JUSTICE NEWS

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Thursday, November 13, 2014

Vascular Solutions Inc. and its CEO Charged with Selling Unapproved Medical Devices and Conspiring to Defraud the United States

An indictment was filed today charging Vascular Solutions Inc. (VSI) and its chief executive officer, Howard Root, with selling medical devices without U.S. Food and Drug Administration (FDA) approval and conspiring to defraud the United States by concealing the illegal sales activity. The announcement was made today by Acting Assistant Attorney General Joyce R. Branda for the U.S. Department of Justice's Civil Division, U.S. Attorney Robert Pitman for the Western District of Texas and Special Agent in Charge Antoinette V. Henry of the U.S. Food and Drug Administration (FDA)'s Office of Criminal Investigations, Metro Washington Field Office. The devices at issue are from VSI's "Vari-Lase" product line, a system designed to treat varicose veins by burning or "ablating" them with laser energy.

Root and VSI are each charged with one count of conspiracy and eight counts of introducing adulterated and misbranded medical devices into interstate commerce. The case is pending in the U.S. District Court for the Western District of Texas.

"These charges involve a deceptive sales campaign led by the CEO of a public company," said Acting Assistant Attorney General Branda. "The indictment charges that the sales campaign persisted in the face of FDA warnings, a whistleblower's complaint to the CEO and a failed clinical trial showing that the device was less safe and less effective than a product that had already been approved. We will take action to hold corporations and their leaders responsible when they violate laws intended to protect public health."

According to the indictment, the Vari-Lase products were cleared by the FDA only for the treatment of superficial veins, but Root and VSI sold them for the ablation, or removal, of "perforator" veins, which connect the superficial vein system to the deep vein system. Because perforator veins come into direct contact with deep veins, treating them with lasers was a more difficult and risky procedure.

Root is charged with leading the illegal sales campaign, which lasted from 2007 until 2014, and conspiring with others to hide it from the FDA. The indictment alleges that Root authorized the campaign after VSI failed to obtain FDA authorization to sell the Vari-Lase system for ablation of perforator veins. The sales campaign is alleged to have ignored FDA concerns about the safety and effectiveness of the procedure and specific warnings from the FDA not to sell Vari-Lase products for treatment of perforator veins. The indictment alleges that, with Root's approval, the sales continued even after the company sponsored an unsuccessful clinical trial that showed that the Vari-Lase system was less safe and effective than a competing device that the FDA had cleared for perforator vein treatment. According to the indictment, the sales continued even after a whistleblower complained to Root in 2009 and the government told the company about its investigation in 2011.

The indictment also charges VSI and Root with deceiving the FDA. In late 2007, Root decided to launch a special "Short Kit" designed for perforator vein treatment, despite the lack of FDA marketing authorization, by claiming that the product was intended for "short vein segments" or "short veins." At the same time, the government alleged that internal company documents approved by Root taught the sales force that these terms included perforator veins and urged salespeople to suggest to health care providers that Vari-Lase devices could be used to treat perforator veins. After learning about the government's investigation, members of the sales force began using the term "short vein segments" in field trip reports to disguise that they were still selling Vari-Lase devices for perforator vein treatment, according to the indictment. Two other members of the sales force are alleged to have misled investigators; in addition, the indictment charges that one member falsely denied his conduct and another tried to scapegoat a low-level salesman.

In July 2014, VSI agreed to pay $520,000 to resolve allegations that it caused false claims to be submitted to federal health programs by marketing the Vari-Lase devices for treating perforator veins. In that civil action, the government alleged that VSI knowingly caused physicians and other purchasers of the Short Kit to submit false claims to federal health care programs for uses of the Short Kit that were not reimbursable.

"FDA is committed to protecting the public health and the integrity of the regulatory system," said Special Agent in Charge Henry.

The case is being prosecuted by Trial Attorney Timothy Finley of the Civil Division's Consumer Protection Branch and Assistant U.S. Attorney Bud Paulissen of the Western District of Texas. The case was investigated by the FDA's Office of Criminal Investigations and the U.S. Department of Health and Human Services' Office of the Inspector General.

An indictment is merely an allegation, and every defendant is presumed innocent until proven guilty beyond a reasonable doubt.

