UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
JACKSONVILLE DIVISION

ROBERT C. HOVEY,

Plaintiff, **CASE NO.: 3:22-cv-970**

v.

TRACPATCH HEALTH INC.
F/K/A CONSENSUS ORTHOPEDICS INC.
F/K/A HAYES MEDICAL,
a California corporation.

Defendant.

COMPLAINT FOR DAMAGES AND DEMAND FOR JURY TRIAL

COMES NOW, Plaintiff, ROBERT C. HOVEY (hereinafter "Plaintiff"), by and through his undersigned attorneys and files this Complaint against Defendant, TRACPATCH HEALTH INC. F/K/A CONSENSUS ORTHOPEDICS INC. F/K/A HAYES MEDICAL (hereinafter "TRACPATCH HEALTH" or "Defendant"); and alleges as follows:

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I. Introduction

1. This lawsuit involves causes of action related to a defective hip replacement system that was designed, researched, developed, tested, assembled, manufactured, packaged, labeled, prepared, promoted, marketed, distributed, sold, serviced, and supported by Defendant.

2. The system at issue in this case is the "Consensus Hip System" (often referred to as "the Device" in this Complaint).

3. Defendant marketed the Consensus Hip System as having advantages over other hip devices and hip replacement systems.

4. Despite Defendant's claims of advantages, the Consensus Hip System was defective and unreasonably dangerous because it is unreasonably prone to cause fretting and/or corrosion.

5. When this problem occurs, it can lead to the release of toxic heavy metal ions and/or wear debris.

6. The fretting/corrosion problem with the Consensus Hip System is so severe that components of the Device can wither away until they break apart inside a patient's body. This type of fracture is called a "dissociation" (and may also be referred to as "disassociation").

7. Defendant is and was aware that the Consensus Hip System resulted in unreasonably high rates of negative clinical outcomes, including:

a. Dissociation;
b. Fretting;
c. Corrosion;
d. Trunnionosis;
e. Tissue death; and
f. Bone death.

8. Defendant is and was aware that these negative clinical outcomes:

a. manifest in severe pain and limitations on mobility;
b. are progressive in nature such that the impact worsens with time and exposure;
c. represent an unreasonable risk of harm to patients;
d. results in a higher than expected rate of failure necessitating additional surgeries to replace failed implants; and
e. lead to injuries which can persist even beyond the removal of the failed implant.

9. Plaintiff, ROBERT C. HOVEY, was implanted with the Consensus Hip System and has suffered substantial injuries and damages as a result.

10. As a direct and proximate result of the defects and unreasonable dangers of the Consensus Hip System, Plaintiff suffered extensive injuries, including but not limited to: bodily injury; severe physical pain and suffering; surgeries; rehabilitation; distress; physical impairment; disfigurement; mental anguish; inconvenience; loss of capacity for enjoyment of life; and loss of mobility.

II. Parties, Jurisdiction, and Venue

11. At all times relevant to this complaint, Plaintiff, ROBERT C. HOVEY, was and is a citizen and resident of Jacksonville, Florida.

12. At all times relevant to this complaint, Defendant, TRACPATCH HEALTH, is a California Corporation organized and existing under the laws of state of California with its principal place of business located at 2020 L. Street, Suite 220, Sacramento, California 95811, and conducts business throughout the United States, including the State of Florida.

13. Defendant is a California based corporation that was founded in 1992 by Mr. Daniel Hayes, and the company was originally known as Hayes Medical. In 2008, Defendant changed its name to Consensus Orthopedics Inc.; and in 2021, Defendant changed its name a third time to its current name, TRACPATCH HEALTH, INC.

14. At all times relevant to this complaint, Defendant designed, developed, tested, assembled, manufactured, packaged, labeled, prepared, distributed, marketed, supplied, and sold the Consensus Hip System, either directly or indirectly, to members of the public throughout the United States, including in the State of Florida.

15. This court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §1332(a) in that there is complete diversity of citizenship between the parties and the amount in controversy exceeds the sum of seventy-five thousand dollars ($75,000), exclusive of interests and costs.

16. Venue is proper in this district pursuant to 28 U.S.C. 1391, in that a substantial part of the events giving rise to the claim occurred in this district, Plaintiff's injury occurred in this district, and majority of witnesses reside in this district.

