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12 UNITED STATES DISTRICT COURT  
 13 NORTHERN DISTRICT OF CALIFORNIA  
 14 SAN FRANCISCO DIVISION

15 UNITED STATES OF AMERICA,	)	No. CR 02-0179 SI
16 Plaintiff,	)	PLEA AGREEMENT
17 v.	)	
18 ENDOVASCULAR TECHNOLOGIES,	)	
19 INC.,	)	
20 Defendant.	)	

21  
 22 ENDOVASCULAR TECHNOLOGIES, INC., a wholly owned subsidiary of Guidant  
 23 Corporation, (“defendant”), and the United States Department of Justice, by the United States  
 24 Attorney’s Office for the Northern District of California and the Office of Consumer Litigation  
 25 (“the government”) enter into this written Plea Agreement (the “Agreement”) pursuant to Rule  
 26 11(c)(1)(C) of the Federal Rules of Criminal Procedure:

27 Defendant’s Promises

28 1. Defendant agrees to waive indictment and plead guilty to a criminal Information

1 charging it with one felony count of making false statements within the jurisdiction of a federal  
2 agency, in violation of 18 U.S.C. § 1001, and nine felony counts of shipping misbranded medical  
3 devices in interstate commerce, in violation of 21 U.S.C. §§ 331(a) and 333(a)(2). Defendant  
4 agrees that the elements of the offense of making false statements within the jurisdiction of a  
5 federal agency are as follows: (1) defendant made a false statement or representation; (2) the  
6 defendant acted knowingly and willfully, that is deliberately and with knowledge that the  
7 statement or representation was untrue; and (3) the statement or representation was material to  
8 the activities or decision of a government agency or department, meaning that the statement or  
9 representation could have influenced the agency's decisions or activities. Defendant agrees that  
10 the maximum penalties for making a false statement are as follows:

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|----|----|------------------------------|---|
| 11 | a. | Maximum fine                 | \$500,000 or the greater of twice the gross<br>gain or twice the gross loss |
| 12 | b. | Maximum term of probation    | 5 years   |
| 13 | c. | Mandatory special assessment | \$400   |
| 14 | d. | Restitution                  | Up to the amount of the loss  |

15 Defendant agrees that the elements of the offense of shipping misbranded medical devices in  
16 interstate commerce are as follows: (1) that defendant caused a device to be introduced, and  
17 delivered for introduction, into interstate commerce; (2) the device was misbranded when it was  
18 so introduced, and delivered for introduction, into interstate commerce; and (3) defendant, in  
19 introducing the misbranded device into interstate commerce, acted with the intent to defraud and  
20 mislead. Defendant agrees that the maximum penalties for each count of shipping misbranded  
21 medical devices in interstate commerce are as follows:

- |    |    |                              |   |
|----|----|------------------------------|---|
| 22 | a. | Maximum fine                 | \$500,000 or the greater of twice the gross<br>gain or twice the gross loss |
| 23 | b. | Maximum term of probation    | 5 years   |
| 24 | c. | Mandatory special assessment | \$400   |
| 25 | d. | Restitution                  | Up to the amount of the loss  |

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28 2. Defendant agrees that it is guilty of the offenses to which it will plead guilty, and

1 agrees that the following facts are true:

2 Defendant is a corporation engaged in the development, manufacture, and distribution of  
3 medical devices and is located in Menlo Park, California. Defendant developed, manufactures,  
4 and distributes a medical device known as the Ancure Endograft System ("Ancure Device").  
5 Following its acquisition in November 1997, defendant was a wholly owned subsidiary of  
6 Guidant Corporation, a corporation engaged in the development, manufacture, and distribution of  
7 medical devices, whose principal offices are located in Indianapolis, Indiana.

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

19 Defendant developed and marketed the Ancure Device as an alternative to the traditional  
20 and more invasive treatment for abdominal aortic aneurysms: surgery in which the patient's  
21 abdomen is cut open to enable the physician to reach the aorta. The use of the Ancure Device  
22 was indicated at the time of its approval for commercial marketing by the United States Food &  
23 Drug Administration ("FDA") for the endovascular treatment of infrarenal abdominal or aorto-  
24 iliac aneurysms in patients having (i) adequate iliac/femoral access; (ii) infrarenal non-  
25 aneurysmal neck length of at least 15 millimeters and a diameter of no greater than 26  
26 millimeters; (iii) distal segment lengths of at least 20 millimeters and diameters no greater than  
27 13.4 millimeters; and (iv) morphology suitable for endovascular repair. The Ancure Device was  
28 and is a medical device within the meaning of the Federal Food, Drug, and Cosmetic Act

1 (“FD&C Act”). Each Ancure Device sold by defendant costs approximately \$10,000.

