IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND
Southern Division

ROBERT B. CONNOR 4620 North Park Ave., Ph 8E Chevy Chase, Maryland 20815 (Montgomery County)	:	
Plaintiff	:	**COMPLAINT AND JURY DEMAND**
v.	:	Civil No. 24-cv-03525
CARTIVA, INC., 6120 Windward Parkway, Suite 220 Alpharetta, Georgia 30005	:	
and	:	
WRIGHT MEDICAL GROUP, N.V. 1023 Cherry Road Memphis, Tennessee 38117	:	
and	:	
STRYKER, B.V. 2825 Airview Boulevard Kalamazoo, Michigan 49002	:	
Defendants	:	

COMPLAINT AND JURY DEMAND

NOW COMES THE PLAINTIFF, Robert B. Connor, by and through his attorneys Jenner Law, P.C. and Alex Davis Law, PLLC, and for his causes of action against the Defendants Cartiva, Inc. ("Cartiva"), Wright Medical Group, N.V. ("Wright"), and Stryker, B.V. f/ka Wright Medical Group f/k/a Cartiva, Inc. ("Stryker"), alleges and states as follows:

PREAMBLE

This is a products liability lawsuit involving a defective toe implant device that fails in approximately two thirds of patients, but which continued to be sold in the U.S. market for years until it was recalled about a month ago. Plaintiff, Robert B. Connor, had a Cartiva Synthetic Cartilage Implant, also known as a Cartiva SCI, manufactured and marketed by Defendants implanted in his left foot on April 23, 2021. The Cartiva SCI suffered from a defect that caused it to fail almost immediately, resulting severe pain, swelling, and limited mobility to the Plaintiff. As a result of the defect, Plaintiff was required to undergo a painful and costly revision surgery to remove the implant and have his left toe bones fused together.

As a further result of the product defect, Plaintiff has suffered and will suffer both economic and non-economic losses, including health care bills, untold pain and suffering, and loss of enjoyment of life.

PARTIES

1. Plaintiff Robert B. Connor is, and at all times relevant to this action was, a citizen and resident of the State of Maryland, with a residence at 4620 North Park Ave., Ph 8E, Chevy Chase, Maryland 20815 (Montgomery County).

2. 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. As a manufacturer of medical devices, Cartiva is, and at all times relevant was, subject to regulations and consensus industry standards governing the medical device industry, including those promulgated by the United States Food and Drug Administration ("FDA").

3. Wright Medical Group, N.V. is, and at all times relevant to this action was, a corporation with its principal place of business and headquarters located at 1023 Cherry Road, Memphis, Tennessee 38117. As a manufacturer of medical devices, Wright is subject to regulations and consensus industry standards governing the medical device industry, including those promulgated by the FDA.

4. Stryker B.V. is, and at all times relevant to this action was, a corporation with its principal place of business and headquarters located at 2825 Airview Boulevard, Kalamazoo, Michigan 49002. As a manufacturer of medical devices, Stryker is subject to regulations and consensus industry standards governing the medical device industry, including those promulgated by the FDA.

5. At all times material hereto, Defendants developed, tested, assembled, manufactured, packaged, labeled, prepared, distributed, marketed, supplied, and/or sold the defective product under the name "Cartiva SCI" (hereinafter "SCI" or "Defective Device"), either directly or indirectly, to Maryland residents, including Plaintiff.

JURISDICTION AND VENUE

6. This Court has original jurisdiction pursuant to diversity jurisdiction prescribed by 28 U.S.C. § 1332 in that the amount in controversy exceeds $75,000.00, exclusive of costs and interest, and involves citizens of different states.

7. Venue is proper in the U.S. District Court for the District of Maryland pursuant to 28 U.S.C. § 1391 because it is the judicial district in which a substantial part of the events or omissions giving rise to the claim occurred and all Defendants are subject to personal jurisdiction in that District.

FACTUAL ALLEGATIONS

8. This case arises out of Defendants' individual and collective violations of various sections of the Federal Code of Regulations, along with parallel state law claims, with those violations actually and proximately causing damages suffered by Plaintiff as a result.

9. Big toe arthritis affects about 2.2 million people in the United States. As arthritis deteriorates the joint's cartilage, a person develops painful bone-on-bone friction. This condition is treated surgically via two methods: (1) arthrodesis (also known as "fusion"); or (2) implant of a Cartiva SCI, or Synthetic Cartilage Implant, which purportedly acts like a cushion to prevent bone-on-bone pain.

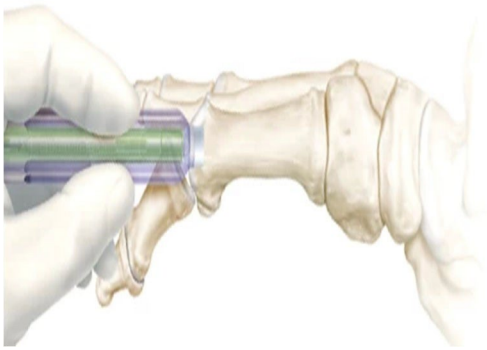
10. Although toe fusion and implantation each carry risks, research shows that the risk of repair surgery is far lower with toe fusion.[1]

The Cartiva SCI Option.

11. The Cartiva SCI 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:[2]

[1] Lewis, et. al., *Cartiva Interpositional Arthroplasty Versus Arthrodesis in the Treatment of Hallux Rigidus: A Retrospective Comparative Study with Mean 2 Year Follow Up*, J. Foot and Ankle Surgery, Oct. 2024, available at https://www.sciencedirect.com/science/article/abs/pii/S1268773124001036 (last visited Dec. 2, 2024).

[2] *See* Home > For Physicians > Implant Procedure(https://www.cartiva.net) (https://www.cartiva.net/for-physicians/)



Press Fit Application of Cartiva Implant

12. Defendants tout the implantation of the Cartiva SCI as a simple procedure, which enables surgeons to replace the damaged cartilage with a bullet-sized implant they can place into an intraoperatively created pilot hole in the first metatarsal head.

13. The Cartiva SCI implant is used in the treatment of 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.

14. The surgeon uses instrumentation to drill an appropriately sized cavity in the metatarsal head and deploy the Cartiva SCI into the prepared cavity. Defendants allege 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.[3]

15. Cartilage is a specialized tissue responsible for mediating contact between bones on surfaces with relative movement. Since cartilage is not vascularized, chondrocytes depend mainly on anaerobic metabolism and get their nutrients through diffusion from the synovial fluid into the matrix.

16. As it is not vascularized, cartilage does not restore itself or recover quickly from injury; the complete turnover of the human femoral head cartilage would take approximately 400

[3] *See id.*

years.[4] As such, replacement of cartilage with polyvinyl alcohol-based hydrogels ("PVA"), such as the Cartiva SCI, is an alternative to traditional fusion treatment.

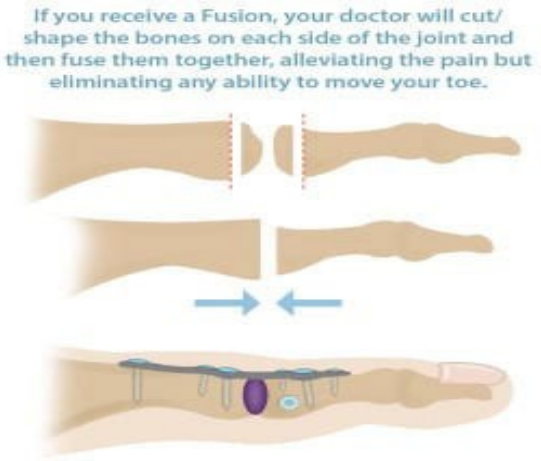
17. The biomechanical design of these implants relies on "hard-on-hard" and "hard-on-soft" interactions. This type of design does not mimic the soft-on-soft interactions that occur in natural cartilage.

18. While PVA is biocompatible and has good swelling properties,[5] the characteristics thereof could also be tailored by adjusting the production method or by combining PVA with other materials to produce a more suitable and stable material than the current design.[6]

The Fusion Treatment Option.

19. In contrast to the procedure utilizing a Cartiva SCI, a fusion is a procedure where the phalangeal and metatarsal bones are cut and shaped to fit (fuse) together to relieve toe joint pain:

[4] Maroudas a. Physicochemical properties of cartilage in the light of ion exchange theory. Biophys J. 1968;8(5):575-595. doi:10.1016/S0006-3495(68)86509-9.
[5] *Id.*
[6] *Id.*; *see also* Ma R, Xiong D, Miao F, Zhang J, Peng Y. Novel PVP/PVA hydrogels for articular cartilage replacement. Mater Sci Eng C. 2009;29(6):1979-1983. doi:10.1016/j.msec.2009.03.010; Fathi E, Atyabi N, Imani M, Alinejad Z. Physically crosslinked polyvinyl alcohol-dextran blend xerogels: Morphology and thermal behavior. Carbohydr Polym. 2011;84(1):145-152. doi:10.1016/j.carbpol.2010.11.018



20. The two bones are then aligned, set at a predetermined angle and permanently fixed with either screws and/or a plate so the two bones "fuse" together permanently. A typical fusion procedure restricts the ability to move the big toe but eliminates the patient's pain.

Degradation of the Cartiva SCI.

21. As noted above, the Cartiva SCI is a PVA implant. SCI implants have had degradation of the PVA membrane with findings of loosening, marring and deformity of implant according to an independent study (the "Rosas Study").[7] This degradation directly and proximately causes implant failure, subsequent fusion surgery, pain, loss of mobility and bone loss.