III. Hip Replacement Surgery

17. A patient's natural hip joint connects the thigh (femur) bone of his or her leg to the pelvis. The hip joint is characterized as a ball and socket joint. The socket is the cup shaped portion of the acetabulum into which the femoral head (ball) at the top of the femur bone inserts and articulates. Both

the femoral head and acetabular socket are covered with cartilage forming a natural surface upon which the parts may move freely.

18. In some patients, cartilage can be damaged due to either trauma, disease, or aging (arthritis). When this occurs, a hip replacement may be indicated. A total hip replacement utilizes parts manufactured from metal alloys, plastic, or ceramic to replace a patient's damaged native anatomy.

19. A total hip replacement typically consists of four separate components: (1) a femoral stem, (2) a femoral head, (3) an acetabular liner, and (4) an acetabular shell. The procedure requires removing the arthritic femoral head and replacing the patient's natural anatomy with a femoral stem upon which a femoral head is impacted. The acetabulum is then reamed to accommodate the acetabular shell into which, once fixed, the liner is then placed. Once all the parts are inserted, the ball articulates within the acetabular liner much like the patient's natural hip.

20. The Consensus Hip System was intended to replace Plaintiff's damaged or diseased natural anatomy.

21. The Consensus Hip System is indicated for patients, like Plaintiff, requiring total hip arthroplasty.

IV. Defendant Used a Loophole to Market the Consensus Hip System

22. Defendant received "clearance" from the Food and Drug Administration (hereinafter referred to as the "FDA") to market the Consensus Hip System in the United States pursuant to Section 510(k) of the Food, Drug and Cosmetic Act. [1]

23. A medical device cleared under Section 510(k) does not have to go through any clinical study to gain clearance by the FDA, meaning it does not have to be tested in a single human being before placed on the market.

24. The 510(k) pathway to market is a "grandfather" clause which allows devices to avoid clinical study and any testing for safety or efficacy. Instead, it allows devices to be fast-tracked to market within 90 days based solely on a showing of "substantial equivalence" to any number of multiple products previously cleared through the same 510(k) pathway, including products which may have since been abandoned due to safety concerns.

[1] *See,* https://www.consensusortho.com/wp-content/uploads/2015/10/K922560_Clearance-and-Summary.pdf containing Defendant's Premarket 510(k) Notification (last accessed Aug. 25, 2022).

25. This is compared with the "Premarket Approval" pathway which requires stringent laboratory and clinical testing for safety or efficacy prior to a product being marketed.

26. "Because of this loophole, companies that market these devices are often legally able to obtain clearance without demonstrating safety and effectiveness through clinical studies, but by claiming substantial equivalence to earlier "predicate devices" - or pieces of those devices - which may also have been found substantially equivalent to even earlier devices, and so on, all the way back to preamendment devices. Because many predicates have never been assessed for safety and effectiveness, an FDA finding of substantial equivalence does not mean that a new device is safe and effective; it means only that the device is deemed no less safe and no less effective than a predicate." [2]

27. Defendant knew or should have known that the 510(k) pathway did not adequately assess the safety or efficacy of the Consensus Hip System. Despite this, Defendant used the 510(k) "grandfather clause" loophole to fast track the Consensus Hip System to market without adequate testing.

[2] Ardaugh, BM, et al. The 510(k) Ancestry of a Metal-on-Metal Hip Implant. N Engl. J. Med. 2013; 97-100.

28. Had Defendant conducted reasonable pre-market testing for safety and efficacy on the Consensus Hip System, Defendant would have known of the Device's unreasonable propensity to harm patients, consistent with the harm Plaintiff experienced.

V. The Design of the Consensus Hip System

29. The Consensus Hip System is a hip prosthesis that Defendant asserts is compatible with previously cleared cobalt-chrome/cobalt chromium (CoCr) heads, zirconia heads, unipolar heads, bipolar heads, ultra-high-molecular-weight-polyethylene (UHMWPE) inserts and acetabular cups. It is designed for total or partial hip arthroplasty and is intended to be used with compatible components for impaired joints.

30. The flawed design of the Consensus Hip System caused Plaintiff's hip to experience fretting and corrosion of the trunnion. This is the area of the implant in which the femoral head and femoral stem connect. This process led to heavy metal poisoning. Ultimately, the fretting and corrosion process wore completely through, shearing off at the top of the trunnion. This "dissociation" left Plaintiff with no skeletal connection between his torso and his leg.

