

**IN THE UNITED STATES DISTRICT COURT FOR THE
NORTHERN DISTRICT OF ILLINOIS**

JOE KROLICKI,)	
)	
Plaintiff,)	
)	
v.)	No.
)	
CARTIVA, INC.)	
)	
Defendants.)	

COMPLAINT AT LAW

NOW COMES the Plaintiff, JOE KROLICKI, by and through his attorneys, PULLANO & SIPORIN, and for his cause of action against Defendant, CARTIVA, INC., states as follows:

COUNT I – STRICT PRODUCT LIABILITY

1. Plaintiff, JOE KROLICKI, is and at all times relevant to this action, was a citizen and resident of the State of Illinois, County of Cook, and Village of Northbrook.

2. Defendant, CARTIVA, INC. is, and at all times relevant to this action, was a corporation with its principal place of business and headquarters located at 6120 Windward Parkway, Suite 220, Alpharetta, Georgia 30005 and process may be served upon its registered agent, CT Corporation System, 289 South Culver Street, Lawrenceville, Georgia 30046-4805.

3. Complete diversity exists as Plaintiff and Defendant are domiciled in different states.

4. The amount in controversy is well in excess of \$75,000.00.

5. At all times material hereto, Defendant, CARTIVA, INC. (hereinafter referred to collectively as “Defendant”) developed, tested, assembled, manufactured, packaged, labeled, prepared, distributed, marketed, supplied, and/or sold the defective product sold under the name

“Cartiva SCI” (hereinafter “Cartiva” or “Defective Device”), either directly or indirectly, to members of the general public within the State of Illinois, including Plaintiff.

6. In 2018, Plaintiff treated with Dr. Khalid Hameed at Midwest Orthopedics at Rush for discomfort in his first metatarsophalangeal joint.

7. In 2018, Dr. Hameed recommended surgery that included but was not limited to implanting a relatively new device called a CARTIVA SCI to help increase his range of motion and decrease his symptoms.

8. On or about June of 2018, Defendant’s Defective Device was placed into the stream of interstate commerce and was surgically implanted in Plaintiff by Dr. Hameed at Midwest Orthopedics at Rush located in Chicago, Illinois.

9. Subsequent to the surgery, Plaintiff experienced worsening pain and decreased range of motion in his joint.

10. Subsequent to the surgery, Plaintiff continually followed up with various physicians on a regular basis due to the worsening pain, limitations, progressive erosion of the joint and shortening of his toe.

11. Eventually, Plaintiff saw Dr. Simon Lee for a second opinion.

12. Subsequent to the surgery, Dr. Lee concluded that the CARTIVA SCI had failed.

13. Subsequent to the surgery, Dr. Lee recommended removal of the defective device and undergoing a fusion surgery.

14. As a result of the CARTIVA SCI failure, Plaintiff has experienced extreme pain and physical limitations and ongoing medical care, including numerous steroid injections and orthotics.

15. As a direct and proximate result of Defendant placing the Defective Product into the stream of commerce, Plaintiff has suffered and continues to suffer both injuries and damages

within the State of Illinois including but not limited to: past, present and future physical and mental pain and suffering; and past, present and future medical, hospital, monitoring, rehabilitation and pharmaceutical expenses and lost wages.

16. Upon information and belief, at all relevant times, Defendant was present and transacted, solicited and conducted business in the State of Illinois through their employees, agents and/or sales representatives, and derived substantial revenue from such business.

17. The Cartiva implant is a molded cylindrical implant that is placed into the metatarsal head in the first metatarsophalangeal joint via press-fit implantation using instruments specifically designed for placement of the device.

18. Defendant touts Cartiva as a simple procedure, which enables surgeons to replace the damaged cartilage with a gummy bear-sized implant they can place into an intraoperatively created pilot hole in the first metatarsal head.

