

SUMMARY OF COMPLAINT

4. Guidant claims to provide therapeutic medical solutions for customers, patients and healthcare systems worldwide. The Company, which was spun off from Eli Lilly & Co. in 1994, develops, manufactures and distributes implantable medical devices, including stents, defibrillators, and pacemakers, designed to treat a variety of ailments including cardiac arrhythmias, heart failure, and coronary and peripheral disease.

5. Prior to the Class Period, Guidant pled guilty in June 2003 to concealing from the FDA known defects and patient problems reported to the Company that arose from the use of a stent product called the Ancure Endograft System (“Ancure Device”) that Guidant designed and manufactured. When the information regarding this defective stent product came to light, Guidant pled guilty to 10 counts of fraud and was ordered to pay the enormous fine of \$92.4 million.

6. As a result of Guidant’s June 2003 plea, the Company’s revenue attributable to stent devices fell precipitously, as did Guidant’s stock price and market value. Moreover, many patients receiving the defective stents filed private lawsuits. These private lawsuits created a huge problem for Guidant when the Company’s insurers declined coverage for stent-related actions and refused to offer coverage for claims made in future litigation. As a result Guidant was forced to become self-insured.

7. With Guidant’s reputation as a major player in manufacturing and developing stent medical devices irreparably tarnished and its stent-related revenue drastically reduced, the Defendants refocused Guidant’s business emphasis away from stents in favor of the Company’s business in the design and manufacture of ICD and pacemaker devices. The success of this shift of focus of the Company’s business is

reflected in the growth in revenue of Guidant's ICD-related sales from \$1.47 billion in fiscal year 2003 to \$1.78 billion in fiscal year 2004.

8. Because Defendants were officers and directors of Guidant during the time its business suffered devastating consequences from governmental penalties imposed on the Company for fraudulent acts associated with Guidant's Ancure Device, they knew and/or recklessly disregarded the importance and impact on the Company's business and revenue of failures to disclose manufacturing and design defects in Guidant's ICD and pacemaker devices. Notwithstanding this experience, Defendants engaged in the same recidivistic behavior that led to the indictment and guilty plea with regard to Guidant's Ancure Device, by concealing exactly the same types of facts about the Company's ICD and pacemaker products as is set forth more fully in this Consolidated Complaint.

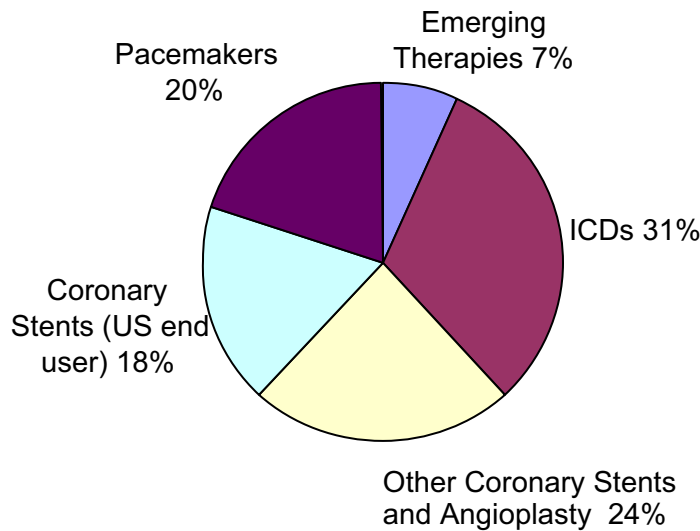
9. During the Class Period, Defendants intentionally failed to disclose to the market, to their shareholders, and to patients receiving ICD and pacemaker devices, material information regarding known defects in these devices. An independent panel of experts found that Defendants had identified a dangerous and potentially life-threatening defect in Guidant's defibrillator product lines as early as April of 2002, and had secretly taken deliberate steps to introduce manufacturing changes resulting in a series of revisions to the manufacturing process in April and November of 2002. After the revisions to the manufacturing process, the Company nevertheless concealed the existence of the life-threatening defect from physicians and patients as it continued to sell its remaining inventory of nearly 4,000 defective devices to customers and healthcare providers. All told, nearly 78,000 defective ICD and pacemaker devices were manufactured and sold.

Pre-Class Period Events

Guidant's Felony Convictions for the Concealment of Serious Defects and Malfunctioning of its Stent Medical Devices

10. In 1999, Guidant received FDA approval for the Ancure Device, a cardiac stent designed to prevent an abdominal aneurysm in a patient's aorta, the heart's main artery, from rupturing. The Ancure Device consisted of a delivery catheter attached to a woven fabric patch that was permanently implanted with small hooks to the inside of the aorta in order to strengthen its weakened vascular wall. The FDA's approval of the Ancure Device was conditioned on a Guidant sales representative's being present in the operating room during each surgical implanting of the device.

11. Guidant and the Defendants enjoyed immense success from the Ancure Device, with sales approaching *\$3 billion at the end of fiscal 2002*. At that time, the Ancure Device comprised nearly half of Guidant's product offerings.



12. However, the appalling truth behind Guidant's immense success was the highly unethical and illegal dumping of defective implantable heart stents and cardiac rhythm devices by the Defendants. Shortly after the Ancure Device hit the market,

Guidant's officers and directors secretly began to receive information from their sales representatives that doctors using the Ancure Device were experiencing an extraordinary number of device malfunctions during surgical installation. Those malfunctions, including the failure of the device's delivery catheter to retract properly during surgery, contributed to deaths and serious injuries.

13. Between 1999 and March 2001, there were an astounding number of problems and incidents involving the Ancure Device which the Company's sales representatives, present in the operating room during each and every surgery, reported to Guidant but which were otherwise concealed from physicians, their patients and the investing public. Defendants not only knew about the problems associated with removing the delivery catheter used to set the fabric patch in the artery, they instructed their sales personnel to disseminate to doctors performing the surgeries an unapproved method of retracting the device from patients' arteries. Guidant had an ethical responsibility to advise the healthcare community of these alarming and dangerous problems and was under a legal duty to report them to the FDA. Under federal law, Guidant was required to report to the FDA any incident in which its medical device may have caused or contributed to a death or serious injury or the medical device experienced a malfunction that would be likely to cause or contribute to a death or serious injury if the malfunction were to recur. The reports to the FDA are called Medical Device Reports ("MDRs"). Out of 7,362 Ancure Devices sold, an astounding 2,800 reportable incidents of malfunction or its use was associated with death or serious bodily harm. Notwithstanding both ethical and legal obligations in this regard, however, the Defendants actively and intentionally concealed from the FDA MDRs for each and every

one of **2,628** separate incidents of malfunction of the Ancure Device, resulting in serious injuries, including **12** deaths and **57** emergency procedures.