31. The Consensus Hip System's femoral head is available in metal as a Cobalt Chrome alloy, or in ceramic as a Biolox delta or Zirconia variant.

32. The Device's acetabular component consists of a metal shell made of a titanium alloy and an insert made of polyethylene plastic.

33. The Device's femoral stem is made from a metal cobalt chrome alloy or titanium alloy.

34. Defendant knew or should have known that the poor design and material choices of the Defendant's Consensus Hip System would lead to micro-motion, fretting, corrosion and ultimately the total failure of the implant.

35. This process can result in so much material wearing off of the area where the head and stem connect that the femoral head can actually fall off the femoral stem, a phenomenon described in medical literature as catastrophic dissociation. This is exactly what occurred in Plaintiff's case.

VI. Plaintiff was Implanted with the Consensus Hip System

36. On or about November 9, 2010, Plaintiff underwent a right total hip arthroplasty at Baptist Medical Center in Jacksonville, Florida, by Steven J. Lancaster, M.D.

37. During this surgery, Dr. Lancaster implanted Plaintiff with the Consensus Hip System, consisting of the following components:

a. Hayes Medical, Inc. Acetabular Shell, Flared Rim with Holes, PC Ti; Size 58mm; Ref 1708-0-0058; Lot 271182A

b. Consensus Hip System Acetabular Insert, 10° Hood, X-Link PE; Size 36mm x 58mm; Ref 1008-0-3658; Lot 750196 2014-10

c. Consensus Hip System Femoral Stem, Collarless, Ti, PC; Size 14; Lot 473630 2014-12; Ref 1610-3-0014

d. Consensus Hip System Femoral Head, 36mm (+5mm); Ref 0007-1-3603; Lot 740320

38. Plaintiff recovered from the surgery and utilized the implant in a reasonably foreseeable manner.

39. Post Plaintiff's surgery, he did not experience any symptoms with the implant which would lead to any concern about any failure of the Device.

40. Over the ensuing years since the implant and unbeknownst to Plaintiff, however, fretting and corrosion began to take place, causing the Device's trunnion to weaken and to release toxic metal ions and particles into Plaintiff's body.

41. At the time Defendant sold the Consensus Hip to Plaintiff, Defendant knew or should have known the defects in the Device resulted in an unreasonable risk that it would cause severe and unusual fretting, corrosion, and toxic metal release, leading to a catastrophic failure.

VII. The Consensus Hip System Withered Away and Fell Apart Inside Plaintiff's Hip

42. On or about November 30, 2021, Plaintiff was at Admira Dentistry in Jacksonville, Florida, sitting in a chair waiting to be seen by his dentist.

43. While seated, suddenly and without warning, Plaintiff began experiencing excruciating pain in the right hip.

44. Plaintiff was unable to move his right leg and he was unable to get up from the chair.

45. Jacksonville Fire and Rescue was immediately called to the scene, and they transported Plaintiff to Baptist Medical Center in Jacksonville, Florida.

46. While at Baptist Medical Center, medical personnel examined Plaintiff and discovered a dissociated right femoral head from the femoral stem.

47. This means that Plaintiff's Consensus Hip System had fallen apart in his body, severing any skeletal connection between his hip and his leg.

48. This was the first notice to Plaintiff that the Consensus Hip System had failed.

49. Plaintiff was forced to wait days in the above-described condition before medical providers could perform revision surgery.

50. As a result of the catastrophic failure, the Consensus Hip System had to be completely removed from Plaintiff's body.

51. On or about December 1, 2021, Plaintiff underwent revision surgery of the right hip at Baptist Medical Center, in Jacksonville, Florida, by Brett P. Frykberg, M.D.

52. During the revision surgery, Dr. Frykberg made note of, "significant metal staining and metallosis throughout the entirety of the hip…we removed all necrotic tissue using rongeurs. The hip was already disassociated with the cobalt-chrome femoral head and the acetabular component. The femoral stem had sheared off the top portion of the trunnion, likely over time, and had a large notch on the neck of the femoral stem. As we expected, the femoral stem would have had to have been removed to fix this problem."

