UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MINNESOTA

In re: GUIDANT CORP. IMPLANTABLE DEFIBRILLATORS PRODUCT LIABILITY LITIGATION

MDL No. 05-1708 (DWF/AJB)

EMMETT DAVID BROWN

Plaintiff,

v.

GUIDANT CORPORATION, an Indiana Corporation; ENDOVASCULAR TECHNOLOGIES, INC., a California Corporation and a Division of GUIDANT CORPORATION; GUIDANT SALES CORPORATION, an Indiana Corporation; DR. LELAND B. HOUSMAN, M.D.; et al.

Defendants.

Case No. 0:07-cv-1487 (DWF/AJB)

NOTICE OF LODGMENT BY DEFENDANT LELAND HOUSMAN, M.D. IN SUPPORT OF MOTION TO SEVER MEDICAL MALPRACTICE ACTION AND REMAND CASE BACK TO SUPERIOR COURT OF THE STATE OF CALIFORNIA, COUNTY OF SANTA CLARA

TO ALL PARTIES AND THEIR ATTORNEYS OF RECORD:

PLEASE TAKE NOTICE that defendant LELAND B. HOUSMAN, M.D., hereby lodges the following exhibit in support of his Motion To Sever and to Remand case to Superior Court of the State of California, County of Santa Clara:

EXHIBIT NO.	DESCRIPTION
Exhibit "A"	Plaintiff's Complaint dated October 24, 2006.
Exhibit "B"	Defendant Guidant's Notice of Removal of Action by Defendants Guidant Corporation, Guidant Sales Corporation and Endovascular Technologies, Inc. Under 28 U.S.C. §§ 1441, 1446 and 1332 (Diversity) and Request for Jury Trial.

Respectfully submitted.

Dated: May 18, 2007

/s/ David P. Burke

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EXHIBIT “A”

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(ENDORSED)
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SUPERIOR COURT OF CA
COUNTY OF SANTA CLARA
J. Zenzen DEPUTY

HERSHANDHERSH
A Professional Corporation

SUPERIOR COURT OF THE STATE OF CALIFORNIA

COUNTY OF SANTA CLARA

BY FAX

EMMETT DAVID BROWN, Plaintiff, vs. GUIDANT CORPORATION, an Indiana Corporation; ENDOVASCULAR TECHNOLOGIES, INC., a California Corporation and a Division of GUIDANT CORPORATION; GUIDANT SALES CORPORATION, an Indiana Corporation; DR. LELAND B. HOUSMAN, M.D.; and DOES ONE through SIXTY, inclusive. Defendants.	CASE NUMBER 106CV-073640 COMPLAINT FOR DAMAGES AND DEMAND FOR JURY TRIAL (1) Strict Liability – Failure to Warn, (2) Strict Liability – Defective Design, (3) Negligence – Product Liability, (4) Breach of Implied Warranties (5) Breach of Express Warranty (6) Fraud (7) Fraud by Concealment (8) Negligent Misrepresentation (9) Violations of CLRA §1750, *et seq.* (10)Negligence (11)Medical Negligence

Plaintiff EMMETT DAVID BROWN, by and through his undersigned counsel, for causes of action against Defendants, Guidant Corporation, Guidant Sales

Corporation and Endovascular Technologies (hereinafter "Guidant"), and Dr. Leland B. Housman, M.D., makes the following allegations based upon his personal knowledge, and upon information and belief, as well as upon his attorneys' investigative efforts, and allege as follows:

PARTIES

1. Plaintiff, EMMETT DAVID BROWN, at all times relevant herein, was and is a resident of the County of Riverside in the State of California. On or about September 9, 2003, Plaintiff was implanted with a Guidant Automatic Implantable Cardioverter Defibrillator (hereinafter "ICD"). Plaintiff's Guidant ICD failed and required replacement. On or about August 17, 2005, Plaintiff's ICD was explanted and replaced and Plaintiff underwent epicardial lead placement.

2. Plaintiff was not advised and did not suspect that his defibrillator possessed any defect (much less the serious life-threatening defect) until learning of it on or about June 2005 when his ICD was recalled and problems with Guidant's ICDs were made public.

3. Plaintiff does not know the true names of the Defendants referred to as DOES 1 through 60. Plaintiff alleges that each of the fictitiously named Defendants is responsible in some manner for the occurrences herein alleged and caused the injuries and damages sustained by Plaintiff as herein alleged.

4. Defendant Guidant Corporation, and DOES 1 through 20, inclusive, and each of them, developed, tested, marketed, and sold the ICDs directly and through wholly owned operating divisions and subsidiaries. At all times relevant herein, Guidant Corporation was and is a corporation duly formed and existing under and by virtue of the laws of the State of Indiana.

5. Defendant Guidant Sales Corporation, and DOES 21 through 30, inclusive, and each of them, developed, tested, marketed, and sold ICDs directly and through wholly owned operating divisions and subsidiaries. At all times relevant herein,

Guidant Sales Corporation was and is a corporation duly formed and existing under and by virtue of the laws of the State of Indiana.

