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SUPERIOR COURT OF THE STATE OF CALIFORNIA
COUNTY OF VENTURA

STEVEN RUSSAK,

Plaintiff,

vs.

GREGORY TCHEJEYAN, M.D.; ZIMMER BIOMET HOLDINGS, INC.; CANARY MEDICAL, USA LLC; and DOES 1 through 50, inclusive,

Defendants.

Case No.: 2026CUPL064721

SECOND AMENDED COMPLAINT FOR:

1. MEDICAL BATTERY;
2. LACK OF INFORMED CONSENT;
3. FRAUD AND INTENTIONAL MISREPRESENTATION;
4. STRICT PRODUCTS LIABILITY – FAILURE TO WARN; and
5. NEGLIGENCE

DEMAND FOR JURY TRIAL

Plaintiff alleges,

PRELIMINARY STATEMENT

1. The true names or capacities, whether individual, corporate, associate, or otherwise, of DOES 1 through 50, inclusive, defendants herein, are unknown to plaintiff who therefore sues said defendants by such fictitious names and will ask leave of court to amend this Complaint to show their true names and capacities when the same have been ascertained.

2. Plaintiff, STEVEN RUSSAK is an individual residing in the County of Ventura, State of California.

3. Plaintiff is informed and believes, and thereon alleges, that each Defendant named in this Complaint was at all times mentioned herein and now is the agent and employee of each of the other defendants herein and was at all times acting within the course and scope of said agency and employment.

4. Plaintiff is informed and believes, and thereon alleges, that ZIMMER BIOMET HOLDINGS INC, is a corporation doing business in the County of Ventura, State of California and transacting business within the above-entitled county. Plaintiff is informed and believes, and thereon alleges, that defendant CANARY MEDICAL, USA, LLC. is a limited liability company doing business in the County of Ventura, State of California and transacting business within the above-entitled county. Defendant GREGORY TCHEJEYAN, M.D. is a physician licensed in California.

5. Jurisdiction is proper in this Court because the acts and omissions complained of occurred in Ventura County, California. Venue is proper under Code of Civil Procedure § 395 because Plaintiff resides in Ventura County and the surgery was performed there.

6. This is a civil action arising from the unauthorized implantation of the Zimmer Biomet Persona IQ "Smart Knee" device into Plaintiff STEVEN RUSSAK on March 11, 2025. Plaintiff consented only to a standard, passive mechanical total knee replacement. Without his knowledge or consent, Defendants instead implanted a sophisticated active electronic device containing a lithium-ion battery, a multi-axis sensor array, a gyroscope, and a radio-frequency wireless transmitter engineered to continuously collect and transmit Plaintiff's biometric and kinematic data to Defendants' corporate cloud servers.

7. Defendants knowingly bypassed Zimmer Biomet's own pre-operative patient-enrollment protocols, which expressly require the patient to create an account, review disclosure materials, and provide affirmative consent before the Canary Medical Canturio™ Tibial Extension ("CTE") device

may be implanted. No such consent was obtained. The implant was activated intraoperatively by a Zimmer Biomet corporate representative present in the operating room, while Plaintiff lay under general anesthesia, incapable of consent or objection.

8. Plaintiff first learned that an electronic device had been placed inside his body not from his surgeon, but from a series of unsolicited text messages and telephone calls from Zimmer Biomet urging him to set up a "Home Base Station" and activate the mymobility data-sharing application. When Plaintiff confronted Defendant GREGORY TCHEJEYAN, M.D. regarding this nondisclosure, the surgeon admitted that he had not informed any prior patients in whom he had implanted the same device of its electronic nature, wireless transmission capabilities, or data-collection functions.

9. The Persona IQ's own FDA-mandated regulatory labeling states that the kinematic data collected by the device's CHIRP system is "not intended to support clinical decision-making" and has "not been shown to provide any clinical benefit" to patients. Defendants concealed this finding from Plaintiff and induced him to serve as an unwitting, uncompensated data-generating node for Defendants' commercial artificial intelligence platform (WalkAI) and corporate research programs, without benefit to his health and at permanent risk to his bodily safety.