19. The Cartiva implant is marketed as safe for use to treat patients with painful degenerative or post-traumatic arthritis (hallux limitus or hallux rigidus) in the first metatarsophalangeal joint with or without the presence of mild hallux valgus.

20. The Cartiva instrumentation is used to drill an appropriately sized cavity in the metatarsal head and deploy the Cartiva implant into the prepared cavity.

21. Defendant claims the joint resurfacing with a Cartiva implant is simple, does not require significant removal of healthy tissue, and typically results in nominal surgical trauma and rapid recovery.

22. The biomechanical design of these implants relies on “hard-on-hard” and “hard-on-soft” interactions.

23. The biomechanical design of these implants does not mimic the soft-on-soft interactions that occur in natural cartilage.

24. The efficacy and the validity of success rates boasted by Defendant have been criticized by doctors and peer reviewed literature.

25. The actual success rate patients experience was significantly less than what Defendant marketed and initially claimed.

26. Since the Cartiva device has been used in the market, Defendant was notified that doctors were unable to replicate the success rates in practice that Defendant claimed existed in promotional materials.

27. Cigna Insurance stopped covering the use of the device as it was deemed there was insufficient scientific evidence to support its successful treatment claims boasted by Defendant.

28. On or about June of 2018, Plaintiff underwent an implantation of Defendant's Defective Device at Midwest Orthopedics at Rush in the State of Illinois.

29. The Cartiva implant surgical procedure was not effective at alleviating Plaintiff's pain or restoring his range of motion and, in fact, made his symptoms dramatically worse.

30. In addition to a loss of range of motion of the great toe, Plaintiff experienced loss of mobility, nerve damage and debilitating pain of the great toe, along with constant irritation and discomfort in the location of the artificial Cartiva device.

31. At all times material hereto, the Cartiva implant device used in Plaintiff's surgery was designed, manufactured, marketed, retailed, distributed, and/or supplied by Defendant.

32. As a result of the implantation of the Defective Device, Plaintiff has suffered additional medical expenses for removal of the implant and fusion of the first metatarsal joint that

has resulted in on going pain, range of motion limitations and drastically impacted the quality of his life.

33. As a result of the implantation of the Defective Device, Plaintiff will incur future medical expenses for treatment of his physical pain and suffering and the impact upon his normal life.

34. On information and belief, the Defendant had knowledge at all relevant times of the clinical guidelines and peer reviewed and medical literature referenced herein and suppressed the medical data and information, failed to update the label, failed to update physicians and failed to voluntarily recall the defective device.

35. On information and belief, the Defendant misrepresented the failure rates in practice to the FDA.

36. Prior to the implantation of Plaintiff's Cartiva implant, Defendant was aware of higher than reported loss of toe mobility, pain and high failure rates of the Cartiva implant including but not limited to over 144 adverse reports filed with the FDA.

37. The Patient Brochure does not list loss of range of motion of the toe, bone lysis, shrinkage of implant, bone erosion or the inability to walk as a known risk of the Cartiva implant.

38. The Defendant did not warn Plaintiff of the aforementioned risks of implanting the Cartiva device.

39. Defendant's label and patient brochure failed to provide accurate substantive or quantitative prevalence rates of failure or other adverse effects to Plaintiff prior to his surgery.

40. Defendant has represented in patient marketing literature that Cartiva is a quick 35-minute procedure where your physician replaces the damaged cartilage in your big toe with a new synthetic cartilage that behaves like the natural cartilage of your big toe joint.

41. In addition to promises about increased toe mobility and function, Defendant alleges in marketing that the Cartiva implant is proven to provide long-term pain reduction and increased foot mobility, with 97% reduction in pain demonstrated at almost six years post-procedure.

42. The Defendant alleged the Cartiva implant was determined to be statistically equivalent to arthrodesis (fusion surgery) but with the added benefit of greater mobility and less surgical downtime.

43. The aforementioned statements made by Defendant regarding pain reduction and increased foot mobility and success being equivalent to arthrodesis exceeded the scope of the FDA approved label and was false and/or misleading.