6. Defendant Endovascular Technologies, Inc., a division of Guidant Corporation, and DOES 31 through 40, inclusive, and each of them, was and is a corporation existing under the laws of incorporation of the State of California, with its principal place of business in Menlo Park, California, a corporate resident of the State of California, doing business in the State of California, County of Santa Clara. At all times herein mentioned, Defendant Endovascular Technologies, Inc. designed, manufactured, tested, analyzed, distributed, recommended, merchandised, advertised, promoted, supplied and sold to distributors, and retailers for resale to physicians, hospitals, medical practitioners and the general public, a certain pharmaceutical product, hereinafter referred to as the Ancure Endograft Device.

7. At all times relevant herein, Defendant Dr. Leland Houseman, and DOES 41 through 50, were physicians licensed to practice in the State of California, and were, at all times stated herein, practicing their profession within the County of La Jolla. On or about July 27, 2006, Plaintiff mailed Dr. Leland Housman a 90-day letter of intent to file a medical malpractice legal action.

8. At all times relevant herein, DOES 51 through 60, inclusive, and each of them, were nurses, midwives, medical assistants, technicians and other persons rendering medical care to patients and were at all times herein mentioned providing services, care and treatment to Plaintiff within the County of La Jolla, California.

9. At all times relevant herein all Defendants were acting as the agents and/or employees of all other Defendants, and all Defendants were acting within the scope and purpose of their agency or employment.

JURISDICTION AND VENUE

10. Venue in this Court is proper in that substantial part of the events or omissions giving rise to the claims asserted herein occurred in this District. Endovascular

Technologies, Inc., resides in Santa Clara County in the State of California and is subject to personal jurisdiction in this District. Further, Guidant Corporation and Guidant Sales Corporation sell, market, manufacture and distribute ICDs within California and nationwide

FACTUAL ALLEGATIONS

11. Guidant designs, develops, manufactures, distributes, markets, supplies and sells products that focus on the treatment of cardiac arrhythmia, heart failure and coronary and peripheral disease. One product line consists of implantable defibrillator systems used to detect and treat abnormally fast heart rhythms (tachycardia) or irregular heartbeats that could result in sudden cardiac death. An implanted defibrillator is designed to be inserted under the skin and to shock the heart back into a normal rhythm when it starts beating irregularly.

12. Guidant designed, developed, manufactured, distributed, marketed, supplied and sold implantable defibrillators. This case involves, *inter alia*, Guidant's failure to warn doctors and patients of information within its knowledge or possession or both, indicating that the subject ICDs, including Plaintiff's device, were affected by a design and manufacturing defect making them unreasonably dangerous, unfit for their intended use, and that they posed health risks, including risk of serious injury or death to the ICD recipients.

The Device and Its Intended Functions

13. An ICD is used to monitor and regulate a recipient's heart rhythm. An ICD responds to fluctuations in heart rhythm by detecting heart irregularities and delivering life-saving electrical shocks to the heart in order to restore a normal heartbeat.

14. If an ICD fails to engage when necessary to restore a normal heartbeat or if the ICD engages when the recipient has a normal heartbeat, the recipient may sustain serious injuries or death.

Guidant's Conduct Regarding the ICDs

15. Guidant designed, developed, manufactured, distributed, marketed, supplied and sold ICDs, touting the device's exceptional design and reliability in monitoring and regulating heart rhythm, and reviving a person's heart during a cardiac event. In its public disclosures and promotional advertisements, Guidant has represented that its implantable cardioverter defibrillators are essential for saving lives. Guidant omitted material facts, intentionally withholding information regarding malfunctions and mechanical design defects, and failed to timely and adequately warn the medical community and the general public, placing ICD recipients, including Plaintiff, at unnecessary risk, without their informed consent.

16. In Guidant's 2003 Annual Report, it states "Experienced technicians- supported by continued investment in state-of-the-art automated manufacturing equipment and expansion- have streamlined manufacturing processes to reduce cost, improve quality, increase out-put and shorten the product development and manufacturing cycle, speeding the delivery of lifesaving therapies to physicians and patients worldwide." Guidant emphasized in its 2003 Annual Report that it has "an unrelenting focus on quality in everything it does." Indeed, Guidant proclaims that: "Quality is essential; lives depend on us. We pledge together to build most reliable products and services. We work every day to drive Quality into everything that is Guidant."

17. Guidant also publicly claimed to be an open provider of information to patients and physicians. In its 2003 Annual Report, it stated that "information for patients, physicians and the public is available around the clock through Guidant's dedicated customer and technical service representatives, as well as its comprehensive web site (www.guidant.com)."

18. In marked contrast to these assurances, at some point prior to April 2002, Guidant learned that certain Guidant ICDs were short-circuiting and could cause serious injury or possibly death.

19. Specifically, according to the May 24, 2005 New York Times article, a short circuit can occur when the device builds a charge to deliver the type of high-energy shock needed in emergency situations. In three cases, when doctors intentionally induced abnormal heart rhythms during routine checkups, the Guidant device failed to work, forcing doctors to rescue those patients by jolting them with the type of external Defibrillator used in emergency rooms.