10. This action seeks compensatory damages, including general and special damages, as well as punitive damages for Defendants' malicious, oppressive, and fraudulent conduct, pursuant to California Civil Code § 3294.

JURISDICTION AND VENUE

11. This Court has subject matter jurisdiction over this action pursuant to California Constitution, Article VI, § 10. The amount in controversy exceeds Thirty-Five Thousand Dollars ($35,000), exclusive of interest and costs, making this an Unlimited Civil Case.

12. Venue is proper in the Superior Court of California, County of Ventura, pursuant to Code of Civil Procedure § 395(a) because: (a) Plaintiff resides in Ventura County; (b) the subject surgery was performed at a medical facility located in Ventura County; (c) Defendant TCHEJEYAN maintains his principal medical practice in Ventura County; and (d) the material acts and omissions giving rise to this action occurred within Ventura County.

PARTIES

13. Plaintiff STEVEN RUSSAK ("Plaintiff") is, and at all relevant times was, an individual residing in Ventura County, State of California. Plaintiff underwent a total knee arthroplasty on March 11, 2025, which forms the basis of this action.

14. Defendant GREGORY TCHEJEYAN, M.D. ("Dr. Tchejeyan") is a physician licensed to practice medicine in the State of California. At all relevant times, Dr. Tchejeyan maintained his principal medical office in Ventura County, California, and performed the subject surgical procedure on Plaintiff at a Ventura County medical facility.

15. Defendant ZIMMER BIOMET HOLDINGS, INC. ("Zimmer Biomet") is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business in Warsaw, Indiana. Zimmer Biomet is a global medical device manufacturer and distributor that designs, manufactures, markets, and sells the Persona IQ "Smart Knee" system, including the proprietary ZBEdge Connected Intelligence Suite, the mymobility patient engagement platform, and the WalkAI artificial intelligence data engine. At all relevant times, Zimmer Biomet regularly conducted business within the County of Ventura and the State of California.

16. Defendant CANARY MEDICAL, INC. ("Canary Medical") is a corporation organized and existing under the laws of the State of Delaware. Canary Medical designed, manufactured, and distributed the Canary canturio™ te (CTE) tibial extension and the embedded Canary Health

Implanted Reporting Processor ("CHIRP") system, the active electronic components housed within the Persona IQ device implanted in Plaintiff's body. Canary Medical is a joint participant in the marketing and distribution of the Persona IQ system and bears joint and several liability for the defects in warnings, instructions, and disclosures associated with the device.

17. The true names and capacities of Defendants sued herein as DOES 1 through 50, inclusive, are currently unknown to Plaintiff. Plaintiff is informed and believes, and on that basis alleges, that each of the fictitiously named Defendants is responsible in some manner for the acts, omissions, and injuries alleged herein. Plaintiff will amend this Complaint to state the true names and capacities of such Defendants when ascertained. Each reference to "Defendants" herein is intended to include and refer to all named Defendants and all DOE Defendants.

18. Plaintiff is informed and believes, and on that basis alleges, that at all times relevant herein, each Defendant was the agent, servant, employee, partner, joint venturer, co-conspirator, of each remaining Defendant, and in doing the acts alleged herein, was acting within the course and scope of such agency, employment, or relationship, with the permission, authorization, ratification, and/or knowledge of the remaining Defendants.

FACTUAL ALLEGATIONS

A. The Persona IQ "Smart Knee": An Active Electronic Surveillance Device

19. The Zimmer Biomet Persona IQ is not a standard passive orthopedic implant. It is an active electronic device classified within the Internet of Medical Things ("IoMT"). The device consists of the standard Persona tibial baseplate combined with the Canary canturio™ te (CTE) tibial extension, which houses the following electronic components permanently implanted within the patient's body:

a. A lithium-ion battery, constituting a permanent internal power source;

b. A three-axis accelerometer;

c. A gyroscope;

d. A temperature sensor; and

e. A radio-frequency (RF) wireless transmitter operating through the proprietary CHIRP (Canary Health Implanted Reporting Processor) system.

