

## SETTLEMENT AGREEMENT

This Settlement Agreement (“Agreement”) is entered into among the United States of America, acting through the United States Department of Justice and on behalf of the Office of Inspector General (OIG-HHS) of the Department of Health and Human Services (HHS) (collectively, the “United States”); Biotronik, Inc. (“Biotronik” or “Defendant”); and Jeffrey Bell and Andrew Schmid (together, “Relators”), through their authorized representatives. Collectively, all of the above will be referred to as “the Parties.”

### RECITALS

A. Biotronik is a Delaware corporation headquartered in Oregon. At all relevant times, Biotronik marketed and sold cardiac rhythm management (CRM) devices, including pacemakers, defibrillators, and cardiac resynchronization therapy (CRT) devices throughout the United States.

B. On March 7, 2018, Relators filed a *qui tam* action in the United States District Court for the Central District of California captioned *United States, et al., ex rel. John Doe Number One and John Doe Number Two v. Biotronik Inc., et al.*, No. CV 18-1895, pursuant to the *qui tam* provisions of the False Claims Act, 31 U.S.C. § 3730(b) (the “Civil Action”). Relators’ complaint alleges, among other things, that Biotronik knowingly caused the submission of false claims for payment to federal healthcare programs by providing remuneration to physicians to induce them to use Biotronik’s CRM devices in violation of the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b). The United States intervened in the Civil Action on June 21, 2021.

C. Biotronik has entered into, or will be entering into, separate settlement agreements with certain states (hereafter referred to as the “Medicaid Participating States”) that will be receiving settlement funds from Biotronik, as described in Paragraph 1 of this Agreement and as

further described in the separate settlement agreements between Biotronik and the Medicaid Participating States, related to the Covered Conduct described in Paragraph E of this Agreement.

D. The United States contends that Biotronik caused the submission of claims for payment to the Medicare Program, Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395-1395lll (“Medicare”) and to multiple Medicaid Programs, 42 U.S.C. §§ 1396-1396w-5 (“Medicaid”).

E. The United States contends that it and the Medicaid Participating States have certain civil claims against Biotronik for engaging in the following conduct during the period from January 1, 2013 through October 1, 2021, (hereinafter referred to as the “Covered Conduct”). Specifically,

1. The United States contends that Biotronik knowingly paid excessive payments to physicians with a purpose of inducing and rewarding their use of Biotronik’s pacemakers, defibrillators, and other cardiac devices. Specifically, Biotronik abused its new employee training program (“Training Program”) by knowingly paying some of its physician customers (“Training Physicians”) to provide excessive employee trainings. Under the terms of written agreements between Biotronik and the Training Physicians, the Training Physicians were to be paid a fixed fee of approximately \$400.00 each time a Biotronik employee trainee received training during one of the Training Physician’s CRM implant procedures. During a Training Program implant procedure, the Training Physician was supposed to educate the employee trainee on Biotronik’s devices and teach how to assist a physician during an implant procedure. At various points during the relevant time period, Biotronik’s compliance and training departments warned that Biotronik’s salespeople had too much influence in the selection of Training Physicians, that the Training program and resulting payments were being over-utilized, and that the goal of educating Biotronik employees could be achieved without paying Training Physicians. Nevertheless, in certain circumstances, Biotronik permitted trainees to attend an excessive number of training procedures for which Training Physicians received payment from Biotronik without first conducting an adequate assessment of the trainee’s need for additional training. Additionally, in some instances, Biotronik salespeople, including managers, intentionally prevented otherwise qualified trainees from successfully completing the Training Program, not because they needed additional training, but rather as a means of ensuring that the trainee could attend more trainings, thereby purportedly justifying additional payments to Training Physicians. Biotronik also knowingly paid Training Physicians for some trainings that either never occurred

or were of little or no value to trainees. For example, Biotronik knowingly paid one Training Physician for certain trainings for which there was no trainee physically present to observe the implant procedure. Beginning in 2017, Biotronik added new compliance measures and oversight of the Training Program, limited the number of Training Program events, and reduced payments made in connection with such Training Program events; and