22. The PVA degradation is not an anticipated or intended outcome of the manufacturing of the Cartiva SCI but is a mechanical defect that rendered the Cartiva SCI not reasonably safe.

23. The importance of swelling behavior is connected to the mechanical and tribological properties of the Cartiva SCI hydrogel, as well as how swelling behavior impacts the

[7] *See* Rosas K, Hurley ET, Kennedy JG. *Early Failures of Polyvinyl Alcohol Hydrogel Implant for the Treatment of Hallux Rigidus*. Foot & Ankle Orthopaedics. October 2020. doi:10.1177/2473011420S0041, available at https://pmc.ncbi.nlm.nih.gov/articles/PMC8702944/ (last visited Dec. 2, 2024).

risk of implant failure. In 2007, PVA hydrogels were used for treatment of knee cartilage defects in adult rabbits. Results revealed growth over the implant and implant shrinkage.[8] Hydrogels can react to osmotic gradients and swell and de-swell accordingly, even in hydrated conditions. This volume change may induce detachment from the tissue or implant and interfacial debonding.[9]

24. Since SCIs are composed of PVA, which is soluble in water, crosslinking is a crucial step for PVA gel formation. Without a stable structure, the gel is not able to withstand the swelling pressure upon fluid intake and may dissolve.[10]

25. The Defective Device is a proprietary PVA-based hydrogel, and its production consists of successive freeze-thawing cycles. PVA hydrogels are problematic because the method of manufacturing may result in 1) air bubbles, 2) PVA clumping, 3) fragility of the PVA hydrogel, 4) improper binding of crystallites, 5) disintegration and 6) striation.

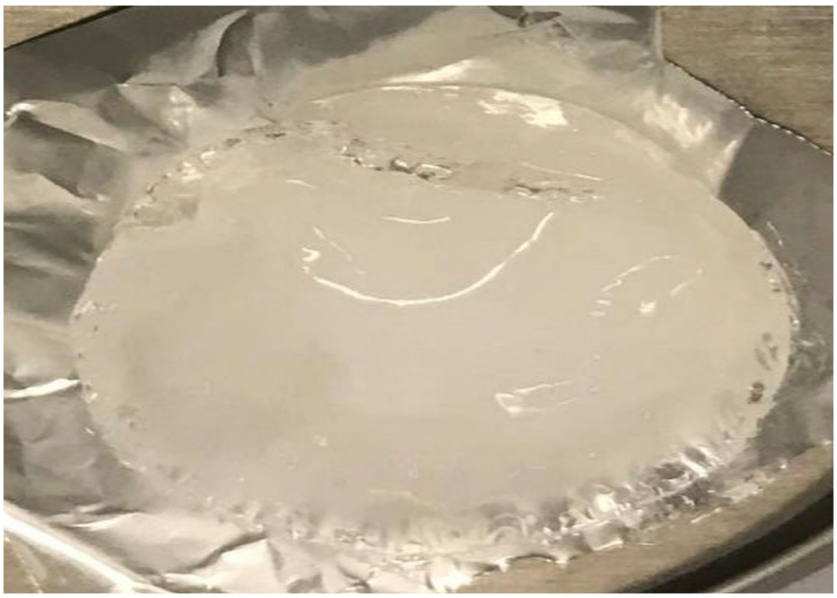


Figure 1 - Partially disintegrated Freeze Thawed PVA gel

[8] Maher SA, Doty SB, Torzilli PA, et al. *Nondegradable hydrogels for the treatment of focal cartilage defects. J Biomed Mater Res - Part A*. 2007;83(1):145-155. doi:10.1002/jbm.a.31255
[9] Carolina Borges, Rogério Colaço & Ana Paula Serro (2019) *Poly(vinyl alcohol)-based hydrogels for joint prosthesis,Annals of Medicine*, 51:sup1, 105, DOI: 10.1080/07853890.2018.1562711
[10] Peppas NA. *Hydrogels in Medicine and Pharmacy*. Boca Raton: CRC Press; 1989

Figure 2 - Striations on gel caused by rapid cooling and oxygenation of pre gel solution.

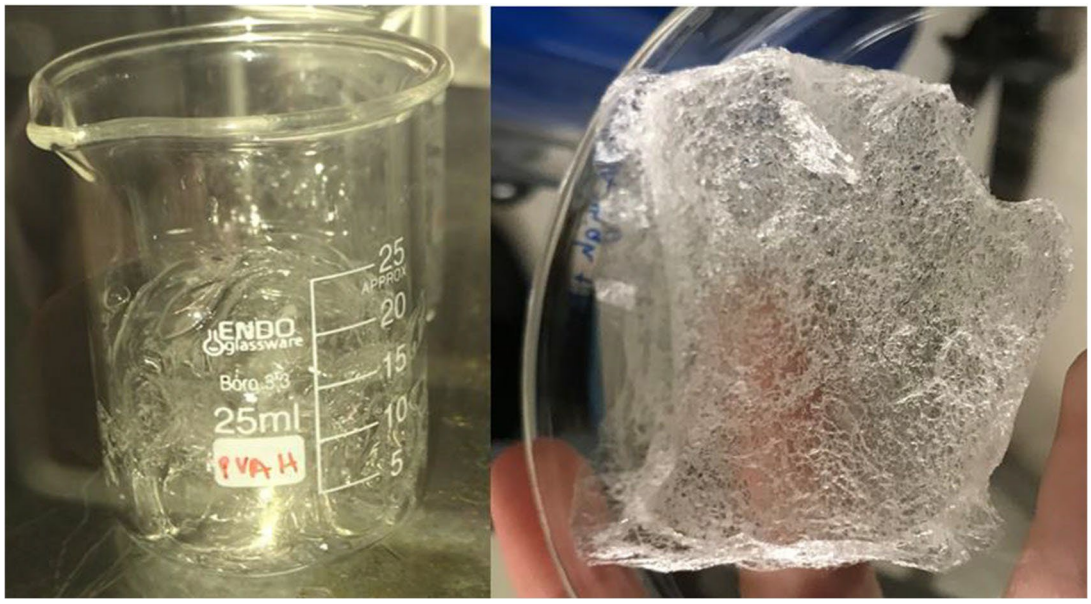


Figure 3 - Effects of vacuum on gelation of PVA cause air bubbles to be trapped inside hydrogel.

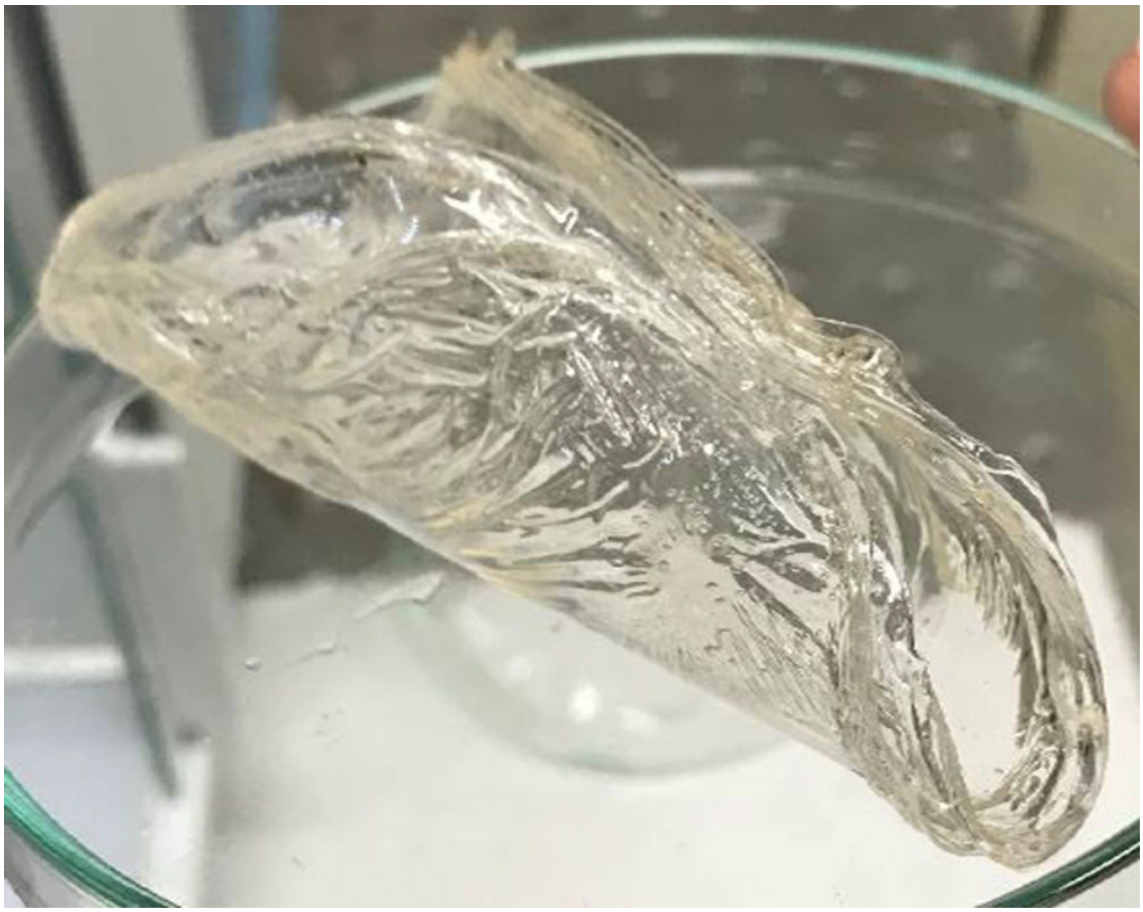


Figure 4 - Semi-irreversible contracture of thick PVA hydrogel

26. Manufacturing methods are more problematic for thicker gels like the Cartiva implant. Thicker gels are prone to a lot more variation, and small tweaks in temperature and aeration can contribute to these variations. Consistent temperature and aerations are much harder to produce on a larger scale in a manufacturing environment.

