IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF TEXAS
HOUSTON DIVISION

MARY JANE MARTINE, Plaintiff, V. CONFORMIS, INC., Defendant.	§ § § § § § § §	CIVIL ACTION NO. _____

COMPLAINT

Plaintiff Mary Jane Martine files this suit against ConforMIS, Inc., ("ConforMIS") and for cause of action would show the Court the following:

NATURE OF THE CASE

1. This is a diversity jurisdiction, personal injury, and products liability case. Plaintiff Mary Jane Martine had two separate defective ConforMIS iTotal G2 custom knees implanted in her, the first in October 2012 and the second in April 2013. In December 2013, both ConforMIS knees failed, and Mary Jane was forced to undergo bilateral revision surgery. The Plaintiff alleges, *inter alia*, that ConforMIS sold a defective product to Mary Jane and hundreds of other patients around the country.

PARTIES

2. Plaintiff Mary Jane Martine is a resident of Houston, Harris County, Texas.

3. Defendant ConforMIS is a foreign corporation organized and existing under the laws of Delaware, having its principal place of business located at 28 Crosby Drive, Bedford, Massachusetts 01803. ConforMIS can be served through its registered agent for service of process, **David. J. Cerveny, 11 North Ave, Burlington, Massachusetts 01803**. ConforMIS conducts business throughout the United States, including in the State of Texas.

JURISDICTION AND VENUE

4. This Court has diversity jurisdiction under 28 U.S.C. § 1332. The amount in controversy, exclusive of interest and costs, is substantially in excess of Seventy Five Thousand Dollars ($75,000). Venue is proper in this District by virtue of 28 U.S.C. § 1391.

FACTS

This suit has been necessitated by virtue of the following facts.

THE CONFORMIS iTOTAL

5. ConforMIS is a privately-held Massachusetts company that specialized in the development and sale of medical devices, including knee implants. The company's most important and cherished product is the iTotal CR Knee Replacement System ("iTotal").

6. In January 2011, ConforMIS received 510(k) clearance[1] from the U.S. Food and Drug Administration to commercially market the iTotal. ConforMIS touted the iTotal as "the only true patient-specific system available for patients who would traditionally receive a standard total knee replacement."[2]

7. The iTotal system incorporates technology that generates patient-specific knee implants using CT scans to build a 3D image of a patient's knee. That image is used to design and manufacture personalized knee implants. ConforMIS touts these customized knee implants as having "unparalleled advantages" because they precisely fit each patient resulting in

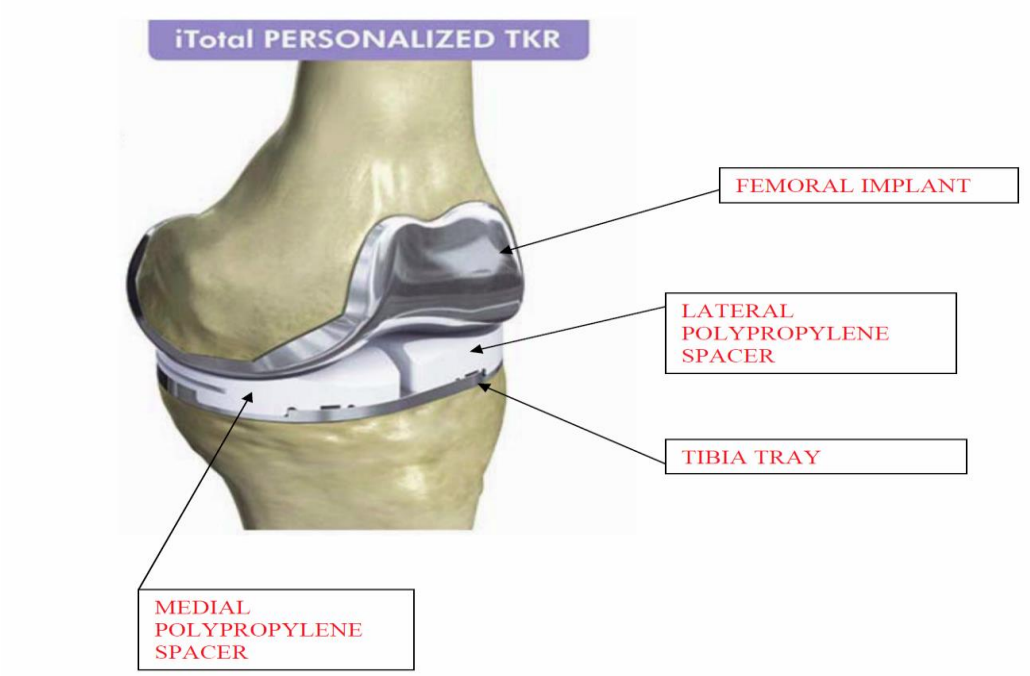
[1] "FDA 510(k) clearance" gives the mistaken impression that the product has been approved by the FDA, and that the FDA has determined that the product is safe and effective. "The FDA reviews the vast majority of medical devices through a process commonly known as 510(k), a reference to its origin in the Food, Drug and Cosmetics Act (Public Law 75-717). The FDA does not require 510(k) devices to undergo clinical testing to demonstrate safety and effectiveness prior to clearing them for commercial sale. Instead, the device manufacturer must show only that the device is similar or 'substantially equivalent' in design, technology and use as a previously approved device, known as a 'predicate'. Once a device receives FDA clearance, manufacturers can use it as a predicate for future devices. However, the 510(k) process was not designed to evaluate the safety and effectiveness of a device. Rather, a finding of 'substantial equivalence' by FDA signifies only what its name implies – that the device is similar in certain respects to a previous predicate device. No determination about risks to safety or effectiveness comes as a result of clearance through the 510(k) process." *See* Defective Devices, Destroying Lives, Prepared by the Office of Congressman Edward J. Markey.

