IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF ILLINOIS
EAST ST. LOUIS DIVISION

CAROL McGREW,	§	
PHYLLIS ANN GOOD,	§	Case No.: 3:14-cv-00430-DRH-PMF
THOMAS DAY,	§	
TERRI LYN DAY,	§	
COLLEEN JAEGER,	§	Judge: _____
WILLIAM JAEGER,	§	
REBECCA KASPERS,	§	
JACKIE PARKS,	§	**COMPLAINT WITH JURY DEMAND ENDORSED HEREON**
STEVEN PARKS,	§	
STEPHEN PEPKE,	§	
TARA PEPKE,	§	David W. Zoll (0008548)
DONNA ZARETZSKA,	§	James G. O'Brien (0088460)
ANGELA MONEYMAKER, and	§	ZOLL, KRANZ & BORGESS, LLC
DONALD MONEYMAKER,	§	6620 W. Central Ave., Suite 100
	§	Toledo, OH 43617
Plaintiffs,	§	Tel. (419) 841-9623
	§	Fax. (419) 841-9719
v.	§	Email: david@toledolaw.com
	§	Email: jim@toledolaw.com
HOWMEDICA OSTEONICS CORP.,	§	
	§	*Counsel for Plaintiffs*
Defendant.	§	
	§	

Now come Plaintiffs Carol Mcgrew, Phyllis Ann Good, Thomas Day, Terri Lyn Day, Colleen Jaeger, William Jaeger, Rebecca Kaspers, Jackie Parks, Steven Parks, Stephen Pepke, Tara Pepke, Donna Zaretzska, Angela Moneymaker, and Donald Moneymaker, by and through the undersigned counsel, and for their Complaint hereby aver and state:

NATURE OF THE ACTION

1. This is an action for damages suffered by Plaintiffs and caused by Defendant Howmedica Osteonic Corp.'s medical device known as CerviCore. Plaintiffs allege Howmedica created, designed, and marketed CerviCore as a safe and effective solution for certain cervical spine

problems, but that the product was unreasonably dangerous due to design defects, manufacturing defects, and insufficient warnings; that Howmedica was negligent in improperly conducting human trials on Plaintiffs; that Howmedica falsely promoted the product; that Howmedica misled Plaintiffs, the medical community, and regulators; that Howmedica created express and implied warranties regarding CerviCore and breached those; and that once CerviCore was installed in multiple people, Howmedica abandoned its duties to Plaintiffs by misleading, concealing information, callously ignoring dangers, curtailing monitoring, and refusing to provide ongoing care. Plaintiffs allege they suffered damages as a result.

PARTIES

2. Plaintiff Carol McGrew is a resident of Edwardsville, Illinois.

3. Plaintiff Phyllis Ann Good is a resident of Southfield, Michigan.

4. Plaintiffs Thomas Day and Terri Lyn Day are residents of Creede, Colorado.

5. Plaintiffs Colleen Jaeger and William Jaeger are residents of Mill Valley, California.

6. Plaintiff Rebecca Kaspers is a resident of Issaquah, Washington.

7. Plaintiffs Jackie Parks and Steven Parks are residents of Clearwater, Florida.

8. Plaintiffs Stephen Pepke and Tara Pepke are residents of Wyandotte, Michigan.

9. Plaintiff Donna Zaretzka is a resident of Hartsville, South Carolina.

10. Plaintiffs Angela Moneymaker and Donald Moneymaker are residents of Raphine, Virginia.

11. Defendant Howmedica Osteonics Corporation is a corporation organized and existing under the laws of the State of New Jersey, with its principal place of business and its headquarters located at 325 Corporate Drive, Mahwah, New Jersey 07430.

12. Defendant does business as, *inter alia*, Stryker Orthopaedics, Stryker Howmedica Osteonics, Inc., and Stryker Spine.

13. Defendant engaged in the business of designing, licensing, manufacturing, testing, advertising, warranting, distributing, supplying, selling, and introducing into the stream of commerce a product it called CerviCore. Defendant marketed, sold, and introduced CerviCore into the stream of commerce in all states, particularly Michigan, Colorado, California, Illinois, Florida, Washington, South Carolina, and Virginia.

JURISDICTION AND VENUE

14. Plaintiff Carol McGrew is a citizen of Illinois.

15. Plaintiffs Phyllis Ann Good, Stephen Pepke, and Tara Pepke are citizens of Michigan.

16. Plaintiffs Thomas Day and Terri Lyn Day are citizens of Colorado.

17. Plaintiffs Colleen Jaeger and William Jaeger are citizens of California.

18. Plaintiff Rebecca Kaspers is a citizen of Washington.

19. Plaintiffs Jackie Parks and Steven Parks are citizens of Florida.

20. Plaintiff Donna Zaretzka is a citizen of South Carolina.

21. Plaintiffs Angela Moneymaker and Donald Moneymaker are citizens of Virginia.

22. Defendant Howmedica Osteonics Corporation is a citizen of New Jersey.

23. Each Plaintiff had a CerviCore unit installed in his or her cervical spine and has suffered medical costs, pain and suffering, lost wages, loss of enjoyment of life, and other damages. The amount in controversy exceeds $75,000, exclusive of interest and costs for each named plaintiff as an individual.

24. Complete diversity exists between Plaintiffs and Defendant Howmedica and the amount in controversy exceeds the jurisdictional threshold, so this Court has jurisdiction. 28 U.S.C. § 1332.

25. Plaintiff Carol McGrew lives in this judicial district and lived in this district at all times relevant to the allegations in this Complaint.

26. Howmedica and its affiliated companies have a presence in this district and marketed their products in this district, including direct-to-consumer marketing, communication with and marketing to physicians, and sale of many of its other products in this district. Therefore, venue is proper in this district under 28 U.S.C. § 1391(b)(1) and 1391(d).

JOINDER ALLEGATIONS

27. Plaintiffs incorporate by reference all other paragraphs of this Complaint as if fully set forth herein, and further allege as follows:

28. The various claims Plaintiffs make herein all arise from a series of actions Howmedica took and a series of transactions Howmedica entered into. To wit, all Plaintiffs' injuries emanate from:

a. Howmedica's fraud, deceit, intentional misstatements, negligent misstatements, intentional omissions, and negligent omissions in how it applied for, conducted, and portrayed the CerviCore trial;

b. Howmedica's change of CerviCore's design and its deceit about the changes;

c. Howmedica's substandard manufacturing processes; and,

d. Howmedica's breach of its duty to provide care for the Plaintiffs as program participants;

29. Plaintiffs' claims can only be resolved by answering numerous common questions of law and fact. These include, but are not limited to:

a. whether Howmedica was negligent, grossly negligent, or reckless in how it designed CerviCore;

b. whether Howmedica was negligent, grossly negligent, or reckless in how it manufactured CerviCore;

c. whether Howmedica had a duty to warn Plaintiffs of CerviCore's risks and whether it breached that duty;

d. whether Howmedica had a duty to provide ongoing medical care and monitoring to Plaintiffs and whether it breached that duty;

e. whether Howmedica had a duty to disclose adverse events to Plaintiffs, to the medical community, and to the FDA and whether it breached that duty;

f. whether Howmedica committed fraud in how it recruited Plaintiffs to be a part of its CerviCore study;

g. whether Howmedica negligently or recklessly misrepresented facts to induce Plaintiffs to be a part of its CerviCore study;

h. whether Howmedica committed fraud by inducing Plaintiffs to sign additional releases under the guise of extending the CerviCore study and providing ongoing care; and,

i. whether Howmedica is liable for compensatory damages, pre-judgment and post-judgment interest, attorneys' fees, and punitive damages as a result of its conduct.

30. These common questions of law and fact are of such significant importance to the rest of the action that joinder is prudent and desirable.

31. Plaintiffs all seek relief of the same general character.

32. Howmedica will not be prejudiced by joinder. In fact, it would be prejudiced by the opposite: having to try multiple cases in multiple jurisdictions all alleging the same underlying facts. Without joinder, Howmedica risks inconsistent—and even conflicting—rulings on the same or similar issues.

33. Joinder of Plaintiffs in one action will bring economy of actions and trial convenience. *Boyd v. Travelers Ins. Co.*, 652 N.E.2d 267, 272 (Ill. 1995).

