KEVIN V. RYAN (CSBN 118321)
United States Attorney

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN FRANCISCO DIVISION

UNITED STATES OF AMERICA, Plaintiff, v. ENDOVASCULAR TECHNOLOGIES, INC., Defendant.	No. CR 03 0179 SI VIOLATIONS: 18 U.S.C.§ 1001 – False Statements; 21 U.S.C. §§ 331(a), 333(a)(2) – Interstate Shipment of Misbranded Devices SAN FRANCISCO VENUE **FILED UNDER SEAL**

INFORMATION

The United States Attorney charges:

GENERAL ALLEGATIONS

At times relevant to this Information, the following facts were true:

1. Defendant ENDOVASCULAR TECHNOLOGIES, INC., a wholly owned subsidiary of Guidant Corporation, ("defendant") was a corporation engaged in the development, manufacture, and distribution of medical devices located in Menlo Park, California. Defendant developed, manufactured, and distributed a medical device known as the ANCURE ENDOGRAFT SYSTEM ("Ancure Device"). Following its acquisition in November 1997,

defendant was a wholly owned subsidiary of Guidant Corporation, a corporation engaged in the development, manufacture, and distribution of medical devices whose principal offices were located in Indianapolis, Indiana.

The Medical Device At Issue

2. Defendant designed the Ancure Device for use in the treatment of abdominal aortic aneurysms, a potentially life threatening condition. An abdominal aortic 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 Device sold by defendant has two primary parts. One 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 of the Ancure Device is a vascular endograft that is placed in the patient's aorta using a delivery system to prevent an aneurysm from rupturing. The vascular endograft consists of a woven fabric graft with an attachment system that includes hooks. 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.

3. Defendant developed and marketed the Ancure Device as an alternative to the traditional and more invasive treatment for abdominal aortic aneurysms: surgery in which the patient's abdomen is cut open to enable the physician to reach the aorta. The use of the Ancure Device was indicated at the time of its approval for commercial marketing by the United States Food & Drug Administration ("FDA") 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 and a diameter of no greater than 26 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 Device sold by defendant costs approximately $10,000.

4. The Ancure Device was and is a medical device within the meaning of the Federal Food, Drug, and Cosmetic Act ("FD&C Act").

Federal Regulation of the Entry of the Ancure Device onto the Market

5. The FDA was, and is, the agency responsible for protecting the health and safety of the American public by ensuring, among other things, that medical devices designed for use in humans are safe and effective for their intended uses and are labeled accurately and in compliance with the law. Toward this end, FDA, pursuant to its statutory mandate, regulates and monitors the manufacture, processing, packing, labeling, and shipment in interstate commerce of medical devices and makes information available to the public and to physicians about medical devices.

6. In order to legally distribute a medical device in interstate commerce, defendant was required to include adequate instructions for use unless expressly exempted from this requirement. In the case of the Ancure Device, defendant was required to provide instructions for use, approved by FDA, as part of the labeling of the Ancure Device. These instructions explain to doctors how to use the the Ancure Device for the indicated medical purposes, including any methods of administration, relevant hazards, contraindications and precautions. Changes to the instructions for use that affect safety or effectiveness of a medical device may not be made without the approval of FDA.

7. Defendant could not legally sell the Ancure Device in the United States without the approval of FDA. In order to be approved by FDA, the premarket approval application ("PMA") was required to include the results of clinical studies conducted upon humans that demonstrated that the device was safe and effective for its intended use(s). In addition, defendant was and is required to submit a PMA Supplement for review and approval by FDA before making a change that affects the safety or effectiveness of the Ancure Device. Among the changes that require a PMA Supplement are any new indications for use of the Ancure Device and changes in the components or physical layout of the Ancure Device that affect its safety or effectiveness.

The Competitive Environment for Ancure Device

8. FDA first approved the Ancure Device for commercial sale in the United States on September 30, 1999. On the same day, FDA also approved a competing product for commercial sale in the United States. The competing product approved by FDA also was designed to treat abdominal aortic aneurysms by the insertion of an endograft into the aorta. From the first day the Ancure Device was approved for commercial sale in the United States, defendant faced competition for market share.

9. Before FDA approved the Ancure Device for commercial sale, defendant learned from physicians during clinical trials that the delivery system of the Ancure Device was perceived as more difficult to use than the competing product. Certain of defendant's employees viewed the complexity of the delivery system of the Ancure Device as the company's primary marketing challenge. Certain officials of defendant believed that if the Ancure Device could not be successfully deployed in a significant number of cases, it had the potential to harm marketing efforts and discourage physician customers from choosing the Ancure Device.