20. The CHIRP system continuously monitors and wirelessly transmits kinematic data from within the patient's body, including gait metrics, range of motion, step count, walking speed, and cadence, to external cloud servers operated by Zimmer Biomet and Canary Medical, including the ZBEdge Connected Intelligence platform and the WalkAI artificial intelligence data engine.

21. The Persona IQ is materially and fundamentally different from the standard Persona mechanical knee prosthesis. A standard Persona implant contains no battery, no sensor array, no wireless transmitter, imposes no data-collection obligations, and creates no post-mortem surgical requirements. The Persona IQ imposes all of the foregoing.

B. Zimmer Biomet's Mandatory Pre-Operative Patient Consent Protocol

22. Defendants' own documentation establishes that the implantation of the CTE device is legally and procedurally contingent upon documented pre-operative patient participation and affirmative consent. Specifically, Zimmer Biomet's patient-facing materials state in relevant part that a patient "must create an account prior to surgery to receive the CTE Implant." These materials further provide that:

a. The patient may decline participation in the data-collection program during the enrollment setup process;

b. If the patient declines, "your doctor can provide you with a standard knee implant instead"; and

c. The patient may "change your mind at any time before having your surgery."

23. The device's activation protocol requires coordinated action by operating room personnel, a Zimmer Biomet or Canary Medical system representative, and proprietary software to activate the implant and associate it with the patient's account during or immediately following surgery.

24. This pre-operative enrollment and consent process is not optional or aspirational. It is a mandatory prerequisite that Zimmer Biomet's own protocols treat as a condition precedent to implantation of the CTE device. These protocols exist to ensure that no patient receives an active data-harvesting electronic implant without their knowing, voluntary, and documented consent.

C. Defendants' Deliberate Bypass of Required Consent Protocols

25. Plaintiff STEVEN RUSSAK did not create any account associated with the Persona IQ device prior to surgery.

26. Plaintiff did not knowingly enroll in the mymobility application, the ZBEdge platform, or any other data-collection system associated with the Persona IQ device prior to surgery.

27. Plaintiff did not receive any disclosure, oral or written informing him that: (a) the device proposed for implantation contained an active electronic component; (b) the device would transmit data from his body; (c) the implantation was contingent upon his pre-operative consent; or (d) he had the right to decline the CTE device and receive a standard mechanical prosthesis instead.

28. Despite Plaintiff's failure to complete the required pre-operative enrollment, Defendants proceeded with the implantation of the Persona IQ CTE device. Plaintiff is informed and believes, and on that basis alleges, that:

a. A Zimmer Biomet and/or Canary Medical corporate representative was physically present in the operating room during the March 11, 2025 surgery;

b. This representative participated in the activation of the electronic components of the Persona IQ device intraoperatively, while Plaintiff was under general anesthesia and entirely incapable of providing or withholding consent; and

c. Defendants knew, at the time of implantation and activation, that Plaintiff had not completed the required pre-surgical enrollment and had not provided the affirmative consent that Defendants' own protocols mandated as a prerequisite to implantation.

D. Post-Operative Conduct and Plaintiff's Discovery

29. Plaintiff's discovery of the electronic nature of his implant did not occur through any clinical disclosure by his treating physician. Instead, while Plaintiff was still recovering from surgery:

a. Zimmer Biomet transmitted unsolicited text messages to Plaintiff urging him to set up his "Home Base Station" for the device;

b. Zimmer Biomet made additional contact with Plaintiff while he was still hospitalized; and

c. Approximately three (3) days post-surgery, Zimmer Biomet placed a telephone call to Plaintiff informing him, for the first time, that an active electronic implant had been placed in his body.