FACTS

34. Plaintiffs incorporate by reference all other paragraphs of this Complaint as if fully set forth herein, and further allege as follows:

35. The CerviCore product was initially developed by a company called SpineCore, Inc. In 2004, Stryker Corporation (parent company to Defendant Howmedica) purchased SpineCore for $120 million in cash plus promises of up to $265 million more when CerviCore and another SpineCore product (FlexiCore) gained FDA approval and were launched. Stryker incorporated the former SpineCore and its products into a division of Stryker's wholly-owned subsidiary, Defendant Howmedica Osteonics Corporation and brought several key SpineCore employees into that division.

36. CerviCore is an artificial cervical disc system that is implanted between two cervical vertebrae. It was developed as an alternative to anterior discectomy and fusion procedures, which have been a common treatment for patients with degenerated or herniated cervical discs.

37. The CerviCore device has an upper and lower plate that articulate (that is, the plates form a joint by moving against each other). The device does not attach with screws; each plate has teeth meant to engage the disc above or below the unit.

38. Howmedica portrayed CerviCore as advantageous over disc fusions, claiming its articulating surfaces would afford the patient range of motion where fusions, by their nature, limit motion.

39. At certain points, Howmedica portrayed CerviCore as a device made entirely of titanium.

40. In contrast to its portrayal of the metals in CerviCore, Howmedica used cobalt, chromium, molybdenum, titanium, and nickel to construct many or all of the CerviCore units implanted in Plaintiffs.

41. Were the CerviCore ever to have gained FDA approval, it would be classified as a "Class III Device." 21 C.F.R. § 860.93.

42. According to FDA regulations,

> Class III means the class of devices for which premarket approval is or will be required in accordance with section 515 of the act. A device is in class III if insufficient information exists to determine that general controls are sufficient to provide reasonable assurance of its safety and effectiveness or that application of special controls described in paragraph (c)(2) of this section would provide such assurance and if, in addition, the device is life-supporting or life-sustaining, or for a use which is of substantial importance in preventing impairment of human health, or if the device presents a potential unreasonable risk of illness or injury.

21 C.F.R. § 860.3(c)(3).

43. To capitalize on its investment of $120 million to $385 million by selling CerviCore units, Howmedica first needed to obtain FDA approval. Premarket approval (PMA) requires a successful human study.

44. Through its affiliated doctors and its field representatives, Howmedica recruited Plaintiffs along with 391 other people to take part in a study. Study participants did not know if they would receive a CerviCore unit or a fusion surgery when they were prepped and entered surgery. Each Plaintiff received a CerviCore unit.

45. Plaintiff Carol McGrew had a CerviCore unit implanted on March 14, 2006 by Dr. Steven Wright, MD at Barnes Jewish Hospital in St. Louis, Missouri.

a. Initially, the CerviCore unit appeared to provide Ms. McGrew some relief. However, after a few years, her neck pain returned and worsened.

b. Ms. McGrew started suffering from increased pain in her neck that radiated down her left arm.

c. A CT scan showed additional bone growth (posterior osteophytes at C6-7).

d. Ms. McGrew suffers ongoing neck pain, arm pain, and headaches.

e. Ms. McGrew suffers ailments consistent with metallosis.

f. Ms. McGrew has repeatedly appealed to Howmedica to provide her the necessary care, including a revision of the faulty CerviCore unit; Howmedica has rebuffed these requests.

46. Plaintiff Colleen Jaeger had a CerviCore unit implanted by Dr. James Zucherman, MD in May 2006, at the St. Mary's Medical Center in San Francisco, California.

a. Within six weeks of her implantation surgery, x-rays showed the bone had grown completely around part of Ms. Jaeger's implant.

b. Although the first years with the implant were uneventful, over the years, the unit caused her increasing pain and illness. As the situation worsened, Ms. Jaeger described her pain to her doctor as "throbbing," "shooting," "intense," and "radiating." It prevented her from doing or enjoying normal daily activities.

c. Ms. Jaeger also began suffering from the debilitating effects of metallosis. She demanded, and, after much consternation, received a copy of her metallosis test results

from Howmedica. They showed elevated blood chromium levels and they also showed that Howmedica was not testing for nickel.

d. Howmedica field representative Flor Mendoza attended every doctor's appointment with Ms. Jaeger and Dr. Zucherman. In 2008, as Ms. Jaeger's pain was increasing, Ms. Mendoza presented her with additional agreements to sign that included additional waivers of liability for Stryker and Howmedica.

e. By 2010, Ms. Jaeger's pain was barely manageable and she intended to raise serious concerns with Dr. Zucherman when she attended her March 2010 yearly study visit. Ms. Mendoza contacted her prior to the visit and demanded she sign yet another addendum to the study agreement. When Ms. Jaeger refused, Ms. Mendoza informed her she would not be able to see Dr. Zucherman.

f. Ms. Mendoza called Ms. Jaeger repeatedly, attempting to cajole her into signing the addendum, but Ms. Jaeger bravely resisted. Ms. Jaeger even accused Ms. Mendoza and Howmedica of violating the Medical Research Bill of Rights, which Howmedica had made a part of the original consent form.

g. Even though she threatened Ms. Jaeger that she would be out of the study if she did not sign the form, and even though Ms. Jaeger did not sign the form, Ms. Mendoza still attended Ms. Jaeger's March 2010 doctor's appointment where she quizzed Ms. Jaeger on a variety of issues trying to build a case that the pain and metallosis was not due to the device failing.

h. Later, after Ms. Jaeger told Ms. Mendoza not to attend her appointments or pressure her to sign releases, Howmedica appealed to Dr. Zucherman to get Ms. Jaeger to sign further forms. Meanwhile, Dr. Zucherman was treating Ms. Jaeger with regular

cortisone shots to help her manage the pain. The shots themselves, though, are extremely painful.

i. By mid 2012, x-rays showed a bone mass pushing against Ms. Jaeger's esophagus and Dr. Zucherman determined he needed to remove the CerviCore device.

j. On November 6, 2012, Dr. Zucherman removed Ms. Jaeger's CerviCore unit and fused her C5 and C6 vertebrae. On removal, he noted slivery fluid surrounding the implant and sent the device and the fluid to the FDA for further testing. Neither Howmedica nor the FDA has contacted Ms. Jaeger to explain the true nature and ramifications of the fluid.

k. To this day, Ms. Jaeger suffers from permanent nerve damage and excruciating pain in her neck and arm. One-and-a-half years after her revision surgery, Ms. Jaeger's C6 vertebra is not properly fused with the C5. The bone is not growing or holding the replacement device and she has to use a bone growth stimulator for the next one-and-a-half years and then, if it is not fixed, have another revision surgery.

l. Ms. Jaeger's localized bone deterioration is consistent with metallosis.

m. Plaintiff William Jaeger is the husband of Ms. Jaeger. Howmedica's conduct and the injury it has caused Ms. Jaeger have deprived Mr. Jaeger of Ms. Jaeger's society and services.

47. Plaintiff Phyllis Ann Good had a CerviCore unit implanted on February 21, 2008 by Dr. Jeffrey S. Fischgrund, MD at the Beaumont Health System facility in Royal Oak, Michigan.

a. Prior to implantation, Dr. Fischgrund performed a bone scan on Ms. Good that, upon later review, indicates Ms. Good's physical condition was outside the study parameters.

b. Howmedica did not inform Ms. Good that CerviCore contained nickel, to which she is allergic.

c. Around two months after the surgery, Ms. Good began suffering from rashes.

d. Later that year, when the pain was so great she could no longer move her neck, Ms. Good began receiving pain management treatments. She has received pain management therapy and medication, including high doses of morphine and oxycodone, for the ensuing six years.

e. Ms. Good suffers from metallosis. In particular, her blood nickel level is nearly twice the upper limit of the acceptable range.

f. Ms. Good suffers from severe cervical neck pain, indentation of the ventral thecal sac, headaches, stenosis of her right side foraminal, reversal of lordosis, nerve root irritation,

g. Ms. Good's post-surgical pain greatly exceeds her pre-surgical pain. She has now been deemed disabled, uses a cane to walk, cannot work, and suffers daily.

h. Ms. Good has repeatedly appealed to Howmedica to provide her the necessary care, including a revision of the faulty CerviCore unit; Howmedica has rebuffed these requests.