44. Defendant violated federal regulations in the labeling of Plaintiff's Cartiva implant thereby causing a misbranded medical device to be ultimately implanted into Plaintiff's body.

45. At all times relevant hereto, the Cartiva implant and instruments were defective in design and/or manufacture.

46. At all times relevant hereto, the Cartiva implant defects existed when the components left the hands of Defendant making the components unreasonably dangerous as it biomechanically destroys the first metatarsal joint contrary to what Defendant claims in promotional material.

47. At all times relevant hereto, the Cartiva device was not safe for use in patients like Plaintiff despite Defendant's claims to the contrary.

48. At all times relevant hereto, Defendant failed to implicitly and expressly warn Plaintiff and other patients of the risks of using the Cartiva device.

49. At all times relevant hereto, including but not limited to June 2018, when the Cartiva device was implanted in Plaintiff, the device was unreasonably dangerous in one or more of the following ways:

- a. The device actually destroys the joint Defendant claims the Cartiva Device is designed to protect and improve motion in;
- b. Failed to accurately establish the in vivo life expectancy of the Cartiva SCI, in violation of 21 C.F.R. 820.30(f).
- c. Failed to validated the anticipated wear of the Cartiva SCI prior to its release into commercial distribution, in violation of 21 C.F.R. 820.30(g).
- d. Failed to establish and maintain appropriate reliability assurance testing to validate the Cartiva design both before and after its entry into the marketplace, in violation of 21 C.F.R. 820.30(g);
- e. Failed to conduct adequate bio-compatibility studies to determine the Cartiva implant's propensity to migrate from the joint space.
- f. Failed to identify the component discrepancy, in violation of 21 C.F.R. 820(80)(c);
- g. Failed to capture the component discrepancy or defect during their Final Acceptance Activities, in violation of 21 C.F.R. 820.80(d);
- h. Failed to establish and maintain procedures for implementing corrective and preventative action in response to, inter alia, complaints regarding the Cartiva, returned Cartiva, and other quality problems associated with the Cartiva, in violation of 21 C.F.R. 820.100;
- i. Failed to appropriately respond to adverse incident reports that strongly indicated the Cartivia implant was Malfunctioning [as defined in 21 C.F.R. 803.3], or otherwise not responding to its Design Objection Intent, in violation of 21 C.F.R. 820.198.
- j. Failed to warn the public of accurate failure rates;
- k. Failed to warn the public of the true and accurate risks associated with using the device
- l. Failed to initiate a voluntary recall after medical professionals and the health care industry reported to Defendant that the device's success rate was significantly worse then Defendant claimed previously;

- m. Failed to conduct complete device investigations on returned Cartiva implants and components in violation of 21 C.F.R. 820.198.
- n. Defendants failed to investigate and analyze Cartiva implant failures; and/or
- o. Continued to inject Cartiva implants into the stream of interstate commerce when Defendants knew, or should have known, that the Cartiva implants were Malfunctioning [as defined in 21 C.F.R. 803.3] or otherwise not responding to its Design Objective Intent.

50. As a direct and proximate result of one or more of the aforementioned ways the Cartiva device is unreasonably dangerous, the device was implanted into Plaintiff and directly caused and/or contributed to Plaintiff's severe and permanent injuries.

51. As a direct and proximate result of the aforementioned ways the Cartiva Device was unreasonably dangerous, the Cartiva implant used on Plaintiff failed and such failure directly caused and/or contributed to Plaintiff's severe and permanent injuries.

52. As a direct and proximate result of the design and/or manufacturing defects, failure to warn and breach of express and implied warranties related to Defendant's Cartiva implant and corresponding instruments designed, manufactured, distributed, sold and/or placed into the stream of commerce by the Defendant, Plaintiff suffered severe and permanent injuries, including, but not limited to, scarring and disfigurement, pain and suffering and had required an additional and debilitating surgery and has incurred significant medical expenses in the past and will incur additional medical expenses in the future; physical pain and suffering; both past and future; mental anguish and emotional distress, both past and future, including but not limited to, annoyance and aggravation, and has been damaged in an amount in excess of Seventy Five Thousand Dollars (\$75,000.00).

