CONSOLIDATED AMENDED COMPLAINT
FOR VIOLATIONS OF THE FEDERAL SECURITIES LAWS

JURY TRIAL DEMANDED

Plaintiffs, through their attorneys, bring this action on behalf of themselves and all others similarly situated, and on personal knowledge as to themselves and their activities, and on information and belief as to all other matters, based on investigation conducted by counsel, hereby allege as follows:

NATURE OF THE ACTION

1. This is a class action on behalf of purchasers of the securities of Guidant Corporation ("Guidant" or the "Company") between June 23, 1999 and June 12, 2003, inclusive (the "Class Period"), seeking remedies under the Securities Exchange Act of 1934 (the "Exchange Act"). Defendants include Guidant, its President and Chief Executive Officer Ronald W. Dollens ("Dollens"), its Chief Financial Office Keith E. Brauer ("Brauer"), its then President of the Cardiovascular and Vascular Surgical Group Thomas J. Watkins ("Watkins"), its wholly owned subsidiary, EndoVascular Technologies, Inc. ("EVT"), and Beverly A. Huss ("Huss"), President of EVT.
2. Guidant designs, manufactures and markets therapeutic medical devices for the treatment of cardiovascular and vascular diseases. During the Class Period the Company designed, developed, and manufactured its Ancure Endograft System (the “Ancure”) through EVT. Defendants marketed the Ancure as a less-invasive alternative to the standard open surgical procedure used to treat abdominal aortic aneurysms.

3. The Ancure is an implant that is folded inside a plastic jacket which is attached to a long cable. If the device works properly, the surgeon simply manipulates several wires at the other end of the cable to retract the plastic jacket and unfold and attach the implant to the aorta’s walls. The problem with the device was that it frequently did not work properly and became lodged in patients.

4. The Ancure was specifically marketed for the endovascular treatment of infrarenal abdominal or aorto-iliac aneurysms in patients having: (i) adequate iliac/femoral access; (ii) infrarenal non-aneurysmal neck length of at least 15 millimeters; (iii) distal segment lengths of at least 20 millimeters and diameters no greater than 13.4 millimeters; and (iv) morphology suitable for endovascular repair. Each Ancure sold by defendants costs approximately $10,000 per device.

5. Doctors and patients had serious problems with the Ancure almost immediately after its release, including: (i) difficulties removing the plastic jacket covering the implant; (ii) getting the jacket, with its hooks, wires, and miniature balloons, stuck in patients’ arteries; (iii) having the wires get caught in the hooks used to attach the device while the Ancure was inside the patient’s body; and (iv) difficulties implanting the Ancure in a way that was consistent with the approved instructions for use. If an Ancure became lodged within the patient, a doctor would suddenly find the himself being forced to cut open his patient’s stomach to remove it. As a result, doctors began devising spontaneous methods for
removing the lodged device from their patients. These methods of removal were quickly reported to Guidant by its sales representatives, who observed each and every implantation.

6. After discovering the Ancure stuck in a patient, one surgeon and a creative sales representative of defendants decided to break the handle used to insert the device, while the device was still in the patient, and then pull the Ancure out of the patient piece by piece. Throughout Guidant, this method soon became known as the “handle-breaking technique” (the “Handle-Breaking Technique”). In an effort to avoid resorting to traditional open surgical repair, Guidant sales representatives, without the approval of the United States Food & Drug Administration (“FDA”) or proper training, started recommending that surgeons use the Handle-Breaking Technique when problems with the Ancure arose.

7. The FDA is the public agency responsible for protecting the health and safety of the American public. Among other things, the FDA is responsible for ensuring that medical devices designed for use in humans, such as the Ancure, are safe and effective for their intended uses and are labeled accurately and in compliance with the law. Accordingly, the FDA regulates and monitors the manufacture, processing, packing, labeling and shipment of medical devices. The FDA then makes that information available to the public and physicians.

8. Pursuant to statutory mandate, a company must include adequate instructions for the use of all medical devices, unless expressly exempted by the FDA, prior to any device being entered into interstate commerce. A company may also not legally sell a medical device in the United States without the approval of the FDA.

9. For the FDA to approve a medical device such as the Ancure, the company must submit a premarket approval application (“PMA”) to the FDA which includes the results of clinical studies conducted on humans and which demonstrates that the device is safe and effective
for its intended use. In addition, the company must submit a PMA Supplement for review and approval by the FDA before it makes any changes that affect the safety or effectiveness of a device.

10. As the Handle-Breaking Technique became more popular, and Guidant began recommending it to surgeons, several Guidant employees raised concerns during monthly Quality Meetings suggesting that the Handle-Breaking Technique be thoroughly tested and the problem be reported to the FDA for review and approval. While some testing was completed, neither the existence of the Handle-Breaking Technique nor its common usage was reported to the FDA or the investing public.

11. Pursuant to statutory mandate a company is required to file a report with the FDA whenever it receives or otherwise becomes aware of information from any source that reasonably suggests that a medical device: (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 a death or serious injury if the malfunction were to recur. These reports, known as Medical Device Reports (MDRs), must be provided to the FDA within 30 days. MDRs are subsequently made available to physicians and other members of the public to warn them of recurring malfunctions and other risks concerning medical devices.

12. During the Class Period at least 75 patients died and 991 were injured after receiving the Ancure. The Ancure malfunctions, including at least 12 deaths, were widely known at EVT, and were purposefully not reported to the FDA. Defendants Guidant, Brauer, Dollens, Watkins and Huss knew of these problems through reporting systems at the Company, including but not limited to Guidant Management Board (“GMB”) meetings, a series of audits of EVT which revealed that the Ancure had malfunctioned thousands of times, weekly EVT Senior Management meetings, and monthly All-Employee Quality meetings.
13. Defendants intentionally withheld detrimental information from the FDA because they knew once the MDRs became public it would have a devastating impact on defendants’ financial performance and stock price.

14. On June 12, 2003, the last day of the Class Period, the Company announced that Guidant’s EndoVascular Technologies division pled guilty to 10 felonies relating to the Ancure device, including misbranding and making false statements to government regulators. As part of the settlement it reached with the United States Attorney’s Office for Northern District of California, the United States Department of Justice, and the FDA, and the Department of Veterans Affairs, EVT agreed to pay a record fine of $92.4 million.

15. As a result, on June 13, 2003, Guidant’s stock price fell $6.26, or 15%, from its June 12, 2003 opening price.

16. The government’s investigation regarding individual criminal misconduct is ongoing. The Company stopped selling the Ancure device in October 2003.

**JURISDICTION AND VENUE**


18. This action arises under §§10(b) and 20(a) of the Exchange Act and Rule 10b-5 promulgated thereunder (17 C.F.R. §240.10b-5).
19. Venue is proper in this district pursuant to §27 of the Exchange Act and 28 U.S.C. 1391(b) because the acts charged herein, including the dissemination of materially false and misleading information, occurred in this district.

20. Guidant maintains its principal executive offices in this district at 111 Monument Circle, 29th Floor, Indianapolis, Indiana.

21. In connection with the conduct complained of herein, defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including the mails and interstate telephone communications, and the facilities of a national securities exchange.

PARTIES

22. Lead plaintiff Nancy Gaynor purchased Guidant securities as detailed in the attached certification and was damaged thereby. Ms. Gaynor was appointed lead plaintiff by Order of the Court dated October 6, 2003.

23. Lead plaintiff Geoffrey Gaynor purchased Guidant securities as detailed in the attached certification and was damaged thereby. Mr. Gaynor was appointed lead plaintiff by Order of the Court dated October 6, 2003.

24. Lead plaintiff George Gaynor purchased Guidant securities as detailed in the attached certification and was damaged thereby. Mr. Gaynor was appointed lead plaintiff by Order of the Court dated October 6, 2003.

25. Lead plaintiff Geoffrey Gaynor, Jr. purchased Guidant securities as detailed in the attached certification and was damaged thereby. Mr. Gaynor was appointed lead plaintiff by Order of the Court dated October 6, 2003.

26. Guidant is a corporation organized under the laws of Indiana with its principal executive offices located at 111 Monument Circle, 29th Floor, Indianapolis, Indiana. Guidant designs, develops, manufactures and markets therapeutic medical devices for the treatment of
cardiovascular and vascular diseases. On June 12, 2003, Guidant’s wholly owned subsidiary, EndoVascular Technologies, Inc., pled guilty to 10 felonies and agreed to pay $92.4 million to settle criminal and civil charges that it covered up thousands of incidents, including 12 deaths and 57 emergency procedures, in which a medical device used to treat aneurysms in the aorta malfunctioned.

27. Defendant Endo Vascular Technologies, Inc. (“EVT”) is a Delaware corporation with its principal place of business at 1360 O’Brien Drive, Menlo Park, California. Following its acquisition in November 1997, EVT is and has been a wholly owned subsidiary of Guidant. EVT designs, develops and manufactures minimally invasive endovascular systems to repair diseased or damaged vascular structures.

28. Ronald W. Dollens ("Dollens") was, at all relevant times, Guidant’s President and Chief Executive Officer.

29. Defendant Keith E. Brauer ("Brauer") was, at all relevant times, Guidant’s Vice President and Chief Financial Officer.

30. Defendant F. Thomas Jay Watkins III ("Watkins") was, at all relevant times, a Vice President of Guidant, President of Guidant’s Cardiovascular and Vascular Surgical Group, and President of Compass, Guidant’s corporate new ventures and business development organization. During his employment with Guidant, defendant Watkins was the senior executive in charge of EVT and the development, marketing and sale of Ancure.

31. Defendant Beverly A. Huss ("Huss") was, at all relevant times, President of EVT, also known as EndoVascular Solutions, a position she has held from December 2000 to present. Defendant Huss is, and at relevant times has been, a member of Guidant’s Management Committee.
32. Defendants Dollens, Brauer, Watkins and Huss are collectively referred to herein as the “Individual Defendants.”

33. As officers, directors and/or controlling persons of a Company whose common stock is traded on the New York Stock Exchange (“NYSE”) and governed by the provisions of the federal securities laws, defendants Dollens, Brauer, Watkins and Huss had a duty to disseminate truthful information promptly and accurately with respect to the Company’s operations, products, markets, management, earnings and business prospects, to correct any previously issued statements that had become materially misleading or untrue, and to disclose any trends that would materially affect earnings and the financial results of Guidant so that the market price of the Company’s publicly traded securities would be based upon truthful and accurate information.

34. Under rules and regulations promulgated by the SEC under the Exchange Act, defendants Dollens, Brauer, Watkins and Huss also had a duty to report all trends, demands or uncertainties that were likely to influence Guidant’s liquidity; net sales, revenues and/or income. Dollens, Brauer, Watkins and Huss’ representations during the Class Period violated these specific requirements and obligations.