48. Plaintiff Stephen Pepke had a CerviCore unit implanted on March 20, 2008 by Dr. Jeffrey S. Fischgrund, MD at the Beaumont Health System facility in Royal Oak, Michigan.

a. Within a few days of implantation, Mr. Pepke began experience extreme pain. That pain worsened over the next two years.

b. Within two years, the device had failed so badly that Dr. Fischgrund operated again, this time fusing Mr. Pepke's C5 and C6 vertebrae, but leaving the CerviCore unit in place.

c. Mr. Pepke's pain, numbness, and headaches continued. He was unable to grip things. A year later, a surgeon performed ulner nerve surgery, but it did not resolve the root problems.

d. Mr. Pepke suffers from dizziness, is in excruciating pain, is still unable to grip objects, and suffers other related ailments.

e. Mr. Pepke suffers ailments consistent with metallosis.

f. Mr. Pepke has repeatedly appealed to Howmedica to provide him the necessary care, including a revision of the faulty CerviCore unit; Howmedica has rebuffed these requests.

g. Plaintiff Tara Pepke is Mr. Pepke's wife. Howmedica's conduct and the injury it has caused Mr. Pepke have deprived Mrs. Pepke of Mr. Pepke's society and services.

49. Plaintiff Angela Moneymaker had a CerviCore unit implanted by Dr. Harold F. Young, MD in May or June, 2006 at the VCU Medical Center in Richmond, Virginia.

a. At a six-week visit, Dr. Young ordered an X-Ray, found the CerviCore had shifted, and immediately scheduled a removal surgery.

b. Dr. Young reported the adverse event to the FDA's MAUDE (Manufacturer and User Facility Device Experience) database. https://www.accessdata.fda.gov /scripts/cdrh/cfdocs/cfmaude/detail.cfm?mdrfoi__id=739251

c. The device's failure caused nerve damage and rendered Ms. Moneymaker unable to work. She retired early.

d. Plaintiff Donald Moneymaker is the husband of Ms. Moneymaker. Howmedica's conduct and the injury it caused Ms. Moneymaker deprived Mr. Moneymaker of Ms. Moneymaker's society and services.

50. Plaintiff Jackie Parks had a CerviCore unit implanted in July 2008 by Dr. Michael R. Piazza MD at the Morton Plant Meade Hospital in Clearwater, Florida.

a. Ms. Parks' pain never went away after surgery and she suffers numbness in her right arm. She continues to suffer constant pain between her neck and shoulder blades. Dr. Piazza ordered physical therapy and injections, but to no avail. Ms. Parks has such bad migraines she sees a neurologist. She has also been diagnosed with psoriatic arthritis.

b. Ms. Parks suffers ailments consistent with metallosis.

c. Ms. Parks has repeatedly appealed to Howmedica to provide her the necessary care, including a revision of the faulty CerviCore unit; Howmedica has rebuffed these requests.

d. Plaintiff Steven Parks is the husband of Ms. Parks. Howmedica's conduct and the injury it caused Ms. Parks deprived Mr. Parks of Ms. Parks' society and services.

51. Plaintiff Thomas Day had a CerviCore unit implanted by Dr. Jim A. Youssef, MD on November 20, 2006 at the Mercy Regional Medical Center in Durango, Colorado.

a. Since receiving the CerviCore implant, Mr. Day has had constant issues with pain, spasms, severe rashes, headaches, and other related issues.

b. Because of Howmedica's relentless insistence that nothing is wrong with the CerviCore design, Mr. Day's doctor initially insisted his issues must be psychiatric.

c. Mr. Day has been treated with pain medications, sleep aids, nerve blocks, physical therapy, and injections in the neck.

d. Howmedica had Mr. Day's doctor draw blood for metals testing, but refused to release the results to him. Nevertheless, Dr. Youssef expressed concern about the high metal levels in Mr. Day's blood. Mr. Day has even become a vegetarian to eliminate the possibility that meat consumption could be causing his high blood metal levels.

e. Finally, in March 2013, at Mr. Day's growing insistence, Howmedica released some metal ion blood test results, which demonstrate sporadically high values for Chromium and Molybdenum.

f. Mr. Day suffers ailments consistent with metallosis.

g. Howmedica has met Mr. Day at his follow up appointments and has insisted that Mr. Day sign additional agreements. Most recently, Howmedica obtained Mr. Day's signature on December 1, 2011 with an agreement to extend the CerviCore study to eight years after implantation.

h. Nevertheless, within six months of obtaining the last signature on its eight-year study extension, Howmedica contacted Mr. Day through Dr. Youssef's office and told him it was abandoning the CerviCore study and he would no longer have his condition evaluated regularly.

i. Mr. Day has repeatedly appealed to Howmedica to revise his CerviCore implant, to provide him with information about the study, to provide him with information about the unit and how it is affecting his health, and to provide him with the necessary medical care promised in the study. Howmedica has rebuffed every request.

j. Mr. Day's deteriorating health condition has affected his happiness, his ability to perform at work, his ability to be a good father, and his ability to enjoy many things in life, including sexual activity.

k. Plaintiff Terri Lyn Day is Mr. Day's wife. Howmedica's conduct and the injury it has caused Mr. Day have deprived Mrs. Day of Mr. Day's society and services.

52. Plaintiff Rebecca Kaspers had a CerviCore unit implanted by Dr. Jay Williams in June 2007 at Swedish Hospital in Seattle, Washington.

a. Ms. Kaspers was eager to be a part of the CerviCore study because it was portrayed as having a lower risk of releasing metals into the bloodstream than the traditional fusion surgery (This was illustrated by the fact that the CerviCore unit is smaller and has less metal than the fusion unit, but, of course ignores the fact that the CerviCore unit grinds its metal plates on itself, releasing ions into the body.)

b. While the surgery appeared to be successful at a clinical level, Ms. Kaspers never got any pain relief.

c. Follow up CT scans and MRIs indicated problems, but Howmedica brushed those off, saying they were just normal indications.

d. As the pain grew through the years, Ms. Kaspers was put on higher and higher doses of pain medication. These, of course, caused a variety of deleterious side effects.

e. In 2009, Ms. Kaspers started experience rashes. The study sponsor said it must be due to the increasing medication she was on.

f. To show Howmedica that her rashes were unrelated to the medication, Ms. Kaspers decided to remove herself from all pain medication in 2010. The rashes continued nonetheless.

g. By late 2012, the pain had built to the unbearable level. Ms. Kaspers also heard a disturbing crack from the area and felt pain shooting down her arm.

h. Ms. Kaspers doctor would like to remove the CerviCore unit, but says the swelling in the area is so extreme, he cannot present remove it. Ms. Kaspers suffers from swelling and itching and an allergist has indicated that something in her body is causing these reactions.

i. Ms. Kaspers suffers from crushing headaches.

j. Ms. Kaspers' blood tests indicate Cobalt and Chromium in her bloodstream, and her Chromium levels are elevated above safe parameters.

k. Ms. Kaspers suffers ailments consistent with metallosis.

l. Ms. Kaspers' constant pain and deteriorating health condition has effected her ability to work (she had to abandon working at the store she founded), her happiness, and her ability to enjoy life.

53. Plaintiff Donna Zaretzska had a CerviCore unit implanted by Dr. Willie Edwards in June 2006 at the McLeod Regional Medical Center in Florence, South Carolina.

a. Ms. Zaretzska started experiencing pain immediately following her implantation surgery. She had severe joint swelling, which made it difficult for her to move, even, in many cases, requiring her to have assistance to move.

b. Ms. Zaretzska's neck has begun to make clicking, grating, and grinding noises as she turns.

c. Ms. Zaretzska has now suffered permanent nerve damage and she suffers from numbness, tingling and burning. Most days, it is excruciating for her to move her neck.

d. As her condition has worsened, Ms. Zaretzska has developed recurring abscesses on her neck and scalp.

e. Ms. Zaretzska suffers ailments consistent with metallosis.

f. When Howmedica abruptly informed Ms. Zaretzska that it was abandoning the CerviCore study, it supplied her with a wallet card reading: "I have been implanted with a CerviCore® Intervertebral Disc replacement, manufactured by Stryker Spine. The implant is made of metal (Cobalt, Chromium, and Molybdenum) and is located in the cervical spine."