COUNT II - NEGLIGENCE -- CARTIVA, INC.

53. Plaintiff repeats, reiterates and re-alleges each and every allegation of this Complaint in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

54. Plaintiff is in the class of persons that Defendant should reasonably foresee as being subject to the harm caused by defectively designed Cartiva implants insofar as Plaintiff was the type of person for whom Cartiva implant was intended to be used.

55. At all times herein mentioned, Defendant created, designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and/or distributed its Cartiva implant as hereinabove described that was used by the Plaintiff.

56. Defendant reasonably foresaw that its Cartiva were expected to and did reach the usual consumers, handlers, and persons coming into contact with said product without substantial change in the condition in which they were produced, manufactured, sold, distributed and marketed by Defendant.

57. The Cartiva implant inserted into Plaintiff on June of 2018 was a class III device while the instruments used to insert Cartiva implants are all Class II devices designed and/or manufactured by Defendant and placed into the interstate stream of commerce.

58. Defendant marketed, distributed and/or permitted use of its Cartiva implants in violation of the Act and regulations promulgated to it.

59. At all times relevant hereto, Defendant had a duty of reasonable care in its design, manufacture, marketing, sale and distribution of the Cartiva Device.

60. Notwithstanding the aforesaid duty, Defendant violated their duty of reasonable care in one or more of the following ways:

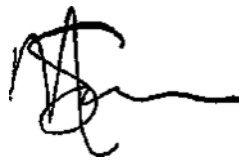
- a. Failed to accurately establish the in vivo life expectancy of the Cartiva, in violation of 21 C.F.R. 820.30(f);
- b. Failed to accurately validate the anticipated wear of the Cartiva SCI prior to its release into commercial distribution, in violation of 21 C.F.R. 820.30(g) and the PMA approval order for Cartiva;
- c. Failed to establish and maintain appropriate reliability assurance testing to validate the Cartiva SCI design both before and after its entry into the marketplace, in violation of 21 C.F.R. 820.30(g) and the PMA approval order for Cartiva;
- d. Failed to conduct adequate bio-compatibility studies to determine the Cartiva SCI's latent propensity to loosen, migrate into bone and failure to integrate into the joint space as required by the PMA approval order for Cartiva;
- e. Failed to identify the component discrepancy, in violation of 21 C.F.R. 820.80(c);
- f. Failed to capture the component discrepancy or defect during their Final Acceptance Activities, in violation of 21 C.F.R. 820.80(d) and as required by the PMA approval for Cartiva;
- g. Failed to establish and maintain procedures for implementing corrective and preventative action in response to, inter alia, complaints regarding the Cartiva SCI, returned Cartiva SCI, and other quality problems associated with the Cartiva SCI, in violation of C.F.R. 820.100 and the PMA approval order for Cartiva;
- h. Failed to appropriately respond to adverse incident reports that strongly indicated the Cartiva implant was malfunctioning [as defined in 21 C.F.R. 803.3], or otherwise not responding to its Design Objection Intent, in violation of 21 C.F.R. 820.198 and the PMA approval order for Cartiva;
- i. Failed to conduct complete device investigations on returned Cartiva implants and components, in violation of 21 C.F.R. 820.198 and the PMA approval order for Cartiva; and/or
- j. Failed to comply with the FDA policies and procedures to transfer ownership of the 510k and/or PMA.
- k. Failed to properly warn doctors and patients of the actual risks of using the device;

1. Failed to properly issue a recall of the device when it knew or should have known it was destroying patients joint surfaces at a far greater rate than it previously claimed.

