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 of the Department of Health and Human Services ("OIG-HHS") (collectively, the "United States"); Aesculap Implant Systems, LLC ("Defendant"); and John J. Marien, Michael P. McGee, and Brad Stafford (collectively, "Relators") through their authorized representatives. All of the above will be referred to herein collectively as "the Parties."

RECITALS

A. Defendant is a medical device company based in Center Valley, Pennsylvania. Until late 2024, Defendant was in the business of importing and distributing medical devices in the United States, including a line of implants used in knee replacement surgery known as the VEGA System® Knee System ("Vega").

B. On August 11, 2017, John J. Marien and Michael P. McGee filed a *qui tam* action in the United States District Court for the Northern District of California captioned *United States ex rel. Marien & McGee, et al. v. Aesculap, Inc., et al.*, Case No. 17-cv-4650, pursuant to the *qui tam* provisions of the False Claims Act, 31 U.S.C. § 3730(b) ("the Marien Civil Action"). On February 12, 2019, Brad Stafford filed a *qui tam* action in the United States District Court for the Eastern District of Missouri captioned *United States ex rel. Stafford v. B. Braun Medical, Inc., et al.*, Case No 4:19-cv-217, pursuant to the *qui tam* provisions of the False Claims Act, 31 U.S.C. § 3730(b) ("the Stafford Civil Action"). After filing, the Marien Civil Action and the Stafford Civil Action were transferred to the United States District Court for the Eastern District of Pennsylvania, Case Nos. 19-cv-1618 and 19-cv-4108, respectively. The Marien Civil Action and the Stafford Civil Action will be referred to herein collectively as "the Civil Actions." The

United States will promptly file notices of intervention in the Civil Actions for the purposes of settlement following the execution of this Agreement.

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

D. The United States contends that it has certain civil claims against Defendant arising under the False Claims Act, 31 U.S.C. § 3729 *et seq.*, and the common law.

1. First, the United States contends that Defendant sold the Vega while knowing that it would fail prematurely at a higher than acceptable rate and was not reasonable and necessary for use during knee replacement surgeries, thereby causing the submission of false claims to the Medicare and Medicaid programs, as follows:

The Vega is a prosthetic implant used in knee replacement surgery. In such surgeries, physicians remove arthritic bone in the knee and implant the Vega, which is fixed in place using bone cement. Although the Vega is made of metal, it was only available in the United States with a ceramic coating made of zirconium nitride that Defendant refers to as its "Advanced Surface" technology. Defendant knew shortly after the Vega was released in the United States that bone cement did not properly adhere to the implant. As a result, the Vega was prone to becoming loose from the patient's bone prematurely, often shortly after surgery. Patients who experienced loosening could have pain, instability, and difficulty walking, and such patients required a revision surgery to remove and replace the Vega implant. Despite its knowledge of the Vega's propensity to become loosened, Defendant sold the Vega to physicians and hospitals in the United States without disclosing this known problem. In connection with the marketing of the Vega, Defendant made or caused others to make false and misleading statements concerning the safety and efficacy

of the Vega. Although Defendant received multiple reports of Vega loosenings from most of the top users of the device, Defendant failed to record, track, or report adverse events for the Vega. In addition, Defendant was aware that no appropriate investigation or meaningful testing had been conducted to determine the root cause of the Vega failures and did not take adequate steps to remediate the problem.

Defendant's conduct resulted in damages to the Medicare and Medicaid programs. By marketing the Vega while knowing that it would fail prematurely at a higher than acceptable rate and was not reasonable and necessary for use during knee replacement surgeries, Defendant knowingly caused false claims to be submitted to the Medicare and Medicaid programs. Given the Vega's propensity to loosen from the bone, surgeries in which the Vega was implanted were not eligible for reimbursement under the Medicare and Medicaid programs because such surgeries were not medically reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member. The claims were thus "false or fraudulent" for purposes of the False Claims Act. The time period for this allegation is July 30, 2010, to June 17, 2023.