27. The violations of federal regulations, including but not limited to making an adulterated device because the manufacture of the defective device failed to meet established performance standards, or if the methods, facilities or controls used for its manufacture, packing, storage or installation are not in conformity with federal requirements. *See* 21 U.S.C. § 351.

Defendants Suppressed Adverse Data and Testing Results.

28. Defendants have a duty to be truthful about the risks of their products in marketing

and promotion of their product. Yet, Defendants have suppressed medical industry knowledge from the FDA and public that Cartiva SCI's have a high failure rate due to migration of the implant caused by implant shrinkage.

29. To place the Cartiva SCI on the market, Defendants obtained PMA approval for Cartiva SCI as a Class III device, yet the approval was largely based on the "substantial equivalence" of the Cartiva SCI performing similarly to the gold standard treatment of fusion. Substantial equivalence is generally used for Class II medical devices and evades a full FDA safety review.

30. One of the conditions of approval required a post-approval study ("PAS") that demonstrates no greater than 13.5% complication rate and tracking the number of patients that were converted to fusion surgery.

31. The pivotal study[11] (the "Motion Study") for the Defective Device compared it to the fusion gold standard. The study was a non-inferiority clinical study of 202 subjects treated at 12 sites in the United Kingdom and Canada. The Motion Study reported on a prospective, randomized non-inferiority study to compare the efficacy and safety of the Cartiva SCI to great toe fusion surgery for advanced-stage hallux rigidus. The study included 152 implant and 50 fusion patients. The study assessed pain, function, and safety. There were no cases of implant fragmentation, wear, or bone loss. This study is the basis of the PMA approval for the Cartiva SCI.

[11] Baumhauer JF, Singh D, Glazebrook M, Blundell C, De Vries G, Le IL, Nielsen D, Pedersen ME, Sakellariou A, Solan M, Wansbrough G, Younger AS, Daniels T; for and on behalf of the CARTIVA Motion Study Group. *Prospective, Randomized, Multi-centered Clinical Trial Assessing Safety and Efficacy of a Synthetic Cartilage Implant Versus First Metatarsophalangeal Arthrodesis in Advanced Hallux Rigidus*. Foot Ankle Int. 2016 May;37(5):457-69. doi: 10.1177/1071100716635560. Epub 2016 Feb 27. PMID: 26922669.

32. The Motion Study, put simply, is a comparison to a fusion procedure. However, the results of the Motion Study have not been replicated in clinical practice, and the Cartiva SCI failure rate is much higher.[12]

33. Nonetheless, a follow up to the "Motion Study", Baumhauer et al. (2017) ("Motion II Study"), a study funded by Defendants, retrospectively evaluated the Motion study I (Baumhauer, et al., 2016) finding identical success rates between fusion surgery and the Cartiva SCI. These success rates do not exist in clinical practice. Actual patient results identified in the Rosas Study have reported failure rates of 64% as opposed to the 13.5% failure rate Defendants reported to the FDA.[13] A more recent analysis of 236 adverse event reports showed a 74 percent removal rate for the Cartiva, and said the device "… represents the unfortunately repetitive rise and fall of new surgical devices accepted too early in the usage life cycle before mid- to -long-term outcomes exist."[14]

34. The Cartiva SCI was initially considered to be a revolution in great toe arthritis therapy. It came out with a splash as the original studies cited herein—to get the implant through FDA approval—showed striking results. Bob Baravarian, DPM, FACFAS, was involved in helping launch the Cartiva SCI and educating other surgeons on the proper use thereof. Dr. Baravarian's clinic, University Foot and Ankle Institute, began to see failures due to the implant slipping into the bone, a process referred to as subsidence. Dr. Baravarian and his clinic will no

[12] *See* https://www.medtechdive.com/news/wright-medical-shares-tumble-amid-report-of-cartiva-slowdown/558132/.
[13] *See* n. 6.
[14] Michael Radcliffe, et. al, A Review of Adverse Events Related to Synthetic Cartilage Implant for the First Metatarsophalangeal Joint: An Analysis of Manufacturer and User Facility Device Experience database from 2016 to 2023, Foot & Ankle Surgery: Techniques, Reports and Cases, Spring 2024, available at https://www.sciencedirect.com/science/article/pii/S2667396723000940 (last visited Dec. 2, 2024).

longer use Cartiva SCIs because their failure in clinical practice occurs more frequently than the results noted in Defendants' Motion Study.

35. Dr. Baravarian is not alone in his findings; a retrospective review of 64 Cartiva SCI procedures by Cedars Sinai Medical Center showed a higher level of patient dissatisfaction with implant outcomes than was seen in the Motion Study. In the Cedars Sinai trial, 37.5% of the patient underwent revision surgery an average of 20.9 months. More importantly, the radiographic loss of MTP (great toe) joint space and progression of arthritis were present for all cases studied. MRI revealed bony channel widening and a smaller implant-evidence of subsidence (a/k/a shrinkage) with peri-implant fluid suggesting instability at the implant-bone interface. Persistent edema was observed in soft tissues and bone.

36. On July 12, 2019 the FDA approved Defendants' updated label based upon the findings of the Motion Study and Motion II Study to include implant subsidence. However, in securing that approval, Defendants incorrectly claimed a majority (76%; 13/17) of Cartiva SCI serious adverse events were for pain. Additionally, Defendants incorrectly stated in the updated label that 9.2% of Cartiva SCI subjects and 12% of fusion subjects had the implant and/or hardware removed during the course of the study. On information and belief, the Defendants have misrepresented the failure rates to the FDA by labeling the adverse event as pain rather than implant subsidence.

37. Additionally, on information and belief, Defendants did not report the Rosas study[15] to the FDA until very recently despite the study's findings which confirmed high failure rates due to implant shrinkage coupled with lysis and bone erosion around the implant. Plain radiographs were assessed postoperatively at 2, 4, 8 weeks and final follow-up. Of 14 patients

[15] *See id.*

who had taken adequate postoperative plain radiographs, implant subsidence ("shrinkage") was observed in 9 patients (64%) at 4 weeks after surgery and 11 patients (79%) at final follow-up. Eight patients (57%) showed radiologic lucency around the implant. Six patients (40%) had erosion of the proximal phalanx of great toe. Six patients (43%) reported no improvement following surgery at final follow up. Three patients required additional surgery, including debridement and fixation of implant using fibrin glue for loosening. Additionally, the Rosas study found significant radiologic subsidence with disintegration of bone around the implant, erosion of the proximal phalanx countersurface as well as recorded implant wear and tear. These are significant harbingers for concern in the long term.

38. Further still, outside the United States, the National Institute for Health and Care Excellence ("NICE") published Interventional Procedure Guidance in 2005 based on analysis of seven case series: Hanyu et al. (2001); Sharnkar, et al., (1991); Cracchiolo et al., (1992); Granberry et al., (1991); Bommireddy et al., (2003); Ibrihim et al., (2004); and Malviya et al., (2004). The guidance also states there is little evidence on the durability of newer implants, and that complications may necessitate removal of the joint. These complications include persistent pain, infection, implant loosening, implant fracture, osteolysis, bone over-production, cyst formation, silastic granulomas and transfer metatarsalgia.

39. The wide criticism of the Motion Study by industry experts because of its insufficient sample size prompted insurance carrier Cigna to deem the use of the Cartiva SCI to treat big toe arthritis "experimental" based upon the lack of sufficient scientific evidence to support the successful treatment claims made by Defendants.[16]

[16] Partial or total replacement of the first MTP joint or any other foot joint using ANY of the following is considered experimental, investigational or unproven: Page 2 of 12 Medical Coverage Policy: 0446; ceramic implant (e.g., Moje prosthesis [Orthosonics, Ltd., Devon UK]); synthetic cartilage implant (e.g., Cartiva Synthetic Cartilage Implant)

40. Cigna cited a report by Hayes, Inc.[17], which found individual outcome measures are inconsistent and some suggest better outcomes with fusion. The body of evidence is limited by the publication of the Motion Study, within which results were conflicting and did not demonstrate a clear benefit of the Cartiva SCI over fusion surgery. The Hayes report concluded that a very-low-quality body of evidence is insufficient to draw conclusions regarding the effectiveness and safety of Cartiva SCI for treatment of first MTP joint arthritis. Substantial uncertainty exists due to a single identified trial, inconsistencies within the individual study results, and lack of long-term comparative effectiveness data. Large studies assessing the comparative effectiveness and safety of the Cartiva SCI are needed.