35. As officers and directors of the Company, defendants Dollens, Brauer, Watkins and Huss controlled and/or possessed the power and authority over the contents of Guidant’s reports, press releases and presentations to the public. Defendants Dollens, Brauer, Watkins and Huss were 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.

36. Defendants Dollens, Brauer, Watkins and Huss are also liable as individual participants in a fraudulent scheme and course of conduct that operated as a fraud and/or deceit upon the
class. Because of their managerial positions with the Company, Dollens, Brauer, Watkins and Huss had access to the adverse, non-public information about the business, finances and future business prospects of Guidant as particularized herein and acted to misrepresent, misstate or conceal such information from plaintiffs and the investing public.

37. During the Class Period, in addition to disseminating information to shareholders and the investing public through press releases, SEC filings, and the press, defendants Guidant, Dollens, Brauer, Watkins and Huss disseminated information through analysts covering the Company’s common stock. Each of the defendants is liable as a participant in a fraudulent scheme and course of business that operated as a fraud or deceit on purchasers of Guidant securities by disseminating materially false and misleading statements and/or concealing material adverse facts. The scheme: (i) deceived the investing public regarding Guidant’s businesses, operations, management and the intrinsic value of its securities; (ii) enabled Guidant insiders to sell millions of dollars of their personally held Guidant stock to the unsuspecting public; and (iii) caused plaintiff and other members of the Class to purchase Guidant securities at artificially inflated prices.

SUBSTANTIVE ALLEGATIONS

38. Guidant claims to be a global leader in technology for the treatment of cardiac and vascular disease. The tagline to its press releases, published throughout the Class Period, stated as follows:

Guidant Corporation pioneers lifesaving technology, giving an opportunity for better life today to millions of cardiac and vascular patients worldwide. The company, driven by a strong entrepreneurial culture of more than 10,000 employees, develops, manufactures and markets a broad array of products and services that enable less invasive care for some of life’s most threatening medical conditions.

39. At all relevant times, the Company’s reputation for honesty and high-quality medical products was essential to its successful financial performance.
40. In September 1999, Guidant received FDA approval to market the Ancure for use in the treatment of abdominal aortic aneurysms. An abdominal aneurysm is a weak area that develops in the wall of the aorta, the artery that brings blood flow from the heart through the abdomen to the rest of the body. The Ancure has two primary parts. The first part is a delivery catheter used to place the vascular endograft into the aorta. The delivery catheter is inserted into a blood vessel through an incision made in the patient’s leg. The second part is a vascular endograft that is placed in the patient’s aorta using a delivery system to prevent the aneurysm from rupturing. The vascular endograft is designed to remain in the patients’ aorta permanently after being implanted. The delivery catheter is designed to be removed from the patient after the vascular endograft is implanted.

41. On the same day that the FDA approved the Ancure for commercial sale in the United States, it also approved a competing product called the “AneurRx Stent Graft Systems” (the “AneurRx System”) manufactured by Minneapolis-based Medtronic Inc. (“Medtronic”). The Medtronic AneurRx System also was designed to treat abdominal aortic aneurysms by the insertion of an endograph into the aorta. Consequently, from the first day that the Ancure was approved for commercial sale in the United States, Guidant faced fierce competition for market share.

42. At all times relevant herein, the Company was aware of every malfunction of the Ancure, and methods used to remove Ancure devices lodged in patients, because, as a condition of FDA approval, it had a sales representative present in the operating room during each surgery. After a surgery, the sales representatives phoned in their reports to a voice mail which other sales representatives, employees and managers would review. Information regarding failures of the Ancure were routinely tabulated and distributed to Company officials. In addition, all Ancure usage problems, including physician complaints about the
product, were reviewed at monthly EVT All-Employee Quality meetings, monthly Pre-meetings (held before the All-Employee Quality meetings) and monthly Senior Management meetings. During his tenure as the senior executive in charge of EVT, defendant Watkins directly received the information contained in the voice mails, distributions and Pre-meetings during his regular one-on-one conversations with EVT personnel, and at the All-Employee Quality meetings and Senior Management meetings. Defendant Watkins directly transmitted the information he learned to defendants Dollens and Brauer at the quarterly GMB meetings, and in his weekly telephone reports to his director supervisor, defendant Dollens. After defendant Huss became President of EVT in December 2000, Huss also learned of the information contained in the voice mails, distributions and Pre-meetings during her one-on-one meetings with EVT personnel, and at the All Employee Quality meetings and Senior Management meetings. Defendant Huss directly transmitted the information she learned to the other defendants: (i) in the quarterly GMB meetings; (ii) through Huss’ weekly telephone reports to her direct supervisor, defendant A. Jay Graf (“Graf”), Office of the President Group Chairman; and (iii) through Huss and Graf’s one-on-one in person meetings, held separate from the GMB meetings at least once per quarter. Graf, like Watkins, reported directly to defendant Dollens. Any information reported by Huss to defendant Graf at times other than the GMB meetings was then reported by Graf to Dollens and Brauer.

43. Unbeknownst to investors, defendants had learned from physicians during clinical trials that the delivery system for the Ancure was seriously flawed. In some instances, physicians were unable to implant the Ancure due to a problem with the device’s delivery system. In other instances, physicians were able to implant the Ancure, but could not do so in a way that was consistent with FDA approved instructions for use. Some of the malfunctions resulted in the
delivery system becoming improperly lodged in the body. In these latter cases, some of the patients had to undergo traditional open surgical repair to remove the delivery system of the Ancure.

44. As a result of Ancure devices being lodged within their patients, doctors and sales representatives began devising spontaneous and methods for removing them.

45. One surgeon and a creative sales representative decided to break the handle used to insert the device, while the device was still in the patient, and then pulled the Ancure out of the patient piece by piece. This became widely known as the Handle-Breaking Technique. Once this method of breaking or cutting the handle was reported to Guidant, sales representatives began recommending it to surgeons needing to remove lodged Ancure devices. The sales representatives told the surgeons how to perform the Handle-Breaking Technique even though there was: (i) no testing of the Handle-Breaking Technique; (ii) no training for the Handle-Breaking Technique provided to the surgeons or sales representatives; (iii) no modifications of the Ancure’s instructions for use to include the Handle-Breaking Technique; and (iii) no review or approval of the Handle-Breaking Technique by the FDA. As a result of its widespread use, complications from the Handle-Breaking Technique became known throughout EVT and Guidant.

46. For example, on or about January 26, 2000, the Handle-Breaking Technique was utilized in an operation and the surgeon lost a long wire inside the patient. The wire drifted up an artery towards his heart, and the patient died from complications.

47. Additionally, in February of 2000, a sales representative reported in his voice mail message report that the Ancure was “just severely tight” as the doctor attempted to insert the Ancure into a Minnesota man in his 60s. This was after the Ancure had already torn through another artery and they had extensively re-lubricated the device. When the Ancure became lodged
into the man, the surgeon had to break apart the device’s handle to move it. As a result of the Ancure becoming blocked, the man’s legs became paralyzed and had to be amputated.

48. Despite these and other complications, as defendants were made aware, Guidant sales representatives continued to recommend, and doctors continued to use, the Handle-Breaking Technique.

49. Do to the prolific use of the Handle-Breaking Technique, in early January 2000, a Guidant Engineer e-mailed a superior proposing that the Handle-Breaking Technique be thoroughly tested and the problem reported to the FDA for review and approval. While some testing was done, the Handle-Breaking Technique was never reported to the FDA. Defendants Watkins and Huss knew of the Handle-Breaking Technique, and the decision to not report the Handle-Breaking Technique nor the problems associated with it to the FDA, through their regular one-on-one conversations with EVT personnel, monthly All-Employee Quality meetings and weekly Senior Management meetings. Defendants Dollens and Brauer knew of the Handle-Breaking Technique, and the decision to not report the Handle-Breaking Technique nor the problems associated with it to the FDA, through the GMB meetings and Watkins and Huss’ regular reports. At all relevant times herein, the Company kept these problems a secret from the FDA and investing public to avoid damaging the Company’s reputation, and materially affecting its financial performance.

50. According to a Guidant Quality Engineer who worked on the Ancure device during the Class Period, while Guidant knew the Ancure could become lodged in the body of a patient, there were absolutely no information in the instructions for use (“IFU”) informing a physician on how he should deal with the lodged device. Moreover, physicians could not follow the FDA approved IFU as written because the instructions did not cover many of the issues that arose during implantation. Despite this, defendants never submitted a PMA Supplement outlining
and requesting approval for the Handle-Breaking Technique, in direct contravention of FDA requirements.

51. In July 2000, an inspector from the FDA’s San Jose office, Eric Anderson, began an investigation of EVT, its records and its procedures. During that inspection, Guidant and EVT specifically withheld information regarding complications related to the Ancure from FDA. For example, Mr. Anderson specifically requested a list of all complaints regarding difficulties of the catheter’s jacket to retract properly during surgical use of the delivery system of the Ancure. While the Company knew they had more than 200 complaints concerning this malfunction that occurred between October 1999 and April 2000 alone, Mr. Anderson was only provided a list 55 complaints. Because of defendants’ specific and systematic concealment of the truth from the FDA and investing public, the Company was then only cited with minor infractions.

52. In its plea agreement entered into with the United States Department of Justice, by the United States Attorney’s Office of the Northern District of California and the Office of Consumer Litigation, and filed with United States District Court for the Northern District of California, San Francisco Division, Case No. CR 03-0179 SI, on June 12, 2003 (the “Plea Agreement”), EVT, as a wholly owned subsidiary of Guidant, admitted that it “knowingly and intentionally misled the FDA about the frequency with which the delivery system of the Ancure Device malfunctioned” as a result of “difficulties of the catheter’s jacket to retract properly during surgical use of the delivery system.”

53. In response to Guidant’s concealment and the limits it directly placed on the FDA’s inspection, in October 2000 seven anonymous employees sent a letter to Michael Gropp, Guidant’s Chief Compliance Officer. In that letter the employees outlined ethical, legal and safety concerns related to the Ancure. The employees stated that the Company had
purposefully failed to report numerous problems to the FDA, and also sent a copy of the letter to the FDA. Among other concerns, the letter stated that defendants had: (i) conducted incomplete testing and analysis on currently recommended procedures; (ii) recommended the use of the device in a manner that was outside the directions for use approved by the FDA; (iii) failed to notify or rectify a problem with the jacket retraction failure mode, which had a complaint rate of approximately 20 percent; and (iv) failed to submit MDRs to the FDA as legally required.

54. Subsequently, the Company began a series of audits of the subsidiary which revealed thousands of malfunctions with the Ancure. Although the audits were completed by January 2001, the Company did not present any information to the FDA until March 2001.

55. According to its Plea Agreement, the audits revealed that EVT “had serious quality system regulation violations, incomplete and untimely complaint handling and documentation, incomplete MDR reporting, inadequate corrective and preventative action activities, incomplete record keeping and poor traceability practices, and was significantly out of compliance with FDA regulations and its own internal policies.”