14-1268
Consumer Protection

Civil Division

UNITED STATES DISTRICT COURT

WESTERN DISTRICT OF TEXAS

SAN ANTONIO DIVISION

UNITED STATES OF AMERICA	§	CRIMINAL NO. SA14CR0926 FB
	§	
Plaintiff	§	**INDICTMENT**
	§	
V.	§	VIOLATIONS:
	§	18 U.S.C. § 371 (Conspiracy - 1 count)
VASCULAR SOLUTIONS, INC., (1), &	§	21 U.S.C. §§ 331(a), 351(f)(1)(B), 333(a)(1)
HOWARD C. ROOT, (2)	§	(Adulteration – 4 counts)
	§	21 U.S.C. §§ 331(a), 352(o); 352(f)(1) and
Defendants.	§	333(a)(1) (Misbranding – 4 counts)

THE GRAND JURY CHARGES:

COUNT ONE
[18 U.S.C. § 371 – conspiracy]

Introduction

At all times relevant to this Indictment:

The Defendants

1. Defendant VASCULAR SOLUTIONS, INC. (VSI) was a corporation organized under the laws of the State of Minnesota, with its principal place of business located at Minneapolis, Minnesota. Defendant VSI sold medical devices throughout the United States, including in the Western District of Texas.

2. Since 1997, Defendant HOWARD C. ROOT was the Chief Executive Officer of VSI.

FDA Approval Process for Medical Devices

3. The Food and Drug Administration ("FDA") is an agency of the United States government responsible for protecting the health and safety of the public by assuring, among

other things, that medical devices are safe and effective for their intended uses and that the labeling of such devices bear true and accurate information. Under the Federal Food, Drug and Cosmetic Act (21 U.S.C. §§ 301-397, the "FDCA"), the FDA regulates the manufacture, labeling, and shipment in interstate commerce of such devices.

4. Under the FDCA, every manufacturer of a device is required to obtain authorization from the FDA prior to marketing its device, unless the devices are subject to an exemption not applicable here.

5. If the manufacturer intends to market a previously cleared device for a new or different indication for use other than the intended use cleared by the FDA, a new marketing authorization is required.

6. The FDCA does not prohibit doctors, in the exercise of medical judgment, from using medical devices for unapproved uses not included in the FDA-approved labeling. However, a manufacturer may not distribute medical devices in interstate commerce with the intent that those devices be used for unapproved purposes.

7. A device is "adulterated" if it is required to have, but does not have, FDA pre-market approval ("PMA approval"), a type of marketing authorization, for its intended use. The FDCA prohibits the introduction of adulterated medical devices into interstate commerce. 21 U.S.C. § 331(a); 21 U.S.C. § 351(f)(1)(B).

8. A device is "misbranded" if the manufacturer of that device was required to file a 510(k) pre-market notification with FDA 90 days prior to introducing the device into interstate commerce and failed to do so.

9. A device must have labeling that bears adequate instructions for its intended use unless it qualifies for an exemption from this requirement. A medical device that requires and

lacks adequate instructions for its intended use is also "misbranded." 21 U.S.C. § 352(f)(1).

10. The FDCA prohibits the introduction of misbranded medical devices into interstate commerce. 21 U.S.C. § 331(a).

The Vari-Lase Devices

11. Under the brand name Vari-Lase, VSI sold medical devices – including laser consoles, needles, fibers, sheaths, and other accessories – needed to ablate incompetent veins (often referred to as varicose veins) with laser energy. This process used heat to shut varicose veins permanently, allowing the body to recruit healthier veins to move the blood. The Vari-Lase products were available individually, and were also packaged into procedure kits. The kits generally contained fibers and sheaths, as well as introducer needles, which doctors used to puncture the skin and introduce the sheath into the vein.

12. The Vari-Lase devices were cleared for marketing by the FDA solely for treatment of superficial veins and the Great Saphenous Vein. Specifically, in June 2007, the indication for these devices stated: "The VARI-LASE Bright Tip kit (and Console) is indicated for the treatment of varicose veins and varicosities associated with superficial reflux of the Great Saphenous Vein, and for the treatment of incompetence and reflux of superficial veins in the lower extremity." The Vari-Lase products could not legally be sold in the United States for any use or purpose outside of this cleared indication.

Perforator Veins

13. The Vari-Lase devices did not have any form of FDA marketing authorization for treatment of perforator veins. Perforator veins are short, tortuous veins that connect the superficial and deep vein systems. By the mid-2000s, a small number of doctors had begun treating perforator veins using radiofrequency and laser ablation. Because of their twisting shape

and proximity to the deep vein system, perforator veins are more difficult and risky to ablate than superficial veins. For this reason, and because such treatment was considered experimental at the time, insurers generally did not pay for these procedures.

14. For perforator ablations using radiofrequency, this began to change in 2006, when VSI's radiofrequency competitor – referred to here as "RF Company" – gained FDA clearance to market its system for perforator treatment. This permitted doctors to get reimbursed by Medicare and private insurers for performing perforator ablations with the radiofrequency device. This gave the radiofrequency device a reimbursement advantage over its laser competitors, and VSI's competitor began distributing a special kit (referred to here as the "RF Perforator Kit") specifically designed and authorized for treatment of perforator veins.