54. On information and belief, CerviCore contains dangerous metals not disclosed to Plaintiffs.

a. Plaintiff Donna Zaretzska's wallet card listed CerviCore's metal makeup as "Cobalt, Chromium, and Molybdenum."

b. Plaintiff Colleen Jaeger's original Consent to Participate in a Research Study contains a description of the CerviCore unit: "The CerviCore Disc is made of two saddle-shaped plates and it is implanted in place of the degenerated disc after it is removed. It is made entirely of metal (a cobalt/chrome/molybdenum alloy **with a titanium coating**)." (emphasis added).

c. Dr. Jonathan R. Stieber, Dr. Jeffrey S. Fischgrund, and Dr. Jean-Jacques Arbitbol co-authored a book chapter entitled "The CerviCore Cervical Intervertebral Disc Replacement" in which they listed one of CerviCore's contraindications as: "Allergy to components of the device, including cobalt, chromium, molybdenum, titanium, or **nickel**." James Yue, *et al.*, MOTION PRESERVATION SURGERY OF THE SPINE: ADVANCED TECHNIQUES AND CONTROVERSIES, p. 238, Saunders, 2008 (emphasis added).

d. In 2011, Howmedica took out a full page ad in the program for the April Las Vegas meeting of the SAS International Society for the Advancement of Spine Surgery that bragged its product CerviCore was "[c]omprised of CoCrMo – biocompatible

material with a history of safety and proven durability with low metal ion release and wear rates in orthopedic implants." (footnote omitted). "CoCrMo" is shorthand for Cobalt, Chromium, and Molybdenum.

e. Nickel is a known allergen, a known carcinogen, and is associated with a wide variety of toxic reactions in the human body.

f. Titanium exposure can cause an allergic reaction manifesting as muscle pain, rashes, and fatigue.

g. Cobalt chromium metal poisoning resulting from metal ion release as improperly designed or manufactured articulating parts abrade is well known and the subject of numerous studies and lawsuits.

h. Molybdenum is known to trigger immune reactions and is associated with aseptic osteolysis (dissolution of bone) near the point of implant abrasion debris.

55. Howmedica endangered Plaintiffs by exposing them to dangerous metals through a device that was likely to release metal ions because of its design and not monitoring their metal levels.

a. All the metals in the implant have the potential to be dangerous, particularly when the device is designed so that a large area grinds and releases the metals and/or when its coating is designed or manufactured such that it tends to delaminate.

b. Howmedica advertised it took 400 patients into the study and gave half (200) of them CerviCore units. (The other 200 received conventional fusion surgery).

c. The Consent Agreement Howmedica entered into with Plaintiff Colleen Jaeger informed her she was one of the few that would have her metal levels monitored: "As one

of the 60 subjects (30 CerviCore™ and 30 Fusion) in the metal ion part of the study, the added risks that you will be exposed to are related to having your blood drawn."

d. Thus, fully 85% of the CerviCore recipients were to have no monitoring of their blood metal ion levels.

e. And, on information and belief, Howmedica never told this vast majority of participants they would be getting some lesser form of health monitoring than other study participants.

f. Furthermore, Howmedica flatly refused to conduct metal ion tests in many patients and flatly refused to provide most with the results of any tests it had conducted.

56. Howmedica's manufacturing processes were so faulty they increased the metal-on-metal CerviCore device's likelihood of emitting metal ions into the subject's body.

a. Howmedica's Stryker Spine division had traditionally made parts of titanium and steel that screwed in place and did not articulate or abrade against each other. Howmedica typically heat-treated those non-articulating parts to add strength.

b. Heat-treating cobalt chromium alloys also adds strength, but it simultaneously hardens surface atoms. In devices with pieces that articulate or abrade against each other, this added strength has a deleterious effect: it increases the rate at which the abrasion loosens and releases metal ions.

c. Howmedica had a plant in Mahwah, New Jersey that was somewhat familiar with preparing cobalt chromium alloy articulating products—knees and hips. However, Howmedica produced CerviCore at one of its traditional Stryker Spine plaints in Cestas, France that was used to heat-treating non-articulating products and was unfamiliar with producing articulating cobalt chromium products.

d. Howmedica choice to not use its own best processes contributed to the CerviCore's poor quality and raised its propensity to give off metal ions and poison Plaintiffs' blood.

57. Through its agents, Howmedica misled Plaintiffs, the public, and the medical community regarding CerviCore's rate of failure. For instance:

a. In 2010, through four of its affiliated doctors, Dr. Jean-Jacques Abitbol, MD, Dr. Joseph C. Maroon, MD, Dr. Willie S. Edwards, MD, and Dr. Jeffrey S. Fischgrund, MD, Howmedica bragged: "At 2 years, there were fewer device-related surgical interventions in the CerviCore® group (2%) than in the Control group (4%)." 2-Year Results from Four IDE Study Sites: CerviCore® Intervertebral Disc vs. Fusion, THE SPINE JOURNAL, Volume 10, issue 9 Supplement, Pages S139–S140, September 2010.

b. However, the article's sample size was only 49 CerviCore patients and the authors admit they lost track of 18 of the patients, so even one surgical revision would be 3.2% of the population.

c. Furthermore, co-author Dr. Fischgrund operated on Plaintiff Stephen Pepke to correct his CerviCore prior to this article's publication.

d. Furthermore, since long before this article's publication, Plaintiff Donna Zaretzka has repeatedly reported to her surgeon, co-author Dr. Willie S. Edwards, that she has unresolved neck pain, hears clicking and grinding noises, is suffering from metallosis symptoms, and would like a surgical revision of her CerviCore, but he refuses.

e. Furthermore, since long before this article's publication, Plaintiff Phyllis Ann Good has repeatedly informed her surgeon, co-author Dr. Fischgrund, that she has

unresolved neck pain, is suffering from metallosis symptoms, and would like a surgical revision of her CerviCore, but he refuses.

f. Furthermore, on information and belief, a Ms. Melinda Killen was implanted with a CerviCore unit in 2008 by co-author Dr. Maroon, complained repeatedly of pain, numbness, tingling, and scraping noises, and had her CerviCore unit revised by Dr. Maroon prior to publication of this article. Complaint, *Killen v. Stryker*, No. 2:11-cv-1508 (W.D. Pa., Nov. 28, 2011).

g. Furthermore, on information and belief, Ms. Killen has had to endure two more surgeries after her revision because of damage caused by the CerviCore and one of those occurred prior to publication of this article (although it was done by a surgeon who was not a co-author). *Id.*

h. Thus, prior to this article's publication, these co-authors knew of at least five surgical interventions caused by the CerviCore device, which is 16% of the responding sample size, not 2%.

58. CerviCore units were adulterated and contaminated by Howmedica's manufacturing processes:

a. In March 2007, the FDA's Inspections, Compliance, Enforcement, and Criminal Investigations unit warned Stryker Ireland of an extensive list of quality control problems at its Cork, Ireland plant, including repeated instances where Stryker/Howmedica failed to maintain quality control processes, lacked procedures for implementing corrective action, and lacked procedures for tracking and reacting to consumer complaints and adverse event reports. FDA Letter, http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2006/ucm076326.htm.

b. In November 2007, the FDA's Inspections, Compliance, Enforcement, and Criminal Investigations unit warned Stryker Orthopedics of an extensive list of quality control problems at its Mahwah, New Jersey facility. FDA Letter 08-NWJ-03, http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2007/ucm076583.htm.

i. Among other things, the FDA cited Howmedica for failing "to establish and maintain procedures for identifying all of the actions needed to correct and prevent the recurrence of nonconforming product and other quality problems . . ." *Id.*

ii. The FDA cited Howmedica for taking complaints on failures of one of its hip products, but not applying lessons learned from that failure to its other products (which would include CerviCore): "Your firm has been receiving complaints since 2005, concerning various types of dimensional mismatches between implant components or implants and [redacted] but your firm has not implemented effective corrective or preventive actions in order to prevent the recurrence of nonconforming product and other quality problems." *Id.*

iii. "Your August 1, 2007 response states that a trend analysis was performed by your firm on April 19, 2005 which shows an increase in product complaints/product experience reports (PERs). However, no effective actions were taken to control nonconforming product in distribution." *Id.*

c. In April 2008, the FDA's Inspections, Compliance, Enforcement, and Criminal Investigations unit warned Stryker Biotech of quality control problems at its Hopkinton, Massachusetts facility and that it had violated the law by conducting human experiments without a proper IDE.

i. Among the quality control problems were citations for "[f]ailure to adequately establish and maintain procedures analyzing processes, work operations, concessions, quality audits reports, quality records, service records, complaints, returned product, and other sources of quality data to identify existing and potential causes of nonconforming product, or other quality problems, as required by 21 CFR 820.100(a)(1)." *Id.*

d. On information and belief, Howmedica first manufactured CerviCore units in its Cestas, France facility, then shipped them to Mahwah, New Jersey for final coating and packaging.

e. System wide, Howmedica had rampant quality control problems and substandard processes for tracking and correcting problems.

f. In particular, Howmedica's Mahwah facility had rampant quality control problems that caused unsafe, unreliable, and contaminant-ridden devices to be released into the market at the very time Howmedica was manufacturing CerviCore in that facility.

g. As evidenced by the extensive problems detailed herein, CerviCore units suffered from the effects of Howmedica's manufacturing defects.

