

CORPORATE INTEGRITY AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL
OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
BOSTON SCIENTIFIC CORPORATION

I. PREAMBLE

Boston Scientific Corporation 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). Notwithstanding the fact that Boston Scientific Corporation (“Boston Scientific”) is the party to this CIA and responsible for ensuring its implementation, the undertakings in this CIA relate only to its Cardiac Rhythm Management business activities and the following related corporate entities: Guidant Corporation, Cardiac Pacemakers, Inc. and Guidant Sales Corporation (collectively, “Guidant/CRM”) and those persons who meet the definition of Covered Persons set forth below in Section II. Contemporaneously with this CIA, Boston Scientific is entering into a Settlement Agreement with the United States. This CIA shall apply only to the U.S. operations of Guidant/CRM that are subject to U.S. Federal health care program requirements.

Boston Scientific is the parent corporation of each of the corporate entities that comprise Guidant/CRM. Prior to the effective date of this CIA Boston Scientific established a voluntary compliance program (known as the “Global Compliance Program”), which includes a Chief Compliance Officer, Global Compliance Program staff, a Global Compliance Steering Committee, a Code of Conduct, written policies and procedures, a compliance education and training program, review and disciplinary procedures, a confidential disclosure program, an ineligible persons screening program, and internal audit and review procedures. The Global Compliance Program is fully applicable to Guidant/CRM. Boston Scientific shall continue to apply the Global Compliance Program to Guidant/CRM operations throughout the term of the CIA and shall do so in accordance with the terms set forth below. The Global Compliance Program may be modified, as deemed appropriate by Boston Scientific, but at a

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minimum, Boston Scientific shall ensure that during the term of this CIA, it shall comply with the obligations as set forth herein.

II. TERM AND SCOPE OF THE CIA

A. The period of the compliance obligations assumed by Boston Scientific under this CIA shall be 5 reporting periods as defined below. The effective date of this CIA shall be the date on which the final signatory of this CIA executes this CIA (Effective Date). The first Reporting Period shall be from the Effective Date through December 31, 2010. The second and subsequent Reporting Periods shall be from January 1 through December 31 for each of the subsequent four calendar years. Each period, beginning with the 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) Boston Scientific's final Annual Report; or (2) any additional materials submitted by Boston Scientific pursuant to OIG's request, whichever is later.

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

1. "Arrangements" shall mean every arrangement or transaction entered into by or on behalf of Guidant/CRM that involves, directly or indirectly, the offer, payment, solicitation, or receipt of anything of value; and is between Guidant/CRM and any actual or potential source of U.S. health care business or referrals to Guidant/CRM or any actual or potential recipient of U.S. health care business or referrals from Guidant/CRM. The term "source" shall mean any U.S. Health Care Provider (HCP), Health Care Institution (HCI), physician, contractor, vendor, or agent and the term "health care business or referrals" shall be read to include referring, recommending, arranging for, ordering, leasing, or purchasing of any good, facility, item, or service for which payment may be made in whole or in part by a Federal health care program.

a. "Contractual Arrangements" shall mean every Arrangement that is contractual in nature and shall include all Arrangements related to provision of services to Guidant/CRM, including, but not limited to, training, education, speaking, consulting, research, clinical studies, focus groups, and physician advisory boards; and intellectual property.

b. "Non-Contractual Arrangements" shall mean all Arrangements that are not Contractual Arrangements.

2. "Covered Persons" includes:

a. all owners of Boston Scientific 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 directors of Boston Scientific;

c. all officers and employees of Guidant/CRM who are based in the United States or have job responsibilities in the United States with respect to Guidant/CRM; and all officers and employees of Boston Scientific who have line or management responsibility with respect to the sales or marketing of Guidant/CRM products, except as carved out below in this Section II.C.2; and

d. all contractors, subcontractors, agents, and other persons who are not Third Party Personnel who perform sales or marketing of Government Reimbursed Products that would otherwise be performed by Guidant/CRM employees on behalf of Guidant/CRM. This definition does not include HCP and/or HCIs who enter into Arrangements as defined above with Guidant/CRM.

Notwithstanding the above, the term "Covered Persons" does not include: (1) 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; or (2) employees, contractors, subcontractors, agents, and other persons of Boston Scientific and/or Guidant/CRM who perform only (i) product building, movement or inspection functions, including product builders, inspectors, material handlers and manufacturing or warehouse functions; (ii) customer service, technical support services and telephone operators; and (iii) physical plant maintenance and janitorial duties, cafeteria-related duties, and/or similar non-core Guidant/CRM business related duties.

3. "Arrangements Covered Persons" includes each Covered Person involved with the development, approval, management, or review of Guidant/CRM's Arrangements, as such term is defined in Section II.C.1.

4. "Government Reimbursed Products" refers to all Guidant/CRM medical devices manufactured, promoted or sold by Guidant/CRM in the U.S. that are reimbursed by Federal health care programs.

5. The term "Third Party Educational Activity" shall mean any continuing medical education (CME), disease awareness, or other scientific, educational, or professional program, meeting, or event conducted by a Third Party and financially supported by Boston Scientific, including but not limited to, sponsorship of third-party symposia at medical conferences.

6. "Third Party Personnel" shall mean personnel of the entities with whom Boston Scientific has or may in the future (during the term of this CIA) enter into agreements to co-sell or market a Government Reimbursed Product in the United States or to engage in joint sales and marketing activities in the United States relating to such a product. Boston Scientific has represented that: (a) Third Party Personnel are employed by entities independent of Boston Scientific; (b) Boston Scientific does not control the Third Party Personnel; and (c) it would be commercially impracticable to compel the compliance of Third Party Personnel with the requirements set forth in this CIA. Boston Scientific agrees to promote compliance by Third Party Personnel with Federal health care programs by complying with the provisions set forth below in Sections III.B.2, III.C.7, V.A.3 and 6.c.

III. CORPORATE INTEGRITY OBLIGATIONS

Boston Scientific shall continue to maintain and apply the Global Compliance Program to the operations of Guidant/CRM and ensure that it includes the following elements:

A. Chief Compliance Officer, Committee, and Board Responsibilities.

1. *Chief Compliance Officer.* Boston Scientific has appointed, and shall maintain during the term of the CIA, an individual to serve as its Chief Compliance

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Officer. To the extent necessary, within 120 days after the Effective Date, Boston Scientific shall modify the position description, scope of responsibility, and authority of the Chief Compliance Officer such that the following requirements are satisfied. The Chief Compliance Officer shall be primarily responsible for developing and implementing policies, procedures, and practices designed to ensure compliance with the requirements set forth in this CIA and with Federal health care program requirements. The Chief Compliance Officer shall be a member of senior management of Boston Scientific, shall make periodic (at least quarterly) reports regarding compliance matters directly to the Board of Directors of Boston Scientific (or designated committee), and shall be authorized to report on such matters to the Board of Directors (or designated committee) 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 Boston Scientific as applied to Guidant/CRM as well as for any reporting obligations created under this CIA.

