

**CORPORATE INTEGRITY AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL
OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
BIOTRONIK, INC.**

I. PREAMBLE

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

In consideration of the obligations of Biotronik in this CIA, the OIG-HHS shall release and refrain from instituting, directing, or maintaining any administrative action seeking exclusion from Medicare, Medicaid, and other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) against Biotronik under 42 U.S.C. § 1320a-7a (Civil Monetary Penalties Law) or 42 U.S.C. § 1320a-7(b)(7) (permissive exclusion for fraud, kickbacks, and other prohibited activities) for the Covered Conduct referenced in the Settlement Agreement entered into between the United States of America, acting through the United States Department of Justice and on behalf of OIG-HHS, and Biotronik effective June 16, 2022. The OIG-HHS expressly reserves all rights to comply with any statutory obligations to exclude Biotronik from Medicare, Medicaid, and other Federal health care programs under 42 U.S.C. § 1320a-7(a) (mandatory exclusion) based upon the Covered Conduct referenced above. Nothing in this paragraph precludes the OIG-HHS from taking action against entities or persons except Biotronik, or for conduct and practices which are not included in the above-referenced Covered Conduct.

II. EFFECTIVE DATE, TERM, AND DEFINITIONS

A. Effective Date. The “Effective Date” of this CIA shall be the signature date of the final signatory of this CIA.

B. Term. The term of this CIA shall be five years from the Effective Date, except that Sections VII and X shall continue for 120 days after OIG’s receipt of: (1) Biotronik’s final Annual Report or (2) any additional documentation relating to the final Annual Report requested by OIG, whichever is later. In addition, if OIG issues a Stipulated Penalties Demand Letter pursuant to Section X.C.1 or a Notice of Material Breach and Intent to Exclude pursuant to

Section X.E.2 prior to the expiration of the 120 day period, then Section X shall remain in effect until the Stipulated Penalties Review described in Section X.E.2 or the Exclusion Review described in Section X.E.3 has been completed, and Biotronik complies with the decision.

C. Definitions.

1. “Certifying Covered Persons” means the following:

- President;
- Vice President of Finance;
- General Counsel;
- Vice President of Marketing;
- Vice President of Clinical Studies;
- Vice President of Medical & Academic Affairs;
- Vice President of Regulatory Affairs & New Product Development;
- Vice President of Commercial Excellence and Corporate Accounts;
- Head of Digital Health & Diagnostics; and
- Area Vice Presidents of Sales (East, South, West, and Pacific).

2. “Covered Functions” means: (a) the selling, marketing, advertising, promoting, or branding of Government Reimbursed Products; (b) the preparation or external dissemination of promotional materials or information about, or the provision of services relating to, Government Reimbursed Products, including those functions relating to Biotronik’s review and approval processes for promotional materials; (c) the preparation or external dissemination of non-promotional materials about Government Reimbursed Products, including those functions relating to Biotronik’s review and approval process for any non-promotional materials; (d) contracting with health care professionals (HCPs) for consulting services (including but not limited to speaker programs, speaker training programs, training and education services, product development activities, presentations, consultant task force meetings, advisory boards, ad hoc advisory activities, research and any research-related activities, and authorship of articles or other publications relating to Government Reimbursed Products), or other fee-for service arrangements relating to Government Reimbursed Products; (e) reviewing and/or approving requests for grants or charitable contributions; and (f) the review and approval of sales representative expenses relating to travel, entertainment, and meals involving HCPs.

3. “Covered Persons” means: (a) all owners of Biotronik who are natural persons (other than shareholders who: (i) have an ownership interest of less than 5% and (ii) acquired the ownership interest through public trading); (b) all officers and board members; (c) all employees who are engaged in or who supervise personnel who are engaged in Covered Functions on behalf of Biotronik; and (d) all contractors who perform any of the Covered Functions on behalf of Biotronik. Covered Persons does not include part-time or per diem

employees or contractors who are not reasonably expected to work more than 160 hours during a Reporting Period, except that any such individuals shall become Covered Persons at the point when they work more than 160 hours during a Reporting Period.

4. “Covered Recipient” is defined for purposes of Section III.N of this CIA, as specified in 42 U.S.C. § 1320a-7h and the related regulations and guidance (including FAQs) published by the Centers for Medicare and Medicaid Services (CMS).

5. “Disclosure Program” means a program that enables individuals to disclose to the Compliance Officer or some other person who is not in the disclosing individual’s chain of command any potential violations of criminal, civil or administrative law related to the Federal health care programs or any issues or questions associated with Biotronik’s policies, conduct, practices, or procedures.

6. “Exclusion Lists” means the HHS/OIG List of Excluded Individuals/Entities (LEIE) (available at <http://www.oig.hhs.gov>) and State Medicaid program exclusion lists that are publicly available.

7. “Government Reimbursed Products” means all Biotronik products that are: (a) marketed or sold by Biotronik in the United States (or pursuant to contracts with the United States) and (b) reimbursed by Federal health care programs.

8. “Ineligible Person” means an individual or entity who: (a) is currently excluded from participation in any Federal health care program or (b) has been convicted of a criminal offense that falls within the scope of 42 U.S.C. § 1320a-7(a) (mandatory exclusion) but has not yet been excluded from participation in any Federal health care program.

9. “Payments” is defined for purposes of Section III.N of the CIA as specified in 42 U.S.C. § 1320a-7h and the related regulations and guidance (including FAQs) published by CMS.

10. “Reportable Event” means: (a) a matter that a reasonable person would consider a probable violation of criminal, civil, or administrative laws applicable to any Federal health care program for which criminal or civil monetary penalties under Section 1128A or 1128B of the Social Security Act (the “Act”) or exclusion under Section 1128 of the Act may be authorized; (b) a matter that a reasonable person would consider a probable violation of FDA requirements relating to the marketing or sale of Government Reimbursed Products, unless otherwise reported to the FDA in accordance with Section III.J below; (c) the employment of or contracting with a Covered Person who is an Ineligible Person; or (d) the filing of a bankruptcy petition by Biotronik.

11. “Reporting Period” means each one-year period during the term of this CIA, beginning with the one-year period following the Effective Date.

12. “Sponsorships” means support for a program, event, or organization in return for the advertisement, or promotion of Biotronik products, including healthcare-related conventions and conference sponsorships, promotional booths, exhibit space, advertisements, memberships, signage rights, naming rights, and subscriptions.

13. “Third Party Educational Activity” means any scientific, educational, or professional program, meeting, or event for HCPs conducted by a third party and supported by Biotronik, including but not limited to, continuing medical education (CME), disease awareness, or sponsorship of symposia at medical conferences.

14. “Training Plan” means a written plan that outlines the steps Biotronik will take to ensure that Covered Persons receive training on a periodic basis during the term of the CIA regarding Biotronik’s CIA requirements and compliance program, and that all Covered Persons who engage in Covered Functions receive training on a periodic basis during the term of the CIA regarding: (a) all applicable Federal health care program and FDA requirements relating to Covered Functions and (b) all Biotronik Policies and Procedures and other requirements applicable to Covered Functions.

15. “Transition Plan” means a plan to address whether and how Biotronik’s compliance program will continue to include the compliance program requirements set forth in Section III of the CIA, following the end of the CIA’s term.

16. “Biotronik Affiliate” means any entity, that is owned or controlled directly or indirectly by Biotronik and whose employees or contractors perform any Covered Functions, including but not limited to Medical Equipment Distribution, Inc. In addition, Biotronik Corporate Services U.S., Inc. is considered a Biotronik Affiliate for purposes of the CIA to the extent that it, or any of its employees or contractors perform any Covered Functions. All requirements set forth in Section III below shall apply to the Covered Functions performed by any Biotronik Affiliate and all references to “Biotronik” in the defined terms set forth in this Section II shall mean Biotronik and any Biotronik Affiliate. In addition, the notice requirements in Section IV and the certification requirements set forth in Section V below shall apply to both Biotronik and any Biotronik Affiliate.

III. COMPLIANCE PROGRAM REQUIREMENTS

Biotronik shall establish and maintain a compliance program that includes the following elements:

A. Compliance Officer, Compliance Committee, Board Oversight, and Management Certifications.

1. *Compliance Officer.* Within 90 days after the Effective Date, Biotronik shall appoint a Compliance Officer who is an employee and a member of senior management of Biotronik. The Compliance Officer shall report directly to the President of Biotronik and shall not be or be subordinate to the General Counsel or Chief Financial Officer or have any responsibilities that involve acting in any capacity as legal counsel or supervising legal counsel functions for Biotronik. The Compliance Officer shall be authorized to report to the Board of Directors of Biotronik (Board) regarding compliance matters at any time. The Compliance Officer shall be responsible for, without limitation:

- a. 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 and FDA requirements;
- b. making at least quarterly reports regarding compliance matters to the Board;
- c. monitoring the day-to-day compliance activities engaged in by Biotronik; and
- d. all reporting requirements of this CIA.

The Compliance Officer shall not have any noncompliance job responsibilities that, in OIG's discretion, may interfere or conflict with the Compliance Officer's ability to perform the duties outlined in this CIA.

Biotronik shall report to OIG, in writing, any changes in the identity, duties, or job responsibilities of the Compliance Officer within five business days after such a change.

2. *Compliance Committee.* Within 90 days after the Effective Date, Biotronik shall appoint a Compliance Committee that is chaired by the Compliance Officer. The Compliance Committee shall include, at a minimum, the members of senior management necessary to meet the requirements of this CIA. The Compliance Committee shall be responsible for, among other things, reviewing the policies and procedures required by Section

III.B below at least annually, reviewing the training required by Section III.C below at least annually, implementation and oversight of the risk assessment and internal review process required by Section III.E below, and the development and implementation of the Transition Plan required by Section III.O below. The Compliance Committee shall meet at least quarterly.