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

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

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

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

1 Ancure Device was approved for commercial sale in the United States, defendant faced  
2 competition for market share.

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

10 After defendant began selling the Ancure Device in the United States, the company  
11 became aware of various malfunctions (as defined in the relevant regulations) that occurred in the  
12 delivery system of the Ancure Device. In some instances, physicians were unable to implant the  
13 Ancure Device due to a problem in using the delivery system of the Ancure Device. In other  
14 instances, physicians were able to implant the Ancure Device but could not do so in a way that  
15 was consistent with the approved instructions for use. Some of the malfunctions resulted in the  
16 delivery system of the Ancure Device becoming improperly lodged in the body. In these latter  
17 cases, some of the patients had to undergo traditional open surgical repair to remove the delivery  
18 system of the Ancure Device and correct the aneurysm. The malfunctions in this Plea Agreement  
19 relate only to the delivery system of the Ancure Device, and do not relate to the Ancure Device  
20 after it has been implanted.

21 Some sales representatives of defendant provided information to doctors regarding a  
22 procedure that involved breaking or cutting the handle of the Ancure Device when the delivery  
23 system became lodged in a patient and could not be removed without resorting to traditional open  
24 surgical repair ("Handle Breaking Technique"). The Handle Breaking Technique was devised in  
25 part by a sales representative of defendant. The Handle Breaking Technique involved breaking  
26 or cutting the handle of the delivery system and removing the catheters housed within the  
27 delivery system of the Ancure Device individually from the patient's body.

28 At the time defendant first provided information to doctors regarding the Handle

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

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

17 Defendant was required by law to report to FDA within 30 days whenever it received or  
18 otherwise became aware of information from any source that reasonably suggested that the  
19 Ancure Device (1) may have caused or contributed to a death or serious injury; or (2) had  
20 malfunctioned and the device would be likely to cause or contribute to a death or serious injury if  
21 the malfunction were to recur. These reports are known as Medical Device Reports (MDRs).  
22 FDA makes MDRs available to physicians and other members of the public so that they can be  
23 aware of recurring malfunctions and other risks concerning medical devices. Pursuant to federal  
24 regulation, submission of an MDR does not constitute an admission by a manufacturer that a  
25 device caused or contributed to the event that is reported.

26 Pursuant to federal law, a medical device causes or contributes to a death or serious injury  
27 (as defined in the relevant regulations) whenever a death or serious injury was, or may have been,  
28 attributed to a medical device, or that a medical device was or may have been a factor in a death

1 or serious injury, including events occurring as a result of failure, malfunction, improper or  
2 inadequate design, manufacture, labeling, or user error.

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

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

16 During this time period, when the deployment of the Ancure Device required additional  
17 surgical procedures, it was reportable as an MDR. Defendant promoted the device as an  
18 alternative for patients who would otherwise undergo traditional open surgical repair.

19 As a condition of FDA approval, defendant initially was required to have sales  
20 representatives present to observe each surgical procedure in which the Ancure Device was  
21 implanted, or an implant was attempted. There was a company policy to require any employee  
22 with knowledge of allegations of death, serious injury, or malfunctions that were caused, or may  
23 have been caused, by the Ancure Device to report such information to defendant. These  
24 allegations were to be reported to defendant's Customer Service Department.

25 After FDA approved the Ancure Device for commercial sale in the United States,  
26 defendant received information about the number and type of malfunctions (as defined in the  
27 relevant regulations) through complaints by physicians, reports from the company's own sales  
28 representatives, and from other company employees. The incidences of recurring malfunctions

1 were repeatedly tabulated, distributed to certain officials within defendant, and discussed  
2 internally.

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

8 In or about July 2000, FDA conducted an inspection of defendant's headquarters in  
9 Menlo Park, California. During the inspection, the inspector requested a list of all complaints  
10 regarding difficulties of the catheter's jacket to retract properly during surgical use of the delivery  
11 system of the Ancure Device. Defendant provided the FDA inspector with a list of 55  
12 complaints. In fact, as defendant well knew, there were more than 200 incidents that constituted  
13 complaints (as defined in the relevant regulations) concerning this malfunction that had occurred  
14 between October 1999 and April 2000 alone. Defendant knowingly and intentionally misled  
15 FDA about the frequency with which the delivery system of the Ancure Device malfunctioned in  
16 this manner.