15. This development posed a competitive threat to VSI's Vari-Lase business. Doctors who wanted to perform perforator procedures would have to choose the radiofrequency system over the Vari-Lase in order to get reimbursement for those procedures from Medicare (and many private insurers). Because consoles were relatively expensive (approximately $25,000 each), a physician's practice that purchased a radiofrequency console had an incentive to use it for all of its vein ablation procedures (both superficial and perforator), locking in future kit and accessory purchases. Thus, the radiofrequency company's advantage in perforator treatment could effectively lock VSI out of many physician practices that performed vein procedures.

16. VSI responded to the competitive threat in January 2007 by instructing the sales force, in a national sales meeting presentation approved by HOWARD C. ROOT, to criticize the RF Perforator Kit as bulky, difficult to use, and inferior to laser technology. In the same year, VSI sales representatives began promoting the Vari-Lase system for perforator use.

HOWARD C. ROOT encouraged these efforts, as detailed below.

17. In order to make the Vari-Lase system easier to use on perforator veins, VSI designed a special "Short Kit," which was launched in October 2007. The Short Kit had several design modifications from the standard kit, such as a shorter sheath and introducer tip that were easier to guide through shorter, tortuous perforator veins. In an April 2008 presentation to the VSI board of directors, HOWARD C. ROOT and a VSI Vice President (Vice President 1) remarked upon the Short Kit's role in "blunting" the radiofrequency company's "competitive activity." They explained that VSI had lost business in part because of

> competitive activity by the radiofrequency competition [RF Company] which has been aggressively going after laser accounts by dropping off RF consoles ... for 90 day trials using their perforator vein system as a hook. Our Vari-Lase Short kit helped to blunt some of [RF Company]'s efforts on the perforator product line, but until we have the specific perforator ind[ica]tion ... we will still be at a competitive disadvantage.

VSI's Unsuccessful Effort to Gain FDA Marketing Authorization

18. In June 2007, VSI submitted a "510(k) notification" to FDA to "clarify the indications for use statement of the currently marketed Vari-Lase Endovenous Laser System." The application sought to obtain an indication for the treatment of perforator veins that would allow VSI to sell Vari-Lase products, including the Short Kit, for that purpose. Specifically, VSI requested the following language in the indications for use for its label: "The VARI-LASE Bright Tip Procedure Kits and Console are indicated for the treatment of varicose veins and varicosities in the lower extremity that is associated with superficial venous incompetency and reflux in the Great Saphenous Vein, Short Saphenous Vein, *and perforator and tributary veins*." (Emphasis added.)

19. In September 2007, the FDA informed VSI that its marketing application was deficient and requested data regarding the safety and efficacy of the Vari-Lase system for the

laser treatment of perforator veins. In a letter dated September 18, 2007, FDA warned: "Please remember that the Safe Medical Devices Act of 1990 states that you may not place this device into commercial distribution until you receive a decision letter from FDA allowing you to do so."

20. The following month, VSI released the Short Kit for distribution in the United States.

21. In late 2007 and early 2008, VSI conducted a clinical trial to investigate the safety and efficacy of treating perforator veins with lasers. The study was titled "Safety and Efficacy of Endovenous Laser Ablation for the Resolution of Incompetent Perforator Veins" and referred to as the RELIEVE study. VSI anticipated that the RELIEVE trial would supply the evidence that it needed to gain approval for the perforator indication.

22. On March 21, 2008, the FDA informed VSI that based on the lack of response to its earlier request for data, the FDA "now considered [VSI's] 510(k) [application] to be withdrawn." The FDA's letter warned: "If you market the device without FDA clearance/approval, you will be in violation of the [FDCA]."

23. VSI had the option of resubmitting its application with the data requested by FDA, but it chose not to. The RELIEVE study had produced disappointing results. With regard to safety, fourteen percent of the patients experienced a deep vein thrombosis (DVT) defined as a "major adverse event" under the study protocol. The Vari-Lase system was also less effective than VSI had hoped. The main purpose of an ablation procedure is to permanently close an incompetent vein, and the primary endpoint of the trial was success at closing veins. The percentage of perforators that were still closed after six months (the "closure rate") was 69.7%, whereas the study protocol had set the expected closure rate at 98%, roughly the same as the rate for superficial veins. The 69.7% figure was also lower than the reported 70-93% closure rate

achieved by RF Company's FDA cleared perforator device.

24. In October 2009, VSI ultimately informed its Board of Directors that "Clinical data for the Vari-Lase Perforator Vein indication was not adequate to support 510k clearance, so there will be no 510k submitted."

Sales of Vari-Lase Devices for Unapproved Use

25. VSI and HOWARD C. ROOT were aware that VSI had not received any form of FDA marketing authorization to sell Vari-Lase devices for use in treating perforator veins. Nevertheless, they distributed Short Kits and other Vari-Lase products for this unapproved intended use from 2007 through May 2014. HOWARD C. ROOT oversaw this conduct from beginning to end.