Boston Scientific shall report to OIG, in writing, any changes in the identity or the 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 15 days after such a change.

2. *Compliance Committee.* Prior to the Effective Date, Boston Scientific established a Global Compliance Steering Committee, and Boston Scientific shall maintain a Global Compliance Steering Committee during the term of this CIA. To the extent necessary, within 120 days after the Effective Date, Boston Scientific shall amend the duties, responsibilities, and authorities of the Global Compliance Steering Committee to meet the requirements set forth below. The Global Compliance Steering Committee shall, at a minimum, include the Chief Compliance Officer and other members of senior management of Boston Scientific and/or Guidant/CRM necessary to meet the requirements of this CIA (e.g., senior executives of relevant departments, such as Human Resources, Corporate Analysis and Control (internal audit), Legal, Clinical Affairs, and Sales and Marketing). The Compliance Officer shall chair the Global Compliance Steering Committee and the Global Compliance Steering Committee shall support the Chief Compliance Officer in fulfilling his/her responsibilities including with regard to the CIA (e.g., shall assist in the analysis of the organization's risk areas and shall oversee monitoring of internal and external audits and investigations).

Boston Scientific shall report to OIG, in writing, any changes in the functions or management levels of individuals that make up the composition of the Global Compliance Steering Committee, or any actions or changes that would affect the Global Compliance Steering 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 Committee Resolution.* The Audit or Quality Compliance committee of the Board of Directors of Boston Scientific (Board Committee) shall be responsible for the review and oversight of matters related to compliance with Federal health care program requirements and the obligations of this CIA. The Board Committee shall, at a minimum, be responsible for the following:

a. meeting in person or via tele- or video-conference at least quarterly to review and oversee Boston Scientific's Compliance Program, as applied to Guidant/CRM, including but not limited to the performance of the Chief Compliance Officer and other Global Compliance Program personnel.

b. for each Reporting Period of the CIA, adopting a resolution summarizing its review and oversight of Boston Scientific's compliance with Federal health care program requirements and the obligations of this CIA by Boston Scientific and/or Guidant/CRM, as applicable. Each individual member of the Board Committee shall sign a statement indicating that he or she agrees with the resolution.

At minimum, the resolution shall include the following language:

"The [Name of the Board Committee] has made a reasonable inquiry into the operations of Boston Scientific's Compliance Program as applied to Guidant/CRM, including the performance of the Chief Compliance Officer and the Global Compliance Program personnel. Based on its inquiry, [Name of the Board Committee] has concluded that, to the best of its knowledge, Boston Scientific has implemented an effective Global Compliance Program, as applied to Guidant/CRM, to meet the Federal health care program requirements and the obligations of the CIA."

If the Board Committee is unable to provide such a conclusion in the resolution, the Board Committee shall include in the resolution a written explanation of the reasons why it is unable to provide the conclusion and the steps it is taking to implement an effective Global Compliance Program at Boston Scientific, as applied to Guidant/CRM.

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

4. *Management Accountability and Certifications:* Within 120 days after the Effective Date, Boston Scientific represents that for each Covered Person who is an employee compliance shall be a component of his or her performance objective. In addition to the responsibilities set forth in this CIA for all Covered Persons, certain Boston Scientific employees ("Certifying Employees") are specifically expected to monitor and oversee activities within their areas of authority and shall annually certify, in writing or electronically, that the applicable Boston Scientific Corporation component is compliant with Federal health care program requirements and the obligations of this CIA. These Certifying Employees shall include, at a minimum, the following individuals from Guidant/CRM: President and all vice presidents of Sales and Marketing as well as the Vice President and General Manager of electrophysiology and the head of Clinical Affairs.

For each Reporting Period, each Certifying Employee shall sign a certification that states:

"I have been trained on and understand the applicable Federal health care program compliance requirements and obligations of the CIA and responsibilities as they relate to [department or functional area], an area under my supervision. My job responsibilities include ensuring compliance with regard to the [insert name of the department or functional area.] To the best of my knowledge, except as otherwise described herein, the _____ [insert name of department or functional area] of Guidant/CRM is in compliance with all applicable Federal health care program requirements and the obligations of the CIA."

B. Written Standards.

1. *Code of Conduct.* Prior to the Effective Date, Boston Scientific developed, implemented and distributed or otherwise made available a written Code of Conduct to its employees, officers, and directors, including those of its subsidiaries, including Guidant/CRM. Boston Scientific currently requires all newly employed Covered Persons to certify in writing or electronically, that they have received, read, understood, and shall abide by Boston Scientific's Code of Conduct. Boston Scientific

shall make the promotion of, and adherence to, the Code of Conduct an element in evaluating the performance of all employees who are Covered Persons for all performance review cycles that begin after the Effective Date.

The Code of Conduct sets forth and shall continue to set forth, at a minimum, the following elements:

- a. the commitment to full compliance with all Federal health care program requirements;
- b. the requirement that all Covered Persons shall be expected to comply with all Federal health care program requirements and with Boston Scientific's and/or Guidant/CRM's own Policies and Procedures as implemented pursuant to Section III.B (including the requirements of this CIA);
- c. the requirement that all Covered Persons shall be expected to report to the Chief Compliance Officer, or other appropriate individual designated by Boston Scientific, suspected violations of any Federal health care program requirements or of Boston Scientific's and/or Guidant/CRM's own Policies and Procedures;
- d. the possible consequences to both Boston Scientific and Covered Persons of failure to comply with Federal health care program requirements and with Boston Scientific's and/or Guidant/CRM's own Policies and Procedures and the failure to report such noncompliance; and
- e. the right of all individuals to use the Disclosure Program described in Section III.F, and the commitment to nonretaliation and to maintain, as appropriate, confidentiality and anonymity with respect to such disclosures.

To the extent not already accomplished, within 120 days after the Effective Date, the Code of Conduct shall be distributed to each Covered Person. By May 31, 2010, each Covered Person shall certify, in writing or electronically, that he or she has received, read, understood, and shall abide by Boston Scientific's Code of Conduct. New Covered Persons shall receive the Code of Conduct within 30 days after becoming a Covered

Person or within 120 days after the Effective Date, whichever is later and shall complete the required certification within 30 days after becoming a Covered Person or by May 31, 2010, whichever is later.