2. The United States also contends that Biotronik knowingly paid for lavish meals, entertainment, and travel for certain physicians who are known to Biotronik and the United States (hereinafter the “Subject Physicians”) with a purpose of inducing and rewarding their use of Biotronik’s pacemakers, defibrillators, and other cardiac devices. For example, during the relevant time period, Biotronik frequently did not require sign in sheets for lavish meals with physicians and did not use adequate methods to verify the number or identity of attendees or to confirm whether the meals were for a legitimate business purpose. In absence of sufficient controls, some Biotronik employees falsified receipts and participant lists, making it possible to exceed the company’s compliance spending limit per attendee. As a result, Biotronik paid for winery tours, annual office holiday parties, and lavish meals with certain Subject Physicians and their guests at high-end restaurants. Certain Biotronik employees and Subject Physicians recalled that these meals and outings often included little or no legitimate business discussion. Biotronik also paid for one Subject Physician's international business class airfare and honoraria in the thousands of dollars for a short, 30-minute talk at an international conference. In April 2021, Biotronik hired a new Vice President of Compliance and added new compliance measures related to the provision of meals and travel to healthcare providers which provided additional employee training, imposed new restrictions, and improved oversight to identify and prevent meal and travel policy violations.

As a result of the foregoing conduct, the United States alleges that Biotronik caused false or fraudulent claims for its CRM devices to be submitted to Medicare and Medicaid.

F. This Settlement Agreement is neither an admission of liability by Biotronik, nor a concession by the United States that its claims are not well founded. Biotronik denies the United States’ allegations in Paragraph E and the Relators’ allegations set forth in the Civil Action.

G. Relators claim entitlement under 31 U.S.C. § 3730(d) to a share of the proceeds of this Settlement Agreement and to Relators’ reasonable expenses, attorneys’ fees and costs.

To avoid the delay, uncertainty, inconvenience, and expense of protracted litigation of the above claims, and in consideration of the mutual promises and obligations of this Agreement, the Parties agree and covenant as follows:

TERMS AND CONDITIONS

1. Biotronik shall pay to the United States and the Medicaid Participating States, collectively, the sum of Twelve Million Nine Hundred Fifty Thousand Dollars (\$12,950,000), and interest on the Settlement Amount at a rate of 1.375% per annum from December 10, 2021, and continuing until and including the date of payment (the “Settlement Amount”) under the terms and conditions set forth in this Agreement. Of the Settlement Amount, Six Million Four Hundred Seventy Five Thousand Dollars (\$6,475,000) is restitution. The Settlement Amount shall be paid to the United States and the Medicaid Participating States as follows:

(a) Biotronik shall pay to the United States the sum of Twelve Million Sixteen Thousand Five Hundred Ninety-Four Dollars (\$12,016,594), plus accrued interest as set forth above (“Federal Settlement Amount”). The Federal Settlement Amount shall be paid by electronic funds transfer pursuant to written instructions from the United States no later than thirty (30) business days after the Effective Date of this Agreement.

(b) Biotronik shall pay the Medicaid Participating States the sum of Nine Hundred Thirty Three Thousand Four Hundred Six Dollars (\$933,406), plus accrued interest as set forth above, to be disbursed in accordance with written instructions from the Medicaid Participating States and under the terms and conditions of the agreements that Biotronik will enter into with the Medicaid Participating States.

2. Biotronik agrees to pay to Relators and their counsel the sum of One Million Two Hundred and Fifty Thousand Dollars (\$1,250,000) (the “Relator Settlement Amount”) no later

than thirty (30) business days after the Effective Date of this Agreement by electronic funds transfer pursuant to written instructions to be provided by Relators' counsel. The Relator Settlement Amount shall be paid as follows:

(a) Biotronik shall pay to Relator Schmid the sum of Three Hundred and Sixty Thousand Dollars (\$360,000);

(b) Biotronik shall pay to Relator Bell the sum of Three Hundred and Ninety Thousand Dollars (\$390,000); and

(c) Biotronik shall pay to the Relators' counsel the sum of Five Hundred Thousand Dollars (\$500,000) for statutory fees and costs.