56. On March 16, 2001, the Company was forced to withdraw the Ancure from the market. Despite this action, Guidant still did not reveal the dangers of the Ancure to the investing public. Rather, in a release issued on the Business Wire, the Company stated that the recall was “a result of Guidant’s identification of certain deficiencies in the company’s ANCURE-related regulatory processes and communications with the U.S. Food and Drug Administration (FDA). These regulatory deficiencies were primarily related to the deployment system of the ANCURE product.”

57. During the Class Period, defendants introduced approximately 7,632 Devices into interstate commerce. From September 30, 1999 until March 15, 2001, defendants filed only 172
MDRs for the Ancure’s delivery system. In March 2001, defendants finally disclosed to the FDA that approximately 2,628 additional MDRs concerning the Ancure’s delivery system had not been previously reported to the FDA, as required by law. In its Plea Agreement, defendants admitted to violating these reporting requirements.

58. In truth, between September 1999, when the Ancure went on the market, and March 16, 2001, when it was withdrawn, the Company filed a total of 172 medical device reports to the FDA concerning the Ancure when, as Guidant subsequently admitted in a post-Class Period plea agreement, there were an additional 2,682 Medical Device reports it had failed to file (and which it concealed from the investing public) - each representing an incident in which the Ancure malfunctioned or its use was associated with death or serious injury - and that among the unreported incidents were 12 deaths and 57 emergency procedures in which a physician converted the operation into a more invasive procedure after the Ancure had become lodged in the patient’s body.

59. In August 2001, when the Ancure was returned to the market, the investing public was still kept in the dark regarding the extent of the Ancure’s problems. It was not until August 13, 2002 that the Company revealed, deep in a regulatory filing with the SEC, that matters relating to the Ancure were being investigated by the U.S. Department of Justice and the FDA’s Office of Criminal Investigations. At no time in that filing did defendants disclose the nature of the investigation or its knowledge of the dangers of the Ancure. Rather, defendants only stated the U.S. Department of Justice and the FDA’s Office of Criminal Investigations were “conducting an investigation into matters relating to the Company’s ANCURE ENDOGRAFT System.”

60. The truth did not emerge until June 12, 2003. On that date, the United States Attorney’s Office for the Northern District of California issued a news release in which it announced
that EVT, Guidant’s wholly owned subsidiary, had pled guilty to 10 felonies and agreed to pay $92.4 million to settle criminal and civil charges that it had covered up thousands of incidents in which the Ancure had malfunctioned and the fact that use of the Ancure had resulted in 12 deaths and dozens of invasive surgeries. The felonies were one count of making false statements within the jurisdiction of a federal agency in violation of 18 U.S.C. § 1001, and nine counts of shipping misbranded medical devices within interstate commerce, in violation of 21 U.S.C. §§ 331(a) and 333(a)(2). In connection with the charges of shipping misbranded medical devices, the Company admitted in a plea agreement, that, “in introducing the misbranded device into interstate commerce, [EVT] acted with the intent to defraud and mislead.” (Emphasis added).

61. With respect to Guidant’s conduct, the release stated:

In announcing the guilty pleas, U.S. Attorney Kevin V. Ryan, a member of President Bush’s Corporate Fraud Task Force said, “Guidant’s EVT division violated the fundamental trust that exists between the medical device industry, doctors, patients and the public at large. Because of the company’s conduct, thousands of patients underwent surgeries without knowing the risks they faced, and their doctors - through no fault of their own - were unprepared to deal with those risks. The actions were criminal, and I am happy to say that today, for the first time in more than three years, the public will be able to learn the truth.”

62. The Company reported a 65% increase in earnings per share between 2000 and 2002, with its stock rising from $1.21 per share to $2.00 per share, and its revenues from the Ancure totaled $183 million during this same period. Throughout this period, from 2000 to 2002, the Company’s shares were artificially inflated and fluctuated with the Company’s partial disclosures with respect to the Ancure. During the Class Period, Company insiders sold thousands of their personally held Guidant shares to the investing public for millions of

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1 Emphasis has been added unless otherwise noted.
dollars in proceeds. For example, in November 2001, when the inherent dangers of the Ancure were apparent to insiders, John M. Capek, Guidant’s President of Vascular Intervention, sold 40,000 of his personally held Guidant shares for proceeds of $2 million and on April 24, 2002, defendant Dollens, just three months before announcing the Department of Justice investigation, sold 280,341 of his personally held Guidant shares for proceeds of $7,069,000.

MATERIALLY FALSE AND MISLEADING STATEMENTS ISSUED DURING THE CLASS PERIOD

JUNE 23, 1999 - MARCH 15, 2001: Guidant Begins To Market The Ancure

63. The Class Period begins on June 23, 1999. On that date, the Company issued a release over the Business Wire to announce that the FDA Advisory Panel had unanimously recommended approval of the Ancure for minimally invasive treatment of abdominal aortic aneurysms. The release stated in pertinent part, as follows:

*Guidant’s data, presented to the Panel today, showed that patients implanted with the Ancure™ System experienced significantly fewer complications than those who underwent conventional surgery.* “We are pleased by the Panel’s decision to recommend approval of Guidant’s Ancure (TM) System,” said Jay Watkins, president of Guidant’s Cardiac & Vascular Surgery Group. “Today’s vote is a significant milestone, which moves us closer to our ultimate goal of providing these patients with a minimally invasive alternative to conventional AAA surgery.

“The Panel’s recommendation to the FDA for approval of Guidant’s Ancure (TM) System,” marks a significant step in our mission of building a position on unquestioned leadership in cardiovascular and vascular medicine,” said Ron Dollens, president and chief executive officer of Guidant Corporation. A global leader in the medical device industry, Guidant provides innovative, minimally invasive and cost-effective products and services for the treatment of cardiovascular and vascular disease. For more information about Guidant’s products and services, visit the company’s Web site at http://www.guidant.com.
On June 23, 1999, the Company’s shares opened for trading at $45.95. On news of the FDA’s Advisory Panel recommendation, the Company’s share price jumped 6.3% to $48.87 and closed the day at $47.97.

The statements referenced above in the June 23, 1999 press release were materially false and misleading when made because they misrepresented and/or omitted the following adverse facts which then existed and disclosure of which was necessary to make the statements not false and/or misleading, including, but not limited to:

a. Patients implanted with the Ancure did not experience significantly fewer complications than those who underwent conventional surgery;

b. Defendants learned from physicians during clinical trials that the delivery system for the Ancure was seriously flawed. In some instances, physicians were unable to implant the Ancure due to a problem with its delivery system. In other instances, physicians were able to implant the Ancure, but could not do so in a way that was consistent with FDA approved instructions for use. Some of the malfunctions resulted in the delivery system becoming improperly lodged in the body. In these latter cases, some of the patients had to undergo traditional open surgical repair to remove the Ancure’s delivery system because the IFU approved by the FDA failed to provide full assistance to surgeons implanting the device;

c. These malfunctions rendered the Ancure unsafe and potentially deadly, and were known throughout the Class Period by defendants through: (i) weekly telephone conferences between Watkins and Dollens during Watkins’ tenure as the senior executive in charge of Ancure and, after December 2000, weekly telephone conferences between Huss and Graf; (ii) quarterly face-to-face meetings between defendant Huss and Graf, the information from which Graf then provided to his direct supervisor, defendant Dollens; and (iii) quarterly GMB meetings which were attended by each of the defendants. Moreover, Huss and the defendants knew of the problems associated with
Ancure because of voice mail reports by sales representatives who attended each and every implantation of an Ancure, monthly EVT All-Employee Quality meetings, Pre-meetings, EVT Senior Management meetings, and tabulations of the sales representative reports distributed to Company officials.

d. By marketing the Ancure, the Company exposed itself to massive civil and criminal liability and damage to its reputation that would have a materially adverse effect on its financial performance, particularly in light existence of Medtronic’s competing product.

66. On September 28, 1999, the Company issued a news release over the Business Wire in which it announced that it had received FDA approval for its Ancure, repeated its false claims for the Ancure and, additionally, claimed that introduction of the device constituted a “quantum leap Ancure (TM) System” in the treatment of abdominal aortic aneurysms. In this regard, the release stated, in pertinent part:

Guidant Announces FDA Approval for its Ancure System for Minimally Investigation Treatment of Abdominal Aortic Aneurysms

Guidant . . . a global leader in cardiovascular and vascular therapy, announced today that the U.S. Food and Drug Administration has approved for market release its minimally invasive treatment of abdominal aortic aneurysms (AAA) in the United States. As a result, Guidant is cleared to begin shipping its Ancure(TM) System for the minimally invasive treatment of AAA to hospitals throughout the U.S. This device will provide many of the estimated 1.5 million people afflicted by this life-threatening disease an alternative to the current method of treatment, which is a highly invasive surgical procedure. This FDA approval culminates 10 years of development of a minimally invasive treatment of AAA by Guidant and Endovascular Technologies, which was the first medical device company to successfully perform an endovascular implant in the U.S. in 1993. [ . . . ]

“The Ancure System represents a quantum leap in the treatment of AAA,” said Jay Watkins, president of Guidant’s Cardiac & Vascular Surgery Group. “Guidant pioneered the development of this significant alternative to conventional AAA surgery.” “We believe the approval of this device will come as good news to the
estimated million and a half people in the United States who have abdominal aortic aneurysm disease. Up until this point, patients with this disease were facing either the prospect of a highly invasive surgical procedure or the unpleasant alternative of taking their chances and waiting for the advent of a better alternative. With the development of the Ancure System we can offer these patients for the first time, a minimally invasive approach to treating AAA that has fewer complications and requires a shorter hospital stay.

67. The statements contained in ¶ 66 were materially false and misleading for the reasons stated in ¶ 65.

68. On January 22, 2000, Robertson Stephens issued a release over the PR Newswire in which it announced that it was initiating coverage of Guidant with a “Buy” rating based, in part, on the apparent strength of Guidant’s Ancure. In this regard, the release stated as follows:

Robertson Stephens Senior Medical technology Analyst Wade H. King, M.D., a 1999 Wall Street Journal All-Star Analyst, today initiated coverage of Guidant Corp. (NYSE:GDT) with a Buy rating. Guidant is a leading cardiovascular franchise with broad product offerings in cardiac rhythm management, vascular intervention, and cardiac and vascular surgery.

“We are initiating coverage of Guidant with a Buy rating,” said King. “Through both internal growth and an aggressive acquisition strategy, Guidant has generated solid top-and bottom-line growth, in our view. Despite stiff competition and pricing pressures, we believe that Guidant will remain an industry leader.

“On the new product front, Guidant recently received FDA approval for its TRISTAR coronary stent system on both OTW and RX platforms. The company also received approval for Ancure, a device designed to treat abdominal aortic aneurysms in a minimally invasive manner,” said King. “Finally, we anticipate the near-term approval of Guidant’s VENTAK PRIZM dual chambered AICD system.”