20. Also at some point prior to April 2002, Guidant also learned that the short-circuit in the affected Guidant ICDs could prevent the ICDs from functioning as intended and could cause the ICDs to fail.

21. At that time, Guidant was also specifically notified of at least one death that resulted from such a failure of an affected Guidant ICD.

22. In April 2002, after determining what it thought to be the nature of

death that resulted from such a failure of an affected Guidant ICD.

22. In April 2002, after determining what it thought to be the nature of the defect, Guidant changed the design to certain ICDs. The changes failed to cure the defect and did not resolve the failure rates of the device. Despite Guidant's continued marketing to patients, it made no disclosure of this change to patients or doctors.

23. In November 2002, Guidant again changed the design in its ICDs, particularly to the PRIZM 2 DR models, but failed to report these changes to the FDA until August 2003. Guidant made no disclosure of this change to patients or doctors, and, incredibly, continued to sell the defective ICDs.

24. According to the May 24, 2005 New York Times article, Guidant continued to keep physicians and ICD recipients in the dark about the defects, even after at least 26 short-circuits and the death of one ICD recipient had been reported to Guidant, until they learned that the New York Times was preparing an article about its defective ICDs. The day before that article's publication, Guidant initiated a communication to physicians advising them that it was aware of 26 Guidant ICD failures, including one recent death.

25. Guidant's failure to warn precluded over 20,000 individual patients

with the potentially defective ICDs from discovering the defect and the potential risk of serious harm and possibly death.

26. Undeterred by its knowledge of the mechanical failures and potential harm due to the defect, Guidant widely marketed its ICDs across the world, including marketing, promotional and advertising campaigns extolling the virtues of its ICDs.

27. Guidant failed to publicly disclose the known design and/or manufacturing defects in its ICDs until FDA intervention and public scrutiny.

28. On June 17, 2005, the FDA posted a Nationwide Notification for certain Guidant ICDs, citing "patient safety" as the FDA's first priority and concern based on two reported deaths due to malfunctioning devices.

29. On June 17, 2005, in response to the FDA recall, Guidant released a "Worldwide Physician Communication" regarding important safety information and corrective action about its ICDs. In this correspondence, Guidant admitted that it had known about ICD defects in 2002 or earlier, but intentionally chose to withhold the findings until 2005 and only after being threatened with public scrutiny.

30. On or about June 24, 2005, Guidant finally began advising patients and doctors about safety problems with additional ICD models and, for the first time, recommended that physicians cease implanting any additional Guidant ICDs containing the design and/or manufacturing defects due to the associated risks.

31. Until shortly before Plaintiff filed this complaint, Plaintiff had no knowledge that the Guidant ICDs were defective, unsafe, and dangerous and because the Plaintiff had no reasonable way to discover this defect until shortly before Plaintiff filed this complaint when the information was made public.

32. Guidant was under a duty to disclose that the Guidant ICDs were defective, unsafe, and inherently dangerous for its intended use, and failed to do so.

Guidant's Breach of the Corporate Integrity Agreement

33. On June 12, 2003, The Honorable Susan Illston, United States

District Court for the Northern District of California, accepted the criminal fraud guilty plea and criminal and civil settlements of Guidant and Guidant's wholly owned subsidiary, Endovascular Technologies ("EVT"), by way of a Board of Director authorized representative. EVT was guilty of making false statements and interstate shipments of the misbranded ANCURE Endograft System ("ANCURE"), a medical device. In addition to the nine misbranding counts, Guidant's EVT division also pled guilty to one felony count of making false statements to the Food and Drug Administration.

34. On June 30, 2003, pursuant to the June 12, 2003, plea and settlement agreements, Guidant entered into a Corporate Integrity Agreement ("CIA") with the Office of Inspector General of the Department of Health and Human Services ("OIG").

35. The period of the compliance obligations assumed by Guidant under the CIA was 5 years from the effective date of the CIA, on June 30, 2003. The scope of the CIA included "all officers, employees, contract workers, and agents of Guidant located in the United States."

36. The term and scope of the CIA was not limited to the ANCURE devices. In fact, Guidant agreed, at a minimum, to "ensure that during the term of CIA, it shall comply with certain integrity obligations enumerated in this CIA."

37. Guidant's history and past conduct, reflects a corporate policy of deception with a reckless disregard for the health and safety of the public.

Medical Negligence

38. On or about August 17, 2005, Plaintiff EMMETT DAVID BROWN underwent explantation and replacement of his Guidant ICD and epicardial leads.

39. The epicardial leads were placed in such a way that, shortly after surgery, Plaintiff felt discomfort and noticed the leads right underneath his skin. Within approximately six weeks of the epicardial lead replacement, the leads sawed through Plaintiff's skin and erupted. As a result, Plaintiff had to undergo two further surgeries.

40. As a result of the improper and negligently placed epicardial leads, as

well as the defective defibrillator, Plaintiff EMMETT DAVID BROWN suffered severe injuries.