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

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

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

24 c. The jacket retraction failure mode, which involved the failure of the sheath  
25 of the Ancure Device to retract as intended, had a corresponding complaint rate of approximately  
26 20 percent;

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

1 e. defendant failed to submit MDRs to FDA as legally required.

2 The letter listed numerous circumstances that were not reported and specifically named  
3 two surgeries during which the Ancure Device malfunctioned that had resulted in death.

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

10 From September 30, 1999 to March 16, 2001, defendant introduced approximately 7,632  
11 Devices into interstate commerce.

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

14 On or about March 23, 2001, defendant disclosed to FDA the existence of approximately  
15 2,628 additional MDRs concerning the delivery system of the Ancure Device that had not been  
16 previously reported to FDA, as required by law. Among those 2,628 MDRs that had not been  
17 timely filed were 12 deaths and 57 conversions to traditional open surgical repair. Defendant  
18 suspended commercial sale of the Ancure Device as of March 16, 2001.

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

22 On or about November 3, 1999, defendant, with the intent to defraud or mislead, shipped  
23 an Ancure device from Menlo Park, California, to Baltimore, Maryland.

24 On or about November 13, 1999, defendant, with the intent to defraud or mislead,  
25 shipped an Ancure device from Menlo Park, California, to Phoenix, Arizona.

26 On or about February 16, 2000, defendant, with the intent to defraud or mislead, shipped  
27 an Ancure device from Menlo Park, California, to Minneapolis, Minnesota.

28 On or about May 17, 2000, defendant, with the intent to defraud or mislead, shipped an

1 Ancure device from Menlo Park, California, to Fort Myers, Florida.

2 On or about May 17, 2000, defendant, with the intent to defraud or mislead, shipped an  
3 Ancure, device from Menlo Park, California, to Norfolk, Virginia.

4 On or about May 11, 2000, defendant, with the intent to defraud or mislead, shipped an  
5 Ancure device from Menlo Park, California, to Richmond, Indiana.

6 On or about July 12, 2000, defendant, with the intent to defraud or mislead, shipped an  
7 Ancure device from Menlo Park, California, to St. Louis, Missouri.

8 On or about September 6, 2000, defendant, with the intent to defraud or mislead, shipped  
9 an Ancure device from Menlo Park, California, to Fargo, North Dakota.

10 On or about September 22, 2000, defendant, with the intent to defraud or mislead,  
11 shipped an Ancure device from Menlo Park, California, to Cleveland, Ohio.

12 3. Defendant agrees to give up all rights that it would have if it chose to proceed to  
13 trial, including the rights to a jury trial with the assistance of an attorney; to confront and cross-  
14 examine government witnesses; to move to suppress evidence or raise any other Fourth or Fifth  
15 Amendment claims; to any further discovery from the government; and to pursue any affirmative  
16 defenses and present evidence.

17 4. Defendant agrees to give up its right to appeal its convictions, the judgment, and  
18 orders of the Court. Defendant also agrees to waive any right it may have to appeal its sentence.

19 5. Defendant agrees not to file any collateral attack on its convictions or sentence,  
20 including a petition under 28 U.S.C. § 2255, at any time in the future after it is sentenced, except  
21 for a claim that its constitutional right to the effective assistance of counsel was violated.

22 6. Defendant agrees not to ask the Court to withdraw its guilty plea at any time after  
23 it is entered, unless the Court declines to accept the sentence agreed to by the parties. Defendant  
24 agrees that the government may withdraw from this agreement if the Court does not accept the  
25 agreed upon sentence set out below.

26 7. Defendant agrees that it will make a good faith effort to pay any fine, forfeiture or  
27 restitution it is ordered to pay. After sentencing, defendant will, upon request of the Court, the  
28 government, or the U.S. Probation Office, release any of funds and property under its control in

1 order to pay any fine, forfeiture, or restitution. Defendant agrees to pay the special assessment at  
2 the time of sentencing.

3 8. In addition to any fine, defendant agrees to forfeit to the United States within ten  
4 days after sentencing and voluntarily a sum of ten million, nine hundred thousand dollars  
5 (\$10,900,000), pursuant to 18 U.S.C. § 981. The defendant agrees to forfeit all interest in these  
6 funds and to take whatever steps are necessary to pass clear title of this sum to the United States.  
7 These steps include but are not limited to making the sum available to the United States after the  
8 imposition of sentence, as directed by the government. Defendant agrees not to file a claim in  
9 any forfeiture proceeding or to contest, in any manner, the forfeiture of said assets.