“In our view, Guidant represents an excellent long-term investment opportunity in an established, dynamic cardiovascular franchise,” said King. “By the end of 2000, we look for shares of Guidant to trade at 35 times our 2001 earnings-per-share estimate of $1.95. This yields our price target of approximately $70.”

69. On January 16, 2000, the Company issued a release over the Business Wire in which it announced its financial results for the fourth quarter and year ended December 31, 1999.
The Company reported record financial results and “phenomenal” physician interest in the Ancure. In this regard, the release stated as follows:

Guidant Corporation (NYSE:GDT)(PCS:GDT), today announced record fourth quarter sales of $576.1 million, an increase of 16 percent over the fourth quarter of 1998. Full year 1999 sales totaled a record $2.352 billion, increasing 23 percent over the prior year. Excluding special charges in both periods [footnote omitted], record fourth quarter net income of $112.3 million and earnings per share of $0.36 grew 38 percent and 37 percent, respectively, over the fourth quarter of 1998. Reported net income and earnings per share for the quarter were $95.5 million and $0.31, respectively, compared to $34.6 million or $0.11 share in the fourth quarter of 1998. [. . .]

“Initial physician interest and the ramp-up in training for the Ancure System has been phenomenal,” commented Dollens. “We now have trained and equipped nearly one third of the market, or over 200 cardiac centers and 400 physicians, to perform endovascular AAA repair procedures with Ancure in the U.S.” Dollens continued, “Relative to CTS and less invasive cardiac surgery, we estimate that approximately 20% of all CABG procedures are now performed using the off pump technique pioneered by this organization. Guidant is delivering exciting new technologies to our cardiac surgeon customers that will create significant growth opportunities in 2000 and beyond.”

70. On April 13, 2000, the Company issued a release over the Business Wire in which it announced its financial results for the first quarter ended March 31, 2000. The release was headlined “Guidant Posts All-Time Record Sales and Earnings in First Quarter; Earnings per Share of $0.38 Grow 21 Percent” and it attributed Guidant’s financial success, in substantial part, to the strong performance of its Ancure. In this regard, the release stated, in pertinent part:

Guidant Corporation (NYSE:GDT)(PCX:GDT), today announced all-time record sales of $630.7 million, an increase of 6 percent over the first quarter of 1999. Excluding unfavorable exchange rate impact and 1999 revenues from the general surgery business divested last summer, revenue growth for Guidant in the quarter would have totaled 10 percent. On the strength of significant product launches during the first quarter, sales grew 9 percent on a sequential basis versus the fourth quarter 1999. Record first quarter net income of $118.8 million and earnings per share of $0.38 each grew 21 percent over the first quarter of 1999, excluding special charges in the prior period. [. . .]
Sales of cardiac and vascular surgery products totaled $20.7 million worldwide, and were up 47 percent sequentially from the fourth quarter of 1999. “The robust sequential growth in cardiac and vascular surgery product sales in the first quarter reflects strong performances of the Ancure® System for minimally invasive treatment of Abdominal Aortic Aneurysms (AAA) as well as Cardio Thoracic Systems, Inc.’s line of less invasive coronary artery bypass surgical products,” reflected Dollens. “Physician interest and the ramp-up in training for the Ancure System continued to accelerate in the first quarter, with over 350 cardiac centers and 700 physicians now trained in the use of the Ancure product line,” Dollens continued.

71. The statements contained in ¶¶ 68-69 were materially false and misleading for the reasons stated in ¶ 65 and, additionally, because “Initial physician interest and the ramp-up in training for the Ancure System” was not “phenomenal,” but rather, by this time, the Ancure was malfunctioning, being misused at the urging of Guidant sales representatives and had already caused death and injury.

72. On June 12, 2000, Guidant published a news release over the Business Wire under the headline “Clinical data Demonstrates Guidant’s Ancure Bifurcated Endograft System for Abdominal Aortic Aneurysms as a Safe and Effective Minimally Invasive Treatment.” The release states in pertinent part:

Two years of clinical data demonstrate that Guidant Corporation’s Ancure™ Bifurcated Endograft System is an effective and safe, minimally invasive treatment for abdominal aortic aneurysms (AAA). Results from clinical trials were presented by Wesley Moore, M.D., professor of vascular surgery at UCLA Medical Center, at the Society for Vascular Surgery’s 54th annual meeting in Toronto, Canada. The data show decreasing or controlling the size of AAAs in 98 percent of all cases. Approximately two-thirds of patients with the ANCURE device experienced a decrease in aneurysm diameter and nearly one-third of cases resulted in a stabilization of the aneurysm diameter.

Guidant compared its bifurcated endograft to the traditional surgical method of AAA repair. After implanting more than 500 bifurcated endografts since 1995-some with greater than 4 years of follow-up -there were no incidences of ruptures. Additionally, patients who received the minimally invasive treatment lost considerably less blood than recipients of conventional surgery and their respiratory and cardiac complications were reduced by one-half and one-third, respectively. More than 2,000 total bifurcated implants have been performed to date. [. . .]
“The results of Guidant’s latest research on abdominal aortic aneurysms are incredibly encouraging for physicians faced with treating abdominal aortic aneurysms,” said Moore. “The data clearly demonstrates the ANCURE System’s position as the best-in-class treatment for this life-threatening disease.”

Treatment with the ANCURE System requires significantly shorter recovery periods than surgical procedures because the implant is delivered through small incisions to two arteries in the groin. A delivery catheter containing the implant is inserted into one of these arteries and delivered through the patient’s vasculature to the site of the aneurysm.

Once inside the patient’s body, the ANCURE device’s unique positioning hooks secure the implant to the vessel wall. This attachment mechanism, combined with ANCURE’s woven polyester body, allows the implant to adapt to changes that occur over time in the size and shape of the aorta, while maintaining the implant’s original position within this high pressure artery.

The U.S. Food and Drug Administration approved the ANCURE System in September of 1999, making this method for endovascular repair available to hospitals throughout the U.S.

A global leader in the medical technology industry, Guidant provides innovative, minimally invasive and cost-effective products and services for the treatment of cardiovascular and vascular disease. For more information about Guidant’s products and services, visit the company’s web site at http://www.guidant.com.

73. The statements contained in the June 20, 2000 press release were materially false and misleading for the reasons stated in ¶ 65 and in ¶ 71, and because defendants knew they were in direct violation FDA rules because they had intentionally not submitted a PMA Supplement to the FDA concerning the Handle-Breaking Technique.

74. On July 18, 2000, the Company published a release over the Business Wire in which it announced its financial results for the second quarter ended June 30, 2000. The release was headlined: “Guidant Posts All-Time Record Sales of $668.4 Million in Second Quarter; Record Net Income and Earnings Per Share of $0.40 Grow 22 Percent,” and stated, in pertinent part:

Sales of cardiac and vascular surgery product totaled $27.8 million worldwide, and were up 34 percent from the first quarter of 2000. “The success of our ANCURE(R) ENDOGRAFT(R) System for endovascular abdominal aortic
aneurysm (AAA) repair, the ULTIMA(TM) and VORTEX(TM) Stabilization Systems for beating heart’ cardiac bypass procedures, and the VASOVIEW UNIPORT(TM) PLUS Vessel Harvesting System demonstrates the strong clinical acceptance of minimally invasive surgical approaches. This underscores the significant immediate contribution to growth they provide,” said Dollens. He continued, “For example, two-years of clinical data in over 500 patients implanted with the ANCURE bifurcated graft show excellent clinical success with no ruptures. The enthusiasm about this procedure and the ANCURE system has been remarkable.” Versus the prior year, sales of cardiac and vascular surgery products grew 18%. The comparison includes Guidant’s general surgery product line, which was sold in July of 1999.

75. The representations made in the July 18, 2000 press release were materially false and misleading when made for the reasons stated in ¶¶ 65, 71, and 73 and because defendants knew they “knowingly and intentionally misled the FDA about the frequency with which the delivery system of the Ancure Device malfunctioned[.]

76. On October 16, 2000, Guidant published a news release over the Business Wire in which it announced its financial results for the third quarter ended September 30, 2000. The release was headlined “Guidant Posts Third Quarter Sales of $600.8 million; Net Income and Earnings Per Share of $0.40 Grow 25 Percent” and stated in pertinent part:

Reporting strong implantable defibrillator, pacemaker, and angioplasty revenues as well as growth from emerging therapies such as endovascular abdominal aortic aneurysm (AAA) repair and heart failure, Guidant Corporation (NYSE:GDT) (PCX:GDT) today reported third quarter sales of $600.8 million, an increase of 6 percent over the same period of 1999, [. . .]

Sales of cardiac and vascular surgery products totaled $31.4 million worldwide. Our cardiac and vascular surgery product sales are accelerating rapidly, and are now two and one half times greater than last year’s third quarter totals. The ANCURE(R) ENDOGRAFT(R) System for endovascular AAA repair continues to set the standard for clinical success and patency as the endovascular graft technique gains acceptance in the clinical community,” stated Dollens. He continued, “The ANCURE System, the ACHIEVE(TM) Off-Pump System for beating heart’ bypass procedures, which was launched during the third quarter, along with the VASOVIEW UNIPORT(TM) PLUS Vessel Harvesting System created substantial new platforms for growth going forward in these important clinical categories.”

Summarizing, Dollens stated, “Our core markets in vascular intervention and cardiac rhythm management are strong. Further, we have an extraordinary opportunity to
advance our share positions in each of our markets while we prepare to launch exciting new technologies for heart failure, radiation therapy, and peripheral vascular disease during 2001.”

77. On October 24, 2000, the Company published a release over the Business Wire headlined, “Three-Year Data On Guidant’s ANCURE System Shows Control of Abdominal Aortic Aneurysms Following Endovascular Repair.” The release stated:

Three-year follow-up data on Guidant’s (NYSE:GDT)(PCX:GDT) ANCURE™ System for the treatment of abdominal aortic aneurysm (AAA) shows that use of the ANCURE system leads to a steadily decreasing aneurysm diameter over time in a majority of patients. The data were presented today at the 86th Annual Clinical Congress of the American College of Surgeons by Dr. Michel S. Makaroun in Chicago, Ill.

“Endovascular repair of abdominal aortic aneurysm using the ANCURE system is now a viable option for many patients,” said Dr. Makaroun, Professor of Surgery and Chief, Division of Vascular Surgery, University of Pittsburgh Medical Center. “These clinical results are very encouraging because they show stable aneurysm repair at three years, which bodes well for the long-term.”

Key findings show:

- Guidant’s bifurcated implant completely prevented aortic ruptures and decreased or controlled aneurysm size in 96.2 percent of all cases at three years.