Biotronik shall report to OIG, in writing, any changes to the membership of the Compliance Committee within 15 business days after such a change.

3. *Board Oversight.* The Board shall be responsible for the review and oversight of Biotronik's compliance with Federal health care program requirements, FDA requirements, and the requirements of this CIA. The Board must include at least one independent (*i.e.*, non-employee and non-executive) member.

The Board shall, at a minimum, be responsible for the following:

- a. meeting at least quarterly to review and oversee Biotronik's compliance program, including but not limited to the performance of the Compliance Officer and Compliance Committee;
- b. submitting to OIG a description of the materials it reviewed and any additional steps taken, such as the engagement of an independent advisor or other third party resources, in its oversight of the compliance program and in support of making the resolution below during each Reporting Period;
- c. for each Reporting Period of the CIA, adopting a resolution, approved by each member of the Board regarding its review and oversight of Biotronik's compliance with Federal health care program requirements, FDA requirements, and the requirements of this CIA; and
- d. for the second and fourth Reporting Periods, the Board shall retain an individual or entity with expertise in compliance with Federal health care program and FDA requirements (Compliance Expert) to perform a review of the effectiveness of Biotronik's compliance program. The Compliance Expert must not be employed or engaged by Biotronik and must not have a current or prior relationship to Biotronik that would cause a reasonable person to question the Compliance Expert's objectivity in performing the review. The Compliance Expert shall prepare a written report that includes a description of the review and any recommendations

with respect to Biotronik's compliance program. The Board shall review the Compliance Program Review Report as part of its review and oversight of Biotronik's compliance program. A copy of the Compliance Program Review report shall be provided to OIG in the Annual Reports submitted by Biotronik for the second and fourth Reporting Periods, along with a certification from the Compliance Expert that it does not have a prohibited relationship with Biotronik as set forth above and a summary of any current or prior relationships with Biotronik. In addition, copies of any materials provided to the Board by the Compliance Expert, along with minutes of any meetings between the Compliance Expert and the Board, shall be made available to OIG upon request.

At minimum, the resolution shall include the following language:

“The Board has made a reasonable inquiry into the operations of Biotronik's compliance program including the performance of the Compliance Officer and the Compliance Committee. Based on its inquiry and review, the Board has concluded that, to the best of its knowledge, Biotronik has implemented an effective compliance program to meet Federal health care program requirements, FDA requirements, and the requirements of Biotronik's Corporate Integrity Agreement with the Office of Counsel to the Inspector General for the Department of Health and Human Services.”

If the Board is unable to adopt such a resolution, the Board shall provide a written explanation of the reasons why it is unable to adopt the resolution and the steps it is taking to implement an effective compliance program at Biotronik.

Biotronik shall report to OIG, in writing, any changes to the membership of the Board, within 15 business days after such a change.

4. *Management Certifications.* The Certifying Covered Persons shall monitor compliance within the business unit for which they are responsible and annually certify that the applicable Biotronik business unit is in compliance with applicable Federal health care program and FDA requirements and with the requirements of this CIA. For each Reporting Period, each Certifying Covered Person shall certify as follows:

“I have been trained on and understand the compliance requirements and responsibilities as they relate to [insert name of business unit], an area under my supervision. My job responsibilities include ensuring [business unit]'s compliance with all applicable Federal health care program requirements, FDA

requirements, requirements of the Corporate Integrity Agreement, and Biotronik's policies and procedures. To the best of my knowledge, the [insert name of business unit] of Biotronik is in compliance with all applicable Federal health care program requirements, FDA requirements, and the requirements of the Corporate Integrity Agreement. I understand that this certification is being provided to and relied upon by the United States.”

If any Certifying Covered Person is unable to provide such a certification, the Certifying Covered Person shall provide a written explanation of the reasons why he or she is unable to provide the certification.

Within 90 days after the Effective Date, Biotronik shall develop and implement a written process for Certifying Covered Persons to follow for the purpose of completing the certification required by this section (e.g., reports that must be reviewed, assessments that must be completed, sub-certifications that must be obtained, etc. prior to the Certifying Covered Person making the required certification).

B. Written Standards. Within 90 days after the Effective Date, Biotronik shall develop and implement written policies and procedures (Policies and Procedures) that address the following: (1) the operation of its compliance program, including the compliance program requirements outlined in this CIA and (2) Biotronik's compliance with Federal health care program and FDA requirements. Biotronik shall enforce its Policies and Procedures and shall make compliance with its Policies and Procedures an element of evaluating the performance of all Covered Persons. The Policies and Procedures shall be made available to all Covered Persons. At a minimum, the Policies and Procedures shall address the following:

1. appropriate ways to conduct Covered Functions in compliance with all: (a) applicable Federal healthcare program requirements, including, but not limited to the Federal Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b), and the False Claims Act, 31 U.S.C. §§ 3729-3733, and (b) all applicable FDA requirements;
2. the materials and information that may be distributed by Biotronik sales representatives (including any contract sales force) about Government Reimbursed Products and the manner in which Biotronik sales representatives respond to requests for information about uses of Government Reimbursed Products that are not FDA approved, cleared or exempt (“non-FDA approved uses”);
3. the materials and information that may be distributed and the mechanisms through, and manner in which, Biotronik receives and responds to requests for information from an HCP or another individual or entity about non-FDA approved uses of Government

Reimbursed Products; the form and content of information disseminated by Biotronik in response to such requests; and the internal review process for the information disseminated;

4. the manner and circumstances under which Biotronik medical personnel interact with or participate in meetings or events with HCPs, health care institutions (HCIs), or payors (either alone or with Biotronik sales representatives) and the role of Biotronik medical personnel at such meetings or events, as well as how they handle responses to requests for information about non-FDA approved uses of Government Reimbursed Products;

5. the materials and information that may be distributed or made available by Biotronik through social media and/or direct-to-consumer advertising;

6. the development, implementation, and review of policies for the distribution of Government Reimbursed Products for evaluation purposes (Evaluation Product). This shall include a review of the bases upon, and circumstances under, which HCPs and HCIs belonging to specified medical specialties or types of clinical practice may receive Evaluation Product from Biotronik (including, separately, from sales representatives, or through other channels);

7. consultant or other fee-for-service arrangements entered into with HCPs or HCIs (including but not limited to speaker programs, speaker training programs, training and education services, product development activities, presentations, consultant task force meetings, advisory boards, ad hoc advisory activities, research and research-related activities, authorship activities, and any other financial engagement or arrangement with an HCP or HCI) and all events and expenses relating to such engagements or arrangements;

8. agreements or arrangements with HCPs or HCIs for the purchase or licensing of intellectual property (including, but not limited to, patents, patent applications, and the payment of royalties);

9. programs by HCPs to educate sales representatives or other Biotronik employees, including but not limited to presentations by HCPs at sales meetings, preceptorships, tutorials, and experience-based learning activities;

10. review and approval of, and payment for, travel, meals, gifts, gratuities, entertainment, and related expenses for HCPs including those in connection with HCP

participation in educational, research, training, or other Biotronik-sponsored programs or activities;

11. sponsorship or funding of grants (including educational grants) or charitable contributions involving HCPs and HCIs;

12. funding of, or participation in, any Sponsorships or Third-Party Educational Activity as defined in Section II.C.10 and II.C.11 above;

13. review of promotional, reimbursement-related, and disease state materials and information intended to be disseminated outside Biotronik by appropriate qualified personnel (such as regulatory, medical, and/or legal personnel) in a manner designed to ensure that legal, regulatory, and medical concerns are properly addressed during Biotronik's review and approval process and are elevated when appropriate;

14. compensation (including through salaries, bonuses, or other means) for Covered Persons who are sales representatives and their managers; and

15. disciplinary policies and procedures for violations of Biotronik's Policies and Procedures, including policies relating to Federal health care program and FDA requirements.

The Compliance Committee shall review the Policies and Procedures at least annually and update the Policies and Procedures, as necessary. Any new or revised Policies and Procedures shall be made available to all Covered Persons. All Policies and Procedures shall be made available to OIG upon request.

C. Training and Education

1. *Covered Persons Training.* Within 90 days after the Effective Date, Biotronik shall develop a Training Plan that includes the following information: (a) training topics; (b) categories of Covered Persons and required to attend each training session; (c) length of the training session(s); (d) schedule for training; and (e) format of the training. The Compliance Committee shall review the Training Plan at least annually and update the Training Plan as necessary.

2. *Board Training.* Within 90 days after the Effective Date, members of the Board shall receive training regarding their responsibilities for corporate governance and review and oversight of the compliance program. The training shall address the specific responsibilities of health care board members, including the risks, oversight areas, and approaches to conducting effective oversight of a health care entity and shall include a discussion of OIG's guidance on

board member responsibilities. Each member of the Board also shall receive the training described in Section III.C.1.

New members of the Board shall receive the training described in this Section III.C. 2 above within 30 days after becoming a member or within 90 days after the Effective Date, whichever is later. The Compliance Committee shall review the Board training at least annually and update the Board training as necessary.

3. *Training Records.* Biotronik shall make available to OIG, upon request, training materials and records verifying that the training described in Sections III.C.1 and III.C.2 has been provided.