59. On information and belief, Howmedica illegally used or promoted the use of its TCP putty (also called Calstrux, Osteogenic Protein-1, or OP-1) in CerviCore patients.

a. By design, CerviCore has no screws and grips the vertebrae above and below it just by jagged teeth. Thus, CerviCore relies on some bone growth to hold it in place.

b. Nevertheless, on information and belief, Howmedica neither sought nor obtained any FDA permission or approval to use a bone growth stimulator like OP-1.

c. OP-1 is approved as a bone growth stimulator for use only in long bones (i.e., leg and arm bones), which does not include cervical vertebrae.

d. In 2008, the FDA's Inspections, Compliance, Enforcement, and Criminal Investigations unit discovered Stryker Biotech had illegally entered into contracts with clinical investigators to use OP-1 in combination with some investigational device study.[1] FDA Letter NEW-11-08W, http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2008/ucm1048324.htm.

e. The FDA told Stryker: "You failed to obtain an IDE prior to the conduct of this investigation. . . . Your introduction of the OP-1 Implant into interstate commerce for a new intended use is a violation of the law." *Id.*

f. OP-1 causes significant, spontaneous bone growth. Unexplained significant, spontaneous bone growth is not otherwise typical in fully mature adults.

g. Plaintiff Colleen Jaeger, who received her CerviCore in 2006 (two years prior to the FDA's discovery that Howmedica was using OP-1 illegally in conjunction with some investigational device), had to be revised because, among other things, she developed a large bone mass growing from the area of her CerviCore and that pushed against her esophagus.

[1] The investigation does not specify which investigational study OP-1 was used with, but this is expected; when a medical device is not approved by the FDA, as is the case with CerviCore, its records remain sealed. Food and Drug Administration Amendments Act of 2007, PL 110-85, September 27, 2007, 121 Stat 823. This may explain why the FDA letter cites Stryker's use "of the OP-1 Implant in combination with either an **[redacted]**." (emphasis in original). And, even though the redacted portion of the letter may say something other than CerviCore, Plaintiffs base their allegation regarding the use of OP-1 on significantly more than this FDA letter. At the very minimum, the letter demonstrates Stryker's propensity to conduct studies on human beings without an IDE and to use OP-1 in conjunction with some unapproved study.

h. Plaintiff Phyllis Ann Good, who received her CerviCore in early 2008 (the same year the FDA discovered Howmedica was using OP-1 illegally in conjunction with some investigational device), was found to have a boney growth (osteophyte) at the C5 vertebrae, which is one of the two vertebrae that abuts her CerviCore implant.

i. On information and belief, other Plaintiffs are suffering the ill effects of improper use of OP-1, but, since Howmedica has consistently resisted providing more testing, providing proper and accurate information, providing proper medical care, and/or removing faulty units, it has concealed the true nature of whether it used OP-1 from Plaintiffs.

60. Even if Howmedica could show it was completely unaware of CerviCore's dangers and that it properly conducted a human trial study, it became aware of CerviCore's grave dangers at some point during the study period and abandoned Plaintiffs.

a. Howmedica abandoned the CerviCore product, presumably because it realized it was unfeasible due to the adverse events and its potential for causing metal poisoning.

b. Nonetheless, Howmedica continued the human study, actively attending Plaintiffs' doctors' appointments and actively denying CerviCore was faulty.

c. Howmedica field representatives aggressively pursued study participants to get them to sign additional forms.

d. Shortly after getting all the signatures it could (and undoubtedly realizing it would not be able to gather more signatures), Howmedica abruptly ended the CerviCore program and abandoned the ongoing patient monitoring and care.

e. In spite of promising to provide medical care to CerviCore recipients, Howmedica cut off contact with Plaintiffs and abandoned the study.

f. Howmedica has never provided Plaintiffs with accurate information about what is in their bodies, the dangers their doctors need to watch for and treat for, and other information it knows that might help Plaintiffs recover from the damage CerviCore caused.

61. As a direct and proximate result of Howmedica's acts and omissions, Plaintiffs:

a. have suffered and continue to suffer severe and permanent injuries that they will be forced to endure for the remainder of their lives, including bodily injury, disfigurement, conscious pain, suffering, mental anguish, mental suffering, embarrassment, shame, loss of enjoyment of life, shortened life expectancy, loss of association, loss of earnings, loss of profits, and loss of salary;

b. have suffered bodily injury, physical impairment, and disfigurement;

c. have endured physical pain and suffering;

d. have endured conscious pain, mental pain, mental anguish, mental suffering, shame, and embarrassment;

e. have suffered loss of enjoyment of life and a reduction in life expectancy,

f. have suffered a loss of association and society;

g. have incurred substantial costs for medical care in the past, and will, in reasonable medical probability, incur substantial costs for medical care in the future;

h. have suffered a loss of earnings, a loss of profits, a loss of future earnings and profits, and a loss of future earning capacity; and,

i. have incurred attorneys' fees and expenses of litigation related to this action.

ALLEGATION THAT DEFENDANTS ARE NOT ENTITLED TO PREEMPTION

62. Plaintiffs incorporate by reference all other paragraphs of this Complaint as if fully set forth herein, and further allege:

63. Even though CerviCore is a medical device, Howmedica is not entitled to preemption under the Medical Device Act because, as alleged in detail herein:

a. it operated outside the scope of any IDE;

b. it released products containing manufacturing defects including contamination, delamination, and other defects;

c. it knew of but withheld the true nature and dangers of the product, including its true metal composition;

d. it improperly heat treated the devices;

e. it did not properly report adverse events during the study;

f. it was negligent in how it conducted the study;

g. it was negligent in how it designed the product;

h. it was negligent in how it manufactured the product;

i. it was negligent in how it labeled the product and/or warned Plaintiffs of its dangers;

j. it made express warranties and breached those;

k. it is bound by implied warranties of minimum quality standards (merchantability) and fitness for a particular purpose and breached those; and,

l. it committed fraud, intentionally misrepresented, and/or negligently misrepresented the safety of CerviCore, the efficacy of CerviCore, the metal makeup of CerviCore, the integrity and compliance of the study, and other relevant matters.

DISCOVERY RULE AND TOLLING ALLEGATIONS

64. Plaintiffs incorporate by reference all other paragraphs of this Complaint as if fully set forth herein, and further allege:

65. Howmedica actively concealed information and actively misled Plaintiffs regarding CerviCore's dangers, the study's noncompliance, the cause and nature of Plaintiffs' injuries, the rate of CerviCore failure and revision, the products defects, and Howmedica's tortious wrongdoing that led to Plaintiffs' injuries.

66. Howmedica continues to actively conceal all this information and continues to actively mislead Plaintiffs, Plaintiffs' physicians, and the public in general.

67. Howmedica has refused—and continues to refuse—to provide the testing and medical care that would allow Plaintiffs to know how gravely the CerviCore units have damaged their bodies and, in turn, what medical treatment may be warranted or appropriate.

68. Howmedica has refused—and continues to refuse—to provide Plaintiffs with true and accurate information about their CerviCore's metal content, about the actual risks that the CerviCore units continue to present to them in their bodies, about any unapproved products (such as OP-1) that were used during their implantation and which might affect whether the units are removable, and about the other risks CerviCore presents.

69. Howmedica demanded Plaintiffs see only their study doctors and the Howmedica representatives for medical help related to the CerviCore units but then used those relationships to sharply control Plaintiffs' access to information about their health.

70. To further its concealment, Howmedica insisted each study participant sign study renewal agreements that contained further waivers in order to continue receiving medical care. Then,

shortly after obtaining each renewal and waiver it could, Howmedica abruptly ended its study early and informed Plaintiffs it would no longer provide any care for them.

71. Because of Howmedica concealment of and misrepresentations regarding the true risks associated with CerviCore, Plaintiffs could not have reasonably discovered Howmedica's wrongdoing or the relationship between CerviCore and their extensive ailments at any time prior to the commencement of this action.

