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8 Counsel for Plaintiff

9 **UNITED STATES DISTRICT COURT**  
10 **CENTRAL DISTRICT OF CALIFORNIA**

11 INDIVIDUALLY AND ON BEHALF  
12 OF ALL OTHERS SIMILARLY  
13 SITUATED,

14 Plaintiff,

15 vs.

16 CARDIOVASCULAR SYSTEMS,  
17 INC., DAVID L. MARTIN, and  
18 LAURENCE L. BETTERLEY,  
19

20 Defendants.

Case No.:

CLASS ACTION COMPLAINT FOR  
VIOLATIONS OF THE FEDERAL  
SECURITIES LAWS

JURY TRIAL DEMANDED

21  
22 Plaintiff, individually and on behalf of all other persons similarly  
23 situated, by her undersigned attorneys, for her complaint against  
24 Defendants, alleges the following based upon personal knowledge as to herself and  
25 her own acts, and information and belief as to all other matters, based upon, *inter*  
26 *alia*, the investigation conducted by and through her attorneys, which included,  
27 among other things, a review of the defendants' public documents, conference calls  
28 and announcements made by defendants, United States Securities and Exchange

1 Commission (“SEC”) filings, wire and press releases published by and regarding  
2 Cardiovascular Systems, Inc. (“CSI” or the “Company”), analysts’ reports and  
3 advisories about the Company, the action brought on behalf of the United States of  
4 America and twenty-seven states (“Qui Tam States”) against CSI on July 15, 2013,  
5 and information readily obtainable on the Internet. Plaintiff believes that  
6 substantial evidentiary support will exist for the allegations set forth herein after a  
7 reasonable opportunity for discovery.

### 8 NATURE OF THE ACTION

9 1. This is a federal securities class action on behalf of a class consisting  
10 of all persons other than Defendants (defined below) who purchased or otherwise  
11 acquired CSI securities between September 12, 2011 and January 21, 2016, both  
12 dates inclusive (the “Class Period”). Plaintiff seeks to recover compensable  
13 damages caused by Defendants’ violations of the federal securities laws and to  
14 pursue remedies under Sections 10(b) and 20(a) of the Securities Exchange Act of  
15 1934 (the “Exchange Act”) and Rule 10b-5 promulgated thereunder, against the  
16 Company and certain of its officers and/or directors.

17 2. CSI is a medical technology company that develops, manufactures,  
18 and markets devices to treat vascular diseases, such as Peripheral Arterial Disease  
19 (“PAD”). The Company sells its products directly to hospitals, doctors, and office-  
20 based labs.

21 3. Throughout the Class Period, Defendants made materially false and  
22 misleading statements as well as failed to disclose material adverse facts about the  
23 Company’s business, operational, and financial performance. Specifically,  
24 Defendants made false and/or misleading statements and/or failed to disclose that:  
25 (1) CSI distributed illegal kickbacks to health care providers; (2) CSI engaged in  
26 the off-label promotion of its medical devices; and (3) CSI violated the Food and  
27 Drug Administration’s (the “FDA”) laws and regulations in connection with its  
28

1 medical devices. As a result of the foregoing, the Company’s public statements  
2 were materially false and misleading at all relevant times.

3 4. On July 15, 2013, an action styled *Thams v. Cardiovascular Systems,*  
4 *Inc.*, Docket No. 3:13-cv-00404 (W.D.N.C Jul 16, 2013) (the “*Qui Tam* Action”)   
5 was brought by a former CSI sales manager pursuant to the *qui tam* provisions of   
6 the Federal Civil False Claims Act, 31 U.S.C. § 3729, *et seq.* and pursuant to the   
7 *qui tam* provisions of twenty-seven States.<sup>1</sup> The *Qui Tam* Action is incorporated by   
8 reference herein and is attached hereto as Exhibit A.

9 5. According to the *Qui Tam* Action, CSI engaged in a fraudulent  
10 marketing scheme to maximize its profits through an ongoing pattern of fraud and  
11 deception involving illegal kickbacks, off-label promotion, and violations of FDA  
12 laws and regulations in connection with its medical devices used for the treatment  
13 of PAD. Those devices include CSI’s Diamondback 360 device, Predator 360  
14 device, and Stealth 360 device (collectively, the “PAD devices”). CSI markets the  
15 PAD devices as treatments for PAD.

16 6. According to the *Qui Tam* Action, CSI engaged in a broad, unlawful  
17 scheme to increase the sales of its PAD devices in order to obtain a more favorable  
18 valuation of its stock to attract new investors. In order to effectuate this fraudulent  
19 scheme, beginning at least as early as 2010, CSI engaged in a deliberate pattern of  
20 fraud and violating FDA laws and regulations.

21 7. CSI executed its scheme primarily through unlawful kickbacks and  
22 utilizing its sales force to illegally promote off-label<sup>2</sup> sales and the use of its  
23 medical devices in order to obtain reimbursement for non-FDA-approved  
24  
25

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26  
27 <sup>1</sup> The *Qui Tam* Action was under seal until July 8, 2015.

28 <sup>2</sup> If the drug usage is officially indicated they are “FDA approved” (also called  
‘labeled’) and if it is prescribed or taken outstanding to its applied indications the  
term “Non-approved” (or ‘off-label’) is used.

1 indications<sup>3</sup>.