- 73.7 percent of patients with bifurcated implants had a decrease in aneurysm diameter size between discharge and their third annual visit, as compared to 64.8 percent at their second annual visit, and 53.8 percent at their first annual visit.

- There were no reports of aneurysm rupture with bifurcated implants.

- EndoGraft migration was observed in only one patient; demonstrating that bifurcated Endografts remain securely attached following implantation.

Abdominal aortic aneurysm is an enlargement of the aorta - the largest blood vessel in the human body - that results from a weakening of the vessel wall. If left untreated, the enlargement can lead to the rupture of the aorta, which is fatal in nearly 80 percent of cases. Approximately 200,000 new cases of AAA are diagnosed per year in the United States. This disease results in major surgery for more than 45,000 patients per day. Approximately 15,000 deaths each year are attributed to AAA, making it the nation’s 13th leading cause of death. It is one of the leading causes of sudden death in men over the age of 65.
The traditional method of repairing abdominal aortic aneurysms involves an extremely invasive surgical procedure, which requires a long incision from the breastbone to the pubic bone. The internal organs are moved aside to provide access to the aorta, which lies deep within the abdominal cavity. The surgeon then incises the aorta and implants a surgical graft with sutures to bypass the aneurysm. Recipients of this treatment remain in the hospital for one week on average, often with two or three days in the intensive care unit. Patients also must endure several months of home convalescence to fully recuperate. Treatment with the ANCURE System requires significantly shorter recovery periods than surgical procedures because the implant is delivered through small incisions to two arteries in the groin.

Guidant compared the ANCURE System to the traditional surgical method of AAA repair. Results from this study contain data from 88 patients implanted with bifurcated ANCURE Grafts who completed three annual follow-up examinations. The diameter of the aneurysm sac was measured by a core laboratory at each follow-up visit to monitor its change in size. Long-term safety data were analyzed using Kaplan-Meier methodology.

After implanting more than 500 bifurcated devices in U.S. clinical trials since 1995, there were no incidences of ruptures. Additionally, patients who were treated with endovascular AAA repair lost considerably less blood than recipients of conventional surgery and their respiratory and cardiac complications were reduced by one-half and one-third, respectively. More than 4,000 bifurcated implants have been performed to date.

“The three-year data for the bifurcated system shows zero ruptures and year-to-year improvement over what was presented earlier this year at the Society of Vascular Surgeons conference,” said Jay Watkins, president of Guidant’s Cardiac &Vascular Surgery Group. “As awareness of AAA grows among physicians and patients, we’re confident that endovascular repair with the ANCURE System will be the treatment of choice for this silent, unrecognized killer.”

A delivery catheter containing the ANCURE System is inserted into an artery in the groin and delivered through the patient’s vasculature to the site of the aneurysm. Once inside the patient’s body, the ANCURE device’s unique positioning hooks secure the implant to the vessel wall. This attachment mechanism, combined with ANCURE’s woven polyester body, allows the implant to adapt to changes that occur over time in the size and shape of the aorta, while maintaining the implant’s original position within this high-pressure artery.

Earlier this month, Guidant announced its support of “AAA: Screening for a Silent Threat,” a continuing medical education (CME) program on AAA. The program is available exclusively at www.medscape.com, and is designed to raise awareness of AAA among primary care and family physicians, and underscore the importance of early diagnosis.
78. The statements contained in ¶¶ 76-77 were materially false and misleading for the reasons stated ¶¶ 65, 71, 73 and 75.

MARCH 16, 2001 - AUGUST 17, 2001: Guidant Recalls
The Ancure And Lies About The Reasons Why

79. On March 16, 2001, Guidant issued a news release over the Business Wire announcing the purportedly voluntary recall of the Ancure due to certain “regulatory deficiencies” relating to the deployment of the product. In this regard, the release stated as follows:

Guidant Corporation (NYSE:GDT)(PCX:GDT) today announced it has voluntarily halted production and sales of its ANCURE(R) System. The ANCURE System is designed to provide a less invasive approach than conventional surgery for treating life threatening abdominal aortic aneurysms (AAA). This action was taken as a result of Guidant’s identification of certain deficiencies in the company’s ANCURE-related regulatory processes and communications with the U.S. Food and Drug Administration (FDA). These regulatory deficiencies were primarily related to the deployment system of the ANCURE product. “The FDA has been notified and a meeting has been scheduled to discuss these issues,” said Ron Dollens, President and Chief Executive Officer. “This review is a top priority and we will be doing everything we can to correct the deficiencies and their causes and to resume normal operations as soon as possible.”

Patients who have received ANCURE ENDOGRAFT(R) implants to date are not affected by this action. The safety of the implanted product is supported by extensive positive long-term data. The problems are limited to the regulatory issues associated with the deployment system of the product. As a result, the company does not recommend that physicians take any actions with regard to implanted devices, other than to continue normal follow-up. Existing inventories of product in hospitals will be recalled. Guidant is working closely with the FDA to address all identified deficiencies in order to quickly resume production and availability of the ANCURE system. [Emphasis added.]

80. On this news, the Company’s shares, which had traded as high as $51 during the previous six months, fell to $46.25 on March 19, 2001, the first trading day following the announcement.

81. To prevent further erosion in the share price, the Company put out the word that the recall was based on limited regulatory issues, that the Ancure was still safe for use and that the Company and the FDA were working cooperatively to get the product back on the market.
The Company thereby minimized the danger posed by the Ancure and concealed the Ancure’s failure as a viable medical device. Moreover, defendants’ communications in the above-referenced release and in the statements to analysts and journalists set forth herein, further served to conceal the civil and criminal liabilities arising from the Ancure and the disastrous effect this would have on Guidant’s business and reputation.

82. Analysts accepted and repeated Guidant’s explanation for the recall. In this regard, on March 16, 2001, The Street.com published an item that stated: “The problems are limited to the regulatory issues associated with the deployment system of the product, the company said.”

83. On March 21, 2001, Guidant’s hometown newspaper, The Indianapolis Star, published an article stating that the FDA was allowing continued usage of the Ancure provided that patients signed special consent forms. The article included Dollens’ explanation for the recall in which he again attempted to conceal his knowledge of the hazards of the Ancure.

In this regard, the article stated, in pertinent part:

Doctors may still use the fabric grafts if their patients sign consent forms acknowledging they’re aware of the recall, which doesn’t have anything to do with the safety or effectiveness of the graft, said Ronald W. Dollens, president of Guidant, on Tuesday.

Guidant, an Indianapolis medical device maker, manufacturers and sells the graft. It voluntarily stopped sales Friday after internal audits turned up deficiencies in the regulatory process related to the catheter system used to install the sleeve-like graft by pushing it in place through an artery near the groin, Dollens said.

The FDA allowed the implants to continue as long as patients sign consent forms, Dollens said at an investor briefing at the American College of Cardiology convention in Florida. [. . .]

Dollens said an internal audit at Guidant showed three deficiencies in the regulatory process and communications with the FDA involving the delivery system for the graft called the Ancure Endograft.
84. On March 21, 2001, U.S. Bancorp Piper Jaffray issued its daily Market Report over the PR Newswire which contained Piper Jaffray analyst Thom Gunderson’s comments on Guidant:

“With the latest info the ANCURE (AAA graft) recall appears less onerous than some had expected,” said Thom Gunderson, senior medical technology analyst. “Our range had been from a $25-$75 million revenue hit, and while the final issues are not yet resolved, we are comfortable with the lowest end of the range, which translates into a $0.03 fiscal 2001 earnings-per-share reduction, from $1.78 to $1.75.

85. The statements referenced above in ¶¶ 79, 82-84 were each materially false and misleading when made for the reasons stated ¶¶ 65, 71, 73 and 75, and for additional reasons, including but not limited to:

a. The Company had not “voluntarily” recalled the Ancure but actually was forced by the FDA to take it off the market because it had filed to a PMA Supplement concerning the Handle-Breaking Technique and over 2,628 additional MDRs.

b. The Ancure was not taken off the market solely because of “deficiencies” in the Company’s ANCURE-related “regulatory processes” and communications with the FDA but because, in violation of FDA regulations, the Company (i) encouraged a dangerous usage of the Ancure that had not been authorized by the FDA, and (ii) failed to file 2,628 Medical Device reports - each representing an incident in which the Ancure malfunctioned or its use was associated with death or serious injury;

c. As a result of the foregoing conduct, the Company was the target of a criminal investigation; and

d. The Company had not properly reserved for the consequences of its massive criminal and civil liability nor adjusted its recorded goodwill to account for the inevitable harm to its reputation that would ensue.
On April 23, 2001, the Company issued a release over the Business Wire headlined: “Guidant Reports All Time Record Sales And Pre-Charge Earnings; Sales Reach $671 Million and Generate Adjusted Earnings Per Share of $0.41,” which stated, in pertinent part:

Guidant Corporation (NYSE:GDT)(PCX:GDT), a global leader in technology for the treatment of cardiac and vascular disease, today reported all time record sales of $671.0 million in the first quarter compared to $630.7 million in the prior year. Sales growth was 9 percent on a constant currency basis. Adjusted for the previously announced charge associated with the ANCURE(R) ENDOGRAFT(R) System recall and first-generation VENTAK(R) PRIZM(TM) defibrillator field action(a), record net income of $126.9 million and earnings per share of $0.41 were recorded versus $118.8 million in net income and $0.38 per share in the first quarter 2000. Reported net income and earnings per share for the quarter were $111.2 million and $0.36 per share, respectively.

The release further stated, with respect to the Ancure that given “the uncertainties” surrounding the “previously announced ANCURE System [. . .] field actions, the Company was revising its second quarter revenue and earnings estimates the second quarter downward to sales of between $630 and $665 million, and earnings per share between $0.35 to $0.39.

That same day, on April 23, 2001, the Company held a conference for analysts and, with respect to the Ancure, Andy Reit, Guidant’s director of investor relations, stated, in pertinent part, as follows:

As final summary comment and as you know in Q1, we had a voluntary recall of the ANCURE endovascular AAA system. We continue to work closely with FDA to resolve the situation, as expeditiously as possible, for the benefit of our patients, physician customers and shareholders. [. . .]

With regard to the status of the ANCURE situation, we continue to work constructively with the FDA to resolve documentation and reporting deficiencies previously described and are continuing with the recall activities. Guidant recorded an $11 million charge in the first quarter related to expenses associated with the recall. At this time, it is not possible to discern the timing of ANCURE’s full return to market availability.

Also in respect to Ancure, the following exchange occurred between analyst Sheryl Zimmer and Ginger Graham, Guidant’s assistant to the president:
SHERYL ZIMMER: Sure, if the ANCURE is back on the line in the third quarter, would there be any change in the earnings or in the sales for Q3 and Q4?

GINGER GRAHAM: Let me try a couple of things Sheryl, how are you, this is Ginger.

SHERYL ZIMMER: Hi Ginger.

