

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA**

Case No.

BERNARD G. OWEN
individually and on behalf of all others
similarly situated,

Plaintiff,

v.

HOWMEDICA OSTEONICS CORPORATION,
a New Jersey Corporation, d/b/a Stryker Orthopedics,

Defendant.

CLASS ACTION COMPLAINT FOR MEDICAL MONITORING

Plaintiff, Bernard G. Owen (hereinafter referred to as “Plaintiff”), through undersigned counsel, brings this action pursuant to Federal Rule of Civil Procedure 23 for himself and others similarly situated, and sues Defendant, Howmedica Osteonics Corporation, a New Jersey Corporation, d/b/a Stryker Orthopedics (hereinafter “Stryker”). Plaintiff seeks certification of this matter as a class action. Plaintiff alleges as follows:

NATURE OF THE CASE

1. This is an action for medical monitoring based on the increased risk of injury caused by one of Defendant’s defective modular-neck hip stem systems.

2. Defendant Stryker markets 57,000 products including hip implant systems worldwide and generates more than \$8 billion in annual sales. One recent Stryker implant system —“The Rejuvenate ® System,”—was voluntarily recalled by the company in July 2012, after numerous complaints from some of the thousands of patients who have had the product

implanted. The recall of “The Rejuvenate ® System,” (“Rejuvenate”) stems from serious post-implant side effects, including loosening of the implant and the release of toxic metals into patients. Thousands of the defective implants were sold before the recall.

3. Plaintiff and the class he seeks to represent are the unfortunate recipients of the Rejuvenate implant that Defendant Stryker designed, manufactured, distributed and sold in Florida.

4. Defendant’s failure to manufacture and produce a non-defective, less-dangerous hip implant caused Plaintiff and Class Members to require medical monitoring. Stryker itself has advised recipients to receive follow-up tests and evaluation due to the risk the device poses to recipients.

5. In this action, Plaintiff therefore requests that the Court institute a medical monitoring program paid for by Defendant and/or order Defendant to establish a fund to pay for the medical monitoring necessitated by the defective Rejuvenate hip implant system.

THE PARTIES

6. At all material times, Plaintiff Bernard G. Owen has resided in Boynton Beach, Florida, and has been a citizen of the state of Florida. All Class Members are citizens of Florida.

7. On July 6, 2011, Plaintiff was implanted with a Rejuvenate System manufactured and marketed by Defendant Stryker. The surgery took place at Bethesda Medical Center in Boynton Beach, Florida. Robert B. Zahn, MD, performed the surgery.

8. Defendant Howmedica Osteonics Corporation, d/b/a Stryker Orthopedics, is a New Jersey Corporation, has its principal place of business in New Jersey, and is a citizen of New Jersey.

9. At all material times, Defendant Stryker developed, tested, assembled, manufactured, packaged, labeled, prepared, distributed, marketed, supplied, and/or sold the defective product at issue sold under the name “The Rejuvenate ® System,” either directly or indirectly, to members of the general public within the State of Florida, including Plaintiff and Class Members.

STATEMENT OF JURISDICTION AND VENUE

10. This court has jurisdiction over the cause of action asserted herein pursuant to 28 U.S.C. § 1332(d), because in the aggregate, the matter in controversy exceeds the sum or value of \$5,000,000, and diversity of citizenship between the proposed Class Members and Defendant.

11. Plaintiff and the putative class are all citizens of the State of Florida and all received their Rejuvenate modular neck hip stem system while residing in the State of Florida.

12. Defendant Stryker, at all times relevant to this Complaint operated, conducted, engaged in, or carried on a business in Florida or had an office or agency in Florida, and placed the Rejuvenate modular neck hip stems in the stream of commerce for distribution throughout the State of Florida, including this District.

13. Venue is proper in this District pursuant to 28 U.S.C. § 1391(a) (2). Substantial acts in furtherance of the alleged improper conduct, occurred within this District.

14. This Court has jurisdiction over Defendant because it has registered with the Florida Secretary of State to do business in Florida; it maintains offices and representatives in Broward County; and at all times material, Defendant had continuous and systematic contacts with Florida by actively pursuing sales of its device here and placing its device in the stream of commerce knowing that it would be sold here. At all relevant times, Defendant expected or should have expected that its acts and omissions would have consequences within the United States and the State of Florida.