Boston Scientific 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 or made available (electronically or in hard-copy form) within 30 days after any revisions are finalized by Global Compliance Program staff. Each Covered Person shall certify, in writing or electronically, 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. *Third Party Personnel.* Within 120 days after the Effective Date, and annually thereafter by the anniversary of the Effective Date, Boston Scientific shall send a letter to each entity employing Third Party Personnel. The letter shall outline Boston Scientific's obligations under the CIA and its commitment to full compliance with all Federal health care program requirements. The letter shall include a description of Boston Scientific's Global Compliance Program, include a link to Boston Scientific's Code of Conduct and request the entity employing Third Party Personnel to either: (a) make a copy of the Global Compliance Program available to its employees, contractors and agents; or (b) represent to Boston Scientific that it has and enforces a substantially comparable code of conduct and compliance program for its employees, contractors and agents.

3. *Policies and Procedures.* Prior to the Effective Date, Boston Scientific implemented written Policies and Procedures regarding the operation of the Global Compliance Program and compliance with Federal health care program requirements. To the extent not already accomplished, within 120 days after the Effective Date, Boston Scientific shall implement written Policies and Procedures regarding the operation of its Global Compliance Program and Guidant/CRM's compliance with Federal health care program 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 requirements set forth in Section III.D (Compliance with the Anti-Kickback Statute), including but not limited to the Arrangements Database, the internal review and approval

process, and the tracking of remuneration to and from sources of health care business or referrals;

- c. compensation (including salaries and bonuses) for Arrangements Covered Persons. These Policies and Procedures shall be designed to ensure that financial incentives do not inappropriately motivate such individuals to engage in improper promotion, sales, marketing, pricing, or contracting for Boston Scientific's products;
- d. disciplinary policies and procedures for violations of Boston Scientific's Policies and Procedures, including policies relating to Federal health care program requirements;
- e. appropriate ways to conduct sales and marketing of Government Reimbursed Products in compliance with all applicable Federal health care program requirements, including, but not limited to the Federal anti-kickback statute (codified at 42 U.S.C. § 1320a-7b), and the False Claims Act (codified at 31 U.S.C. §§ 3729-3733);
- f. consultant or other fee-for-service arrangements entered into with HCPs or HCIs (including, but not limited to, speaker programs, speaker training programs, advisory boards, proctorships, preceptorships, or any other financial relationship with an HCP or HCI) and all events and expenses relating to such engagements or arrangements. These Policies and Procedures shall be designed to ensure that the engagements, arrangements, and related events are used for legitimate and lawful purposes in accordance with applicable Federal health care program requirements. The policies shall include requirements about the uses, content, and circumstances of such engagements, arrangements, and events; and
- g. sponsorship or funding of grants (including educational grants) or charitable contributions to HCPs and/or HCIs. These Policies and Procedures shall be designed to ensure that Guidant/CRM's

sponsorship or funding complies with all applicable Federal health care program requirements;

- h. funding of, or participation in, any Third Party Educational Activity as defined in Section II.C.5 above. These Policies and Procedures shall be designed to ensure that Guidant/CRM's sponsorship or funding of, or participation in, such programs satisfies all applicable Federal health care program requirements related to the sponsorship of any Third Party Educational Activity;
- i. sponsorship or funding of research or related activities (including clinical trials and market research, or authorship of articles or other publications) by Guidant/CRM in a manner that is designed to ensure that Guidant/CRM's funding or sponsorship of, or participation in, such activities complies with all applicable Federal health care program requirements. In addition, such Policies and Procedures shall ensure that sales and marketing activities are separate from research activities (i.e. enrollment in post-market studies or clinical trials).

To the extent not already accomplished, within 120 days after the Effective Date, the relevant portions of the Policies and Procedures shall be distributed and/or made available (electronically or in hard-copy form) to all Covered Persons to the extent that their 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), Boston Scientific 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 and/or made available (electronically or in hard-copy form) to all individuals whose job functions relate to those Policies and Procedures.

C. Training and Education.

Boston Scientific represents that it and/or Guidant/CRM provides training to Guidant/CRM employees on a regular basis concerning a variety of topics. The training covered by this CIA need not be separate and distinct from the regular training provided,

but instead may be integrated fully into such regular training so long as the training covers the areas specified below.

1. *General Training.* Within 120 days after the Effective Date, Boston Scientific shall provide at least one hour of General Training to each Covered Person. This training, at a minimum, shall explain:

- a. CIA requirements; and
- b. The Global Compliance Program and its applicability to Guidant/CRM (including the Code of Conduct and the Policies and Procedures as they pertain to general compliance issues).

New Covered Persons shall be required to complete 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 be required to complete at least one hour of General Training in each subsequent Reporting Period.

2. *Arrangements Training.* Within 120 days after the Effective Date, each Arrangements Covered Person shall be required to complete at least three hours of Arrangements Training, in addition to the General Training required above. The Arrangements Training shall include a discussion of:

- a. Arrangements that potentially implicate the Anti-Kickback Statute, as well as related regulations and other guidance documents related to this statute;
- b. all Boston Scientific policies, procedures, and other requirements relating to Arrangements, including but not limited to the Arrangements Database, the internal review and approval process, and the tracking of remuneration to and from sources of health care business or referrals required by Section III.D of the CIA;
- c. the personal obligation of each individual involved in the development, approval, management, or review of Guidant/CRM's Arrangements to know the applicable legal requirements and Boston Scientific's policies and procedures;

- d. the legal sanctions under the Anti-Kickback Statute; and
- e. examples of violations of the Anti-Kickback Statute.

New Arrangements Covered Persons shall be required to complete this training within 30 days after the beginning of their employment or becoming Arrangements Covered Persons, or within 120 days after the Effective Date, whichever is later. A Guidant/CRM employee who has completed the Arrangements Training shall review a new Arrangements Covered Person's Arrangements-related work until such time as the new Arrangements Covered Person completes his or her Arrangements Training.

After receiving the initial Arrangements Training described in this Section, each Arrangements Covered Person shall receive at least two hours of Arrangements Training in each subsequent Reporting Period.

3. *Certification.* Each individual who is required to complete training shall certify, in writing, or electronically, that he or she has completed the required training. The certification shall specify the type of training completed 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.

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

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

6. *Computer-based Training.* Boston Scientific may provide the training required under this CIA through appropriate computer-based training approaches. If Boston Scientific 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. If Boston Scientific chooses to provide computer-based training, all applicable references to "hours" in this Section III.C shall mean "normative hours", meaning the number of hours usually

required to complete the requirements of a training course through computer-based modules. Normative hours may vary from actual hours of training.

7. *Third Party Personnel.* Boston Scientific shall use its best efforts to encourage Third Party Personnel's attendance and participation in General and Arrangements Training, as applicable. The Chief Compliance Officer shall maintain records of the names and percentage of all such Third Party Personnel who do and do not attend General and/or Arrangements Training, and shall include such percentages in the Implementation Report and each Annual Report to the OIG. Such records shall also be available for inspection by the OIG.