61. As a direct and proximate result of Defendant's negligent acts or omissions, the Cartiva implant was used on the Plaintiff, failed and such failure directly caused and/or contributed to the severe and permanent injuries sustained and endured by Plaintiff.

62. As a direct and proximate result of Defendant's aforementioned actions, Plaintiff prays for judgment against Defendants in an amount in excess of Seventy Five Thousand Dollars (\$75,000.00).

Respectfully submitted,



Attorneys for Plaintiff

Richard L. Pullano (ARDC: 6183972)
Mathew T. Siporin (ARDC: 6287406)
Michael J. Pullano (ARDC: 6327875)
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mts@pullanolaw.com
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Defendants.)	

RULE 222 AFFIDAVIT

The undersigned attorney, on oath and affirmation, states that the total money damages sought in this action does exceed \$75,000.00.

Respectfully submitted,



By: _____
One of Plaintiffs' Attorneys

Richard L. Pullano (ARDC: 6183972)
Mathew T. Siporin (ARDC: 6287406)
Michael J. Pullano (ARDC: 6327875)
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)	
Plaintiff,)	
)	
v.)	No.
)	
CARTIVA, INC.)	
)	
Defendants.)	

JURY DEMAND

The undersigned demands a jury trial.

Respectfully submitted,



By: _____

One of Plaintiffs' Attorneys

Richard L. Pullano (ARDC: 6183972)
Mathew T. Siporin (ARDC: 6287406)
Michael J. Pullano (ARDC: 6327875)
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The ILND 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. (See instructions on next page of this form.)

I. (a) PLAINTIFFS**JOE KROLICKI****(b)** County of Residence of First Listed Plaintiff **Cook County, Illinois**
(Except in U.S. plaintiff cases)**(c)** Attorneys (firm name, address, and telephone number)**Pullano & Siporin, 1 E. Wacker Drive, 38th Floor, Chicago, IL 60601****DEFENDANTS****CARTIVA, INC.**County of Residence of First Listed Defendant **Gwinnett County, Georgia**
(In U.S. plaintiff cases only)

Note: In land condemnation cases, use the location of the tract of land involved.

Attorneys (If Known)

Duane Morris, 30 South 17th Street, Philadelphia, PA 19103**II. BASIS OF JURISDICTION** (Check one box, only.)

- ☐ 1 U.S. Government Plaintiff
- ☐ 2 U.S. Government Defendant
- ☐ 3 Federal Question
(U.S. Government not a party.)
- ☒ 4 Diversity
(Indicate citizenship of parties in Item III.)

III. CITIZENSHIP OF PRINCIPAL PARTIES (For Diversity Cases Only.)(Check one box, only for plaintiff and one box for defendant.)

- | | PTF | DEF | | PTF | DEF |
|---|---------------------------------------|----------------------------|---|----------------------------|---------------------------------------|
| Citizen of This State | <input checked="" type="checkbox"/> 1 | <input type="checkbox"/> 1 | Incorporated or Principal Place of Business in This State | <input type="checkbox"/> 4 | <input type="checkbox"/> 4 |
| Citizen of Another State | <input type="checkbox"/> 2 | <input type="checkbox"/> 2 | Incorporated and Principal Place of Business in Another State | <input type="checkbox"/> 5 | <input checked="" type="checkbox"/> 5 |
| Citizen or Subject of a Foreign Country | <input type="checkbox"/> 3 | <input type="checkbox"/> 3 | Foreign Nation | <input type="checkbox"/> 6 | <input type="checkbox"/> 6 |