41. Cigna also recognized that clinical practice guidelines suggest a different implant design is recommended which renders the Cartiva SCI unreasonably dangerous by design. Clinical practice guidelines published by the First Metatarsophalangeal Joint Disorders Panel of the American College of Foot and Ankle Surgeons in 2003 state that interposition arthroplasty with double-stem silicone hinged implants is still a useful procedure for the end-state arthrosis of hallux, and that titanium grommets are recommended to minimize ectopic bone formation and protect the implant from the adjacent bone. In addressing total joint systems, the guideline states that numerous implant systems have been developed during the years and several are still used clinically, although long-term clinical usefulness has yet to be established. Judicious use and strict criteria are recommended to avoid complications and problematic revisions (Vanore, et al., 2003).

42. Prior to the implantation of Plaintiff's Cartiva SCI, Defendants were aware of higher than reported loss of toe mobility, pain and high failure rates of the Defective Device due

[17] Hayes, Inc. Hayes Health Technology Brief. Cartiva Synthetic Cartilage Implant (Wright Medical Group) for Treatment of First Metatarsophalangeal Joint Arthritis. Hayes, Inc., March 2019; updated May 2020.

to shrinkage, including but not limited to 144 adverse event reports in the Maude database with the majority of events attributed to implant loosening. The loosening is likely due to shrinkage of the implant that is well supported by peer-reviewed literature mentioned herein.

Defendants Issue a Recall of the Cartiva SCI Device

43. As failure rates continued to rise, Defendants issued a recall of the Cartiva SCI device on October 31, 2024 based on reports, including the Rosas study, indicating patients, including Plaintiff, who received a Cartiva SCI implant experienced alarmingly high rates of revision, removal, displacement, pain, or nerve damage than previously disclosed in premarket and post-approval studies[18].

44. The recall notice instructed healthcare providers to remove and quarantine any remaining Cartiva SCI devices in their inventory and return them to Stryker. It also asked physicians to continue monitoring their patients, and look for new or worsening symptoms including pain, and difficulties walking.

45. A recall is an alternative to a Food and Drug Administration-initiated court action for removing or correcting violative, distributed products by setting forth specific recall procedures for the Food and Drug Administration to monitor recalls and assess the adequacy of a firm's efforts in recall. *See* 21 CFR § 7.40(a).

46. The Defendants knew or should have known the Cartiva SCI should have been recalled long before October 31, 2024, in violation of federal regulations including making an adulterated device that proximately and directly caused Plaintiff's injuries and damages.

Product Representations.

[18]Urgent Medical Device Recall, Oct. 31, 2024, available at https://www.stryker.com/content/dam/stryker/foot-and-ankle/resources/CartivaFSN30Oct2024_US.pdf (last visited Dec. 2, 2024).

47. Defendants' label and patient brochure failed to provide accurate substantive or quantitative prevalence rates of failure or other adverse effects to customers, including Plaintiff, prior to use and prior to his surgery.

48. Defendants have represented in patient marketing literature that Cartiva SCI implant is a quick 35-minute procedure where their physician replaces the damaged cartilage in their big toe with a new synthetic cartilage that behaves like the natural cartilage of their big toe joint.

49. Defendants additionally tell patients, including Plaintiff that "movement matters" further stating in marketing materials - "Your big toe joint is uniquely designed for movement and provides most of the force needed for walking and running. Unlike fusion surgery, which locks the joint in place, CARTIVA Synthetic Cartilage Implant (SCI) reduces pain while also allowing your joint to move how it's supposed to."

50. In addition to promises about the increased toe mobility and function, Defendants allege in marketing that the Cartiva SCI is proven to provide long-term pain reduction and increased foot mobility, with 97% reduction in pain demonstrated at almost six years post procedure. These statements exceed the scope of the FDA approved label.

51. By contrast, the Patient Brochure does not list the significant adverse consequences of use of the Cartiva SCI, including:

a. 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 SCI; and,

b. the true failure rate due to migration and prevalence of those failures sufficient for her to make an informed decision prior to her surgery. Defendants' label reflects SCI failure rate of 13.5%. However, in view of continual and ongoing reports and studies, the actual rate of failure of the SCI is likely 6-7 times higher than Defendants' reported failure rate.

52. The conditional approval letter relating to the Cartiva implant stated: "CDRH does not evaluate information related to contract liability warranties, however you should be aware that any such warranty statements must be truthful, accurate, and not misleading, and must be consistent with applicable Federal and State laws". Failure to comply with the conditions of approval invalidates this approval order.

53. Commercial distribution of a device that is not in compliance with these conditions is a violation of the Food, Drug and Cosmetic Act. 21 U.S.C. §§ 301 et seq.

54. Defendants violated the conditional approval requirements and consequently the federal regulations in, among other things, making untrue, inaccurate and/or misleading statements regarding Plaintiff's Cartiva SCI. If Defendants had not made these statements and violated the requirements and regulations, Plaintiff would have chosen an alternative treatment option or a different device for implantation into his body.

55. Unfortunately for patients with SCI failure, many in the medical community believe that loss of toe range of motion is a symptom of shrinkage (aka implant subsidence), which is a precursor to failure. By any account, the number of SCI failures is not only exponentially greater than Defendants will admit, but the failure rate is reaching alarming proportions.

56. During the time Defendants have marketed, labeled and sold their Cartiva SCI they knew, or should have known, that the likelihood of patients experiencing implant shrinkage was significantly higher than they reported, and in fact is higher than any comparable product on the market and that pain and discomfort would be a likely consequence of implant shrinkage and migration.

Defendants Failed to Comply with PMA Post-Approval Surveillance Study Requirements.

57. The PMA approval order of the Cartiva implant required Defendants collect data to assess the following primary and secondary study endpoints:

a. Primary Study Endpoints – The primary endpoint will evaluate the long-term safety of the Cartiva implant by demonstrating the following:

1. Durability of the implant over the longer term; and,.

2. Assessment of unanticipated safety concerns that arise after month 24 up to 5 years. This is addressed by:

i. determining the incidence of serious device-related adverse events per year and overall from Month 24 to Year 5; and

ii. summarizing device-related radiographic major complications over time from Month 24 to Year 5.

b. Secondary Study Endpoints – in addition, Defendants were obligated to provide the following:

1. Evaluation of maintenance of range of motion;

2. Wear characteristics or device degradation for any SCI removed;

3. Pain and function over time (Visual Analog Scale [VAS] pain scores, Foot and Ankle Ability Measure [FAAM] Activities of Daily Living [ADL] function scores and FAAMSports function scores); and

4. Evaluation of radiographic findings (radiolucency, bony reactions, and heterotopic ossification) looking at presence or progression from 24 months to 5+ years as well as correlation with the 5+ years clinical outcomes (effectiveness and safety).

58. In addition to not following the PMA post-approval orders, Defendants have largely ignored these endpoints the FDA placed in the PMA to protect public safety. The safety data the FDA established did not narrow the Defendants' focus to the Motion study participants. Yet, Defendants have violated the FDA's PMA order by not assessing the safety of each endpoint for each device with reported adverse events, including the Plaintiff's defective device.

59. The lack of safety surveillance served to suppress information from the FDA in violation of the PMA order and the lack of safety surveillance makes the product not reasonably safe for end consumers, including Plaintiff.

60. Defendants failed to develop practices and procedures to assure compliance with 21 C.F.R. § 814 concerning device modifications, instructions for use, pre-market approval conditions; and to comply with 21 C.F.R. §§ 803, 806 and 820, concerning maintaining MDRs, implementing device Removals and Corrections and establishing Quality Systems.

61. Defendants failed to develop practices and procedures to assure compliance with the federal requirements for reporting adverse events, or MDRs, in accordance with 21 U.S.C. § 360.

62. Despite the obligations described above, and the obligations of every medical device manufacturer to comply with federal law, Defendants failed to meet numerous federal requirements in their manufacture and sale of the SCI prior to Plaintiff's surgery and implantation of his SCI, which caused him to have implanted a defective and adulterated device causing him injuries and damages.

63. Defendants' failure to meet the specific federal requirements outlined above which are applicable to Plaintiff's SCI, directly and proximately caused Plaintiff's SCI to be defective, and proximately caused harm and injury to Plaintiff.

64. The causes of action set forth in this first amended complaint are not preempted by § 360k, because the violations alleged are all based on an exclusively federal statutory and regulatory standard of care which includes no "requirement, which is different from, or in addition to, any requirement applicable under" the Food, Drug and Cosmetic Act and regulations promulgated thereunder. As such, the claims set forth in this cause of action contain requirements

that are parallel to the Food, Drug and Cosmetic Act and regulations promulgated thereunder.

Defendants' Relevant Corporate Facts.

65. Prior to obtaining FDA approval, Cartiva raised revenue on July 24, 2013 with an equity fund by offering a round of Regulation D security offerings totaling $4,312,712.00.

66. Three years later on July 1, 2016 Cartiva obtained premarket approval of the SCI.[19]

67. On or about October 10, 2018, Wright purchased Cartiva for $435 million.[20] Stock analysts considered it a hefty price tag, but also were impressed with strong early adoption of SCI, which offers an alternative to fusion surgery.[21]

68. Despite the initial excitement at product launch, stock analysts quickly caught wind of the reports of SCI failure. By July 2019, RBC stock analysts found some surgeons were implanting fewer of the devices or they had even stopped offering the treatment altogether. Problems with post-operative pain, degree of motion, or the device slipping into the bone in a process known as subsidence ("shrinkage") were reported.[22] Doctors have been unable to replicate the positive results of the company's Motion Study in the broader patient population and have stopped implanting the device or are more cautious about using it.