D. Compliance with the Anti-Kickback Statute.

1. *Arrangements Procedures.* Within 120 days after the Effective Date, Boston Scientific and/or Guidant/CRM, as appropriate, shall create procedures reasonably designed to ensure that each existing Arrangement under which a transfer of value will occur during the term of this CIA and new or renewed Arrangement does not violate the Anti-Kickback Statute or the regulations, directives, and guidance related to the Anti-Kickback statute (Arrangements Procedures). These procedures shall include the following:

- a. creating and maintaining a database of all existing Arrangements under which a transfer of value will occur during the term of this CIA and new or renewed Contractual Arrangements that shall contain the information specified in Appendix B (Arrangements Database);
- b. tracking remuneration to and from all parties to the Contractual Arrangements;
- c. tracking service and activity logs to ensure that parties to the Contractual Arrangement are performing the services required under the applicable Contractual Arrangement(s) (if applicable);
- d. establishing and implementing a written review and prior approval process for all Contractual Arrangements, including but not limited to a legal review by counsel with expertise in the Anti-Kickback Statute and appropriate documentation of all internal

controls, the purpose of which is to help ensure that all new or renewed Contractual Arrangements under which a transfer of value will occur during the term of this CIA do not violate the Anti-Kickback Statute;

e. establishing and implementing a written process for monitoring Non-Contractual Arrangements, including but not limited to an annual legal review by counsel with expertise in the Anti-Kickback Statute and appropriate documentation of all internal controls, the purpose of which is to help ensure that all Non-Contractual Arrangements do not violate the Anti-Kickback Statute;

f. requiring the Chief Compliance Officer to review the Arrangements Database, internal review and approval process, and other Arrangements Procedures on at least a quarterly basis and to provide a report on the results of such review to the Global Compliance Steering Committee; and

g. implementing effective responses when suspected violations of the Anti-Kickback Statute are discovered, including disclosing Reportable Events pursuant to Section III.I (Reporting) when appropriate.

2. *New or Renewed Contractual Arrangements.* Prior to entering into new Contractual Arrangements or renewing existing Contractual Arrangements, in addition to complying with the Arrangements Procedures set forth above, Boston Scientific and/or Guidant/CRM, as appropriate, shall comply with the following requirements (Arrangements Requirements):

a. Ensure that each Contractual Arrangement is set forth in writing and signed by Boston Scientific and/or Guidant/CRM, as appropriate, and the other parties to the Contractual Arrangement;

b. Include in the written agreement a requirement that all individuals who meet the definition of Covered Persons shall comply with the Global Compliance Program, including the training related to the Anti-Kickback Statute. Additionally, Guidant/CRM shall include a description of the Global Compliance Program, a link to the Boston

Scientific Code of Conduct and an outline of Boston Scientific's and Guidant/CRM's obligations under the CIA and its commitment to full compliance with all Federal health care program requirements.

c. Include in the written agreement a certification or a representation and warranty by the parties to the Contractual Arrangement that the parties shall not violate the Anti-Kickback Statute with respect to the performance of the Contractual Arrangement.

3. *Records Retention and Access.* Boston Scientific shall retain and make available to OIG, upon request, the Arrangements Database and all supporting documentation of the Arrangements subject to this Section and, to the extent available, all non-privileged communications related to the Arrangements and the actual performance of the duties under the Arrangements.

E. Review Procedures.

1. *General Description.*

a. *Engagement of Independent Review Organization.* Within 120 days after the Effective Date, Boston Scientific shall engage an individual and/or entity (or entities), such as an accounting, auditing, law or consulting firm (hereinafter "Independent Review Organization" or "IRO"), to perform reviews required by this CIA to assist Boston Scientific in assessing compliance with the obligations under Section III.D of this CIA (Arrangements Review) The applicable requirements relating to the IRO(s) are outlined in Appendix A to this CIA, which is incorporated by reference.

Each IRO engaged by Boston Scientific shall have expertise in applicable Federal health care programs as may be appropriate to the Review for which the IRO is retained. Each IRO shall assess, along with Boston Scientific, 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.

b. *Frequency of Arrangements Reviews.* The Arrangements Review shall be performed annually and shall cover each of the Reporting Periods. If there are no material changes in Guidant/CRM's systems, processes, policies, and procedures relating to Post-Approval Studies, the Studies Systems Review shall be performed for the first and fourth Reporting Period. If Guidant/CRM materially changes its systems, processes, policies, and procedures relating to Post-Approval Studies, the IRO shall perform a Studies Systems Review for the Reporting Period(s) in which such changes were made in addition to conducting the Review of 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 changes. The IRO(s) shall perform all components of each Annual Arrangements Review.

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

2. *Arrangements Review.* The IRO shall perform a review to assess whether Boston Scientific and/or Guidant/CRM, as appropriate, is complying with the Arrangements Procedures and Arrangements Requirements required by Section III.D.1 and III.D.2 of this CIA. The IRO shall randomly select a sample of 40 Contractual Arrangements for which payments were made during the applicable Reporting Period. The IRO shall assess whether Boston Scientific and/or Guidant/CRM, as appropriate, has implemented the Arrangements Procedures and, for each selected Arrangement, the IRO shall assess whether Boston Scientific and/or Guidant/CRM, as appropriate, has complied with the Arrangements Procedures and Arrangements Requirements specifically with respect to that Arrangement. The IRO's assessment shall include, but is not limited to: (a) verifying that the Contractual Arrangement is listed in the Arrangements Database; (b) verifying that the Contractual Arrangement was subject to the internal review and approval process (including both a legal/compliance and business review) and obtained the necessary approvals and that such review and approval is

appropriately documented; (c) verifying (using a representative sample of Contractual Arrangements) that the remuneration related to the Contractual Arrangement is properly tracked; (d) verifying that the service and activity logs (if applicable) and/or other documented proof of performance is provided to and reviewed by Boston Scientific and/or Guidant/CRM, as appropriate; (e) verifying that the Chief Compliance Officer is reviewing the Arrangements Database, internal review and approval process, and other Arrangements Procedures on a quarterly basis and reporting the results of such review to the Global Compliance Steering Committee; (f) verifying that effective responses are being implemented when violations of the Anti-Kickback Statute are discovered; and (g) verifying that Boston Scientific and/or Guidant/CRM, as appropriate, has met the requirements of Section III.D.2.

3. *Systems Review for Post-Approval Studies.* The IRO shall have sufficient expertise in clinical research and applicable federal laws and regulations to perform a review of each of Guidant/CRM's extant post-approval studies. The IRO shall assess whether the study is designed to achieve its stated purpose, including whether the study is designed to obtain clinical information or whether it is designed to market the product. The IRO shall summarize each study by providing a description of the purpose, protocol, and timeframe. In assessing the study, the IRO shall consider, at a minimum, the following questions: i) the purpose of the research; ii) whether the research has been approved by an institutional review board; iii) whether participation in the study will require subjects to make extra visits to HCPs and if so, who will pay for the visits and how much will be paid; iv) how long the study will continue; v) whether a patient may be part of a control group that will receive no treatment or a placebo; vi) what the participants will be told after the study ends; vii) whether participants are informed that the issue of whether the device is the best treatment remains a research question; viii) whether every piece of data collected has been verified; and ix) the name(s) and credential(s) of each person who designed the study and any underlying protocol. Where applicable, the IRO shall review protocols provided to the FDA, as well as any correspondence with the FDA, concerning the study under review. The IRO shall maintain copies of this information in its files.