30. These communications, initiated by a corporate device manufacturer rather than the treating physician constituted Plaintiff's first notice that the device implanted in his body was fundamentally different from the standard mechanical knee replacement to which he had consented.

31. Upon confronting Dr. Tchejeyan, Plaintiff was informed that the surgeon had not disclosed the electronic nature, wireless transmission functions, or data-collection capabilities of the Persona IQ to prior patients in whom he had implanted the same device. This admission establishes

that the nondisclosure of which Plaintiff complains was not an oversight or miscommunication, it was a deliberate, repeated, and systematic practice.

32. The account-creation and terms-of-service acceptance that Zimmer Biomet's own protocols treat as a condition precedent to implantation were solicited from Plaintiff entirely after the surgery and the irreversible implantation of the device. The mymobility enrollment outreach began while Plaintiff was still in post-surgical recovery and continued for days afterward, and was followed only later by the telephone call disclosing that an electronic implant was already inside his body. The pre-operative consent gate that Defendants' own materials describe as mandatory was thereby inverted: it was deployed not before implantation as a safeguard, but after implantation as a post-hoc onboarding formality, at a point when Plaintiff could no longer exercise the right to decline the device and receive a standard knee implant instead.

33. Plaintiff is informed and believes, and on that basis alleges, that Zimmer Biomet's own enrollment records reflect that the mymobility account associated with Plaintiff's device was created by or at the direction of the surgeon's office rather than by Plaintiff personally, and that Plaintiff never personally created an account or affirmatively accepted the device's data-sharing terms of service. No patient-authenticated consent preceded the surgery.

E. Absence of Clinical Benefit

34. The Persona IQ's regulatory labeling, as approved and required by the U.S. Food and Drug Administration ("FDA"), expressly states that the objective kinematic data generated by the CTE with CHIRP System "are not intended to support clinical decision-making and have not been shown to provide any clinical benefit."

35. This regulatory finding of clinical futility appears consistently across multiple FDA submissions and is not qualified or limited to any specific patient population or condition. Defendants were aware of this finding at all times relevant to this action.

36. The intended data collected and transmitted by the Persona IQ device would not have benefited Plaintiff clinically. Its primary function and value is the generation of a proprietary data asset for Zimmer Biomet's WalkAI artificial intelligence platform and commercial research programs.

37. The commercial and research record confirms that the data generated by the Persona IQ is collected for Defendants' commercial and product-development purposes rather than for Plaintiff's health. Defendants' registered clinical investigation states that the device data will be used in exploratory analyses to direct future product feature development, data-algorithm products, and research, and Defendants market the resulting data capability through the WalkAI artificial-intelligence engine and the ZBEdge Connected Intelligence Suite. Defendants thereby had a direct commercial incentive to maximize the number of devices generating data, to minimize enrollment friction, and to keep patient consent perfunctory.

F. Known Product Hazards Not Disclosed to Plaintiff

38. The Persona IQ exposes Plaintiff to a range of undisclosed physical hazards inherent in the implantation of a lithium-ion battery and active electronic system within a weight-bearing orthopedic joint, including but not limited to:

39. Post-Mortem Cremation Hazard. The lithium-ion battery contained within the Persona IQ is permanently integrated into the tibial bone structure and cannot be removed through standard mortuary procedures. Published studies on implantable electronic devices demonstrate that lithium-ion batteries subjected to cremation temperatures below 500°C undergo explosive thermal runaway,

producing sound pressure levels exceeding 120 decibels and releasing toxic decomposition byproducts including hydrogen fluoride (a corrosive acid) and benzene (a known carcinogen) capable of injuring crematorium staff and damaging cremation equipment. Because the Persona IQ is bone-integrated, its removal prior to cremation requires a full orthopedic surgical procedure. Plaintiff was never informed of this lifelong and post-mortem obligation.

40. MRI Limitations. The Persona IQ is labeled MRI Conditional so safe only under specific conditions. The Persona IQ creates limitations on Plaintiff's ability to undergo Magnetic Resonance Imaging ("MRI") for conditions wholly unrelated to his knee, potentially compromising future diagnostic care throughout his lifetime.