D. Review Procedures.

1. *General Description.*

- a. *Engagement of Independent Review Organization.* Within 90 days after the Effective Date, Biotronik shall engage an entity (“Independent Review Organization” or “IRO”) that meets the qualifications outlined in Appendix A to this CIA, which is incorporated by reference, to perform the reviews described in this Section III.D.
- b. *Retention of Records.* The IRO and Biotronik shall retain and make available to OIG, upon request, all work papers, supporting documentation, correspondence, and draft reports exchanged between the IRO and Biotronik related to the reviews described in this Section III.D.
- c. *Access to Records and Personnel.* Biotronik shall ensure the IRO has access to all records and personnel necessary to complete the reviews listed in this Section III.D, and that all records furnished to the IRO are accurate and complete.

2. *System Review, Transactions Review, and Additional Items Review.* The IRO shall perform a Systems Review and a Transactions Review relating to the Covered Functions, and (if required) an Additional Items Review, and shall prepare a Systems Review Report, a Transactions Review Report, and (if applicable) an Additional Items Review Report, as outlined in Appendix B to this CIA, which is incorporated by reference.

3. *Independence and Objectivity Certification.* The IRO shall include in its report(s) to Biotronik a certification that the IRO has: (a) evaluated its professional independence and objectivity with respect to the reviews required under this Section III.D; and (b) concluded that it is, in fact, independent and objective in accordance with the requirements specified in Appendix A to this CIA. The IRO's certification shall include a summary of current and prior engagements between Biotronik and the IRO.

E. Risk Assessment and Internal Review Process. Within 90 days after the Effective Date, Biotronik shall develop and implement a centralized annual risk assessment and internal review process to identify and address risks associated with each Government Reimbursed Product, including risks associated with the Covered Functions. The Compliance Committee shall be responsible for implementation and oversight of the risk assessment and internal review process. The risk assessment and internal review process shall be conducted annually and shall require Biotronik to: (1) identify and prioritize risks, (2) develop work plans or internal audit plans (as appropriate) related to the identified risk areas, (3) implement the work plans and internal audit plans, (4) develop corrective action plans in response to the results of any internal audits performed, and (5) track the implementation of the work plans and any corrective action plans and assess the effectiveness of such plans.

F. Disclosure Program. Within 90 days after the Effective Date, Biotronik shall establish a Disclosure Program. Biotronik shall appropriately publicize the existence of the Disclosure Program and the disclosure mechanism (e.g., via periodic e-mails to employees, or by posting the information in prominent common areas). The Disclosure Program shall include a reporting mechanism for anonymous communications for which appropriate confidentiality shall be maintained. The Disclosure Program shall prohibit retaliation against Covered Persons relating to the use of the Disclosure Program and Biotronik shall not retaliate against Covered Persons for use of the Disclosure Program. The Compliance Officer (or designee) shall conduct a review of each disclosure received through the Disclosure Program, including gathering all relevant information from the disclosing individual, and ensure that appropriate follow-up is conducted.

The Compliance Officer (or designee) shall record all disclosures (whether or not related to a potential violation of criminal, civil or administrative law related to Federal health care programs or FDA requirements) in a written disclosure log within two business days of receipt of the disclosure. The disclosure log shall include the following information: (1) a summary of each disclosure received (whether anonymous or not), (2) the date the disclosure was received, (3) the individual or department responsible for reviewing the disclosure, (4) the status of the review, (5) any corrective action taken in response to the review, and (6) the date the disclosure was resolved.

G. Ineligible Persons.

1. *Screening Requirements.* Biotronik shall:
 - a. screen all prospective 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. screen all current Covered Persons against the Exclusion Lists within 90 days after the Effective Date and on an annual basis thereafter; and
 - c. require all Covered Persons to disclose immediately to the Compliance Officer (or designee) if they become an Ineligible Person.

2. *Removal Requirement.* If Biotronik has actual notice that a Covered Person has become an Ineligible Person, Biotronik 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 any Federal health care program(s) from which the Covered Person has been excluded, at least until such time as the Covered Person is reinstated into participation in such Federal health care program(s). Items or services furnished, ordered, or prescribed by excluded persons are not payable by Federal health care programs and Biotronik may be liable for overpayments and/or criminal, civil, and administrative sanctions for employing or contracting with an excluded person regardless of whether Biotronik meets the requirements of Section III.G.

H. Notification of Government Investigation or Legal Proceeding. Biotronik shall notify OIG, in writing, of any ongoing investigation or legal proceeding by a governmental entity or its agents involving an allegation that Biotronik has committed a crime or has engaged in fraudulent activities, within 30 days of Biotronik receiving notice of such investigation or legal proceeding. This notification shall include a description of the allegation(s), the identity of the investigating or prosecuting agency, and the status of the investigation or legal proceeding. Within 30 days after resolution of the matter, Biotronik shall notify OIG, in writing, of the resolution of the investigation or legal proceeding.

I. Reportable Events. Biotronik shall notify OIG, in writing, within 30 days after determining that a Reportable Event exists, as follows:

1. *Probable Violation of Law.* The report to OIG shall include:

- a. a complete description of all details relevant to the Reportable Event, including, at a minimum, the types of claims, transactions or other conduct giving rise to the Reportable Event, the period during which the conduct occurred, and the names of individuals and entities believed to be implicated, including an explanation of their roles in the Reportable Event;
- b. a statement of the Federal criminal, civil or administrative laws that are probably violated by the Reportable Event, if any;
- c. the Federal health care programs affected by the Reportable Event, if any; and
- d. a description of Biotronik's actions taken to correct the Reportable Event and prevent it from recurring.

include:

2. *Probable Violation of FDA Requirements.* The report to OIG shall

- a. a complete description of all details relevant to the Reportable Event, including, at a minimum, the types of claims, transactions or other conduct giving rise to the Reportable Event, the period during which the conduct occurred, and the names of individuals and entities believed to be implicated, including an explanation of their roles in the Reportable Event;
- b. a statement of the FDA requirements probably violated by the Reportable Event, if any; and
- c. a description of Biotronik's actions taken to correct the Reportable Event and prevent it from recurring.

3. *Ineligible Person.* The report to OIG shall include:

- a. the identity of the Ineligible Person and the job duties performed by that individual;
- b. the dates of the Ineligible Person's employment or contractual relationship;

- c. a description of the Exclusion Lists screening that Biotronik completed before and/or during the Ineligible Person's employment or contract and any flaw or breakdown in the screening process that led to the hiring or contracting with the Ineligible Person;
- d. a description of how the Ineligible Person was identified; and
- e. a description of any corrective action implemented to prevent future employment or contracting with an Ineligible Person.

4. *Bankruptcy*. The report to OIG shall include documentation of the bankruptcy filing and a description of any Federal health care program or FDA requirements implicated.

J. Notification of Communications with FDA. Within 30 days after the date of any written report, correspondence, or communication between Biotronik and the FDA that materially discusses Biotronik's or a Covered Person's actual or potential unlawful or improper marketing or sale of Biotronik's products, Biotronik shall provide a copy of the report, correspondence, or communication to OIG. Within 30 days after resolution of the matter, Biotronik shall notify OIG, in writing, of the resolution.

K. Requirements Relating to Speaker Programs. Within 90 days following the Effective Date, Biotronik shall establish and implement the following requirements relating to arrangements with HCPs to serve as presenters on behalf of Biotronik or participate in training programs related to such presentations (Speaker Programs).

1. An annual budget and needs assessment process that identifies the business needs for, and the estimated numbers of, Speaker Programs for the following year. As part of the process, Biotronik shall identify the business need for the planned Speaker Programs and shall collect specific details about the speaker programs (e.g., the expected number of programs, the topics of the programs, and the identity and qualifications of the proposed speakers). The annual Speaker Programs budget shall identify the total budgeted amounts to be spent on Speaker Programs. Biotronik compliance personnel shall be involved in the review and approval of such plans, including any subsequent modification of approved plans. The purpose of this review shall be to ensure that Speaker Programs are used for legitimate and lawful purposes in accordance with applicable Federal health care program and FDA requirements and Biotronik Policies and Procedures.

2. A process to require all speakers to complete training and enter written agreements that describe the scope of work to be performed, the speaker fees to be paid, and

compliance requirements for the speakers (including requirements regarding the use of Biotronik approved materials and requirements that speakers may not directly or indirectly promote the product for non-FDA approved uses).

3. A centralized, electronic system to initiate and track all Speaker Programs that includes controls designed to ensure that Speaker Programs are used for legitimate and lawful purposes in accordance with all applicable Federal health care program and FDA requirements.

4. A process to ensure speakers are paid according to a centrally managed, pre-set rate structure determined based on an independent fair-market value analysis.

5. A comprehensive list of Speaker Program attendees through its centralized system. In addition, Biotronik shall use its centralized systems to handle all logistics and spending associated with Speaker Programs, including the tracking and review of the aggregate amount (including speaker fees, travel, and other expenses) paid to each speaker in connection with Speaker Programs.

6. A requirement for certifications by sales representatives or other Biotronik personnel that Speaker Programs comply with Biotronik requirements, or in the event of non-compliance, Biotronik shall require the identification of the policy violation and ensure appropriate follow up activity to address the violation.

7. A Speaker Monitoring Program under which Biotronik compliance or other appropriately trained Biotronik personnel who are independent from the functional area being monitored (Monitoring Personnel) shall attend 15 Speaker Programs during each Reporting Period and conduct live audits of the programs (Speaker Program Audits). The Speaker Programs subject to Speaker Program Audits shall be selected using either a risk-based targeting approach or a random sampling approach. For each Speaker Program reviewed, Monitoring Personnel shall review slide materials and other materials used as part of the Speaker Program, speaker statements made during the program, and Biotronik sales representative activities during the program to assess whether the Speaker Programs were conducted in a manner consistent with Biotronik's Policies and Procedures. Results from the Speaker Monitoring Program shall be compiled and reported to the Compliance Officer for review and remediation as appropriate.