IV. NATURE OF SUIT (Check one box, only.)

CONTRACT	TORTS	PRISONER PETITIONS	LABOR	OTHER STATUTES	
<input type="checkbox"/> 110 Insurance	PERSONAL INJURY <input type="checkbox"/> 310 Airplane <input type="checkbox"/> 315 Airplane Product Liability <input type="checkbox"/> 320 Assault, Libel & Slander <input type="checkbox"/> 330 Federal Employers' Liability <input type="checkbox"/> 340 Marine <input type="checkbox"/> 345 Marine Product Liability <input type="checkbox"/> 350 Motor Vehicle <input type="checkbox"/> 355 Motor Vehicle Product Liability <input type="checkbox"/> 360 Other Personal Injury <input type="checkbox"/> 362 Personal Injury - Medical Malpractice	PERSONAL INJURY <input checked="" type="checkbox"/> 365 Personal Injury - Product Liability <input type="checkbox"/> 367 Health Care/Pharmaceutical Personal Injury Product Liability <input type="checkbox"/> 368 Asbestos Personal Injury Product Liability PERSONAL PROPERTY <input type="checkbox"/> 370 Other Fraud <input type="checkbox"/> 371 Truth in Lending <input type="checkbox"/> 380 Other Personal Property Damage <input type="checkbox"/> 385 Property Damage Product Liability	<input type="checkbox"/> 510 Motions to Vacate Sentence <input type="checkbox"/> 530 General <input type="checkbox"/> 535 Death Penalty Other: <input type="checkbox"/> 540 Mandamus & Other <input type="checkbox"/> 550 Civil Rights <input type="checkbox"/> 555 Prison Condition <input type="checkbox"/> 560 Civil Detainee - Conditions of Confinement	<input type="checkbox"/> 710 Fair Labor Standards Act <input type="checkbox"/> 720 Labor/Management Relations <input type="checkbox"/> 740 Railway Labor Act <input type="checkbox"/> 751 Family and Medical Leave Act <input type="checkbox"/> 790 Other Labor Litigation <input type="checkbox"/> 791 Employee Retirement Income Security Act PROPERTY RIGHTS <input type="checkbox"/> 820 Copyright <input type="checkbox"/> 830 Patent <input type="checkbox"/> 835 Patent - Abbreviated New Drug Application <input type="checkbox"/> 840 Trademark <input type="checkbox"/> 880 Defend Trade Secrets Act of 2016 (DTSA) <input type="checkbox"/> 870 Taxes (U.S. Plaintiff or Defendant) <input type="checkbox"/> 871 IRS—Third Party	<input type="checkbox"/> 375 False Claims Act <input type="checkbox"/> 376 Qui Tam (31 USC 3729 (a)) <input type="checkbox"/> 400 State Reapportionment <input type="checkbox"/> 410 Antitrust <input type="checkbox"/> 430 Banks and Banking <input type="checkbox"/> 450 Commerce <input type="checkbox"/> 460 Deportation <input type="checkbox"/> 470 Racketeer Influenced and Corrupt Organizations <input type="checkbox"/> 480 Consumer Credit <input type="checkbox"/> 485 Telephone Consumer Protection Act (TCPA) <input type="checkbox"/> 490 Cable/Sat TV <input type="checkbox"/> 850 Securities/Commodities/Exchange <input type="checkbox"/> 890 Other Statutory Actions <input type="checkbox"/> 891 Agricultural Arts <input type="checkbox"/> 893 Environmental Matters <input type="checkbox"/> 895 Freedom of Information Act <input type="checkbox"/> 896 Arbitration <input type="checkbox"/> 899 Administrative Procedure Act/Review or Appeal of Agency Decision <input type="checkbox"/> 950 Constitutionality of State Statutes
<input type="checkbox"/> 120 Marine					
<input type="checkbox"/> 130 Miller Act					
<input type="checkbox"/> 140 Negotiable Instrument					
<input type="checkbox"/> 150 Recovery of Overpayment & Enforcement of Judgment					
<input type="checkbox"/> 151 Medicare Act					
<input type="checkbox"/> 152 Recovery of Defaulted Student Loan (Excludes Veterans)					
<input type="checkbox"/> 153 Recovery of Veteran's Benefits					
<input type="checkbox"/> 160 Stockholders' Suits					
<input type="checkbox"/> 190 Other Contract					
<input type="checkbox"/> 195 Contract Product Liability					
<input type="checkbox"/> 196 Franchise					
REAL PROPERTY <input type="checkbox"/> 210 Land Condemnation <input type="checkbox"/> 220 Foreclosure <input type="checkbox"/> 230 Rent Lease & Ejectment <input type="checkbox"/> 240 Torts to Land <input type="checkbox"/> 245 Tort Product Liability <input type="checkbox"/> 290 All Other Real Property	CIVIL RIGHTS <input type="checkbox"/> 440 Other Civil Rights <input type="checkbox"/> 441 Voting <input type="checkbox"/> 442 Employment <input type="checkbox"/> 443 Housing/Accommodations <input type="checkbox"/> 445 Amer. w/ Disabilities-Employment <input type="checkbox"/> 446 Amer. w/Disabilities - Other <input type="checkbox"/> 448 Education	BANKRUPTCY <input type="checkbox"/> 422 Appeal 28 USC 158 <input type="checkbox"/> 423 Withdrawal 28 USC 157 IMMIGRATION <input type="checkbox"/> 462 Naturalization Application <input type="checkbox"/> 463 Habeas Corpus - Alien Detainee (Prisoner Petition) <input type="checkbox"/> 465 Other Immigration Actions	FORFEITURE/PENALTY <input type="checkbox"/> 625 Drug Related Seizure of Property 21 USC 881 <input type="checkbox"/> 690 Other	SOCIAL SECURITY <input type="checkbox"/> 861 HIA (1395ff) <input type="checkbox"/> 862 Black Lung (923) <input type="checkbox"/> 863 DIWC/DIWW (405(g)) <input type="checkbox"/> 864 SSID Title XVI <input type="checkbox"/> 865 RSI (405(g)) FEDERAL TAXES <input type="checkbox"/> 870 Taxes (U.S. Plaintiff or Defendant) <input type="checkbox"/> 871 IRS—Third Party 26 USC 7609	

