

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”); and Brian Sant (the “Relator”) through their authorized representatives. Collectively, all of the above hereafter will be referred to as “the Parties.”

RECITALS

A. Biotronik, Inc. is an Oregon Corporation that sells healthcare products and is an affiliate (sister company) of German Company Biotronik SE & Co. KG. At all relevant times herein, Biotronik through its Cardiac Rhythm and Disease Management (“CRDM”) business developed, distributed, marketed, and sold cardiac rhythm management devices in the United States, including pacemakers, implantable cardioverter defibrillators (“ICDs”), and cardiac resynchronization therapy (“CRT”) devices (collectively “CRDM devices”).

B. On December 31, 2009, Brian Sant filed a *qui tam* action in the United States District Court for the Eastern District of California captioned *U.S. ex rel. Doe v. Biotronik, Inc., and Western Medical, Inc. 2:09 - 03617 KJM EFB*, pursuant to the *qui tam* provisions of the False Claims Act, 31 U.S.C. § 3730(b) (the “Civil Action”).

C. The United States contends that Biotronik caused to be submitted claims for payment to the Medicare Program (Medicare), Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395-1395kkk-1 and to the Medicaid Program (Medicaid), Title XIX of the Social Security Act, 42 U.S.C. §§ 1396-1396w-5.

D. Biotronik has entered or will be entering into separate settlement agreements, described in Paragraph 1(b) below (hereinafter referred to as the “Medicaid State Settlement Agreements”) with certain states in settlement of the Covered Conduct. States with which Biotronik executes a Medicaid State Settlement Agreement in the form to which Biotronik and the National Association of Medicaid Fraud Control Units (“NAMFCU”) Negotiating Team have agreed, or in a form otherwise agreed to by Biotronik and an individual State, shall be defined as “Medicaid Participating States.”

E. The United States contends that it and the Medicaid Participating States have certain civil claims against Biotronik arising from the following conduct: between January 1, 2006 and December 31, 2011, Biotronik, acting through its employees and/or independent distributors, improperly induced electrophysiologists and cardiologists practicing in Nevada and Arizona who implant CRDM devices (“implanting physicians”) to continue using Biotronik CRDM devices or to convert their business from a competitor’s product to Biotronik CRDM devices by paying the implanting physician remuneration in the form of repeated meals at expensive restaurants and monthly payments for membership on a physician advisory board without proper documentation of any specific work performed. As a result of the foregoing conduct, the United States alleges that Biotronik knowingly caused false claims for the implantation of CRDM devices to be submitted to Medicare and Medicaid by the facility at which the implant occurred. This conduct is referred to below as the “Covered Conduct.”

F. Biotronik denies that it caused the submission of any false claims. 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.

G. Relator claims entitlement under 31 U.S.C. § 3730(d) to a share of the proceeds of this Settlement Agreement and to Relator's 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 Settlement 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 \$4,900,000 (the "Settlement Amount"). The Settlement Amount shall be paid to the United States and the Medicaid Participating States, under the following terms and conditions:

(a) Biotronik shall pay to the United States \$4,699,816.60 ("Federal Settlement Amount"). The Federal Settlement Amount shall be paid by electronic funds transfer pursuant to written instructions to be provided by the Office of the United States Attorney for the Eastern District of California seven (7) business days after the Effective Date of this Agreement.

(b) Pursuant to the terms of a separate agreement entered into between Biotronik and the Medicaid Participating States, Biotronik shall pay to the Medicaid Participating States \$200,183.40 ("Medicaid State Settlement Amount"). The Medicaid State Settlement Amount shall be paid by Biotronik pursuant to written instructions to be provided by the Nevada State Attorney General.

2. Conditioned upon the United States receiving the Settlement Amount from Biotronik and as soon as feasible after receipt, the United States shall pay \$845,967.00 of the Settlement Amount to Relator by electronic funds transfer.

3. Subject to the exceptions in Paragraph 5 (concerning excluded claims) below, and conditioned upon Biotronik's full payment of the Settlement Amount, the United States releases Biotronik, together with its current and former parent corporations; direct and indirect subsidiaries; brother or sister corporations; divisions; current or former owners; and officers, directors, and affiliates; and the successors and assigns of any of them, 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. Conditioned upon Biotronik's full payment of the Settlement Amount, Relator, for himself and for his heirs, successors, attorneys, agents, and assigns, releases Biotronik together with its predecessors, successors, subsidiaries, affiliates, and its present and former directors, officers, shareholders, members, employees, administrators, partners, agents, attorneys and accountants (collectively "the Releasees") from all of the following claims: Any and all claims, whether disclosed or undisclosed, which Relator has asserted, could have asserted, or may assert now or in the future against the Releasees related to the Civil Action, the Covered Conduct, and the Relator's investigation and prosecution thereof, including but not limited to any civil monetary claim the Relator, for himself or on behalf of the United States, has or may have for the Covered Conduct under

the False Claims Act, 31 U.S.C. §§ 3729-3733; and any claims with respect to Relator's employment with Biotronik, including but not limited to any claim for retaliation under 31 U.S.C. § 3730(h). Notwithstanding the foregoing, Relator does not release any conduct that arises after the date of this settlement agreement.