L. Field Force Monitoring and Review Efforts. Within 90 days after the Effective Date, Biotronik shall establish a comprehensive Field Force Monitoring Program (FFMP) to evaluate and monitor its sales personnel's interactions with HCPs and HCIs. The FFMP shall be a formalized process designed to directly and indirectly observe the appropriateness of sales personnel's interactions with HCPs and HCIs and to identify potential improper promotional

activities or other improper conduct. As described in more detail below, the FFMP shall include: (1) direct field observations (Observations) of sales personnel and (2) the monitoring and review of other records relating to sales personnel's interactions with HCPs and HCIs (Records Reviews).

1. *Observations.* As a component of the FFMP, Monitoring Personnel shall conduct observations of sales representatives (including any contract sales personnel) to assess whether the messages delivered and materials distributed to HCPs and HCIs are consistent with applicable legal requirements and with Biotronik's Policies and Procedures. These observations shall be full day ride-alongs with sales representatives (Observations), and each Observation shall consist of directly observing all meetings between a sales representative and HCPs and HCIs during the workday. The Observations shall be scheduled throughout the year, judgmentally selected by Monitoring Personnel, and be conducted across the United States.

At the completion of each Observation, Monitoring Personnel shall prepare a report which includes: (a) the identity of the sales representative; (b) the identity of the Monitoring Personnel who conducted the Observation; (c) the date and duration of the Observation; (d) the product(s) promoted during the Observation; (e) an overall assessment of compliance with Biotronik Policies and Procedures; and (f) the identification of any potential improper promotional activity or other improper conduct by the field sales representative.

Monitoring Personnel shall conduct at least 25 Observations during each Reporting Period. Monitoring Personnel shall have access to all relevant records and information necessary to assess sales representatives' interactions with HCPs and HCIs and to identify potential or actual compliance violations.

2. *Records Reviews.* As a component of the FFMP, Biotronik shall also review various types of records to assess sales representatives' interactions with HCPs and HCIs and to identify potential or actual compliance violations.

- a. For each Reporting Period, Biotronik shall develop and implement a plan for conducting Records Reviews associated with at least 5 Government Reimbursed Products. The Records Reviews shall include a review of records relating to the activities of sales representatives in every separate district and/or region (as applicable) who promoted the products under review.
- b. The Records Reviews shall include the monitoring and review of:
 - (i) records and systems associated with sales representatives' interactions with HCPs and HCIs (including records

- relating to consulting and other fee-for-service arrangements, speaker program activities, travel and entertainment, expense reports, any payments to HCPs or HCIs, and sales communications from managers);
- (ii) records relating to requests for medical information about or inquiries relating to, the Government Reimbursed Products under review;
- (iii) sales representative call notes;
- (iv) sales representatives' e-mails and other electronic records; and
- (v) recorded results of the Observations of sales force representatives, coaching guides, and manager notes.

3. *Reporting and Follow-up.* Results from the FFMP shall be compiled and reported to the Compliance Officer for review and remediation as appropriate.

M. Requirements Relating to Certain Non-Promotional Activities. To the extent that Biotronik engages HCPs for services other than for speaker programs (e.g., training and education services (including but not limited to employee training programs), product development activities, presentations, consultant task force meetings, advisory boards, ad hoc advisory activities, research and research-related activities, authorship activities, and any other financial engagement or arrangement with an HCP), such HCPs shall be referred to herein as Consultants. Within 90 days after the Effective Date, Biotronik shall develop policies, procedures, and systems to implement the requirements outlined below relating to the following types of activities: (1) Consultant activities; and (2) grant and charitable contribution activities involving HCPs and HCIs.

1. *Consulting Activities.* Biotronik shall:
 - a. Require all Consultants to enter written agreements describing the scope of work to be performed, the fees to be paid, and compliance requirements for the Consultants. Consultants shall be paid according to a centrally managed, pre-set rate structure that is determined based on an independent fair-market value analysis.
 - b. Establish a process to develop an annual budgeting plan that specifies (i) the business needs for, and the estimated numbers of,

the various Consultant engagements and activities to occur during the following year and (ii) the budgeted amounts to be spent on Consultant-related activities. Biotronik compliance personnel shall be involved in the review and approval of such plans, including any subsequent modification of an approved plan for the purpose of ensuring that Consultant arrangements and related events are used for legitimate and lawful purposes in accordance with applicable Federal health care program and FDA requirements and Biotronik Policies and Procedures.

- c. Establish a process to ensure that a needs assessment has been completed to justify the retention of a Consultant prior to the retention of the Consultant. The needs assessment shall identify the business need for the retention of the Consultant and provide specific details about the consulting arrangement (e.g., information about the numbers and qualifications of the HCPs and HCIs to be engaged, the agenda for the proposed activity, and a description of the proposed work to be done and the type of work product to be generated). Any deviations from the Consultant budgeting plans shall be documented in the needs assessment form and shall be subject to review and approval by Biotronik compliance personnel.
- d. Amend its policies and procedures in a manner designed to ensure that each Consultant performs the work for which the Consultant is engaged and that, as applicable, Biotronik receives the work product generated by the Consultant.
- e. Establish a Consultant Monitoring Program through which it shall conduct audits of at least 20 Consultant arrangements during each Reporting Period. The Consultant Monitoring Program shall select Consultant arrangements for review using either a risk-based targeting approach or a random sampling approach. Monitoring Personnel shall review needs assessment documents, Consultant contracts, and materials relating to the program or work of the Consultant (including work product resulting from any program or event), in order to assess whether the programs and arrangements were conducted in a manner consistent with Biotronik's Policies and Procedures. Results from the Consultant Monitoring Program, including the identification of potential violations of Biotronik's policies, shall be compiled and reported to the Compliance Officer

(or compliance personnel designee) for review and follow up as appropriate.

2. *Grant and Charitable Contribution Activities.* Biotronik shall:
 - a. Establish a centralized system which shall be the exclusive mechanism through which requestors may request or be awarded amounts for Third Party Educational Activities, other grant activities involving HCPs and HCIs (referred to below as “Grants”), and charitable contributions involving HCPs and HCIs supported by Biotronik (referred to below as “Contributions”).
 - b. Establish a process to review requests for Grants and Contributions according to standardized, objective criteria developed by Biotronik (such as based upon the qualifications of the requestor, or the quality of the program funded by the Grant or Contribution) and to ensure that Grants or Contributions are provided only pursuant to a written agreement with the funding recipient and that payments to the funding recipient are consistent with the written agreement. Biotronik’s sales and marketing personnel shall not be involved in, or influence, the review and approval of requests for Grants or Contributions.
 - c. Establish a Grants and Contributions Monitoring Program through which it shall conduct audits for each Reporting Period of at least 5 Grants and Contributions. The Grants and Contributions Monitoring Program shall select Grants and Contributions for review both on either a risk-based targeting approach or a random sampling approach. Monitoring Personnel shall review proposal documents (including requests), approval documents, contracts, payments and materials relating to the review of the requests, and documents and materials relating to the Grants or Contributions and any events or activities funded through the Grants or Contributions to assess whether the activities were conducted in a manner consistent with Biotronik’s Policies and Procedures. Results from the Grants and Contributions Monitoring Programs, including the identification of potential violations of policies, shall be compiled and reported to the Compliance Officer (or compliance personnel designee) for review and follow-up as appropriate.

N. Reporting of Physician Payments. Within 90 days after the Effective Date, Biotronik shall post on its website a description of the types of Payments it makes to Covered Recipients and include a link to CMS's Open Payments Data website (www.openpaymentsdata.cms.gov). Biotronik also shall include on its website instructions regarding how to utilize the CMS Open Payments Data search tool to search for information regarding Payments provided to Covered Recipients from Biotronik.

O. Transition Plan. Prior to the end of the fourth Reporting Period, Biotronik shall develop a Transition Plan that is reviewed and approved by the Board. The Transition Plan shall be implemented following the end of the CIA's term. A copy of Biotronik's approved Transition Plan shall be included in Biotronik's fourth Annual Report.

IV. SUCCESSOR LIABILITY

If, after the Effective Date, Biotronik proposes to (a) sell any or all of its business, business units or locations (whether through a sale of assets, sale of stock or other type of transaction) that engage in any of the Covered Functions; or (b) purchases or establishes a new business, business unit or location relating to or that will engage in any of the Covered Functions, the CIA shall be binding on the purchaser of any business, business unit or location and any new business, business unit or location (and all Covered Persons at each new business, business unit or location) shall be subject to the requirements of this CIA, unless otherwise determined and agreed to in writing by OIG. Biotronik shall notify OIG, in writing, of such sale or purchase within 30 days following the closing of the transaction and shall notify OIG, in writing, within 30 days of establishing such new business, business unit or location.

If Biotronik wishes to obtain a determination by OIG that a proposed purchase or proposed acquisition will not be subject to the CIA requirements, Biotronik must notify OIG in writing at least 30 days in advance of the proposed sale or purchase. This notification shall include a description of the business, business unit, or location to be sold or purchased, a brief description of the terms of the transaction and, in the case of a proposed sale, the name and contact information of the prospective purchaser.