For purposes of this subsection Post-Approval Studies shall mean research studies wherein Guidant/CRM is compensating HCPs or HCIs for collecting procedure and/or device performance information on the use of commercially available Guidant/CRM devices. Studies in which either the HCPs/HCIs or Guidant/CRM are blinded to the respective party's identity shall be excluded from this definition (studies that are blinded in either direction). Studies in which Guidant/CRM

has provided an unrestricted research grant to a third party to conduct a study that does not involve Guidant/CRM product development or marketing shall also be excluded from this definition.

4. *IRO Review Reports.* The IRO(s) shall prepare a report (or reports) based upon the Arrangements Review performed. The Arrangements Review Report shall include the IRO's findings with respect to: (a) whether Boston Scientific and/or Guidant/CRM, as appropriate, has generally implemented the Arrangements Procedures described in Section III.D.1; and (b) specific findings as to whether Boston Scientific and/or Guidant/CRM, as appropriate, has complied with the Arrangements Procedures and Arrangements Requirements with respect to each of the randomly selected Arrangements reviewed by the IRO. In addition, the Arrangements Review Report shall include any observations, findings, and recommendations on possible improvements to Boston Scientific's and/or Guidant/CRM's policies, procedures, and systems in place to ensure that all Arrangements do not violate the Anti-Kickback Statute.

5. *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 results are inaccurate, OIG may, at its sole discretion, conduct its own review to determine whether the applicable IRO Review complied with the requirements of the CIA and/or the findings or Review results are inaccurate (Validation Review). Boston Scientific 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 Boston Scientific's final Annual Report shall be initiated no later than one year after Boston Scientific's final submission (as described in Section II) is received by OIG.

Prior to initiating a Validation Review, OIG shall notify Boston Scientific 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, Boston Scientific 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. Boston Scientific agrees to provide any additional information as may be requested by OIG under this Section III.E.3 in an expedited manner. OIG will attempt in good faith to resolve any Review issues with Boston Scientific 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.

6. *Independence and Objectivity Certification.* The IRO shall include in its report(s) to Boston Scientific 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 IRO Review and that it has concluded that it is, in fact, independent and objective.

F. Disclosure Program.

Boston Scientific currently has a disclosure program that Boston Scientific represents is designed to facilitate communications relating to compliance with Federal health care program requirements and Boston Scientific's policies (the "Disclosure Program"). During the term of this CIA, Boston Scientific shall continue to maintain a Disclosure Program that includes a mechanism (e.g., a toll-free compliance telephone line and/or online electronic reporting) 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 Guidant/CRM's policies, conduct, practices, or procedures with respect to a Federal health care program believed by the individual to be a potential violation of criminal, civil, or administrative law. Boston Scientific shall appropriately publicize the existence of the disclosure mechanism (e.g., via periodic 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, Boston Scientific 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 confidential disclosure log pertaining to Guidant/CRM, which shall include a record and summary of each disclosure received that is related to Guidant/CRM (whether anonymous or not), the

status of the respective internal reviews, and any corrective action taken in response to the internal reviews. The confidential disclosure log as to allegations involving Guidant/CRM shall be made available to OIG upon request.

G. 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.* Boston Scientific shall ensure that all prospective and current Covered Persons are not Ineligible Persons, by implementing the following screening requirements.

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

c. Boston Scientific 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) Boston Scientific to (if applicable) refrain from billing Federal health care programs for items or services furnished, ordered, or prescribed by an Ineligible Person. Boston Scientific understands that items or services furnished by excluded persons are not payable by Federal health care programs and that Boston Scientific may be liable for criminal, civil, and administrative sanctions for employing or contracting with an excluded person regardless of whether Boston Scientific meets the requirements of Section III.G.

3. *Removal Requirement.* If Boston Scientific has actual notice that a Covered Person has become an Ineligible Person, Boston Scientific shall remove such Covered Person from responsibility for, or involvement with, Boston Scientific's 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 Boston Scientific 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, Boston Scientific 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.

H. Notification of Government Investigation or Legal Proceedings.

Within 30 days after discovery by Boston Scientific, Boston Scientific shall notify OIG, in writing, of any ongoing investigation or legal proceeding known to Boston Scientific's senior management conducted or brought by a U.S.-based governmental entity or its agents involving an allegation that Guidant/CRM 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. Boston Scientific 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.

I. Reporting.

1. *Reportable Events.*

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

- i. a matter brought to the attention of Boston Scientific's senior management (i.e. a member of the corporate Operating Committee or any successor committee/group) relating to conduct of Guidant/CRM that a reasonable person would consider a probable violation of criminal, civil, or administrative laws applicable to any Federal health care program for which penalties and/or exclusion may be authorized; or
- ii. the filing of a bankruptcy petition by Boston Scientific.

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

b. *Reporting of Reportable Events.* If Boston Scientific determines (after a reasonable opportunity to conduct an appropriate review or investigation of the allegations) through any means that there is a Reportable Event, Boston Scientific 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 authorities implicated;
- ii. a description of Boston Scientific's actions taken to correct the Reportable Event; and
- iii. any further steps Boston Scientific 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 authorities implicated.
- v. Boston Scientific shall not be required to report as a Reportable Event any matter previously disclosed under Section III.H.

J. Reporting of Physician Payments.

1. *Posting of Payment Information*

By June 30, 2011, Guidant/CRM shall post in a prominent position on its website an easily accessible and readily searchable listing of all U.S.-based physicians and Related Entities (as defined below in Section III.J.2) or Product Decision-Makers (as defined below in Section III.J.2) who or which received Payments (as defined below in Section III.J.2) directly or indirectly from Guidant/CRM during the first three months of 2011.

After the initial posting, 90 days after the end of each subsequent calendar quarter, Guidant/CRM shall also post on its website a listing of updated information about all Payments provided during the preceding calendar quarter(s) in each calendar year. No later than March 31, 2012, and each March 31 of each of the three successive Reporting Period years, Guidant/CRM shall also post on its website a report of the cumulative

information about Payments made by Guidant/CRM during the preceding calendar year. The quarterly and annual reports shall be easily accessible and readily searchable.