10 9. Defendant agrees that an appropriate disposition of this case is as follows:  
11 defendant shall, in addition to the \$10.9 million in forfeiture described in paragraph 8 above, pay  
12 a criminal fine of thirty-two and a half million (\$32.5 million), pursuant to Chapter Eight of the  
13 United States Sentencing Guidelines, for the 10 felony violations specified in the Information.  
14 This will result in a total sum of forty-three point four million dollars (\$43.4 million) to be paid  
15 in accordance with the commitments made within this criminal plea agreement. In addition, in  
16 connection with the settlement of this matter, defendant has agreed to pay a civil settlement of  
17 forty-nine million dollars (\$49 million) to the United States as set forth in the settlement  
18 agreement on this date. The criminal fine shall be payable by defendant within 10 days of the  
19 day that it is sentenced, in the manner directed by the government. The parties agree that,  
20 pursuant to U.S.S.G. § 8D1.1, a sentence of probation would not be appropriate and that there  
21 shall be no organizational probation imposed. In addition, the parties agree that no restitution  
22 shall be imposed pursuant to 18 U.S.C. § 3663 in that resolving any potential claims would  
23 unduly complicate the sentencing process and is most appropriately determined in this instance  
24 by the civil justice system.

25 10. Defendant and its parent corporation agree to cooperate with the government  
26 before and after it is sentenced. Each of the obligations sets forth in this paragraph shall apply  
27 equally to Defendant's parent corporation, except as to paragraph c. The cooperation will  
28 include, but will not be limited to, the following:

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- a. Except as provided in subparagraph 10(c), defendant will, upon reasonable notice and without requiring service of process, take all steps within its power to make available for interviews or testimony any current employees, officers, or directors of defendant or its parent corporation or parent corporation's wholly owned subsidiaries;
- b. Except as provided in subparagraph 10(c), defendant will provide all documents and other materials created on or before May 1, 2001 asked for by the government without requiring service of process;
- c. Defendant and the government have a common interest in a prompt and fair resolution of the investigation. Accordingly, defendant will not object, including asserting any privilege against the government, to the government's access to interviews, testimony, or providing documents that relate to, concern, or are associated in any way with the Ancure Device between June 1, 1999 and March 23, 2001, as well as interview memoranda created between January 1, 2001 through May 7, 2001. The government will maintain the confidentiality of these materials and will not disclose them to any third party, except to the extent that disclosure is required by law or would be in furtherance of the government's discharge of its duties and responsibilities, as the government may decide in its sole discretion; and
- d. Defendant will withdraw from and not participate in any existing joint defense agreement or common interest agreement that pertain to the subject matter of the investigation. Defendant will not initiate contacts with former employees designated by the government without prior approval of the government and, if contacted by such designated individuals, will notify the government of the fact and the substance of such contacts.

As an alternative to the remedies set forth in paragraphs 11 and 12 of this agreement, if the U.S. Attorney's Office determines in the exercise of its reasonable discretion that these obligations of cooperation have not been met, defendant agrees to pay the costs of the

1 government's investigation between November 1, 2000, and the date of this Agreement.

2 Defendant's obligations of cooperation under this agreement shall cease either upon five years  
3 from the date of the execution of this agreement or upon the conclusion of any proceedings that  
4 may arise from the investigation, whichever is later.

5 11. Defendant agrees not to commit or attempt to commit any crimes before sentence  
6 is imposed; intentionally provide false information or testimony to the Court, the Probation  
7 Office, or the government; or fail to comply with any of the other promises it has made in this  
8 Agreement. Defendant agrees that, if it fails to comply with any promises it has made in this  
9 Agreement, including but not limited to payment of the \$10.9 million forfeiture amount, the  
10 \$32.5 million criminal fine, and the \$49 million civil settlement amount as described in  
11 Paragraphs 8 and 9 above then the government will be released from all of its promises, but  
12 defendant will not be released from its guilty plea.