DISCOVERY OF DEFECT

15. When Plaintiff and Class Members were implanted with the Rejuvenate System, they were unaware of any problems associated with the implantation of these devices. It was not until Defendant Stryker recalled the Rejuvenate System in July, 2012, indicating that this device presented risk of fretting and corrosion at the modular neck junction, that Plaintiff and Class Members reasonably could have known that they have increased health risks from Defendant's device or that they may have a cause of action arising from Defendant's conduct.

16. Prior to July 6, 2011, Plaintiff Bernard G. Owen did not discover, and could not reasonably have discovered, that the Rejuvenate modular neck hip stems were fraught with the problems alleged herein. Plaintiff was blamelessly unaware of the defective and dangerous condition of the Rejuvenate modular neck hip stems until Defendant's July, 2012 recall.

17. In or about July, 2012, Plaintiff Bernard G. Owen received an undated letter from Stryker which stated the following:

Dear Patient,

You are receiving this letter because your surgeon has identified that you are a recipient of a Rejuvenate or ABG II modular-neck hip stem. Stryker Orthopedics, the manufacturer, initiated a voluntary recall of these modular-neck hip stems.

This voluntary recall was initiated due to the potential risks associated with modular-neck stems. These risks include the potential for fretting and/or corrosion at or about the modular-neck junction which may result in ALTR (adverse local tissue reactions) manifesting with pain and/or swelling.

If you have no symptoms, you should continue to follow the post-operative plan that your surgeon has outlined for you. However, if you have symptoms of pain and/or swelling in or around your replaced hip, you should schedule an office visit with your surgeon and discuss your symptoms.

We understand that this information may raise questions. To help address your questions, Stryker has the following resources available:

- **Patient Call Center – 1-888-317-0200**
- **Web Resource – www.AboutStryker.com/ModularNeckStems**

GENERAL ALLEGATIONS

18. A total hip replacement (“THR”) is a surgical procedure that replaces the hip joint with a prosthetic implant. THRs are commonly performed to relieve chronic pain that is limiting a patient’s activities. More than 300,000 THRs are performed each year in the United States, making it one of the most frequently performed surgical procedures.¹

19. The Food and Drug Administration (“FDA”) approved Stryker’s Rejuvenate System in June 2008. The system is made up of standardized components that are implanted based on standardized protocols and indications.

¹FastStats, Center for Disease Control (“CDC”), <http://www.cdc.gov/nchs/fastats/insurg.htm>

20. The FDA approved the Rejuvenate System through the FDA's 510(k) Premarket Notification Process. Under the 510(k) process, a drug or medical device may be marketed to the public without undergoing clinical trials, if the product is shown to be substantially similar to an existing product with FDA approval. Stryker's Rejuvenate System was approved because it was similar to other already sanctioned technologies.

21. Thus, instead of testing the device before it was marketed, the company was only required to conduct post-market surveillance. In other words, product safety did not have to be proven in advance. The obvious flaw in this system is that problems in 510(k) devices can only be found after they have been implanted in patients. Worse, the new Stryker devices were modeled on systems that already were suspected of having serious design problems themselves — problems that led to bone fractures and adverse tissue responses.

22. In 2010, other hip implant manufacturers, including Johnson & Johnson/DePuy, Wright Medical and others came under scrutiny for safety issues allegedly plaguing their metal on metal ("MoM") hip implants which had a metal ball and metal socket and which were tied to metallosis, heavy metal toxicity and other failures.

23. Stryker seized on the promotional opportunity presented by the intense scrutiny that its competitors were receiving for their MoM hip implants, by touting features of the Rejuvenate system that they claimed made their devices better and safer.

24. First, Stryker claimed that their dual modular systems would provide better fit. Stryker's Rejuvenate is "dual modular", meaning that the stem that connects to the femur and the "neck" that connects the stem to the ball are separate parts. Traditional modular hip implants have had "singular modularity," meaning that the stem and neck are

one piece. Stryker promoted this dual modularity feature as a benefit that allows surgeons to “custom fit” the implant system to each patient’s unique anatomy by selecting necks of different lengths and offset angles.

25. In addition, Stryker claimed that the Rejuvenate system was safer because it did not have one metal surface moving on another metal surface, unlike the MoM devices which had a metal ball moving on a metal socket.

