

**CORPORATE INTEGRITY AGREEMENT  
BETWEEN THE  
OFFICE OF INSPECTOR GENERAL  
OF THE  
DEPARTMENT OF HEALTH AND HUMAN SERVICES  
AND  
SPECTRANETICS CORPORATION**

**I. PREAMBLE**

The Spectranetics Corporation (Spectranetics) hereby enters into this Corporate Integrity Agreement (CIA) with the Office of Inspector General (OIG) of the United States Department of Health and Human Services (HHS) to promote compliance with the statutes, regulations, and written directives of Medicare, Medicaid, and all other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) (Federal health care program requirements) and with the statutes, regulations, and written directives of the Food and Drug Administration (FDA requirements). Contemporaneously with this CIA, Spectranetics is entering into a Settlement Agreement with the United States.

Spectranetics represents that before the effective date of this CIA (as defined below) and before commencement of the government's investigation, Spectranetics initiated a voluntary compliance program applicable to all Spectranetics employees. Spectranetics's compliance program (Compliance Program) includes a Chief Compliance Officer, who reports to the Board of Directors and the Chief Executive Officer, a Board of Directors Compliance Committee, and a Management Compliance Committee. The Compliance Program also includes a Code of Conduct for all employees, written policies and procedures, educational and training initiatives, review and disciplinary procedures, a disclosure program that allows for the confidential disclosure and investigation of potential compliance violations and appropriate disciplinary procedures, an ineligible persons screening program, and regular internal audit and review procedures, an arrangements database and a Commercial Activities and Grants Committee to monitor Anti-kickback statute compliance.

Spectranetics shall continue its Compliance Program throughout the term of this CIA and shall do so in accordance with the terms set forth below. Spectranetics may modify its Compliance Program as appropriate, but, at a minimum, Spectranetics shall

ensure that during the term of this CIA it shall comply with the obligations enumerated herein.

## **II. TERM AND SCOPE OF THE CIA**

A. The period of the compliance obligations assumed by Spectranetics under this CIA shall be five years from the effective date of this CIA, unless otherwise specified. The effective date shall be the date on which the final signatory of this CIA executes this CIA (Effective Date). Each one-year period, beginning with the one-year period following the Effective Date, shall be referred to as a “Reporting Period.”

B. Sections VII, IX, X, and XI shall expire no later than 120 days after OIG’s receipt of: (1) Spectranetics’ final annual report; or (2) any additional materials submitted by Spectranetics pursuant to OIG’s request, whichever is later.

C. The scope of this CIA shall be governed by the following definitions:

1. “Covered Persons” includes:

a. all owners of Spectranetics who are natural persons, (other than shareholders who: (1) have an ownership interest of less than 5%; and (2) acquired the ownership interest through public trading);

b. all officers and directors of Spectranetics; all U.S.-based employees of Spectranetics; and all employees of Spectranetics who are based outside the United States and have responsibilities relating to Promotional and Product Services Related Functions (as defined below in Section II.C.2) in the U.S., Clinical Investigation Related Functions related to FDA requirements (as defined below in Section II.C.3), or Reporting Related Functions (as defined below in Section II.C.4);

c. all contractors, subcontractors, agents, and other persons who perform Promotional and Product Services Related Functions (as defined below in Section II.C.2) on behalf of Spectranetics;

d. all contractors, subcontractors, agents, and other persons who perform Clinical Investigation Related Functions (as defined below in Section II.C.3) on behalf of Spectranetics and

e. all contractors, subcontractors, agents, and other persons who perform Reporting Related Functions (as defined below in Section II.C.4) on behalf of Spectranetics.

Notwithstanding the above, this term does not include part-time or per diem employees, contractors, subcontractors, agents, and other persons who are not reasonably expected to work more than 160 hours per year, except that any such individuals shall become “Covered Persons” at the point when they work more than 160 hours during the calendar year.

2. “Promotional and Product Services Related Functions” includes: (a) the selling, detailing, marketing, advertising, and promotion of Spectranetics products; and (b) the preparation and dissemination of materials or information about, or the provision of services relating to, devices that are distributed within the United States.

3. “Clinical Investigation Related Functions” includes organizing, coordinating, administering, providing training for, monitoring, and FDA reporting related to clinical investigations and patient registries as well as all relevant obligations under FDA’s Investigational Device Exemption regulations, 21 C.F.R. Part 812.

4. “Reporting Related Functions” includes identifying, tracking, and gathering information and preparing and submitting reports to the FDA for Spectranetics devices. This includes reporting of adverse events (including reports required under 21 U.S.C. § 360i and the Medical Device Reporting (MDR) regulation at 21 C.F.R. Part 803 and other reporting under FDA requirements, (including those required under 21 C.F.R. § 814.84).

5. “Relevant Promotional and Product Services Covered Persons” includes all Covered Persons whose job responsibilities relate to Promotional and Product Services Related Functions.

6. “Relevant Clinical Investigation Covered Persons” includes all Covered Persons whose job responsibilities relate to Clinical Investigation Related Functions.

7. “Relevant Reporting Covered Persons” includes all Covered Persons whose job responsibilities relate to Reporting Related Functions.

### **III. CORPORATE INTEGRITY OBLIGATIONS**

Spectranetics shall establish and maintain a Compliance Program that includes the following elements:

#### **A. Chief Compliance Officer and Committee.**

1. *Chief Compliance Officer.* Prior to the Effective Date, Spectranetics appointed a Chief Compliance Officer and Spectranetics shall maintain a Chief Compliance Officer for the term of the CIA. The Chief Compliance Officer shall be responsible for developing and implementing policies, procedures, and practices designed to ensure compliance with the requirements set forth in this CIA, with Federal health care program requirements and with FDA requirements. The Chief Compliance Officer shall be a member of senior management of Spectranetics, shall make periodic (at least quarterly) reports regarding compliance matters directly to the Board of Directors of Spectranetics, and shall be authorized to report on such matters to the Board of Directors at any time. The Chief Compliance Officer shall not be or be subordinate to the General Counsel or Chief Financial Officer. The Chief Compliance Officer shall be responsible for monitoring the day-to-day compliance activities engaged in by Spectranetics as well as for any reporting obligations created under this CIA. Any noncompliance job responsibilities of the Chief Compliance Officer shall be limited and must not interfere with the Chief Compliance Officer’s ability to perform the duties outlined in this CIA.

Spectranetics shall report to OIG, in writing, any changes in the identity or position description of the Chief Compliance Officer, or any actions or changes that would affect the Chief Compliance Officer’s ability to perform the duties necessary to meet the obligations in this CIA, within 5 days after such a change.

2. *Compliance Committee.* Prior to the Effective Date, Spectranetics formed a Board of Directors Compliance Committee (Board Compliance Committee), consisting of two non-management members of the Board. Spectranetics also formed a

Management Compliance Committee (Compliance Committee), consisting of the Chief Compliance Officer and other members of senior management, including the Chief Operating Officer; the Chief Financial Officer; the General Counsel, the Senior Vice President, Vascular Intervention and Lead Management; Vice President, Clinical Affairs; and the Chief Compliance Officer. Spectranetics's Compliance Committee shall continue to have members of senior management necessary to meet the requirements of this CIA, (e.g. senior executives of relevant departments, such as legal, regulatory affairs, clinical affairs, finance, and vascular intervention and lead management). Spectranetics shall maintain a Compliance Committee and Board Compliance Committee for the term of the CIA. The Chief Compliance Officer shall chair the Compliance Committee and the Committee shall support the Chief Compliance Officer in fulfilling his/her responsibilities (e.g., shall assist in the analysis of the organization's risk areas and shall oversee monitoring of internal and external audits and investigations).

Spectranetics shall report to OIG, in writing, any changes in the composition of the Compliance Committee, or any actions or changes that would affect the Compliance Committee's ability to perform the duties necessary to meet the obligations in this CIA, within 15 days after such a change.

3. *Board of Directors Compliance Obligations.* Spectranetics' Board of Directors shall be responsible for the review and oversight of matters related to compliance with Federal health care program requirements, FDA requirements, and the obligations of this CIA.

a. The Board shall meet at least quarterly to review and oversee Spectranetics' Compliance Program, including but not limited to receiving reports from the Chief Compliance Officer to evaluate the effectiveness of Spectranetics' Compliance Program, Chief Compliance Officer, and Compliance Committee. The Board may also meet with the Board Compliance Committee and the Compliance Committee to evaluate the effectiveness of Spectranetics' Compliance Program, Chief Compliance Officer, and Compliance Committee.

b. For each Reporting Period of the CIA, the Board shall, in reliance upon the aforementioned reports and its reasonable further inquiry, adopt a resolution, signed by each individual member of the Board, summarizing its review and oversight of Spectranetics' compliance with Federal health care program requirements, FDA requirements, and obligations of this CIA.

- i. Resolution: At a minimum, the resolution shall address whether:
  - (a) The Board has made a reasonable inquiry into the effectiveness of Spectranetics' Compliance Program for the Reporting Period; and
  - (b) Based on its reasonable inquiry, the Board concludes that Spectranetics is implementing an effective Compliance Program.
  - (c) If the Board is unable to reach a conclusion that Spectranetics has implemented an effective Compliance Program, the Board shall include in the resolution a written explanation of the reason(s) why it has been unable to reach such a conclusion and the steps that it is taking to implement an effective compliance program.
- ii. The Board resolution and any attachments shall be submitted with Spectranetics' Annual Report to the OIG.