[2] http://www.conformis.com/fda-clears-first-patient-specific-implant-system-for-total-knee-replacement/

"extremely low polyethylene contact stress," preserve significantly more bone than standard knee implants, and give patients a "long lasting" and "naturally feeling" knee.

7. In October 2012, ConforMIS announced they had received 510(k) approval for the new iTotal G2 Knee Replacement System, "the next generation version of the iTotal." ConforMIS stated that the iTotal G2 "incorporates improvements, based on a year's worth of surgeon feedback to the implants, instrumentation and patient specific planning guides." [3] The new iTotal G2 was specifically designed to address issues of patient dissatisfaction, errors in knee placement, functional limitations of standard knee replacements, and greater bone preservation. *Id*.

8. The basic components of the iTotal G2 include an implant that is attached to the base of the femur. Likewise, a tray is implanted into the head of the tibia. Two polypropylene spacers are locked into the top of the tibia tray on both the medial and lateral aspects:



[3] http://www.conformis.com/conformis-launches-next-generation-of-only-patient-specific-total-knee-replacement-implant-system-available-on-market/

9. Despite the FDA's 510(k) clearance and their media puffing, ConforMIS was selling a dangerous and defectively designed product to the public. A review of FDA data shows that the iTotal G2 exhibited product defects as soon as it hit the market.

RED FLAGS AND ADVERSE EVENT DATA

10. The medical device industry believes that adverse event reports received from both actual physicians and patients are a major, and important, source of safety information. The FDA's MedWatch program was set up to monitor this information. Although anyone can file a report with the company or the FDA, the majority of such reports are filed by concerned physicians who suspect that there is some connection between their patient's adverse event and the specific medical device in question.

11. ConforMIS, like other companies, collects data from all available sources about adverse events that are reported to it and makes some attempt to determine the probable association or relationship between the medical device and the reported adverse event. Between the launch of the iTotal G2 and March 1, 2014 there were approximately 30 reported adverse events related to spacer dislodgment or tibia tray loosing.

12. It is widely recognized within the medical device industry that adverse events are vastly under-reported. The industry accepted rule of thumb is that somewhere between 1% and 10% of real world events are actually reported to MedWatch. Therefore, these roughly 30 adverse event reports put ConforMIS on notice that between the launch of the iTotal G2 and March 2014, there are somewhere between 300 and 3,000 real-world ConforMIS patients who had experienced spacer dislocations or tibia tray loosening during that same time period.

13. On information and belief, in one or more instances, ConforMIS's own internal causality assessments for these cases reflected that one or more of the adverse events were, more likely than not, "associated with" or causally related to a defect in the design of the iTotal G2.