53. After Plaintiff's complex revision surgery, he began the recovery process.

54. Plaintiff was prescribed medication for pain relief, he was instructed to place ice over his right hip to help with pain and inflammation, and he was instructed to attend physical therapy.

55. Plaintiff followed the instructions given by his medical providers and began the long road to recovery.

VIII. Plaintiff's Hip Dislocates

56. The damage and trauma caused by the defects in Defendant's implant, and the surgery necessitated by the dissociation, left Plaintiff's hip in a weakened condition and prone to horrific and excruciatingly painful dislocations.

57. On March 7, 2022, Plaintiff was getting up from a chair when his right hip suddenly dislocated.

58. EMS were called to the scene, and Plaintiff was taken to the nearest hospital for care.

59. At the hospital, medical personnel took x-rays, and they discovered that Plaintiff's right hip had dislocated.

60. Medical personnel performed a closed reduction and put Plaintiff's femoral head back into the socket.

IX. Damages

61. Defendant's conduct and defective product, as described above, was the direct and proximate cause of Plaintiff's injuries.

62. Plaintiff was forced to endure incredible pain and lack of mobility due to the traumatic nature of the catastrophic dissociation and dislocation, as well as the invasive and damaging nature of the surgeries required to treat the failed Device in Plaintiff's right hip.

63. As a direct and proximate result of the defective Device, Plaintiff was required to undergo surgical removal of the Device, a post-revision dislocation, and now has a hip replacement with decreased longevity.

64. As a direct and proximate result of the defective Device, Plaintiff suffered injuries including but not limited to significant pain, tissue destruction, bone destruction, metal wear, toxic heavy metal poisoning, and decreased mobility.

65. As a direct and proximate result of the defective Device, Plaintiff expects to continue suffering such injuries in the future.

66. As a direct and proximate result of the defective Device, Plaintiff incurred medical expenses and expects to incur additional medical expenses in the future.

67. As a direct and proximate result of the defective Device, Plaintiff experienced emotional trauma, distress, and is likely to experience emotional trauma and distress in the future.

X. Causes of Action

COUNT ONE -- Strict Liability Failure to Warn

68. Plaintiff re-alleges and incorporates by reference all paragraphs in Section IX above as if fully stated herein.

69. At all times relevant to this action, while Defendant engaged in the business of designing, developing, promoting, manufacturing, selling, marketing, and placing into the stream of commerce the Consensus Hip System, the Device contained defects that made it unreasonably dangerous beyond the expectations of the ordinary consumer, such as Plaintiff, and the Device was unfit for its intended use.

70. The Consensus Hip System reached Plaintiff without substantial change in the condition in which it was designed, developed, promoted, manufactured, and sold.

71. At the time and on the occasions in question, the Consensus Hip System was being properly used for the purpose for which it was intended, and such device was in fact defective, unsafe, and unreasonably dangerous.

72. The foreseeable risk of harm from the defects in the Consensus Hip System could have been reduced or avoided by providing adequate instructions or warnings.

73. At all times relevant to the action, the dangerous propensities of the Consensus Hip System were known to Defendant or were reasonably and scientifically available to them through appropriate research and testing by known methods, at the time they distributed, supplied, or sold their respective product, and not known to the ordinary consumers.

74. The Consensus Hip System was defective and unreasonably dangerous in that labeling was insufficient to warn users of the hazardous conditions posed by said items, including but not limited to its propensity to cause permanent tissue and muscle death associated to release of heavy metal ions.

75. The Consensus Hip System was defective due to inadequate, or the absence of, warnings or instructions, including warning stickers, placards, or proper documentation to alert users regarding the hazards posed by the Consensus Hip System.

76. Defendant has a duty to warn, including a continuing post-sale duty to warn, regarding the unreasonable risk of harm associated with the Consensus Hip System, particularly due to the progressive nature of the risk of the toxic heavy metal poisoning.

77. Defendant failed to exercise reasonable care to inform Plaintiff, Plaintiff's doctors, and the medical community about the dangers regarding the Consensus Hip System.

78. As a direct and proximate result of the lack of reasonable and adequate instructions or warnings regarding the defects in the Consensus Hip System, Plaintiff suffered the injuries described in Section IX above.