FIRST CAUSE OF ACTION

[Strict Liability - Failure To Warn]

41. Plaintiff hereby incorporates by reference as if fully set forth herein each and every allegation set forth above, inclusive, of this Complaint.

42. Guidant developed, manufactured, marketed, and distributed ICDs for sale and sold them in the course of their business and continued to do so even after acquiring knowledge that the defective devices could short-circuit and cause the Plaintiff serious injuries or death.

43. The ICD manufactured by Guidant that was implanted in Plaintiff was unreasonably dangerous when implanted due to the possibility of a cardiac failure resulting from short-circuit.

44. At all times herein mentioned, the aforesaid ICD was defective and unsafe in manufacture, and was so at the time it was distributed by Guidant and implanted into Plaintiff. The aforesaid ICD was defective in that it was not accompanied by proper warnings regarding all known or scientifically knowable adverse side effects associated with its use, and given the severity of the adverse effects, the warnings given did not accurately reflect the severity of the adverse effects. The ICD was also defective in that the product manufactured and distributed differed from the manufacturer's intended results. These defects caused serious injuries to the user when used in its intended and foreseeable manner, i.e., when it was implanted into Plaintiff, and in the manner recommended by Guidant, and each of them.

45. Guidant knew that the aforesaid ICD was to be used by the user without inspection for defects therein.

46. The aforesaid ICD was unaccompanied by warnings of its dangerous propensities that were known or reasonably scientifically knowable at the time of

distribution. The reasonably foreseeable use of the products involved substantial dangers not readily recognizable by the ordinary user of the product. Guidant failed to warn of the known or knowable likelihood of injuries, including but not limited to, the likelihood the user would develop serious and permanent injuries, including increased risk of death, and would necessitate ICD removal and revision.

47. The aforementioned ICD designed, manufactured, tested, analyzed, distributed, recommended, promoted, and/or supplied by Guidant was further defective due to inadequate warning or instruction because, after Guidant knew or should have known of the risks of injury from the aforementioned ICD, it failed to promptly monitor, respond to and warn about the likelihood of injury.

48. Plaintiff did not know, nor have reason to know, at the time of the use of the aforesaid ICD, or at any time prior thereto, of the existence of the foregoing described defects. These defects caused the herein described injuries to Plaintiff.

49. As a direct and proximate result of Guidant's failure to warn of this serious risk, Plaintiff has suffered damages. Specifically, as a result of having an ICD implanted in him, Plaintiff, among other things, has suffered permanent injuries, including increased risk of death, and necessitated ICD removal and revision.

50. Even though Guidant altered the design of its defibrillators, it continued to sell defective versions without any warning to physicians or patients. Guidant knew the ICDs were defective and dangerous and thereby showed complete indifference to or conscious disregard for the safety of Plaintiff.

WHEREFORE, Plaintiff prays for judgment against Defendants as hereinafter set forth.

SECOND CAUSE OF ACTION

[Strict Liability - Defective Design]

51. Plaintiff hereby incorporates by reference as if fully set forth herein each and every allegation set forth above, inclusive, of this Complaint.

52. The aforementioned ICD manufactured and/or supplied by Guidant was placed into the stream of commerce by Guidant in a defective and unreasonably dangerous condition in that the foreseeable risks exceeded the benefits associated with the design or formulation.

53. Alternatively, the aforementioned ICD manufactured and/or supplied by Guidant, was defective in design or formulation in that when it was placed in the stream of commerce, it was unreasonably dangerous, and it was more dangerous than an ordinary consumer would expect.

54. As a result of Guidant's defective design, the ICDs were unreasonably dangerous to Plaintiff at the time Guidant sold them, and at the time they were implanted and used for their intended purposes.

55. When it manufactured and sold ICDs Guidant was aware of the purpose and manner of their use. Guidant knew that the products would reach consumers without substantial and/or significant change in the condition which Guidant sold them, and the ICDs in fact reached consumers and Plaintiff without substantial and/or significant change in condition.

56. As a proximate and legal result of the defective unreasonably dangerous condition of these products manufactured and/or supplied by Guidant, Plaintiff was caused to suffer the herein described injuries.

WHEREFORE, Plaintiff prays for judgment against Defendants as hereinafter set forth.

THIRD CAUSE OF ACTION

[Negligence]

57. Plaintiff hereby incorporates by reference as if fully set forth herein each and every allegation set forth above, inclusive, of this Complaint.

58. Guidant was negligent in the design, manufacture, testing, advertising, marketing, promotion, labeling, failure to warn, and sale of its ICDs.

59. At all times herein mentioned, Guidant had a duty to properly manufacture, compound, test, inspect, package, label, distribute, market, examine, maintain and prepare for use and sell the aforesaid ICDs.

60. At all times herein mentioned, Guidant knew, or in the exercise of reasonable care should have known, that the aforesaid ICDs were of such a nature that if they were not properly manufactured, compounded, tested, inspected, packaged, labeled, distributed, marketed, examined, sold and prepared they were likely to injure the user of said ICDs.