Each listing made pursuant to this Section shall include a complete list of all individual physicians, Related Entities and/or Product Decision-Makers to whom or to which Guidant/CRM directly or indirectly made Payments in the preceding calendar quarter or year (as applicable). Each listing shall be arranged alphabetically according to the physicians' last name, the name of the Related Entity, or the name of the Product Decision-Maker. The Payment amount for each physician, Related Entity, or Product Decision Maker shall be reported in increments up to \$10,000 (*e.g.*, \$0 – 100; \$0 - \$1,000, \$0 - \$5,000; \$0 - \$10,000; \$0 - \$20,000; *etc.*) or in the actual amount paid, provided, however, that the Payment amounts shall be listed in the same way (incrementally or in actual amounts) for all physicians and/or Related Entities, or Product Decision-Maker on the listing. For each entry, the applicable listing shall include the following information: i) payee information (physician's, Product Decision-Maker's, HCI's full name); ii) if payment is to a Related Entity for services of a specific physician or Product-Decision-Maker, the name of Related Entity on whose behalf payment was made to the physician or Product Decision-Maker (if applicable); iii) city and state that the physician or Related Entity has provided to Guidant/CRM for contact purposes, or the Product Decision-Maker (as applicable); iii) the purpose of the Payment; and iv) the aggregate value of the Payment(s) in the preceding quarter(s) or year (as applicable).

2. Definitions and Miscellaneous Provisions.

Boston Scientific shall continue to make each annual listing and the most recent quarterly listing of Payment information available on its website at least throughout the term of this CIA. Boston Scientific shall retain and make available to OIG, upon request, all existing work papers, supporting documentation, correspondence, and records related to all applicable Payments and to the annual and quarterly listings of Payments. Nothing in this Section III.J affects the responsibility of Boston Scientific to comply with (or liability for noncompliance with) all applicable Federal health care program requirements and state laws as they relate to all applicable Payments made to physicians, Related Entities, or Product Decision-Makers.

If the proposed Physician Payments Sunshine Act of 2009 or similar legislation is enacted, the OIG shall determine whether the purposes of this Section III.J are reasonably satisfied by Boston Scientific's compliance with such legislation. In such case, and in its

sole discretion, the OIG may agree to modify or terminate provisions of Section III.J as appropriate.

For purposes of this Section III.J, the term “Payments” is defined to include all payments or transfers of value (whether in cash or in kind) made to physicians, Related Entities, and/or Product Decision-Makers. The term Payments includes, for example, payments or compensation for services rendered, grants, fees, honoraria, and payments relating to research or education. The term Payments also includes food, entertainment, gifts, trips or travel, product(s)/item(s) provided for less than fair market value; or other economic benefit. The term Payments does not include discounts, rebates, or other pricing terms.

For purposes of this Section III.J, the term “Related Entity” is defined to be any entity by or in which any physician receiving Payments is employed, has tenure, or has an ownership interest. The term “physician” as used herein does not include bona fide employees of Boston Scientific or its subsidiaries.

For purposes of this Section III.J, the term “Product Decision-Maker” is defined to be any individual or entity in a position to arrange for or recommend the purchasing, prescribing, ordering, or furnishing of any Government Reimbursed Product.

3. If Guidant/CRM does not make any Payments to physicians, Related Entities, or Product Decision-Makers during a Reporting Period, Boston Scientific shall not be required to post Payment information as set forth in Section III.K.1 for that Reporting Period. Instead, the Chief Compliance Officer shall certify that Guidant/CRM made no such Payments during the applicable Reporting Period. Boston Scientific shall include such certification(s) in the applicable Annual Report(s).

IV. CHANGES TO BUSINESS UNITS OR LOCATIONS

A. Change or Closure of Unit or Location. In the event that, after the Effective Date, Guidant/CRM changes locations or closes a business unit or location engaged in sales or marketing of Government Reimbursed Products, Boston Scientific 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. Transfers to Affiliates. Boston Scientific and/or Guidant/CRM may transfer the capital stock, or substantially all of the assets of Guidant/CRM, or any of the legal

entities that comprise Guidant/CRM to Boston Scientific or a direct or indirect wholly-owned subsidiary of Boston Scientific, provided that Boston Scientific shall notify the OIG of such transfer within 30 days thereafter, and the CIA shall be binding on such transferee with respect to the Guidant/CRM business unit, functions, and/or products.

C. Purchase or Establishment of New Unit or Location. In the event that, after the Effective Date, Guidant/CRM purchases or establishes a new business unit or location engaged in sales or marketing of Government Reimbursed Products for Guidant/CRM, Boston Scientific shall notify OIG no later than the date the purchase or establishment is publicly disclosed 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 program provider and/or supplier number, 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.

D. Sale of Unit or Location. In the event that, after the Effective Date, Guidant/CRM proposes to sell any or all of its business units or locations that are subject to this CIA, Boston Scientific shall notify OIG of the proposed sale no later than the date the sale is publicly disclosed. 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.

E. For purposes of this section IV, “business unit or location” shall mean physical places of business, where employees routinely carry out job responsibilities and does not include non-Boston Scientific-owned or leased properties such as offices operated out of individuals’ residences.

V. IMPLEMENTATION AND ANNUAL REPORTS

A. Implementation Report. Within 150 days after the Effective Date, Boston Scientific 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, and a summary of other noncompliance job responsibilities the Chief Compliance Officer may have;

2. the names and positions of the members of the Global Compliance Steering Committee required by Section III.A;

3. a copy of Boston Scientific's Code of Conduct required by Section III.B.1 and a copy of the letter (including all attachments) required by Sections III.B.2 sent to each party employing Third Party Personnel; (b) a list of all such existing Third Party Personnel agreements; and (c) a description of the Third Party Personnel entities' response to Boston Scientific's letter;

4. a copy of all Policies and Procedures required by Section III.B.3;

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

6. 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 for in-person training, a schedule of training sessions;

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

c. the percentage of Third Party Personnel who do and do not attend General and/or Arrangements Training (as referenced in Section III.C.)

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

7. 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 Boston Scientific and the IRO;

8. a certification from the IRO regarding its professional independence and objectivity with respect to Boston Scientific;

9. a description of the Disclosure Program required by Section III.F;

10. a description of the process by which Boston Scientific fulfills the requirements of Section III.G regarding Ineligible Persons;

11. the name, title, and responsibilities of any person who is determined to be an Ineligible Person under Section III.G; the actions taken in response to the screening and removal obligations set forth in Section III.G;

12. a list of all of Guidant/CRM's United States-based business units and locations (as that term is defined in Section IV) (including locations and mailing addresses, but excluding non-Boston Scientific-owned or leased properties such as offices operated out of individuals' residences) at which it performs sales and marketing of Government Reimbursed Products; the corresponding name under which each location is doing business; the corresponding phone numbers and fax numbers; each location's Federal health care provider or supplier number(s) (if applicable), and the name and address of each Federal health care program contractor to which Boston Scientific currently submits claims (if applicable);

13. a description of Guidant/CRM's corporate structure, including identification of any parent and sister companies, subsidiaries, and their respective lines of business; and

14. the certifications required by Section V.C.