26. The July 2007 World Sales Meeting presentation prepared the sales force for the launch of the Short Kit, which VSI had designed especially for treating perforator veins. But by the time of the meeting, VSI had a problem. It had become clear that the FDA likely would not grant authorization to market the Short Kit for perforator use before the planned launch in September. The solution to this problem came from HOWARD C. ROOT, who decided to launch the Short Kit anyway and claim that it was for "short vein segments," a term with no specific meaning. The presentation explained that because the kit was not yet approved by FDA for perforator veins, the company "will only promote for short vein segments." Yet the presentation did not provide any information about short vein segments. By contrast, the presentation contained many slides about perforator veins, including customer demand for a perforator kit, perforator anatomy, perforator incompetence, reasons why doctors should use lasers to treat perforators, tips for treating them, and reimbursement guidance for doctors.

27. VSI refrained from officially defining the terms "short vein" or "short vein

segment." The January 2008 National Sales Meeting presentation, which was edited and approved by HOWARD C. ROOT, stated that although the Short Kit was not "specifically" approved for perforator veins, it was approved for "short vein segments," and there was "[n]o definition of 'short vein segment' – physician decides."

28. In fact, VSI's official design dossier for the Short Kit stated that the term "short vein segments" includes "perforator veins." Throughout VSI's marketing and training materials, the company taught the sales force that the term "short vein" included perforator veins by using those terms interchangeably.

29. At other times, however, VSI abandoned this pretense and simply told the sales force to market the Vari-Lase system for treating perforators. In the January 2008 National Sales Meeting presentation and in training materials from that year, VSI instructed the sales force to "target" doctors who had the experience necessary to treat perforators, or who were already using the competing RF device to treat perforators, when selling the Short Kit. HOWARD C. ROOT approved these materials.

30. VSI employees, under the direction and supervision of VSI management, including HOWARD C. ROOT, distributed adulterated and misbranded medical devices to doctors throughout the United States, including in the Western District of Texas. VSI employees and managers documented this effort in "Field Trip Reports" and emails received by HOWARD C. ROOT, who knew about these efforts and encouraged them.

The Sales Campaign Was Misleading

31. Apart from illegality, there were other obstacles to selling the Vari-Lase system for perforator use. First, VSI knew that, because of the lack of FDA marketing authorization, doctors who used the Vari-Lase system to treat perforators could not obtain reimbursement from

Medicare and many private insurers. Second, 14% of the patients in VSI's clinical trial had "major adverse events" involving DVTs. Third, the closure rate from that trial – 69.7% – was less than the expected rate of 98% and substantially less than the reported closure rate of the RF Company's device (70-93%), which had successfully obtained FDA marketing authorization. Had they known these material facts, many doctors would not have used the Vari-Lase system to treat perforators.

32. As set forth in greater detail below, VSI overcame these obstacles by misrepresenting and concealing the relevant facts. VSI repeatedly misinformed doctors that Medicare and private insurers would pay for laser perforator procedures. On at least two occasions, VSI sales representatives encouraged doctors to conceal that they had treated a perforator vein when billing so they could still get paid. VSI concealed the primary safety result from the RELIEVE trial from doctors because it did not want them to know that 14% of the patients in the trial developed DVTs that were considered "major adverse events" under the study protocol. VSI also instructed the sales force to tell doctors that the closure rate achieved by the trial was 91%, even though it knew that the actual rate was 69.7%.

THE CONSPIRACY

33. Beginning at least as early as May 2007 and continuing until March 2014, in the Western District of Texas and elsewhere, Defendants,

VSI and **HOWARD C. ROOT**

and others known and unknown to the Grand Jury, agreed to participate in a conspiracy with the following objects:

a. commit an offense against the United States by introducing into interstate commerce adulterated medical devices for which VSI had not received PMA approval, in

violation of Title 21, United States Code, Sections 331(a) and 351(f)(1)(B) ;

b. commit an offense against the United States by introducing into interstate commerce medical devices that were misbranded in the following ways: (i) VSI failed to provide the notice required by 21 U.S.C. § 360(k), in violation of 21 U.S.C. § 352(o); and (ii) their labeling lacked adequate directions for their intended use and the devices did not qualify for an exemption to this requirement, 21 U.S.C. § 352(f)(1); and

c. defraud the United States and its agencies by concealing their sale of medical devices for unapproved use on perforator veins in order to impair and defeat the lawful function of the FDA and other law enforcement agencies.