14. In October of 2000, in response to Defendants' unethical and illegal business practices, seven Guidant employees anonymously sent a letter to the FDA, describing the Ancure Device's defective heart stent. The letter outlined numerous ethical, legal and safety concerns, including the facts that the testing and analysis of recommended procedures for the implantation of the Ancure Device was incomplete and that the Company had failed to file MDRs with the FDA, as legally required.

15. The U.S. Government thereupon initiated an investigation to determine whether Guidant's corporate policies or practices were endangering the lives of healthcare consumers, and as a part of its investigation, the U.S. Department of Justice ("DOJ") interviewed numerous Guidant employees and officers. In March 2001, based on these interviews and other investigative materials, the FDA suspended Guidant's sale of the Ancure Device.

16. On June 12, 2003, negotiations between the United States government and Guidant led to the simultaneous filing of the Criminal Information and Felony Plea Agreement ("Plea Agreement") in *United States of America v. Endovascular Technologies, Inc.*, Case No. CR 02-0179 SI (N. D. Cal.). As part of the Plea Agreement, Guidant acknowledged that it misled the FDA by not disclosing that the Ancure Device was linked to 12 deaths and thousands of injuries. Defendants also admitted that Guidant "**knowingly and willfully,**" "**deliberately and with knowledge**" made false statements that were "material to the activities or decision of a government agency or department" in connection with the FDA's approval and monitoring of the Ancure Device.

17. As part of the Plea Agreement, Guidant was ordered to pay a \$92.4 million fine. The ten count guilty plea and \$92.4 million fine caused immense damage to Guidant's reputation, as well as to the Company's goodwill. Standard & Poor's Rating Services warned on June 12, 2003, that "cash settlements such as this . . . erode a portion of Guidant's financial insulation at a time when the company is expecting a drop in its vascular segment sales."

18. To make matters worse, the Company was sued by scores of recipient patients who were injured by the defective Ancure Device, some of whom sought punitive damages and class action status. The Company incurred approximately \$37 million in costs settling individual Ancure-related actions during fiscal 2004 alone. Shockingly, between 2000 and June 13, 2003, while the Plea Agreement was being negotiated and finalized and at a time in which Guidant's stock price was trading at inflated levels, Defendants Cornelius and Dollens collectively sold over \$36 million worth of Guidant stock.

19. After the Ancure Device fiasco, Guidant was faced with the "triple threat" of: (1) reduced earnings and revenues from its stent related products; (2) a growing number of private lawsuits stemming from the Ancure Device defects, potentially without access to liability insurance coverage; and (3) reputational damage arising from the Company's egregious behavior and felony convictions.

20. Not surprisingly, following the Plea Agreement, Guidant stent sales dropped dramatically, falling from approximately \$0.8 billion or 23% of sales in 2003, to \$0.5 billion or 14% of sales in 2004. Moreover, in October of 2003, Guidant's insurers began declining coverage on Ancure Device-related liability. Allianz Insurance

Company, Guidant's first-layer carrier, alleging common-law fraud, declined coverage on Guidant's Ancure Device-related liability on the basis that Guidant made "false representations and concealed and failed to disclose the status of the Ancure product defects and claims arising therefrom" in the course of Guidant's application for insurance policies issued in 2000 and 2001.

Guidant Conceals its ICD and Pacemaker Defects

21. Guidant signed a rigorous "Corporate Integrity Agreement" (CIA) as part of its Plea Agreement with the DOJ. The intent of the CIA was to impose integrity measures – giving the public some assurance that Guidant would abide by its disclosure and reporting obligations. In the eyes of the investment community, the CIA stood as an assurance to regulators that the Company would "clean house" of its troubled business culture, one that had failed to adhere to ethical standards, and would implement corrective and preventative actions mandated by FDA regulations.

22. During the very time that Guidant was entering the CIA with the DOJ in June 2003, the Defendants were in the midst of yet another well-orchestrated and elaborate scheme and artifice to conceal from patients, physicians and investors other defective Guidant medical devices, the ICD and pacemaker products. At the same time Defendants caused the CIA to be publicized on the Company's website, thereby providing false assurances of a commitment to abide by disclosure and reporting obligations, all Defendants were well aware of defective Guidant ICD and pacemaker devices whose defects and malfunctions were then being concealed from the public. Though defects in these devices had prompted changes to the manufacturing process as

early as April 2002, the defective devices manufactured before that date continued to be sold until the Company's inventory of such devices could be exhausted.

23. Amongst the various ICD and pacemaker device defects known to the Company, but concealed from patients, physicians and investors, was the "short circuit" defect, causing the implantable defibrillator to stop functioning for a 24-hour period, then to resume function, but erasing the device's "memory." The memory function of the ICD is critical, since it contains a record of the function of the ICD over time, including indications of device malfunction, which could necessitate some form of intervention, including the replacement of the device. Because the memory in this device is erased after the malfunction, physicians were only able to detect the malfunction in the rare event that the defibrillator malfunctions while being tested in the physician's office.

24. Defendants were also aware of other serious pacemaker issues including problems with a hermetic sealing component and malfunctions causing the devices to lose their pacing output or achieve sustained high rate pacing. Defendants received and confirmed at least 20 reports of pacemaker output-related malfunctions, including one death, in connection with observation of sustained high rate pacing. This information was kept concealed from physicians, patients, government authorities and the investing public during the Class Period.