B. Written Standards.

1. *Code of Conduct*. Within 120 days after the Effective Date, Spectranetics shall develop, implement, and distribute a revised written Code of Conduct to all Covered Persons. Spectranetics shall make the promotion of, and adherence to, the Code of Conduct an element in evaluating the performance of all employees. The Code of Conduct shall, at a minimum, set forth:

- a. Spectranetics' commitment to full compliance with all FDA and Federal health care program requirements;
- b. Spectranetics' requirement that all of its Covered Persons shall be expected to comply with all FDA and all Federal health care program requirements and with Spectranetics' own Policies and Procedures as implemented pursuant to Section III.B (including the requirements of this CIA);

- c. the requirement that all of Spectranetics' Covered Persons shall be expected to report to the Chief Compliance Officer, or other appropriate individual designated by Spectranetics, suspected violations of any FDA or Federal health care program requirements or of Spectranetics' own Policies and Procedures; and
- d. the right of all individuals to use the Disclosure Program described in Section III.E, and Spectranetics' commitment to nonretaliation and to maintain, as appropriate, confidentiality and anonymity with respect to such disclosures.

Within 120 days after the Effective Date, each Covered Person shall certify, in writing or electronically, that he or she has received, read, understood, and shall abide by Spectranetics' Code of Conduct. Spectranetics shall maintain documentation of such certification. New Covered Persons shall receive the Code of Conduct and shall complete the required certification within 30 days after becoming a Covered Person or within 120 days after the Effective Date, whichever is later. Spectranetics shall maintain documentation of the Code of Conduct certifications consistent with section VIII of the CIA.

Spectranetics shall periodically review the Code of Conduct to determine if revisions are appropriate and shall make any necessary revisions based on such review. Any revised Code of Conduct shall be distributed within 30 days after any revisions are finalized. Each Covered Person shall certify, in writing, that he or she has received, read, understood, and shall abide by the revised Code of Conduct within 30 days after the distribution of the revised Code of Conduct.

2. *Policies and Procedures.* To the extent not already accomplished, within 120 days after the Effective Date, Spectranetics shall implement written Policies and Procedures regarding the operation of Spectranetics' compliance program and its compliance with Federal health care program and FDA requirements. At a minimum, the Policies and Procedures shall address:

- a. The subjects relating to the Code of Conduct identified in Section III.B.1;
- b. The appropriate manner in which to conduct Promotional and Product Services Related Functions and Clinical Investigation

Related Functions in compliance with all applicable Federal healthcare program requirements, including, but not limited to the False Claims Act (codified at 31 U.S.C. § 3729-3733), and the Federal anti-kickback statute (codified at 42 U.S.C. § 1320a-7b);

- c. The appropriate manner in which to conduct Promotional and Product Services Related Functions and Clinical Investigation Related Functions in compliance with all applicable FDA requirements, including the requirements applicable to investigational devices under 21 C.F.R. §812.7;
- d. The materials and information that may be distributed by Spectranetics sales representatives and account executives about Spectranetics' products and the manner in which Spectranetics sales representatives and account executives respond to requests for information about unapproved or uncleared uses (or "off label" uses) of Spectranetics' products;
- e. The materials and information that may be distributed by Spectranetics' Medical Services Department and the mechanisms through, and manner in which, such medical personnel receive and respond to requests for information about off-label uses of the products; the form and content of the information disseminated by Spectranetics in response to such requests; and the internal review process for the information disseminated.

The Policies and Procedures shall include a requirement that Spectranetics develop a database (Inquiry Database) to track all requests for information about Spectranetics' products that are submitted by Spectranetics' sales representatives and account executives or by physicians or members of the public regarding off-label uses of Spectranetics products. The Inquiry Database shall include the following items of information for each inquiry received for information about Spectranetics' products: 1) date of inquiry; 2) form of inquiry (*e.g.*, email, letter, fax, phone, etc.); 3) name of the requesting health care professional (HCP) or health care institution (HCI) in accordance with applicable privacy laws; 4) nature and topic of the request, including the

exact language of the inquiry; 5) the nature/form of the response from Spectranetics to the HCP or HCI in response to the request; 6) the name of the Spectranetics representative or account executive who called on or interacted with the HCP or HCI, if known;

- f. The appropriate manner in which to conduct Reporting Related Functions in compliance with all applicable FDA requirements;
- g. The protection of human subjects, as required by 45 C.F.R. Part 45 and 21 C.F.R. Parts 50 and 56, and financial disclosure, as required by 21 C.F.R. Part 54;
- h. Systems, processes, policies and procedures for ensuring that all devices Spectranetics introduces or causes to be introduced into interstate commerce are the subject of: (1) an FDA-approved pre-market approval application, under 21 U.S.C. § 360e(a)(2) and 21 C.F.R. Part 814; (2) a "510(k) clearance" by FDA for marketing because it is found to be substantially equivalent to an appropriate, legally marketed device, under 21 U.S.C. §§ 360c(a)(1) and 360(k) and 21 C.F.R. Part 807 -- Subpart E; (3) an investigational device exemption under 21 U.S.C. § 360j(g), for the use of a device on humans on an experimental basis; or (4) an exemption for certain devices as set forth in 21 U.S.C. § 360(l); and
- i. Disciplinary policies and procedures for violations of Spectranetics' Code of Conduct and Policies and Procedures.

Within 120 days after the Effective Date, the relevant portions of the Policies and Procedures shall be distributed to all individuals whose job functions relate to those Policies and Procedures. Appropriate and knowledgeable staff shall be available to explain the Policies and Procedures.

At least annually (and more frequently, if appropriate), Spectranetics shall assess and update, as necessary, the Policies and Procedures. Within 30 days after the effective date of any revisions, the relevant portions of any such revised Policies and Procedures

shall be distributed to all individuals whose job functions relate to those Policies and Procedures.

C. Training and Education.

1. *General Training.* Within 120 days after the Effective Date, Spectranetics shall provide at least two hours of General Training to each Covered Person. This training, at a minimum, shall explain Spectranetics’:

- a. CIA requirements; and
- b. Spectranetics’ Compliance Program (including the Code of Conduct and the Policies and Procedures as they pertain to general compliance issues).

New Covered Persons shall receive the General Training described above within 30 days after becoming a Covered Person or within 120 days after the Effective Date, whichever is later. After receiving the initial General Training described above, each Covered Person shall receive at least one hour of General Training in each subsequent Reporting Period.

2. *Specific Promotional and Product Services Training.* Within 120 days after the Effective Date, each Relevant Promotional and Product Services Covered Person shall receive at least 4 hours of Specific Promotional and Product Services Training in addition to the General Training required above. This Specific Training shall include a discussion of:

- a. all applicable Federal health care program and FDA requirements and all Spectranetics’ Policies and Procedures relating to Promotional and Product Services Related Functions;
- b. the personal obligation of each individual involved in Promotional and Product Services Related Functions to comply with all applicable Federal health care program and FDA requirements and with Spectranetics Policies and Procedures;

- c. the legal sanctions for violations of the Federal health care program and FDA requirements, the False Claims Act, and the Anti-kickback statute;
- d. examples of proper and improper practices related to Promotional and Product Services Related Functions; and
- e. the possible consequences to both Spectranetics and Relevant Covered Promotional and Product Services Persons of failure to comply with FDA and Federal health care program requirements and with Spectranetics' own Policies and Procedures and the failure to report such noncompliance.

New Relevant Promotional and Product Services Covered Persons shall receive this training within 30 days after the beginning of their employment or becoming Relevant Promotional and Product Services Covered Persons, or within 120 days after the Effective Date, whichever is later. A Spectranetics employee who has completed the Specific Promotional and Product Services Training shall review a new Relevant Promotional and Product Services Covered Person's work, to the extent that the work relates to Promotional and Product Services Functions, until such time as the new Relevant Promotional and Product Services Covered Person completes his or her Specific Promotional and Product Services Training.

After receiving the initial Specific Promotional and Product Services Training described in this Section, each Relevant Promotional and Product Services Covered Person shall receive at least three hours of Specific Promotional and Product Services Training in each subsequent Reporting Period.

3. *Specific Clinical Investigation and Reporting Training.* Within 120 days after the Effective Date, each Relevant Clinical Investigation Covered Person and Reporting Covered Person shall receive at least 4 hours of Specific Clinical Investigation and Reporting Training in addition to the General Training required above. This Specific Clinical Investigation and Reporting Training shall include a discussion of:

- a. all applicable Federal health care program and FDA requirements and all Spectranetics' Policies and Procedures relating to Clinical Investigation Related Functions and Reporting Related Functions;

- b. the personal obligation of each individual involved in Clinical Investigation Related Functions and Reporting Related Functions to comply with all applicable Federal health care program and FDA requirements and with Spectranetics' Policies and Procedures, including the requirement to submit complete and accurate information to the FDA;
- c. the legal sanctions for violations of the Federal health care program and FDA requirements;
- d. examples of proper and improper practices related to Clinical Investigation Related Functions and Reporting Related Functions, including those that address the following issues:
  - (i) when a patient registry is, in fact, a clinical investigation;
  - (ii) when FDA approval, FDA clearance, or an applicable Investigational Device Exemption is necessary for interstate distribution of a device; and
  - (iii) the receipt, investigation, and evaluation of events and the record keeping requirements under 21 C.F.R. § 803.17(b); and
- e. the possible consequences to both Spectranetics and Relevant Clinical Investigation Covered Persons and Relevant Reporting Covered Persons of failure to comply with FDA and Federal health care program requirements and with Spectranetics' own Policies and Procedures and the failure to report such noncompliance.