61. Guidant negligently and carelessly manufactured, compounded, tested, failed to test, inspected, failed to inspect, packaged, labeled, distributed, recommended, displayed, examined and failed to examine the aforesaid ICDs that they were dangerous and unsafe for the use and purpose for which they were intended and were likely to injure the user of said products.

62. As a result of the aforesaid carelessness and negligence of Guidant, the ICD caused severe injury to Plaintiff's body and thereby caused Plaintiff to sustain damages and injuries as herein alleged.

WHEREFORE, Plaintiff prays for judgment against Defendants as hereinafter set forth.

FOURTH CAUSE OF ACTION

[Breach Of Implied Warranties]

63. Plaintiff hereby incorporates by reference as if fully set forth herein each and every allegation set forth above, inclusive, of this Complaint.

64. At all times herein mentioned, Guidant manufactured, compounded, packaged, distributed, recommended and promoted the aforesaid ICDs, as hereinabove described, and prior to the time that the said product was used by Plaintiff, Guidant impliedly warranted to Plaintiff that said ICDs were of merchantable quality and safe for the use for which they were intended.

65. Plaintiff relied on the skill and judgment of Guidant in using the aforesaid ICDs.

66. Said ICDs were unsafe for their intended use, nor were they of merchantable quality, as warranted by Guidant, in that they had very dangerous propensities when put to their intended use and would cause severe injury to the user. The aforesaid ICDs did cause the Plaintiff to sustain damages and injuries as herein alleged.

67. After Plaintiff was made aware of his injuries as a result of the aforesaid ICD, notice was duly given to Guidant of the breach of said warranty.

WHEREFORE, Plaintiff prays for judgment against Defendants as hereinafter set forth.

FIFTH CAUSE OF ACTION

[Breach Of Express Warranty]

68. Plaintiff hereby incorporates by reference as if fully set forth herein each and every allegation set forth above, inclusive, of this Complaint.

69. The aforementioned manufacturing, compounding, packaging, designing, distributing, testing, constructing, fabricating, analyzing, recommending, and promoting by Guidant of the aforesaid ICDs, were expressly warranted to be safe for Plaintiff and other members of the general public.

70. At the time of making said express warranties, Guidant had knowledge of the purpose for which the aforesaid ICDs were to be used and warranted the same to be, in all respects, fit, safe, effective and proper for such purpose.

71. Plaintiff reasonably relied upon the skill and judgment of Guidant, and upon said express warranty, in using the aforesaid ICDs. The said warranty and representations were untrue in that the ICDs caused severe injury to Plaintiff and were unsafe and were, therefore, unsuited for the use for which they were intended, and could and did thereby cause Plaintiff to sustain damages and injuries as herein alleged.

72. As soon as the true nature of the products, and the fact that the

warranty and representations were false, were ascertained, Guidant was notified of the breach of said warranty.

WHEREFORE, Plaintiff prays for judgment against Defendants as hereinafter set forth.

SIXTH CAUSE OF ACTION

[Fraud]

73. Plaintiff hereby incorporates by reference as if fully set forth herein each and every allegation set forth above, inclusive, of this Complaint.

74. On or about June 30, 2003, Guidant specifically executed the CIA, Settlement Agreement and the Court's Order with the United States, promising to uphold and maintain ethical and legal disclosure and reporting practices regarding all Guidant devices developed, sold, and marketed by Guidant.

75. Guidant, while in possession of unique and pertinent information involving the safety and mechanical reliability of its products, presented its Guidant ICDs as mechanically sound and failed to warn of its inherent design defects. Guidant suppressed this information and continued sales and marketing of its product to the general public. Guidant knew or should have known Plaintiff and other ICD recipients had no reasonable means, other than Guidant's full, accurate, and objective disclosure, of obtaining the relevant information.

76. Through its unique knowledge and expertise regarding the affected nature of the Guidant ICDs, and through its statements to physicians and their patients in advertisement, promotional materials, and other communications, Guidant professed and affirmed to Plaintiff and other ICD recipients its knowledge of the truth of the representation that its ICDs were safe for their intended use and were free from defects.

77. Guidant's misrepresentations and omissions were made intentionally to induce Plaintiff and other ICD recipients to purchase Guidant ICDs, in order to reap the high profit margin relating to Guidant's affected ICDs.

78. Guidant's conduct took unconscionable advantage of its dominant position of knowledge, engaging in fraud in its relationship with the Plaintiff and other ICD recipients. Misled by the veil of fraud, Plaintiff and other ICD recipients relied on Guidant's representations.

79. As a result of Guidant's fraud and deceit, Plaintiff has sustained and will continue to sustain severe damages and therefore entitled to relief according to proof.

80. In committing the acts herein alleged, Guidant acted with oppression, fraud, and malice, and Plaintiff is therefore entitled to punitive damages to deter Guidant and others from engaging in similar conduct in the future. Said wrongful conduct was done with the advance knowledge, authorization and/or ratification of an officer, director and/or managing agent of Guidant.