14. According to some of the MedWatch reports, ConforMIS's response to these reported spacer dislocations or tibia tray loosenings was to blame the implanting doctor's technique rather than the design of their product. On information and belief ConforMIS knew or should have knew about these adverse events and purposefully did not inform implanting doctors and the public about them. This silence directly led to the injuries sustained by Plaintiff Mary Jane Martine.

MARY JANE'S STORY

15. In 2012, Mary Jane had osteoarthritis in both her left and right knees. She was referred by colleagues to Dr. Terry Clyburn at Houston Orthopedic & Spine Hospital (HOSH). At their first appointment Mary Jane, her husband, and Dr. Clyburn discussed various treatment options including knee replacement surgery with a variety of knee replacements.

16. Dr. Clyburn and Mary Jane decided on the ConforMIS iTotal G2 because of its perceived benefits when compared to "off the shelf" knee replacements. These perceived benefits included improved bone preservation, a more precise fit for long-term comfort, and decreased risk of fitting or rotational errors.

17. In August 2012, Mary Jane underwent a CT per the ConforMIS protocol. On October 23, 2012 Mary Jane underwent left knee replacement with a ConforMIS iTotal G2 at HOSH. Surgery was performed by Dr. Clyburn. She remained in the hospital for several days, followed by several weeks of intensive outpatient physical therapy.

18. On April 30, 2013 Dr. Clyburn performed ConforMIS iTotal G2 total right knee replacement surgery on Mary Jane. As with her left knee replacement, Mary Jane had a 2-3 day hospital stay followed by weeks of painful outpatient rehabilitation. She returned to work roughly a month later.

19. On December 9, 2013, Mary Jane was at work when she heard a popping sound in her right knee. She was unable to extend the right knee or stand on it. It was incredibly painful. She saw Dr. Clyburn that afternoon for evaluation. Dr. Clyburn found that the lateral polyethylene spacer in the right ConforMIS iTotal G2 had displaced.

20. At a scheduled December 12, 2013 appointment Dr. Clyburn examined Mary Jane's left knee. A left knee CT scan was order that showed the left knee tibia component was collapsing. Mary Jane was placed on a walker until a solution could be found.

21. On December 16, 2013, Dr. Clyburn called Mary Jane and informed her that she would have to undergo bilateral knee revision surgery because both of her ConforMIS implants had failed and could not be salvaged. She would have to undergo bilateral knee surgery at the same time because, due to the defective ConforMIS implants in both knees, she did not have a good knee to rehab on.

22. On December 18, 2013, because of terrible pain and increase risk of falling, Mary Jane was forced to retire from her nursing job at M.D. Anderson Cancer Center. Retirement was not far off, but she was not ready to leave both her job and friends so abruptly. Mary Jane's work colleagues understood her situation as the entire office could hear the loud popping sound her right knee made whenever she stood up from her chair. This was an undignified exit from a job she loved.

23. Mary Jane and her family's Christmas holiday were filled with anxiety and pain rather than happiness and joy. She was confined to a recliner. Family plans were cancelled. The pain in the right knee worsened. She could not shower because she was unable to raise her leg high enough to step into the tub area. Every time she turned in her sleep she would be awakened with terrible right knee pain. She became very distraught. A chair lift was installed at her house to allow her to get up the stairs. Grab bars were also installed in her shower.

24. Over Christmas Eve and the following day Mary Jane began experiencing rapid heartbeats and difficulty breathing. She went to her internist who performed an EKG and lab work. It was determined that the likely cause of her rapid heartbeats and shortness of breath was her anxiety about the upcoming bilateral knee surgery. To add to the misery, Mary Jane's husband was undergoing treatment for recently diagnosed bladder cancer. Mary Jane was unable to fully be there to support him through the difficult treatment process.

25. On January 14, 2014, Dr. Clyburn performed bilateral knee revision surgery on Mary Jane. During the surgery Dr. Clyburn discovered that the lateral polyethylene spacer in the right knee had dislocated from its attachment to the tibia tray and was turned and twisted up into her femur. He also discovery that the left knee tibia component was subsided into the bone—particularly posteriorly—such that the component was flexed and the implant itself was loose. Dr. Clyburn found clear bone damage to the aspect of the left tibia that was caused by the collapsed ConforMIS component.