The Handle Breaking Technique

10. After defendant began selling the Ancure Device in the United States, the company became aware of various malfunctions (as defined in the relevant regulations) that occurred in the delivery system of the Ancure Device. In some instances, physicians were unable to implant the Ancure Device due to a problem in using the delivery system of the Ancure Device. In other instances, physicians were able to implant the Ancure Device but could not do so in a way that was consistent with the approved instructions for use. Some of the malfunctions resulted in the delivery system of the Ancure Device 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 Device and correct the aneurysm.

11. Some sales representatives of defendant provided information to doctors regarding a procedure that involved breaking or cutting the handle of the Ancure Device when the delivery system became lodged in a patient and could not be removed without resorting to traditional open surgical repair (the "Handle Breaking Technique"). The Handle Breaking Technique was

devised in part by a sales representative of defendant. The Handle Breaking Technique involved breaking or cutting the handle of the delivery system and removing the catheters housed within the delivery system of the Ancure Device individually from the patient's body.

12. At the time defendant first provided information to doctors regarding the Handle Breaking Technique through its sales representatives, the technique had not been tested; doctors had not been trained on its use; sales representatives who described the technique to doctors during surgery had not been trained by the company on its use; the instructions for use had not been altered to include the Handle Breaking Technique; and defendant had failed to seek prior approval of FDA concerning the use of the Handle Breaking Technique. On or about January 26, 2000, the Handle Breaking Technique was utilized in an operation unsuccessfully. The patient in that operation ultimately died. This incident caused a group of defendant's employees to conclude that the safety of the Handle Breaking Technique was uncertain; that the Handle Breaking Technique required testing and validation; and, if it were to be used, that the Handle Breaking Technique should be submitted to FDA.

13. Defendant became aware that physicians continued to use the Handle Breaking Technique and that its sales representatives continued to provide information to doctors regarding the Handle Breaking Technique during surgical procedures where it was believed necessary to avoid standard open surgical repair. During the times relevant to this Information, the Handle Breaking Technique was not submitted to FDA for its review and approval and was not included in the instructions for use.

The Failure to Report Deaths, Serious Injuries, and Malfunctions to FDA

14. Defendant was required by law to report to FDA within 30 days whenever it received or otherwise became aware of information from any source that reasonably suggested that the Ancure Device (1) may have caused or contributed to a death or serious injury; or (2) had malfunctioned and the device would be likely to cause or contribute to a death or serious injury if the malfunction were to recur. These reports are known as Medical Device Reports (MDRs). FDA makes MDRs available to physicians and other members of the public so that they can be aware of recurring malfunctions and other risks concerning medical devices. Pursuant to federal

regulation, submission of an MDR does not constitute an admission by a manufacturer that a device caused or contributed to the event that is reported.

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

16. Pursuant to the relevant federal law, a patient undergoing a surgical procedure using the Ancure Device suffered a serious injury (as defined in the relevant regulations) when he or she (1) experienced an injury that was life-threatening; (2) experienced an injury or an illness that resulted in permanent impairment of a body function or permanent damage to body structure; or (3) experienced an injury that required medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure. Evidence of actual causation is not required for there to be an obligation to file an MDR report.

17. Where the use of the delivery system of the Ancure Device was unsuccessful and the result was a conversion to traditional surgical repair, it was reportable as an MDR. Patients who experienced an unsuccessful endovascular repair attempt, and as a result, underwent conversion to traditional open surgical repair, could have increased complications, such as arterial trauma, renal insufficiency, and bleeding.

18. During this time period, when the deployment of the Ancure Device required additional surgical procedures, it was reportable as an MDR. Defendant promoted the device as an alternative for patients who would otherwise undergo traditional open surgical repair. As a condition of FDA approval, defendant initially was required to have sales representatives present to observe each surgical procedure in which the Ancure Device was implanted, or an implant was attempted. There was a company policy to require any employee with knowledge of allegations of death, serious injury, or malfunctions that were caused, or may have been caused, by the Ancure Device to report such information to defendant. These allegations were to be reported to defendant's Customer Service Department.

19. After FDA approved the Ancure Devicee for commercial sale in the United States, defendant received information about the number and type of malfunctions (as defined in the relevant regulations) through complaints by physicians, reports from the company's own sales representatives, and from other company employees. The incidences of recurring malfunctions were repeatedly tabulated, distributed to certain officials within defendant, and discussed internally.

20. Defendant received information that some of these malfunctions (i) may have caused or contributed to patients' deaths and serious injuries or (ii) would be likely to cause a death or serious injury if the malfunction were to recur. Defendant did not provide information to FDA of the malfunctions by filing MDRs, or otherwise, and did not seek FDA approval to modify its instructions for use to reflect this information.