72. As alleged herein, Howmedica's fraudulent misrepresentations, fraudulent omissions, reckless misrepresentations, reckless omissions, negligent misrepresentations, and negligent omissions tolled the running of any statute of limitations.

73. Where applicable, the discovery rule should be applied to toll the running of the statute of limitations until Plaintiffs knew, or, through the exercise of reasonable care and diligence should have known, of facts indicating that Plaintiffs had been injured, the cause of the injury, the nature of the defective product, and the tortious nature of the wrongdoing that caused the injury.

74. Despite diligent investigation by Plaintiffs, Plaintiffs did not know the cause of their injuries, the nature of the defective product, or the tortious nature of Howmedica's wrongdoing until a date within the applicable statute of limitations for filing Plaintiffs' claims. Therefore, under the appropriate application of the discovery rule, Plaintiffs' suit was filed well within the applicable statute of limitations period.

75. The running of the statute of limitations in this case should also be tolled due to equitable tolling. Howmedica is estopped from asserting a statute of limitations defense due to Howmedica's fraudulent concealment, through affirmative misrepresentations and omissions from Plaintiffs and/or their physicians, of the true risk associated with the product. As a result of Howmedica's fraudulent concealment, Plaintiffs and/or Plaintiffs' physicians were unaware and

could not have known or learned through reasonable diligence that Plaintiffs had been exposed to the risks alleged herein and that those risks were the direct, proximate result of Howmedica's wrongful acts and omissions.

76. Plaintiffs assert all applicable state statutory and common law rights and theories related to the tolling or extension of any applicable statute of limitation, including equitable tolling, estoppel, delayed discovery, the discovery rule, and fraudulent concealment.

77. Therefore, Plaintiffs timely filed this action.

CAUSES OF ACTION

COUNT I
DESIGN DEFECT

78. Plaintiffs incorporate by reference all other paragraphs of this Complaint as if fully set forth herein, and further allege:

79. Howmedica is "Manufacturers" in that it designed, produced, made, fabricated, and introduced into the stream of commerce CerviCore.

80. Howmedica had a duty to design, manufacture, test, market, advertise, label, distribute, and sell CerviCore so that it was reasonably safe for its foreseeable use.

81. Each Plaintiffs' use of CerviCore as a cervical implant was not only anticipated by Howmedica, but, in fact, each Plaintiffs' use was solicited by Howmedica.

82. Due to design defects, CerviCore is unreasonably dangerous in that:

a. its metal composition has a tendency to delaminate and release metal ions into the bloodstream and surrounding tissue;

b. its metal-on-metal articulating design causes the release of dangerous heavy metal ions as the two all-metal pieces abrade on each other;

c. its relatively large metal-on-metal articulating surface area increases the abrasion area which leads to increased wear, increased failure rates, and increased release of metal ions;

d. its design includes the use of cobalt, chromium, molybdenum, titanium, aluminum, vanadium, and nickel, some or all of which are unnecessarily highly toxic and dangerous, particularly when the parts are abrading and scraping ions of these metals off into the bloodstream;

e. its metal coating process increases the likelihood of delamination and wear problems;

f. its designed heat treating processes were insufficient or inappropriate to give the metals the proper characteristics and function;

g. its design does not effectively consistently adhere to cervical bones above and below the implant, increasing the chances the device will shift; and,

h. on information and belief, its propensity to shift compelled Howmedica to dictate CerviCore units be installed with OP-1 bone grown putty, which carried the danger of spontaneous and unwanted bone growth in the cervical area.

83. Plaintiffs' injuries are caused by CerviCore's design defects and there is no other reasonable, secondary cause of Plaintiffs' injuries.

84. CerviCore's design is defective in that, when it left the hands of Howmedica, it was more dangerous than an ordinary consumer would expect when used in its intended or reasonably foreseeable manner.

85. CerviCore's design is defective in that, when it left the hands of Howmedica, its known, knowable, and/or foreseeable risks outweighed any potential benefit it might provide.

86. CerviCore's design is defective in that, when it left the hands of Howmedica, it was more dangerous than necessary, as evidenced by the extensive set of competing, but less dangerous, alternatives.

87. CerviCore's dangers are so great that reasonable health care professionals would not prescribe its use if they knew of CerviCore's true nature.

88. CerviCore's dangers are so great that reasonable consumers in general and all Plaintiffs in specific would not have allowed its implantation if they knew of CerviCore's true nature.

89. Howmedica knew or should have known of CerviCore's dangers; knew or should have known of safer alternatives; and disregarded the risks to Plaintiffs.

90. Notwithstanding that, Howmedica is strictly liable for CerviCore's design defects and the injuries they caused.

91. As a direct and proximate result of Howmedica's wrongful actions, Plaintiffs suffer from the serious medical conditions alleged herein.

WHEREFORE, Plaintiffs demand judgment against Defendant for compensatory, statutory, and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems appropriate.

COUNT II
MANUFACTURING DEFECT

92. Plaintiffs incorporate by reference all other paragraphs of this Complaint as if fully set forth herein, and further allege:

93. Howmedica is a "Manufacturers" in that it designed, produced, made, fabricated, and introduced into the stream of commerce CerviCore.

94. Howmedica had a duty to design, manufacture, test, market, advertise, label, distribute, and sell CerviCore so that it was reasonably safe for its foreseeable use.

95. Each Plaintiffs' use of CerviCore as a cervical implant was not only anticipated by Howmedica, but, in fact, each Plaintiffs' use was solicited by Howmedica.

96. As detailed in the FDA's November 28, 2007 letter,[2] and on other information and belief, CerviCore contained multiple manufacturing defects because Howmedica:

a. deviated from Current Good Manufacturing Practice (CGMP);

b. allowed adulteration by contamination in the Mahwah, New Jersey manufacturing facility;

c. failed "to establish and maintain procedures for identifying all of the actions needed to correct and prevent the recurrence of nonconforming product and other quality problems, and verifying or validating the corrective and preventive action to ensure that such action is effective as required by 21 CFR § 820.100(a)(3) & (a)(4)." FDA Letter 08-NWJ-03; and,

d. failed to properly collect all relevant information on a variety of patient complaints, failed to track that information, and failed to apply corrective action based on those.

Many or all of which violate 21 CFR 820.1 *et seq.*

[2] The FDA's letter does not name CerviCore as one of the products in the Mahwah facility, however, the identity of a trial device is confidential and the Mahwah facility was the point of manufacture (or, at least, the last point in the manufacturing process; other suits against Stryker allege that at least some CerviCore manufacturing steps were done in France).

97. Due to manufacturing defects, at the time CerviCore left the control of Howmedica and entered the stream of commerce, it contained one or more conditions that rendered it defective and unreasonably dangerous in light of its nature and intended use.

98. These manufacturing defects made CerviCore more dangerous than an ordinary consumer would expect when used in its intended or reasonably foreseeable manner.

99. These manufacturing defects made CerviCore known, knowable, and/or foreseeable risks outweigh any potential benefit it might provide.

100. These manufacturing defects made CerviCore more dangerous than necessary, as evidenced by the extensive set of competing, but less dangerous, alternatives.

101. CerviCore's manufacturing defects render it so dangerous that reasonable health care professionals would not prescribe its use if they knew of its defects.

102. CerviCore's manufacturing defects render it so dangerous that reasonable consumers in general and all Plaintiffs in specific would not have allowed its implantation if they knew of its defects.

103. Plaintiffs' injuries are caused by CerviCore's manufacturing defects and there is no other reasonable, secondary cause of Plaintiffs' injuries.

104. Howmedica knew or should have known of CerviCore's manufacturing defects; knew or should have known of safer alternative manufacturing methods; and disregarded the risks to Plaintiffs.

105. Notwithstanding its level of knowledge, Howmedica is strictly liable for CerviCore's manufacturing defects and the injuries they caused.

106. As a direct and proximate result of Howmedica's wrongful actions, Plaintiffs suffer from the serious medical conditions alleged herein.

WHEREFORE, Plaintiffs demand judgment against Defendant for compensatory, statutory, and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems appropriate.

COUNT III
FAILURE TO WARN

107. Plaintiffs incorporate by reference all other paragraphs of this Complaint as if fully set forth herein, and further allege:

108. Alternatively or additionally, CerviCore was defective because Howmedica failed to properly label, market, and warn Plaintiffs of its risks and adverse events.