V. IMPLEMENTATION REPORT AND ANNUAL REPORTS

A. Implementation Report. Within 120 days after the Effective Date, Biotronik shall submit a written report (Implementation Report) to OIG that includes, at a minimum, the following information:

1. the name, business address, business phone number, and position description of the Compliance Officer required by Section III.A.1, and a detailed description of any noncompliance job responsibilities;

2. the names and positions of the members of the Compliance Committee required by Section III.A.2;
3. the names of the Board members who are responsible for satisfying the Board compliance requirements described in Section III.A.3;
4. the following information regarding the individual or entity retained by the Board to be the Compliance Expert: (a) identity, address, and phone number, (b) information to demonstrate the individual's or entity's expertise in compliance with Federal health care program requirements, and (c) a certification from the Compliance Expert that they do not have a current or prior relationship to Biotronik that would cause a reasonable person to question the Compliance Expert's objectivity in performing the review.
5. the names and positions of the Certifying Covered Persons required by Section III.A.4 and a copy of the written process for Certifying Covered Persons to follow in order to complete the certification required by Section III.A.4;
6. a list of the Policies and Procedures required by Section III.B;
7. the Training Plan required by Section III.C.1 and a description of the Board training required by Section III.C.2 (including a summary of the topics covered, the length of the training and when the training was provided);
8. the following information regarding the IRO(s): (a) identity, address, and phone number; (b) a copy of the engagement letter; (c) information to demonstrate that the IRO has the qualifications outlined in Appendix A to this CIA; and (d) a certification from the IRO regarding its professional independence and objectivity with respect to Biotronik that includes a summary of all current and prior engagements between Biotronik and the IRO;
9. a description of the risk assessment and internal review process required by Section III.E;
10. a description of the Disclosure Program required by Section III.F;
11. a description of the Ineligible Persons screening and removal process required by Section III.G;
12. a description of policies, procedures, and systems implemented pursuant to the Requirements Relating to Speaker Programs outlined in Section III.K;

13. a description of the FFMP required by Section III.L;
14. a description of the policies, procedures, and systems implemented pursuant to the Requirements Relating to Certain Non-Promotional Activities outlined in Section III.M;
15. a certification from the Compliance Officer that information regarding Payments has been posted on Biotronik's website as required by Section III.N;
16. a list of all of Biotronik's locations (including mailing addresses); the corresponding name under which each location is doing business; and the locations' Medicare and state Medicaid provider number and/or supplier number(s), if any;
17. a description of Biotronik's corporate structure, including identification of any parent and sister companies, subsidiaries, and their respective lines of business; and
18. a certification by the Compliance Officer and President that:
 - a. to the best of his or her knowledge, except as otherwise described in the report, Biotronik has implemented and complies with is in compliance with all requirements of this CIA;
 - b. he or she has reviewed the report and has made reasonable inquiry regarding its content and believes that the information in the report is accurate and truthful; and
 - c. he or she understands that the certification is being provided to and relied upon by the United States.

B. Annual Reports. Biotronik shall submit a written report (Annual Report) to OIG for each of the five Reporting Periods that includes, at a minimum, the following information:

1. any change in the identity, position description, or noncompliance job responsibilities of the Compliance Officer; a current list of the Compliance Committee members; a current list of the Board members who are responsible for satisfying the Board compliance requirements; and a current list of the Certifying Covered Persons, along with the identification of any changes made during the Reporting Period to the Compliance Committee, Board, or Certifying Covered Persons;
2. the dates of each meeting of the Compliance Committee (copies of the meeting minutes shall be made available to OIG upon request);

3. the dates of each report made by the Compliance Officer to the Board (written documentation of such reports shall be made available to OIG upon request);
4. the Board resolution required by Section III.A.3, a description of the materials reviewed by the Board and any additional steps taken in its oversight of the compliance program and in support of making the resolution;
5. a copy of the Compliance Expert's report and a certification from the Compliance Expert that they do not have a current or prior relationship to Biotronik that would cause a reasonable person to question the Compliance Expert's objectivity in performing the review of Biotronik's compliance program.
6. a description of any changes to the written process for Certifying Covered Persons to follow in order to complete the certification required by Section III.A.4;
7. the certifications of Certifying Covered Persons required by Section III.A.4;
8. a list of any new or revised Policies and Procedures required by Section III.B developed during the Reporting Period;
9. a description of any changes to the Training Plan required by Section III.C and a summary of all training furnished to Covered Persons and Board members during the Reporting Period;
10. a complete copy of all reports prepared pursuant to Section III.E and Biotronik's response to the reports, along with corrective action plan(s) related to any issues raised by the reports;
11. a certification from the IRO regarding its professional independence and objectivity with respect to Biotronik, including a summary of all current and prior engagements between Biotronik and the IRO;
12. a description of any changes to the risk assessment and internal review process required by Section III.E, including the reason(s) for such changes;
13. a summary of the following components of the risk assessment and internal review process during the Reporting Period: (a) risk areas identified, (b) work plans and internal audit plans developed, (b) internal audits performed, (c) corrective action plans developed in response to internal audits, and (d) steps taken to track the implementation of the

work plans and any corrective action plans. Copies of any work plans, internal audit reports, and corrective action plans shall be made available to OIG upon request;

14. a summary of the disclosures in the disclosure log required by Section III.F that relate to Federal health care programs, FDA requirements, or Government Reimbursed Products, including at least the following information: (a) a description of the disclosure, (b) the date the disclosure was received, (c) the resolution of the disclosure, and (d) the date the disclosure was resolved. The complete disclosure log shall be made available to OIG upon request;

15. a description of any changes to the Ineligible Persons screening and removal process required by Section III.G, including the reason(s) for such changes;

16. a summary describing any ongoing investigation or legal proceeding required to have been reported pursuant to Section III.H that includes a description of the allegation(s), the identity of the investigating or prosecuting agency, and the status of such investigation or legal proceeding;

17. a summary of all Reportable Events required to have been reported pursuant to Section III.I during the Reporting Period;

18. a summary describing any written communication with the FDA required to have been reported pursuant to Section III.J that includes a description of each matter and the status of each matter;

19. a summary of any changes to the policies, procedures, and systems relating to the Requirements Relating to Speaker Programs and Trainings described in Section III.K, including the reason(s) for such changes;

20. the results of the FFMP required by Section III.L, including copies of the Observations for any instances in which it was determined that improper conduct occurred and a description of the action(s) that Biotronik took as a result of such determinations;

20. a summary of any changes to the policies, procedures, and systems relating to the Requirements for Certain Non-Promotional Activities described in Section III.M, including the reason(s) for such changes;

21. a certification from the Compliance Officer that information regarding Payments has been posted on Biotronik's website as required by Section III.N;

22. (in the fourth Annual Report), a copy of the Transition Plan required by Section III.O;
23. a description of all changes to the most recently provided list of Biotronik's locations (including addresses) as required by Section V.A.16;
24. a description of any changes to Biotronik's corporate structure, including any parent and sister companies, subsidiaries, and their respective lines of business; and
25. a certification by the Compliance Officer and President that:
 - a. to the best of his or her knowledge, except as otherwise described in the report, Biotronik has implemented and complies with is in compliance with all requirements of this CIA;
 - b. he or she has reviewed the report and has made reasonable inquiry regarding its content and believes that the information in the report is accurate and truthful; and
 - c. he or she understands that the certification is being provided to and relied upon by the United States.

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

C. Designation of Information. Biotronik 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. Biotronik 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 using the following contact information:

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
Email Address: officeofcounsel@oig.hhs.gov

Biotronik:

Jason Spinazzola, Compliance Officer
6024 Jean Road
Lake Oswego, Oregon 97035
Telephone: 737.999.5740
Email Address: jason.spinazzola@biotronik.com

Unless otherwise requested by OIG, all notifications and reports required by this CIA shall be submitted electronically. OIG shall notify Biotronik in writing of any changes to the OIG contact information listed above. Biotronik shall notify OIG in writing within two business days of any changes to the Biotronik contact information listed above.

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 conduct interviews, examine and/or request copies of or copy Biotronik's books, records, and other documents and supporting materials, and conduct on-site reviews of any of Biotronik's locations, for the purpose of evaluating: (a) Biotronik's compliance with the terms of this CIA and (b) Biotronik's compliance with Federal health care program requirements and with all applicable FDA requirements. The documentation described above shall be made available by Biotronik to OIG or its duly authorized representative(s) at all reasonable times for inspection, audit, and/or reproduction. For purposes of this provision, OIG or its duly authorized representative(s) may interview any of Biotronik's owners, employees, contractors and Board members 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. Biotronik shall assist OIG or its duly authorized representative(s) in contacting and arranging interviews with such individuals upon OIG's request. Biotronik's owners, employees, contractors and Board members may elect to be interviewed with or without a representative of Biotronik present.

*Corporate Integrity Agreement
Biotronik, Inc.*

VIII. DOCUMENT AND RECORD RETENTION

Biotronik shall maintain for inspection all documents and records relating to reimbursement from the Federal health care programs and 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 Biotronik prior to any release by OIG of information submitted by Biotronik pursuant to its requirements under this CIA and identified upon submission by Biotronik as trade secrets, or information that is commercial or financial and privileged or confidential, under the FOIA rules. With respect to such releases, Biotronik shall have the rights set forth at 45 C.F.R. § 5.42(a).