3. Subject to the exceptions in Paragraph 5 below, and upon the United States' receipt of the Federal Settlement Amount, the United States releases Biotronik, together with its parent corporation; brother or sister corporations; divisions; current or former corporate owners; and the corporate successors and assigns of any of them (the "Biotronik Entities"), from any civil or administrative monetary claim the United States has for the Covered Conduct under the False Claims Act, 31 U.S.C. §§ 3729-3733; the Civil Monetary Penalties Law, 42 U.S.C. § 1320a-7a; the Program Fraud Civil Remedies Act, 31 U.S.C. §§ 3801-3812; or the common law theories of payment by mistake, unjust enrichment, and fraud.

4. Subject to the exceptions in Paragraph 5 (concerning reserved claims) below, and upon the United States' receipt of the Federal Settlement Amount, each Relator, for himself and for his heirs, successors, attorneys, agents, and assigns, releases each Biotronik Entity from any civil claim the Relator has on behalf of himself or on behalf of the United States under the False Claims Act, 31 U.S.C. §§ 3729-3733 and any claims each Relator has asserted, could have asserted, or may assert in the future, related to (a) the Covered Conduct or (b) any other allegations and claims

in the Civil Action related to conduct prior to the date of the execution of this Agreement. Relators expressly reserve, and do not release, any claims or rights they may have pursuant to the California Insurance Frauds Prevention Act Cal. Ins. Code § 1871 *et seq.*

5. Notwithstanding the releases given in Paragraph 3 of this Agreement, or any other term of this Agreement, the following claims and rights of the United States are specifically reserved and are not released:

- (a) Any liability arising under Title 26, U.S. Code (Internal Revenue Code);
- (b) Any criminal liability;
- (c) Except as explicitly stated in this Agreement, any administrative liability or enforcement right, including mandatory or permissive exclusion from Federal health care programs;
- (d) Any liability to the United States (or its agencies) for any conduct other than the Covered Conduct;
- (e) Any liability based upon obligations created by this Agreement; and
- (f) Any liability of individuals.

6. Relators and their heirs, successors, attorneys, agents, and assigns shall not object to this Agreement but agree and confirm that this Agreement is fair, adequate, and reasonable under all the circumstances, pursuant to 31 U.S.C. § 3730(c)(2)(B) and that the Settlement Amount described in Paragraph 1, above, is fair, adequate, and reasonable under all the circumstances. In connection with this Agreement and this Civil Action, Relators and their heirs, successors, attorneys, agents, and assigns agree that neither this Agreement, any intervention by the United States in the Civil Action in order to dismiss the Civil Action, nor any dismissal of the Civil Action, shall waive or otherwise affect the ability of the United States to contend that provisions in the

False Claims Act, including 31 U.S.C. §§ 3730(d)(3) and 3730(e), bar Relator from sharing in the proceeds of this Agreement. Moreover, the United States and Relator and his/her heirs, successors, attorneys, agents, and assigns agree that they each retain all of their rights pursuant to the False Claims Act on the issue of the share percentage, if any, that Relator should receive of any proceeds of the settlement of their claims.

7. Each Relator, for himself and for his heirs, successors, attorneys, agents, and assigns, releases each Biotronik Entity, and its affiliates, owners, officers, directors, agents, consultants and employees, from any liability to such Relator arising from the Civil Action, or under 31 U.S.C. § 3730(d) for expenses or attorneys' fees and costs, and any other claims that such Relator, individually or collectively, has asserted, could have asserted, or may assert in the future against each Biotronik Entity and its affiliates, owners, officers, directors, agents, consultants and employees, related to conduct prior to the date of the execution of this Agreement. Each Biotronik Entity, and its affiliates, owners, officers, directors, agents, consultants and employees releases each Relator, from any liability to such Biotronik Entity for any claims such Biotronik Entity could have asserted or may assert in the future against each Relator, related to conduct prior to the date of the execution of this Agreement.