41. Missing Patient Identification Card. Because the electronic and MR-Conditional nature of the device was concealed from Plaintiff, Plaintiff was never issued the Patient Identification Card that the device's MR-Conditional labeling contemplates a patient must present to imaging and emergency personnel. As a result, Plaintiff cannot reliably alert future radiology or emergency providers to the presence and conditions of the implant, compounding the lifetime imaging hazard described above.

42. Lithium-ion batteries within medical implants are subject to mechanical stresses, temperature fluctuations, and long-term degradation. Failure modes include internal short circuits leading to thermal runaway, electrolyte leakage producing toxic chemical byproducts within the tibial canal (including hydrogen fluoride capable of causing bone necrosis and systemic toxicity), and seal failure over the 15-to-20-year implant lifespan. Plaintiff was never informed of these risks.

G. Defendants' Financial Incentives and Conflicts of Interest

43. The ZBEdge Connected Intelligence Suite creates direct financial incentives for physicians who adopt the Persona IQ system. Physicians may bill for Remote Therapeutic Monitoring ("RTM") services using CPT codes predicated on the data generated by patients'

implanted devices, creating a revenue stream for the physician that is entirely absent with standard passive implants.

44. The failure to disclose these financial conflicts constitutes a material omission under California's informed consent doctrine.

FIRST CAUSE OF ACTION – MEDICAL BATTERY

(Against All Defendants)

45. Plaintiff incorporates by reference each and every allegation set forth in paragraphs 1 through 44 above as though fully set forth herein.

46. Medical battery occurs under California law when a physician performs a medical procedure that is substantially different from the procedure to which the patient consented, or when a physician performs any procedure without the patient's consent.

47. Plaintiff consented to a standard mechanical total knee replacement, a passive, non-electronic, non-transmitting orthopedic prosthesis. Plaintiff did not consent, expressly or impliedly, to the implantation of any device containing: (a) a lithium-ion battery; (b) a sensor array; (c) a wireless radio-frequency transmitter; or (d) any system designed to collect, process, or transmit his biometric data to any third party.

48. The device actually implanted, the Persona IQ with Canary CTE, is substantially different from a standard passive knee prosthesis. The distinction is not a matter of degree or technique. It is a categorical difference between a passive mechanical device and an active electronic surveillance and data-transmission system permanently embedded in Plaintiff's skeleton.

49. No reasonable patient would consent to the implantation of a battery-powered electronic transmitter within their body as long-term risks far outweigh any short-term benefits. The procedure actually performed was "substantially different" from the procedure consented to.

50. Defendant ZIMMER BIOMET and CANARY MEDICAL are directly liable for the battery because their corporate representative was physically present in the operating room, participated in the intraoperative activation of the device, and directed or assisted in the completion of the unconsented procedure while Plaintiff was under anesthesia.

51. As a direct and proximate result of Defendants' commission of medical battery, Plaintiff has suffered and continues to suffer: (a) violation of bodily autonomy and dignitary harm; (b) severe emotional distress, anxiety, and fear arising from the permanent implantation of an undisclosed electronic device in his body; (c) exposure to undisclosed physical hazards, including battery failure and post-mortem cremation risk; (d) future economic losses, including the anticipated cost of post-mortem device extraction and any future revision surgery.

52. Because medical battery is an intentional tort, the statutory limitations on non-economic damages imposed by the Medical Injury Compensation Reform Act ("MICRA"), Civil Code § 3333.2, do not apply to this cause of action.

SECOND CAUSE OF ACTION – LACK OF INFORMED CONSENT

(Against Defendant TCHEJEYAN and DOES 1–50)

53. Plaintiff incorporates by reference each and every allegation set forth in paragraphs 1 through 52 above as though fully set forth herein.