69. Despite analyst concerns that physicians were dropping offering Cartiva SCIs to patients due to failed implants, Wright CEO Bob Palmisano remained upbeat on prospects for SCI. On the company's earnings call in May 2019, Palmisano said sales growth for the device was

[19] PMA # P150017
[20] Press Release, available Δat https://www.globenewswire.com/news-release/2018/10/10/1619047/0/en/Wright-Medical-Group-N-V-%20Completes-Acquisition-of-Cartiva-Inc.html (last visited Dec. 2, 2024).
[21] https://www.medtechdive.com/news/wright-medical-shares-tumble-amid-report-of-cartiva-slowdown/558132/
[22] *Id.*

exceeding expectations, and he identified the market for treatment of big toe arthritis as a $400 million opportunity.[23]

70. As set forth herein, failure rates of the SCI were much higher in clinical practice than reported in the Motion Study. Mr. Palmisano confirmed SCI sales in the second quarter second quarter of 2019 fell short of Wright's expectations while touting Wright still maintained gross profit margins of 79%.19 Palmisano further commented:

> The unexpected weakness in our U.S. lower extremities business was due to a combination of factors, including the significant reduction in sales by the Cartiva distributors and disappointing performance in our core foot products driven by a higher-than-normal level of sales rep turnover that occurred in a concentrated period of time mid-quarter. To address this, we acted quickly and terminated the Cartiva distributors, and as of August 1, the U.S. Cartiva business has been transitioned to our direct U.S. lower extremities sales force. We also adjusted the sales compensation program for our entire U.S. lower extremities sales team and are increasing the size of the sales force and aggressively adding experienced reps. We are confident that the actions we have taken will improve the growth rates of Cartiva and the whole U.S. lower extremities business; however it will take some time for the benefits of these actions to be evident in the sales results, and we believe our updated guidance takes that timing appropriately into account.

71. On November 11, 2020, Stryker purchased Wright for $4.7 billion.[24]

72. Since 2016 Stryker has manufactured, introduced and/or delivered the Cartiva SCI into the stream of interstate commerce in clear violation of the PMA, which explicitly stated that "[c]ommercial distribution of a device that is not in compliance with these conditions is a violation of the [Food, Drug and Cosmetic] act, [21 U.S.C. §§301, et seq.]."

Plaintiff's Medical Facts and Injuries.

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[23] *Id.*

[24] https://investors.stryker.com/press-releases/news-details/2020/Stryker-completes-acquisition-of-Wright- Medical/default.aspx

73. Plaintiff was induced to purchase an SCI based on the Defendants' representations about the safety and efficacy of the product. On or about April 23, 2021, Plaintiff underwent an SCI implant procedure at Maui Memorial Medical Center with Dr. Barron Elleby due to diagnosed hallux rigidus in his left foot. Dr. Elleby also reported using the Cartiva implant system to complete the procedure.

74. At all times relevant, the SCI used in Plaintiff's surgery was designed, manufactured, marketed, retailed, distributed, and/or supplied by Defendants.

75. Contrary to all representations by Defendants, the SCI has not been effective at alleviating pain or restoring range of motion. In fact, Plaintiff has suffered permanent restrictions in the use of his big toe; forced adaptations to account for this restriction in neighboring joints; increased wear and tear on other components of the foot and leg; and, limitations on footwear options and active recreational activities.

76. Additionally, as a result of the Cartiva CSI implantation, Plaintiff has endured past and future medical expenses, including surgical removal of the device on February 8, 2024, by Dr. Andre Gazdag, at Piccard Surgery Center, in Rockville, Maryland, resulting in loss of income, medical expenses, and pain and suffering based upon his reliance of Defendants' product representations and will continue to have future expenses to repair the bodily harm caused by the Defective Product. Additional damages caused by Defendants include: (1) past, present and future physical and mental pain and suffering; and, (2) past, present and future medical, hospital, monitoring, rehabilitative and pharmaceutical expenses and lost wages.

COUNT I
(Strict Products Liability)

77. 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.

78. The SCI implanted in Plaintiff on April 23, 2021 was designed and/or manufactured in violation of the Federal Food, Drug and Cosmetic Act ("Act") and regulations promulgated pursuant to it, including but not limited to improper workmanship and errors at the point of manufacture which caused defects in the SCIs that occurred in the manufacturing process. These defects caused Plaintiff's SCI to shrink and migrate from the initial implant site causing pain, loss of mobility and bone loss due to the defective product.

79. At the time the Cartiva SCI was implanted in Plaintiff on April 23, 2021 it was not reasonably safe due to non-compliance by Defendants and the regulations promulgated pursuant to it in one or more of the following ways:

a. Failed to accurately establish the in vivo life expectancy of the Cartiva SCI, in violation of 21 C.F.R. § 820.30(f). There have been reports of synthetic cartilage implant failure with ballooning osteolytic cyst formation throughout the first metatarsal head.[25]

b. Failed to 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). Despite peer-reviewed literature backed by radiological evidence that SCI does not perform as expected long-term as seen is the Rosas and Fogelman literature, Defendants have not reported these findings to the FDA or undertaken any similar study;

c. 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);

d. Failed to conduct adequate bio-compatibility studies to determine the Cartiva implant's propensity to migrate from the joint space. Radiologic evidence of implant shrinkage is evident in peer-reviewed literature, but Defendants have not undertaken studies to analyze the implant shrinkage when exposed to deep matrix bone;

e. Failed to identify the component discrepancy, in violation of 21 C.F.R. §

[25] Fogleman J, Robles A, Hollyfield J, Whitlow S, Lundeen GA. Failed Hydrogel Synthetic Cartilage Implant With Osteolytic Cyst Formation in the First Metatarsophalangeal Joint. Foot & Ankle Orthopaedics. July 2020. doi:10.1177/2473011420934384

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);

g. 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;

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. Physician complaints report failure rates of 50-64% with Cartiva implants and Defendants have largely ignored the clinical evidence by not adequately responding to adverse incident reports or initiating a voluntary recall;

i. Failed to conduct complete device investigations on returned Cartiva implants and components in violation of 21 C.F.R. § 820.198. Defendant has failed to investigate and analyze Cartiva implant failures; and/or

j. Continued to inject Cartiva implants into the stream of interstate commerce when Defendants knew, or should have known, that the Cartiva implants was Malfunctioning [as defined in 21 C.F.R. § 803.3] or otherwise not responding to its Design Objective Intent. Multiple press releases by Wright demonstrate an awareness of high Cartiva failure rates coupled with physicians ceasing to use SCI, but Defendants responded to these failures by increasing sales commissions and aggressive sales strategies.

80. The defects existing in the Cartiva SCI implanted in Plaintiff existed at the time the Defective Device was in Defendants' possession, insofar as (i) one or more were defective because they deviated in a material way from the manufacturers or designer's specifications, (ii) such defective condition rendered them unreasonably dangerous to the user, and (iii) such condition proximately caused the damages for which recovery is sought herein.

81. At all relevant times, there existed a feasible alternative design and/or procedure that would have prevented the harm and injury which occurred to Plaintiff.

82. This cause of action is based entirely on the contention that Defendants violated federal safety statutes and regulations. Plaintiff does not bring the underlying action as an implied

statutory cause of action, but rather they are pursuing parallel state common law claims based upon Defendants' violations of the applicable federal regulations.

83. Under Maryland law, Defendants' violations of the aforementioned federal statutes and regulations establish an inference of products liability that can be asserted in Maryland: defective design, defective manufacturing, and failure-to-warn.

84. The cause of action set forth in this Claim for Relief is not preempted by 21 U.S.C. § 306(k) because the violations alleged are all based on an exclusively federal statutory and regulatory set of requirements which include no "requirement, which is different from, or in addition to, any requirement applicable under" the Act and regulations promulgated thereunder.[26] As such, the claims set forth herein contain requirements that are parallel to the Act and regulations promulgated thereunder and not preempted.

85. As a direct and proximate result of Defendants violations of one or more of these federal statutory and regulatory standards of care, the Cartiva implant implanted in Plaintiff, failed and such failure directly caused and/or contributed to the severe and permanent injuries sustained and endured by Plaintiff as defined in 21 C.F.R. § 803.3.

86. As a direct and proximate result, Plaintiff endured pain and suffering, including, but not limited to failure of the Cartiva SCI, migration of the implant with swelling and pain, bone loss, loss of mobility which will require additional fusion surgeries and he 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.

[26] "We concluded that federal manufacturing and labeling requirements applicable across the board to almost all medical devices did not pre-empt the common-law claims of negligence and strict liability at issue in Lohr. *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 322 (2008).

COUNT II
(Negligent Design, Manufacture and/or Distribution)

87. 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.

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

89. At all times herein mentioned, Defendants created, designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and/or distributed its SCI as herein above described that was used by the Plaintiff.

90. Defendants could reasonably have foreseen that its SCI was 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 Defendants.

91. The SCI inserted into Plaintiff on April 23, 2021 was a class III device while the instruments used to insert SCIs are all Class II devices designed and/or manufactured by Defendants and placed into the interstate stream of commerce. Defendants marketed, distributed and/or permitted use of its SCI in violation of the Act and regulations promulgated to it.