25. Defendants, who were officers and directors of Guidant during the time when Guidant pled guilty to the concealment of the defective nature of the Company's Ancure Device, are well aware of the devastating impact that any disclosures relating to manufacturing and designs defects in ICD and pacemaker devices would have on

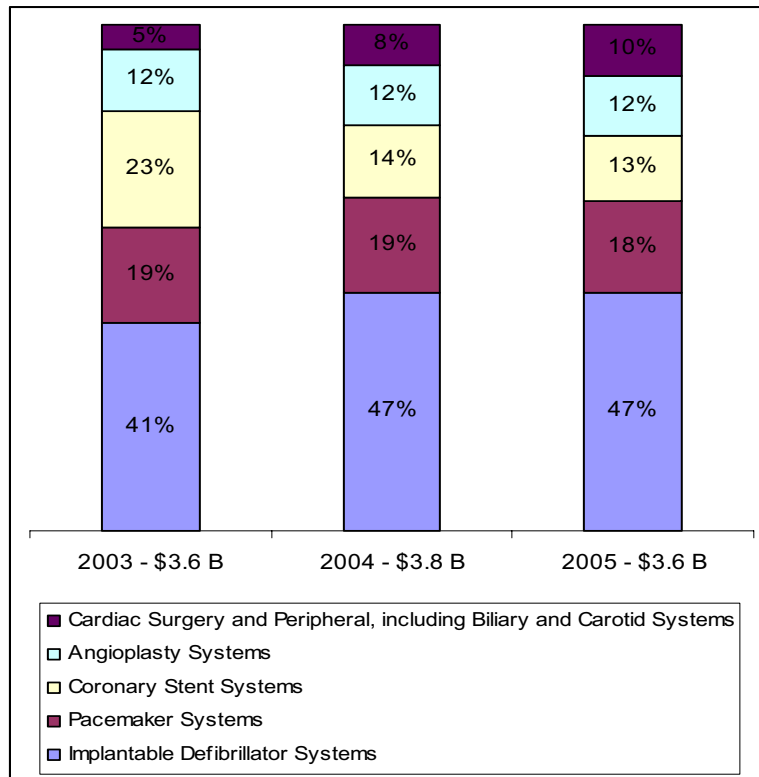
Guidant's revenues, business prospects and merger opportunities. These material omissions constitute intentional fraud by the Company and the Individual Defendants.

26. During the Class Period, Defendants knowingly and intentionally failed to disclose to healthcare providers and the investing community, material information regarding known defects in the Company's ICD and pacemaker devices. Moreover, MDRs filed by Guidant with the FDA regarding the failed ICD and pacemaker devices did not convey an accurate picture of facts known by Guidant at the time – that the defects in the ICD and pacemaker devices were serious enough that Guidant changed how these devices were manufactured in April 2002; that despite these changes, ICD and pacemaker devices manufactured prior to April 2002 were still sold; that disclosures of known defects and problems associated with the pre-April 2002 ICD and pacemaker devices were not made to patients in whom those devices had been or would continue to be installed or to their physicians or the public. Defendants' concealment was intentional and calculated. Their omissions were made in the face of Guidant's public agreement to openly disclose matters relating to the safety and quality of its medical device products. Defendants' concealment during the Class Period was necessary to effectuate Guidant's sale to J&J and to maintain an artificially inflated stock price, which financially benefited the Defendants, who unloaded nearly \$89 million of their own stock when they, but not the investing public, knew the truth.

Guidant Refocuses its Business Strategy

27. Desperate to save face and potentially Guidant as a going concern, the Defendants embarked on a plan to have the Company acquired. To succeed in doing so, however, Defendants would be forced to refocus Guidant's business model away from its

stent sales to its ICD pacemaker business segment. Defendants’ efforts were successful, such that by the end of fiscal year end 2004, revenues from Guidant’s Cardiac Rhythm Management (“CRM”) business unit increased by 25%:



28. As a result of initial discussions during the spring of 2004, Guidant endeavored to strike a merger deal with J&J. Accordingly, on August 4, 2004, J&J and Guidant executed a confidentiality agreement. Thereafter, numerous discussions between several of the Defendants and the officers and directors of J&J ensued. On October 4, 2004, draft merger agreements were circulated to senior management and advisors of each company.

29. The Class Period begins on December 1, 2004, whereupon Guidant issued highly positive news regarding accelerating growth prospects for the Company’s defibrillator business. Following this, on December 15, 2004, Defendants issued a press

release stating that Guidant had been sold to J&J for approximately \$25 billion in cash and J&J stock, with an imputed value of approximately \$76 per share. In anticipation of this announcement, the Company's stock price had already surged in the preceding two weeks, from \$65 to \$70 per share and hovered between \$71 and \$75 per share throughout the spring of 2005.

30. Defendants failed to make a full and complete disclosure regarding Guidant's ICD and pacemaker devices to J&J during merger negotiations, specifically: that the defects in the ICD and pacemaker devices were serious enough that Guidant changed how these devices were manufactured in April 2002; that despite this change, ICD and pacemaker devices manufactured prior to April 2002 were still sold; that disclosures of known defects and problems associated with the pre-April 2002 ICD and pacemaker devices were not made to patients or physicians. Neither public statements issued by Guidant nor the Individual Defendants nor SEC filings made by the Company disclosed this material information.

Class Period Events and Statements

31. Throughout the Class Period, Defendants continued their pattern of making knowing and intentional omissions of material fact in their press releases and SEC filings, resulting in a lack of full and fair disclosure of materially adverse information regarding defective ICD and pacemaker devices. On December 21, 2004, January 7, 2005, and January 19, 2005, Defendants filed three separate SEC Form 425's, ostensibly to provide continuing and real-time updates to investors of all the material information about Guidant's planned merger with J&J, including the advantages and material risks resulting from the merger. In all three of these Form 425 filings,

Defendants once again deceived the investing public and the healthcare providers using the defective devices on which so much of the Company's revenues and the success of the Company's business outlook was based by failing to make a full and fair disclosure of the life-threatening risks facing patients implanted with thousands of Guidant's defective ICD and pacemaker devices.

32. Similar press releases and SEC filing were made from January 27, 2005, through March 13, 2005, including Forms 10-K, 8-K, and two additional Form 425 filings. In these documents, Defendants presented, among other things, financial information regarding the Company's performance during the fourth quarter of fiscal 2004, as well as another "update" on the Company's pending merger with J&J. Each of these documents again intentionally failed to disclose material facts regarding Guidant's defective ICD and pacemaker devices.