13 12. If defendant is prosecuted after failing to comply with any promises it has made in  
14 this Agreement, then (a) defendant agrees that any statements made by its or its parent  
15 corporation's employees, officers or directors to any law enforcement or other government  
16 agency or in Court, whether or not made pursuant to the cooperation provisions of this  
17 Agreement, may be used in any way; (b) defendant waives any and all claims under the United  
18 States Constitution, Rule 11(e)(6) of the Federal Rules of Criminal Procedure, Rule 410 of the  
19 Federal Rules of Evidence, or any other federal statute or rule, to suppress or restrict the use of  
20 my statements, or any leads derived from those statements; and (c) defendant waives any defense  
21 to any prosecution that it is barred by a statute of limitations, if the limitations period has run  
22 between the date of this Agreement and the date it is indicted.

23 13. Defendant agrees that this Agreement and the Settlement Agreement entered on  
24 the same date contains all of the promises and agreements between it and the government, and it  
25 will not claim otherwise in the future.

26 14. Except to the extent specifically noted, defendant agrees that this Agreement  
27 binds the U.S. Department of Justice and U.S. Attorney's Office for the Northern District of  
28 California only, and does not bind any other federal, state, or local agency.

1           15. Defendant and the government agree to waive their rights to have the Probation  
2 Department prepare a Presentence Report. Defendant and the government will request that the  
3 Court accept defendant's pleas of guilty and impose sentence on an expedited schedule as early  
4 as the date of arraignment, under the provisions of Federal Rule of Criminal Procedure 32(b)(1),  
5 U.S.S.G. § 6A1.1, and Local Criminal Rule 32-1(b).

6 The Government's Promises

7           15. Pursuant to Federal Rule of Criminal Procedure 11(c)(1)(C), the government  
8 agrees that the appropriate disposition of the case is as set forth in paragraph 9.

9           16. The government agrees not to file or seek any additional charges against  
10 defendant or any affiliates, subsidiaries, or parent corporations that could be filed as a result of  
11 the investigation that led to the pending information or that are related to the conduct described  
12 in the pending information.

13           17. The government agrees not to use any statements made by defendant pursuant to  
14 this Agreement against defendant or any affiliates, subsidiaries, or parent corporations, in or in  
15 connection with any legal proceeding, whether criminal, civil, or administrative, unless defendant  
16 fails to comply with any promises in this agreement. The government may, however, provide  
17 defendant's statements in any federal criminal proceeding. The government may also tell the  
18 Court and the U.S. Probation Department about the full extent of the defendant's criminal  
19 activities in connection with the calculation of the Sentencing Guidelines.

20 Defendant's Affirmations

21           18. Defendant confirms that it has had adequate time to discuss this case, the  
22 evidence, and this Agreement with its attorneys, and that they have provided it with all the legal  
23 advice requested.

24           19. Defendant confirms that while its representatives considered signing this  
25 Agreement and, at the time its representatives signed it, its representatives were not under the  
26 influence of any alcohol, drug, or medicine.

27           20. Defendant confirms that its decision to enter a guilty plea is made knowing the  
28 charges that have been brought against it, any possible defenses, and the benefits and possible

1 detriments of proceeding to trial. Defendant also confirms that its decision to plead guilty is  
2 made voluntarily, and no one coerced or threatened it to enter into this agreement.

3 I am the authorized representative of defendant, as well as the authorized representative  
4 of defendant's parent corporation with respect to paragraphs 10, 12 and 20 of this agreement, and  
5 in that capacity, I have read this agreement and carefully reviewed every part of it with the  
6 attorneys of defendant. Pursuant to a valid corporate resolution by the Board of Directors (a copy  
7 of which is attached to this agreement), I have been authorized to enter into this agreement on the  
8 behalf of defendant and its parent corporation. The representations contained in this agreement  
9 are true to the best of our knowledge and belief.

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Dated: \_\_\_\_\_

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Authorized Representative  
ENDOVASCULAR TECHNOLOGIES,  
INC. and its Parent Corporation

KEVIN V. RYAN  
United States Attorney

Dated: \_\_\_\_\_

\_\_\_\_\_  
MATTHEW J. JACOBS  
Assistant United States Attorney

\_\_\_\_\_  
DOUGLAS W. STEARN  
Trial Attorney  
Office of Consumer Litigation

1 We have fully explained to our client all the rights that a criminal defendant has and all the terms  
2 of this Agreement. In our opinion, our client understands all the terms of this Agreement and all  
3 the rights it is giving up by pleading guilty, and, based on the information now known to us, its  
4 decision to plead guilty is knowing and voluntary.

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7 Dated: \_\_\_\_\_

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PETER S. SPIVACK  
Attorney for Defendant

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ROBERT BREAKSTONE  
Attorney for Defendant

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