26. Stryker claims to have designed its Rejuvenate modular hip system to allow surgeons to appropriately size the implant to each patient’s unique anatomy by making femoral stem and neck components in a variety of sizes and offsets.

27. The Rejuvenate components were made from, among other things, cobalt and chromium in the neck, and a proprietary titanium alloy in the stem.

28. In August, 2010, widespread reports of excessive MoM device failures caused by heavy metal toxicity and metallosis led Johnson & Johnson/DePuy to recall their ASR MoM implants.

29. In November, 2010, Stryker started a clinical study, Rejuvenate Modular Outcomes Study, as part of its 510(k) approval.

30. Stryker did not complete any clinical studies related to the safety or effectiveness of the Rejuvenate System, before marketing this system to the public.

31. The FDA maintains the Manufacturer and User Facility Device Experience Database (“MAUDE”) to track reports of adverse events involving medical devices. By April, 2012, MAUDE data reflected a series of significant adverse events associated with both the Rejuvenate system.

32. In May, 2011, the FDA issued more than one hundred orders to 21 MoM device manufacturers demanding that they study the extent and risk associated with heavy metal toxicity and metallosis.

33. A study published in April, 2012 found that modular hip neck stem systems were at increased risk of fretting and corrosion, which may contribute to elevated metal ion levels in patient's blood.

34. In April, 2012, Stryker issued an Urgent Field Safety Notice in response to the adverse events reported in MAUDE. Stryker reported that fretting, deterioration, or corrosion at or near the modular neck junction were potential hazards associated with both systems.

35. Stryker also reported that this fretting, deterioration or corrosion could lead to increased amounts of metal ion generation in the surrounding joint space, contact between metal ions and tissues which could lead to an adverse local tissue reaction ("ALTR") and inflammation of affected tissues.

36. In this Safety Alert, Stryker reported the following: (a) that ALTR may require revision surgery; (b) that some patients may require revision surgery because of allergic or increased sensitivity to the presence of ions; and (c) that metallosis, necrosis, osteolysis, and pain may result from the fretting, deterioration and corrosion of these systems.

37. In June, 2012, the Devices Panel of the Medical Devices Advisory Committee of the FDA held two days of public hearings to discuss the safety and effectiveness of MoM hip implants.

38. In June, 2012 Stryker recalled its Rejuvenate hip implants due to potential fretting and corrosion at the modular neck junction which may result in ALTR as well as possible pain and/or swelling at or around the hip.

39. In July 2012, Stryker composed a form letter for physicians to send to their Rejuvenate patients advising them essentially that if they had no symptoms then no medical exam, testing, or treatment was necessary.

40. Then in or about January 2013, Stryker advised patients who have received a Rejuvenate modular neck hip stem to contact their surgeon to schedule a follow-up appointment even if they are **not** experiencing symptoms such as pain and/or swelling at or around their hip.

41. Further, in or about January 2013, Stryker advised that surgeons should consider performing a clinical examination, including blood work and cross section imaging on all patients who received a Rejuvenate System modular-neck hip stem regardless of whether a patient is experiencing pain and/or swelling. Stryker also recommended that repeat follow-up examination, such as blood work and cross section imaging, should be considered even in the presence of normal initial findings.

42. Despite Stryker's claims to the contrary, their Rejuvenate System does contain a metal-on-metal articulation. Two different types of metals come in contact at the point where the modular neck inserts into the femoral stem. This junction is known as the "taper neck junction." The metal-on-metal contact at the taper neck junction is leading to fretting, corrosion and the creation of metal debris.

THE CASE FOR MEDICAL MONITORING

43. Plaintiff, Bernard G. Owen and Class Members require medical monitoring to ensure that the Rejuvenate System modular hip necks implanted within their bodies have not yet fretted, corroded or otherwise failed and if so, be given their treatment options.

44. This action for medical monitoring seeks to recover the quantifiable costs of periodic medical examinations necessary to detect the onset of physical harm, but does not seek a damage award attributable to the increased risk of injury caused by the implantation of the defective Rejuvenate system. Plaintiff requests that the court exercise its equitable powers to create and supervise a fund for the purpose of monitoring the condition of Plaintiff and Class Members because such monitoring is reasonably necessary.