8. Biotronik waives and shall not assert any defenses Biotronik may have to any criminal prosecution or administrative action relating to the Covered Conduct that may be based in whole or in part on a contention that, under the Double Jeopardy Clause in the Fifth Amendment of the Constitution, or under the Excessive Fines Clause in the Eighth Amendment of the Constitution, this Agreement bars a remedy sought in such criminal prosecution or administrative action.

9. Biotronik fully and finally releases the United States, its agencies, officers, agents, employees, and servants, from any claims (including attorneys' fees, costs, and expenses of every kind and however denominated) that Biotronik has asserted, could have asserted, or may assert in the future against the United States, its agencies, officers, agents, employees, and servants, related to the Covered Conduct or the United States' investigation or prosecution thereof.

10. Biotronik fully and finally releases the Relators from any claims (including attorneys' fees, costs, and expenses of every kind and however denominated) that Biotronik has asserted, could have asserted, or may assert in the future against the Relators, related to the Covered Conduct and the Relators' investigation and prosecution thereof.

11. The Settlement Amount shall not be decreased as a result of the denial of claims for payment now being withheld from payment by any Medicare contractor (*e.g.*, Medicare Administrative Contractor, fiscal intermediary, carrier) or any state payer, related to the Covered Conduct; and Biotronik agrees not to resubmit to any Medicare contractor or any state payer any previously denied claims related to the Covered Conduct, agrees not to appeal any such denials of claims, and agrees to withdraw any such pending appeals.

12. Biotronik agrees to the following:

(a) Unallowable Costs Defined: All costs (as defined in the Federal Acquisition Regulation, 48 C.F.R. § 31.205-47; and in Titles XVIII and XIX of the Social Security Act, 42 U.S.C. §§ 1395-1395lll and 1396-1396w-5; and the regulations and official program directives promulgated thereunder) incurred by or on behalf of Biotronik, its present or former officers, directors, employees, shareholders, and agents in connection with:

(1) the matters covered by this Agreement;



- (2) the United States' audit(s) and civil investigation(s) of the matters covered by this Agreement;
- (3) Biotronik's investigation, defense, and corrective actions undertaken in response to the United States' audit(s) and civil investigation(s) in connection with the matters covered by this Agreement (including attorneys' fees);
- (4) the negotiation and performance of this Agreement; and
- (5) the payment Biotronik makes to the United States pursuant to this Agreement and any payments that Biotronik may make to Relators, including costs and attorneys' fees,

are unallowable costs for government contracting purposes and under the Medicare Program, Medicaid Program, TRICARE Program, and Federal Employees Health Benefits Program (FEHBP) (hereinafter referred to as Unallowable Costs).

(b) Future Treatment of Unallowable Costs: Unallowable Costs shall be separately determined and accounted for by Biotronik, and Biotronik shall not charge such Unallowable Costs directly or indirectly to any contracts with the United States or any State Medicaid program, or seek payment for such Unallowable Costs through any cost report, cost statement, information statement, or payment request submitted by Biotronik or any of its subsidiaries or affiliates to the Medicare, Medicaid, TRICARE, or FEHBP Programs.

(c) Treatment of Unallowable Costs Previously Submitted for Payment: Biotronik further agrees that within ninety (90) days of the Effective Date of this Agreement it shall identify to applicable Medicare and TRICARE fiscal intermediaries, carriers, and/or contractors, and Medicaid and FEHBP fiscal agents, any Unallowable Costs (as defined in

Paragraph 12) included in payments previously sought from the United States, or any State Medicaid program, including, but not limited to, payments sought in any cost reports, cost statements, information reports, or payment requests already submitted by Biotronik or any of its subsidiaries or affiliates, and shall request, and agree, that such cost reports, cost statements, information reports, or payment requests, even if already settled, be adjusted to account for the effect of the inclusion of the Unallowable Costs. Biotronik agrees that the United States, at a minimum, shall be entitled to recoup from Biotronik any overpayment plus applicable interest and penalties as a result of the inclusion of such Unallowable Costs on previously-submitted cost reports, information reports, cost statements, or requests for payment.