26. Following surgery on both knees, Mary Jane was transported via ambulance to Memorial Hermann Rehabilitation Hospital in Katy, Texas, where she underwent 6 hours of excruciatingly painful inpatient rehabilitation every day for 10 days. She remembers falling asleep when visitors came to see her because of her exhaustion. After she was discharged she had 5 more weeks of outpatient rehabilitation that was equally difficult.

27. Currently Mary Jane continues to recover. Her pain and mobility have improved, but the revision surgery has taken a toll on her body. She suffered additional trauma that is difficult for a 65 year old to completely recover from. She lost addition bone mass. She suffered additional scarring. She now has an increased rate of future prosthetic failure, pain, and discomfort.

CONFORMIS KNEW OF THE DEFECT

28. As previously stated, a review of FDA data shows that the iTotal G2 exhibited clear product defects as soon as it went on the market. Starting in October 2012, lateral spacer dislocations and tibia tray loosenings were frequently reported.

29. More disturbing is the 510(k) summary submitted by ConforMIS to the FDA on April 11, 2013. In this 510(k), ConforMIS asks the FDA for clearance to make design modifications to the iTotal G2. On information and belief, ConforMIS wished to make these modifications because of the spacer dislodgments and tibia tray loosenings that were being reported by physicians.

30. Specifically, this 510(k) submission called for (1) increased undercuts on medial and lateral side with central spine, (2) reduced posterior scallops on tray, (3) step-up removed on inserts, (4) and increased insert snap width features. These changes to the iTotal were necessary because when the knee was flexed, the femoral component exerts an inordinate amount of pressure on the posterior side of the lateral tibia spacer. This led to a grinding of the spacer, and in some cases spacer dislodgment and/or tibia tray loosening. This is exactly what happened in Mary Jane's case.

30. What is particularly disturbing about Mary Jane's case is that ConforMIS knew of these defects well before the April 11, 2013 510(k) submission to the FDA, and certainly before Mary Jane's April 30, 2013 right knee implantation surgery. Prior to April 11, 2013 Mary Jane's implant was measured and manufactured by ConforMIS with the known design defect, despite corporate knowledge of reported adverse events and their specific causes. ConforMIS did not contact Dr. Clyburn or send out a recall letter to doctors about the design defects. As a consequence, Mary Jane had a defective knee implanted in her on April 30, 2013. How many other patients were given a defective knee that ConforMIS was certainly aware about?

COUNT ONE - STRICT LIABILITY - DEFECTIVE MANUFACTURE

31. One or more of the defects in the iTotal G2 is a result of improper or incorrect manufacturing processes that resulted in the iTotal G2 deviating from its intended design. The defects caused by manufacturing defect rendered the iTotal G2 unreasonably dangerous to consumers and to the Plaintiff. The iTotal G2 implanted in Plaintiff existed from the time of its manufacture; therefore the defects were present when it left the possession and control of ConforMIS. As a direct and proximate result of the defective manufacture of the iTotal G2, Plaintiff has suffered serious bodily injury, mental and physical pain and suffering, and has incurred economic loss.

COUNT TWO - STRICT LIABILITY - DEFECTIVE DESIGN

32. The iTotal G2 was unreasonably dangerous and dangerously defective as designed because it was designed with numerous defects that adversely affect patient health. The defects in the iTotal G2 existed from its inception; therefore the defects were present when it left the possession and control of ConforMIS. The foreseeable risks of harm posed by the design of the iTotal G2 could have been reduced and/or avoided by the adoption of a reasonable alternative design by ConforMIS such as the safer alternative design submitted to the FDA on April 11, 2013. The failure of ConforMIS to adopt a safer alternative design rendered the iTotal G2 unreasonably unsafe. As a direct and proximate result of the defective design of the iTotal G2, Plaintiff has suffered serious bodily injury, mental and physical pain and suffering, and has incurred economic loss.