GINGER GRAHAM: Just a couple of things, one is, of course, as we have been out of the market now for a period of time, we do notice there are some centers where they will be looking to reenter the market based on some clarity around the product and the product reentry, so we do believe that there will be some kind of reentry curve coming back in. We have done three things, one is, we obviously still believe we have a very significant product with long-term data that is the best in class, and reinforce that as we continue to gather that data now approaching 4 years. So we think that the product category itself will still be with us, and we will have opportunities to get back into the market with the strongest clinical statement out there. The second thing is that we have gone about putting the information into the FDA [delivery system issues that we have mentioned, and those are current practices, so we won’t be reentering the market to teach physicians any different practices. So we think that both are going well. And then the third piece being that we do have other product configurations that is submitted to the FDA, which we think will expand our potential for usage on to a broader variety of patients. So we think all of those are very positive. There is the reality that we need to be able to go back to the customer and restock shelves, put inventory back in place, get customers back up, and running on endovascular repair, and we do think that will have an impact on the third and fourth quarter. And that the market size itself will not have reached the same level, as if we had been in the market the whole year telling the story about endovascular repair.

90. On July 17, 2001, Guidant issued a release over the Business Wire in which it announced that it had received an “investigational device exemption” from the FDA that allowed it to resume Ancure implants and repeated its false explanation for the recall, i.e. that the recall was “based on deficiencies the company identified in regulatory processes and communications with the FDA.” The release stated, in pertinent part:

Guidant Corporation (NYSE:GDT) (PCX:GDT), a world leader in the treatment of cardiac and vascular disease, announced today that it has received an investigational device exemption from the U.S. Food and Drug Administration (FDA) that will allow implants to resume using Guidant’s ANCURE(R) ENDOGRAFT(R) System. Several implants were performed yesterday, and additional implants are expected in the coming days. Guidant’s ANCURE system is a minimally invasive method for repair of abdominal aortic aneurysm (AAA).
The clinical trial protocol allows Guidant’s ANCURE system to be used to treat patients under informed consent at up to 300 hospitals with physicians already trained and with implant experience on the ANCURE system. The protocol also requires collection of delivery system performance data during the implant procedure, as well as 30-day patient follow-up.

“We are pleased with the FDA’s willingness to work with Guidant to resume implants of ANCURE,” said Guidant Corporation’s Beverly Huss, President, Endovascular Solutions. “We believe strongly in the patient benefits of treatment with the ANCURE system and we look forward to getting this important therapy back into the hands of physicians.”

In March 2001, Guidant initiated a voluntary recall of the ANCURE system based on deficiencies the company identified in regulatory processes and communications with the FDA. Guidant subsequently filed ANCURE-related PMA supplements and a corrective action plan with the FDA; these documents are under review.

“Guidant is continuing to work closely and constructively with the FDA to return the ANCURE System to market as soon as possible,” added Huss. “We have resumed ANCURE implants this week and we are also preparing for full market release in the fourth quarter pending FDA approval.”

91. The statements referenced above in ¶¶ 86-90 each materially false and misleading when made for the reasons stated ¶¶ 65, 71, 73, 75, and 85.

AUGUST 17, 2001 TO AUGUST 13, 2002: Guidant Returns The Ancure to the Market And Continues The Coverup

92. On August 17, 2001, Guidant issued a release over the Business Wire in which it announced that the FDA had granted Premarket Approval (PMA) on
supplemental filings for the Ancure. The release stated, in pertinent part:

Guidant Corporation (NYSE:GDT) (PCX:GDT), a world leader in the treatment of cardiac and vascular disease, announced today that it has received approval of the required PMA supplement filings from the U.S. Food and Drug Administration (FDA), allowing the company to proceed with full market release of the ANCURE(R) ENDOGRAFT(R) System. Guidant’s ANCURE system is a less invasive method for repair of abdominal aortic aneurysm (AAA).

“We are extremely pleased about beginning the full commercial release of our ANCURE system,” said Beverly Huss, President, Endovascular Solutions, Guidant Corporation.

“We are prepared to return the ANCURE system to the market this quarter. We also appreciate the FDA’s cooperation in working with us to return this important therapy to physicians and patients.”

“Guidant’s emerging therapies, like ANCURE, will continue to fuel new growth for Guidant going forward - AAA alone represents a billion dollar market opportunity,” said Ronald W. Dollens, Guidant President and CEO. “We believe our market release program will position Guidant favorably to begin realizing our previous sales levels within one to two quarters of the ANCURE system’s full market release.”

On August 20, 2001, Medical Industry Today published an article in which it reported on the re-release of the Ancure which revealed that the device had suffered from serious deficiencies and stated, in this regard, as follows:

Guidant had to file several supplemental PMAs with corrective action plans for the device after it was recalled in March, as reported in Medical Industry Today. Guidant voluntarily recalled the device, claiming that it had identified “certain deficiencies” in regulatory processes with the FDA. The deficiencies were associated with the deployment system for Ancure, according to the company.

But the FDA released an opposing view of the situation in May. In a letter to physicians, the FDA claimed that “serious problems” occurred with AAA endovascular graft devices made by Guidant and MEDTRONIC INC. (Minneapolis, MN). In that letter, the FDA said Guidant had told regulators that it had failed to report many device malfunctions and adverse events, “including severe vessel damage associated with problems with the deployment of the device.”

The FDA said that physicians needed to carefully monitor patients with implants, instead of recommending the removal of AAA or the alteration of its use.
On September 9, 2001, Medical Devices & Surgical Technology Week September 9, 2001 published an article on the Ancure which stated as follows:

Doctors and patients were thrilled when the FDA in 1999 approved the first alternative to risky open-abdominal surgical repair. The patches - Guidant Corp.’s (GDT) Ancure and Medtronic’s AneuRx - are slipped through a small incision in a groin artery and threaded up to the aorta to form a sleeve-like new path for blood. Clinical trials showed the patches saved lives while cutting in half surgical side effects and hospital stays.

Thousands have since been treated, largely successfully. But the FDA has reports of 530 injuries and 28 deaths among Ancure users, and 95 injuries and 13 deaths among AneuRx users. What’s happening?

With Guidant’s Ancure, the implantation system - tubes and other gadgets used to position the patch, almost like building a ship in a bottle - sometimes got stuck. Guidant voluntarily stopped Ancure sales last spring while redesigning it and now is testing the new-generation Ancure in a 2,000-patient study that Beebe says shows improvement.

However, neither the FDA nor Guidant disclosed to the public the extent of the problems caused by the Ancure, including but not limited to the fact that: (i) the Ancure had resulted in 2,628 Medical Device reports; (ii) 12 of those reports involved the death of the patient; (iii) Guidant’s sales representatives had been encouraging the improper use of the Ancure; or (iv) Guidant had initially concealed the Medical Device reports from the FDA.

On January 29, 2002, the Company issued a release over the Business Wire in which it announced record sales and earnings for the fourth quarter and 2001 year ended December 31, 2001. The release stated, in pertinent part:

Fourth Quarter sales increased 11%, Net Income and EPS, as adjusted, grew in excess of 15%; Double-digit growth leads to Earnings Per Share of $0.47, as adjusted.

Guidant Corporation (NYSE:GDT) (PCX:GDT), a global leader in technology for the treatment of cardiac and vascular disease, today reported fourth quarter 2001 sales of $718.7 million, representing an all-time record. Guidant achieved sales growth of 11 percent versus the prior year, and 12 percent on a constant currency basis. Net income of $144.6 million and diluted earnings per share of $0.47 were also all-time records, each as adjusted. For the full year 2001, sales, net income, and
diluted earnings per share were $2.708 billion, $509.2 million, and $1.66, respectively, on a comparable basis.

Sales of endovascular products, including the ANCURE(R) ENDOGRAFT(R) System, were $32.2 million, returning to levels near those of the prior year. “Sales of peripheral vascular and endovascular graft products contributed over $7.0 million of revenue growth versus the third quarter of this year,” said Dollens. Cardiac surgery product sales grew 24 percent over the prior year to $19.2 million in the quarter.

On August 13, 2002, in its quarterly report on Form 10-Q for the period ended June 30, 2002, the Company revealed for the first time that it was under criminal investigation:

The Company is aware that the U.S. Department of Justice and the Office of Criminal Investigations of the U.S. Food & Drug Administration are conducting an investigation into matters relating to the Company’s ANCURE ENDOGRAFT System for the treatment of abdominal aortic aneurysms. In March 2001, the Company voluntarily halted production and sale of the product and performed a voluntary recall following the discovery of certain regulatory compliance deficiencies in the business unit responsible for the sales of the product. The product was returned to full market release in August 2001 with FDA approval. The Company is cooperating fully in the investigation.

On January 22, 2003, the Company issued a news release over the Business Wire in which it reported the results of its long-term follow-up study evaluating the Ancure Bifurcated Endograft. The release stated, in pertinent part, as follows:

Guidant Corporation (NYSE:GDT) (PCX:GDT), a world leader in the treatment of cardiac and vascular disease, today reported data from the company’s long-term follow-up study evaluating the ANCURE(R) Bifurcated ENDOGRAFT(R) System in 319 patients for up to five years. The ANCURE Bifurcated ENDOGRAFT System is a minimally invasive treatment for abdominal aortic aneurysm (AAA).

With 147 patients achieving four years of follow-up and 55 patients reaching five years, no long-term follow-up bifurcated study patients have experienced aneurysm rupture. Additionally, the ANCURE Bifurcated ENDOGRAFT System led to a steadily decreasing aneurysm size in a majority of patients. Barry T. Katzen, M.D., founder and director of the Miami Cardiac and Vascular Institute, presented the data today at the 15th International Symposium on Endovascular Therapy in Miami Beach, Fla.

“The major reason physicians perform AAA surgery using the ANCURE system is to prevent aneurysm rupture and related death,” said Dr. Katzen. “The data from this group of patients compare very favorably to the long-term performance of
conventional surgical repair of aneurysms, and we were very pleased to note that all long-term follow-up study patients treated with the ANCURE Bifurcated ENDOGRAFT System have been and continue to be free from rupture at five years.”

Key findings from the study, in which 55 patients have been followed for five years after treatment with the ANCURE Bifurcated ENDOGRAFT System, show:

- 100 percent of patients were free from aneurysm rupture. (In Guidant’s entire bifurcated clinical study experience, one patient did experience aneurysm rupture.)

- 78.6 percent of patients had a decrease in aneurysm diameter size between hospital discharge and their five-year follow-up visit. An additional 19 percent of patients had a stable aneurysm size at five years.

- The cumulative rate of postoperative conversion to open repair of aneurysm remains low, with a 2.8 percent late conversion rate.

- 99 percent of ANCURE Bifurcated ENDOGRAFT patients were free from graft migration.