New Relevant Clinical Investigation Covered Persons and New Relevant Reporting Covered Persons shall receive this training within 30 days after the beginning of their employment or becoming Relevant Clinical Investigation Covered Persons or Relevant Reporting Covered Persons, or within 120 days after the Effective Date, whichever is later. A Spectranetics who has completed the Specific Clinical Investigation and Reporting Training shall review (a) a new Relevant Clinical Investigation Covered Person's work, to the extent that the work relates to Clinical Investigation Related Functions, until such time as the new Relevant Clinical Investigation Covered Person

completes his or her Specific Training and (b) a new Relevant Reporting Covered Person's work, to the extent that the work relates to Reporting Related Functions, until such time as the new Relevant Reporting Covered Person completes his or her Specific Training.

After receiving the initial Specific Clinical Investigation and Reporting Training described in this Section, each Relevant Clinical Investigation Covered Person and Relevant Reporting Covered Person shall receive at least three hours of Specific Clinical Investigation and Reporting Training in each subsequent Reporting Period.

4. *Certification.* Each individual who is required to attend training shall certify, in writing, or in electronic form, if applicable, that he or she has received the required training. The certification shall specify the type of training received and the date received. The Chief Compliance Officer (or designee) shall retain the certifications, along with all course materials. These shall be made available to OIG, upon request.

5. *Qualifications of Trainer.* Persons providing the training shall be knowledgeable about the subject area, including applicable Federal health care program and FDA requirements.

6. *Update of Training.* Spectranetics shall review the training annually, and, where appropriate, update the training to reflect changes in Federal health care program and FDA requirements, any issues discovered during internal audits or the IRO Review, and any other relevant information.

7. *Computer-based Training.* Spectranetics may provide the training required under this CIA through appropriate computer-based training approaches. If Spectranetics chooses to provide computer-based training, it shall make available appropriately qualified and knowledgeable staff or trainers to answer questions or provide additional information to the individuals receiving such training.

#### D. Review Procedures.

##### 1. *General Description.*

a. *Engagement of Independent Review Organization.* Within 120 days after the Effective Date, Spectranetics shall engage an entity (or entities), such as an accounting, auditing, or consulting firm

(hereinafter “Independent Review Organization” or “IRO”), to perform reviews to assist Spectranetics in assessing and evaluating its Clinical Investigation Related Functions, Reporting Related Functions, and certain of its Promotional and Product Services Related Functions. The applicable requirements relating to the IRO are outlined in Appendix A to this CIA, which is incorporated by reference.

Each IRO engaged by Spectranetics shall have expertise in applicable Federal health care program and FDA requirements as may be appropriate for the Review for which the IRO is retained. Each IRO shall assess, along with Spectranetics, whether it can perform the engagement in a professionally independent and objective fashion, as appropriate to the nature of the review, taking into account any other business relationships or other engagements that may exist.

The IRO(s) shall conduct reviews that assess Spectranetics’ systems, processes, policies, procedures, and practices relating to Clinical Investigation Related Functions, Reporting Related Functions and Promotional and Product Services Related Functions (collectively, “IRO Review”).

b. *Frequency and Brief Description of Reviews.* As set forth more fully in Appendix B, the IRO Review shall consist of two components – a Systems Review and a Transaction Review.

i. *Systems Review.* The Systems Review shall assess Spectranetics' systems, processes, policies, and procedures relating to Clinical Investigation Related Functions, Reporting Related Functions, and Promotional and Product Services Related Functions. If there are no material changes in Spectranetics' systems, processes, policies, and procedures relating to Clinical Investigation Related Functions, Reporting Related Functions, and Promotional and Product Services Related Functions, the Systems Review shall be performed in the first and fourth Reporting Periods. If Spectranetics materially changes its systems, processes, policies, and procedures relating to Clinical Investigation Related Functions, Reporting Related Functions, and Promotional and Product Services Related Functions, the IRO shall perform a Systems Review for the Reporting Period in which such changes were made in addition to conducting the Systems Review for the first and fourth Reporting Periods.

ii. *Transactions Review.* The Transactions Review shall be performed annually and shall cover each of the five Reporting Periods. The IRO(s) shall perform all components of each annual Transactions Review.

c. *Retention of Records.* The IRO and Spectranetics shall retain and make available to OIG, upon request, all work papers, supporting documentation, correspondence, and draft reports (those exchanged between the IRO and Spectranetics) related to the reviews.

2. *IRO Review Reports.* The IRO shall prepare a report (or reports) based upon each Review performed (IRO Review Report). Information to be included in the IRO Review Report is described in Appendix B.

3. *Validation Review.* In the event OIG has reason to believe that: (a) any IRO Review fails to conform to the requirements of this CIA; or (b) the IRO's findings or Review are inaccurate, OIG may, at its sole discretion, conduct its own review to determine whether the applicable Review complied with the requirements of the CIA and/or the findings or Review results are inaccurate (Validation Review). Spectranetics shall pay for the reasonable cost of any such review performed by OIG or any of its

designated agents. Any Validation Review of Reports submitted as part of Spectranetics' final Annual Report shall be initiated no later than one year after Spectranetics' final submission (as described in Section II) is received by OIG.

Prior to initiating a Validation Review, OIG shall notify Spectranetics of its intent to do so and provide a written explanation of why OIG believes such a review is necessary. To resolve any concerns raised by OIG, Spectranetics may request a meeting with OIG to: (a) discuss the results of any Review submissions or findings; (b) present any additional information to clarify the results of the applicable Review or to correct the inaccuracy of the Review; and/or (c) propose alternatives to the proposed Validation Review. Spectranetics agrees to provide any additional information as may be requested by OIG under this Section III.D.3 in an expedited manner. OIG will attempt in good faith to resolve any Review issues with Spectranetics prior to conducting a Validation Review. However, the final determination as to whether or not to proceed with a Validation Review shall be made at the sole discretion of OIG.

4. *Independence and Objectivity Certification.* The IRO shall include in its report(s) to Spectranetics a certification or sworn affidavit that it has evaluated its professional independence and objectivity, as appropriate to the nature of the engagement, with regard to the applicable Review and that it has concluded that it is, in fact, independent and objective.

#### E. Disclosure Program.

To the extent not already accomplished, within 120 days after the Effective Date, Spectranetics shall establish a Disclosure Program that includes a mechanism (e.g., a toll-free compliance telephone line) to enable individuals to disclose, to the Chief Compliance Officer or some other person who is not in the disclosing individual's chain of command, any identified issues or questions associated with Spectranetics' policies, conduct, practices, or procedures with respect to a Federal health care program or FDA requirements believed by the individual to be a potential violation of criminal, civil, or administrative law. Spectranetics shall appropriately publicize the existence of the disclosure mechanism (e.g., via periodic "all-hands meetings," newsletters and/or e-mails to employees or by posting the information in prominent common areas).

The Disclosure Program shall emphasize a nonretribution, nonretaliation policy, and shall include a reporting mechanism for anonymous communications for which appropriate confidentiality shall be maintained. Upon receipt of a disclosure, the Chief

Compliance Officer (or designee) shall gather all relevant information from the disclosing individual. The Chief Compliance Officer (or designee) shall make a preliminary, good faith inquiry into the allegations set forth in every disclosure to ensure that he or she has obtained all of the information necessary to determine whether a further review should be conducted. For any disclosure that is sufficiently specific so that it reasonably:

- (1) permits a determination of the appropriateness of the alleged improper practice; and
- (2) provides an opportunity for taking corrective action, Spectranetics shall conduct an internal review of the allegations set forth in the disclosure and ensure that proper follow-up is conducted.

The Chief Compliance Officer (or designee) shall maintain a disclosure log, which shall include a record and summary of each disclosure received (whether anonymous or not), the status of the respective internal reviews, and any corrective action taken in response to the internal reviews. The disclosure log shall be made available to OIG upon request.

#### F. Ineligible Persons.

##### 1. *Definitions.* For purposes of this CIA:

- a. an “Ineligible Person” shall include an individual or entity who:
  - i. is currently excluded, debarred, suspended, or otherwise ineligible to participate in the Federal health care programs or in Federal procurement or nonprocurement programs; or
  - ii. has been convicted of a criminal offense that falls within the scope of 42 U.S.C. § 1320a-7(a), but has not yet been excluded, debarred, suspended, or otherwise declared ineligible.
- b. “Exclusion Lists” include:
  - i. the HHS/OIG List of Excluded Individuals/Entities (available through the Internet at <http://www.oig.hhs.gov>); and

ii. the General Services Administration's List of Parties Excluded from Federal Programs (available through the Internet at <http://www.epls.gov>).