33. Then, on March 13, 2005, the life-threatening defect inherent in thousands of Guidant's defective ICD devices caused the death of Joshua Oukrop. Unbeknownst to investors, Dr. Barry J. Maron, one of Mr. Oukrop's treating physicians, began his own investigation into the cause of Mr. Oukrop's death. Guidant learned of Mr. Oukrop's death on March 16, 2005, also that his death was the result of a Guidant ICD device's failure to deliver a life saving electrical shock. Although armed with knowledge of not only known defects in ICD and pacemaker devices, but also that the defective device had caused a death, Defendants continued to conceal from healthcare providers and the investing public this material information.

34. Undeterred by Oukrop's death and its obvious implications, on March 24, 2005, Defendants filed a Form DEFM 14A with the SEC, their preliminary proxy

statement, which was distributed to shareholders, to inform them of the advantages, material risks and other details regarding the merger, seeking their approval of the sale of Guidant to J&J pursuant to the agreed upon terms. Again, the document failed to disclose material facts regarding Guidant's defective ICD and pacemaker devices, also that at least one recipient patient had died as a result of and ICD malfunction.

35. In fact, in press releases and SEC filing made by the Individual Defendants and Guidant from March 13, 2005, through July 2005, material information continued to be intentionally omitted, namely disclosures regarding Guidant's defective ICD and pacemaker devices and also that at least one recipient patient had died as a result of an ICD malfunction.

36. Incredibly, while hoarding knowledge of this material information to himself, Dollens, on April 7, 2005, three weeks after Guidant was notified of Joshua Oukrop's Guidant-device-related death, sold 271,404 shares or 52% of his beneficially-owned Guidant stock, for proceeds of \$20.1 million.

37. Defendants met with Dr. Maron on May 7, 2005, and again on May 12, 2005, to put on a presentation appropriately characterized as a "dog and pony show" at which Defendants argued that it would "cause more harm than good by publicizing the issue" of Dr. Maron's patient's death and identified defects in the Company's devices. So egregious was Guidant's callous disregard of Oukrop's tragic death and the life-threatening risks facing other patients implanted with thousands of Guidant's defective ICD devices that Dr. Maron would later be called upon to testify about the details before Congress. In the meantime, from May 10, 2005 through May 23, 2005, Defendants Spaulding and Lorell together sold 54,164 shares of their Guidant stock, for combined

proceeds of \$3.9 million. As a result of her transactions, Lorell had, as of May 23, 2005, liquidated virtually all of her holdings of Guidant stock.

38. Defendants knowingly and intentionally disregarded their obligations under both the Plea Agreement and the federal securities laws to protect patients from a catastrophic defect in the Guidant's ICD and pacemaker devices, and to disclose this material non-public information to healthcare providers, patients, investors and J&J. Defendants were motivated to do so because of the impending \$25.4 billion merger with J&J and a desire to increase the value of their personal holdings of Guidant stock or at least maintain the value until they could sell off their stock before the truth came out.

39. Only after learning that a New York Times article was to be published that same day, Guidant on May 23, 2005 was forced to drop a bomb-shell, disclosing to the market for the first time that there were reported problems with its ICDs and pacemaker devices, specifically that there had been 26 reports of failure and at least one death. Still this press release only partially disclosed the severity of the problems associated with these devices.

40. The federal authorities quickly responded. On June 17, 2005, the FDA issued a nationwide recall notification on certain of Guidant's implantable defibrillators and cardiac resynchronization therapy defibrillators. Within that notification, the FDA advised the public that the malfunction of Guidant's devices could lead to a serious, life-threatening event for a patient. Moreover, the FDA advised that there had been two reported deaths suspected to be associated with this malfunction.

41. On this shocking news, the Company's shares fell \$3.36, losing 4.5% of its value over the two trading days immediately following the FDA recall, closing on

June 21, 2005 at \$70.33. Guidant investors lost over \$1.09 billion in market share value as a result.

42. Then, on July 18, 2005, the FDA published a “Recall - Firm Press Release” on its website. In the recall publication, Guidant warned physicians and patients to seek replacement of at least nine different cardiac pacemaker models and product lines. Guidant identified its PULSAR® MAX, PULSAR, DISCOVERY®, MERIDIAN®, PULSAR MAX II, DISCOVERY II, VIRTUS PLUS® II, INTELIS II and CONTAK® TR pacemakers as potentially impacted by one or more of the identified defects. The press release noted that as many as 78,000 pacemaker devices were affected.

43. On this news, the Company’s shares fell another \$2.10, losing 3.0% of market value, closing on July 18, 2005, at \$67.31. Guidant investors lost another \$660 million in market share value as a result. On the exact same day, while in possession of material non-public information that additional adverse information was yet to be disclosed, Defendant Cornelius dumped 450,000 or 47% of his beneficially owned shares, for proceeds of \$30.5 million.

44. Additional adverse information that safety recommendations made to physicians after the defects were initially disclosed actually increased the risk to patients and adverse information that certain of the Company’s pacemakers were also defective, trickled out on July 22, 2005. Even then, the Company had not disclosed to the investing public, the material adverse information that the defects and deaths had not been disclosed to J&J when the merger terms were set.

45. Finally, on October 18, 2005, J&J announced that as a direct result of adverse “developments” at Guidant, it would seek *alternatives to the merger deal* entered into with Guidant on December 14, 2004.

46. Again, Guidant shares plummeted, this time to the astounding tune of *\$8.28 or 11.4% per share*. In all, Guidant investors lost over \$3.1 billion in share value from June 17, 2005 through October 18, 2005, as a direct result of the fraud of the defendants.

47. During the Class Period, Defendants knew and intentionally concealed material information, including the facts that:

(a) certain ICD and pacemaker devices produced prior to the Class Period had manufacturing defects;

(b) patients with Guidant’s ICD and pacemaker devices were experiencing serious and life threatening health issues, and in some instances death, as a result of these manufacturing defects;

(c) revenue from ICD and pacemaker devices would be significantly impacted when disclosure of known defects were revealed to the public, particularly against the backdrop of Guidant’s criminal history for the same conduct; and

(d) revelations of ICD and pacemaker defects would potentially constitute a “material adverse effect” that could severely affect the \$24.5 billion merger agreement between Guidant and J&J.