2 8. According to the *Qui Tam* Action, CSI's kickback scheme was  
3 designed to, and ultimately did, influence doctors and other medical personnel to  
4 use CSI's medical devices. The kickbacks included: (1) "free" all-expense-paid  
5 training programs followed by explicit demands by CSI employees that attendees  
6 use CSI products on future patients; (2) using reimbursement calculators while  
7 selling PAD devices in order to show physicians how they could maximize their  
8 financial return by using CSI devices, including for unnecessary procedures; (3)  
9 giving "free" product to induce the purchase of other product; (4) using referral  
10 channel marketing, through which CSI would reward physicians who used or  
11 purchased CSI devices by referring patients to those physicians; (5) giving  
12 substantial financial assistance to help physicians open outpatient cardiac  
13 catheterization labs ("OBLs"); and (6) giving sham Speaker Bureau payments for  
14 high-prescribers and others whom CSI sought to cultivate. CSI's *quid pro quo*  
15 kickback strategy was intended to and did induce physicians to use and obtain  
16 reimbursement for use of CSI medical devices on patients covered by Medicare,  
17 Medicaid, and other government payors.

18  
19 9. According to the *Qui Tam* Action, CSI's off-label marketing ("OLM")  
20 scheme was designed to and did influence doctors and other medical personnel to  
21 use CSI's medical devices for procedures that were not medically necessary or  
22 medically reasonable. The OLM included: promotion of CSI's PAD devices for  
23 use with a smaller catheter – 4-French – the approval was limited to the larger 6-  
24 French catheter; and promotion for use in the areas of the body (e.g., coronaries  
25

26 \_\_\_\_\_  
27 <sup>3</sup> In medicine, an indication is a valid reason to use a certain test, medication,  
28 procedure, or surgery. Indications for medications are regulated by the FDA, and  
are included in the package insert under the phrase "Indications and Usage".

1 and the arms) and disease states (e.g., chronic total occlusions) for which the  
2 devices lacked FDA-approval. CSI's OLM strategy was intended to and did induce  
3 physicians to sue and obtain reimbursement for use of CSI medical devices on  
4 patients covered by Medicare, Medicaid, and other government payors.

5 10. CSI's unlawful kickbacks and off-label promotion involved the  
6 unlawful making of false records or statements and/or causing false claims to be  
7 submitted for the purpose of obtaining payment or reimbursement for false or  
8 fraudulent claims in violation of the Federal Civil False Claims Act, 31 U.S.C. §  
9 3729, *et seq.* (the "False Claims Act") and state analogs of the False Claims Act.

10 11. Indeed, on May 9, 2014, CSI received a letter from the U.S.  
11 Attorney's Office for the Western District of North Carolina stating that it is  
12 investigating the Company to determine whether the Company has violated the  
13 False Claims Act, *resulting in the submission of false claims to federal and state*  
14 *health care programs, including Medicare and Medicaid.*

15 12. On this news, shares of CSI fell \$1.62 per share or approximately 6%  
16 from its previous closing price to close at \$27.43 per share on May 12, 2014.

### 17 JURISDICTION AND VENUE

18 13. The claims asserted herein arise under §§10(b) and 20(a) of the  
19 Exchange Act (15 U.S.C. §§78j(b) and 78t(a)) and Rule 10b-5 promulgated  
20 thereunder by the SEC (17 C.F.R. §240.10b-5).

21 14. This Court has jurisdiction over the subject matter of this action under  
22 28 U.S.C. §1331 and §27 of the Exchange Act.

23 15. Venue is proper in this District pursuant to §27 of the Exchange Act  
24 (15 U.S.C. §78aa) and 28 U.S.C. §1391(b) as a significant portion of the  
25 Defendants' actions, and the subsequent damages, took place within this District.  
26 Additionally, CSI has an office in this District.

27 16. In connection with the acts, conduct and other wrongs alleged in this  
28

1 Complaint, Defendants, directly or indirectly, used the means and instrumentalities  
2 of interstate commerce, including but not limited to, the United States mail,  
3 interstate telephone communications and the facilities of the national securities  
4 exchange.

5  
6 **PARTIES**

7 17. Plaintiff as set forth in the accompanying Certification, which  
8 is incorporated by reference herein, purchased CSI securities at artificially  
9 inflated prices during the Class Period and was damaged upon the revelation of  
10 the alleged corrective disclosures.

11 18. Defendant CSI is a medical technology company that develops,  
12 manufactures, and markets devices to treat vascular diseases in the United States of  
13 America. The Company is incorporated in Delaware with an office in California in  
14 this District. CSI's common stock trades on the NASDAQ under the ticker symbol  
15 "CSII".

16 19. Defendant David L. Martin ("Martin") has been the President and  
17 Chief Executive Officer of CSI since February 2007, and a director since August  
18 2006.

19 20. Defendant Laurence L. Betterley has been the Chief Financial Officer  
20 of CSI since April 2008.

21 21. The Defendants Martin and Betterley are sometimes referred to herein  
22 as the "Individual Defendants."

23 22. Defendant CSI and the Individual Defendants are referred to herein,  
24 collectively, as the "Defendants."

25 **SUBSTANTIVE ALLEGATIONS**

26 **BACKGROUND OF REGULATORY FRAMEWORK**

27 23. The Anti-Kickback Statute ("AKS") prohibits the payment and  
28 receipt of kickbacks in return for either procuring or recommending the

1 procurement of a good, facility, or item to be paid in whole or in part by a federal  
2 healthcare program. 42 U.S.C. § 1320a-7b(b).