WHEREFORE, Plaintiff prays for judgment against Defendants as hereinafter set forth.

SEVENTH CAUSE OF ACTION

[Fraud By Concealment]

81. Plaintiff hereby incorporates by reference as if fully set forth herein each and every allegation set forth above, inclusive, of this Complaint.

82. Guidant had a duty to disclose the defects in the design and/or manufacture of the ICDs as soon as such defects became known to Guidant.

83. Guidant knew or should have known that Plaintiff would rely on Guidant to disclose any defects in the design and/or manufacture of the ICDs as soon as such defects became known to Guidant.

84. Guidant did not disclose the defects in the design and/or manufacture of the ICDs to the Plaintiff or Plaintiff's physician when such defects became known to Guidant.

85. Guidant had superior knowledge concerning the defects in the design and/or manufacture of the ICDs and the Plaintiff had no reasonable opportunity to discover

or otherwise learn of the defects without disclosure by Guidant.

86. But for Guidant's fraudulent concealment of the facts known to Guidant concerning the defects in the design and/or manufacture of the ICDs, Plaintiff would not have purchased the defective ICD nor would Plaintiff have allowed the ICD to be implanted into his body.

87. Plaintiff reasonably relied on Guidant to disclose material defects in the ICDs known to Guidant before the ICD was sold to Plaintiff and before the ICD was implanted into Plaintiff's body.

88. As a result of Guidant's fraudulent concealment, Plaintiff has sustained and will continue to sustain severe damages and therefore entitled to relief according to proof.

89. In committing the acts herein alleged, Guidant acted with oppression, fraud, and malice, and Plaintiff is therefore entitled to punitive damages to deter Guidant and others from engaging in similar conduct in the future. Said wrongful conduct was done with the advance knowledge, authorization and/or ratification of an officer, director and/or managing agent of Guidant.

WHEREFORE, Plaintiff prays for judgment against Defendants as hereinafter set forth.

EIGHTH CAUSE OF ACTION

[Negligent Misrepresentation]

90. Plaintiff hereby incorporates by reference as if fully set forth herein each and every allegation set forth above, inclusive, of this Complaint.

91. Guidant made misrepresentations and omissions of material facts, including, but not limited to:

a. That the affected ICDs were fit for their intended use.

b. That the affected ICDs were of merchantable quality.

c. That the affected ICDs were safe and efficacious in the treatment of

the medical conditions of Plaintiff and other recipients.

d. That the affected ICDs would function as intended when necessary.

e. That the affected ICDs were defective, such that the affected ICDs would short circuit and fail to function as intended.

f. That the affected ICDs were inherently dangerous.

92. These misrepresentations and/or omissions were false and misleading at the time they were made.

93. Guidant negligently and carelessly made the foregoing misrepresentations without a basis and did not possess information on which to accurately base those representations.

94. Guidant was aware that it did not possess information on which to accurately base the foregoing representations and concealed from Plaintiff that there was no reasonable basis for making said representations herein.

95. When Guidant made the foregoing representations, they knew or should have known them to be false.

96. In reliance upon the foregoing misrepresentations by the Guidant, Plaintiff was induced to and did subject herself to the use of the ICD. If Plaintiff had known of the true facts, he would not have taken such action and risk. The reliance of Plaintiff on Guidant's misrepresentations and omissions was reasonable because said representations were made by individuals and entities who are in a position to know the true facts.

97. As a result of the foregoing negligent misrepresentations by Guidant, Plaintiff suffered and will continue to suffer injuries and damages as herein alleged.

WHEREFORE, Plaintiff prays for judgment against Defendants as hereinafter set forth.

HERSHANDHERSH
A Professional Corporation

NINTH CAUSE OF ACTION

[Violations of the Consumer Legal Remedies Act, Civil Code §1750 *et seq.*]

98. Plaintiff hereby incorporates by reference as if fully set forth herein each and every allegation set forth above, inclusive, of this Complaint.

99. On June 12, 2003, The Honorable Susan Illston, United States District Court for the Northern District of California, accepted the criminal fraud guilty plea of Guidant and Guidant's wholly owned subsidiary, Endovascular Technologies ("EVT"), by way of a Board of Director authorized representative. EVT was guilty of making false statements and interstate shipments of the misbranded ANCURE Endograft System ("ANCURE"), a medical device. The plea included an agreement to pay to the United States $43 million in fines ("Plea Agreement") and $49 million in settlement of civil and administrative claims ("Settlement Agreement").

100. On June 30, 2003, pursuant to the June 12, 2003, plea and settlement agreements, EVT and Guidant entered into a Corporate Integrity Agreement ("CIA") with the Office of Inspector General of the Department of Health and Human Services ("OIG").

101. The period of the compliance obligations assumed by Guidant under the CIA was 5 years from the effective date of the CIA, on June 30, 2003. The scope of the CIA included "all officers, employees, contract workers, and agents of Guidant and EVT located in the United States."