Any payments due after the adjustments have been made shall be paid to the United States pursuant to the direction of the Department of Justice and/or the affected agencies. The United States reserves its rights to disagree with any calculations submitted by Biotronik or any of its subsidiaries or affiliates on the effect of inclusion of Unallowable Costs (as defined in this Paragraph 12) on Biotronik or any of its subsidiaries or affiliates' cost reports, cost statements, or information reports.

(d) Nothing in this Agreement shall constitute a waiver of the rights of the United States to audit, examine, or re-examine Biotronik's books and records to determine that no Unallowable Costs have been claimed in accordance with the provisions of Paragraph 12.

13. This Agreement is intended to be for the benefit of the Parties only. The Parties do not release any claims against any other person or entity, except to the extent provided for in Paragraph 14 (waiver for beneficiaries paragraph), below.

14. Biotronik agrees that it waives and shall not seek payment for any of the health care billings covered by this Agreement from any health care beneficiaries or their parents, sponsors,

legally responsible individuals, or third party payors based upon the claims defined as Covered Conduct.

15. Upon receipt of the payment described in Paragraph 1, above, the United States and Relators shall promptly sign and file in the Civil Action a Joint Stipulation of Dismissal of the Civil Action pursuant to Rule 41(a)(1) (the “Stipulation”). The Stipulation shall state that: (1) claims for the allegations described in the Covered Conduct are dismissed with prejudice as to the United States; (2) all other claims in the Civil Action against Biotronik shall be dismissed without prejudice as to the United States; and (3) all claims in the Civil Action against Biotronik shall be dismissed with prejudice as to the Relators. Each Relator agrees not to oppose the redactions proposed by Biotronik to the complaint filed in the Civil Action.

16. Each Party shall bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Agreement.

17. Each Party and signatory to this Agreement represents that it freely and voluntarily enters into this Agreement without any degree of duress or compulsion.

18. This Agreement is governed by the laws of the United States. The exclusive jurisdiction and venue for any dispute relating to this Agreement is the United States District Court for the Central District of California. For purposes of construing this Agreement, this Agreement shall be deemed to have been drafted by all Parties to this Agreement and shall not, therefore, be construed against any Party for that reason in any subsequent dispute.

19. This Agreement constitutes the complete agreement between the Parties. This Agreement may not be amended except by written consent of the Parties.

20. The undersigned counsel represent and warrant that they are fully authorized to execute this Agreement on behalf of the persons and entities indicated below.

21. This Agreement may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same Agreement.

22. This Agreement is binding on Biotronik's successors, transferees, heirs, and assigns.


23. This Agreement is binding on Relators' successors, transferees, heirs, and assigns.

24. All Parties consent to the United States' disclosure of this Agreement, and information about this Agreement, to the public.

25. This Agreement is effective on the date of signature of the last signatory to the Agreement ("Effective Date"). Facsimiles and electronic transmissions of signatures shall constitute acceptable, binding signatures for purposes of this Agreement.

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**THE UNITED STATES OF AMERICA**

DATED: 6/16/2022 BY:   
BREANNA L. PETERSON  
JONATHAN K. HOERNER  
Trial Attorneys  
Commercial Litigation Branch  
Civil Division  
United States Department of Justice

DATED: BY: \_\_\_\_\_  
KAREN PAIK  
Assistant United States Attorney  
Central District of California

DATED: BY: \_\_\_\_\_  
LISA M. RE  
Assistant Inspector General for Legal Affairs  
Office of Counsel to the Inspector General  
Office of Inspector General  
United States Department of Health and Human Services