2. *Screening Requirements.* Spectranetics shall ensure that all prospective and current Covered Persons are not Ineligible Persons, by implementing the following screening requirements.

a. Spectranetics shall screen all prospective and current Covered Persons against the Exclusion Lists prior to engaging their services and, as part of the hiring or contracting process, shall require such Covered Persons to disclose whether they are Ineligible Persons.

b. Spectranetics shall screen all Covered Persons against the Exclusion Lists within 120 days after the Effective Date and on an annual basis thereafter.

c. Spectranetics shall implement a policy requiring all Covered Persons to disclose immediately any debarment, exclusion, suspension, or other event that makes that person an Ineligible Person.

Nothing in this Section affects the responsibility of (or liability for) Spectranetics to refrain from billing Federal health care programs for items or services furnished, ordered, or prescribed by an Ineligible Person. Spectranetics understands that items or services furnished by excluded persons are not payable by Federal health care programs and that Spectranetics may be liable for overpayments and/or criminal, civil, and administrative sanctions for employing or contracting with an excluded person regardless of whether Spectranetics meets the requirements of Section III.F.

3. *Removal Requirement.* If Spectranetics has actual notice that a Covered Person has become an Ineligible Person, Spectranetics shall remove such Covered Person from responsibility for, or involvement with, Spectranetics' business operations related to the Federal health care programs and shall remove such Covered Person from any position for which the Covered Person's compensation or the items or services furnished, ordered, or prescribed by the Covered Person are paid in whole or part, directly or indirectly, by Federal health care programs or otherwise with Federal funds at least until such time as the Covered Person is reinstated into participation in the Federal health care programs.

4. *Pending Charges and Proposed Exclusions.* If Spectranetics has actual notice that a Covered Person is charged with a criminal offense that falls within the scope of 42 U.S.C. §§ 1320a-7(a), 1320a-7(b)(1)-(3), or is proposed for exclusion during the Covered Person's employment or contract term, Spectranetics shall take all appropriate actions to ensure that the responsibilities of that Covered Person have not and shall not adversely affect the accuracy of any claims submitted to any Federal health care program.

#### G. Notification of Government Investigation or Legal Proceedings.

Within 30 days after discovery, Spectranetics shall notify OIG, in writing, of any ongoing investigation or legal proceeding known to Spectranetics conducted or brought by a governmental entity or its agents involving an allegation that Spectranetics has committed a crime or has engaged in fraudulent activities. This notification shall include a description of the allegation, the identity of the investigating or prosecuting agency, and the status of such investigation or legal proceeding. Spectranetics shall also provide written notice to OIG within 30 days after the resolution of the matter, and shall provide OIG with a description of the findings and/or results of the investigation or proceedings, if any.

#### H. Reporting.

##### 1. *Reportable Events.*

a. *Definition of Reportable Event.* For purposes of this CIA, a "Reportable Event" means anything that involves:

- i. a matter that a reasonable person would consider a probable violation of criminal, civil, or administrative laws applicable to FDA requirements and/or applicable to any Federal health care program for which penalties or exclusion may be authorized; or
- ii. an adverse event that Spectranetics: (1) was required to report as an MDR and (2) failed to report to the FDA under 21 U.S.C. § 360i and 21 C.F.R. Part 803 within 30 days; or
- iii. the filing of a bankruptcy petition by Spectranetics.

A Reportable Event may be the result of an isolated event or a series of occurrences.

b. *Reporting of Reportable Events.* If Spectranetics determines (after a reasonable opportunity to conduct an appropriate review or investigation of the allegations) through any means that there is a Reportable Event, Spectranetics shall notify OIG, in writing, within 30 days after making the determination that the Reportable Event exists. The report to OIG shall include the following information:

- i. a complete description of the Reportable Event, including the relevant facts, persons involved, and legal and Federal health care program and/or FDA authorities implicated;
- ii. a description of Spectranetics' actions taken to correct the Reportable Event;
- iii. any further steps Spectranetics plans to take to address the Reportable Event and prevent it from recurring;
- iv. If the Reportable Event involves the filing of a bankruptcy petition, the report to the OIG shall include documentation of the filing and a description of any Federal health care program and/or FDA authorities implicated.

I. Notification of Communication with FDA.

Within 30 days after the date of any written report, correspondence, or communication between Spectranetics and the FDA that materially discusses Spectranetics' or a Covered Person's actual or potentially unlawful or improper promotion of Spectranetics' products (including any improper dissemination of information about off-label indications) or improper practices relating to Clinical Investigation Related Functions, Spectranetics shall provide a copy of the report, correspondence or communications to the OIG. Spectranetics shall also provide written notice to the OIG within 30 days after the resolution of any matter disclosed in accordance with the requirements set forth above, and it shall provide the OIG with a description of the findings and/or results of the matter, if any.

IV. CHANGES TO BUSINESS UNITS OR LOCATIONS

A. Change or Closure of Unit or Location. In the event that, after the Effective Date, Spectranetics changes locations or closes a business unit or location engaged in Promotional or Product Services Related Functions, Reporting Related Functions, or Clinical Investigation Related Functions, Spectranetics shall notify OIG of this fact as soon as possible, but no later than within 30 days after the date of change or closure of the location.

B. Purchase or Establishment of New Unit or Location. In the event that, after the Effective Date, Spectranetics purchases or establishes a new business unit or location engaged in Promotional or Product Services Related Functions, Reporting Related Functions, or Clinical Investigation Related Functions, Spectranetics shall notify OIG at least 30 days prior to such purchase or the operation of the new business unit or location. This notification shall include the address of the new business unit or location, phone number, fax number, Federal health care provider number and/or supplier number (if applicable), and the name and address of the contractor that issued each number (if applicable). Each new business unit or location and all Covered Persons at each new business unit or location shall be subject to the applicable requirements of this CIA.

C. Sale of Unit or Location. In the event that, after the Effective Date, Spectranetics proposes to sell any or all of its business units or locations that are subject to this CIA, Spectranetics shall notify OIG of the proposed sale at least 30 days prior to the sale of such business unit or location. This notification shall include a description of

the business unit or location to be sold, a brief description of the terms of the sale, and the name and contact information of the prospective purchaser. This CIA shall be binding on the purchaser of such business unit or location, unless otherwise determined and agreed to in writing by the OIG.

## V. IMPLEMENTATION AND ANNUAL REPORTS

A. Implementation Report. Within 150 days after the Effective Date, Spectranetics shall submit a written report to OIG summarizing the status of its implementation of the requirements of this CIA (Implementation Report). The Implementation Report shall, at a minimum, include:

1. the name, address, phone number, and position description of the Chief Compliance Officer required by Section III.A.1, and a summary of other noncompliance job responsibilities the Chief Compliance Officer may have;
2. the names and positions of the members of the Compliance Committee required by Section III.A.2;
3. the names of the members Spectranetics' Board of Directors referenced in Section III.A.3;
4. a copy of Spectranetics' Code of Conduct required by Section III.B.1;
5. a copy of all Policies and Procedures required by Section III.B.2;
6. the number of individuals required to complete the Code of Conduct certification required by Section III.B.1, the percentage of individuals who have completed such certification, and an explanation of any exceptions (the documentation supporting this information shall be available to OIG, upon request);
7. the following information regarding each type of training required by Section III.C:
  - a. a description of such training, including a summary of the topics covered, the length of sessions, and a schedule of training sessions; and

- b. the number of individuals required to be trained, percentage of individuals actually trained, and an explanation of any exceptions.

A copy of all training materials and the documentation supporting this information shall be available to OIG, upon request.

8. a description of the Disclosure Program required by Section III.E;
9. the following information regarding the IRO(s): (a) identity, address, and phone number; (b) a copy of the engagement letter; and (c) a summary and description of any and all current and prior engagements and agreements between Spectranetics and the IRO;
10. a certification from the IRO regarding its professional independence and objectivity with respect to Spectranetics;
11. a description of the process by which Spectranetics fulfills the requirements of Section III.F regarding Ineligible Persons;
12. the name, title, and responsibilities of any person who is determined to be an Ineligible Person under Section III.F; the actions taken in response to the screening and removal obligations set forth in Section III.F;
13. a list of all of Spectranetics' locations (including locations and mailing addresses) at which it performs Promotional and Product Services Related Functions, Reporting Related Functions, and Clinical Investigation Related Functions; the corresponding name under which each location is doing business; the corresponding phone numbers and fax numbers; each location's Federal health care provider number and/or supplier number(s) (if applicable); and the name and address of each Federal health care program contractor to which Spectranetics currently submits claims (if applicable);
14. a description of Spectranetics' corporate structure, including identification of any parent and sister companies, subsidiaries, and their respective lines of business; and
15. the certifications required by Section V.C.

B. Annual Reports. Spectranetics shall submit to OIG annually a report with respect to the status of, and findings regarding, Spectranetics' compliance activities for each of the five Reporting Periods (Annual Report).