102. The term and scope of the CIA was not limited to the ANCURE devices. In fact, Guidant agreed, at a minimum, to "ensure that during the term of CIA, it shall comply with certain integrity obligations enumerated in this CIA."

103. Defendant Guidant, *inter alia*, agreed to the following specific obligations of the CIA:

a. To commit to "full compliance with all FDA and Federal health care program requirements."

b. To establish a written Code of Business Conduct that requires "all of their Covered Persons... to comply with all Federal health care program requirements, FDA regulatory requirements and with

Guidant's own Policies and Procedures...."

c. To implement written Policies and Procedures regarding the operation of Guidant's compliance program, which at a minimum, must address:

(1) written Medical Device Reporting ("MDR") procedures to include those procedures required by 21 C.F.R. §803.17.

(2) written policies and procedures for employees on how to handle customer complaints and MDRs in accordance with 21 §C.F.R. 803.

(3) complaint handling procedures, including guidelines for evaluating and investigating complaints and implementing the appropriate corrective action to ensure that problems have been remedied and that recurrence of problems have been prevented in accordance with 21 C.F.R. §820.198.

(4) corrective and preventive action procedures to analyze quality problems, and investigate the root cause of nonconformities reported in accordance with 21 C.F.R. §820.

(5) procedures in place to notify appropriate individuals directly responsible of quality problems and their correction in accordance with 21 C.F.R. §820.

(6) recall and notification procedures to promptly notify FDA, hospitals, and affected physicians of any correction or removal of a device in accordance with the reporting requirements of FDA's corrections and removal regulations in 21 C.F.R. Part 806.

(7) establishing and maintaining MDR, Removals and Corrections, and Quality Systems files in compliance with 21 C.F.R. §§803.18, 806.20 and 820.198.

d. To maintain a Disclosure Program that mandates the Compliance Officer to make a "preliminary, good faith inquiry into all allegations set forth in every disclosure...." Further, for every disclosure that is sufficiently specific so that it reasonably (1) permits a determination of the appropriateness of the alleged improper practice; and (2) provides an opportunity for taking corrective action, "Guidant shall conduct an internal review of the allegations set forth in such a disclosure and ensure that proper follow-up is conducted."

e. To "notify OIG, in writing, within 30 days after making the determination that the Reportable Event exits."

104. On or about May 24, 2005, The New York Times reported Guidant did not tell doctors or patients for three (3) years that a Guidant defibrillator implanted in an estimated 24,000 people that was designed to shock a faltering heart contained a flaw. On or about June 17 and 24, 2005, Guidant apprised the FDA of safety information regarding the defective devices, and FDA classified these defibrillators as recalls.

105. Plaintiff brings this action against Guidant for, *inter alia*, violating the obligations of the CIA, the Settlement Agreement, and Court order. Guidant, the parent corporation of EVT, made legally binding promises to maintain ethical and legally mandated disclosure policies regarding all devices that they developed, marketed, and sold. Guidant failed to maintain these standards, and in fact, continued unlawfully making false statements and misrepresentations to the FDA, Department of Justice and Plaintiff.

106. Both agreements were drafted and executed to ensure the safety of the people of the United States such as Plaintiff. Guidant's conduct reflects a violation of the public trust and reckless disregard for the health and safety of the ICD recipients. Guidant owed a duty to the Court and Plaintiff to disclose, per CIA and Settlement Agreement, to Plaintiff any known defect of the Guidant devices.

107. Guidant knew of the defective nature of Guidant ICDs since approximately 2002. Guidant did not disclose or report any information regarding the defective nature of Guidant ICDs until the summer of 2005.

108. Plaintiff has been directly and adversely affected by the violation of these two agreements. If it were not for the breach of the agreements, Plaintiff would not have suffered injury.

109. Guidant's breach of CIA and Settlement Agreement was a proximate cause of the increased risk of harm suffered by Plaintiff as previously set forth herein.

110. This Cause of Action is brought pursuant to the Consumer Legal Remedies Act ("CLRA"), California Civil Code §1750, *et seq.*

111. Guidant provides "goods" and "services" within the meaning of Civil Code sections 1761(a), 1761(b) and 1770.

112. Guidant is a "person" within the meaning of Civil Code sections 1761© and 1770.

113. Purchasers of Guidant's goods and services, including Plaintiff, are "consumers" within the meaning of Civil Code section 1761(d) and 1770.

114. Plaintiff's purchase of the good and services sold by Guidant constitute "transactions" within the meaning of Civil Code sections 1761(e) and 1770.

115. The policies, acts, and practices described above were intended to result, and did result, in the sale of ICDs to Plaintiff EMMETT DAVID BROWN and the general public. These actions violated, and continued to violate, the CLRA in at least the following respects:

(a) In violation of §1770(a)(2), misrepresenting the source, sponsorship, approval, or certification of the ICDs;

(b) In violation of §1770(a)(4), deceptive representations or designations of geographic origin in connection with goods or services provided regarding the ICDs;

(c) In violation of §1770(a)(5), representing that the ICDs have sponsorship, approval, characteristics, ingredients, uses, benefits, or quantities which they do not have;

(d) In violation of §1770(a)(7), representing that the ICDs are of a particular standard, quality, or grade;

(e) In violation of §1770(a)(9), advertising goods with the intent not to sell them as advertised;

(f) In violation of §1770(a)(16), representing that the ICDs have been supplied in accordance with a previous representation, when it has not.