MANNER AND MEANS

It was part of the conspiracy that:

34. From approximately April 2007 to May 2014:

a. VSI and HOWARD C. ROOT, and others known and unknown to the Grand Jury, instructed and encouraged the sales force to sell Vari-Lase devices for unapproved perforator use.

b. Consistent with direction from VSI and HOWARD C. ROOT, the sales force called on doctors throughout the United States, including the Western District of Texas, in order to sell Vari-Lase devices for unapproved perforator use. In more than one hundred "Field Trip Reports" to VSI management, including HOWARD C. ROOT, sales representatives documented their efforts to sell Vari-Lase devices for treatment of perforators.

c. VSI employees, under the direction and supervision of VSI and HOWARD C. ROOT, distributed adulterated and misbranded medical devices to doctors throughout the United States.

d. VSI employees, under the direction and supervision of VSI and HOWARD C. ROOT, trained and assisted health care providers throughout the United States in treating perforator veins with Vari-Lase devices.

e. VSI employees misled health care providers by stating or suggesting that Medicare and other insurers would pay for laser perforator procedures. In fact, Medicare and numerous private insurers did not pay for laser perforator procedures because laser devices were not approved for this purpose by the FDA.

35. Members of the conspiracy used the terms "short vein segments" and "short veins" to hide their intent to sell Vari-Lase devices for perforator use:

a. VSI and HOWARD C. ROOT knew that the company could not sell Vari-Lase devices for intended use on perforator veins without some form of FDA marketing authorization. Without such authorization, VSI and HOWARD C. ROOT launched the Short Kit in late 2007 by claiming that this product was intended for "short vein segments" or "short veins." VSI and HOWARD C. ROOT taught the sales force that these terms included perforator veins and instructed the sales force to suggest to health care providers that Vari-Lase devices could be used to treat perforator veins.

b. Consistent with the guidance they had received from VSI and HOWARD C. ROOT, members of the sales force used the terms "short vein segments" and "short veins" to conceal from law enforcement, including the FDA, that they were selling Vari-Lase devices for unapproved perforator use.

OVERT ACTS

In furtherance of the conspiracy, VSI, HOWARD C. ROOT, and others known and unknown to the Grand Jury committed the following overt acts in the Western District of Texas

and elsewhere:

Selling Devices for Unapproved Use

36. From April 2007 or earlier until March 2014 or later, VSI and HOWARD C. ROOT caused hundreds of shipments throughout the United States of Vari-Lase devices intended for unapproved perforator use. These included the shipments to the Western District of Texas described in Counts Two through Nine below, each of which was an overt act.

37. As part of the January 2007 National Sales Meeting Presentation, VSI, HOWARD C. ROOT and others known and unknown to the Grand Jury encouraged the sales force to sell Vari-Lase devices for perforator use by criticizing RF Company's recently launched Perforator Kit as clumsy, difficult to use, and inferior to the Vari-Lase system in terms of clinical results and profit for doctors.

38. In April 2007, when Salesperson A visited a prominent vein doctor for his first use of VSI's new "bright tip" fiber on a superficial vein, he used the opportunity to market the fiber for perforator use. When the doctor expressed interest, A sent an email directly to HOWARD C. ROOT:

> Dr. [name omitted] was quite impressed with the product and is very excited to use it with perforator cases. One of the biggest obstacles with perforator cases is seeing where your fiber is in the vein. This product will alleviate that problem 10 fold.

HOWARD C. ROOT forwarded the email to the entire sales force with the message, "Thanks [A], and congratulations on the great result."

39. Another salesperson, B, saw A's initial email containing the language quoted above and forwarded it to a health care provider with the message, "This is a sample of what is going on out there in the field with the bright tip and perforators." Upon seeing his email, a Regional Sales Manager (Regional Sales Manager 1) sent him an email praising his perforator

marketing and copied HOWARD C. ROOT.

40. In May 2007, Salesperson B continued his effort to sell Vari-Lase devices for unapproved perforator use. In an email to the same health care provider on the subject of perforator treatment, he wrote, "We have several sites ... that are using 600 micron fibers (specifically our Bright Tip) with great success." B copied HOWARD C. ROOT and other members of VSI's senior management, including Vice President 1, who emailed information about laser perforator treatment to the health care provider in order to help B make the sale.

41. As part of the World Sales Meeting Presentation in July 2007, VSI, HOWARD C. ROOT, and others known and unknown to the Grand Jury encouraged the VSI sales force to sell Vari-Lase products for unapproved perforator use by (i) providing them with arguments for why lasers were better for treating perforators than the competing RF Perforator Kit; (ii) educating them on how to treat perforators during the discussion of VSI's new Short Kit; (iii) citing articles suggesting that lasers were effective at treating perforators; and (iv) instructing them on how doctors can get paid by insurance for treating perforators.

42. In the January 2008 National Sales Meeting Presentation, VSI, HOWARD C. ROOT and others known and unknown to the Grand Jury instructed the sales force to "target" doctors who had the experience necessary to treat perforators, or who were already using the competing RF Perforator Kit to treat perforators, when selling the Short Kit. The same presentation instructed salespeople to "[h]ave accounts purchase at least one 10 pack [of microintroducers] with Short Kit" so they could "[t]reat multiple perforators with one Short Kit."