3 24. Compliance with the AKS is a condition of receiving payment from  
4 federally-funded healthcare programs, including Medicare, Medicaid, and  
5 TRICARE.

6 25. For example, in order to establish eligibility to receive reimbursement  
7 from Medicare, both hospitals and physicians must sign a Provider Agreement that  
8 states: “I understand that payment of a claim by Medicare is conditioned upon the  
9 claim and the underlying transaction complying with such laws, regulations, and  
10 program instructions (including, but not limited to, the Federal anti-kickback  
11 statute and the Stark law), and on the [provider’s] compliance with all applicable  
12 conditions of participation in Medicare.” Hospitals must also submit a Hospital  
13 Cost Report along with their claims for reimbursement that states: “if services  
14 identified in this report [were] provided or procured through the payment directly  
15 or indirectly of a kickback or where otherwise illegal, criminal, civil and  
16 administrative action, fines and/or imprisonment may result,” and “certify that I am  
17 familiar with the laws and regulations regarding the provisions of health care  
18 services, and that the services identified in this cost report were provided in  
19 compliance with such laws and regulations.” Physicians and hospitals that used  
20 CSI PAD devices and sought reimbursement for those products and procedures  
21 from government-funded health care programs signed and/or certified compliance  
22 with these Provider Agreements and/or Hospital Cost Reports.

23 26. A “claim that includes items or services resulting from a violation of”  
24 the AKS “constitutes a false or fraudulent claim for purposes of” the FCA. 42  
25 U.S.C. § 1320a-7b(g).

26 27. Compliance *vel non* with the AKS is a material requirement that  
27 determines whether federally-funded healthcare programs, like Medicare,  
28

1 Medicaid, and TRICARE, will reimburse claims. Essentially, the presence of  
2 kickbacks will influence federally-funded healthcare programs' decisions as to  
3 whether to pay hospital and physician claims.

4 28. The Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. §  
5 301 *et seq.*, regulates the approval and marketing of medical devices.

6 29. No medical device may be marketed in the United States without prior  
7 approval by the FDA for its intended use. 21 U.S.C. § 360.

8 30. The FDCA creates three categories of devices that are subject to  
9 increasing levels of regulatory oversight: Class I (low risk, general controls), Class  
10 II (medium-risk, special controls), and Class III (high-risk, premarket approval). 21  
11 U.S.C. § 360(a)(1).

12 31. A Class II device – like each of CSI's PAD systems – is a "device  
13 which cannot be classified as a class I device because the general controls by  
14 themselves are insufficient to provide reasonable assurance of the safety and  
15 effectiveness of the device, and for which there is sufficient information to  
16 establish special controls to provide such assurance, including the promulgation of  
17 performance standards, postmarket surveillance, patient registries, development  
18 and dissemination of guidelines (including guidelines for the submission of clinical  
19 data in premarket notification submissions in accordance with section 510(k) [21  
20 U.S.C. § 360(k)], recommendations, and other appropriate actions as the Secretary  
21 deems necessary to provide such assurance. For a device that is purported or  
22 represented to be for a use in supporting or sustaining human life, the Secretary  
23 shall examine and identify the special controls, if any, that are necessary to provide  
24 adequate assurance of safety and effectiveness and describe how such controls  
25 provide such assurance." 21 U.S.C. § 360c(a)(1)(B).

26 32. A medical device is approved only for its specific "intended uses" or  
27 "the objective intent of the persons legally responsible for the labeling of the  
28



1 devices.” 21 C.F.R. § 801.4.

2 33. To avoid the costly and time-consuming FDA premarket-approval  
3 process, manufacturers of medical devices can seek “510(k)” clearance based upon  
4 prior approval of a substantially equivalent device. 21 U.S.C. § 360(k); 21 C.F.R. §  
5 807.87(k).

6 34. To obtain 510(k) clearance to market a device, the manufacturer must  
7 submit a premarket notification, including a certified “statement that the submitter  
8 believes, to the best of his or her knowledge, that all data and information  
9 submitted in the premarket notification are truthful and accurate and that no  
10 material fact has been omitted.” 21 C.F.R. § 807.87(k). The notification must  
11 include the intended uses of the device, the conditions the device is designed to  
12 treat, and the relevant patient population. 21 C.F.R. § 807.92(a)(5).

13 35. Clearance through the 510(k) process does not constitute FDA  
14 “approval” of the device; it limits the cleared use of the device to those indications  
15 listed in the 510(k) application as the intended uses. 21 U.S.C. § 352(f); 21 C.F.R.  
16 § 801.5; 21 C.F.R. § 807.97. These limited indications must be listed on the label,  
17 and a manufacturer may only promote a device for cleared or approved indications.  
18 21 U.S.C. § 352(f); 21 C.F.R. § 807.81(a)(3).

19 36. Any promotion of a device for any indication not approved or cleared  
20 by the FDA and indicated on the label is considered an “off-label” promotion and  
21 is unlawful. *See* 21 U.S.C. § 331(d).

22 37. The Medicare Act only excludes coverage for “any expenses incurred  
23 for items or services [which] are not reasonable and necessary for the diagnosis or  
24 treatment of illness or injury or to improve the functioning of a malformed body  
25 member[.]” 42 U.S.C. § 1395y(a)(1)(A).

26 38. TRICARE has similar restrictions on reimbursement for off-label use.  
27 *See* 32 C.F.R. § 199.4(a)(1)(i) & 2007 TRICARE Policy Manual, ch. 8, §  
28

1 5.1(III)(B) (excluding coverage for “off-label uses of devices”).