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Commercial Litigation Branch  
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United States Department of Justice

DATED: 06/16/2022

BY:

  
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KAREN PAIK  
Assistant United States Attorney  
Central District of California

DATED:

BY:

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LISA M. RE  
Assistant Inspector General for Legal Affairs  
Office of Counsel to the Inspector General  
Office of Inspector General  
United States Department of Health and Human Services

**THE UNITED STATES OF AMERICA**

DATED:

BY:

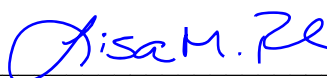
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BREANNA L. PETERSON  
JONATHAN K. HOERNER  
Trial Attorneys  
Commercial Litigation Branch  
Civil Division  
United States Department of Justice

DATED:

BY:


\_\_\_\_\_  
KAREN PAIK  
Assistant United States Attorney  
Central District of California

DATED: 06/15/2022 BY:

  
\_\_\_\_\_  
LISA M. RE  
Assistant Inspector General for Legal Affairs  
Office of Counsel to the Inspector General  
Office of Inspector General  
United States Department of Health and Human Services

**BIOTRONIK - DEFENDANT**

DATED: 6.16.22

BY: 

RYAN WALTERS  
President of Biotronik, Inc.

DATED: \_\_\_\_\_

BY: \_\_\_\_\_

JOHN L. BROWNLEE  
MEGAN MOCHO  
Holland & Knight LLP  
1650 Tysons Blvd., Suite 1700  
McLean, Virginia 22102

LAURA N. PERKINS  
Hughes Hubbard & Reed LLP  
1775 I Street, N.W., 7th floor  
Washington, DC 20006-2401

ERIN E. DIERS  
Hughes Hubbard & Reed LLP  
One Battery Park Plaza  
New York, NY 10004

*Counsel for Biotronik, Inc.*

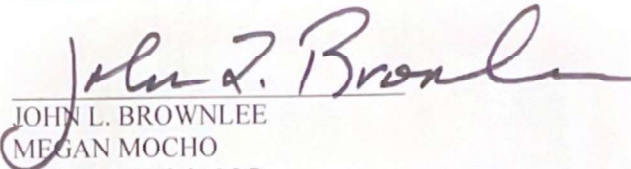


BIOTRONIK - DEFENDANT

DATED: \_\_\_\_\_

BY: \_\_\_\_\_  
RYAN WALTERS  
President of Biotronik, Inc.

DATED: 6/15/22

BY:   
\_\_\_\_\_  
JOHN L. BROWNLEE  
MEGAN MOCHO  
Holland & Knight LLP  
1650 Tysons Blvd., Suite 1700  
McLean, Virginia 22102

LAURA N. PERKINS  
Hughes Hubbard & Reed LLP  
1775 I Street, N.W., 7th floor  
Washington, DC 20006-2401

ERIN E. DIERS  
Hughes Hubbard & Reed LLP  
One Battery Park Plaza  
New York, NY 10004

*Counsel for Biotronik, Inc.*

**JEFFREY BELL AND ANDREW SCHMID - RELATORS**


DATED: 6/15/2022

BY:   
\_\_\_\_\_  
JEFFREY BELL

DATED:

BY: \_\_\_\_\_  
ANDREW SCHMID

DATED: 6/14/2022


BY:   
\_\_\_\_\_  
JOHN R. PARKER  
Cutter Law P.C.  
401 Watt Avenue, Suite 100  
Sacramento, California 95864


*Counsel for Relators*

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**JEFFREY BELL AND ANDREW SCHMID - RELATORS**

DATED: BY: \_\_\_\_\_  
JEFFREY BELL

DATED: 6/14/2022 BY:  \_\_\_\_\_  
ANDREW SCHMID

DATED: 6/14/2022 BY:  \_\_\_\_\_  
JOHN R. PARKER  
Cutter Law P.C.  
401 Watt Avenue, Suite 100  
Sacramento, California 95864  
  
*Counsel for Relators*