Each Annual Report shall include, at a minimum:

1. any change in the identity, position description, or other noncompliance job responsibilities of the Chief Compliance Officer and any change in the membership of the Compliance Committee, or the membership of the Board of Directors described in Section III.A;

2. a copy of the Board's resolution described in Section III.A.3.b;

3. a summary of any significant changes or amendments to the Policies and Procedures required by Section III.B and the reasons for such changes (e.g., change in applicable requirements);

4. the number of individuals required to complete the Code of Conduct certification required by Section III.B.1, the percentage of individuals who have completed such certification, and an explanation of any exceptions (the documentation supporting this information shall be available to OIG, upon request);

5. the following information regarding each type of training required by Section III.C:

a. a description of such training, including a summary of the topics covered, the length of sessions, and a schedule of training sessions; and

b. the number of individuals required to be trained, percentage of individuals actually trained, and an explanation of any exceptions.

A copy of all training materials and the documentation supporting this information shall be available to OIG, upon request.

6. a complete copy of all reports prepared pursuant to Section III.D, along with a copy of the IRO's engagement letter (if applicable);

7. Spectranetics' response and corrective action plan(s) related to any issues raised by the reports prepared pursuant to Section III.D;

8. a summary and description of any and all current and prior engagements and agreements between Spectranetics and the IRO, if different from what was submitted as part of the Implementation Report;

9. a certification from the IRO regarding its professional independence and objectivity with respect to Spectranetics;

10. a summary of Reportable Events (as defined in Section III.H) identified during the Reporting Period and the status of any corrective and preventative action relating to all such Reportable Events;

11. a summary of the disclosures in the disclosure log required by Section III.E that relate to Federal health care programs;

12. any changes to the process by which Spectranetics fulfills the requirements of Section III.F regarding Ineligible Persons;

13. the name, title, and responsibilities of any person who is determined to be an Ineligible Person under Section III.F;

14. a summary describing any ongoing investigation or legal proceeding required to have been reported pursuant to Section III.G. The summary shall include a description of the allegation, the identity of the investigating or prosecuting agency, and the status of such investigation or legal proceeding;

15. a summary describing any written communication with the FDA required to have been reported pursuant to Section III.I. This summary shall include a description of the matter and the status of the matter;

16. a description of all changes to the most recently provided list of Spectranetics' locations (including addresses) as required by Section V.A.14; the corresponding name under which each location is doing business; the corresponding phone numbers and fax numbers; each location's Federal health care program provider number(s) and/or supplier number(s); and the name and address of each Federal health care program contractor to which Spectranetics currently submits claims; and

17. the certifications required by Section V.C.

The first Annual Report shall be received by OIG no later than 60 days after the end of the first Reporting Period. Subsequent Annual Reports shall be received by OIG no later than the anniversary date of the due date of the first Annual Report.

C. Certifications. The Implementation Report and Annual Reports shall include a certification by the Chief Compliance Officer that:

1. to the best of his or her knowledge, except as otherwise described in the applicable report, Spectranetics is in compliance with Federal health care program and FDA requirements and all of the requirements of this CIA;

2. he or she has reviewed the Report and has made reasonable inquiry regarding its content and believes that the information in the Report is accurate and truthful; and

3. to the best of his or her knowledge, Spectranetics has complied with its obligations under the Settlement Agreement: (a) not to resubmit to any Federal health care program payors any previously denied claims related to the Covered Conduct addressed in the Settlement Agreement, and not to appeal any such denials of claims; (b) not to charge to or otherwise seek payment from federal or state payors for unallowable costs (as defined in the Settlement Agreement); and (c) to identify and adjust any past charges or claims for unallowable costs; and

4. Spectranetics': 1) Policies and Procedures as referenced in Section III.B.3 above; 2) templates for standardized contracts and other similar documents related to Promotional and Product Services Related Functions and Clinical Investigation Related Functions; and 3) training materials used for purposes of Section III.C all have been reviewed by competent legal counsel and/or legal personnel working at Spectranetics and have been found to be in compliance with all applicable Federal health care program and FDA requirements. In addition, Spectranetics' promotional material containing claims or information about Spectranetics products and other materials and information to be distributed outside of Spectranetics have been reviewed by competent regulatory, medical, and/or legal personnel to ensure that legal, medical, and regulatory concerns are properly addressed and are elevated when appropriate and to ensure that the materials and information when finally approved are in compliance with all applicable Federal health

care program and FDA requirements. If the applicable legal requirements have not changed, after the initial review of the documents listed above, only material changes to the documents must be reviewed by competent regulatory, medical, and/or legal personnel. The certification shall include a description of the documents reviewed and approximately when the review was completed. The documentation supporting this certification shall be available to the OIG upon request.

D. Designation of Information. Spectranetics shall clearly identify any portions of its submissions that it believes are trade secrets, or information that is commercial or financial and privileged or confidential, and therefore potentially exempt from disclosure under the Freedom of Information Act (FOIA), 5 U.S.C. § 552. Spectranetics shall refrain from identifying any information as exempt from disclosure if that information does not meet the criteria for exemption from disclosure under FOIA.

## VI. NOTIFICATIONS AND SUBMISSION OF REPORTS

Unless otherwise stated in writing after the Effective Date, all notifications and reports required under this CIA shall be submitted to the following entities:

OIG:

Administrative and Civil Remedies Branch  
Office of Counsel to the Inspector General  
Office of Inspector General  
U.S. Department of Health and Human Services  
Cohen Building, Room 5527  
330 Independence Avenue, S.W.  
Washington, DC 20201  
Telephone: 202.619.2078  
Facsimile: 202.205.0604

Spectranetics:

Michael K. Handley  
Chief Compliance Officer  
Vice President, Global Regulatory Affairs  
Spectranetics Corporation  
9965 Federal Drive  
Colorado Springs, CO 80921  
Email: michael.handley@spnc.com  
Phone: 719.447.2318  
Fax: 719.447.2070

Unless otherwise specified, all notifications and reports required by this CIA may be made by certified mail, overnight mail, hand delivery, or other means, provided that there is proof that such notification was received. For purposes of this requirement, internal facsimile confirmation sheets do not constitute proof of receipt. Upon request by OIG, Spectranetics may be required to provide OIG with an electronic copy of each notification or report required by this CIA in searchable portable document format (pdf), either instead of or in addition to, a paper copy.

**VII. OIG INSPECTION, AUDIT, AND REVIEW RIGHTS**

In addition to any other rights OIG may have by statute, regulation, or contract, OIG or its duly authorized representative(s) may examine or request copies of Spectranetics' books, records, and other documents and supporting materials and/or conduct on-site reviews of any of Spectranetics' locations for the purpose of verifying and evaluating: (a) Spectranetics' compliance with the terms of this CIA; and (b) Spectranetics' compliance with the requirements of the Federal health care programs in which it participates and with all applicable FDA requirements. The documentation described above shall be made available by Spectranetics to OIG or its duly authorized representative(s) at all reasonable times for inspection, audit, or reproduction. Furthermore, for purposes of this provision, OIG or its duly authorized representative(s) may interview any of Spectranetics' employees, contractors, or agents who consent to be interviewed at the individual's place of business during normal business hours or at such other place and time as may be mutually agreed upon between the individual and OIG.

Spectranetics shall assist OIG or its duly authorized representative(s) in contacting and arranging interviews with such individuals upon OIG's request. Spectranetics' employees may elect to be interviewed with or without a representative of Spectranetics present.

**VIII. DOCUMENT AND RECORD RETENTION**

Spectranetics shall maintain for inspection all documents and records relating to reimbursement from the Federal health care programs, or to compliance with this CIA, for six years (or longer if otherwise required by law) from the Effective Date.

**IX. DISCLOSURES**

Consistent with HHS's FOIA procedures, set forth in 45 C.F.R. Part 5, OIG shall make a reasonable effort to notify Spectranetics prior to any release by OIG of information submitted by Spectranetics pursuant to its obligations under this CIA and identified upon submission by Spectranetics as trade secrets, or information that is commercial or financial and privileged or confidential, under the FOIA rules. With respect to such releases, Spectranetics shall have the rights set forth at 45 C.F.R. § 5.65(d).

**X. BREACH AND DEFAULT PROVISIONS**

Spectranetics is expected to fully and timely comply with all of its CIA obligations.

A. Stipulated Penalties for Failure to Comply with Certain Obligations. As a contractual remedy, Spectranetics and OIG hereby agree that failure to comply with certain obligations as set forth in this CIA may lead to the imposition of the following monetary penalties (hereinafter referred to as "Stipulated Penalties") in accordance with the following provisions.

1. A Stipulated Penalty of \$2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day Spectranetics fails to establish and implement any of the following obligations as described in Section III:

- a. a Chief Compliance Officer;
- b. a Compliance Committee;

- c. a resolution from the Board of Directors;
- d. a written Code of Conduct;
- e. written Policies and Procedures;
- f. the training of Covered Persons and Relevant Covered Persons;
- g. a Disclosure Program;
- h. Ineligible Persons screening and removal requirements;
- i. notification of Government investigations or legal proceedings;
- j. notification of written communications with FDA as required by Section III.I; and
- k. reporting of Reportable Events.

2. A Stipulated Penalty of \$2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day Spectranetics fails to engage an IRO, as required in Section III.D and Appendix A.