2 39. CSI’s PAD devices are considered medium-risk, Class II devices.  
3 These devices were cleared by the FDA for entry into the market through the less-  
4 costly and less-comprehensive 510(k) process.

5 40. In August 2007, the FDA granted CSI 510(k) clearance for the use of  
6 the Diamondback 360 as a therapy in patients with PAD. CSI was granted 510(k)  
7 clearance of the Predator 360 in March 2009 and the Stealth 360 in March 2011.

8 **MATERIALLY FALSE AND MISLEADING STATEMENTS ISSUED**  
9 **DURING THE CLASS PERIOD**

10 41. On September 12, 2011, the Company filed a Form 10-K for the fiscal  
11 year ended June 30, 2011 (the “2011 10-K”) with the SEC, which provided the  
12 Company’s year-end financial results and position and stated that the Company’s  
13 internal control over financial reporting was effective as of June 30, 2011. The  
14 2011 10-K was signed by Defendants Martin and Betterley. The 2011 10-K also  
15 contained signed certifications required pursuant to the Sarbanes-Oxley Act of  
16 2002 (“SOX”) by Defendants Martin and Betterley, who both certified that:

- 17 1. I have reviewed this annual report on Form 10-K of  
18 Cardiovascular Systems, Inc.;
- 19 2. Based on my knowledge, this report does not contain any  
20 untrue statement of a material fact or omit to state a material  
21 fact necessary to make the statements made, in light of the  
22 circumstances under which such statements were made, not  
23 misleading with respect to the period covered by this report;
- 24 3. Based on my knowledge, the financial statements, and other  
25 financial information included in this report, fairly present in all  
26 material respects the financial condition, results of operations  
27 and cash flows of the registrant as of, and for, the periods  
28 presented in this report;

42. Attached to the 2011 10-K as Exhibit 14.1 was the Company’s

1 “CODE OF ETHICS AND BUSINESS CONDUCT”, which stated in part:

2 Bribery, kickbacks or other improper or illegal payments have no  
3 place in CSI’s business.

4 [P. 5].

5 \* \* \*

6  
7 **Business Courtesies and Gratuities**

8 **CSI’s policy is not to offer or accept kickbacks or bribes, or gifts**  
9 **of substantial value.**

10 CSI Representatives may only exchange non-monetary and modestly-  
11 valued gifts that promote goodwill with our business partners and do  
12 not improperly influence others. We will accept only approved and  
13 widely available discounts and do not encourage, accept or exchange  
14 gratuities or payments for providing services to others.

15 Business courtesies such as meals, transportation and entertainment  
16 provided to a vendor, supplier, customer or other business  
17 associations must be modest in amount and related to a legitimate  
18 business purpose (e.g., explanation or demonstration of CSI products,  
19 application of products, service capabilities, or training). Such  
20 courtesies must not violate the law, regulations, or reasonable customs  
21 of the market-place. If you have any question about whether any  
22 business courtesies, gratuities or gifts are appropriate, please contact  
23 your supervisor or other CSI management. **CSI’s SOP for guidance  
24 when having interactions with Health Care Professionals or  
25 customers because there is a general prohibition on most gifts to  
26 Health Care Professionals and customer.**

27 **CSI’s Representatives having relationship with Customers and  
28 Health Care Professionals have a separate SOP for guidance as  
these relationships are highly regulated**

Representatives must deal fairly and honestly with the Company’s  
customers (including potential customers and Health Care  
Professionals or entities in a position to recommend or influence the  
purchase or use of Company products) and not take actions that are

1 prohibited by applicable law or ethical standards. The Company  
2 intends to follow its own company-established “CSI’s Standard  
3 Operating Procedures For Interactions With Health Care  
4 Professionals” (“SOP”) which are largely based upon the standards set  
5 forth by AdvaMed in its Code of Ethics on Interactions with Health  
6 Care Professionals - Revised and Restated Code of Ethics effective  
7 July 1, 2009 which is found at <http://www.advamed.org>. All  
8 Representatives who deal with customers and Health Care  
9 Professionals are separately required to read and understand the SOP  
10 and sign an acknowledgement related thereto.

11 The SOP is intended to provide Representatives guidance about  
12 appropriate interactions with customers and Health Care Professionals  
13 when conducting business within the United States to enable the  
14 Company to remain in compliance with the Federal Anti-kickback  
15 Statute and Stark Law. Representatives conducting business on behalf  
16 of CSI, must also comply with this SOP and these policies apply to  
17 any expenditure by CSI Representatives, regardless of whether the  
18 expenditure is reimbursed by the Company. In other words, any  
19 “personal” money given to or spent for the benefit of a CSI customer  
20 is considered money given or spent by the Company.

21 As used in this Code, and the Guidelines, the term “customer” means  
22 any individual or organization that purchases, recommends, uses, or  
23 prescribes products manufactured or distributed by CSI or an  
24 individual who is in a position to determine whether a CSI product is  
25 purchased, recommended, used, or prescribed. This can include  
26 physicians, nurses, office administrators, purchasing agents, within  
27 hospitals, clinical practices, HMOs, GPOs, etc.

28 The following general standards and principles should at all times  
guide our interactions with customers and Health Care Professionals:

- CSI will encourage ethical business practices and socially responsible industry conduct, and will not use any unlawful inducement in order to sell, recommend or arrange the sale, or prescription of its products.