2. Second, the United States contends that Defendant knowingly and willfully paid unlawful remuneration to an orthopedic surgeon located in Georgia who experienced problems with the device with the intent to induce him to use and recommend the use of the Vega Knee System, in violation of the Anti-Kickback Statute, 42 U.S.C. 1320a-7b(b). This remuneration, among other things, took the form of consulting agreements, free international travel, and entertainment. Claims submitted for surgical procedures performed by this orthopedic surgeon that used Vega implants were thus "false or fraudulent" for purposes of the False Claims Act. The time period for this allegation is July 30, 2010, to June 17, 2023.

3. Third, the United States contends that Defendant sold bone allograft that was not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member. The claims were thus "false or fraudulent" for purposes of the False Claims Act. The time period for this allegation is February 12, 2013, to July 2, 2018.

This conduct is collectively referred to below as the "Covered Conduct."

E. The United States acknowledges, pursuant to the Department of Justice's Guidelines for Taking Voluntary Disclosure, Cooperation and Remediation into Account in False Claims Act Matters (Justice Manual § 4.4.112), that Defendant and related entities doing business in the United States have made significant governance changes including hiring new officers, creating new board-level committees (including a Risk Management Committee), adding independent directors to the board, hiring an independent compliance expert, strengthening compliance and post-market surveillance procedures and policies, and increasing compliance and post-market surveillance resources. In addition, the United States acknowledges that Defendant ended sales in the United States of all products, including the Vega System, and wound down its operations in 2024.

F. This Settlement Agreement is neither an admission of liability by Defendant nor a concession by the United States that its claims are not well founded.

G. Defendant denies the United States' allegations in Paragraph D.

H. 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 Settlement Agreement, the Parties agree and covenant as follows:

TERMS AND CONDITIONS

1. Defendant shall pay to the United States thirty-eight million, five hundred and twenty-seven thousand, three hundred and ninety-eight dollars and thirty cents ($38,527,398.30) plus interest at 5 per cent per annum from October 1, 2024 ("Settlement Amount"), of which nineteen million, two hundred sixty-three thousand, six hundred and ninety-nine dollars and fifteen cents ($19,263,699.15) is restitution. Defendant shall make the payment no later than 14 days after the Effective Date of this Agreement by electronic funds transfer pursuant to written instructions to be provided by the Civil Division of the United States Department of Justice. Of the Settlement Amount, twenty-four million, seven hundred twenty-seven thousand, three hundred ninety-eight dollars and thirty cents ($24,727,398.30) is attributable to the allegations in Recital D.1., for which Relators Marien and McGee claim entitlement to a relator share; thirteen million, one hundred thousand dollars ($13,100,000) is attributable to the allegations is Recital D.2.; and seven hundred thousand dollars ($700,000) is attributable to the allegations in Recital D.3., for which Relator Stafford claims entitlement to a relator share.

2. Conditioned upon the United States receiving the Settlement Amount and as soon as feasible after receipt, the United States shall (a) pay four million, four hundred and seventy-five thousand dollars ($4,475,000.00), plus a proportionate share of any interest paid by Defendant, to Relators Marien and McGee and (b) pay one hundred fifty-four thousand dollars ($154,000.00), plus a proportionate share of any interest paid by Defendant, to Relator Stafford by electronic funds transfer (collectively, "Relators' Share"). No other relator payments shall be made by the United States with respect to the matters covered by this Agreement.

3. Defendant shall pay, pursuant to 31 U.S.C. §3730(d), Relators' attorneys' fees, expenses, and costs relating to the Marien Civil Action in the total amount of $11,417.00 no later than ten (10) business days after the Effective Date of this Agreement by electronic funds

transfer as follows: $9,615.63 to the Valor Law Firm, pursuant to the written instructions to be provided by Mr. Colon (Counsel for Marien/McGee); and $1,801.85 to The Buzbee Law Firm, pursuant to the written instructions to be provided by Mr. Buzbee (Counsel for Marien/McGee).

4. Defendant shall pay, pursuant to 31 U.S.C. §3730(d), Relator's attorneys' fees, expenses, and costs relating to the Stafford Civil Action in the amount of $110,695.00, no later than ten (10) business days after the Effective Date of this Agreement by electronic funds transfer to the Kasper Law Firm, LLC, pursuant to the written instructions to be provided by Mr. Kasper (Counsel for Stafford). Defendant shall also pay $100,000.00, no later than ten (10) business days after the Effective Date of this Agreement by electronic funds transfer to the Kasper Law Firm, LLC, pursuant to the written instructions to be provided by Mr. Kasper (Counsel for Stafford) to settle Relator Stafford's pending retaliation claims pursuant to 31 U.S.C. §3730(h) or any state analog.