V. ORIGIN (Check one box, only.)

- ☒ 1 Original Proceeding ☐ 2 Removed from State Court ☐ 3 Remanded from Appellate Court ☐ 4 Reinstated or Reopened ☐ 5 Transferred from Another District (specify) ☐ 6 Multidistrict Litigation - Transfer ☐ 8 Multidistrict Litigation - Direct File

VI. CAUSE OF ACTION (Enter U.S. Civil Statute under which you are filing and write a brief statement of cause.)**Defective medical device; product liability action****VII. PREVIOUS BANKRUPTCY MATTERS** (For nature of suit 422 and 423, enter the case number and judge for any associated bankruptcy matter previously adjudicated by a judge of this Court. Use a separate attachment if necessary.)**VIII. REQUESTED IN COMPLAINT:**☐ Check if this is a class action under Rule 23, F.R.C.V.P.

Demand \$ In excess of \$75,000.00

CHECK Yes only if demanded in complaint:

Jury Demand: ☒ Yes ☐ No**IX. RELATED CASE(S) IF ANY** (See instructions):

Judge

Case Number

X. Is this a previously dismissed or remanded case?☐ Yes ☒ No If yes, Case #

Name of Judge

Date: **03/31/2025**Signature of Attorney of Record **/s/Mathew T. Siporin**

INSTRUCTIONS FOR ATTORNEYS COMPLETING CIVIL COVER SHEET FORM JS 44

Authority For Civil Cover Sheet

The JS 44 civil cover sheet and the information contained herein neither replaces nor supplements the filings and service of pleading or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. Consequently, a civil cover sheet is submitted to the Clerk of Court for each civil complaint filed. The attorney filing a case should complete the form as follows:

- I.(a) Plaintiffs-Defendants.** Enter names (last, first, middle initial) of plaintiff and defendant. If the plaintiff or defendant is a government agency, use only the full name or standard abbreviations. If the plaintiff or defendant is an official within a government agency, identify first the agency and then the official, giving both name and title.
- (b) County of Residence.** For each civil case filed, except U.S. plaintiff cases, enter the name of the county where the first listed plaintiff resides at the time of filing. In U.S. plaintiff cases, enter the name of the county in which the first listed defendant resides at the time of filing. (NOTE: In land condemnation cases, the county of residence of the "defendant" is the location of the tract of land involved.)
- (c) Attorneys.** Enter the firm name, address, telephone number, and attorney of record. If there are several attorneys, list them on an attachment, noting in this section "(see attachment)".
- II. Jurisdiction.** The basis of jurisdiction is set forth under Rule 8(a), F.R.Cv.P., which requires that jurisdictions be shown in pleadings. Place an "X" in one of the boxes. If there is more than one basis of jurisdiction, precedence is given in the order shown below.
 United States plaintiff. (1) Jurisdiction based on 28 U.S.C. 1345 and 1348. Suits by agencies and officers of the United States are included here.
 United States defendant. (2) When the plaintiff is suing the United States, its officers or agencies, place an "X" in this box.
 Federal question. (3) This refers to suits under 28 U.S.C. 1331, where jurisdiction arises under the Constitution of the United States, an amendment to the Constitution, an act of Congress or a treaty of the United States. In cases where the U.S. is a party, the U.S. plaintiff or defendant code takes precedence, and box 1 or 2 should be marked.
 Diversity of citizenship. (4) This refers to suits under 28 U.S.C. 1332, where parties are citizens of different states. When Box 4 is checked, the citizenship of the different parties must be checked. (See Section III below; **NOTE: federal question actions take precedence over diversity cases.**)
- III. Residence (citizenship) of Principal Parties.** This section of the JS 44 is to be completed if diversity of citizenship was indicated above. Mark this section for each principal party.
- IV. Nature of Suit.** Place an "X" in the appropriate box. If there are multiple nature of suit codes associated with the case, pick the nature of suit code that is most applicable. Click here for: [Nature of Suit Code Descriptions](#).
- V. Origin.** Place an "X" in one of the seven boxes.
 Original Proceedings. (1) Cases which originate in the United States district courts.
 Removed from State Court. (2) Proceedings initiated in state courts may be removed to the district courts under Title 28 U.S.C., Section 1441. When the petition for removal is granted, check this box.
 Remanded from Appellate Court. (3) Check this box for cases remanded to the district court for further action. Use the date of remand as the filing date.
 Reinstated or Reopened. (4) Check this box for cases reinstated or reopened in the district court. Use the reopening date as the filing date.
 Transferred from Another District. (5) For cases transferred under Title 28 U.S.C. Section 1404(a). Do not use this for within district transfers or multidistrict litigation transfers.
 Multidistrict Litigation – Transfer. (6) Check this box when a multidistrict case is transferred into the district under authority of Title 28 U.S.C. Section 1407.
 Multidistrict Litigation – Direct File. (8) Check this box when a multidistrict case is filed in the same district as the Master MDL docket.
PLEASE NOTE THAT THERE IS NOT AN ORIGIN CODE 7. Origin Code 7 was used for historical records and is no longer relevant due to changes in statute.
- VI. Cause of Action.** Report the civil statute directly related to the cause of action and give a brief description of the cause. **Do not cite jurisdictional statutes unless diversity.** Example: U.S. Civil Statute: 47 USC 553 Brief Description: Unauthorized reception of cable service
- VII. Requested in Complaint.** Class Action. Place an "X" in this box if you are filing a class action under Rule 23, F.R.Cv.P.
 Demand. In this space enter the actual dollar amount being demanded or indicate other demand, such as a preliminary injunction.
 Jury Demand. Check the appropriate box to indicate whether or not a jury is being demanded.
- VIII. Related Cases.** This section of the JS 44 is used to reference related pending cases, if any. If there are related pending cases, insert the docket numbers and the corresponding judge names for such cases.

Date and Attorney Signature. Date and sign the civil cover sheet.