“These long-term clinical study results show that endovascular repair with the ANCURE Bifurcated System continues to be a safe and effective tool for physicians who treat abdominal aortic aneurysms,” said Beverly A. Huss, president, Endovascular Solutions, Guidant Corporation. “It is gratifying to see that after five years, the patients treated with ANCURE are doing well.”

Guidant Corporation pioneers lifesaving technology, giving an opportunity for better life today to millions of cardiac and vascular patients worldwide. The company, driven by a strong entrepreneurial culture of more than 10,000 employees, develops, manufactures and markets a broad array of products and services that enable less invasive care for some of life’s most threatening medical conditions. For more information visit www.guidant.com.

99. On January 30, 2003, the Company issued a news release over the Business Wire in which it announced its financial results for the fourth quarter and year ended December 31, 2002. The release was headlined: “Guidant Reports All-Time Record Fourth Quarter and Full-Year 2002 Sales and Adjusted Earnings” and stated, in pertinent part:

Guidant Corporation (NYSE:GDT) (PCX:GDT), a world leader in the treatment of cardiac and vascular disease, today reported record full-year sales of $3,239.6 million. Guidant achieved sales growth of $532 million or 20 percent versus the prior year, and 19 percent on a constant currency basis. Adjusted net income and diluted earnings per share of $681.4 million and $2.23 for the year each grew 34 percent, versus the prior year. Generally Accepted Accounting Principles (GAAP)
net income and diluted earnings per share of $611.8 million and $2.00, grew 26 and 27 percent, respectively, and reflect net pre-tax charges for special items totaling $82 million.

For the quarter, Guidant achieved sales growth of 25 percent versus the prior year, and 23 percent on a constant currency basis. Adjusted net income and diluted earnings per share of $199.3 million and $0.65 for the quarter grew 38 and 39 percent, respectively, versus the prior year. GAAP net income and diluted earnings per share of $92.4 million and $0.31, declined 32 and 31 percent, respectively, and reflect pre-tax charges for special items totaling $141 million [. . .]

GAAP net income of $92.4 million includes pre-tax charges for special items totaling $141 million related to the purchase of in-process research and development ($48 million), the termination of the merger agreement with the Cook Group ($61 million), and litigation matters, including amounts related to the previously announced ANCURE(R) ENDOGRAFT(R) System investigation and related matters ($32 million).

100. On April 16, 2003, the Company issued a news release over the Business Wire in which it announced its financial results for the first quarter ended March 31, 2003. In this regard, the release stated:

Guidant Corporation (NYSE:GDT), a world leader in the treatment of cardiac and vascular disease, today reported first quarter record sales of $885.4 million. Guidant achieved sales growth of $175.7 million or 25 percent versus the prior year. For the quarter, foreign exchange translations provided a benefit of $35.0 million.

Generally Accepted Accounting Principles (GAAP) net income and diluted earnings per share (EPS) of $93.4 million and 0.30, each declined 33 percent. Excluding special items in both comparison years, adjusted net income of $186.1 million and adjusted EPS of $0.60 for the quarter each grew 29 percent versus the prior year.

Special items for the first quarter of 2003 include a pre-tax $36.5 million charge for purchased in-process research and development expenses associated with the previously announced agreements with Biosensors International and SyneCor, LLC. Special items also include an additional pre-tax $64.9 million reserve in connection with the anticipated resolution of the previously announced ANCURE® ENDOGRAFT(R) System Department of Justice investigation.

101. The statements referenced above in ¶¶ 92-94, 96-100, were each materially false and misleading when made for the reasons stated in ¶¶ 65, 71, 73, 75, 85 and 95.

THE TRUTH BEGINS TO EMERGE

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102. On June 12, 2003, the United States Attorney’s Office issued a release in which it announced that EVT had pled guilty Thursday to 10 felonies, including lying to the FDA, for covering up malfunctions of a device to treat aneurysms that led to 57 invasive emergency procedures and 12 deaths. The release stated in pertinent part as follows:

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 was announced today at a press conference by the U.S. Attorneys’ 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. [. . .]

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 the 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 the 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 in its use; the instructions accompanying the product did not explain the procedure, and the defendant failed to seek prior approval of the FDA. After a patient died in a case in which the handle breaking technique was used, a group of defendant’s employees concluded that the FDA had to be informed of its use. The company failed to do so, even as its sales representatives continued to describe the handle breaking technique to doctors doing surgeries. [. . .]
On June 13, 2003, The New York Times published an article about Guidant, EVT and the guilty plea in which it reported on the impact of the plea stating, in relevant part, as follows:

As part of the plea, the Guidant division, Endovascular Technologies, also agreed to cooperate in investigations against executives who might have been involved in wrongdoing. As part of that agreement, the company waived attorney-client privilege, meaning that statements made by any employees to company lawyers during the investigation will now be available as potential evidence.

But the company’s legal troubles are far from over. It already faces a number of lawsuits from individuals, and thousands of patients whose procedures did not go as expected could still bring cases. It must also complete aspects of a civil settlement with the Department of Health and Human Services, which would allow it to avoid exclusion from government programs like Medicare. [. . .]

The charges against Endovascular Technologies, a wholly owned subsidiary that Guidant acquired in 1997, describe a company that allowed marketers to influence its scientific decisions when faced with a public health risk. Indeed, the charges say, sales representatives devised a method of their own to deal with problems, telling doctors to physically break into pieces the system used for inserting the graft while it was in a patient’s vessel.

Guidant has still more steps to take before the government’s civil case is resolved. As part of the agreement with Health and Human Services, both Guidant and its subsidiary are required to put in place corporate integrity agreement. In exchange for adopting those requirements - the details of them are still subject to approval by the government - Health and Human Services has agreed not to seek to bar the companies from any government programs, including Medicare. [. . .]

“Because of the company’s conduct, thousands of patients underwent surgeries without knowing the risks they faced, and their doctors - through no fault of their own - were unprepared to deal with those risks,” said Kevin V. Ryan, the United States attorney in San Francisco. “These actions were criminal, and I am happy to say that today, for the first time in more than three years, the public will be able to learn the truth.”

Medical specialists expressed both surprise and concern about the criminal charges. “Whenever a company has a serious ethical, and in this case legal, lapse, it always raises concerns across the product line,” said Dr. Steven Nissen, a cardiologist at Cleveland Clinic.

Still, Dr. Nissen, who has worked with a Guidant project in the past, expressed surprise at the plea, saying that the company had always struck him as ethical.
104. On this news, the price of Guidant shares, which had opened at $43.23 on June 12, 2003, fell to $39 and closed the day at $40.46. The following day, on June 13, 2003, as the market digested the news, the Company’s shares fell to a low of $36.97. On June 16, 2003, the Company announced that it planned to discontinue the Ancure and that EVT would cease ongoing activities.

105. The market for Guidant’s securities was open, well-developed and efficient at all relevant times. As a result of these materially false and misleading statements and failures to disclose, Guidant’s securities traded at artificially inflated prices during the Class Period. Plaintiff and other members of the Class purchased or otherwise acquired Guidant securities relying upon the integrity of the market price of Guidant’s securities and market information relating to Guidant, and have been damaged thereby.

106. During the Class Period, defendants materially misled the investing public, thereby inflating the price of Guidant’s securities, by publicly issuing false and misleading statements and omitting to disclose material facts necessary to make defendants’ statements, as set forth herein, not false and misleading. Said statements and omissions were materially false and misleading in that they failed to disclose material adverse information and misrepresented the truth about the Company, its business and operations, as alleged herein.

107. At all relevant times, the material misrepresentations and omissions particularized in this Complaint directly or proximately caused or were a substantial contributing cause of the damages sustained by plaintiff and other members of the Class. As described herein, during the Class Period, defendants made or caused to be made a series of materially false or misleading statements about Guidant’s business, finances and operations. These material misstatements and omissions had the cause and effect of creating in the market an unrealistically positive assessment of Guidant and its business, finances and operations, thus
causing the Company’s securities to be overvalued and artificially inflated at all relevant times. Defendants’ materially false and misleading statements during the Class Period resulted in plaintiff and other members of the Class purchasing the Company’s securities at artificially inflated prices, thus causing the damages complained of herein.

**SCIENTER ALLEGATIONS**

108. As alleged herein, defendants acted with scienter in that defendants knew that: a) the statements issued or disseminated in the name of the Company were materially false and misleading; b) knew that such statements or documents would be issued or disseminated to the investing public; and c) knowingly and substantially participated or acquiesced in the issuance or dissemination of such statements or documents as primary violations of the federal securities laws. As set forth elsewhere herein in detail, defendants, by virtue of their receipt of information reflecting the true facts regarding Guidant their control over, and/or their associations with the Company which made them privy to confidential proprietary information concerning Guidant, participated in the fraudulent scheme alleged herein. In addition, defendants were motivated to conceal the details of the fraud alleged herein and acted with scienter in order to permit Dollens, Brauer and other insiders to sell millions of dollars of their personally held Guidant stock to the investing public. This case does not involve allegations of false forward-looking statements or projections but instead involves false statements concerning the Company’s business, finances and operations. The ongoing fraudulent scheme described in this complaint could not have been perpetrated over a substantial period of time, as has occurred, without the knowledge and complicity of the personnel at the highest level of the Company, including the Individual Defendants.

109. In his capacity as a Vice President of Guidant and President of Compass, defendant Watkins facilitated Guidant’s 1997 acquisition of EVT. After the acquisition, defendant Watkins,
also President of Guidant’s Cardiovascular and Vascular Surgical Group, became the senior executive in charge of EVT and the development, marketing and sale of Ancure. As a result, Watkins was very proud of EVT and Ancure, and did not want to admit that the device had any flaws. As Watkins bragged in the Company’s September 28, 1999 press release:

“The Ancure System represents a quantum leap in the treatment of AAA,” said Jay Watkins, president of Guidant’s Cardiac & Vascular Surgery Group. “Guidant pioneered the development of this significant alternative to conventional AAA surgery.” “We believe the approval of this device will come as good news to the estimated million and a half people in the United States who have abdominal aortic aneurysm disease. Up until this point, patients with this disease were facing either the prospect of a highly invasive surgical procedure or the unpleasant alternative of taking their chances and waiting for the advent of a better alternative. With the development of the Ancure System we can offer these patients for the first time, a minimally invasive approach to treating AAA that has fewer complications and requires a shorter hospital stay.

110. Despite this bullish statement, in his position as the senior executive in charge of EVT, defendant Watkins knew each and every ethical and legal problem concerning the Ancure.