116. In compliance with the CLRA provision in California Civil Code

§1782. Plaintiff has given written notice to each Defendant named in this Complaint of their intention to file an action for damages under Civil Code §1750, *et seq.*

117. Plaintiff notified Defendants and Defendants have failed, within 30 days after receipt of the Civil Code §1782 notice, to adequately respond to Plaintiff's demand to correct, repair, replace, or otherwise rectify the wrongful conduct described above. Per Civil Code §1782(b), this action for damages under Civil Code §1780 may be maintained because Defendants failed to give, or agree to give within a reasonable time, any appropriate correction, repair, replacement, or other remedy to Plaintiff within 30 days after receipt of the §1782 notice.

118. Plaintiff seeks actual and punitive damages for violations of the CLRA. In addition, Plaintiff has already sought, and is entitled to, pursuant to California Civil Code §1780(a)(2), an order enjoining the above-described wrongful acts and practices, restitution to Plaintiff, costs and attorneys' fees, and any other relief deemed appropriate and proper by the Court and under Civil Code §1780.

WHEREFORE, Plaintiff prays for judgment against Defendants as hereinafter set forth.

TENTH CAUSE OF ACTION

[Negligence]
(Against all Defendants)

119. Plaintiff hereby incorporates by reference as if fully set forth herein each and every allegation set forth above, inclusive, of this Complaint.

120. Defendants, and each of them, were negligent in failing to provide reasonably safe conditions to Plaintiff Emmett David Brown, thereby creating an unreasonable risk of injury.

121. Defendants, and each of them, owed Plaintiff Emmett David Brown a duty to exercise due care to provide reasonably safe conditions and to avoid exposing others to an unreasonable risk of injury.

122. Defendants breached their duties by failing to exercise reasonable care to avoid exposing others to an unreasonable risk of injury and/or failing to prevent unsafe conditions that could reasonably be expected to harm others.

123. Defendants knew or should have known that patients such as Plaintiff Emmett David Brown would foreseeably suffer injury as a result of their failure to exercise reasonable care as described above.

124. As a direct and proximate consequence of Defendants' acts and omissions described herein, Plaintiff sustained serious injuries to his chest when the epicardial leads burst from their incision sites. Plaintiff required healthcare and medical services, and incurred direct medical costs for physician care, monitoring, treatment, medications, and supplies.

WHEREFORE, Plaintiff prays for judgment against Defendants as hereinafter set forth.

ELEVENTH CAUSE OF ACTION

[Medical Negligence]
(Against Dr. Leland Housman and Does 41-60)

125. Plaintiff hereby incorporates by reference as if fully set forth herein each and every allegation set forth above, inclusive, of this Complaint.

126. Defendants, and each of them, were negligent in their provision of care, treatment, and services to Plaintiff Emmett David Brown.

127. Defendants, and each of them, owed Plaintiff Emmett David Brown a duty to exercise reasonable care in the provision of care, treatment, and services to Plaintiff Emmett David Brown.

128. Defendants breached their duties by failing to exercise reasonable care in the provision of care, treatment, and services to Plaintiff Emmett David Brown.

129. Defendants knew or should have known that patients such as Emmett David Brown would foreseeably suffer injury as a result of their failure to exercise

reasonable care as described above.

130. As a direct and proximate consequence of Defendants' acts and omissions described herein, Plaintiff sustained serious injuries to his chest. Plaintiff required healthcare and medical services, and incurred direct medical costs for physician care, monitoring, treatment, medications, and supplies.

131. On or about July 27, 2006, Plaintiff mailed Dr. Leland Housman a 90-day letter of intent to file a medical malpractice legal action.

WHEREFORE, Plaintiff prays for judgment against Defendants as hereinafter set forth.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for judgment as follows:

1. For general damages in a sum within the jurisdiction of this Court;
2. For special damages in a sum within the jurisdiction of this Court;
3. For pre-judgment and post-judgment interest on the above general and special damages;
4. For restitution and disgorgement of profits;
5. For compensatory and other damages, as the Court may determine;
6. For exemplary and punitive damages, to the extent permissible by law and in an amount to be proven at the time of trial, and sufficient to punish Defendant or to deter them and other from repeating the injurious conduct alleged herein or similar conduct;
7. Costs, including experts' fees and attorneys' fees and expenses, and the costs of prosecuting this action; and
8. Such other further relief as the Court deems just and proper.

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DEMAND FOR JURY TRIAL

Plaintiff hereby demands a jury trial as to all claims triable in this action.

DATED: October 24, 2006.

HERSH & HERSH
A Professional Corporation

By _____
CAROLE BOSCH
Attorneys for Plaintiff