X. BREACH AND DEFAULT PROVISIONS

A. Stipulated Penalties. OIG may assess:

1. A Stipulated Penalty of up to \$2,500 for each day Biotronik fails to comply with Section III.A;
2. A Stipulated Penalty of up to \$2,500 for each day Biotronik fails to comply with Section III.B;
3. A Stipulated Penalty of up to \$2,500 for each day Biotronik fails to comply with Section III.C;
4. A Stipulated Penalty of up to \$2,500 for each day Biotronik fails to comply with Section III.D;
5. A Stipulated Penalty of up to \$2,500 for each day Biotronik fails to comply with Section III.E;
6. A Stipulated Penalty of up to \$2,500 for each day Biotronik fails to comply with Section III.F;
7. A Stipulated Penalty of up to \$2,500 for each day Biotronik fails to comply with Section III.G;

8. A Stipulated Penalty of up to \$2,500 for each day Biotronik fails to comply with Section III.H;
9. A Stipulated Penalty of up to \$2,500 for each day Biotronik fails to comply with Section III.I;
10. A Stipulated Penalty of up to \$2,500 for each day Biotronik fails to comply with Section III.J;
11. A Stipulated Penalty of up to \$2,500 for each day Biotronik fails to comply with Section III.K;
12. A Stipulated Penalty of up to \$2,500 for each day Biotronik fails to comply with Section III.L;
13. A Stipulated Penalty of up to \$2,500 for each day Biotronik fails to comply with Section III.M;
14. A Stipulated Penalty of up to \$2,500 for each day Biotronik fails to comply with Section III.N;
15. A Stipulated Penalty of up to \$2,500 for each day Biotronik fails to comply with Section III.O;
16. A Stipulated Penalty of up to \$2,500 for each day Biotronik fails to comply with Section IV;
17. A Stipulated Penalty of up to \$2,500 for each day Biotronik fails to comply with Section V;
18. A Stipulated Penalty of up to \$2,500 for each day Biotronik fails to comply with Section VII;
19. A Stipulated Penalty of up to \$2,500 for each day Biotronik fails to comply with Section VIII; or
20. A Stipulated Penalty of up to \$50,000 for each false certification or false statement made to OIG by or on behalf of Biotronik under this CIA.

B. Timely Written Requests for Extensions. Biotronik 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. 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 Biotronik fails to meet the revised deadline set by OIG. 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 Biotronik 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.* If OIG determines that a basis for Stipulated Penalties under Section X.A exists, OIG shall notify Biotronik of: (a) Biotronik's failure to comply and (b) OIG's demand for payment of Stipulated Penalties (this notification is referred to as the "Demand Letter").

2. *Response to Demand Letter.* Within 15 business days after the date of the Demand Letter, Biotronik shall either: (a) 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.

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.

D. Exclusion for Material Breach

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

- a. failure to comply with any of the requirements of this CIA for which OIG has previously issued a demand for Stipulated Penalties under Section X.C, unless such Stipulated Penalty was overturned by an ALJ on appeal pursuant to the procedures described in Section X.E below;
- b. failure to comply with Section III.A.1;
- c. failure to comply with Section III.D;

- d. failure to comply with Section III.I;
- e. failure to comply with Section V;
- f. failure to respond to a Demand Letter in accordance with Section X.C;
- g. a false statement or false certification made to OIG by or on behalf of Biotronik under this CIA;
- h. failure to pay Stipulated Penalties within 20 days after an ALJ issues a decision ordering Biotronik to pay the Stipulated Penalties or within 20 days after the HHS Departmental Appeals Board (DAB) issues a decision upholding the determination of OIG; or
- i. failure to come into compliance with a requirement of this CIA for which OIG has demanded Stipulated Penalties, pursuant to the deadlines listed in Section X.E.2.

2. *Notice of Material Breach and Intent to Exclude.* The parties agree that a material breach of this CIA by Biotronik constitutes an independent basis for Biotronik's exclusion from participation in the Federal health care programs. The length of the exclusion shall be in OIG's discretion, but not more than five years for each material breach. Upon a preliminary determination by OIG that Biotronik has materially breached this CIA, OIG shall notify Biotronik of: (a) Biotronik's material breach and (b) OIG's intent to exclude Biotronik (this notification is hereinafter referred to as the "Notice of Material Breach and Intent to Exclude").

3. *Response to Notice.* Biotronik shall have 30 days from the date of the Notice of Material Breach and Intent to Exclude to submit any information and documentation for OIG to consider before it makes a final determination regarding exclusion.

4. *Exclusion Letter.* If OIG determines that exclusion is warranted, OIG shall notify Biotronik in writing of its determination to exclude Biotronik (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 the Exclusion Letter. The effect of the exclusion shall be that no Federal health care program payment may be made for any items or services furnished, ordered, or prescribed by Biotronik, including administrative and management services, except as stated in regulations found at 42 C.F.R. §1001.1901(c). The exclusion shall have national effect. Reinstatement to program participation is not automatic. At the end of the period of exclusion, Biotronik 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 issuing a Demand Letter or Exclusion Letter, and as an agreed-upon remedy for the resolution of disputes arising under this CIA, Biotronik 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. 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 DAB, in a manner consistent with the provisions in 42 C.F.R. § 1005.2-1005.21, but only to the extent this CIA does not provide otherwise. Notwithstanding the language in 42 C.F.R. § 1005: (a) the request for a hearing involving Stipulated Penalties shall be made within 15 business days after the date of the Demand Letter and the request for a hearing involving exclusion shall be made within 25 days after the date of the Exclusion Letter and (b) no discovery shall be available to the parties. The procedures relating to the filing of a request for a hearing can be found at <http://www.hhs.gov/dab/divisions/civil/procedures/divisionprocedures.html>.

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 Biotronik was in full and timely compliance with the requirements of this CIA for which OIG demands payment and (b) the period of noncompliance. Biotronik shall have the burden of proving its full and timely compliance. If the ALJ upholds the OIG's determination that Biotronik has breached this CIA and orders Biotronik to pay Stipulated Penalties, Biotronik must (a) come into compliance with the requirement(s) of this CIA that resulted in the OIG imposing Stipulated Penalties and (b) pay the Stipulated Penalties within 20 days after the ALJ issues a decision, unless Biotronik properly and timely requests review of the ALJ decision by the DAB. If the ALJ decision is properly and timely appealed to the DAB and the DAB upholds the determination of OIG, Biotronik must (a) come into compliance with the requirement(s) of this CIA that resulted in the OIG imposing Stipulated Penalties and (b) pay the Stipulated Penalties within 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 whether Biotronik was in material breach of this CIA. If the ALJ sustains the OIG's determination of material breach, the exclusion shall take effect 20 days after the ALJ issues the decision. 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. Biotronik shall waive its right to any notice of such exclusion if a decision

upholding the exclusion is rendered by the ALJ or DAB. If the DAB finds in favor of Biotronik, Biotronik shall be reinstated effective on the date of the 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. 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 and Biotronik agrees not to seek additional review of the DAB's decision (or the ALJ's decision if not appealed) in any judicial forum.

XI. EFFECTIVE AND BINDING AGREEMENT

Biotronik and OIG agree as follows:

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

B. All requirements and remedies set forth in this CIA are in addition to and do not affect (1) Biotronik's responsibility to follow all applicable Federal health care program and FDA requirements or (2) the government's right to impose appropriate remedies for failure to follow applicable Federal health care program or FDA requirements.

C. The undersigned Biotronik signatories represent and warrant that they are authorized to execute this CIA. The undersigned OIG signatories represent that they are signing this CIA in their official capacity and that they are authorized to execute this CIA.

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

ON BEHALF OF BIOTRONIK

/Ryan Walters/
RYAN WALTERS
President, Biotronik, Inc.

8.26.2022
DATE:

/David Blank/
DAVID BLANK, ESQ.
Arnall Golden Gregory LLP
Counsel for Biotronik, Inc.

8/26/2022
DATE:

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

/Lisa M. Re/
LISA M. RE
Assistant Inspector General for Legal Affairs
Office of Inspector General
U.S. Department of Health and Human Services

8/26/2022
DATE

/Andrea Treese Berlin/
ANDREA L. TREESE BERLIN
Senior Counsel
Office of Inspector General
U.S. Department of Health and Human Services

8/26/2022
DATE

APPENDIX A

INDEPENDENT REVIEW ORGANIZATION

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

A. IRO Engagement

1. Biotronik shall engage an IRO that possesses the qualifications set forth in Paragraph B, below, to perform the responsibilities in Paragraph C, below. The IRO shall conduct the review in a professionally independent and objective fashion, as set forth in Paragraph E. Within 30 days after OIG receives the information identified in Section V.A.7 of the CIA or any additional information submitted by Biotronik in response to a request by OIG, whichever is later, OIG will notify Biotronik if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, Biotronik may continue to engage the IRO.

2. If Biotronik engages a new IRO during the term of the CIA, that IRO must also meet the requirements of this Appendix. If a new IRO is engaged, Biotronik 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 this information or any additional information submitted by Biotronik at the request of OIG, whichever is later, OIG will notify Biotronik if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, Biotronik may continue to engage the IRO.

B. IRO Qualifications

The IRO shall:

1. assign individuals to conduct the Systems Review and Transactions Review who have expertise in the medical device industry and in all applicable Federal health care program and FDA requirements relating to the Covered Functions (as defined in Section II.C of the CIA), including but not limited to expertise relating to marketing and promotional activities associated with medical devices and the Federal Anti-Kickback Statute and False Claims Act; and

2. have sufficient staff and resources to conduct the reviews required by the CIA on a timely basis.

C. IRO Responsibilities

The IRO shall:

1. perform each component of the Systems Review and Transactions Review in accordance with the specific requirements of the CIA;
2. follow all applicable Federal health care program and FDA requirements in making assessments in the Systems Review and Transactions Review;
3. respond to all OIG inquires in a prompt, objective, and factual manner; and
4. prepare timely, clear, well-written reports that include all the information required by Appendix B to the CIA.

D. Biotronik Responsibilities

Biotronik shall ensure that the IRO has access to all records and personnel necessary to complete the reviews listed in III.D of this CIA and that all records furnished to the IRO are accurate and complete.