45. In order to determine whether a Rejuvenate System modular hip neck has fretted, corroded, or otherwise failed, blood tests, imaging studies and physician exams must be performed. Blood tests will reflect whether there are elevated levels of chromium and cobalt in the blood; imaging studies may detect local adverse tissue reaction such as pseudotumor formation; and physician examination may reveal symptoms and conditions indicative of device failure.

46. The forms of medical monitoring that will provide early detection and diagnosis of device failure include, but may not be limited to, the following medical procedures:

- a. Blood tests to determine serum chromium and cobalt concentration;
- b. Aspiration of joint fluid;
- c. Imaging studies; and
- d. Regular physicians' visits and examinations.

47. Those people requiring medical monitoring, like Plaintiff Bernard G. Owen and Class Members, are recommended to undergo regular and frequent blood tests at least once every six months. As long as the Rejuvenate System hip implants remain within the body of the patient, the likely potential for future device failure exists. Consequently, these people require regular and frequent medical monitoring for the duration of time the device remains within their bodies.

48. Those eligible for medical monitoring of the Rejuvenate System modular neck hip stems need not have experienced past failure of the device.

49. In addition to the aforementioned blood tests, imaging studies and physician exams may also be used by medical professionals to diagnose or discover whether the Rejuvenate device has fretted, corroded or otherwise failed. Furthermore, surgery may assess the nature and extent of the damage resulting from fretting, corrosion or failure of the device.

50. The need for medical monitoring of Plaintiff and Class Members in this case is a reasonably certain consequence of the placement of the Rejuvenate System modular hip neck stems in their bodies. Each of them is at a significant and likely risk of device failure in the future and this is a risk which they would not be exposed but for the conduct of Defendant Stryker as alleged in this Complaint and the implant of the device within their bodies. The seriousness of the complications that can result from device failure encompasses a spectrum of conditions, up to and including osteolysis, synovitis, pseudo-tumors, fluid in the joint, tissue and bone necrosis, hypersensitivity to metal, decreased lymphocyte cells, decreased CD8+ T cells, DNA changes, and chromosomal aberrations.

51. There is clear clinical value through well-established medical means, to early detection and diagnosis of device failure.

52. All conditions precedent to the filing of this action, if any, have been performed, waived, satisfied or otherwise executed.

CLASS ALLEGATIONS

53. Plaintiff Bernard G. Owen, on behalf of himself and others similarly situated, brings this action pursuant to Rule 23(b)(2) of the Federal Rules of Civil Procedure to create a medical monitoring fund and/or program.

54. The “Class” or “Class Members” Plaintiff seeks to certify is defined as follows:

All individual citizens of Florida who have had implantation of Rejuvenate modular neck hip stems designed, manufactured, distributed and sold by Defendant Stryker and who have the device(s) remaining within their anatomy.

55. This action has been brought and may properly be maintained as a class action against Defendant pursuant to Rule 23 of the Federal Rules of Civil Procedure because there is a well-defined community of interest in the litigation and the proposed Class is easily ascertainable.

Numerosity

56. On information and belief, the Class consists of hundreds of members located throughout the State of Florida. The Class Members are so numerous that joinder of individual members in this action is impracticable. Class Members can be notified of this class action via notice publication and U.S. mail, at addresses that Defendant should or does have in its business records.

Commonality

57. There are common questions of law and/or fact in this action that relate to and affect the rights of each member of the Class and the relief sought.

58. Proof of a common set of facts and/or violation of law will establish the right of each Class Member to recover. Among the questions of law and/or fact common to the Class are:

- a. Whether Plaintiff and Class Members have had a Rejuvenate System modular neck hip stems implanted within their anatomy;
- b. Whether Plaintiff and Class Members are exposed to a significantly increased risk of injury from the existence of a Rejuvenate System device within their anatomy;
- c. Whether Defendant Stryker negligently designed, manufactured and/or failed to warn Plaintiff and Class Members of dangers and risks of harm associated with the Rejuvenate System;
- d. Whether Plaintiff and Class Members require regular, frequent and necessary medical monitoring to detect the onset of disease or injury due to the Rejuvenate System's having fretted, corroded or otherwise failed; and,
- e. Whether Plaintiff and all Class Members have a significantly increased risk of adverse local tissue reaction, metallosis and/or other serious latent diseases due to the fretting, corrosion or other failure of the subject modular neck hip stems.

Typicality

59. Plaintiff Bernard G. Owen's claim is typical of the claims of the Class in that the claims of all Class Members, including Plaintiff, depend on a showing of the acts and omissions of Defendant Stryker upon which liability is based.