3. A Stipulated Penalty of \$2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day Spectranetics fails to submit the Implementation Report or any Annual Reports to OIG in accordance with the requirements of Section V by the deadlines for submission.

4. A Stipulated Penalty of \$2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day Spectranetics fails to submit the IRO Review Reports in accordance with the requirements of Section III.D and Appendix B.

5. A Stipulated Penalty of \$2,000 (which shall begin to accrue on the date the failure to comply began) for each day Spectranetics employs or contracts with an Ineligible Person and that person: (i) has responsibility for, or involvement with, Spectranetics' business operations related to the Federal health care programs; or (ii) is in

a position for which the person's salary or the items or services rendered, ordered, or prescribed by the person are paid in whole or part, directly or indirectly, by Federal health care programs or otherwise with Federal funds (the Stipulated Penalty described in this paragraph shall not be demanded for any time period during which Spectranetics can demonstrate that it did not discover the person's exclusion or other ineligibility after making a reasonable inquiry (as described in section III.F) as to the status of the person).

6. A Stipulated Penalty of \$1,500 for each day Spectranetics fails to grant access as required in Section VII. (This Stipulated Penalty shall begin to accrue on the date Spectranetics fails to grant access.)

7. A Stipulated Penalty of \$5,000 for each false certification submitted by or on behalf of Spectranetics as part of its Implementation Report, Annual Report, additional documentation to a report (as requested by the OIG), or otherwise required by this CIA.

8. A Stipulated Penalty of \$1,000 for each day Spectranetics fails to comply fully and adequately with any obligation of this CIA. OIG shall provide notice to Spectranetics stating the specific grounds for its determination that Spectranetics has failed to comply fully and adequately with the CIA obligation(s) at issue and steps Spectranetics shall take to comply with the CIA. (This Stipulated Penalty shall begin to accrue 10 days after Spectranetics receives this notice from OIG of the failure to comply.) A Stipulated Penalty as described in this Subsection shall not be demanded for any violation for which OIG has sought a Stipulated Penalty under Subsections 1-7 of this Section.

B. Timely Written Requests for Extensions. Spectranetics may, in advance of the due date, submit a timely written request for an extension of time to perform any act or file any notification or report required by this CIA. Notwithstanding any other provision in this Section, if OIG grants the timely written request with respect to an act, notification, or report, Stipulated Penalties for failure to perform the act or file the notification or report shall not begin to accrue until one day after Spectranetics fails to meet the revised deadline set by OIG. Notwithstanding any other provision in this Section, if OIG denies such a timely written request, Stipulated Penalties for failure to perform the act or file the notification or report shall not begin to accrue until three business days after Spectranetics receives OIG's written denial of such request or the original due date, whichever is later. A "timely written request" is defined as a request in writing received by OIG at least five business days prior to the date by which any act is

due to be performed or any notification or report is due to be filed.

C. Payment of Stipulated Penalties.

1. *Demand Letter.* Upon a finding that Spectranetics has failed to comply with any of the obligations described in Section X.A and after determining that Stipulated Penalties are appropriate, OIG shall notify Spectranetics of: (a) Spectranetics' failure to comply; and (b) OIG's exercise of its contractual right to demand payment of the Stipulated Penalties (this notification is referred to as the "Demand Letter").

2. *Response to Demand Letter.* Within 10 days after the receipt of the Demand Letter, Spectranetics shall either: (a) cure the breach to OIG's satisfaction and pay the applicable Stipulated Penalties or (b) request a hearing before an HHS administrative law judge (ALJ) to dispute OIG's determination of noncompliance, pursuant to the agreed upon provisions set forth below in Section X.E. In the event Spectranetics elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until Spectranetics cures, to OIG's satisfaction, the alleged breach in dispute. Failure to respond to the Demand Letter in one of these two manners within the allowed time period shall be considered a material breach of this CIA and shall be grounds for exclusion under Section X.D.

3. *Form of Payment.* Payment of the Stipulated Penalties shall be made by electronic funds transfer to an account specified by OIG in the Demand Letter.

4. *Independence from Material Breach Determination.* Except as set forth in Section X.D.1.c, these provisions for payment of Stipulated Penalties shall not affect or otherwise set a standard for OIG's decision that Spectranetics has materially breached this CIA, which decision shall be made at OIG's discretion and shall be governed by the provisions in Section X.D, below.

D. Exclusion for Material Breach of this CIA.

1. *Definition of Material Breach.* A material breach of this CIA means:

- a. a failure by Spectranetics to report a Reportable Event, and take corrective action as required in Section III.H;
- b. a repeated or flagrant violation of the obligations under this CIA,

including, but not limited to, the obligations addressed in Section X.A;

c. a failure to respond to a Demand Letter concerning the payment of Stipulated Penalties in accordance with Section X.C;

d. a failure to engage and use an IRO in accordance with Section III.D; or

e. a failure of the Board to issue a resolution in accordance with Section III.A.3.

2. *Notice of Material Breach and Intent to Exclude.* The parties agree that a material breach of this CIA by Spectranetics constitutes an independent basis for Spectranetics' exclusion from participation in the Federal health care programs. Upon a determination by OIG that Spectranetics has materially breached this CIA and that exclusion is the appropriate remedy, OIG shall notify Spectranetics of: (a) Spectranetics' material breach; and (b) OIG's intent to exercise its contractual right to impose exclusion (this notification is hereinafter referred to as the "Notice of Material Breach and Intent to Exclude").

3. *Opportunity to Cure.* Spectranetics shall have 30 days from the date of receipt of the Notice of Material Breach and Intent to Exclude to demonstrate to OIG's satisfaction that:

a. Spectranetics is in compliance with the obligations of the CIA cited by OIG as being the basis for the material breach;

b. the alleged material breach has been cured; or

c. the alleged material breach cannot be cured within the 30-day period, but that: (i) Spectranetics has begun to take action to cure the material breach; (ii) Spectranetics is pursuing such action with due diligence; and (iii) Spectranetics has provided to OIG a reasonable timetable for curing the material breach.

4. *Exclusion Letter.* If, at the conclusion of the 30-day period, Spectranetics fails to satisfy the requirements of Section X.D.3, OIG may exclude Spectranetics from participation in the Federal health care programs. OIG shall notify Spectranetics in writing of its determination to exclude Spectranetics (this letter shall be referred to hereinafter as the “Exclusion Letter”). Subject to the Dispute Resolution provisions in Section X.E, below, the exclusion shall go into effect 30 days after the date of Spectranetics’ receipt of the Exclusion Letter. The exclusion shall have national effect and shall also apply to all other Federal procurement and nonprocurement programs. Reinstatement to program participation is not automatic. After the end of the period of exclusion, Spectranetics may apply for reinstatement by submitting a written request for reinstatement in accordance with the provisions at 42 C.F.R. §§ 1001.3001-3004.

#### E. Dispute Resolution

1. *Review Rights.* Upon OIG’s delivery to Spectranetics of its Demand Letter or of its Exclusion Letter, and as an agreed-upon contractual remedy for the resolution of disputes arising under this CIA, Spectranetics shall be afforded certain review rights comparable to the ones that are provided in 42 U.S.C. § 1320a-7(f) and 42 C.F.R. Part 1005 as if they applied to the Stipulated Penalties or exclusion sought pursuant to this CIA. Specifically, OIG’s determination to demand payment of Stipulated Penalties or to seek exclusion shall be subject to review by an HHS ALJ and, in the event of an appeal, the HHS Departmental Appeals Board (DAB), in a manner consistent with the provisions in 42 C.F.R. § 1005.2-1005.21. Notwithstanding the language in 42 C.F.R. § 1005.2(c), the request for a hearing involving Stipulated Penalties shall be made within 10 days after receipt of the Demand Letter and the request for a hearing involving exclusion shall be made within 25 days after receipt of the Exclusion Letter.

2. *Stipulated Penalties Review.* Notwithstanding any provision of Title 42 of the United States Code or Title 42 of the Code of Federal Regulations, the only issues in a proceeding for Stipulated Penalties under this CIA shall be: (a) whether Spectranetics was in full and timely compliance with the obligations of this CIA for which OIG demands payment; and (b) the period of noncompliance. Spectranetics shall have the burden of proving its full and timely compliance and the steps taken to cure the noncompliance, if any. OIG shall not have the right to appeal to the DAB an adverse ALJ decision related to Stipulated Penalties. If the ALJ agrees with OIG with regard to a finding of a breach of this CIA and orders Spectranetics to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a

decision unless Spectranetics requests review of the ALJ decision by the DAB. If the ALJ decision is properly appealed to the DAB and the DAB upholds the determination of OIG, the Stipulated Penalties shall become due and payable 20 days after the DAB issues its decision.

3. *Exclusion Review.* Notwithstanding any provision of Title 42 of the United States Code or Title 42 of the Code of Federal Regulations, the only issues in a proceeding for exclusion based on a material breach of this CIA shall be:

- a. whether Spectranetics was in material breach of this CIA;
- b. whether such breach was continuing on the date of the Exclusion Letter; and
- c. whether the alleged material breach could not have been cured within the 30-day period, but that: (i) Spectranetics had begun to take action to cure the material breach within that period; (ii) Spectranetics has pursued and is pursuing such action with due diligence; and (iii) Spectranetics provided to OIG within that period a reasonable timetable for curing the material breach and Spectranetics has followed the timetable.

