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KEVIN V. RYAN (CSBN 118321)
United States Attorney

3:15
DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN FRANCISCO DIVISION

CR 03 0179

SI

UNITED STATES OF AMERICA,
Plaintiff,
v.
ENDOASCULAR TECHNOLOGIES,
INC.,
Defendant.

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 ENDOASCULAR 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,

CRIMINAL INFORMATION

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

4 The Medical Device At Issue

5 2. Defendant designed the Ancure Device for use in the treatment of abdominal
6 aortic aneurysms, a potentially life threatening condition. An abdominal aortic aneurysm is a
7 weak area that develops in the wall of the aorta, the artery that brings blood flow from the heart
8 through the abdomen to the rest of the body. The Ancure Device sold by defendant has two
9 primary parts. One part is a delivery catheter used to place the vascular endograft into the aorta.
10 The delivery catheter is inserted into a blood vessel through an incision made in the patient's leg.
11 The second part of the Ancure Device is a vascular endograft that is placed in the patient's aorta
12 using a delivery system to prevent an aneurysm from rupturing. The vascular endograft consists
13 of a woven fabric graft with an attachment system that includes hooks. The vascular endograft is
14 designed to remain in the patients aorta permanently after being implanted. The delivery catheter
15 is designed to be removed from the patient after the vascular endograft is implanted.

16 3. Defendant developed and marketed the Ancure Device as an alternative to the
17 traditional and more invasive treatment for abdominal aortic aneurysms: surgery in which the
18 patient's abdomen is cut open to enable the physician to reach the aorta. The use of the Ancure
19 Device was indicated at the time of its approval for commercial marketing by the United States
20 Food & Drug Administration ("FDA") for the endovascular treatment of infrarenal abdominal or
21 aorto-iliac aneurysms in patients having (i) adequate iliac/femoral access; (ii) infrarenal non-
22 aneurysmal neck length of at least 15 millimeters and a diameter of no greater than 26
23 millimeters; (iii) distal segment lengths of at least 20 millimeters and diameters no greater than
24 13.4 millimeters; and (iv) morphology suitable for endovascular repair. Each Ancure Device
25 sold by defendant costs approximately \$10,000.

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

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

4 12. At the time defendant first provided information to doctors regarding the Handle
5 Breaking Technique through its sales representatives, the technique had not been tested; doctors
6 had not been trained on its use; sales representatives who described the technique to doctors
7 during surgery had not been trained by the company on its use; the instructions for use had not
8 been altered to include the Handle Breaking Technique; and defendant had failed to seek prior
9 approval of FDA concerning the use of the Handle Breaking Technique. On or about January 26,
10 2000, the Handle Breaking Technique was utilized in an operation unsuccessfully. The patient in
11 that operation ultimately died. This incident caused a group of defendant's employees to
12 conclude that the safety of the Handle Breaking Technique was uncertain; that the Handle
13 Breaking Technique required testing and validation; and, if it were to be used, that the Handle
14 Breaking Technique should be submitted to FDA.

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

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

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

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

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

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

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

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

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

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

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

7 **ENDOASCULAR TECHNOLOGIES, INC.,**

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

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

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

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

19 **ENDOASCULAR TECHNOLOGIES, INC.,**

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

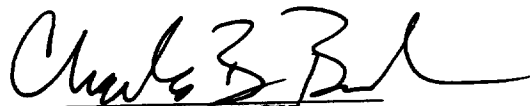
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<u>Count</u>	<u>Date Shipped</u>	<u>Destination</u>
Two	November 3, 1999	Baltimore, Maryland
Three	November 13, 1999	Phoenix, Arizona
Four	February 16, 2000	Minneapolis, Minnesota
Five	May 17, 2000	Fort Myers, Florida
Six	May 17, 2000	Norfolk, Virginia
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).

KEVIN V. RYAN
United States Attorney



CHARLES B. BURCH
Chief, Criminal Division

(APPROVED AS TO FORM)



AUSA MATTHEW J. JACOBS
DOJ TRIAL ATTORNEY DOUGLAS W. STEARN