5. Subject to the exceptions in Paragraph 7 (concerning reserved claims) below, and upon the United States' receipt of the Settlement Amount plus interest due under Paragraph 1, the United States releases Defendant, together with its current and former direct and indirect parent corporations and limited liability companies; direct and indirect subsidiaries; brother or sister corporations and limited liability companies; divisions; current or former corporate owners; and the corporate 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.

6. Subject to the exceptions in Paragraph 7 below, and upon the United States' receipt of the Settlement Amount plus interest due under Paragraph 1, Relators, for themselves

and for their heirs, successors, attorneys, agents, and assigns, release Defendant, together with its current and former direct and indirect parent corporations and limited liability companies, direct and indirect subsidiaries; brother or sister corporations and limited liability companies; affiliates; divisions; current or former corporate owners including those named as defendants in the Civil Actions; and the corporate successors and assigns of any of them as well as all their current and former officers, directors, and employees, from any civil monetary claim the Relators have on behalf of the United States for the Covered Conduct under the False Claims Act, 31 U.S.C. §§ 3729-3733.

7. Notwithstanding the releases given in Paragraph 5 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;

f. Any liability of individuals;

h. Any liability for failure to deliver goods or services due;

i. Any liability for personal injury or property damage or for other consequential damages arising from the Covered Conduct.

8. 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). Conditioned upon Relators' receipt of the Relators' Share, Relators and their 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 Actions or under 31 U.S.C. § 3730, and from any claims to a share of the proceeds of this Agreement and/or the Civil Actions.

9. Relators, for themselves, and for their heirs, successors, attorneys, agents, and assigns, release Defendant, together with its current and former direct and indirect parent corporations and limited liability companies; direct and indirect subsidiaries; brother or sister corporations and limited liability companies; affiliates; divisions; current or former corporate owners including those named as defendants in the Civil Actions; and the corporate successors and assigns of any of them as well as all their current and former officers, agents, directors, and employees, from any liability to Relators arising from the filing of the Civil Actions, which stand disputed by Defendants, including for all products described and alleged acts identified or otherwise described in those Civil Actions, or under 31 U.S.C. § 3730(d) for expenses or attorneys' fees and costs, and, as to Relator Stafford, his pending retaliation claims pursuant to 31 U.S.C. §3730(h) or any state analog. Notwithstanding the foregoing, nothing in this Release shall be construed to waive, release, or otherwise affect any independent civil, contractual, or statutory right or defense of Relator McGee, including but not limited to claims of indemnification or contribution, and to seek or recover attorneys' fees, costs, or expenses against the Defendant related to actions or matters other than the Marien Civil Action.

10. Defendant waives and shall not assert any defenses Defendant 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.

11. Defendant 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 Defendant 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.

12. Defendant fully and finally releases the Relators from claims (including attorneys' fees, costs, and expenses of every kind and however denominated) that Defendant has asserted, could have asserted, or may assert in the future against the Relator, related to the allegations in the Marien Civil Action and the Stafford Civil Action, and the Relators' investigation and prosecution thereof. However, Defendant does not release any claims that it may have and/or can yet assert against Relators (including claims for indemnification and/or contribution) in pending and/or future products liability litigation.

13. 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 Defendant agrees not to resubmit to any Medicare contractor or any state payer any

previously denied claims related to the Covered Conduct, agree not to appeal any such denials of claims, and agree to withdraw any such pending appeals.

14. Defendant 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 Defendant, 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) Defendant'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 Defendant makes to the United States pursuant to this Agreement and any payments that Defendant 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 Defendant, and Defendant 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 Defendant or any of its subsidiaries or affiliates to the Medicare, Medicaid, TRICARE, or FEHBP Programs.

c. Treatment of Unallowable Costs Previously Submitted for Payment: Defendant 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 Defendant 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. Defendant agrees that the United States, at a minimum, shall be entitled to recoup from Defendant 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 Defendant or any of its subsidiaries or affiliates on the effect of inclusion of Unallowable Costs (as defined in this paragraph) on Defendant 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 Defendant's books and records to determine that no Unallowable Costs have been claimed in accordance with the provisions of this paragraph.