43. a. On or about February 19, 2008, Salesperson A sent a presentation entitled "Tips for Treating Perforator Veins" to members of the sales force from his region. The document showed salespeople how to teach doctors to use the Vari-Lase system on perforator

veins, urged them to actively promote perforator use, and instructed them to "make sure" doctors were billing Medicare and other insurers for the procedure.

b. Later that day, Regional Sales Manager 2 re-sent the "Tips for Treating Perforator Veins" to sales people from his region and to a senior VSI manager as part of a set of "tools" for salespeople to "use out there in the field" in order to "duplicate success."

44. On or about March 12, 2008, the Regional Sales Manager 2 again sent the same "Tips for Treating Perforator Veins" to the members of his region as part of a set of "best practices."

45. On or about April 6, 2008, in follow up to a presentation he gave at a Regional sales meeting the previous week, Salesperson A sent another presentation entitled "Treating Perforator Veins" to the members of the Region. Like his earlier presentation, this document contained instructions for treating perforator veins and tips for selling Vari-Lase devices for that purpose. On the subject of reimbursement, the presentation falsely stated that Medicare paid for laser perforator procedures: "Blue Cross DOES NOT PAY for Perforators, but Medicare does."

46. In March 2008, Vice President 1 gave a training presentation to members of the sales force. His presentation encouraged sales representatives to sell a 10-pack of Vari-Lase Micro-Introducers with each Short Kit so that doctors could "[t]reat multiple perforators with one Short Kit." Like the presentation from the National Sales Meeting in January 2008, the March training presentation instructed salespeople to "target" doctors who had the experience necessary to treat perforators, or who were already using the competing RF Company's device to treat perforators, when selling the Short Kit.

47. In the July 2008 World Sales Meeting Presentation, VSI, HOWARD C. ROOT and others known and unknown to the Grand Jury overstated the effectiveness of the Short Kit in

an effort to increase sales for perforator use. The presentation stated that the completed RELIEVE trial had achieved a 91% closure rate for perforator veins. The actual rate from that trial was 69.7%.

48. In August 2008, Vice President 1 made the same false statement in an email to the sales force. He told them to make several "key points" when competing against RF Company, including that the RF Perforator Kit was "difficult to use on perforators," whereas VSI had "completed a successful clinical trial on using laser for perforators (91% closure) and [was] just waiting for FDA clearance to market the Short Kip [sic] for laser treatment of perforators." This false statement was intended to increase sales of Vari-Lase devices for unapproved perforator use.

49. At a November 2008 conference of vein doctors in Marco Island, Florida, the doctor who conducted the RELIEVE trial gave a presentation that had been written by a VSI consultant and approved by VSI management. With the goal of selling Vari-Lase devices for perforator use, the presentation claimed that the RELIEVE trial was a success. In order to make that claim, the presentation falsely stated that the primary safety objective of the trial was to measure the rate of "serious" adverse events. This enabled VSI to show that the trial had achieved its safety objective because the rate of serious adverse events was 0%. In fact, the actual primary safety objective of the trial was to measure the rate of "major" adverse events, and the rate of major adverse events involving DVT was 14%. VSI omitted this result from the presentation.

50. In a National Sales Meeting Presentation from January 2009, VSI , HOWARD C. ROOT and others known and unknown to the Grand Jury provided the sales force with "tips" for treating perforators and reasons why incompetent perforator veins should be treated.

51. In the July 2009 World Sales Meeting Presentation, VSI, HOWARD C. ROOT and others known and unknown to the Grand Jury encouraged the sales force to sell Vari-Lase devices for unapproved perforator use. In a slide on how to compete against another company's "perforator kits," VSI taught the sales force to emphasize that the Short Kit had better features.

52. In the same July 2009 World Sales Meeting Presentation, VSI, HOWARD C. ROOT and others known and unknown to the Grand Jury gave the sales force false information about reimbursement of laser perforator procedures for the purpose of obtaining sales of Vari-Lase devices. As one of the answers to the question "Why Treat Perforators?", the presentation stated that "[r]eimbursement is generally the same for treating a perforator as treating an incompetent GSV [greater saphenous vein] (>$1400)."

53. In an email to VSI management and HOWARD C. ROOT dated March 27, 2010, Regional Sales Manager 1 described Salesperson C's sustained effort to convince an RF Company customer to switch to the Short Kit for his perforator cases. As described in the email, C highlighted the benefits of the Short Kit for perforator treatment, touted the success that other doctors had using the kit for this purpose, and got the doctor to agree to try the kit on perforators. The manager praised C for this: "This was a great call by [C] and I believe the many, many months of calling on this group and being persistent and helpful in the right way will pay off for him once he does perf cases with them!!"