- 1           •           At CSI, we believe that enduring customer  
2 relationships are based on integrity and trust. We  
3 seek to gain advantage over competitors through  
4 superior products, research, engineering,  
5 manufacturing, marketing and service, never  
6 through improper business practices.
- 7           •           CSI's relationships with customers are intended to  
8 benefit patient care and enhance the practice of  
9 medicine. Interactions should be focused on  
10 informing customers and prospective customers  
11 about products, providing scientific and educational  
12 information, and supporting medical research and  
13 education and should not, at any time, entice  
14 representatives of customers to place their own  
15 personal interests above those of the organizations  
16 they represent or the patients who will use or need  
17 the Company's products.
- 18          •           CSI will not, directly or indirectly, offer or solicit  
19 any kind of payments or contributions for the  
20 purpose of obtaining, giving, keeping or rewarding  
21 business.

22           **No Payments in exchange for business**

23           Representatives may not make payments to customers or provide  
24 meals, travel expenses, entertainment, gifts, or other benefits to  
25 customers or Health Care Professionals in exchange for the  
26 customer's agreement to purchase products or services from the  
27 Company, or as a reward for the purchase of products or services, nor  
28 may Representatives provide benefits to a customer's friends,

1 relatives, or organizations closely affiliated with the customer in  
2 exchange for or as a reward for such business. See **CSI's SOP for**  
3 **guidance when having interactions with Health Care**  
4 **Professionals or customers because any and all entertainment and**  
5 **recreation with Health Care Professionals or customers is**  
6 **prohibited and there is a general prohibition on most gifts.**

7  
8 [P. 7-8].

9 43. On September 10, 2012, the Company filed a Form 10-K for the fiscal  
10 year ended June 30, 2012 (the "2012 10-K") with the SEC, which provided the  
11 Company's year-end financial results and position and stated that the Company's  
12 internal control over financial reporting was effective as of June 30, 2012. The  
13 2012 10-K was signed by Defendants Martin and Betterley. The 2012 10-K  
14 contained signed SOX certifications by Defendants Martin and Betterley,  
15 substantially similar to the certifications contained in ¶41, *supra*.

16 44. On September 11, 2013, the Company filed a Form 10-K for the fiscal  
17 year ended June 30, 2013 (the "2013 10-K") with the SEC, which provided the  
18 Company's year-end financial results and position and stated that the Company's  
19 internal control over financial reporting was effective as of June 30, 2013. The  
20 2013 10-K was signed by Defendants Martin and Betterley. The 2013 10-K  
21 contained signed SOX certifications by Defendants Martin and Betterley,  
22 substantially similar to the certifications contained in ¶41, *supra*.

23 45. The 2013 10-K stated that:

24  
25 In providing billing and coding information to customers, *we make*  
26 *every effort to ensure that the billing and coding information*  
27 *furnished is accurate and that treating physicians understand that*  
28 *they are responsible for all treatment decisions.*

46. On August 28, 2014, the Company filed a Form 10-K for the fiscal

1 year ended June 30, 2014 (the “2014 10-K”) with the SEC, which provided the  
2 Company’s year-end financial results and position and stated that the Company’s  
3 internal control over financial reporting was effective as of June 30, 2014. The  
4 2014 10-K was signed by Defendants Martin and Betterley. The 2014 10-K  
5 contained signed SOX certifications by Defendants Martin and Betterley,  
6 substantially similar to the certifications contained in ¶41, *supra*.

7 47. The 2014 10-K stated that:

8 In providing billing and coding information to customers, *we make*  
9 *every effort to ensure that the billing and coding information*  
10 *furnished is accurate and that treating physicians understand that*  
11 *they are responsible for all treatment decisions.*

12 48. On August 27, 2015, the Company filed a Form 10-K for the fiscal  
13 year ended June 30, 2015 (the “2015 10-K”) with the SEC, which provided the  
14 Company’s year-end financial results and position and stated that the Company’s  
15 internal control over financial reporting was effective as of June 30, 2015. The  
16 2015 10-K was signed by Defendants Martin and Betterley. The 2015 10-K  
17 contained signed SOX certifications by Defendants Martin and Betterley,  
18 substantially similar to the certifications contained in ¶41, *supra*.

19 49. The 2015 10-K stated that:

20 In providing billing and coding information to customers, *we make*  
21 *every effort to ensure that the billing and coding information*  
22 *furnished is accurate and that treating physicians understand that*  
23 *they are responsible for all treatment decisions.*

24 50. The statements referenced in ¶41-49 above were materially false  
25 and/or misleading because they misrepresented and failed to disclose the following  
26 adverse facts pertaining to the Company’s business, products, and directors’  
27 backgrounds, which were known to Defendants or recklessly disregarded by them.  
28 Specifically, Defendants made false and/or misleading statements and/or failed to

1 disclose that: (1) CSI distributed illegal kickbacks to health care providers; (2) CSI  
2 engaged in the off-label promotion of its medical devices; and (3) CSI violated  
3 FDA laws and regulations in connection with its medical devices. As a result of the  
4 foregoing, the Company's public statements were materially false and misleading  
5 at all relevant times.