JURISDICTION AND VENUE

48. Jurisdiction is conferred by §27 of the Exchange Act. The claims asserted herein arise under and pursuant to §§10(b) and 20(a) of the Exchange Act, 15 U.S.C.

§§78j (b) and 78t (a), and Rule 10b 5 promulgated thereunder by the SEC, 17 C.F.R. §240.10b 5.

49. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§1331 and 1337 and 1367, as well as §27 of the Exchange Act, 15 U.S.C. §78aa.

50. Venue is proper in this District pursuant to §27 of the 1934 Act. The corporate headquarters of Guidant are located in the District.

51. In connection with the acts and conduct alleged herein, Defendants, directly and indirectly, used the means and instrumentalities of interstate commerce, including the United States mails and the facilities of the national securities exchanges.

PARTIES

52. Lead Plaintiffs Iron Workers of Western Pennsylvania Pension Plan and David J. Fannon, as set forth in the accompanying certification and incorporated by reference herein, purchased shares of Guidant stock at artificially inflated prices during the Class Period and were damaged thereby.

53. Defendant, Guidant, was and is a Fortune 500 corporation existing under the laws of the State of Indiana, with its principal place of business in Indianapolis, Indiana. The Company is comprised of various subsidiaries and divisions, including Guidant Corp. Inc. of California, Guidant Planning, Inc., Guidant Vascular Intervention Group, Inc., Guidant Cnvs, Inc., Guidant Cardiovascular System, Inc., Guidant Cardiac & Vascular Surgery, Inc., Devices for Vascular Intervention, Inc., Advanced Cardiovascular Systems, Inc., Origin Medsystems, Inc. and Endovascular (collectively, "Guidant"). The Company manufactures and markets products that focus on the treatment of cardiac arrhythmias, heart failure, and coronary and peripheral disease, including Guidant's implantable defibrillator systems, used to detect and treat abnormal heart rhythms that

could result in sudden cardiac death. Guidant was purchased by Boston Scientific on April 26, 2006.

54. Boston Scientific, the successor in interest of Guidant, maintains the corporate and administrative offices of its wholly-owned Guidant subsidiary, where the Company's day-to-day business activities are conducted, at 111 Monument Circle, 29th Floor, Indianapolis, IN 46204-5129.

55. Defendant Ronald W. Dollens served as Chief Executive Officer ("CEO"), President and Director of Guidant throughout the Class Period. During the Class Period, Dollens sold approximately 271,404 shares or 52% his holdings of Guidant stock, for over \$20 million in proceeds. Dollens, serving as CEO, also engaged in communications with the market, including conference calls, reports on Company operations and financing and press releases issued by the Company. Dollens was an officer and/or director for Guidant during the Ancure-Device debacle, when Guidant entered its Plea Agreement with the DOJ in 2003, and when the Company manufactured and sold defective ICD and pacemaker devices. Dollens was also a member of Guidant's Compliance Committee, which was charged with reviewing Guidant's regulatory compliance and internal control procedures and with overseeing compliance with Guidant's Code of Business Conduct, and on its Governance Committee. As such, Dollens was directly responsible for oversight of Guidant's compliance with state and federal laws and FDA regulations and with setting in place proper corporate governance policies and mechanisms. Defendant Dollens, along with Defendant Cornelius, together caused the posting to the Company's website a series of documents entitled "Guidant Code of Business Conduct," including a "Corporate Integrity Agreement", in response to Guidant's felony convictions and plea agreement for violations of the Food, Drug and Cosmetic Act ("FDCA").

56. Defendant James M. Cornelius has been a member of the Company's Board of Directors since 1994 and served as Chairman of the Board throughout the Class

Period. From a time prior to the beginning of the Class Period and continuing throughout the Class Period, Defendant Cornelius acted in an executive capacity, to negotiate and manage Guidant's merger discussions with Johnson and Johnson ("J&J"), including the exercise of influence and control over disclosure of information regarding the progress of the merger discussions with J&J. During the Class Period, Cornelius sold 450,000 shares or 47% of his holdings of Guidant stock for over \$30.5 million in proceeds. Cornelius was an officer and/or director for Guidant during the Ancure-Device debacle, when Guidant entered its Plea Agreement with the DOJ in 2003, and when the Company manufactured and sold defective ICD and pacemaker devices. Defendant Cornelius, along with Defendant Dollens, together caused the posting to the Company's website a series of documents entitled "Guidant Code of Business Conduct", including a "Corporate Integrity Agreement", in response to Guidant's felony convictions and plea agreement for violations of the Food, Drug and Cosmetic Act ("FDCA"). Defendant Cornelius sought to demonstrate that he could lead the Company successfully and generate the growth expected by the market. In November 2005, Cornelius became interim CEO upon the resignation of Defendant Dollens.

57. Defendant Guido J. Neels served as Guidant's Chief Operating Officer ("COO"). As COO, Defendant McCoy, President of the Company's CRM operating unit reported directly to him. Neels conducted interviews where he made misrepresentations regarding Guidant's ICDs' reliability. During the Class Period, Neels sold approximately 60,000 shares of his Guidant stock for over \$4.3 million in proceeds. Neels was an officer and/or director for Guidant during the Ancure-Device debacle, when Guidant entered its Plea Agreement with the DOJ in 2003, and when the Company manufactured and sold defective ICD and pacemaker devices. Defendant Neels sought to demonstrate that he could lead the Company successfully and generate the growth expected by the market.

58. Defendant Keith E. Brauer served as Vice President and Chief Financial Officer (“CFO”) of Guidant throughout the Class Period. Brauer signed and certified pursuant to Section 302 of the Sarbanes-Oxley Act, the Guidant 10-K filed during the Class Period in which the Company’s financial report highlighted increasing defibrillator sales revenues even though Brauer knew of adverse material facts which made those sales revenues false and misleading. Moreover, Brauer as CFO provided the financial reporting and communications with the securities market. Communications with the market, including conference calls and the Company’s internal reports showing Guidant’s forecasted and actual growth were prepared under his direction. Brauer met with representatives of J & J during the merger negotiations in which Brauer made false and misleading representations about the status of Guidant’s ICD and pacemaker business. Defendant Brauer sought to demonstrate that he could lead the Company successfully and generate the growth expected by the market. During the Class Period, Brauer sold approximately 50,000 shares of Guidant stock for over \$3.6 million in proceeds. Brauer was an officer and/or director for Guidant during the Ancure-Device debacle, when Guidant entered its Plea Agreement with the DOJ in 2003, and when the Company manufactured and sold defective ICD and pacemaker devices.