21. In or about July 2000, FDA conducted an inspection of defendant's headquarters in Menlo Park, California. During the inspection, the inspector 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 Device. Defendant provided the FDA inspector with a list of 55 complaints. In fact, as defendant well knew, there were more than 200 incidents that constituted complaints (as defined in the relevant regulations) concerning this malfunction that had occurred between October 1999 and April 2000 alone. Defendant knowingly and intentionally misled FDA about the frequency with which the delivery system of the Ancure Device malfunctioned in this manner.

Ethical, Legal, and Safety Concerns

22. In or about October 2000, seven anonymous employees (the "Anonymous Seven") sent a letter to FDA and to an official of defendant's parent corporation describing ethical, legal and safety concerns with the Ancure Device. Among other such concerns, the letter stated:

a. defendant had conducted incomplete testing and analysis on currently recommended procedures;

b. defendant had recommended the use of the device in a manner that was outside the directions for use approved by FDA;

c. The jacket retraction failure mode, which involved the failure of the sheath of the Ancure Device to retract as intended, had a corresponding complaint rate at approximately 20 percent;

d. defendant had failed to report to FDA product changes that affected safety and efficacy as legally required; and

e. defendant failed to submit MDRs to FDA as legally required. The letter listed numerous circumstances that were not reported and specifically named two surgeries during which the Ancure Device malfunctioned that had resulted in death.

23. Following the receipt of this letter, an investigation authorized by the defendant concluded that at certain times relevant to the Information the defendant had serious quality system regulation violations, incomplete and untimely complaint handling and documentation, incomplete MDR reporting, inadequate corrective and preventive action activities, incomplete record keeping for process changes, poor record keeping, and poor traceability practices, and was significantly out of compliance with FDA regulations and its own internal policies.

24. From September 30, 1999 to March 16, 2001, defendant introduced approximately 7,632 delivery system of the Ancure Devices into interstate commerce.

25. Between September 30, 1999 and March 16, 2001, defendant filed 172 MDRs for the delivery system of the Ancure Device.

Defendant's Descriptions of Its Conduct

26. On or about March 23, 2001, defendant disclosed to FDA the existence of approximately 2,628 additional MDRs concerning the delivery system of the Ancure Device that had not been previously reported to FDA, as required by law. Among those 2,628 MDRs that had not been timely filed were 12 deaths and 57 conversions to traditional open surgical repair. Defendant suspended commercial sale of the Ancure Device as of March 16, 2001.

27. On or about March 23, 2001, defendant informed FDA that it had failed to seek prior approval to amend its instructions for use to include the Handle Breaking Technique as legally required.

COUNT ONE: (18 U.S.C. § 1001 – False Statement Within the Jurisdiction of a Federal Agency)

28. The allegations contained in paragraphs 1 through 27 are realleged and incorporated by reference as if fully set forth here.

29. In or about July of 2000, in the Northern District of California and elsewhere, the defendant

ENDOVASCULAR TECHNOLOGIES, INC.,

knowingly and willfully made a materially false statement and representation to an FDA official in a matter within the jurisdiction of the FDA, a federal agency, in that an incomplete and misleading list of complaints was provided by defendant to an FDA Investigator when he requested all complaints of malfunctions related to jacket retraction between September 1999 and July 2000, in violation of Title 18, United States Code, Section 1001.

COUNTS TWO THROUGH TEN: (21 U.S.C. §§ 331(a) & 333(a)(2) – Interstate Shipment of Misbranded Devices)

30. The allegations contained in paragraphs 1 through 27 are realleged and incorporated by reference as if fully set forth here.

31. On or about the dates below, in the Northern District of California and elsewhere, the defendant

ENDOVASCULAR TECHNOLOGIES, INC.,

with the intent to defraud and mislead, caused to be introduced and delivered for introduction into interstate commerce, from Menlo Park, California, to the below-listed locations, devices consisting of the Ancure Device that were misbranded within the meaning of Title 21, United States Code, Section 352(t)(2), in that defendant failed to report as required pursuant to Title 21, United States Code, Section 360i, within 30 days information of which it became aware that reasonably suggested that the Ancure Device may have caused or contributed to deaths or serious injuries, or that the Ancure Device had malfunctioned and that the malfunction would be likely to cause or contribute to death or serious injury if it were to recur, as follows:

Count	Date Shipped	Destination
Two	November 3, 1999	Baltimore, Maryland
Three	November 13, 1999	Phoenix, Arizona
Four	February 16, 2000	Minneapolis, Minnesota
Five	May 17, 2000	Fort Myers, Florida
Six	May 17, 2000	Norfolk, Virginia
Seven	May 11, 2000	Richmond, Indiana
Eight	July 12, 2000	St. Louis, Missouri
Nine	September 6, 2000	Fargo, North Dakota
Ten	September 22, 2000	Cleveland, Ohio

All in violation of Title 21, United States Code, Sections 331(a) and 333(a)(2).

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(APPROVED AS TO FORM)

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