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"), and Reliance Medical Systems, LLC, Apex Medical Technologies, LLC, Kronos Spinal Technologies, LLC, Bret Berry, and Adam Pike (hereafter collectively referred to as "Defendants"), through their authorized representatives.

RECITALS

- A. Defendants sell medical devices that are used in surgery on the spine to healthcare providers. The healthcare providers, in turn, are reimbursed by Medicare for the costs of surgeries performed of Medicare beneficiaries, and used a portion of the payments they received from Medicare to pay Defendants.
- B. On September 8, 2014, the United States filed an action in the United States

 District Court for the Central District of California captioned *United States v. Reliance Medical*Systems, et al., No. 14-6979-DDP (the "Civil Action").
- C. The United States contends that Defendants 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").
- D. The United States contends that it has certain civil claims against Defendants.

 This conduct is set forth in detail in the United States' amended complaint. ECF No. 231. That conduct is referred to below as the "Covered Conduct."
- E. This Settlement Agreement is neither an admission of liability by Defendants nor a concession by the United States that its claims are not well founded.

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. Defendants shall pay to the United States one lump sum payment of one million dollars (\$1,000,000.00) ("Settlement Amount"), of which the entire amount is restitution, no later than 30 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.
- 2. Subject to the exceptions in Paragraph 3 (concerning reserved claims) below, and upon the United States' receipt of the Settlement Amount, the United States releases civil or administrative monetary claims it has for the Covered Conduct through the date this Agreement is signed, under the False Claims Act, 31 U.S.C. §§ 3729-3733, or the Civil Monetary Penalties Law, 42 U.S.C. § 1320a-7a, against Defendants, together with their current and former parent corporations; direct and indirect subsidiaries; brother or sister corporations; divisions; current or former corporate owners; and the corporate successors and assigns of any of them.
- 3. Notwithstanding the release given in Paragraph 2 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;

- 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;
- 4. Defendants waive and shall not assert any defenses Defendants 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.
- 5. Defendants fully and finally release the United States, its agencies, officers, agents, employees, and servants, from any claims (including attorney's fees, costs, and expenses of every kind and however denominated) that Defendants have 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.
- 6. 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 Defendants agree 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.
 - 7. Defendants agrees to the following:
- a. <u>Unallowable Costs Defined</u>: 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 **Defendants**, its present or former officers, directors, employees, shareholders, and agents in connection with:

- (1) the matters covered by this Agreement and any related plea agreement;
- (2) the United States' audit(s) and civil and any criminal investigation(s) of the matters covered by this Agreement;
- (3) Defendants' investigation, defense, and corrective actions undertaken in response to the United States' audit(s) and civil and any criminal 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 Defendants make to the United States pursuant to this Agreement;

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. <u>Future Treatment of Unallowable Costs</u>: Unallowable Costs shall be separately determined and accounted for by Defendants, and Defendants 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 Defendants or any of their subsidiaries or affiliates to the Medicare, Medicaid, TRICARE, or FEHBP Programs.
- c. <u>Treatment of Unallowable Costs Previously Submitted for Payment:</u>

 Defendants 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 Defendants or any of their 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. Defendants agree that the United States, at a minimum, shall be entitled to recoup from Defendants 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 Defendants or any of their subsidiaries or affiliates on the effect of inclusion of Unallowable Costs (as defined in this paragraph) on Defendants or any of their 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 Defendants books and records to determine that no Unallowable Costs have been claimed in accordance with the provisions of this paragraph.
- 8. 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 9 (waiver for beneficiaries paragraph), below.

- 9. Defendants 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.
- 10. Upon receipt of the payment described in Paragraph 1, above, the Parties shall promptly sign and file in the Civil Action a Joint Stipulation of Dismissal of the Civil Action pursuant to Rule 41(a)(1).
- 11. Each Party shall bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Agreement.
- 12. Each Party and signatory to this Agreement represents that it freely and voluntarily enters into this Agreement without any degree of duress or compulsion.
- 13. This Agreement is governed by the laws of the United States. The exclusive 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.
- 14. This Agreement constitutes the complete agreement between the Parties. This Agreement may not be amended except by written consent of the Parties.
- 15. The undersigned counsel represent and warrant that they are fully authorized to execute this Agreement on behalf of the persons and entities indicated below.
- 16. This Agreement may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same Agreement.
- 17. This Agreement is binding on Defendants successors, transferees, heirs, and assigns.

- All Parties consent to the United States' disclosure of this Agreement, and information about this Agreement, to the public.
- 19. 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.

THE UNITED STATES OF AMERICA

DATED: 7/1/22

BY:

DAVID M. FINKELSTEIN

Trial Attorney

Commercial Litigation Branch

Civil Division

United States Department of Justice

DEFENDANTS

DATED: 30 June 2022	BY:	RELIANCE MEDICAL SYSTEMS, LLC (by: Bret Berry)
DATED: 30 June 2022	BY:	APEX MEDICAL TECHNOLOGIES, LLC (by: Bret Berry)
DATED: 30 June 2022	BY:	KRONOS SPINAL TECHNOLOGIES, LLO (by: Bret Berry)
DATED: <u>30 June 2</u> 022	BY:	BRET BERRY
DATED:	BY:	ADAM PIKE

DATED: <u>6/30/20</u>22 BY: PA

PATRIC HOOPER Counsel for Defendants