59. Defendant Beverly H. Lorell served as Vice President and Chief Medical and Technology Officer (“CMTO”) of Guidant throughout the Class Period. As CMTO Defendant Lorell directly influenced Guidant’s public communications, as she acted as an advocate for the Company on public policy matters, as well as provided corporate oversight and leadership over Guidant’s technology issues, including those impacting the Company’s ICDs and other cardiac rhythm products. Defendant Lorell sought to demonstrate that he could lead the Company successfully and generate the growth expected by the market. During the Class Period, Lorell sold approximately 45,967 shares or virtually all of her holdings of Guidant stock for over \$3.3 million in proceeds.

Lorell was an officer and/or director for Guidant when the Company manufactured and sold defective ICD and pacemaker devices.

60. Defendant Ronald N. Spaulding served as President of Guidant's International Operations, Europe, Middle East, Africa and Canada divisions throughout the Class Period. Defendant Spaulding was identified by both Guidant and J&J as a particularly knowledgeable member of the Guidant executive team, whose continued advice and counsel throughout the merger and transition process was considered critical. For these reasons, on December 15, 2004, J&J and Guidant jointly modified Spaulding's rights and obligations under Guidant's "Change In Control Severance Pay Plan for Select Employees." Defendant Spaulding sought to demonstrate that he could lead the Company successfully and generate the growth expected by the market. During the Class Period, Spaulding sold approximately 58,200 shares of Guidant stock for over \$4.2 million in proceeds. Spaulding was an officer and/or director for Guidant during the Ancure-Device debacle, when Guidant entered its Plea Agreement with the DOJ in 2003, and when the Company manufactured and sold defective ICD and pacemaker devices.

61. Defendant William F. McConnell Jr. served as Vice President and Chief Information Officer for Guidant throughout the Class Period. In his role as Chief Information Officer, McConnell was identified by both Guidant and J&J as a particularly knowledgeable member of the Guidant executive team, whose continued advice and counsel throughout the merger and transition process was considered critical. For these reasons, on December 15, 2004, J&J and Guidant jointly modified McConnell's rights and obligations under Guidant's "Change In Control Severance Pay Plan for Select Employees." Defendant McConnell sought to demonstrate that he could lead the Company successfully and generate the growth expected by the market. During the Class Period, McConnell sold approximately 52,000 shares of Guidant stock for over \$3.7 million in proceeds. McConnell was an officer and/or director for Guidant during the

Ancure-Device debacle, when Guidant entered its Plea Agreement with the DOJ in 2003, and when the Company manufactured and sold defective ICD and pacemaker devices.

62. Defendant John B. King served as a director of Guidant throughout the Class Period. Defendant King acted as counsel to the law firm of Baker & Daniels, which provided legal services to Guidant. Defendant King was a Director of Guidant and served on various Board Committees, including the Company's Compliance Committee, responsible for the review of Guidant's regulatory compliance and internal control procedures, as well as the company's code of business conduct. Defendant King also served on the Company's Committee for Science and Technology Strategy, and the Management Development and Compensation Committee. Defendant King sought to demonstrate that he could lead the Company successfully and generate the growth expected by the market. During the Class Period, King sold 248,944 shares of Guidant stock for over \$18.2 million in proceeds. King was a director for Guidant during the Ancure-Device debacle, when Guidant entered its Plea Agreement with the DOJ in 2003, and when the Company manufactured and sold defective ICD and pacemaker devices.

63. Defendant J. Frederick McCoy Jr. served as President of Cardiac Rhythm Management of Guidant throughout the Class Period. As President of CRM, McCoy had accountability and responsibility for the quality and safety of Guidant's CRM products, including the management of adverse medical and product information derived from "customer complaints," adverse medical reports and other reporting received or otherwise obtained by the Company regarding the quality and safety of CRM products, in accordance with Company policies, the FDA regulations and the Company's CIA with the Office of the Inspector General of the Department of Health and Human Services. ("OIG-HHS"). McCoy, as President of Cardiac Rhythm Management ("CRM") conducted interviews during the Class Period, where he made material omissions and misrepresentations regarding the reliability of Guidant's ICDs. Defendant McCoy was identified by both Guidant and J&J as a particularly knowledgeable member of the

Guidant executive team, whose continued advice and counsel throughout the merger and transition process was considered critical. For these reasons, on December 15, 2004, J&J and Guidant jointly modified McCoy's rights and obligations under Guidant's "Change In Control Severance Pay Plan for Select Employees." Defendant McCoy sought to demonstrate that he could lead the Company successfully and generate the growth expected by the market. McCoy sold approximately 20,412 shares of Guidant for over \$1.5 million in proceeds. McCoy was an officer and/or director for Guidant during the Ancure-Device debacle, when Guidant entered its Plea Agreement with the DOJ in 2003, and when the Company manufactured and sold defective ICD and pacemaker devices.

64. Defendant Roger Marchetti served as Vice President of Human Resources of Guidant throughout the Class Period. Prior to the beginning of the Class Period, Defendant Marchetti served as vice president, finance and information systems and as vice president, human resources, corporate controller and chief accounting officer for Guidant's Vascular Intervention predecessor. Defendant Marchetti participated in, influenced and provided counsel regarding Guidant's merger discussions with J&J. Defendant Marchetti was identified by both Guidant and J&J as a particularly knowledgeable member of the Guidant executive team, whose continued advice and counsel throughout the merger and transition process was considered critical. For these reasons, on December 15, 2004, J&J and Guidant jointly modified Marchetti's rights and obligations under Guidant's "Change In Control Severance Pay Plan for Select Employees." Defendant Marchetti sought to demonstrate that he could lead the Company successfully and generate the growth expected by the market. During the Class Period, Defendant Marchetti sold 9,000 shares of Guidant stock for \$649,530 in proceeds.