15. 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 16 and any other provision herein.

16. Defendant 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.

17. Upon receipt of the payment described in Paragraph 1, above, the United States and Relators shall promptly sign and file in the Civil Actions Notices of Dismissal pursuant to Rule 41(a)(1). The United States' dismissal will be with prejudice to the United States only as to the Covered Conduct released in the Settlement Agreement, and without prejudice to the United States as to any other claims in the Civil Actions. Relators' dismissal shall be as to all claims against all defendants named in the Civil Actions and as to all products listed in the complaints in those Civil Actions.

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

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

20. 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 Pennsylvania. 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.

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

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

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

24. This Agreement is binding on Defendant's successors, transferees, heirs, and assigns.

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

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

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

[SIGNATURE PAGES FOLLOW]

THE UNITED STATES OF AMERICA

DATED: 11-7-25 BY: _____
NICHOLAS C. PERROS
Senior Trial Counsel
Commercial Litigation Branch
Civil Division
United States Department of Justice

DATED: 11-7-25 BY: _____
DAVID METCALF
United States Attorney
Eastern District of Pennsylvania

DATED: 11-7-25 BY: _____
GREGORY B. DAVID
Chief, Civil Division
Eastern District of Pennsylvania

DATED: 11-7-25 BY: _____
CHARLENE KELLER FULLMER
Deputy Chief, Affirmative Litigation
Eastern District of Pennsylvania

DATED: 11/7/25 BY: _____
ERIN E. LINDGREN
Assistant United States Attorney
Eastern District of Pennsylvania

DATED: _____ BY: _____
SUSAN E. GILLIN
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: _____
NICHOLAS C. PERROS
Senior Trial Counsel
Commercial Litigation Branch
Civil Division
United States Department of Justice

DATED: _____ BY: _____
DAVID METCALF
United States Attorney
Eastern District of Pennsylvania

DATED:_____ BY: _____
GREGORY B. DAVID
Chief, Civil Division
Eastern District of Pennsylvania

DATED:_____ BY: _____
CHARLENE KELLER FULLMER
Deputy Chief, Affirmative Litigation
Eastern District of Pennsylvania

DATED:_____ BY: _____
ERIN E. LINDGREN
Assistant United States Attorney
Eastern District of Pennsylvania

DATED: _____ BY: TAMARA FORYS Digitally signed by TAMARA FORYS Date: 2025.11.07 13:57:18 -05'00'
SUSAN E. GILLIN
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

DEFENDANT AESCULAP IMPLANT SYSTEMS, LLC

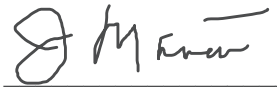
DATED: 11-07-2025 BY: _____
JIM WEST
SVP & President
Aesculap Implant Systems, LLC

DATED: 11/7/25 BY: _____
CHRISTIANA C. JACXSENS
CVP & General Counsel, Life Sciences & Litigation, B. Braun of America Inc. entities, including Aesculap Implant Systems, LLC

DATED: 11/7/25 BY: _____
JESSICA NATALI
Faegre Drinker Biddle & Reath
Counsel for Aesculap Implant Systems, LLC

DATED: 11/7/25 BY: _____
CAROLYN F. MCNIVEN
Faegre Drinker Biddle & Reath
Counsel for Aesculap Implant Systems, LLC

RELATORS JOHN J. MARIEN AND MICHAEL P. MCGEE

DATED: 11/07/2025 BY: 

JOHN J. MARIEN

DATED: 11/07/2025 BY: 

MICHAEL P. MCGEE

DATED: 11/07/2025 BY: 

ANTHONY BUZBEE
Counsel for John J. Marien and Michael P. McGee

DATED: 11/07/2025 BY: 

EDRAUL COLON
Counsel for John J. Marien and Michael P. McGee

RELATOR BRAD STAFFORD

DATED: 11-7-2025 BY: _____
BRAD STAFFORD

DATED: 11-7-2025 BY: _____
KEVIN J. KASPER
Counsel for Brad Stafford