54. A physician owes a patient the duty to disclose all information material to the patient's decision whether to undergo a proposed treatment or procedure. A fact is "material" if a reasonable patient would attach significance to it in deciding whether to consent.

55. Dr. Tchejeyan failed to disclose the following material facts to Plaintiff prior to the March 11, 2025 surgery:

a. That the device proposed for implantation was the Persona IQ, an active electronic implant containing a lithium-ion battery and a wireless data-transmission system, rather than a standard passive mechanical prosthesis;

b. That the Persona IQ would continuously collect and wirelessly transmit Plaintiff's biometric data to Defendants' corporate cloud servers;

c. That, under Zimmer Biomet's own mandatory protocols, Plaintiff was required to create an account, review materials, and provide affirmative written consent prior to receiving the CTE device;

d. That Plaintiff had the express right to decline the Persona IQ and receive a standard knee implant instead;

e. That the FDA had determined the device's data output to have no clinical benefit to the patient;

f. That the device's lithium-ion battery creates a post-mortem cremation hazard requiring surgical removal prior to cremation;

g. That the device creates MRI limitations and is contraindicated for therapeutic ionizing radiation; and

h. That Dr. Tchejeyan had a financial interest in the implantation of the Persona IQ through Remote Therapeutic Monitoring billing opportunities and any commercial relationship with Zimmer Biomet.

56. Had Plaintiff been informed of any one of the material facts identified in paragraph 55, he would have declined the Persona IQ and requested a standard passive knee prosthesis.

57. A reasonable patient in Plaintiff's position would have attached decisive significance to each of the material facts identified in paragraph 55 in deciding whether to consent to the implantation of the Persona IQ device.

58. As a direct and proximate result of Dr. Tchejeyan's failure to provide adequate informed consent, Plaintiff has suffered all of the injuries and damages described in paragraph 51 above.

THIRD CAUSE OF ACTION – FRAUD AND INTENTIONAL MISREPRESENTATION

(Against Defendants ZIMMER BIOMET and CANARY MEDICAL)

59. Plaintiff incorporates by reference each and every allegation set forth in paragraphs 1 through 58 above as though fully set forth herein.

60. California law recognizes causes of action for fraud based on: (1) intentional misrepresentation of a material fact; (2) concealment of a material fact with intent to induce reliance; and (3) false promise with intent not to perform.

61. Defendants ZIMMER BIOMET and CANARY MEDICAL made the following material misrepresentations and/or concealed the following material facts from Plaintiff, with knowledge of their falsity and/or with a duty to disclose, and with the intent to induce Plaintiff's consent to surgery:

a. Defendants represented, through their patient-facing materials and marketing, that the Persona IQ would deliver a "personalized" knee replacement and a "smarter, more informed recovery" focused on the patient's benefit, while concealing that the actual device was an active electronic surveillance implant whose data output had no demonstrated clinical benefit to the patient;

b. Defendants concealed that the Persona IQ's CHIRP system's data had been found by the FDA to have "not been shown to provide any clinical benefit," while Zimmer

Biomet's marketing simultaneously promoted the device as enabling a "smarter, more informed recovery";

c. Defendants concealed the existence of the mandatory pre-operative consent protocol that required Plaintiff's account creation and affirmative participation before the CTE device could lawfully be implanted;

d. Defendants concealed Plaintiff's right to decline the Persona IQ and receive a standard passive prosthesis instead;

e. Defendants concealed the post-mortem cremation hazard associated with the lithium-ion battery and the lifetime obligation of surgical removal prior to cremation; and

f. Defendants concealed the financial incentive structure they created to drive physician adoption of the Persona IQ, including Remote Therapeutic Monitoring billing opportunities and the ZBEdge commercial relationship, and the resulting conflict of interest influencing the decision to implant the Persona IQ rather than a standard prosthesis.

62. Each of the foregoing misrepresentations and concealments was material. Plaintiff would not have consented to surgery if any one of these material facts had been disclosed.