65. Defendant Kathleen Lundberg served as Senior Vice President and Chief Compliance Officer of Guidant throughout the Class Period. Prior to the beginning of the Class Period, defendant Lundberg executed on behalf of Guidant a “Corporate Integrity Agreement” as part of a plea agreement involving Guidant’s unprecedented violations of the Food, Drug and Cosmetic Act (“FDCA”). Lundberg, as the Company’s Chief Compliance Officer (“CCO”) was responsible for assuring the Company’s compliance with FDA regulations and Federal healthcare program requirements, including adherence to the Company’s Corporate Integrity Agreement with OIG-HHS. Amongst other responsible officials at Guidant, defendant Lundberg had joint accountability and responsibility for the quality and safety of Guidant’s CRM products, including the management of adverse medical and product information derived from “customer complaints,” adverse medical reports and other reporting received or otherwise obtained by the Company regarding the quality and safety of CRM products, in accordance with Company policies, the FDA regulations and the Company’s CIA with the OIG-HHS.

66. The individuals named as Defendants in ¶¶ 55-65 are referred to herein as the “Individual Defendants.” The Individual Defendants, because of their positions with the Company, possessed the power and authority to control the contents of Guidant quarterly reports, press releases and presentations to securities analysts, money and portfolio managers and institutional investors, *i.e.*, the market. Each Individual Defendant was provided with copies of the Company’s reports and press releases alleged herein to be misleading prior to or shortly after their issuance and had the ability and opportunity to prevent their issuance or cause them to be corrected. Because of their positions and access to material non-public information available to them, but not to the

public, each Individual Defendant knew that the adverse facts specified herein had not been disclosed and in fact were being concealed from the public and that the positive representations which were being made were materially false and misleading.

67. In addition to the above-described involvement, each Individual Defendant had knowledge of Guidant's problems and each was motivated to conceal such problems. Each Individual Defendant sought to demonstrate that he/she could lead the Company successfully and generate the growth expected by the market.

68. Each Individual Defendant also owed a duty to the Company, its shareholders and investors in the market not to trade on inside information. Each Defendant is liable for (a) making false statements, *or* (b) failing to disclose adverse facts known to him/her about Guidant. Defendants' fraudulent scheme and course of business operated as a fraud or deceit on purchasers of Guidant's publicly traded securities and successfully (a) deceived the investing public regarding Guidant's prospects and business; (b) artificially inflated the prices of Guidant's publicly traded securities; (c) allowed Defendants to negotiate a lucrative \$25.4 billion merger deal with J&J; (d) allowed insider Defendants to sell nearly \$89 million of their own shares at inflated prices; and (e) caused Lead Plaintiffs and other members of the Class to purchase Guidant's publicly traded securities at inflated prices.

DEFENDANTS' FRAUDULENT COURSE OF CONDUCT

The Ancure Device Debacle

69. In 1998, Guidant began designing, manufacturing and marketing the Ancure Device stent graft system. It was marketed as a safer and less invasive alternative treatment for abdominal aortic aneurysm than the conventional method of an open surgical procedure referred to as abdominal aortic aneurysm repair.

70. The Ancure Device was known as a stent graft because it included both a “stent,” a hard cylinder to prop open an artery, and a “graft,” a section of fabric designed to replace the weakened wall of the aorta of a patient. During the Ancure treatment regime, the Ancure stent graft system is inserted into patients by utilizing a non-surgical procedure. The stent is inserted through a one-inch incision in the groin. The stent is then threaded through the artery using a catheter and is positioned so that when deployed, it covers or excludes the aneurysm. This provides a channel through which blood can flow and relieves pressure against the weakened artery wall. The Ancure Device was designed to be attached to the aorta wall with miniature hooks during the delivery and the delivery catheter is supposed to retract within its cover and be safely pulled out of the patient.

71. In September 1999, Defendants received FDA approval of the Ancure Device. The FDA required, as a condition to its approval:

(a) that the device be properly labeled, explaining to doctors how to use the Ancure, including any methods of administration, relevant hazards, contraindications and precautions;

(b) that any changes to the instructions for use that affected the Ancure’s safety or effectiveness not be made without FDA approval;

(c) that a Premarket Approval Supplement would be submitted to the FDA for approval before any changes were made to the Ancure that affected its safety or effectiveness; and

(d) that Guidant was required to have a sales representative present in the operating room to observe each surgical procedure in which the Ancure was implanted, or an implant was attempted.

72. The FDA approval was expressly contingent upon compliance with the terms outlined in the approval letter:

Failure to comply with the conditions of approval invalidates this approval order. Commercial distribution of a device that is not in compliance with these conditions is a violation of the act.

73. Defendants are required by the Safe Medical Devices Act of 1990 to report to the FDA within 30 days whenever they receive or otherwise become aware of information from any source that reasonably suggested that its medical device products (i) may have caused or contributed to a death or serious injury; or (ii) had malfunctioned and the device would be likely to cause or contribute to a death or serious injury if the malfunction were to recur. These reports are known as Medical Device Reports (“MDRs”). The FDA makes MDRs available to physicians and other members of the public so that they can be aware of recurring malfunctions and other risks concerning medical devices. Pursuant to federal regulation, submission of an MDR does not constitute an admission by a manufacturer that a device caused or contributed to the event that is reported.

74. Pursuant to federal law, a medical device causes or contributes to a death or serious injury whenever a death or serious injury was, or may have been, attributed to a medical device, or a medical device was or may have been a factor in a death or serious injury, including events occurring as a result of failure, malfunction, improper or inadequate design, manufacture, labeling, or user error.

75. Pursuant to the relevant federal law, a patient undergoing a surgical procedure using Defendants' medical device products suffered a serious injury when he or she (i) experienced an injury that was life-threatening; (ii) experienced an injury or an illness that resulted in permanent impairment of a body function or permanent damage to body structure; or (iii) experienced an injury that required medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure. Evidence of actual causation is not required for there to be an obligation to file an MDR.