E. IRO Independence and Objectivity

The IRO must perform each component of the Systems Review and Transactions Review in a professionally independent and objective fashion, as defined in the most recent Government Auditing Standards issued by the U.S. Government Accountability Office.

F. IRO Removal/Termination

1. *Biotronik and IRO.* If Biotronik terminates its IRO or if the IRO withdraws from the engagement during the term of the CIA, Biotronik must submit a notice explaining (a) its reasons for termination of the IRO or (b) the IRO's reasons for its withdrawal to OIG, no later than 30 days after termination or withdrawal. Biotronik must engage a new IRO in accordance with Paragraph A of this Appendix and within 60 days of termination or withdrawal of the IRO.

2. *OIG Removal of IRO.* In the event OIG has reason to believe the IRO does not possess the qualifications described in Paragraph B, is not independent and objective as set forth in Paragraph E or has failed to carry out its responsibilities as described in Paragraph C, OIG shall notify Biotronik in writing regarding OIG's basis for determining that the IRO has not met the requirements of this Appendix. Biotronik shall have 30 days from the date of OIG's written notice to provide information regarding the IRO's qualifications, independence or performance of its responsibilities in order to resolve the concerns identified by OIG. If, following OIG's review of any information provided by Biotronik regarding the IRO, OIG determines that the IRO has not met the requirements of this Appendix, OIG shall notify Biotronik in writing that

Biotronik shall be required to engage a new IRO in accordance with Paragraph A of this Appendix. Biotronik must engage a new IRO within 60 days of its receipt of OIG's written notice. The final determination as to whether or not to require Biotronik to engage a new IRO shall be made at the sole discretion of OIG.

APPENDIX B

INDEPENDENT REVIEW ORGANIZATION REVIEWS

The IRO shall perform a Systems Review and a Transactions Review relating to the Covered Functions (as defined in Section II.C of the CIA). If there are no material changes in Biotronik's systems, processes, policies, and procedures relating to the Covered Functions, the IRO shall perform the Systems Review for the first and fourth Reporting Periods. If Biotronik materially changes its systems, processes, policies, and procedures relating to Covered Functions, the IRO shall perform an additional Systems Review for the Reporting Period(s) in which such changes were made that identifies the material changes and reviews the systems, processes, policies, and procedures that materially changed. The IRO shall conduct the Transactions Review for each Reporting Period of the CIA.

A. Systems Review. For the Systems Review, the IRO shall review Biotronik's systems, processes, policies, and procedures associated with the following (hereafter "Reviewed Policies and Procedures"):

1. Biotronik's systems, policies, processes, and procedures relating to the materials and information that may be distributed by Biotronik sales representatives (including any contract sales force) about Government Reimbursed Products and the manner in which Biotronik sales representatives respond to requests for information about uses of Government Reimbursed Products that are not FDA approved, cleared, or exempt ("non-FDA approved uses");

2. Biotronik's systems, policies, processes, and procedures relating to the materials and information that may be distributed and the mechanisms through, and manner in which, Biotronik receives and responds to requests for information from an HCP or another individual or entity about non-FDA approved uses of Government Reimbursed Products; the form and content of information disseminated by Biotronik in response to such requests; and the internal review process for the information disseminated;

3. Biotronik's systems, policies, processes, and procedures relating to the manner and circumstances under which Biotronik medical personnel interact with or participate in meetings or events with HCPs, HCIs, or payors (either alone or with Biotronik sales representatives) and the role of Biotronik medical personnel at such meetings or events, as well as how they handle responses to requests for information about non-FDA approved uses of Government Reimbursed Products;

4. Biotronik's systems, policies, processes, and procedures relating to the materials and information that may be distributed or made available by Biotronik through social media and/or direct-to-consumer advertising;

5. Biotronik's systems, policies, processes, and procedures relating to the development, implementation, and review of all polices for the distribution of Government Reimbursed Products for evaluation purposes (Evaluation Product). This shall include a review of the bases upon, and circumstances under, which HCPs and HCIs belonging to specified medical specialties or types of clinical practice may receive Evaluation Product from Biotronik (including, separately, from sales representatives, or through other channels);

6. Biotronik's systems, policies, processes, and procedures relating to consultant or other fee-for-service arrangements entered into with HCPs or HCIs (including but not limited to speaker programs, speaker training programs, training and education services, product development activities, presentations, consultant task force meetings, advisory boards, ad hoc advisory activities, research and research-related activities, authorship activities, and any other financial engagement or arrangement with an HCP or HCI) and all events and expenses relating to such engagements or arrangements;

8. Biotronik's systems, policies, processes, and procedures relating to agreements or arrangements with HCPs or HCIs for the purchase or licensing of intellectual property (including, but not limited to, patents, patent applications, and payment of royalties);

9. Biotronik's systems, policies, processes, and procedures relating to programs by HCPs to educate sales representatives or other Biotronik employees, including but not limited to presentations by HCPs at sales meetings, preceptorships, tutorials, and experience-based learning activities;

10. Biotronik's systems, policies, processes, and procedures relating to the review and approval of, and payment for, meals, travel, gifts, entertainment, gratuities, and related expenses for HCPs including those in connection with an HCP's participation in educational, research, training, or other Biotronik-sponsored programs or activities;

11. Biotronik's systems, policies, processes, and procedures relating to the sponsorship or funding of grants (including educational grants) or charitable contributions involving HCPs or HCIs;

12. Biotronik's systems, policies, processes, and procedures relating to funding of, or participation in, any Sponsorships or Third-Party Educational Activity as defined in Section II.C.12 and II.C.13 of the CIA;

13. Biotronik's systems, policies, processes, and procedures relating to the review of promotional, reimbursement-related, and disease state materials and information intended to be disseminated outside Biotronik by appropriate qualified personnel (such as regulatory, medical,

and/or legal personnel) in a manner designed to ensure that legal, regulatory, and medical concerns are properly addressed during Biotronik's review and approval process and are elevated when appropriate;

14. Biotronik's systems, policies, processes, and procedures relating to compensation (including through salaries, bonuses, or other means) for Covered Persons who are sales representatives and their managers; and

15. Biotronik's systems, policies, processes, and procedures relating to disciplinary policies and procedures for violations of Biotronik's Policies and Procedures, including policies relating to Federal health care program and FDA requirements.

B. Systems Review Report. The IRO shall prepare a Systems Review Report for each Systems Review that includes the following information:

1. a description of the documentation (including policies) reviewed and any personnel interviewed;

2. a detailed description of Biotronik's systems, policies, processes, and procedures relating to the items identified in Sections B.1-15 above, including a general description of Biotronik's control and accountability systems (e.g., documentation and approval requirements, and tracking mechanisms) and written policies regarding the Reviewed Policies and Procedures;

3. a description of the manner in which the control and accountability systems and the written policies relating to the items identified in Sections B.1-15 above are made known or disseminated within Biotronik;

4. findings and supporting rationale regarding any weaknesses in Biotronik's systems, processes, policies, and procedures relating to the Reviewed Policies and Procedures, if any; and

5. recommendations to improve any of the systems, policies, processes, or procedures relating to the Reviewed Policies and Procedures, if any.

C. Transactions Review. The Transactions Review shall include a review of: (1) a sample of consultant or other fee-for-service arrangements entered into with HCPs (including all events and expenses related to such engagements or arrangements), (2) a sample of medical education grants and charitable contributions involving HCPs and HCIs, and (3) a sample of Payments.

1. *Review of Consulting Activities*. For purposes of this Appendix B, the term "Consulting Activities" shall include all consulting and other fee for service arrangements

entered with HCPs (including but not limited to speaker programs, speaker training programs, training and education services, product development activities, presentations, consultant task force meetings, advisory boards, ad hoc advisory activities, research and research-related activities, authorship and authorship-related activities, and any other financial engagement or arrangement with an HCP or HCI) and all events and expenses relating to such engagements or arrangements.

- a. For the first Reporting Period, the IRO shall randomly select and review a sample of 25 Consulting Activities entered into with HCPs and all related expenses. For the second and subsequent Reporting Periods, at least 60 days prior to the end of the applicable Reporting Period, Biotronik shall provide the following information to OIG: (1) a description of each type of Consulting Activity undertaken during the Reporting Period and a description of the services to be provided under each Consulting Activity; (2) the number of each type of Consulting Activity undertaken during the Reporting Period; and (3) the overall budgeted amount to be spent in connection with each type of Consulting Activity during the Reporting Period. At least 30 days prior to the end of the applicable Reporting Period, the OIG shall select the number of each type of Consulting Activity to be reviewed by the IRO during the second and subsequent Reporting Period, up to a total sample size of 25.
- b. For each Consulting Activity reviewed, the IRO shall determine whether:
 - i. a written agreement was in place for each Consulting Activity that describes the scope of work to be performed, the fees and related expenses to be paid for the Consulting Activity, and the compliance obligations for the Consultant;
 - ii. the compensation to be paid for the Consulting Activity was determined in accordance with a centrally managed, pre-set rate structure established by Biotronik based on an independent fair market value analysis;
 - iii. the Consulting Activity was identified in the annual Consultant budgeting plan developed by Biotronik;
 - iv. a needs assessment that identifies the business need for the Consulting Activity and provides details about the Consulting Activity was completed prior to the initiation of the Consulting Activity;

- v. the Consulting Activity was reviewed and approved in accordance with Biotronik Policies and Procedures;
- vi. Biotronik collected and retained a record of the specific activity performed by the HCP and, if applicable, a copy of the work product generated by the HCP in connection with the Consulting Activity; and
- vii. the activity undertaken by the Consultant and/or the work product generated by the HCP was used by Biotronik in a manner consistent with the needs assessment that was completed prior to the initiation of the Consulting Activity.