5. Notwithstanding the releases given in paragraph 3 of this Agreement, or any other term of this Agreement, the following claims 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, including mandatory and 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;
- (f) Any liability for express or implied warranty claims or other claims for defective or deficient products or services, including quality of goods and services;
- (g) Any liability for failure to deliver goods or services due; and
- (h) Any liability for personal injury or property damage or for other consequential damages arising from the Covered Conduct.

6. Relator and his 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).

Conditioned upon Relator's receipt of the payment described in Paragraph 2, Relator and his heirs, successors, attorneys, agents, and assigns fully and finally release, waive, and forever discharge the United States, its agencies, officers, agents, employees, and servants, from any claims arising from the filing of the Civil Action or under 31 U.S.C. § 3730, and from any claims to a share of the proceeds of this Agreement and/or the Civil Action.

7. Relator and his attorneys have a claim for attorney's fees and costs and will present the claim for fees and costs incurred in the prosecution of this action to Biotronik. Relator's claim for attorney's fees and costs is not released herein. Biotronik acknowledges the claim and agrees to pay the fees and costs that Relator is statutorily entitled to separate and apart from its payment to the United States under this agreement. Should the parties be unable to reach agreement on the amount of the attorney's fees and costs payment, then the United States District Court for the Eastern District of California shall have continuing jurisdiction to issue an order with regard to the payment of attorney's fees and costs.

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. Nothing in this paragraph or any other provision of this Agreement constitutes an agreement by the United States concerning the characterization of the Settlement Amount for purposes of the Internal Revenue laws, Title 26 of the United States Code.

9. Biotronik fully and finally releases the United States and its agencies, officers, agents, employees, and servants, from any claims (including attorney's 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 and its agencies, officers, agents, employees, and servants, related to the Covered Conduct and the United States' investigation and prosecution thereof.

10. Biotronik fully and finally releases the Relator from any claims that Biotronik has asserted, could have asserted, or may assert in the future against the Relator related to the Covered Conduct and the United States' 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, and agrees not to appeal any such denials of claims.

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. §§ 1395-1395kkk-1 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) and/or any criminal investigations(s) of the matters covered by this Agreement;
- (3) Biotronik's investigation, defense, and corrective actions undertaken in response to the United States' audits and civil investigation(s) in connection with the matters covered by this Agreement (including attorney's 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 Relator, 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 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 this Paragraph) 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) 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 this Paragraph.

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 Federal Settlement Amount, the United States and Relator shall file a joint stipulation of dismissal in the Civil Action as follows:

(a) the joint stipulation of dismissal shall be with prejudice as to the United States' and Relator's claims as to the Covered Conduct pursuant to and consistent with the terms and conditions of this Agreement; and

(b) the joint stipulation of dismissal shall be without prejudice as to the United States and with prejudice as to Relator as to all other claims.

16. Except as set forth in paragraph 7, 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 in to 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 Eastern 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 Relator's 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 of this Agreement). Facsimiles and .pdf versions of signatures shall constitute acceptable, binding signatures for purposes of this Agreement.

THE UNITED STATES OF AMERICA

DATED: _____

BY: _____

ADAM J. SCHWARTZ
Trial Attorney
Commercial Litigation Branch, Civil Division
United States Department of Justice

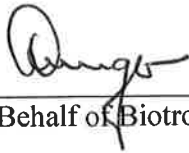
DATED: 5/14/14

BY: 

KELLI L. TAYLOR
Assistant U.S. Attorney
United States Attorney's Office
Eastern District of California

BIOTRONIK, INC.

DATED: 5-12-2014

BY: 
On Behalf of Biotronik, Inc.

DATED: _____

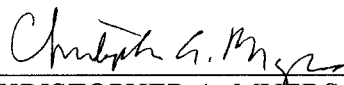
BY: _____
CHRISTOPHER A. MYERS
Holland & Knight
Counsel for Biotronik, Inc.

BIOTRONIK, INC.

DATED: _____

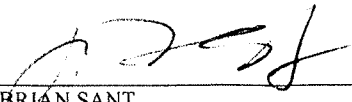
BY: _____
On Behalf of Biotronik, Inc.

DATED: 14 May 2014


BY: 
CHRISTOPHER A. MYERS
Holland & Knight
Counsel for Biotronik, Inc.

RELATOR BRIAN SANT

DATED: 5/19/14

BY: 
BRIAN SANT

DATED: 5/14/14

BY: 
C. BROOKS CUTTER, ESQ.
Kershaw Cutter & Ratinoff, LLP
Counsel for Brian Sant

DATED: _____

BY: _____
MYCHAL WILSON, ESQ.
The Law Offices of Mychal Wilson , LLP
Counsel for Brian Sant

RELATOR BRIAN SANT


DATED: _____

BY: _____
BRIAN SANT

DATED: _____

BY: _____
C. BROOKS CUTTER, ESQ.
Kershaw Cutter & Ratinoff, LLP
Counsel for Brian Sant

DATED: 5/9/14

BY: 
MYCHAL WILSON, ESQ.
The Law Offices of Mychal Wilson , LLP
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