54. a. In approximately May 2010, in the Western District of Texas, Salesperson D sold a Vari-Lase console to an account in Austin, after visiting the account repeatedly during the preceding year to try to close the sale.

b. As part of this sales effort, D discussed laser perforator treatment with a doctor at the Austin account on or about November 3, 2009.

c. In December 2009, D gave the same doctor a "perforator article" that "[s]howed better long-term results for Laser" over a competing technique (sclerotherapy).

d. In January 2010, D talked to the same doctor "about where we are in the Vari-Lase sale process" and learned that RF Company had given him "their pitch." D responded by discussing the drawbacks of RF Company's "perforator system."

e. After the Austin account received the laser console from VSI, D visited the account repeatedly to train and assist the staff with laser perforator procedures. In his Field Trip Reports, D informed VSI management, including HOWARD C. ROOT, about these activities.

f. In December 2010, in San Antonio, Texas, D told a doctor that Vari-Lase devices could be used to treat perforator veins, during a sales call to discuss D's "Vari-Lase business plan" for the account.

55. a. In October 2010, Regional Sales Manager 3 and a salesperson visited an account and "uncovered potential business lost to [a competitor's] perf. Business," according to the manager's email to HOWARD C. ROOT and other VSI executives. Upon learning that the competitor's "perf kits" cost $479, the manager wrote in an email that "we discussed them [the account] getting our kits and us providing them a sliding scale discount matched with volume if we convert all their business to VSI."

b. Upon reading the email, a VSI Senior Vice President responded, "Great kit business opportunity with Dr. [name omitted]!"

c. The following month, the manager brought the account "our VSI Perforator Kit" (*i.e.* Short Kit) for a free trial. She quoted a price of $300 for additional Short Kits.

56. In October 2011, Salespersons B and C secretly shared information about how doctors could bill for unauthorized perforator procedures by concealing that they had treated a perforator vein. In response to B's question about whether C's customers were "able to bill for any Perf work," C responded, "Can't bill for perfs. Not approved." The email chain ends with B's reply, "Txt me what they call them then." C responded by calling him and telling him to use the term "short veins."

57. In March 2014, Salesperson E tried to sell a doctor Vari-Lase equipment for perforator use and described his sales efforts in his Field Trip Report to VSI management and HOWARD C. ROOT.

Concealing Illegal Activity from the United States

58. Aware that they could not openly sell Vari-Lase devices for unapproved perforator use without triggering law enforcement action, VSI and HOWARD C. ROOT instructed the sales force to promote the Short Kit for "short vein segments" or "short veins," then suggested that these terms included perforator veins in the following company documents:

a. The July 2007 World Sales Meeting Presentation explained that because the Short Kit was not yet approved for perforator veins, the company "will only promote for short vein segments." Yet the presentation did not define that term or provide any information about short vein segments. Instead, the presentation's discussion of the Short Kit focused exclusively on perforator veins.

b. Training materials from September 2007 taught salespeople, when asked, "Can I use this kit for the treatment of perforators?", to disclose that the use was unapproved but suggest that the doctor could choose to do so anyway:

> The Vari-Lase short kit is not indicated for the treatment of perforator veins at this time, but as a physician you may use a product as [you] think is appropriate.

Since the product is for short vein segments, I will leave it to you to decide how short you would like to work with.

c. The September 2007 Design Dossier for the Short Kit defines "short vein segments" as "including tributary and perforator veins."

d. The January 2008 National Sales Meeting Presentation stated that although the Short Kit was not "specifically" approved for perforator veins, it was approved for "short vein segments," and there was "[n]o definition of 'short vein segment' – physician decides." By misstating that doctors could define the terms of the Short Kit's approved use, VSI invited doctors to assume that the approved use could include perforator veins.

e. The September 2008 "Camp Vari-Lase" training presentation uses the terms "short vein segments" and "perforators" interchangeably.

f. The October 2008 marketing brochures for the Short Kit in the United States and Europe use the terms "short vein segment" and "perforator vein" interchangeably.

g. VSI developed instructions and warnings concerning perforator use for the labeling on its Vari-Lase devices, but after failing to obtain FDA approval for perforator use, VSI put similar warnings and instructions in its labeling and substituted the term "short vein segments" for the term "perforator veins."

59. HOWARD C. ROOT received copies of Salesperson A's perforator presentations in August 2009 from a former salesperson, who had enclosed the documents with a letter to ROOT accusing VSI of selling Vari-Lase devices for unapproved use. Aware that VSI had engaged in such conduct, HOWARD C. ROOT presided over a sham investigation that found no evidence of any illegal activity.

60. In June 2011, the United States served a subpoena on VSI. As a result of the

subpoena, VSI became aware that United States law enforcement agencies were investigating whether the company had sold Vari-Lase devices for unapproved use. When Salesperson A became aware of the subpoena in July, he deleted the perforator presentations he had written in early 2008 from his laptop. He did this in order to prevent law enforcement from finding out about his perforator sales efforts, which had continued in the years following the presentations and were ongoing at the time.

