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

| | | |
|---|---|---|
| PHILIPPE MAGLOIRE, | ) | |
| | ) | |
| Plaintiff, | ) | |
| | ) | |
| v. | ) | No. |
| | ) | |
| CARTIVA, INC. | ) | |
| | ) | |
| Defendants. | ) | |

**COMPLAINT AT LAW**

NOW COMES the Plaintiff, PHILIPPE MAGLOIRE, 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, PHILIPPE MAGLOIRE, 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 Glenview.

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 2017, Plaintiff treated with Dr. Armen Kelikian at NorthShore University Health System for discomfort in his first metatarsophalangeal joint.

7. In 2017, Dr. Kelikian 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 November 15, 2017, Defendant's Defective Device was placed into the stream of interstate commerce and was surgically implanted in Plaintiff by Dr. Armen Kelikian at NorthShore Skokie Hospital located in Skokie, 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 Dr. Armen Kelikian on a regular basis due to the worsening pain, limitations, progressive erosion of the joint and shortening of his toe.

11. Subsequent to the surgery, Dr. Armen Kelikian performed multiple steroid injections into his toe joint to help moderate his pain.

12. However, the steroid injections wore off and Plaintiff's pain returned and in fact worsened with time.

13. Eventually, Plaintiff saw doctors at Illinois Bone & Joint for a second opinion.

14. Subsequent to the surgery, doctors at Illinois Bone & Joint concluded that the CARTIVA SCI had failed.

15. Subsequent to the surgery, doctors at Illinois Bone & Joint recommended removal of the defective device and undergoing a fusion surgery.

16. Plaintiff continues to receive intermittent steroid injections to moderate his pain and is holding off on the recommended fusion surgery as long as possible.

17. 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.

18. 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.

19. 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.

20. 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.

21. 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.

22. 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.

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

24. 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.

25. The biomechanical design of these implants relies on "hard-on-hard" and "hard-on-soft" interactions.

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

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

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

29. 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.

30. 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.

31. On or about November 15, 2017, Plaintiff underwent an implantation of Defendant's Defective Device at NorthShore Skokie Hospital in the State of Illinois.

32. 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.

33. 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.

34. 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.

35. 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.

36. 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.

37. 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.

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

39. 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.

40. 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.

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

42. 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.

43. 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.

44. 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.

45. 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.

46. 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.

47. 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.

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

49. 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.

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

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

52. At all times relevant hereto, including but not limited to November 15, 2017, 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.

53. 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.

54. 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.

55. 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.**

56. 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.

57. 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.

58. 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.

59. 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.

60. The Cartiva implant inserted into Plaintiff on November 15, 2017 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.

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

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

63. 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. 82030(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;

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

64. 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,.

65. 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)
PULLANO & SIPORIN
Attorney for Plaintiff
1 E. Upper Wacker Drive, 38th Floor
Chicago, IL 60601
(Tel) 312-551-1100
rlp@pullanolaw.com
mts@pullanolaw.com
mjp@pullanolaw.com

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

| | | |
|---|---|---|
| PHILIPPE MAGLOIRE, | ) | |
| | ) | |
| Plaintiff, | ) | |
| | ) | |
| v. | ) | No. |
| | ) | |
| CARTIVA, INC. | ) | |
| | ) | |
| 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)
PULLANO & SIPORIN
Attorney for Plaintiff
1 E. Upper Wacker Drive, 38th Floor
Chicago, IL 60601
(Tel) 312-551-1100
rlp@pullanolaw.com
mts@pullanolaw.com
mjp@pullanolaw.com

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

| | | |
|---|---|---|
| PHILIPPE MAGLOIRE, | ) | |
| | ) | |
| 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)
PULLANO & SIPORIN
Attorney for Plaintiff
1 E. Upper Wacker Drive, 38th Floor
Chicago, IL 60601
(Tel) 312-551-1100
rlp@pullanolaw.com
mts@pullanolaw.com
mjp@pullanolaw.com