92. It was the duty of Defendants to comply with the Act, and the regulations promulgated pursuant to it, yet, notwithstanding this duty, Defendants violated the Act 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 the SCI;

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 the SCI;

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 the SCI;

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 21 C.F.R. § 820.100 and the PMA approval order for the SCI;

h. Failed to appropriately respond to adverse incident reports that strongly indicated the SCI 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 the SCI;

i. Failed to conduct complete device investigations on returned SCIs and components, in violation of 21 C.F.R. § 820.198 and the PMA approval order for the SCI; and/or

j. Failed to comply with the FDA policies and procedures to transfer ownership of the 510k and/or PMA. Without proper transfer of ownership pursuant to FDA requirements it is not certain the SCIs with current Defendants are within the PMA issued for Cartiva, which means preemption is a non-issue for an unregulated manufacturer.

93. The SCI and accompanying instruments have been owned by three corporations: Cartiva (2015–2017), Wright (2018–2020) and Stryker (2020-present). Yet, the 510k for instruments and the SCI is still listed with the FDA as Cartiva with no PMA Supplement approving

new manufacturing sites with ownership changes which implies the FDA has not reviewed or approved ownership of the 510k transfer.

94. The following is the FDA timeline:

Date	**FDA Action**	**Approval Number**
7/1/16	PMA Approval	P150017
8/25/16	PMA Supplement- Change vendor of foil lidstock used to seal primary packaging of SCI device.	S001
9/29/16	PMA Supplement-Approval of protocol for ODE lead PMA Post Approval Study.	S002
11/1/16	PMA Supplement- Approval of 8- and 20-unit shipping configurations for smaller orders	S003
1/6/17	PMA Supplement- Change is supplier of a component used in manufacture of Cartiva SCI	S004
3/1/17	PMA Supplement/Label Change- Modifications to Surgical implantation Technique Guide	S005
11/9/17	PMA Supplement- Expansion of Manufacturing facility	S006
1/29/18	SCI Instruments Reclassified as Class II device.	Q180170
8/28/18	PMA Supplement-Approval of manufacturing site for instruments to Arcamed LLC.	S007
7/2/18	PMA Supplement- Approval of an alternate raw material provider.	S008
7/2/18	PMA Supplement- Add additional clean room for manufacture of SCI.	S009

7/11/19	PMA Supplement- Approval of addition of 6 mm and 12 mm sizes of SCI to the previously approved 8 mm and 10 mm device.	S010
7/12/19	PMA Supplement/Label change based on findings of PAS.	S011
3/22/19	PMA Supplement-Approval to add clarifying statement regarding need for irrigation during drilling within Instructions for Use and the Surgical Implantation Technique for the SCI.	S012
2/9/20	PMA Supplement- add manufacturing site at Steris Synergy Health in Saxonburg, PA.	S013
11/26/19	PMA Supplement - Expanded release criteria of final finished device to accept those that have a homogenously opaque appearance	S014

95. The FDA does permit 510k transfers with the caveat that two companies may not manufacture the same device under a single 510k clearance. Therefore, if a 510k holder wishes to license the right to manufacture a device but also wishes to continue its own manufacturing activity, the FDAs policy is to require the licensee to obtain a new 510(k) clearance.

96. When the holder of an approved PMA enters into an agreement to permit another firm to manufacture and distribute a device under the licensee's private label, FDA approval may be obtained by either of two procedures: (i) the PMA holder may submit a supplement to the approved PMA; or (ii) the licensee may submit an original PMA that includes, or includes by authorized reference to the holder's approved PMA, all appropriate information required by 21 C.F.R. § 814.20 (required information for PMA applications). There is no evidence on the FDA medical device database that the SCI used in Plaintiff was manufactured or marketed with FDA approval for Wright or Stryker.

97. As a direct and proximate result of Defendants violations of one or more of these federal statutory and regulatory standards of care, the Cartiva implant was used on the Plaintiff and failed and such failure directly caused and/or contributed to the severe and permanent injuries sustained and endured by Plaintiff, as defined in 21 C.F.R. § 803.3. As a direct result, Plaintiff endured pain and suffering, including, but not limited to the scarring and disfigurement, and has required additional and debilitating surgeries 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.

98. This cause of action is based entirely on the contention that Defendants violated federal safety statutes and regulations. Plaintiff did not bring the underlying action as an implied statutory cause of action, but rather he is pursuing parallel state common law claims based upon Defendants' violations of the applicable federal regulations.

99. Under Maryland law, Defendants' violations of the aforementioned federal statutes and regulations establish a prima facie case of negligence. Defendants created, designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed a defective product which created an unreasonable risk to the health of consumers and to Plaintiff, in particular, and Defendants are therefore liable for the injuries sustained by the Plaintiff.

100. The cause of action set forth in this Claim for Relief is not preempted by 21 U.S.C. § 306(k) because the violations alleged are all based on an exclusively federal statutory and regulatory set of requirements which include no "requirement, which is different from, or in addition to, any requirement applicable under" the Act and regulations promulgated thereunder. As such, the claims set forth herein contain requirements that are parallel to the Act and regulations

promulgated thereunder and not preempted.[27]

COUNT III
(Misbranded and Adulterated Device)

101. 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.

102. Plaintiff has endured painful surgeries scarring and nerve damage caused by the defective Cartiva implants. The original SCI was a Class III device, and all instruments used to insert the SCI are Class II devices designed and/or manufactured by Defendants and placed into the interstate stream of commerce.

103. Defendants marketed, distributed and/or permitted use of its SCI and insertion instruments in violation of the Act and regulations promulgated to it.

104. It was the duty of Defendants to comply with the Act, and the regulations promulgated pursuant to it, yet, notwithstanding this duty, Defendants violated the Act in one or more of the following ways:

a. Failed to submit a PMA supplement to warn of risk of implant shrinkage, migration and bone loss for review and approval as required by the FDA. 21 C.F.R. §814.39 and PMA approval order for the SCI. Despite Defendants' knowledge of higher failure rates than previously reported to the FDA, Defendants chose to do nothing. It is the Defendants, not the FDA, who had a duty to report the failure rates and manufacturing problems to the FDA. The burden for determining whether a supplement is required is primarily on the PMA holder, changes for which an applicant shall submit a PMA supplement include, but are not limited to, the following types of changes if they affect the safety or effectiveness of the device:

1. New indications for use of the device.

[27] In *Riegel*, the Court noted that § 360k "does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations; the state duties in such a case 'parallel,' rather than add to federal requirements." 552 U.S. at 330.

2. Labeling changes.

3. The use of a different facility or establishment to manufacture, process, or package the device.

4. Changes in sterilization procedures.

5. Changes in packaging.

6. Changes in the performance or design specifications, circuits, components, ingredients, principle of operation, or physical layout of the device.

b. Defendants sold, distributed and permitted use of its devices in violation of the regulations prescribed under 21 U.S.C. § 360j(e) and 21 U.S.C. § 352(q) which required design validation and manufacturing controls to assure the Defendants would not produce a medical device with impurities or inconsistencies. Defendants also had a duty to provide a label that was truthful about the risks associated with the SCI and Defendants have failed to do so;

c. Failed to restrict the use of the SCI and instruments in violation of 21 U.S.C. § 352(r) and the PMA approval order for Cartiva. The Cartiva PMA approval order provided the device is further restricted under section 515(d)(1)(B)(ii) of the act insofar as the labeling must specify the specific training or experience practitioners need in order to use the device. In direct violation of the PMA order, Defendants' Direction For Use merely states "The Cartiva SCI device should only be used by experienced surgeons who have undergone training in the use of this device". There is no limitation on the physician experience-specialty type, years of experience nor do the instructions provide any details about the type of training required. The PMA approval order further states the FDA has determined that these restrictions on sale and distribution are necessary to provide reasonable assurance of the safety and effectiveness of the device. Your device is therefore a restricted device subject to the requirements in sections 502(q) and (r) of the act, in addition to the many other FDA requirements governing the manufacture, distribution, and marketing of devices. As mentioned herein, Defendants had a duty to print on the label and marketing of the Cartiva implant all relevant warnings, precautions, side effects, instructions for use and contraindications and has failed to issue any warnings beyond the generalizations provided in the label;

d. Failed to comply with the requirements of 21 U.S.C. § 360i which provides a device manufacturer shall report to the FDA when the manufacturer receives or otherwise becomes aware of information that reasonably suggests that one of its marketed devices may have caused or contributed to a death or serious injury, or has malfunctioned and that such device or a

similar device marketed by the manufacturer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur. As mentioned herein, Defendants have knowledge that failure rates are higher than reported to the FDA, yet Defendants have taken no action to protect the public, including Plaintiff from harm caused by the SCI; and

e. Defendants have failed to comply with 21 U.S.C. § 360l which required Defendants to submit a surveillance plan for its device once commercial distribution began to detect adverse health events to the public. Instead, Defendants have relied solely on the Motion Study to continue with commercial distribution ignoring the adverse event reports and other studies correlating findings the failure rate is 6–7 times higher than reported by Defendants.

105. As a direct and proximate result of Defendants' violations of one or more of these federal statutory and regulatory standards of care, Plaintiff had a SCI implanted using Cartiva instruments and it failed, and such failure directly caused and/or contributed to the severe and permanent injuries sustained and endured by Plaintiff as defined in 21 C.F.R. § 803.3. As a direct result, Plaintiff endured suffering, including, but not limited to, recurrent dislocations and subluxations with swelling, toe enlargement, and has required additional and debilitating surgeries 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.

106. This cause of action is based entirely on the contention that Defendants violated federal safety statutes and regulations. Plaintiff does not bring the underlying action as an implied statutory cause of action, but rather he is pursuing parallel state common law claims based upon Defendants' violations of the applicable federal regulations.