63. Plaintiff justifiably relied on Defendants' representations and the absence of any disclosure to the contrary. Plaintiff had no reason to suspect, and no means to independently discover, that the device proposed for implantation was an electronic data-harvesting system rather than a standard mechanical prosthesis.

64. As a direct and proximate result of Defendants' fraud and intentional misrepresentation, Plaintiff has suffered all of the injuries and damages described in paragraph 51 above.

FOURTH CAUSE OF ACTION – STRICT PRODUCTS LIABILITY – FAILURE TO WARN

(Against Defendants ZIMMER BIOMET and CANARY MEDICAL)

65. Plaintiff incorporates by reference each and every allegation set forth in paragraphs 1 through 64 above as though fully set forth herein.

66. Defendants ZIMMER BIOMET and CANARY MEDICAL are in the business of designing, manufacturing, assembling, marketing, distributing, and selling the Persona IQ device, including the CTE tibial extension and CHIRP system. As commercial sellers of a product, they are strictly liable for injuries caused by a product that is defective in its design, manufacture, or warnings.

67. The Persona IQ device was defective in that the warnings, labeling, and patient-facing materials accompanying the device were inadequate to inform patients, surgeons, and healthcare providers of the following known risks:

a. The post-mortem cremation explosion hazard arising from the device's integrated lithium-ion battery, and the lifetime obligation of surgical device extraction prior to cremation;

b. The risk of battery failure, thermal runaway, and release of toxic chemical byproducts within the tibial canal, including hydrogen fluoride capable of causing bone necrosis;

c. The MRI limitations created by the device's active electronics and the contraindication for therapeutic ionizing radiation; and

d. The FDA's finding that the device's data output has no clinical benefit to the patient.

68. Dual failure to warn the chain of users. The Persona IQ is an active, battery-powered, data-transmitting electronic implant that is categorically different from a passive mechanical prosthesis and that, by Defendants' own design, cannot be safely or lawfully implanted unless (i) the implanting surgeon understands and discloses the device's electronic nature, lifetime restrictions, and post-mortem hazards, and (ii) the patient knowingly creates an account, accepts the data-sharing terms, and affirmatively elects the device over a standard prosthesis. Defendants' warnings failed at

both links in the chain of foreseeable users: Defendants did not adequately educate or warn implanting surgeons of the disclosure and consent obligations the device carries, and Defendants did not adequately warn patients of the device's nature, restrictions, and hazards. This dual failure to warn is a defect in the Persona IQ as marketed and distributed and is independent of any individual physician's conduct.

69. Inadequate patient-facing warnings. Defendants' patient-facing materials, where they reached patients at all, were themselves inadequate as warnings, in that they: (a) described the device merely as "MR Conditional" and advised patients to inform their doctor before an MRI, without plainly stating that the patient must present a Patient Identification Card to imaging personnel or that a non-compatible scanner risks battery heating and tissue injury; (b) contained no warning of the mandatory surgical removal of the lithium-ion battery prior to cremation, a permanent and irreversible post-mortem hazard; (c) described the battery in reassuring terms while omitting the documented risks of thermal runaway, electrolyte leakage, hydrogen fluoride, and benzene associated with implanted lithium cells; and (d) failed to disclose the device's own FDA-cleared finding of no clinical benefit while Defendants' marketing simultaneously promoted a "smarter, more informed recovery."

70. The learned-intermediary doctrine does not discharge Defendants' duty to warn. First, that doctrine presupposes that the manufacturer provided an adequate warning to the prescribing physician; here, Defendants failed to adequately educate the implanting surgeon as to the device's electronic nature and the disclosure and consent obligations it carries, as evidenced by the surgeon's admission that he disclosed nothing of the device's electronic, wireless, or data-collection nature to any prior patient, and by Defendants' need to send a corporate representative into the operating room to activate the implant. A manufacturer that must dispatch a technician to operate its product cannot

also claim it equipped the physician with complete and adequate warnings. Second, Defendants voluntarily assumed a direct-to-patient duty by building and operating their own patient-facing consent-and-disclosure system—a mandatory patient account, a patient brochure and FAQ, a decline mechanism, the mymobility application, terms of service, and direct communications to the patient. A manufacturer that constructs its own direct-to-patient consent and disclosure system assumes the duty to make that system adequate and cannot retreat behind the physician when the system fails.