According to an Executive Administrator employed throughout the Class Period, and confirmed by an EVT Engineer and EVT Manager, while employed as the senior executive in charge of EVT defendant Watkins was a hands-on manager who regularly walked around EVT, examined the regular course of business, and asked questions of employees. Moreover, throughout his tenure as the senior executive in charge of EVT, Watkins held monthly All-Employee Quality meetings, which included, but were not limited to, sales representatives, managers, administrators, and engineers. These EVT monthly All-Employee Quality meetings included question and answer sessions where Watkins would learn all of the problems at EVT. Prior to each monthly All-Employee Quality meeting, each department would have its own monthly Pre-meeting to discuss problems in their department. The information gathered at these monthly pre-meetings was provided to
Watkins as part of his preparation for the All-Employee Quality meetings. The problems discussed at these monthly All-Employee Quality meetings included the Handle-Breaking Technique and the Company’s failures to file PMA Supplements with the FDA. Defendant Watkins reported the information he learned at these meetings to defendants Dollens and Brauer at the quarterly GMB meetings and during his regular telephone conversations with his direct supervisor, defendant Dollens.

According to an EVT Senior Clinical Research Associate and Manager, Watkins also regularly attended EVT’s Senior Management meetings held every Monday. At the Senior Management meetings the heads of each EVT department would discuss current issues at EVT. Any time a problem arose that would require time and money to examine and/or rectify, a team, headed by a member of Research and Development (R&D), was formed to evaluate and examine the problem. After the evaluation, the team leader would report back to the managers and Watkins at the Senior Management meetings. Problems evaluated by these teams included the Handle-Breaking Technique and the PMA Supplements which EVT failed to file with the FDA regarding the Handle-Breaking Technique. In the Senior Management meetings, each manager and Watkins was made aware of and approved the Company’s decision to not submit a PMA Supplement because it would force the Company to wait at least 90 days to get the Handle-Breaking Technique approved by the FDA, inhibiting the Company’s ability to sell the Ancure. Defendant Watkins also reported the information he learned at these meetings to defendants Dollens and Brauer at the quarterly GMB meetings and during his regular telephone conversations with his direct supervisor, defendant Dollens.

Defendant Huss became the President of EVT, also known as EndoVascular Solutions, in December of 2000. According to an Executive Administrator, EVT Engineer and EVT
Manager, defendant Huss was a very hands-on manager and also held and attended monthly All-Employee Quality meetings and Senior Management meetings. Through her regular contact with EVT personnel and at the meetings, defendant Huss was well-aware of the ongoing ethical and legal problems concerning the Ancure. In fact, according to a Director of Manufacturing who went into the field in February or March of 2001, personally saw Guidant sales representatives “training” doctors on the Handle-Breaking Technique, and informed defendant Huss of this fact, defendant Huss knew that the Handle-Breaking Technique was still being used even though it was not part of the IFU and had not been approved by the FDA. Defendant Huss included this information in her regular reports to defendant Graf and at the GMB meeting.

**APPLICABILITY OF PRESUMPTION OF RELIANCE:**
**FRAUD-ON-THE-MARKET DOCTRINE**

113. Plaintiff will rely, in part, upon the presumption of reliance established by the fraud-on-the-market doctrine in that:

a. the defendants made misleading statements and material omissions during the Class Period;

b. Guidant securities traded on the NYSE which is in an efficient market;

c. stock analysts and the media covered Guidant and its business during the Class Period;

d. the misrepresentation and material omissions alleged in this Complaint would tend to induce a reasonable investor to misjudge the value of the Company’s securities; and

e. Plaintiff and the other Class members purchased their Guidant securities between the time the defendants made the misleading statements and material omissions and the time that the true facts were disclosed, without knowledge of the omitted facts.
114. Based upon the following, plaintiff and members of the Class are entitled to the presumption of reliance upon the integrity of the market.

**STATUTORY SAFE HARBOR**

115. The statutory safe harbor providing for forward-looking statements under certain circumstances does not apply to any of the false forward-looking statements pled in this Complaint. None of the forward-looking statements pled herein were sufficiently identified as a “forward-looking statement” when made. Nor did meaningful cautionary statements identifying important factors that could cause actual results to differ materially from that in the forward-looking statements accompany those statements. To the extent that the statutory safe harbor does apply to any forward-looking statements pled, the defendants are liable for those false forward-looking statements because at the time each of those statements was made, the speaker actually knew the forward-looking statement was false and the forward-looking statement was authorized and/or approved by an executive officer of Guidant who actually knew that those statements were false when made.

**PLAINTIFFS’ CLASS ACTION ALLEGATIONS**

116. Plaintiffs bring this action as a class action pursuant to Rule 23(a) and (b)(3) of the Federal Rules of Civil Procedure on behalf of a Class consisting of all persons and entities who purchased or otherwise acquired Guidant common stock between June 23, 1999 and June 12, 2003, inclusive, and who were damaged thereby. Excluded from the Class are defendants, officers and directors of the Company, members of their immediate families, and their legal representatives, heirs, successors or assigns and any entity in which defendants have or had a controlling interest.
117. During the Class Period, thousands of shares of common stock of Guidant were traded on the NYSE National Market, an efficient and developed securities market. Thousands of brokers nationwide have access to trading information about Guidant through the system. Within minutes of any transaction taking place, this system displays the most recent trades and prices.

118. The members of the Class are so numerous that joinder of all members is impracticable. While the exact number of Class members is unknown to plaintiffs at this time and can only be ascertained through appropriate discovery, plaintiffs believe that there are thousands of members of the Class.

119. Plaintiffs’ claims are typical of the claims of the members of the Class as all members of the Class are similarly affected by defendants’ wrongful conduct in violation of federal law that is complained of herein.

120. Plaintiffs will fairly and adequately protect the interests of the members of the Class and have retained counsel competent and experienced in class and securities litigation. Plaintiffs have no interests that are adverse or antagonistic to those of the Class.

121. A class action is superior to other available methods for the fair and efficient adjudication of this controversy. Because the damages suffered by many individual Class members may be relatively small, the expense and burden of individual litigation makes it virtually impossible for the Class members to individually seek redress for the wrongful conduct alleged herein.

122. Common questions of law and fact exist as to all members of the Class and predominate over any questions affecting solely individual members of the Class. Among the questions of law and fact common to the Class are:
a. whether the federal securities laws were violated by defendants’ acts as alleged herein;

b. whether defendants participated in and pursued the common course of conduct complained of herein;

c. whether documents, press releases and other statements disseminated to the investing public and the Company’s shareholders during the Class Period misrepresented the business condition of Guidant;

d. whether defendants failed to correct prior statements when subsequent events rendered those prior statements untrue or inaccurate;

e. whether defendants acted willfully or recklessly in misrepresenting and/or omitting to state material facts;

f. whether the market price of Guidant’s common stock during the Class Period was artificially inflated due to the misrepresentations and/or non-disclosures complained of herein; and

g. whether the members of the Class have sustained damages, and, if so, what is the proper measure thereof.

123. Plaintiffs will rely, in part, upon the presumption of reliance established by the fraud-on-the-market doctrine in that:

a. defendants made public misrepresentations or omitted material facts during the Class Period, as alleged herein;

b. the misrepresentations and/or omissions were material;

c. Guidant’s common stock was traded in an efficient market;

d. the misrepresentations and/or omissions alleged tended to induce reasonable investors to misjudge the value of Guidant’s shares; and
e. plaintiffs and members of the Class acquired their shares between the time defendants made the misrepresentations and/or omissions and the time the truth was revealed, without knowledge of the falsity of the misrepresentations.

**COUNT I**

*Violations of Section 10(b) of the Exchange Act and Rule 10b-5 Promulgated Thereunder*

124. Plaintiffs incorporate by reference the above paragraphs above as if set forth fully herein.

125. During the Class Period, the defendants, and each of them, carried out a plan, scheme and course of conduct which was intended to and, throughout the Class Period, did: (i) deceive the investing public, including plaintiffs and the other class members, as alleged herein; (ii) artificially inflate and maintain the market price of Guidant; and (iii) cause plaintiffs and other members of the Class to purchase Guidant securities at inflated prices. In furtherance of this unlawful scheme, plan and course of conduct, defendants, and each of them, took the actions set forth herein.

126. Defendants (a) employed devices, schemes, and artifices to defraud; (b) made untrue statements of material fact and/or omitted to state material facts necessary to make the statements not misleading; and (c) engaged in acts, practices, and a course of business which operated as a fraud and deceit upon the purchasers of the Company’s stock in an effort to maintain artificially high market prices for Guidant securities in violation of section 10(b) of the Exchange Act and Rule 10b-5.

127. The statements made by defendants during the Class Period were materially false and misleading because at the time they were made, the Company and persons acting as corporate officers knew or recklessly ignored, but failed to disclose, the matters set forth herein.
128. In ignorance of the artificially high market prices of Guidant’s publicly traded securities, and relying directly on defendants or indirectly on the false and misleading statements made by defendants, upon the integrity of the market in which the securities trade, on the integrity of the regulatory process and the truth of representations made to appropriate agencies throughout the Class Period and/or on the absence of material adverse information that was known to defendants but not disclosed in public statements by defendants during the Class Period, plaintiffs and the other members of the Class acquired Guidant securities during the Class Period at artificially high prices and were damaged thereby.

129. Had plaintiffs and the other members of the Class and the marketplace known of the true financial condition, business prospects and character of leadership of Guidant which were not disclosed by defendants, plaintiffs and other members of the Class would not have purchased or otherwise acquired their Guidant securities during the Class Period, or would have not done so at the artificially inflated prices which they paid. Hence, plaintiffs and the Class were damaged by defendants’ violations of Section 10(b) and Rule 10b-5.

**COUNT II**

*(Violation of Section 20(a) of the Exchange Act Against the Individual Defendants)*

130. Plaintiffs incorporate by reference the above paragraphs above as if set forth fully herein. This Count is asserted against defendants Dollens, Brauer, Watkins and Huss.

131. Defendants Dollens, Brauer, Watkins and Huss acted as a controlling persons of Guidant within the meaning of Section 20 of the Exchange Act as alleged herein. By reasons of their executive and managerial positions with Guidant, defendants had the power and authority to cause the Company to engage in the wrongful conduct complained of herein.
By reasons of the aforementioned wrongful conduct, defendants Dollens, Brauer, Watkins and Huss are liable pursuant to Section 20(a) of the Exchange Act. As a direct and proximate result of their wrongful conduct, plaintiffs and the other members of the Class suffered damages in connection with purchasing the Company’s securities during the Class period.

WHEREFORE, plaintiffs pray for relief and judgment, as follows:

1. Determining that this action is a proper class action, certifying plaintiffs as class representatives under Rule 23 of the Federal Rules of Civil Procedure and their counsel as class counsel;

2. Awarding compensatory damages in favor of plaintiffs and the other class members against all defendants, jointly and severally, for all damages sustained as a result of defendants’ wrongdoing, in an amount to be proven at trial, including interest thereon;

3. Awarding plaintiffs and the Class their reasonable costs and expenses incurred in this action, including counsel fees and expert fees; and

4. Such other and further relief as the Court may deem just and proper.

JURY DEMAND

Plaintiffs hereby demand a trial by jury.

Dated: December 5, 2003

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