### 6 TRUTH EMERGES

7 51. On May 9, 2014, during aftermarket hours, CSI filed an 8-K stating  
8 that it received a letter from the U.S. Attorney's Office for the Western District of  
9 North Carolina stating that it is investigating the Company to determine whether  
10 the Company has violated the False Claims Act, *resulting in the submission of*  
11 *false claims to federal and state health care programs, including Medicare and*  
12 *Medicaid.*

13 52. On this news, shares of CSI fell \$1.62 per share or approximately 6%  
14 from its previous closing price to close at \$27.43 per share on May 12, 2014.

15 53. On August 5, 2015, CSI held an investor conference call to discuss  
16 CSI's Q4 2015 Results and to announce that it is reforming its sales force, and in  
17 an exchange with investors, Defendant Martin stated in part:  
18

19 **As you're aware we're in the process of expanding our sales force**  
20 **while developing a dual franchise sales organization two big**  
21 **things.** An 18 month plan that began at the beginning of fiscal 2015,  
22 once complete we believe this evolution of our organizational position  
23 CSI to drive the adoption of our platform technology and marry those  
24 two valuable things high growth and sustainable profit. At the end of  
25 calendar 2015 our clinically focused sales organization of 250  
26 professionals will have the advantage of selling two high growth, high  
27 margin franchises in small span of controlled territories. The small  
28



1 span of control will allow us to be service intensive and relationship  
2 strong in every major domestic market.

3  
4 54. The decision to reform CSI's sale force was due in part to the  
5 Company's receipt of the letter from the U.S. Attorney's Office for the Western  
6 District of North Carolina stating that it is investigating the Company to determine  
7 whether the Company has violated the False Claims Act.

8 55. On October 7, 2015, CSI disclosed during aftermarket hours that it  
9 expects revenue from its 2016 fiscal first quarter to be approximately \$43.9  
10 million, well below its previously issued guidance of \$48.5 million to \$50.0  
11 million, and expects a net loss between \$13.1 million to \$13.9 million, or \$0.41 to  
12 \$0.43 per common share due to the continued effects of the sales force transition.  
13 The Company reported disappointing financial results due to the continued  
14 reformation of its sales force, which was a materialization of the Company's  
15 receipt of the letter from the U.S. Attorney's Office for the Western District of  
16 North Carolina stating that it is investigating the Company to determine whether  
17 the Company has violated the False Claims Act.

18 56. With respect to these results, Defendant Martin stated:

19 David L. Martin, CSI's President and Chief Executive Officer, said,  
20 "We continued to make progress on our sales optimization strategy to  
21 significantly expand our sales organization, while cross training  
22 representatives to sell both peripheral and coronary applications.  
23 However, as our recent results suggest, some aspects of the transition  
24 have been challenging. After a thorough review, we believe we have  
25 taken the right steps to address the immediate challenges and continue  
26 to expect the vast majority of the optimization effort to be completed  
27 by the third quarter of this fiscal year."

28 57. On this news, shares of CSI fell \$3.01 per share or approximately 18%  
from its previous closing price to close at \$13.62 per share on October 8, 2015 on  
volume of over 7 million shares.

1           58. On January 21, 2016, CSI disclosed during aftermarket hours that it  
2 expects revenue from its 2016 fiscal second quarter to be \$41.4 million, a 4%  
3 decrease from the second quarter of fiscal 2015, and 3% below the guidance range  
4 due to the continued effects of the sales force transition. Similarly, like the October  
5 7, 2015 financial results, the Company reported disappointing financial results due  
6 to the continued reformation of its sales force, which was a materialization of the  
7 Company's receipt of the letter from the U.S. Attorney's Office for the Western  
8 District of North Carolina stating that it is investigating the Company to determine  
9 whether the Company has violated the False Claims Act.

10           59. With respect to these results, Scott Ward, CSI's Chairman and Interim  
11 President and Chief Executive Officer stated:

12           Scott Ward, CSI's Chairman and Interim President and Chief Executive  
13 Officer, said, "CSI's sales force expansion and implementation of a dual  
14 franchise model, selling both coronary and peripheral applications, has been  
15 challenging and is affecting our near term sales performance. We have  
16 gained meaningful insights during the transition and we are encouraged by  
17 recent progress. The sales organization continues to gain valuable  
18 experience and we have begun to adjust our sales model at the local level,  
19 adopting a more flexible approach where warranted. We remain confident  
20 that our sales strategy will lead to sustainable revenue growth and a pathway  
21 to profitability in the future."

22           60. On this news, shares of CSI fell \$3.72 per share or approximately 30%  
23 from its previous closing price to close at \$8.74 per share on January 22, 2016 on  
24 volume of over 6 million shares.

### 25           **PLAINTIFF'S CLASS ACTION ALLEGATIONS**

26           61. Plaintiff brings this action as a class action pursuant to Federal Rule of  
27 Civil Procedure 23(a) and (b)(3) on behalf of a Class, consisting of all those who  
28 purchased or otherwise acquired CSI securities traded on NASDAQ during the  
Class Period (the "Class"); and were damaged upon the revelation of the alleged  
corrective disclosures. Excluded from the Class are Defendants herein, the officers

1 and directors of the Company, at all relevant times, members of their immediate  
2 families and their legal representatives, heirs, successors or assigns and any entity  
3 in which Defendants have or had a controlling interest.

4 62. The members of the Class are so numerous that joinder of all  
5 members is impracticable. Throughout the Class Period, CSI securities were  
6 actively traded on NASDAQ. While the exact number of Class members is  
7 unknown to Plaintiff at this time and can be ascertained only through appropriate  
8 discovery, Plaintiff believes that there are hundreds or thousands of members in the  
9 proposed Class. Record owners and other members of the Class may be identified  
10 from records maintained by CSI or its transfer agent and may be notified of the  
11 pendency of this action by mail, using the form of notice similar to that  
12 customarily used in securities class actions.