71. These warnings were inadequate as a matter of law. A manufacturer in the chain of commerce has a duty to warn of all risks that are known or knowable based on the scientific and medical literature at the time of distribution. Each of the risks identified above was known or knowable to Defendants at the time the Persona IQ was distributed for implantation in Plaintiff.

72. The inadequacy of the warnings was a substantial factor in causing Plaintiff's harm. Had adequate warnings been provided to Plaintiff and/or his surgeon, Plaintiff would have declined the Persona IQ device and requested a standard passive prosthesis.

73. As a direct and proximate result of the defective warnings, Plaintiff has suffered all of the injuries and damages described in paragraph 51 above, and continues to face ongoing and future risks of physical harm arising from the permanent presence of a lithium-ion battery-powered electronic device within his body.

FIFTH CAUSE OF ACTION – PROFESSIONAL NEGLIGENCE

(Against Defendant TCHEJEYAN and DOES 1–25)

74. Plaintiff incorporates by reference each and every allegation set forth in paragraphs 1 through 73 above as though fully set forth herein.

75. At all times relevant herein, Defendant TCHEJEYAN owed Plaintiff a duty of care consistent with the standard of care applicable to board-certified orthopedic surgeons practicing in California under the same or similar circumstances.

76. The standard of care applicable to the implantation of an active electronic medical device such as the Persona IQ required Dr. Tchejeyan to, among other things:

a. Obtain complete, accurate, and documented informed consent disclosing the material characteristics, risks, and alternatives of the Persona IQ prior to surgery;

b. Follow Zimmer Biomet's own mandatory pre-operative patient enrollment and consent protocols as a condition of implanting the CTE device;

c. Disclose to Plaintiff his right to decline the Persona IQ and receive a standard passive knee prosthesis instead;

d. Disclose all known risks of the device, including the post-mortem cremation hazard, battery failure risks, and MRI/radiation contraindications; and

e. Disclose any financial relationship between himself and Zimmer Biomet that could influence his clinical recommendations.

77. Dr. Tchejeyan breached the applicable standard of care by failing to take each of the actions set forth in paragraph 76 above, and by proceeding with implantation of the Persona IQ CTE device in the absence of the required pre-operative consent and account enrollment.

78. As a direct and proximate result of Dr. Tchejeyan's negligence, Plaintiff suffered and continues to suffer all of the injuries and damages described in paragraph 51 above.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff STEVEN RUSSAK prays for judgment against Defendants, and each of them, as follows:

1. General damages for physical injury, violation of bodily autonomy, dignitary harm, emotional distress, anxiety, fear, and loss of enjoyment of life, in an amount to be proven at trial;

2. Special damages for all past and future economic losses, including but not limited to the cost of any revision surgery necessitated by the unauthorized implantation, future medical monitoring and care, and the anticipated cost of post-mortem device extraction, in an amount to be proven at trial;

3. Punitive and exemplary damages pursuant to California Civil Code § 3294, in an amount sufficient to punish Defendants for their malicious, oppressive, and fraudulent conduct and to deter similar conduct in the future;

4. Pre-judgment and post-judgment interest at the maximum rate permitted by law;

5. Costs of suit, including reasonable attorneys' fees to the extent permitted by law; and

6. Such other and further relief as the Court may deem just and proper.

DEMAND FOR JURY TRIAL

Pursuant to California Code of Civil Procedure § 631, Plaintiff STEVEN RUSSAK hereby demands a trial by jury on all issues so triable.

DATED: _____, 2026 LAW OFFICES OF ROBERT M. RUSSAK

By: _____
ROBERT M. RUSSAK
Attorneys for Plaintiff