61. After learning about the investigation, members of the sales force stopped using the word "perforator" in their Field Trip Reports and used the phrase "short vein" instead. By doing so, VSI concealed from the United States that it was continuing to sell devices for unapproved perforator use.

a. In December 2011, Regional Sales Manager 1 and Salesperson F visited an account to assist with a perforator case. After the procedure, they solicited device orders for future perforator treatment. In an email to VSI management, including HOWARD C. ROOT, Regional Sales Manager 1 used the term "short vein segment" to conceal that the sales call was related to perforator veins.

b. In December 2011, Salesperson G assisted an account with a perforator case and sold the account a Short Kit for future perforator use. In his Field Trip Report describing this event to VSI management, including HOWARD C. ROOT, G used the term "short vein segment" to conceal his perforator sales activity.

c. In February 2012, G again assisted the same account with a perforator case. In his Field Trip Report describing this event to VSI management, including HOWARD C. ROOT, G used the term "short vein segment" to conceal his perforator sales activity.

d. In July 2013, he wrote about another visit in which one of his colleagues,

Salesperson C, assisted the same account with another perforator case. In his Field Trip Report describing this event to VSI management, including HOWARD C. ROOT, G used the term "short vein segment" to conceal his perforator sales activity.

62. In August 2012, Regional Sales Manager 4 misled a Special Agent with the FDA Office of Criminal Investigations during an interview. The manager falsely stated that he had repeatedly instructed Salesperson A not to promote the treatment of perforator veins. In fact, the manager was aware that A had promoted this use, but did not instruct A to stop. By making this false statement, the manager concealed the role of company management in the perforator sales activity.

63. In July 2013, in San Antonio, Texas, Salesperson C gave false and misleading testimony to the Grand Jury in order to conceal his and VSI's ongoing sales of devices for unapproved perforator use.

All in violation of Title 18, United States Code, Section 371.

COUNTS TWO THROUGH FIVE
[21 U.S.C. §§ 331(a), 351(f)(1)(B), and 333(a)(1) – Adulteration]

THE GRAND JURY FURTHER CHARGES THAT:

64. The allegations of paragraphs 1 through 63 of Count One are incorporated here.

65. On or about the dates listed below, in the Western District of Texas, Defendants

VSI and HOWARD C. ROOT

caused the introduction into interstate commerce of Vari-Lase medical devices, which were devices within the meaning of 21 U.S.C. § 321(h), and which were adulterated in that they

lacked required PMA approval to be marketed for their intended use, 21 U.S.C. § 351(f)(1)(B), as set out in each count below.

Count	Device	Ship To	Approximate Shipment Date
2	Vari-Lase Console	Austin, TX	May 18, 2010
3	Vari-Lase Short Kits	Austin, TX	August 30, 2010
4	Vari-Lase Short Kits	Austin, TX	January 31, 2011
5	Vari-Lase Short Kits	Austin, TX	October 21, 2011

All in violation of Title 21, United States Code, Sections 331(a), 351(f)(1)(B), and 333(a)(1).

COUNTS SIX THROUGH NINE
[21 U.S.C. §§ 331(a), 352(o), 352(f)(1), and 333(a)(1) – Misbranding]

THE GRAND JURY FURTHER CHARGES THAT:

66. The allegations of paragraphs 1 through 63 of Count One are incorporated here.

67. On or about the dates listed below, in the Western District of Texas, Defendants

VSI and HOWARD C. ROOT

caused the introduction into interstate commerce of Vari-Lase medical devices, which were devices within the meaning of 21 U.S.C. § 321(h), and which were misbranded in the following ways:

a. VSI failed to provide the notice required by 21 U.S.C. § 360(k), 21 U.S.C. § 352(o); and

b. their labeling lacked adequate directions for their intended use and it did

not qualify for an exemption to this requirement, 21 U.S.C. § 352(f)(1).

Count	Device	Ship To	Approximate Shipment Date
6	Vari-Lase Console	Austin, TX	May 18, 2010
7	Vari-Lase Short Kits	Austin, TX	August 30, 2010
8	Vari-Lase Short Kits	Austin, TX	January 31, 2011
9	Vari-Lase Short Kits	Austin, TX	October 21, 2011

All in violation of Title 21, United States Code, Sections 331(a), 352(o), 352(f)(1) and 333(a)(1).

A TRUE BILL

[redacted] OF THE GRAND JURY

ROBERT PITMAN
UNITED STATES ATTORNEY

BY: _____
BUD PAULISSEN
Assistant United States Attorney

_____
TIMOTHY T. FINLEY
Trial Attorney
United States Department of Justice
Consumer Protection Branch