For purposes of the exclusion herein, exclusion shall take effect only after an ALJ decision favorable to OIG, or, if the ALJ rules for Spectranetics, only after a DAB decision in favor of OIG. Spectranetics' election of its contractual right to appeal to the DAB shall not abrogate OIG's authority to exclude Spectranetics upon the issuance of an ALJ's decision in favor of OIG. If the ALJ sustains the determination of OIG and determines that exclusion is authorized, such exclusion shall take effect 20 days after the ALJ issues such a decision, notwithstanding that Spectranetics may request review of the ALJ decision by the DAB. If the DAB finds in favor of OIG after an ALJ decision adverse to OIG, the exclusion shall take effect 20 days after the DAB decision. Spectranetics shall waive its right to any notice of such an exclusion if a decision upholding the exclusion is rendered by the ALJ or DAB. If the DAB finds in favor of Spectranetics, Spectranetics shall be reinstated effective on the date of the original exclusion.

4. *Finality of Decision.* The review by an ALJ or DAB provided for above shall not be considered to be an appeal right arising under any statutes or regulations. Consequently, the parties to this CIA agree that the DAB's decision (or the ALJ's decision if not appealed) shall be considered final for all purposes under this CIA.

## **XI. EFFECTIVE AND BINDING AGREEMENT**

Spectranetics and OIG agree as follows:

A. This CIA shall be binding on the successors, assigns, and transferees of Spectranetics;

B. This CIA shall become final and binding on the date the final signature is obtained on the CIA;

C. This CIA constitutes the complete agreement between the parties and may not be amended except by written consent of the parties to this CIA;

D. OIG may agree to a suspension of Spectranetics' obligations under the CIA in the event of Spectranetics' cessation of participation in Federal health care programs. If Spectranetics ceases participating in Federal health care programs and is relieved of its CIA obligations by OIG, Spectranetics shall notify OIG at least 30 days in advance of Spectranetics' intent to resume participating as a provider or supplier with any Federal health care program. Upon receipt of such notification, OIG shall evaluate whether the CIA should be reactivated or modified.

E. The undersigned Spectranetics signatories represent and warrant that they are authorized to execute this CIA. The undersigned OIG signatory represents that he is signing this CIA in his official capacity and that he is authorized to execute this CIA.

F. This CIA may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same CIA. Facsimiles of signatures shall constitute acceptable, binding signatures for purposes of this CIA.



ON BEHALF OF THE OFFICE OF INSPECTOR GENERAL  
OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES

/Gregory E. Demske/

12/22/09

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GREGORY E. DEMSKE  
Assistant Inspector General for Legal Affairs  
Office of Inspector General  
U. S. Department of Health and Human Services

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DATE

## APPENDIX A

### INDEPENDENT REVIEW ORGANIZATION

This Appendix contains the requirements relating to the Independent Review Organization (IRO) required by Section III.D of the CIA.

#### A. IRO Engagement

Spectranetics shall engage an IRO that possesses the qualifications set forth in Paragraph B, below, to perform the responsibilities in Paragraph C, below. The IRO shall conduct the review in a professionally independent and objective fashion, as set forth in Paragraph D. Within 30 days after OIG receives written notice of the identity of the selected IRO, OIG will notify Spectranetics if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, Spectranetics may continue to engage the IRO.

If Spectranetics engages a new IRO during the term of the CIA, this IRO shall also meet the requirements of this Appendix. If a new IRO is engaged, Spectranetics shall submit the information identified in Section V.A.9 of the CIA to OIG within 30 days of engagement of the IRO. Within 30 days after OIG receives written notice of the identity of the selected IRO, OIG will notify Spectranetics if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, Spectranetics may continue to engage the IRO.

#### B. IRO Qualifications.

The IRO shall:

1. assign individuals to conduct the IRO Reviews who have expertise in all applicable Federal health care program and FDA requirements relating to Promotional and Product Services Related Functions, Clinical Investigation Related Functions, and Reporting Related Functions. The assigned individuals shall also be knowledgeable about the general requirements of the Federal health care program(s) under which Spectranetics products are reimbursed;
2. assign individuals to design and select the samples for the Transaction Reviews who are knowledgeable about the appropriate statistical sampling techniques; and
3. have sufficient staff and resources to conduct the reviews required by the CIA on a timely basis.

C. IRO Responsibilities.

The IRO shall:

1. perform each component of the IRO Review in accordance with the specific requirements of the CIA;
2. follow all applicable Federal health care program and FDA requirements in making assessments in each IRO Review;
3. if in doubt of the application of a particular Federal health care program or FDA requirement, policy, or regulation, request clarification from the appropriate authority (e.g., CMS or FDA);
4. respond to all OIG inquiries in a prompt, objective, and factual manner; and
5. prepare timely, clear, well-written reports that include all the information required by Appendix B to the CIA.

D. IRO Independence and Objectivity.

The IRO must perform the IRO Reviews in a professionally independent and objective fashion, as appropriate to the nature of the engagement, taking into account any other business relationships or engagements that may exist between the IRO and Spectranetics.

E. IRO Removal/Termination.

1. *Spectranetics Termination of IRO.* If Spectranetics terminates its IRO during the course of the engagement, Spectranetics must submit a notice explaining its reasons to OIG no later than 30 days after termination. Spectranetics must engage a new IRO in accordance with Paragraph A of this Appendix.

2. *OIG Removal of IRO.* In the event OIG has reason to believe that the IRO does not possess the qualifications described in Paragraph B, is not independent and/or objective as set forth in Paragraph D, or has failed to carry out its responsibilities as described in Paragraph C, OIG may, at its sole discretion, require Spectranetics to engage a new IRO in accordance with Paragraph A of this Appendix.

Prior to requiring Spectranetics to engage a new IRO, OIG shall notify Spectranetics of its intent to do so and provide a written explanation of why OIG believes such a step is necessary. To resolve any concerns raised by OIG, Spectranetics may request a meeting with OIG to discuss any aspect of the IRO's qualifications,

independence or performance of its responsibilities and to present additional information regarding these matters. Spectranetics shall provide any additional information as may be requested by OIG under this Paragraph in an expedited manner. OIG will attempt in good faith to resolve any differences regarding the IRO with Spectranetics prior to requiring Spectranetics to terminate the IRO. However, the final determination as to whether or not to require Spectranetics to engage a new IRO shall be made at the sole discretion of OIG.

## Appendix B to CIA

### I. General Description

As specified more fully below, Spectranetics shall retain an Independent Review Organization (IRO) to perform reviews to assist Spectranetics in assessing and evaluating its systems, processes, policies, procedures, and practices related to Spectranetics's Clinical Investigation Related Functions, Reporting Related Functions, and Promotional and Product Services Related Functions (IRO Review). The IRO Review shall consist of two components - a systems review (Systems Review), and a transactions review (Transactions Review) as described more fully below. Spectranetics may engage, at its discretion, a single IRO to perform both components of the IRO Review provided that the entity has the necessary expertise and capabilities to perform both.

If there are no material changes in Spectranetics's systems, processes, policies, and procedures relating to Clinical Investigations, Reporting, and Promotional and Product Services Related Functions, the IRO shall perform the Systems Review for the first and fourth Reporting Periods. If Spectranetics materially changes its systems, processes, policies, and procedures relating to Clinical Investigation Related Functions, Reporting Related Functions, and Promotional and/or Product Services Related Functions, the IRO shall perform a Systems Review for the materially changed Related Function for the Reporting Period(s) in which such changes were made in addition to conducting the Review for the first and fourth Reporting Periods. The additional Systems Review(s) shall consist of: 1) an identification of the material changes; 2) an assessment of whether other systems, processes, policies, and procedures previously reported did not materially change; and 3) a review of the systems, processes, policies, and procedures that materially changed. The IRO shall conduct the Transactions Review for each Reporting Period of the CIA.

### II. Systems Review

#### A. Description of Reviewed Policies and Procedures

The Systems Review shall be a review of Spectranetics's systems, processes, policies, and procedures (including the controls on those systems, processes, policies, and procedures) relating to certain Clinical Investigation Related Functions, Reporting Related Functions, and Promotional and Product Services Related Functions. Where practical, Spectranetics personnel may compile documentation, schedule and organize interviews, and undertake other efforts to assist the IRO in performing the Systems Review. The IRO is not required to

undertake a de novo review of the information gathered or activities undertaken by Spectranetics pursuant to the preceding sentence.

Specifically, the IRO shall review certain of Spectranetics's systems, processes, policies, and procedures associated with the following (hereafter "Reviewed Policies and Procedures").