COUNT TWO -- Strict Liability Design and Manufacturing Defect

79. Plaintiff re-alleges and incorporates by reference all paragraphs in Section IX above as if fully stated herein.

80. At the time Defendant designed, manufactured, promoted, marketed, sold, supplied, distributed and/or serviced the Consensus Hip System, the Device contained defects that made the product unreasonably dangerous beyond the expectations of the ordinary consumer, and were unfit for their intended use.

81. Under a Risk-Utility Analysis, the likelihood that the product would cause Plaintiff's harm or similar harms, and the seriousness of those harms, outweighed the Defendant's burden to design a product that would have prevented those harms and the adverse effect that an alternative design that was practical and feasible would have on the usefulness of the product.

82. Under a Consumer Expectation Analysis, the product was more dangerous than the ordinary consumer would reasonably expect, considering relevant factors, such as the product's intrinsic nature, relative cost, severity of potential harm (including death), and the cost and feasibility of minimizing such risk.

83. The Consensus Hip System reached Plaintiff without substantial change in the condition in which it was sold.

84. At the time and on the occasion in question, the Consensus Hip System was being properly used for the purpose for which it was intended, and such product was in fact defective, unsafe, and unreasonably dangerous.

85. As a direct and proximate result of the defects in the Consensus Hip System, Plaintiff suffered the injuries described in Section IX as described above.

COUNT THREE – Negligence

86. Plaintiff re-alleges and incorporates by reference all paragraphs in Section IX above as if fully stated herein.

87. Defendant designed, tested, manufactured, distributed, advertised, sold, marketed, and serviced the Consensus Hip System for implantation into consumers such as Plaintiff.

88. Defendant was negligent and careless in the design, testing, manufacture, distribution, advertising, sale, marketing, and service of the Consensus Hip System.

89. Defendant had a duty to perform adequate evaluation on the safety and efficacy of the Consensus Hip System. This included by reasonably gathering information regarding complaints and revisions and conducting adequate analysis on the information gathered.

90. Defendant further had a duty to share the results of its evaluation so that Plaintiff, Plaintiff's orthopedic surgeons, and the orthopedic community could be adequately apprised of the risks of the Device.

91. Defendant failed to adequately evaluate the safety and efficacy of the Consensus Hip System.

92. Defendant failed to adequately share the results of its evaluations of the Consensus Hip System with Plaintiff, Plaintiff's orthopedic surgeons, or the orthopedic community.

93. Defendant's failure to discharge their duties were a direct and proximate cause of Plaintiff's injuries described in Section IX as described above.

COUNT FOUR – Breach of Warranty

94. Defendant expressly and impliedly warranted that the Consensus Hip System reasonably fit for its intended purpose as a hip replacement.

95. The warranties regarding the Consensus Hip System included, without limitation:

a. That the Device restores the original anatomic position of the femoral shaft to the acetabulum;

b. That the Device restores hip function;

c. That the Device is designed to transmit load to the femur during daily activities including, but not limited to walking, stair climbing, and chair ascent;

d. That the Device is designed to minimize stress shielding at the bone implant interface when compared with CoCr;

e. That the Device is intended to reduce wear of the natural acetabular cartilage;

f. That the Device was clinically proven.

96. Defendant issued these warranties to develop and promote the sale of its product through its distribution chain.

97. As a Florida resident, Plaintiff was a reasonably foreseeable user of the product, and was a beneficiary of all warranties made by Defendant.

98. Defendant's warranties regarding product related to material facts regarding the safety and efficacy of the consensus Hip System.

99. Defendant's warranties were part of the basis of the bargain for Plaintiff's purchase of the product.

100. Defendant's warranties were untrue. The Consensus Hip System did not conform to the representations that were made.

101. As a direct and proximate result of the breach of Defendant's warranties, Plaintiff suffered the injuries described in Section IX as described above.

XI. Prayer for Relief

WHEREFORE, the Plaintiff respectfully requests judgment against Defendant, TRACPATCH HEALTH, and requests that the Court:

(a) Award damages in an amount to be proven at a jury trial;

(b) Award reasonable attorney's fees and costs;

(c) Award such other relief as the Court deems just and proper under the circumstances of this case.

DEMAND FOR JURY TRIAL

Plaintiff hereby demands a trial by jury on all claims in this lawsuit.

DATED: September 7, 2022

Respectfully submitted,

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