13 63. Plaintiff's claims are typical of the claims of the members of the Class  
14 as all members of the Class are similarly affected by Defendants' wrongful  
15 conduct in violation of the federal law that is complained of herein.

16 64. Plaintiff will fairly and adequately protect the interests of the  
17 members of the Class and has retained counsel competent and experienced in class  
18 and securities litigation. Plaintiff has no interests antagonistic to or in conflict with  
19 those of the Class.  
20

21 65. Common questions of law and fact exist as to all members of the  
22 Class and predominate over any questions solely affecting individual members of  
23 the Class. Among the questions of law and fact common to the Class are:

- 24 • whether the federal securities laws were violated by Defendants' acts  
25 as alleged herein;
- 26 • whether statements made by Defendants to the investing public during  
27 the Class Period misrepresented material facts about the business,  
28 operations and management of CSI;

- 1 • whether the Individual Defendants caused CSI to issue false and
- 2 misleading public statements during the Class Period;
- 3 • whether Defendants acted knowingly or recklessly in issuing false and
- 4 misleading public statements;
- 5 • whether the prices of CSI securities during the Class Period were
- 6 artificially inflated because of the Defendants' conduct complained of
- 7 herein; and,
- 8 • whether the members of the Class have sustained damages and, if so,
- 9 what is the proper measure of damages.

10 66. A class action is superior to all other available methods for the fair  
11 and efficient adjudication of this controversy since joinder of all members is  
12 impracticable. Furthermore, as the damages suffered by individual Class members  
13 may be relatively small, the expense and burden of individual litigation make it  
14 impossible for members of the Class to individually redress the wrongs done to  
15 them. There will be no difficulty in the management of this action as a class action.

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

- 18 • Defendants made public misrepresentations or failed to disclose
- 19 material facts during the Class Period;
- 20 • the omissions and misrepresentations were material;
- 21 • CSI securities are traded in efficient markets;
- 22 • the Company's shares were liquid and traded with moderate to heavy
- 23 volume during the Class Period;
- 24 • the Company traded on NASDAQ, and was covered by multiple
- 25 analysts;
- 26 • the misrepresentations and omissions alleged would tend to induce a
- 27 reasonable investor to misjudge the value of the Company's
- 28 securities; and

- 1 • Plaintiff and members of the Class purchased and/or sold CSI  
2 securities between the time the Defendants failed to disclose or  
3 misrepresented material facts and the time the true facts were  
4 disclosed, without knowledge of the omitted or misrepresented facts.

5 68. Based upon the foregoing, Plaintiff and the members of the Class are  
6 entitled to a presumption of reliance upon the integrity of the market.

7 69. Alternatively, Plaintiff and the members of the Class are entitled to  
8 the presumption of reliance established by the Supreme Court in *Affiliated Ute*  
9 *Citizens of the State of Utah v. United States*, 406 U.S. 128, 92 S. Ct. 2430 (1972),  
10 as Defendants omitted material information in their Class Period statements in  
11 violation of a duty to disclose such information, as detailed above.

12 **COUNT I**

13 **Violation of Section 10(b) of The Exchange Act and Rule 10b-5**

14 **Against All Defendants**

15 70. Plaintiff repeats and realleges each and every allegation contained  
16 above as if fully set forth herein.

17 71. This Count is asserted against Defendants and is based upon Section  
18 10(b) of the Exchange Act, 15 U.S.C. § 78j(b), and Rule 10b-5 promulgated  
19 thereunder by the SEC.

20 72. During the Class Period, Defendants engaged in a plan, scheme,  
21 conspiracy and course of conduct, pursuant to which they knowingly or recklessly  
22 engaged in acts, transactions, practices and courses of business which operated as a  
23 fraud and deceit upon Plaintiff and the other members of the Class; made various  
24 untrue statements of material facts and omitted to state material facts necessary in  
25 order to make the statements made, in light of the circumstances under which they  
26 were made, not misleading; and employed devices, schemes and artifices to  
27  
28

1 defraud in connection with the purchase and sale of securities. Such scheme was  
2 intended to, and, throughout the Class Period, did: (i) deceive the investing public,  
3 including Plaintiff and other Class members, as alleged herein; (ii) artificially  
4 inflate and maintain the market price of CSI securities; and (iii) cause Plaintiff and  
5 other members of the Class to purchase or otherwise acquire CSI securities and  
6 options at artificially inflated prices. In furtherance of this unlawful scheme, plan  
7 and course of conduct, Defendants, and each of them, took the actions set forth  
8 herein.

9         73. Pursuant to the above plan, scheme, conspiracy and course of conduct,  
10 each of the Defendants participated directly or indirectly in the preparation and/or  
11 issuance of the quarterly and annual reports, SEC filings, press releases and other  
12 statements and documents described above, including statements made to  
13 securities analysts and the media that were designed to influence the market for  
14 CSI securities. Such reports, filings, releases and statements were materially false  
15 and misleading in that they failed to disclose material adverse information and  
16 misrepresented the truth about CSI's finances and business prospects.