109. Howmedica knew of multiple dangers with CerviCore, including that it might not implant properly, that its design caused excessive wear, that it was prone to breaking down prematurely, that it was prone to delaminating, that they manufactured it using improper processes, that they manufactured it in a facility prone to contamination, that it was made from cobalt, chromium, molybdenum, titanium, and nickel, and that it was likely to cause metallosis.

110. Howmedica did not adequately warn Plaintiffs of these and other dangers. This shortcoming left Plaintiffs incapable of making informed choices and granting informed consent.

111. Furthermore, Howmedica failed to properly warn Plaintiffs, the public, and the medical community at large by not properly posting adverse events. For example, one early adverse event was reported to the MAUDE database (http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/detail.cfm?mdrfoi__id=739251)[3], but no further events can be found therein, in spite of the fact that many people, including all Plaintiffs in this case, have had adverse events.

[3] No doubt the MAUDE database was used even though it is not the typical reporting mechanism for human trials because, without a proper IDE, doctors had no other way of reporting adverse events.

112. Had Plaintiffs known of CerviCore's potential for causing deleterious, permanent harm, and/or of the adverse events, they would not have allowed the devices to be implanted in their bodies.

113. Howmedica is strictly liable for injuries resulting from their failure to warn.

114. As a direct and proximate result of Howmedica's wrongful actions, Plaintiffs suffer from the serious medical conditions alleged herein.

WHEREFORE, Plaintiffs demand judgment against Defendant for compensatory, statutory, and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems appropriate.

COUNT IV
NEGLIGENCE

115. Plaintiffs incorporate by reference all other paragraphs of this Complaint as if fully set forth herein, and further allege:

116. Howmedica owed Plaintiffs and all consumers a duty of reasonable care in how it designed CerviCore, manufactured CerviCore, warned of CerviCore's dangers, and conducted the human trials.

117. As previously alleged under strict liability sections and throughout the Complaint, Howmedica breached its duty of care and was negligent in:

a. how it designed CerviCore;

b. how it manufactured CerviCore; and,

c. how it warned of CerviCore's dangers.

118. A reasonable manufacturer should have known:

a. that CerviCore's risks were unreasonably greater than necessary and/or than other similar products and that these enhanced risks put Plaintiffs and other patients in danger;

b. that it was conducting human trials improperly and in violation of the law and that doing so put Plaintiffs and other patients in danger;

c. that a manufacturing facility as described in FDA Letter 05-NWJ-03 did not meet CGMP, Federal Regulations, or its duties to consumers (particularly considering the notice imparted by a similarly harsh March 2007 Warning Letter issued by the FDA regarding Stryker's Cork, Ireland plant);

d. that its refusal to follow safe, sanitary, and documentable procedures in its manufacturing facilities put Plaintiffs at risk; and,

e. that other of its breaches of duty put Plaintiffs at risk.

119. The dangers presented by Howmedica's various breaches are so great that reasonable health care professionals would not prescribe CerviCore's use if they knew the extent of even one of these breaches

120. The dangers presented by Howmedica's various breaches are so great that reasonable consumers, including Plaintiffs, would not have allowed CerviCore to be implanted in their bodies if they knew of even one of these breaches..

121. As a direct and proximate result of Howmedica's wrongful actions, Plaintiffs suffer from the serious medical conditions alleged herein.

WHEREFORE, Plaintiffs demand judgment against Defendant for compensatory, statutory, and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems appropriate.

COUNT V
GROSS NEGLIGENCE

122. Plaintiffs incorporate by reference all other paragraphs of this Complaint as if fully set forth herein, and further allege:

123. Howmedica owed Plaintiffs and all consumers a duty of reasonable care in how it designed CerviCore, manufactured CerviCore, warned of CerviCore's dangers, and conducted the human trials.

124. Defendants breached their duty of care as alleged herein.

125. Defendants consciously and voluntarily disregarded the risks to Plaintiffs and consumers. In particular:

a. Howmedica knew it operated a human trial outside the bounds of any regulatory approval it obtained;

b. Howmedica knew they did not have regulatory approval to use OP-1 in conjunction with CerviCore on Plaintiffs or other humans and proceeded nonetheless;

c. Howmedica knew CerviCore presented danger to patients, particularly those with allergies to certain metals but knew the study participants were not being tested for metal allergies;

d. Howmedica knew certain adverse events were happening with CerviCore but concealed those or failed to properly report and disclose them; and,

e. Howmedica knew three of their plants had been severely and publicly admonished by the FDA, including the facility responsible for manufacturing CerviCore, and continued processing the units and moving forward with the study.

126. These breaches of duties were wanton and willful and demonstrate blatant, callous, and indifferent conduct towards Plaintiffs and consumers in general.

127. As a direct and proximate result of Howmedica's wrongful actions, Plaintiffs suffer from the serious medical conditions alleged herein.

WHEREFORE, Plaintiffs demand judgment against Defendant for compensatory, statutory, and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems appropriate.

COUNT VI
FRAUD BY CONCEALMENT

128. Plaintiffs incorporate by reference all other paragraphs of this Complaint as if fully set forth herein, and further allege:

129. Howmedica had a duty to disclose certain concealed facts, which include the true risks and dangers posed by CerviCore, the adverse events resulting from CerviCore, the substandard operating conditions in their plants, the use of OP-1 putty, and other negative information.

130. Howmedica cemented its duty to provide Plaintiffs with disclosures by choosing to disclose certain limited contraindications while concealing the other grave dangers that form the basis of this suit. This partial disclosure created a duty to fully disclose all CerviCore's dangers to avoid misleading Plaintiffs and the public.

131. Had Plaintiffs known of CerviCore's potential for causing deleterious, permanent harm, of the fact that Howmedica was operating the study outside the scope of any regulatory approval it received, and/or of the adverse events, they would not have allowed the devices to be implanted in their bodies.

132. As a direct and proximate result of Howmedica's wrongful actions, Plaintiffs suffer from the serious medical conditions alleged herein.

WHEREFORE, Plaintiffs demand judgment against Defendant for compensatory, statutory, and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems appropriate.

COUNT VII
FRAUDULENT MISREPRESENTATION

133. Plaintiffs incorporate by reference all other paragraphs of this Complaint as if fully set forth herein, and further allege:

134. Howmedica had a duty to accurately represent certain material facts, which include those dangers of which they knew.

135. Through its silence and through its statements, Howmedica actively misrepresented CerviCore's safety to Plaintiffs.

136. Had Plaintiffs known of CerviCore's potential for causing deleterious, permanent harm, of the fact that Howmedica was operating the humans trials outside the scope of any regulatory approval it had, and/or of the adverse events, they would not have allowed the devices to be implanted in their bodies.

137. As a direct and proximate result of Howmedica's wrongful actions, Plaintiffs suffer from the serious medical conditions alleged herein.

WHEREFORE, Plaintiffs demand judgment against Defendant for compensatory, statutory, and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems appropriate.

COUNT VIII
NEGLIGENT MISREPRESENTATION

138. Plaintiffs incorporate by reference all other paragraphs of this Complaint as if fully set forth herein, and further allege:

139. Howmedica had a duty to accurately represent certain material facts, which include those dangers of which it knew.

140. Howmedica was negligent in its representations to Plaintiffs.

141. Had Plaintiffs known of CerviCore's potential for causing deleterious, permanent harm, of the fact that Howmedica was operating the humans trials outside the scope of any regulatory approval it had, and/or of the adverse events, they would not have allowed the devices to be implanted in their bodies.

142. As a direct and proximate result of Howmedica's wrongful actions, Plaintiffs suffer from the serious medical conditions alleged herein.

WHEREFORE, Plaintiffs demand judgment against Defendant for compensatory, statutory, and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems appropriate.

COUNT IX
BREACH OF EXPRESS WARRANTY

143. Plaintiffs incorporate by reference all other paragraphs of this Complaint as if fully set forth herein, and further allege:

144. Howmedica created express warranties to Plaintiffs in the original consent agreements and the addenda to those:

a. that they had obtained proper regulatory approval to conduct a study on human subjects and were operating the studies within the scope of that;

b. that the study was in compliance with state law;

c. that the study was following certain specific protocols;

d. that "Medical treatment will be offered if you experience a complication or injury as a result of your participation in the clinical study";

e. that the study sponsor had set up an Institutional Review Board that would "protect the interests of human subjects participating in research"; and,

f. that, by including it with the consent agreement, Howmedica would honor the Medical Research Subject's Bill of Rights.