1. The IRO shall review Spectranetics's systems, policies, processes, and procedures applicable to Promotional and Product Services Related Functions:
  - a. Spectranetics's systems, policies, processes, and procedures applicable to the manner in which Spectranetics sales representatives and account executives handle and submit requests or inquiries about the off-label uses of Spectranetics's products to Spectranetics's Medical Services Department;
  - b. the manner in which Spectranetics's Medical Services Department handles and responds to requests and inquiries regarding off-label uses of Spectranetics's products (including tracking the requests and using pre-approved materials for purposes of responding to the request);
  - c. the form and content of information and materials Spectranetics provides to physicians, pharmacists, or other health care professionals (collectively "HCPs") or health care institutions (HCIs) regarding off-label uses of Spectranetics's products;
  - d. Spectranetics's systems, policies, processes, and procedures, including those associated with Spectranetics's Promotional and Advertising Committee (PARC), relating to Spectranetics's internal review of information and materials regarding Spectranetics's products that Spectranetics disseminates to HCPs or HCIs;
  - e. Spectranetics's systems, processes, policies, and procedures relating to the development and review of call plans for Spectranetics's products. This shall include a review of the bases upon which HCPs and HCIs belonging to specified medical specialties or types of practice are included in, or excluded from, the call plans based on expected utilization of Spectranetics products for FDA-approved uses or non-FDA-approved uses;

- f. the processes and procedures by which Spectranetics's Compliance Office and Spectranetics Medical Services Department monitor and identify situations in which it appears that improper off-label promotion may have occurred; and
  - g. Spectranetics's systems, processes, policies, and procedures for investigating, documenting, resolving, and taking appropriate disciplinary action for potential situations involving off-label promotion.
2. The IRO shall review Spectranetics's systems, policies, processes, and procedures applicable to Clinical Investigation Related Functions:
- a. Spectranetics's systems, policies, processes, and procedures for ensuring that Spectranetics does not introduce or cause to be introduced into interstate commerce devices prior to complying with one of the methods of FDA authorization: (1) an FDA-approved pre-market approval application, under 21 U.S.C. § 360e(a)(2) and 21 C.F.R. Part 814; (2) a "510(k) clearance" by FDA for marketing because it is found to be substantially equivalent to an appropriate, legally marketed device, under 21 U.S.C. §§ 360c(a)(1) and 360(k) and 21 C.F.R. Part 807 -- Subpart E; (3) an investigational device exemption under 21 U.S.C. § 360j(g), for the use of a device on humans on an experimental basis; or (4) an exemption for certain devices as set forth in 21 U.S.C. § 360(l);
  - b. Spectranetics's systems, processes, policies, and procedures to identify or evaluate when the use of a Spectranetics device, including use of a Spectranetics device in connection with a patient registry, is a clinical investigation;
  - c. Spectranetics's systems, processes, policies, and procedures to provide for the protection of human subjects, including obtaining informed consent, as provided in 21 C.F.R. Part 50 and 56 and in 45 C.F.R. Part 45;
  - d. Spectranetics's systems, processes, policies, and procedures for clinical investigations site audits;
  - e. Spectranetics's processes, policies, and procedures regarding disclosure of financial interests of clinical investigators, as

required by 21 C.F.R. Part 54, for studies using Spectranetics's products;

- f. Spectranetics's systems, processes, policies, and procedures for complying with reporting obligations provided in 21 C.F.R. § 812.150 for devices with an approved investigational device exception.
  - g. the processes and procedures by which Spectranetics's Compliance Office identifies situations in which it appears that non-compliance occurred with regard to the requirements for, or Spectranetics's policies and procedures relating to Clinical Investigations Related Functions; and
  - h. Spectranetics's processes, policies, and procedures for investigating, documenting, resolving, and taking appropriate disciplinary action for situations potentially involving non-compliant Clinical Investigations Related Functions.
3. The IRO shall review Spectranetics's systems, policies, processes, and procedures applicable to Reporting Related Functions:
- a. Spectranetics's processes, policies, and procedures for reporting adverse events, including processes to ensure compliance with MDR regulations at 21 C.F.R. Part 803;
  - b. Spectranetics's processes, policies, and procedures relating to reporting obligations as provided in 21 C.F.R. § 814.84, including submission of summaries and bibliographies of information not submitted as part of a pre-market application, for devices with FDA premarket approval under 21 U.S.C. § 360(e)(2),
  - c. the processes and procedures by which Spectranetics's Compliance Office monitors and identifies situations in which it appears that Spectranetics has failed to comply with FDA Reporting Related requirements and/or Spectranetics's own Reporting Related policies and procedures; and
  - d. Spectranetics's processes, policies, and procedures for investigating, documenting, resolving, and taking appropriate disciplinary action for failure to comply with Reporting Related

requirements and/or Spectranetics's own Reporting Related policies and procedures.

#### B. Systems Review Report.

The IRO shall prepare a report based upon each Systems Review. For each of the Reviewed Policies and Procedures identified in Section II.A above, the report shall include the following items:

1. a description of the documentation (including policies) reviewed and any personnel interviewed;
2. a detailed description of Spectranetics's systems, policies, processes, and procedures relating to the items identified in Sections II.A.1-3 above, including a general description of Spectranetics's control and accountability systems (e.g., documentation and approval requirements, and tracking mechanisms) and written policies regarding the Reviewed Policies and Procedures;
3. a description of the manner in which the control and accountability systems and the written policies relating to the items identified in Sections II.A.1-3 above are made known or disseminated within Spectranetics;
4. a detailed description of any system(s) used to track and respond to requests and inquiries regarding off-label uses of Spectranetics products;
5. findings and supporting rationale regarding any weaknesses in Spectranetics's systems, processes, policies, and procedures relating to the Reviewed Policies and Procedures, if any; and
6. recommendations to improve any of the systems, policies, processes, or procedures relating to the Reviewed Policies and Procedures, if any.

#### III. Transactions Review

As described more fully below in Sections III.A-E, the Transactions Review shall be based upon a review of a sample of documents, including patient records and other documents relating to patients participating in clinical investigations or clinical registries involving Spectranetics products. The IRO shall report on all aspects of the Transactions Review in the Transactions Review Reports.

A. Definitions.

1. Sampling Unit: A patient participating in a Clinical Investigation or clinical registry using a Spectranetics product conducted inside the United States.
2. Population: All patients participating in a Clinical Investigation or clinical registry using a Spectranetics product conducted inside the United States during the reporting period.
3. Error: Sampled patients whose medical record and associated documents is missing documentation described in the methodology in Section III.C, below, or for whom there is an adverse finding for Inquiries III.C.3-7 below.

B. Sample: The IRO shall randomly select 40 patients from all patients participating in a Clinical Investigation or clinical registry using a Spectranetics product conducted inside the United States during the reporting period. The IRO shall conduct the review based on supporting documentation in Spectranetics' possession and copies of supporting documentation and patient records obtained from Spectranetics Clinical Investigation and clinical registry sites.

C. Methodology: For each Sampling Unit, the IRO shall review the documentation and evaluate or identify the following ("Inquiries"):

1. Identify the legal authority under which the Spectranetics may distribute, or cause the distribution of, the device used in the Clinical Investigation or Registry;
2. After evaluating the purpose of the study, whether the study was a Clinical Investigation;
3. Whether the patient was clinically eligible for inclusion in the Clinical Investigation or Registry;
4. If applicable, whether Institutional Review Board approval was obtained for the study;
5. Whether patient's informed consent was obtained;

6. If an adverse event occurred, whether it was appropriately reported within Spectranetics; and
7. If an adverse event occurred, whether it was appropriately reported to the FDA under the appropriate reporting requirements at 21 C.F.R. Part 803 or 21 C.F.R. § 812.150.

D. Other Requirements.

1. Replacement Sampling. Replacement sampling is not permitted for Sampling Units with missing documentation.
2. Use of First Samples Drawn. Sampling Units selected in each first sample shall be used (i.e., it is not permissible to generate more than one list of random samples and then select one for use).

E. Transaction Review Report. For each Reporting Period, the IRO shall prepare a report based on its Transactions Review. The report shall include the following:

1. General Elements to Be Included in Report
  - a. Review Objectives: A clear statement of the objective intended to be achieved by the review;
  - b. Population: A description of the Population;
  - c. Review Protocol: A detailed narrative description of the procedures performed and a description of the Sampling Unit and universe utilized in performing the procedures for each Sample Unit reviewed; and
  - d. Sources of Data: A full description of documentation and other information, if applicable, relied upon by the IRO in performing the Transactions Review.
2. Statistical Sampling Documentation.
  - a. The number of Sampling Units in the sample;
  - b. The number of Sampling Units for which an Error was identified and an explanation of the Error;

- c. A copy of the printout of the random numbers generated by the “Random Numbers” function of the statistical sampling software used by the IRO, including the seed number; and
  - d. A description or identification of the statistical sampling software package used to select the sample.
3. Results to be Included in Report. The following results shall be included in each Promotional and Product Services Review Report:
- a. A narrative explanation of the IRO’s findings and supporting rationale (including reasons for Errors and patterns noted, etc.) based on the Inquiries conducted as part of the Transactions Review.
  - b. A narrative explanation of the IRO’s findings and supporting rationale regarding any weaknesses in Spectranetics's systems, processes, policies, procedures, and practices relating to the Inquiries, if any;
  - c. recommendations for improvement in Spectranetics's systems, processes, policies, procedures, and practices relating to the Inquiries; and
  - d. a spreadsheet identifying by Sampling Unit the results of each Inquiry.
4. Credentials. The names and credentials of the individuals who: (a) designed the statistical sampling procedure for the Transactions Review and (b) performed the Transactions Review.