76. From 1999 through March 2001, there were 2,628 separate incidents of malfunction reported to Guidant relating to the Ancure Device, including 12 related deaths and 57 emergency room procedures, for which Guidant had an ethical and legal responsibility to advise the healthcare community and certainly was under a legal duty to report them to the FDA, but for which Guidant had failed to file the required MDRs.

77. Indeed, it is a matter of public record that Defendants engaged in criminal acts associated with illegal medical device development and marketing activities in violation of the FDA, resulting in felony convictions and fines. On June 12, 2003, the DOJ issued a press release announcing a Felony Plea Agreement with Guidant, which stated in pertinent part:

The guilty plea represents the largest amount ever paid by a Defendant for failing to report malfunctions of a medical device to the Food & Drug Administration ("FDA"), and one of the first times there have been felony convictions for such conduct. It is also the second largest criminal and civil settlement in the history of the Northern District of California. The guilty plea and civil settlement was announced today at a press conference by the U.S. Attorney's Office for the Northern District of California, the U.S. Department of Justice's Office of Consumer Litigation and Civil Fraud Section, the FDA and the Federal Bureau of Investigation.

The Defendant, Endovascular Technologies, Inc. ("EVT"), is a wholly owned subsidiary of Guidant Corporation ("Guidant"). The subsidiary is based in Menlo Park, California. According to Guidant's website (www.guidant.com), the Menlo Park facility where the Ancure device was manufactured is also listed as one of Guidant's operating facilities. Guidant is a Fortune 500 company based in Indianapolis, Indiana. The criminal charges relate to a medical device known as the Ancure Endograft System ("Ancure Device"). The Ancure Device treats abdominal aortic aneurysms, a potentially life threatening condition commonly associated with people with heart disease. The Ancure Device is inserted into the patient's body during a surgical procedure.

Under federal law, a company is required to report to FDA any incident in which its medical device may have caused or contributed to a death or serious injury or the medical device experienced a malfunction that would be likely to cause or contribute to a death or serious injury if the malfunction were to recur. The reports to FDA are called Medical Device Reports. ***In this case, the company was aware of every malfunction because, as a condition of FDA approval, it had a sales representative present in the operating room during each surgery and the reports of those failures were repeatedly tabulated and distributed to company officials. In failing to file thousands of Medical Device Reports, the Defendant concealed the true extent of problems with the Ancure Device from patients, doctors and the public.***

According to a Criminal Information which charges EVT with 10 felonies, the Ancure Device was approved for commercial distribution in the United States in September 1999. It was withdrawn from the market on March 15, 2001. During that 19-month span, the company filed a total of 172 Medical Device Reports with FDA concerning the Ancure Device. In pleading guilty, the Defendant admitted that there were an additional 2,628 Medical Device Reports that it had failed to file-each representing an incident in which the Ancure Device malfunctioned or its use was associated with death or serious injury-out of a total of 7,632 medical devices that were sold. Among the unreported incidents were 12 deaths and 57 emergency procedures in which a physician converted the operation into a more invasive procedure. Such a conversion could occur when the delivery system of the Ancure Device became stuck or lodged in the patient's body and could not be removed without opening the patient's stomach during a surgery and slicing open the aorta to remove the broken device and fix the aneurysm.

Company sales representatives attempted to avoid surgical conversions-which were reportable to FDA-by instructing doctors in a technique to free the delivery system of the Ancure Device when it became stuck in a patient's body. The technique had been devised in part by a company sales representative. It involved breaking the handle of the device and removing the catheters housed within the delivery system of the Ancure Device individually from the patient's body. During the relevant time, the handle breaking technique had not been tested; doctors had not been trained on its use; sales representatives who described the technique to doctors during surgery had not been trained by the company on its use; the instructions accompanying the product did not explain the procedure, and the Defendant failed to seek prior

approval of FDA. After a patient died in a case in which the handle breaking technique was used, a group of Defendant's employees concluded that FDA had to be informed about its use. The company failed to do so, even as its sales representatives continued to describe the handle breaking technique to doctors during surgeries.

Guidant Corporation's EVT division pled guilty to a Criminal Information charging it with nine counts of introducing a misbranded medical device into interstate commerce, in violation of 21 U.S.C. §§ 331(a) and 333(a)(2). The Criminal Information was filed under seal on June 9, 2003. It was unsealed this morning. The corporation then pled guilty and was sentenced before District Judge Susan Illston in San Francisco federal court.

In addition to the nine misbranding counts, the company also pled guilty to one count of making false statements to the FDA, in violation of 18 U.S.C. § 1001. That charge stems from an inspection conducted by FDA of the company's Menlo Park headquarters in July 2000. During the inspection, the FDA official asked specifically for all complaints the company had received about one type of malfunction. The company intentionally misled the inspector by giving him a list of 55 complaints when, in fact, the company knew that there had been hundreds of complaints about this particular malfunction.

As part of the plea agreement and a civil settlement agreement, Guidant's EVT subsidiary will pay \$92.4 million. In dollar terms, this is the second largest global criminal and civil settlement in the history of the Northern District of California.

Under the civil settlement, EVT will pay \$49 million to settle claims that the company's actions caused Medicare, Medicaid and the Veterans Affairs Program to pay millions of dollars for the adulterated and misbranded devices. Both EVT and Guidant have agreed to enter into a corporate integrity agreement with the Office of Inspector General for the Department of Health and Human Services. Also, as part of the plea agreement, Guidant, as well as EVT, have agreed to cooperate in the United States' continuing investigation into criminal activities associated with the Ancure product.

According to the charges, the government first became aware of the allegations of fraud and cover up in October 2000 when a group of seven anonymous employees wrote a letter to FDA. Later, an investigation authorized by the Defendant which concluded that some of the complaints by the Anonymous Seven were accurate, and that the company was significantly out of compliance with FDA regulations and its own internal policies.

On March 23, 2001, Guidant's EVT division informed FDA that it had failed to file 2,623 MDRs and that the company had inappropriately provided information to doctors about the handle breaking technique. The Ancure Device was suspended from sale at that time. Later, FDA permitted the Ancure Device to be sold with modifications in its warnings to customers and the instructions provided to physicians. It is still on the market. The allegations in the Criminal Information and Plea Agreement