B. Annual Reports. Boston Scientific shall submit to OIG annually a report with respect to the status of, and findings regarding, Boston Scientific's 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 Global Compliance Steering Committee described in Section III.A;

2. 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 Federal health care program requirements);

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

4. 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, for any in-person training, a schedule of training sessions; and

b. the number of Covered Persons required to be trained, percentage of Covered Persons actually trained, and an explanation of any exceptions (including the percentage of Third Party Personnel who do and do not attend General and/or Arrangements Training.)

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

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

6. Boston Scientific's response and corrective action plan(s) related to any issues raised by the reports prepared pursuant to Section III.E;

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

8. a certification from the IRO regarding its professional independence and objectivity with respect to Boston Scientific;

9. a summary of the disclosures in the confidential Guidant/CRM disclosure log required by Section III.F that relate to Federal health care programs;

10. any changes to the process by which Boston Scientific fulfills the requirements of Section III.G regarding Ineligible Persons;

11. the name, title, and responsibilities of any person who is determined to be an Ineligible Person under Section III.G; the actions taken by Boston Scientific in response to the screening and removal obligations set forth in Section III.G;

12. a summary describing any ongoing investigation or legal proceeding required to have been reported pursuant to Section III.H. 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;

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

14. a description of all changes to the most recently provided list of all business units or locations (as that term is defined in Section IV) (including addresses) as required by Section V.A.12; the corresponding name under which each location is doing business; and the corresponding phone numbers and fax numbers; each location's Federal health care program provider number or supplier number(s) (if applicable); and the name and address of each Federal health care program contractor to which Boston Scientific currently submits claims (if applicable); and

15. the certifications required by Section V.C.

The first Annual Report shall be received by OIG no later than 90 days after the end of the first Reporting Period. Subsequent Annual Reports shall be received by OIG

Boston Scientific Corp.
Corporate Integrity Agreement

no later than the anniversary date of the due date of the first Annual Report.

C. Certifications. The following certifications shall be included in the Implementation and Annual Reports.

1. Certifying Employees: In each Annual Report, Boston Scientific shall include the certifications of Certifying Employees as required by Section III.A.4;

2. Chief Compliance Officer: In the Implementation Report and Annual Reports, Boston Scientific shall include the following individual certifications by the Chief Compliance Officer that:

a. to the best of his or her knowledge, except as otherwise described in the applicable report, Boston Scientific is in compliance with all of the requirements of this CIA;

b. to the best of his or her knowledge, Boston Scientific and/or Guidant/CRM, as appropriate, has implemented procedures reasonably designed to ensure that all Arrangements do not violate the Anti-Kickback Statute, including the Arrangements Procedures required in Section III.D of the CIA.

c. to the best of his or her knowledge Boston Scientific and/or Guidant/CRM, as appropriate, has fulfilled the requirements for New and Renewed Contractual Arrangements under Section III.D.2 of the CIA;

d. to the best of his or her knowledge, Boston Scientific has complied with its obligations under the Settlement Agreement.

e. Boston Scientific's: 1) Policies and Procedures as referenced in Section III.B.2 above; 2) templates for standardized contracts and other similar documents; and 3) the training materials used for purposes of Section III.C all have been reviewed by competent legal counsel and have been found to be consistent with all applicable Federal health care program requirements. The documentation supporting this certification shall be available to OIG, upon request; and

f. 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.

Boston Scientific Corp.
Corporate Integrity Agreement

D. Designation of Information. Boston Scientific 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. Boston Scientific 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

Boston Scientific:

Jean Fitterer Lance
Chief Compliance Officer
One Scimed Place
Maple Grove, MN 55311
Telephone No: 763-494-2688
Facsimile No: 763-494-2616

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, Boston Scientific 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 Boston Scientific's books, records, and other documents and supporting materials and/or conduct on-site reviews of any of Boston Scientific's locations for the purpose of verifying and evaluating: (a) Boston Scientific's compliance with the terms of this CIA; and (b) Guidant/CRM's compliance with the requirements of the Federal health care programs in which it participates. The documentation described above shall be made available by Boston Scientific 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 Boston Scientific's and/or Guidant/CRM's, as appropriate, 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. Boston Scientific shall assist OIG or its duly authorized representative(s) in contacting and arranging interviews with such individuals upon OIG's request. Boston Scientific's employees may elect to be interviewed with or without a representative of Boston Scientific present.

VIII. DOCUMENT AND RECORD RETENTION

Boston Scientific 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 Boston Scientific prior to any release by OIG of information submitted by Boston Scientific pursuant to its obligations under this CIA and identified upon submission by Boston Scientific as trade secrets, or information that is commercial or financial and privileged or confidential, under the FOIA rules. With respect to such releases, Boston Scientific shall have the rights set forth at 45 C.F.R. § 5.65(d).

X. BREACH AND DEFAULT PROVISIONS

Boston Scientific 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, Boston Scientific 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 Boston Scientific fails to establish and/or implement any of the following obligations as described in Section III:

- a. a Chief Compliance Officer;
- b. a Global Compliance Steering Committee;
- c. the Board Committee resolution;
- d. a written Code of Conduct;
- e. written Policies and Procedures;
- f. the training of Covered Persons and Arrangements Covered Persons;
- g. a Disclosure Program;
- h. Ineligible Persons screening and removal requirements;
- i. notification of Government investigations or legal proceedings;
and
- j. posting of Payment information as required by Section III.J.

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 Boston Scientific fails to engage an IRO, as required in Section III.E.

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 Boston Scientific 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 Boston Scientific fails to submit the annual IRO Review Report(s) in accordance with the requirements of Section III.E.

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

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

7. A Stipulated Penalty of \$1,000 for each day Boston Scientific fails to comply fully and adequately with any obligation of this CIA. OIG shall provide notice to Boston Scientific stating the specific grounds for its determination that Boston Scientific has failed to comply fully and adequately with the CIA obligation(s) at issue and steps Boston Scientific shall take to comply with the CIA. (This Stipulated Penalty shall begin to accrue 10 days after Boston Scientific 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 1-6 of this Section.

B. Timely Written Requests for Extensions. Boston Scientific 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 Boston Scientific 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 Boston Scientific 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 Boston Scientific 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 Boston Scientific of: (a) Boston Scientific's 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, Boston Scientific 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 Boston Scientific elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until Boston Scientific 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 Boston Scientific 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 Boston Scientific to report a Reportable Event and take corrective action as required in Section III.I;
- 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.E; or
- e. a failure of the Board Committee 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 Boston Scientific constitutes an independent basis for Boston Scientific's exclusion from participation in the Federal health care programs. Upon a determination by OIG that Boston Scientific has materially breached this CIA and that exclusion is the appropriate remedy, OIG shall notify Boston Scientific of: (a) Boston Scientific's 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.* Boston Scientific 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. Boston Scientific 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) Boston Scientific has begun to take action to cure the material breach; (ii) Boston Scientific is pursuing such action with due diligence; and (iii) Boston Scientific has provided to OIG a reasonable timetable for curing the material breach.

