.

238. As a direct and proximate result of the conduct of Defendants outlined above, Plaintiffs implanted with the recalled Sprint Fidelis Leads have suffered physical injuries including but not necessarily limited to death, emergency and additional surgeries to remove or otherwise replace fractured leads, implantation of additional leads and devices in addition to the leads, excessive and or inappropriate shocking, and various physical manifestations of emotional distress associated with one or more of the following: the implantation, recall, failure, removal/replacement, and/or inability to have the defective Sprint Fidelis Lead removed or replaced.

239. As a direct and proximate result of the conduct of Defendants outlined above, Plaintiffs who have not yet had their recalled Sprint Fidelis Leads removed or replaced, or who are unable to have their recalled Sprint Fidelis Leads removed or replaced, have also been exposed to greater risks of severe injury, including lead fracture and death.

240. As set forth above, the now recalled Sprint Fidelis Leads have a greater propensity to fracture than other leads available on the market. Thus, these plaintiffs have been exposed to an even greater risk of additional and serious injury.

241. As set forth above, the now recalled Sprint Fidelis Leads are defective and dangerous such that they were the subject of a Class I Recall. Class I Recalls are the most serious type of medical device recall and involve situations in which there is a

reasonable probability that the use of the produce will cause serious injury or death.

242. Plaintiffs' increased risk of additional and serious injury is a direct and proximate result of Defendants' negligence and liability as set forth above.

243. As set forth above, the monitoring procedures currently recommend by Medtronic do not adequately detect potential fractures in the Sprint Fidelis Lead wires and more aggressive medical monitoring can and should be implemented for early detection of potential fractures.

244. In the absence of exposure to a now recalled Sprint Fidelis Lead, such Plaintiffs would not be at the increased risk of additional and serious injury. Such Plaintiffs would also not be forced to expend additional monies and incur additional economic damages for such monitoring.

245. As a direct and proximate result of Defendants' negligence and liability, a more aggressive monitoring regime is reasonably necessary and supported by contemporary scientific principles.

246. As a direct and proximate result of Defendants' wrongful conduct, Plaintiffs have sustained and will continue to sustain severe physical injuries and/or death, severe emotional distress and physical manifestations thereof, mental anguish, economic losses and other damages for which they are entitled to compensatory and equitable damages and declaratory relief in amounts to be proven at trial, including but not limited to the establishment of a treatment fund, under the continuing jurisdiction and supervision of this Court, to monitor the health of Plaintiffs, and to pay or reimburse Plaintiffs for all evaluative, monitoring, diagnostic, preventative, and corrective medical,

surgical, and incidental expenses caused by Medtronic's wrongdoing and declaratory judgment that Medtronic is liable to Plaintiffs for all evaluative, monitoring, diagnostic, preventative, and corrective medical, surgical, and incidental expenses, costs and losses caused by Medtronic's wrongdoing.

**COUNT XX**

**UNJUST ENRICHMENT**

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

248. As the intended and expected result of their conscious wrongdoing, Defendants have profited and benefited from the purchase of Defendants' Sprint Fidelis Leads by Plaintiffs.

249. Defendants have voluntarily accepted and retained these profits and benefits, derived from the Plaintiffs, with full knowledge and awareness that, as a result of Defendants' fraud and other conscious and intentional wrongdoing, Plaintiffs were not receiving a product of the quality, nature or fitness that had been represented by Defendants or that Plaintiffs, as reasonable consumers, expected.

250. By virtue of the conscious wrongdoing alleged above, Defendants have been unjustly enriched at the expense of the Plaintiffs, who are entitled to in equity, and hereby seek, the disgorgement and restitution of Defendants' wrongful profits, revenues and benefits, to the extent and in the amount deemed appropriate by the Court; and such other relief as the Court deems just and proper to remedy the Defendants' unjust enrichment.

**COUNT XXI**

**MEDICARE SECONDARY PAYER ACT**

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

252. In addition to their own personal injury claims, Plaintiffs, whose medical care costs arising from the Sprint Fidelis Leads were paid in whole or in part by Medicare, bring this cause of action pursuant to the private cause of action provisions of the Medicare as Secondary Payer Statute [42 U.S.C. § 1395y(b)(3)(A)] (“MSP”) to recover “double damages” of all Medicare expenditures resulting from their injuries suffered in connection with the Recalled Medtronic Sprint Fidelis Leads.

**PRAYER FOR RELIEF**

WHEREFORE, Plaintiffs, pray for judgment against Defendants as follows:

1. Economic and non-economic damages in an amount in excess of \$75,000 as provided by law and to be supported by the evidence at trial;
2. For the equitable relief requested;
3. For compensatory damages according to proof;
4. For all applicable statutory damages under the Medicare Secondary Payer Act and the applicable consumer protection legislation;
5. For declaratory judgment that Defendants are liable to Plaintiffs for all evaluative, monitoring, diagnostic, preventative, and corrective medical, surgical, and incidental expenses, costs and losses caused by Defendants’ wrongdoing;

6. For disgorgement of profits;
7. For an award of attorneys' fees and costs;
8. For prejudgment interest and the costs of suit; and
9. 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: July 2, 2008

Respectfully submitted,

On Behalf of the Plaintiff Steering  
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