107. The cause of action set forth in this Claim for Relief is not preempted by 21 U.S.C. § 306(k) because the violations alleged are all based on an exclusively federal statutory and regulatory set of requirements which include no "requirement, which is different from, or in

addition to, any requirement applicable under" the Act and regulations promulgated thereunder.[28] As such, the claims set forth herein contain requirements that are parallel to the Act and regulations promulgated thereunder and not preempted.

108. As a direct and proximate result of Defendants violations of one or more of these federal statutory and regulatory standards of care, the Cartiva implant implanted in Plaintiff, failed and such failure directly caused and/or contributed to the severe and permanent injuries sustained and endured by Plaintiff as defined in 21 C.F.R. § 803.3.

109. As a direct and proximate result, Plaintiff endured pain and suffering, including, but not limited to failure of the SCI, migration of the implant with swelling and pain, bone loss, loss of mobility which will require additional fusion surgeries and he 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.

COUNT IV
(Common Law Product Liability and Negligence)

110. 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.

111. The SCI and corresponding Cartiva instruments used on Plaintiff on April 23, 2021were designed, manufactured and distributed by Defendants and placed into the stream of interstate commerce by Defendants. Said components were defective in design and/or manufacture. Said defects existed when the components left the hands of Defendants making the

[28] "We concluded that federal manufacturing and labeling requirements applicable across the board to almost all medical devices did not pre-empt the common-law claims of negligence and strict liability at issue in Lohr. *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 322 (2008).

components unreasonably dangerous beyond the contemplation of the ordinary user.

112. Defendants further failed to provide appropriate warnings regarding the potential dangers associated with the use of said components, including warnings regarding the risk of migration and shrinkage of the SCI, such as was experienced by Plaintiff.

113. 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 Defendants' SCI and corresponding instruments designed, manufactured, distributed, sold and/or placed into the stream of commerce by the Defendants, Plaintiff suffered severe and permanent injuries, including, but not limited to, scarring and disfigurement, pain and suffering and has required additional and debilitating surgeries 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 suffered damages in an amount in excess of Seventy Five Thousand Dollars ($75,000.00).

COUNT V
(Breach of Express Warranty)

114. 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.

115. Under Maryland Law, Maryland Commercial Law Code Annotated § 2-313, Defendants expressly warranted, as described above and herein, directly to the Plaintiff that the Cartiva SCI was safe and effective for use when it was not. Defendants, through its own statements, expressly warranted that the Cartiva SCI was safe and effective and that the Cartiva SCI when

distributed would conform to that express affirmation, and Plaintiff relied on those express affirmations in their decision to use the Cartiva CSI.

116. Defendants knew that Cartiva implant had problems, including but not limited to shrinkage and migration out of joint space into the bone. Defendants advertised Cartiva implants as a non-invasive procedure, designed to reduce quickly restore toe mobility with a simple procedure. None of Defendants' advertising, marketing, or informational materials to the Plaintiff, mentioned that Cartiva had the ability to cause a condition that results in a permanent disfigurement to the body that can only be resolved through invasive surgeries resulting in the opposite effect of the device's advertised purpose.

117. Plaintiff relied on the skill and judgment of the Defendants that the device was adequately tested and rendered safe to use for its intended purpose.

118. Plaintiff became interested in and underwent the SCI implant procedure based on the Defendants' representation about the procedure.

119. Because of the innate defective nature of the SCI, Plaintiff and the individuals performing the SCI procedure on Plaintiff, through the use of reasonable care, could not have discovered the defective nature of the Cartiva device or its perceived dangers.

120. As the direct and proximate result of Defendants' conduct, Plaintiff sustained serious injuries that were directly caused by the defective, unsafe, and unreasonably dangerous Cartiva implant that could not safely be used for the purpose for which it was marketed, advertised, promoted and intended.

121. As the direct and proximate result of Defendants' wrongful conduct, Plaintiff suffered and continue to suffer economic losses, emotional distress, permanent disfigurement, physical pain, mental anguish, diminished enjoyment of life and future medical expenses.

COUNT VI
(Breach of Implied Warranty)

122. 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.

123. At all times herein mentioned, Defendants manufactured, compounded, portrayed, distributed, recommended, merchandized, advertised, promoted and sold its SCI and instruments.

124. At the time Defendants marketed, sold, and distributed its SCI and instruments to be used on Plaintiff, Defendants knew of the use for which its SCI was intended and impliedly warranted the product to be of merchantable quality and safe and fit for such use.

125. Defendants impliedly represented and warranted to the users of its Cartiva devices and/or their physicians, and/or healthcare providers, and/or the FDA that its SCIs were safe and of merchantable quality and fit for the ordinary purpose for which said products were to be used.

126. Said representations and warranties aforementioned were false, misleading, and inaccurate in that its SCIs were not reasonably safe, improper, not of merchantable quality, and defective.

127. Plaintiff and/or members of the medical community and/or healthcare professionals did rely on said implied warranties of merchantability and fitness for a particular use and purpose.

128. Plaintiff and/or her physicians and/or healthcare professionals reasonably relied upon the skill and judgment of Defendants as to whether its SCIs were of merchantable quality and safe and fit for it intended use.

129. Defendants' SCIs were injected into the stream of commerce by Defendants in a defective, unsafe, and inherently dangerous condition and the products and materials were

expected to and did reach users, handlers, and persons coming into contact with said products without substantial change in the condition in which they were sold.

130. Defendants herein breached the aforesaid implied warranties, as its SCIs were neither merchantable nor fit for their intended purposes and uses.

131. By reason of the foregoing, Plaintiff has experienced and continues to experience, serious and dangerous side effects including but not limited to, mobility problems and disability, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications.

132. As a result of the foregoing acts and omissions Plaintiff requires and/or will require more health care and services and did incur medical, health, incidental and related expenses. Plaintiff is informed and believes and further alleges that Plaintiff will in the future be required to obtain further medical and/or hospital care, attention, and services.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment against Defendants on each count set forth herein as follows:

a. Past and future medical expenses, as well as the cost associated with past and future life care;

b. Past and future lost wages and loss of earning capacity;

c. Past and future emotional distress;

d. Consequential damages;

e. All available noneconomic damages, including without limitation pain, suffering, and loss of enjoyment of life;

f. Disgorgement of profits obtained through unjust enrichment;

g. Restitution;

h. Reasonable attorneys' fees and costs;

i. Pre-judgment and all other interest recoverable; and

j. Such other additional, further, and general relief as Plaintiff may be entitled to in law or in equity as justice so requires.

DEMAND FOR JURY TRIAL

Plaintiff hereby demands a trial by jury on all issues raised in this Complaint.

Respectfully submitted,

/s/ Robert K. Jenner
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Joshua M. Wolberg (Bar No. 31283)
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Attorneys for the Plaintiff

CIVIL COVER SHEET

The JS 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

Robert B. Connor

(b) County of Residence of First Listed Plaintiff Montgomery
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorneys *(Firm Name, Address, and Telephone Number)*
Robert K. Jenner
Jenner Law, P.C.
3600 Clipper Mill Rd. Suite 240

DEFENDANTS

Cartiva, Inc., Wright Medical Group, N.V., Stryker, B.V.

County of Residence of First Listed Defendant
(IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.

Attorneys *(If Known)*

II. BASIS OF JURISDICTION *(Place an "X" in One Box Only)*

- ☐ 1 U.S. Government Plaintiff
- ☐ 3 Federal Question *(U.S. Government Not a Party)*
- ☐ 2 U.S. Government Defendant
- ☒ 4 Diversity *(Indicate Citizenship of Parties in Item III)*

III. CITIZENSHIP OF PRINCIPAL PARTIES *(Place an "X" in One Box for Plaintiff and One Box for Defendant)*
(For Diversity Cases Only)

	PTF	DEF		PTF	DEF
Citizen of This State	☒ 1	☐ 1	Incorporated *or* Principal Place of Business In This State	☐ 4	☐ 4
Citizen of Another State	☐ 2	☐ 2	Incorporated *and* Principal Place of Business In Another State	☐ 5	☒ 5
Citizen or Subject of a Foreign Country	☐ 3	☐ 3	Foreign Nation	☐ 6	☐ 6

IV. NATURE OF SUIT *(Place an "X" in One Box Only)*

Click here for: Nature of Suit Code Descriptions.