145. Plaintiffs relied on these warranties when agreeing to be a part of the CerviCore study and would not have become a part of the study if they knew any of these was false.

146. Howmedica breached each of these warranties.

147. As a direct and proximate result of Howmedica's wrongful actions, Plaintiffs suffer from the serious medical conditions alleged herein.

WHEREFORE, Plaintiffs demand judgment against Defendant for compensatory, statutory, and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems appropriate.

COUNT X
BREACH OF IMPLIED WARRANTY

148. Plaintiffs incorporate by reference all other paragraphs of this Complaint as if fully set forth herein, and further allege:

149. By introducing CerviCore into the stream of commerce and conducting the human study, Howmedica impliedly warranted the product was merchantable, including: that CerviCore would pass without objection in the trade; that it would be of average quality; that it would be fit for its

ordinary purpose and use; that it would be packaged and labeled properly; and that it would conform to the promises made in the marketing, packaging, and labeling of the product (including those promises made as part of the study).

150. CerviCore is dangerous as alleged herein, is less effective than promised, is not of average quality (particularly when compared with other cervical implants), is not fit for its ordinary purpose and use as a medical device, was not labeled in a way to warn Plaintiffs of its grave dangers, and did not conform to is marketing, packaging, and labeling promises of being safe for use in a human body. Therefore, CerviCore is not merchantable and Howmedica breached this warrant.

151. At the time it distributed CerviCore and conducted the study, Howmedica knew or should have known that CerviCore was not merchantable.

152. Plaintiffs relied on Howmedica warranties when deciding to become party of the study and allow CerviCore units to be implanted in their bodies. They would not have participated or allowed the units to be implanted if they knew the product was not merchantable and was actually profoundly dangerous.

153. As a direct and proximate result of Howmedica's wrongful actions, Plaintiffs suffer from the serious medical conditions alleged herein.

WHEREFORE, Plaintiffs demand judgment against Defendant for compensatory, statutory, and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems appropriate.

COUNT XI
INFLICTION OF EMOTIONAL DISTRESS

154. Plaintiffs incorporate by reference all other paragraphs of this Complaint as if fully set forth herein, and further allege:

155. Howmedica acted in an extreme and outrageous manner in a variety of ways, including by concealing and ignoring CerviCore's risks, by concealing, ignoring, and refusing to correct repeated deficiencies in its manufacturing processes, by misleading Plaintiffs about the contents of CerviCore, by misleading Plaintiffs about Howmedica's commitment to care for their health, and by not actually providing follow-up care as promised.

156. Howmedica should have known and/or did know that its conduct could cause and would cause emotional distress the study participants and their families.

157. CerviCore caused illness and bodily harm to Plaintiffs, caused metallosis, which includes many detrimental effects on the brain, caused pain and suffering, caused loss of enjoyment of life, and caused the risk of shortened life span. These conditions, directly and indirectly caused emotional distress in Plaintiffs.

158. Howmedica intentionally caused, or recklessly disregarded the risks of causing, this emotional distress.

159. Alternatively, Howmedica was negligent in causing Plaintiffs' emotional distress

160. As a direct and proximate result of Howmedica's wrongful actions, Plaintiffs suffer from emotional distress.

WHEREFORE, Plaintiffs demand judgment against Defendant for compensatory, statutory, and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems appropriate.

COUNT XII
LOSS OF CONSORTIUM

161. Plaintiffs incorporate by reference all other paragraphs of this Complaint as if fully set forth herein, and further allege:

162. The Plaintiffs who received CerviCore units have endured permanent, profound, and debilitating physical, emotional, and mental suffering.

163. These illnesses have diminished and deprived their spouses of their services, companionship, and society. Furthermore, they likely will diminish and deprive their services, companionship, and society for the remainder of their lives.

164. As a direct and proximate result of Howmedica's wrongful actions, Plaintiffs suffer from a loss of consortium.

WHEREFORE, Plaintiffs demand judgment against Defendant for compensatory, statutory, and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems appropriate.

PUNITIVE DAMAGES ALLEGATIONS

165. Plaintiffs incorporate by reference all other paragraphs of this Complaint as if fully set forth herein, and further allege:

166. The acts, conduct, and omissions of Stryker, as alleged throughout this Complaint were willful and malicious. Stryker committed these acts with a conscious disregard for the rights of Plaintiffs and other CerviCore victims and for the primary purpose of increasing its profits from the future sales of CerviCore. Stryker's outrageous and unconscionable conduct warrants an award of exemplary and punitive damages against Stryker in an amount appropriate to punish and make an example of it.

167. Prior to some or all of the CerviCore implantations, Stryker knew the CerviCore units were not manufactured as designed, were not manufactured as it told the FDA they were, were not manufactured safely and in a sanitary way, were made from metals that could not withstand articulation, were made from metals that cause metallosis and other adverse reactions, and were dangerous to the human victims into whom they were implanted.

168. Prior to some or all of the CerviCore implantations, Stryker knew of one or more CerviCore failures but failed to properly report and/or disclose this.

169. Stryker, through its officers, directors, managers, and agents, knew CerviCore was dangerous and presented a substantial and unreasonable risk of harm to Plaintiffs but hid this and pushed forward with trials on human victims nonetheless.

170. Stryker's conduct was so despicable and so contemptible that it would be looked down upon and despised by ordinary decent people, and was carried on by Stryker with willful and conscious disregard for the safety of Plaintiffs, entitling Plaintiffs to punitive and exemplary damages.

APPLICABLE STATE STATUTORY REMEDIES

171. By reference, Plaintiffs hereby plead violations of Michigan, Colorado, California, Illinois, Florida, Washington, South Carolina, Virginia, and New Jersey state statutory remedies where those states have adopted state statutory remedies to replace the common law theories espoused in Counts I through XII.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for judgment against the Defendants as follows:

A. For an award of compensatory damages, including damages against Defendants for pain and suffering, medical and hospital expenses, loss of income, and other damages according to proof at trial in excess of $75,000;

B. For an award of punitive or exemplary damages against Defendants in excess of $75,000;

C. For reasonable attorneys' fees and costs;

D. For pre-judgment interest; and

E. For such further and other relief the court deems just, equitable, and proper.

Dated: April 11, 2014

Respectfully Submitted,

/s/ David W. Zoll
ZOLL, KRANZ & BORGESS, LLC
David W. Zoll (0008548)
James G. O'Brien (0088460)
6620 W. Central Ave., Suite 200
Toledo, OH 43617
Tel. (419) 841-9623
Fax (419) 841-9719
Email: david@toledolaw.com
Email: jim@toledolaw.com

Counsel for Plaintiffs

JURY DEMAND

Plaintiff hereby demands a trial by jury on all triable issues.

/s/ David W. Zoll
David W. Zoll (0008548)

JS 44 (Rev. 12/12)

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

Carol McGrew, Thomas Day, Terri Lyn Day, Colleen Jaeger, William Jaeger, Rebecca Kaspers, Phyllis Ann Good, Jackie Parks, Steven Parks, Stephen Pepke, Tara Pepke, Donna Zaretzska, Angela Moneymaker & Donald Moneymaker

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

(c) Attorneys *(Firm Name, Address, and Telephone Number)*
David W. Zoll and James O'Brien, Zoll, Kranz & Borgess, LLC 6620 West Central Ave., Ste. 100, Toledo, OH 43617 (419-841-9623)

DEFENDANTS

Howmedica Osteonics, Corp.

County of Residence of First Listed Defendant Bergen County
(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)*

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

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

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

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

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

PROPERTY RIGHTS
- ☐ 820 Copyrights
- ☐ 830 Patent
- ☐ 840 Trademark

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
- ☐ 400 State Reapportionment
- ☐ 410 Antitrust
- ☐ 430 Banks and Banking
- ☐ 450 Commerce
- ☐ 460 Deportation
- ☐ 470 Racketeer Influenced and Corrupt Organizations
- ☐ 480 Consumer Credit
- ☐ 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

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

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:
Personal Injury - Product Liability

VII. REQUESTED IN COMPLAINT:

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

DEMAND $ 75,000.00

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

VIII. RELATED CASE(S) IF ANY

(See instructions): JUDGE _____ DOCKET NUMBER _____

DATE 04/11/2014

SIGNATURE OF ATTORNEY OF RECORD /s/ David W. Zoll

FOR OFFICE USE ONLY

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