4. *Exclusion Letter.* If, at the conclusion of the 30-day period, Boston Scientific fails to satisfy the requirements of Section X.D.3, OIG may exclude Boston Scientific from participation in the Federal health care programs. OIG shall notify Boston Scientific in writing of its determination to exclude Boston Scientific (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 Boston Scientific’s 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, Boston Scientific 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 Boston Scientific 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, Boston Scientific 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 Boston Scientific was in full and timely compliance with the obligations of this CIA for which

OIG demands payment; and (b) the period of noncompliance. Boston Scientific 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 Boston Scientific to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision unless Boston Scientific 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 Boston Scientific 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) Boston Scientific had begun to take action to cure the material breach within that period; (ii) Boston Scientific has pursued and is pursuing such action with due diligence; and (iii) Boston Scientific provided to OIG within that period a reasonable timetable for curing the material breach and Boston Scientific 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 Boston Scientific, only after a DAB decision in favor of OIG. Boston Scientific's election of its contractual right to appeal to the DAB shall not abrogate OIG's authority to exclude Boston Scientific 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 Boston Scientific 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. Boston Scientific 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 Boston Scientific, Boston Scientific 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

Boston Scientific and OIG agree as follows:

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

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. The undersigned Boston Scientific 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.

E. 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 BOSTON SCIENTIFIC CORPORATION

/J. Raymond Elliott/

J. RAYMOND ELLIOTT
President, Chief Executive Officer and
Chief Operating Officer

DATE

ROBERT D. KEEFE
WilmerHale
Counsel for Boston Scientific Corporation

DATE

GARY W. THOMPSON
Akin Gump Strauss Hauer & Feld
Counsel for Boston Scientific Corporation

DATE

ON BEHALF OF BOSTON SCIENTIFIC CORPORATION

J. RAYMOND ELLIOTT
President, Chief Executive Officer and
Chief Operating Officer

/Robert D. Keefe/

ROBERT D. KEEFE v
WilmerHale
Counsel for Boston Scientific Corporation

DATE

12/22/09

DATE

GARY W. THOMPSON
Akin Gump Strauss Hauer & Feld
Counsel for Boston Scientific Corporation

DATE

ON BEHALF OF BOSTON SCIENTIFIC CORPORATION

J. RAYMOND ELLIOTT
President, Chief Executive Officer and
Chief Operating Officer

DATE

ROBERT D. KEEFE
WilmerHale
Counsel for Boston Scientific Corporation

DATE

/Gary W. Thompson/

~~GARY W.~~ THOMPSON
Akin Gump Strauss Hauer & Feld
Counsel for Boston Scientific Corporation

12/22/09
DATE

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

/Gregory E. Demske/

12/23/09

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

DATE

APPENDIX A

INDEPENDENT REVIEW ORGANIZATION

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

A. IRO Engagement.

Boston Scientific 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 its 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 Boston Scientific if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, Boston Scientific may continue to engage the IRO.

If Boston Scientific 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, Boston Scientific shall submit the information identified in Section V.A.7 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 Boston Scientific if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, Boston Scientific may continue to engage the IRO.

B. IRO Qualifications.

The IRO shall:

1. assign individuals to conduct the IRO Review(s) who have expertise in all applicable Federal health care program requirements related to the Reviews. The individuals shall also be knowledgeable about the general requirements of the Federal health care program(s) under which Boston Scientific products are reimbursed;
2. assign individuals to design and select the Arrangements Review sample(s) 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 IRO Review in accordance with the specific requirements of the CIA;
2. follow all applicable Federal health care program requirements in making assessments in the IRO Reviews;
3. if in doubt of the application of a particular Federal health care program requirement, request clarification from the appropriate authority (e.g., CMS, the 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 the CIA and 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 Boston Scientific.

E. IRO Removal/Termination.

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

Prior to requiring Boston Scientific to engage a new IRO, OIG shall notify Boston Scientific 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, Boston Scientific 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. Boston Scientific 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 Boston Scientific prior to requiring Boston Scientific to terminate the IRO. However, the final determination as to whether or not to require Boston Scientific to engage a new IRO shall be made at the sole discretion of OIG.

APPENDIX B

ARRANGEMENTS DATABASE

Boston Scientific Corporation shall create and maintain an Arrangements Database to track all existing and new and renewed Arrangements, including Contractual and Non-Contractual Arrangements in order to ensure that each Arrangement does not violate the Anti-Kickback Statute.

A. The Arrangements Database shall contain certain information to assist Boston Scientific Corporation in evaluating whether each Contractual Arrangement violates the Anti-Kickback Statute, including but not limited to the following:

1. Each non-Boston Scientific party involved in the Arrangement;
2. The type of Arrangement (e.g., consultant or other fee-for-service arrangements entered into with HCPs or HCIs, including, but not limited to, post-market study, clinical trials, continuing medical education, speaker programs, speaker training programs, advisory boards, proctorships, preceptorships, fellowship grants, symposia, medical directorships, lease agreements);
3. The term of the Arrangement, including the effective and expiration dates and any automatic renewal provisions;
4. The amount of compensation to be paid pursuant to the Arrangement and the means by which compensation is paid;
5. The methodology for determining the compensation under the Arrangements, including the methodology used to determine the fair market value of such compensation;
6. Whether the amount of compensation to be paid pursuant to the Arrangement is determined based on the volume or value of referrals between the parties;
7. Whether each party has fulfilled the requirements of Section III.D.2; and
8. Whether the Arrangement satisfies the requirements of an Anti-Kickback Statute safe harbor.

B. Notwithstanding the timing requirements set forth in III.D.1, Boston Scientific Corporation shall, consistent with the dates set forth for posting physician payment information in Section III.J., create and maintain as part of its Arrangements Database certain information to assist Boston Scientific Corporation in evaluating whether each Non-Contractual Arrangement violates the Anti-Kickback Statute, including but not limited to the following:

1. Name of entity or individual receiving the Non-Contractual remuneration;
2. The type of Non-Contractual remuneration Arrangement (listing in the aggregate multiple distributions of the same type of Non-Contractual remuneration to each individual or entity);
3. The aggregate value of each type of Non-Contractual remuneration given to each entity or individual during the Reporting Period;
4. Whether the Non-Contractual remuneration given pursuant to the Non-Contractual Arrangement is determined based on the volume or value of referrals between the parties;
5. Whether the Non-Contractual Arrangement satisfies the requirements of an Anti-Kickback Statute safe harbor.