CONTRACT
- ☐ 110 Insurance
- ☐ 120 Marine
- ☐ 130 Miller Act
- ☐ 140 Negotiable Instrument
- ☐ 150 Recovery of Overpayment & Enforcement of Judgment
- ☐ 151 Medicare Act
- ☐ 152 Recovery of Defaulted Student Loans (Excludes Veterans)
- ☐ 153 Recovery of Overpayment of Veteran's Benefits
- ☐ 160 Stockholders' Suits
- ☐ 190 Other Contract
- ☐ 195 Contract Product Liability
- ☐ 196 Franchise

TORTS

PERSONAL INJURY
- ☐ 310 Airplane
- ☐ 315 Airplane Product Liability
- ☐ 320 Assault, Libel & Slander
- ☐ 330 Federal Employers' Liability
- ☐ 340 Marine
- ☐ 345 Marine Product Liability
- ☐ 350 Motor Vehicle
- ☐ 355 Motor Vehicle Product Liability
- ☐ 360 Other Personal Injury
- ☐ 362 Personal Injury - Medical Malpractice

PERSONAL INJURY
- ☒ 365 Personal Injury - Product Liability
- ☐ 367 Health Care/ Pharmaceutical Personal Injury Product Liability
- ☐ 368 Asbestos Personal Injury Product Liability

PERSONAL PROPERTY
- ☐ 370 Other Fraud
- ☐ 371 Truth in Lending
- ☐ 380 Other Personal Property Damage
- ☐ 385 Property Damage Product Liability

FORFEITURE/PENALTY
- ☐ 625 Drug Related Seizure of Property 21 USC 881
- ☐ 690 Other

LABOR
- ☐ 710 Fair Labor Standards Act
- ☐ 720 Labor/Management Relations
- ☐ 740 Railway Labor Act
- ☐ 751 Family and Medical Leave Act
- ☐ 790 Other Labor Litigation
- ☐ 791 Employee Retirement Income Security Act

IMMIGRATION
- ☐ 462 Naturalization Application
- ☐ 465 Other Immigration Actions

BANKRUPTCY
- ☐ 422 Appeal 28 USC 158
- ☐ 423 Withdrawal 28 USC 157

INTELLECTUAL PROPERTY RIGHTS
- ☐ 820 Copyrights
- ☐ 830 Patent
- ☐ 835 Patent - Abbreviated New Drug Application
- ☐ 840 Trademark
- ☐ 880 Defend Trade Secrets Act of 2016

SOCIAL SECURITY
- ☐ 861 HIA (1395ff)
- ☐ 862 Black Lung (923)
- ☐ 863 DIWC/DIWW (405(g))
- ☐ 864 SSID Title XVI
- ☐ 865 RSI (405(g))

FEDERAL TAX SUITS
- ☐ 870 Taxes (U.S. Plaintiff or Defendant)
- ☐ 871 IRS—Third Party 26 USC 7609

OTHER STATUTES
- ☐ 375 False Claims Act
- ☐ 376 Qui Tam (31 USC 3729(a))
- ☐ 400 State Reapportionment
- ☐ 410 Antitrust
- ☐ 430 Banks and Banking
- ☐ 450 Commerce
- ☐ 460 Deportation
- ☐ 470 Racketeer Influenced and Corrupt Organizations
- ☐ 480 Consumer Credit (15 USC 1681 or 1692)
- ☐ 485 Telephone Consumer Protection Act
- ☐ 490 Cable/Sat TV
- ☐ 850 Securities/Commodities/ Exchange
- ☐ 890 Other Statutory Actions
- ☐ 891 Agricultural Acts
- ☐ 893 Environmental Matters
- ☐ 895 Freedom of Information Act
- ☐ 896 Arbitration
- ☐ 899 Administrative Procedure Act/Review or Appeal of Agency Decision
- ☐ 950 Constitutionality of State Statutes

REAL PROPERTY
- ☐ 210 Land Condemnation
- ☐ 220 Foreclosure
- ☐ 230 Rent Lease & Ejectment
- ☐ 240 Torts to Land
- ☐ 245 Tort Product Liability
- ☐ 290 All Other Real Property

CIVIL RIGHTS
- ☐ 440 Other Civil Rights
- ☐ 441 Voting
- ☐ 442 Employment
- ☐ 443 Housing/ Accommodations
- ☐ 445 Amer. w/Disabilities - Employment
- ☐ 446 Amer. w/Disabilities - Other
- ☐ 448 Education

PRISONER PETITIONS

Habeas Corpus:
- ☐ 463 Alien Detainee
- ☐ 510 Motions to Vacate Sentence
- ☐ 530 General
- ☐ 535 Death Penalty

Other:
- ☐ 540 Mandamus & Other
- ☐ 550 Civil Rights
- ☐ 555 Prison Condition
- ☐ 560 Civil Detainee - Conditions of Confinement

V. ORIGIN *(Place an "X" in 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

Cite the U.S. Civil Statute under which you are filing ***(Do not cite jurisdictional statutes unless diversity)***:
28 U.S.C. 1332

Brief description of cause:
defective medical device implant resulting in personal injury

VII. REQUESTED IN COMPLAINT:

☐ CHECK IF THIS IS A **CLASS ACTION** UNDER RULE 23, F.R.Cv.P.

DEMAND $ 75001

CHECK YES only if demanded in complaint:
JURY DEMAND: ☒ Yes ☐ No

VIII. RELATED CASE(S) IF ANY

(See instructions): JUDGE _____ DOCKET NUMBER _____

DATE 12/05/2024

SIGNATURE OF ATTORNEY OF RECORD /s/ Robert K. Jenner

FOR OFFICE USE ONLY

RECEIPT # _____ AMOUNT _____ APPLYING IFP _____ JUDGE _____ MAG. JUDGE _____

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.
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.

AO 440 (Rev. 06/12) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

District of Maryland

Robert B. Connor

Plaintiff(s)

v.

Cartiva, Inc., Wright Medical Group, N.V, Stryker, B.V.

Defendant(s)

Civil Action No. 24-cv-03525

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* CARTIVA, INC.,
6120 Windward Parkway, Suite 220
Alpharetta, Georgia 30005

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are: Robert K. Jenner
Jenner Law, P.C.
3600 Clipper Mill Rd, Suite 240
Baltimore, MD 21211

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

CLERK OF COURT

Date: _____

_____
Signature of Clerk or Deputy Clerk

Civil Action No. 24-cv-03525

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))

This summons for *(name of individual and title, if any)* _____

was received by me on *(date)* _____ .

❒ I personally served the summons on the individual at *(place)* _____

_____ on *(date)* _____ ; or

❒ I left the summons at the individual's residence or usual place of abode with *(name)* _____

_____ , a person of suitable age and discretion who resides there,

on *(date)* _____ , and mailed a copy to the individual's last known address; or

❒ I served the summons on *(name of individual)* _____ , who is

designated by law to accept service of process on behalf of *(name of organization)* _____

_____ on *(date)* _____ ; or

❒ I returned the summons unexecuted because _____ ; or

❒ Other *(specify):*

My fees are $ _____ for travel and $ _____ for services, for a total of $ 0.00 .

I declare under penalty of perjury that this information is true.

Date: _____

_____

Server's signature

_____

Printed name and title

_____

Server's address

Additional information regarding attempted service, etc:

Print Save As... Reset

AO 440 (Rev. 06/12) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

District of Maryland

Robert B. Connor

Plaintiff(s)

v.

Cartiva, Inc., Wright Medical Group, N.V, Stryker, B.V.

Defendant(s)

Civil Action No. 24-cv-03525

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* STRYKER, B.V.
2825 Airview Boulevard
Kalamazoo, Michigan 49002

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are: Robert K. Jenner
Jenner Law, P.C.
3600 Clipper Mill Rd, Suite 240
Baltimore, MD 21211

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

CLERK OF COURT

Date: _____

_____
Signature of Clerk or Deputy Clerk

Civil Action No. 24-cv-03525

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))

This summons for *(name of individual and title, if any)* _____ was received by me on *(date)* _____ .

❒ I personally served the summons on the individual at *(place)* _____ on *(date)* _____ ; or

❒ I left the summons at the individual's residence or usual place of abode with *(name)* _____ , a person of suitable age and discretion who resides there, on *(date)* _____ , and mailed a copy to the individual's last known address; or

❒ I served the summons on *(name of individual)* _____ , who is designated by law to accept service of process on behalf of *(name of organization)* _____ on *(date)* _____ ; or

❒ I returned the summons unexecuted because _____ ; or

❒ Other *(specify):*

My fees are $ _____ for travel and $ _____ for services, for a total of $ 0.00 .

I declare under penalty of perjury that this information is true.

Date: _____

_____
Server's signature

_____
Printed name and title

_____
Server's address

Additional information regarding attempted service, etc:

Print Save As... Reset

AO 440 (Rev. 06/12) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

District of Maryland

Robert B. Connor

Plaintiff(s)

v.

Cartiva, Inc., Wright Medical Group, N.V, Stryker, B.V.

Defendant(s)

Civil Action No. 24-cv-03525

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* WRIGHT MEDICAL GROUP, N.V.
1023 Cherry Road
Memphis, Tennessee 38117

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are: Robert K. Jenner
Jenner Law, P.C.
3600 Clipper Mill Rd, Suite 240
Baltimore, MD 21211

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

CLERK OF COURT

Date: _____

_____
Signature of Clerk or Deputy Clerk

Civil Action No. 24-cv-03525

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))

This summons for *(name of individual and title, if any)* _____

was received by me on *(date)* _____ .

❒ I personally served the summons on the individual at *(place)* _____

_____ on *(date)* _____ ; or

❒ I left the summons at the individual's residence or usual place of abode with *(name)* _____

_____ , a person of suitable age and discretion who resides there,

on *(date)* _____ , and mailed a copy to the individual's last known address; or

❒ I served the summons on *(name of individual)* _____ , who is

designated by law to accept service of process on behalf of *(name of organization)* _____

_____ on *(date)* _____ ; or

❒ I returned the summons unexecuted because _____ ; or

❒ Other *(specify):*

My fees are $ _____ for travel and $ _____ for services, for a total of $ 0.00 .

I declare under penalty of perjury that this information is true.

Date: _____

_____

Server's signature

_____

Printed name and title

_____

Server's address

Additional information regarding attempted service, etc:

Print Save As... Reset