17         74. By virtue of their positions at CSI, Defendants had actual knowledge  
18 of the materially false and misleading statements and material omissions alleged  
19 herein and intended thereby to deceive Plaintiff and the other members of the  
20 Class, or, in the alternative, Defendants acted with reckless disregard for the truth  
21 in that they failed or refused to ascertain and disclose such facts as would reveal  
22 the materially false and misleading nature of the statements made, although such  
23 facts were readily available to Defendants. Said acts and omissions of Defendants  
24 were committed willfully or with reckless disregard for the truth. In addition, each  
25 defendant knew or recklessly disregarded that material facts were being  
26 misrepresented or omitted as described above.

27         75. Information showing that Defendants acted knowingly or with  
28

1 reckless disregard for the truth is peculiarly within Defendants' knowledge and  
2 control. As the senior managers and/or directors of CSI, the Individual Defendants  
3 had knowledge of the details of CSI's internal affairs.

4 76. The Individual Defendants are liable both directly and indirectly for  
5 the wrongs complained of herein. Because of their positions of control and  
6 authority, the Individual Defendants were able to and did, directly or indirectly,  
7 control the content of the statements of CSI. As officers and/or directors of a  
8 publicly-held company, the Individual Defendants had a duty to disseminate  
9 timely, accurate, and truthful information with respect to CSI's businesses,  
10 operations, future financial condition and future prospects. As a result of the  
11 dissemination of the aforementioned false and misleading reports, releases and  
12 public statements, the market price for CSI's securities was artificially inflated  
13 throughout the Class Period. In ignorance of the adverse facts concerning CSI's  
14 business and financial condition which were concealed by Defendants, Plaintiff  
15 and the other members of the Class purchased or otherwise acquired CSI securities  
16 at artificially inflated prices and relied upon the price of the securities, the integrity  
17 of the market for the securities and/or upon statements disseminated by  
18 Defendants, and were damaged upon the revelation of the alleged corrective  
19 disclosures.  
20

21 77. During the Class Period, CSI's securities were traded on an active and  
22 efficient market. Plaintiff and the other members of the Class, relying on the  
23 materially false and misleading statements described herein, which the Defendants  
24 made, issued or caused to be disseminated, or relying upon the integrity of the  
25 market, purchased or otherwise acquired shares of CSI securities at prices  
26 artificially inflated by Defendants' wrongful conduct. Had Plaintiff and the other  
27 members of the Class known the truth, they would not have purchased or otherwise  
28 acquired said securities, or would not have purchased or otherwise acquired them

1 at the inflated prices that were paid. At the time of the purchases and/or  
2 acquisitions by Plaintiff and the Class, the true value of CSI securities was  
3 substantially lower than the prices paid by Plaintiff and the other members of the  
4 Class. The market price of CSI's securities declined sharply upon public disclosure  
5 of the facts alleged herein to the injury of Plaintiff and Class members.

6 78. By reason of the conduct alleged herein, Defendants knowingly or  
7 recklessly, directly or indirectly, have violated Section 10(b) of the Exchange Act  
8 and Rule 10b-5 promulgated thereunder.

9 79. As a direct and proximate result of Defendants' wrongful conduct,  
10 Plaintiff and the other members of the Class suffered damages in connection with  
11 their respective purchases, acquisitions and sales of the Company's securities  
12 during the Class Period, upon the disclosure that the Company had been  
13 disseminating materially false and misleading statements to the investing public.  
14

## 15 16 17 **COUNT II**

### 18 **Violation of Section 20(a) of The Exchange Act** 19 **Against The Individual Defendants**

20 80. Plaintiff repeats and realleges each and every allegation contained in  
21 the foregoing paragraphs as if fully set forth herein.

22 81. During the Class Period, the Individual Defendants participated in the  
23 operation and management of CSI, and conducted and participated, directly and  
24 indirectly, in the conduct of CSI's business affairs. Because of their senior  
25 positions, they knew the adverse non-public information regarding CSI's business  
26 practices.

27 82. As officers and/or directors of a publicly owned company, the  
28 Individual Defendants had a duty to disseminate accurate and truthful information



1 with respect to CSI's financial condition and results of operations, and to correct  
2 promptly any public statements issued by CSI which had become materially false  
3 or misleading.

4 83. Because of their positions of control and authority as senior officers,  
5 the Individual Defendants were able to, and did, control the contents of the various  
6 reports, press releases and public filings which CSI disseminated in the  
7 marketplace during the Class Period. Throughout the Class Period, the Individual  
8 Defendants exercised their power and authority to cause CSI to engage in the  
9 wrongful acts complained of herein. The Individual Defendants therefore, were  
10 "controlling persons" of CSI within the meaning of Section 20(a) of the Exchange  
11 Act. In this capacity, they participated in the unlawful conduct alleged which  
12 artificially inflated the market price of CSI securities.

13 84. Each of the Individual Defendants, therefore, acted as a controlling  
14 person of CSI. By reason of their senior management positions and/or being  
15 directors of CSI, each of the Individual Defendants had the power to direct the  
16 actions of, and exercised the same to cause, CSI to engage in the unlawful acts and  
17 conduct complained of herein. Each of the Individual Defendants exercised control  
18 over the general operations of CSI and possessed the power to control the specific  
19 activities which comprise the primary violations about which Plaintiff and the  
20 other members of the Class complain.

21 85. By reason of the above conduct, the Individual Defendants are liable  
22 pursuant to Section 20(a) of the Exchange Act for the violations committed by  
23 CSI.  
24

25 **PRAYER FOR RELIEF**

26 WHEREFORE, Plaintiff demands judgment against Defendants as follows:  
27  
28