COUNT THREE - STRICT LIABILITY - MARKETING DEFECT

33. The iTotal G2 was defective by reason of failure of ConforMIS to provide adequate warnings or instructions.

34. Defendant failed to provide such warnings or instructions that a manufacturer exercising reasonable care would have provided to physicians who implanted the iTotal G2 or to

those patients who have been implanted with the iTotal G2 concerning the following risks, of which Defendant had actual or constructive knowledge at the time the iTotal G2 left Defendant's control:

a. the high failure rate of the iTotal G2;

b. the high rate of tibia spacer dislodgments in the iTotal G2 ;

c. the high rate tibia tray loosenings in the iTotal G2 ;

d. the high rate of chronic pain caused by the iTotal G2 ;

e. the necessity to remove the iTotal G2 from the patient's body in the event of Product failure.

35. After receiving notice of numerous bodily injuries resulting from the iTotal G2, ConforMIS failed to provide such post-marketing or post-sale warnings or instructions that a manufacturer exercising reasonable care should have provided to physicians who implanted the iTotal G2 or those patients who had been implanted with the iTotal G2.

36. As a direct and proximate result of the inadequate warnings and instructions by ConforMIS, both at the time of marketing and after the sale of the iTotal G2, Plaintiff has suffered serious bodily injury, mental and physical pain and suffering, and has incurred economic loss.

COUNT FOUR - NEGLIGENCE

37. ConforMIS failed to exercise ordinary and reasonable care in designing, manufacturing, testing, marketing, labeling, packaging, selling, recalling and/or distributing the iTotal G2 and ConforMIS negligently failed to provide adequate warnings and instructions to Plaintiff or her physician regarding the iTotal G2 . This certainly includes ConforMIS's failure to contact doctors such as Plaintiff's implanting physician about product defects that ConforMIS

clearly had knowledge about. This also certainly includes ConforMIS's failure to recall a defective product that they knew was being implanted in patients such as Plaintiff.

38. As a direct and proximate result of the negligence of ConforMIS, Plaintiff has suffered serious bodily injury, mental and physical pain and suffering, and has incurred economic loss.

COUNT FIVE - BREACH OF WARRANTY

39. The iTotal G2 implanted in Plaintiff failed to function as intended and as represented by ConforMIS because they did not relieve the symptoms or otherwise alleviate the medical problems that it was intended to cure or mitigate. Instead, the iTotal G2 caused Plaintiff to suffer severe adverse health consequences necessitating revision surgeries. Accordingly, the iTotal G2 was not fit for the ordinary purpose for which such goods are used and failed to conform to the affirmations or representations of ConforMIS. Furthermore, ConforMIS knew that the iTotal G2 were to be used for the particular purpose for which they were used on Plaintiff and knew that the expertise of ConforMIS was relied upon to furnish suitable goods. Because the iTotal G2 failed to conform to representations and were not suitable for the purpose for which they were used, ConforMIS has breached express warranties, the implied warranty of merchantability, and the warranty of fitness for a particular purpose. As a result of ConforMIS's breach of warranty, Plaintiff has suffered serious bodily injury, mental and physical pain and suffering, and has incurred economic loss.

PUNITIVE DAMAGES

40. At all times ConforMIS designed, manufactured, marketed, labeled, packaged, sold, and failed to recall the dangerous and defective iTotal G2 and failed to adequately warn Plaintiff of the dangerous and defective nature of the iTotal G2 and thereby caused Plaintiff's

injuries. ConforMIS knew, or in the exercise of the appropriate degree of care should have known, that its conduct created a high degree of probability of injury to others and thereby showed complete and reckless indifference to and conscious disregard for the safety of others, including Plaintiff and hundreds of other patients like her, and such conduct warrants the imposition of punitive damages under all applicable legal standards.

DAMAGES AND REMEDIES

41. Plaintiff sues to recover all elements of compensable damages under Texas law. Additionally, she seeks appropriate prejudgment interest thereon, as provided by law.

42. If the evidence at trial demonstrates the level of culpability necessary for an assessment of punitive or exemplary damages, then Plaintiff seeks an award in such amount as the Jury shall deem appropriate.

JURY DEMAND

43. Plaintiff invokes her constitutional right to trial by jury.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays that Defendant be cited to appear and answer herein, and that upon the final trial of this case, a Final Judgment be entered by this Court in its favor against Defendant ConforMIS awarding such compensatory and punitive damages to Plaintiff as are appropriate, plus interest and costs, and such other relief as is just and proper.

Date: October 21, 2014

Respectfully submitted,

_/s/ Jim M. Perdue, Jr.___
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