2. *Review of Grants and Charitable Contributions.* For purposes of this Appendix B, the term “Grants” shall include any awarded amounts for Third Party Educational Activities (as defined in Section II.C.13 of the CIA) or other grant activities involving HCPs and HCIs, and the term “Contributions” shall include any charitable contributions involving HCPs or HCIs provided by Biotronik. For each Reporting Period, the IRO shall review a sample of 5 Grants and Contributions.

- a. The IRO shall select its sample of Grants and Contributions for review in consultation with OIG after the provision of information about each to OIG. Biotronik shall provide the following information to OIG: (1) a description of each type of Grant and Contribution provided during the Reporting Period and a description of the purpose of, and activity to be undertaken in connection with, each type of Grant and Contribution; (2) the number of each type of Grant and Contribution provided during the Reporting Period; and (3) the budgeted amount to be spent on each type of Grant and Contribution during the Reporting Period.
- b. The IRO’s review shall include, but not be limited to, proposal documents (including Grant and Contribution requests), approval documents, contracts, payments and materials relating to the centralized system’s review of the requests, and documents and materials relating to the Grants and Contributions and any events or activities funded through the Grants and Contributions.
- c. For each Grant and Contribution reviewed, the IRO shall determine whether:

- i. The request for the Grant or Contribution was submitted through Biotronik’s centralized system and processed in accordance with standardized objective criteria;
- ii. The terms of the Grant or Contribution are reflected in a written agreement between Biotronik and the recipient of the grant or contribution;
- iii. The Grant or Contribution was reviewed and approved in accordance with Biotronik policies and procedures;
- iv. Biotronik records identify the purpose or use for which the Grant or Contribution was requested; and
- v. Applicable documents or other records verify that the purpose of use for which the Grant or Contribution was requested occurred or was satisfied (e.g., if the Grant or Contribution was provided to sponsor an event, the IRO shall assess whether the event, in fact, occurred.)

3. *Review of Payments.* For purposes of this Appendix B, the term “Control Documents” shall include all material documents or electronic records associated with each Biotronik Payment reflected in the Open Payments database. For example, the term “Control Documents” includes, but is not limited to, documents relating to the nature, purpose, and amount of the Payment; contracts relating to the Payment; documents relating to the occurrence of Payment; documents reflecting any work product generated in connection with the Payment; documents submitted by sales representatives or headquarters personnel to request approval for the Payment; and business rationale or justification forms relating to the Payment.

- a. For each Reporting Period, the OIG shall have the discretion to identify up to 50 Covered Recipients who received Payments from Biotronik, as reflected in the most recent data available in the Open Payments database. If the OIG elects to exercise this discretion, it shall notify the IRO of the Covered Recipients subject to the IRO Review. If the OIG elects not to exercise its discretion, the IRO shall randomly select 50 Covered Recipients to be included in the review.
- b. For each selected Covered Recipient, the IRO shall review the Control Documents associated with the Payments to the Covered Recipient for all categories reflected in the Open Payments Data except for the Food/Beverage and Travel/Lodging categories of Payments. Specifically,

for each Covered Recipient selected as part of the sample, the IRO shall review the Control Documents identified by the IRO as necessary and sufficient to validate each Payment reported to CMS to evaluate the following:

- i. whether Control Documents are available relating to each Payment;
- ii. whether the Control Documents were completed and archived in accordance with the requirements set forth in Biotronik's policies;
- iii. whether the aggregate value of the Payment as reflected in the Open Payments database is consistent with the value of the Payment reflected in the Control Documents; and
- iv. whether the Control Documents reflect that Biotronik's policies were followed in connection with the Payment (e.g., all required written approvals for the activity were obtained in accordance with Biotronik's policies.)

4. *Review of Additional Items.* As set forth in Section III.D of the CIA, for each Reporting Period, the OIG at its discretion may identify up to three additional items for the IRO to review (hereafter "Additional Items").

- a. No later than 120 days prior to the end of the applicable Reporting Period, the OIG shall notify Biotronik of the nature and scope of the IRO review to be conducted for each of the Additional Items. Prior to undertaking the review of the Additional Items, the IRO and/or Biotronik shall submit an audit work plan to the OIG for approval and the IRO shall conduct the review of the Additional Items based on a work plan approved by the OIG. The IRO shall include information about its review of each Additional Item in the Transactions Review Report (including a description of the review conducted for each Additional Item; the IRO's findings based on its review for each Additional Item; and the IRO's recommendations for any changes in Biotronik's systems, policies, and procedures based on its review of each Additional Item).
- b. Biotronik may propose to the OIG that its internal audit(s), reviews, or monitoring activities, be substituted, subject to the Verification Review requirements set forth below, for one or more of the Additional Items that

would otherwise be reviewed by the IRO for the applicable Reporting Period. The OIG retains sole discretion over whether, and in what manner, to allow Biotronik's internal audit work to be substituted for a portion of the Additional Items review conducted by the IRO.

D. Transactions Review Report. The IRO shall prepare a Transactions Review Report for each Transactions Review that includes the following information:

1. *Transactions Review Methodology*.
 - a. Review Objective: A statement of the objective intended to be achieved by each part of the Transactions Review;
 - b. Review Protocol: A detailed narrative description of how the Transactions Review was performed and what was evaluated; and
 - c. Sources of Data: A description of the documentation and other information relied on by the IRO in performing the Transactions Review.
2. *Transactions Review Findings*.
 - a. Relating to the Review of Consulting Activities
 - i. a description of each type of Consulting Activity reviewed, including the number of each type of Consulting Activity reviewed and an identification of the types of documents and information reviewed for each Consulting Activity;
 - ii. for each Consulting Activity reviewed, the IRO's findings and supporting rationale as to whether:
 - (a) a written agreement was in place for each Consulting Activity that describes the scope of work to be performed, the fees and expenses to be paid for each Consulting Activity, and the compliance obligations for the Consultant;
 - (b) the compensation to be paid for the Consulting Activity was determined in accordance with a centrally managed, pre-set rate structure set by Biotronik that was established based on an independent FMV analysis;

- (c) the Consulting Activity was identified in the annual Consulting budgeting plan developed by Biotronik;
 - (d) a needs assessment that identifies the business need for the Consulting Activity and provides detail about the activity was prepared prior to the initiation of the Consulting Activity;
 - (e) the Consulting Activity was reviewed and approved in accordance with Biotronik Policies and Procedures,
 - (f) Biotronik collected and retained a record of the specific activity performed by the HCP and, if applicable, a copy of the work product generated in connection with the Consulting Activity; and
 - (g) the activity undertaken by the Consultant and/or the work product generated was used by Biotronik in a manner consistent with the needs assessment that was completed prior to the initiation of the Consulting Activity.
- iii. any weaknesses in Biotronik's systems, processes, policies, procedures and/or practices relating to Consulting Activities identified by the IRO; and
 - iv. any recommendations for improvements to Biotronik's systems, processes, policies, procedures and/or practices relating to Consulting Activities.
- b. Relating to the Review of Grants and Charitable Contributions
- i. a description of each type of Grant or Contribution reviewed, including the number of each type of Grant or Contribution reviewed and an identification of the types of documents and information reviewed for each Grant or Contribution reviewed;
 - ii. for each Grant or Contribution reviewed, the IRO's findings and supporting rationale as to whether:

- (a) the request for the Grant or Contribution was submitted through the Biotronik's centralized system and processed in accordance with standardized objective criteria;
- (b) the terms of the Grant or Contribution are reflected in a written agreement between Biotronik and the recipient of the Grant or Contribution;
- (c) the Grant or Contribution was reviewed and approved in accordance with Biotronik policies and procedures;
- (d) the purpose or use for which the Grant or Contribution was requested is identified in Biotronik records;
- (e) records verify that the purpose of use for which the Grant or Contribution was requested occurred or was satisfied;
- (f) the IRO identified any weaknesses in Biotronik's systems, processes, policies, procedures, and/or practices relating to Grants or Contributions; and
- (g) the IRO has recommendations for improvements to Biotronik's systems, processes, policies, procedures and/or practices relating to Grants or Contributions.

c. Relating to the Review of Payments

- i. a description of the entry in the Open Payments Database for each Payment sampled and a description of Control Documents reviewed in connection with each sampled Payment; and
- ii. for each sampled Payment, findings and supporting rationale as to whether:
 - (a) all required Control Documents exist;
 - (b) each Control Document was completed in accordance with all of the requirements set forth in the applicable Biotronik policy;

- (c) the aggregate value of the Payment as reflected in the Open Payments Database is consistent with the value of the Payment reflected in the Control Documents;
 - (d) each Control Document reflects that Biotronik's policies were followed in connection with the underlying activity reflected in the document (all required approvals were obtained); and
 - (e) any corrective action or disciplinary action was undertaken in those instances in which Biotronik policies were not followed.
- d. Relating to the Review of Additional Items
- i. for each Additional Item reviewed, a description of the review conducted;
 - ii. for each Additional Item reviewed, the IRO's findings based on its review;
 - iii. for each Additional Item reviewed, the findings and supporting rationale regarding any weaknesses in Biotronik's systems, processes, policies, procedures, and practices relating to the Additional Item, if any; and
 - iv. for each Additional Item reviewed, recommendations, if any, for changes in Biotronik's systems, processes, policies, and procedures that would correct or address any weaknesses or deficiencies uncovered during the review.