Adequacy of Representation

60. Plaintiff Bernard G. Owen is a member of the Class defined above. He can and will fairly and adequately protect the interests of the Class because it is in his best interest to prosecute the claims alleged herein to obtain medical monitoring and a declaration of his rights. Plaintiff Bernard G. Owen has no interest which conflicts with those of the Class Members because one or more questions of law and/or fact regarding Defendant's liability are common to all Class Members, such that by prevailing on his own claims, Plaintiff necessarily will establish Defendant's liability to other Class Members.

Rule 23(b)(2)

61. The determination of whether a putative class member has a significantly increased risk of contracting a serious latent disease from exposure to the Rejuvenate System does not depend on individual circumstances.

62. The claim and remedy of medical monitoring are intended to prevent a future harm of the diseases mentioned herein that derives from exposure to the Rejuvenate System. It is not intended to preclude a subsequent claim for individual damages brought individually. From the perspective of a medical monitoring regime, Plaintiff and Class Members stand in the same position, making this case entirely appropriate for group-wide, rather than individual relief. Given that a medical monitoring fund is an injunctive remedy, non-preclusive of a future damages claim, and group-wide in nature, the (b)(2) class category adequately protects the due process rights of the Class and Plaintiff.

63. Accordingly, under Rule 23(b)(2) Plaintiff seeks injunctive relief on behalf of Class Members on grounds generally applicable to the entire Class Members in form of establishing a medical monitoring program and enjoining Defendant to comply with it. Plaintiff seeks the establishment of a court-supervised medical monitoring program

managed by court-appointed court-supervised trustees, through which the Class Members will receive periodic examinations, but not damage payments.

64. Because Plaintiffs seek injunctive relief for Class Members, the prosecution of separate actions by individual Class Members would create a risk of inconsistent or varying adjudications with respect to individual Class Members that would establish incompatible standards of conduct for the Defendant. Further, adjudications with respect to individual Class Members would, as a practical matter, be dispositive of the interests of other Class Members who are not parties to the adjudication and may impair and impede their ability to protect their interests.

COUNT I
MEDICAL MONITORING

65. Plaintiff realleges and incorporates by reference each allegation contained in the prior paragraphs.

66. At all times relevant to this cause of action, Stryker was in the business of designing, developing, manufacturing, marketing, and selling sophisticated medical devices, including the Rejuvenate System modular neck hip stems.

67. Stryker, in designing, developing, manufacturing, marketing, labeling, selling, monitoring and overseeing its products had a duty to act with reasonable care and to warn Plaintiff and Plaintiff's physicians of the risk, dangers, adverse events involving fretting, corrosion and other potential failures of the Rejuvenate System modular neck hip stems.

68. At the time of the manufacture and sale of the Rejuvenate System modular neck hip stems (2008 through July, 2012), Defendant Stryker, knew or should have known that the Rejuvenate System modular neck hip stems:

- a. Were designed and manufactured in such a manner so as to present an unreasonable risk of failure;
- b. Were substandard and dangerous in that they combined a cobalt and chromium neck with a titanium stem;
- c. Were designed and manufactured so as to present an unreasonable risk of fretting and/or corrosion;
- d. Were designed and manufactured so as to present an unreasonable risk of metallosis; and/or
- e. Were designed and manufactured to have unreasonable and insufficient strength or structural integrity to withstand normal placement within the human body.

69. Stryker committed one or more breaches of the duty of reasonable care and were negligent in:

- a. Unreasonably and carelessly failing to properly warn of the dangers and risks of harm associated with the Rejuvenate modular neck hip stems, namely the incidence of fretting and/or corrosion and/or the likelihood that these modular neck hip stems could not be safely removed;
- b. Unreasonably and carelessly manufacturing a product, namely, Rejuvenate System modular neck hip stems that were insufficient in strength or structural integrity to withstand the foreseeable use of normal placement within the human body;
- c. Unreasonably and carelessly designing a product, Rejuvenate System modular neck hip stems, that were insufficient in strength or structural integrity to withstand the foreseeable use of normal placement within the human body; and

- d. Unreasonable and carelessly designing a product, namely, Rejuvenate System modular neck hip stems that presented the increased risk of harm to Plaintiff and others similarly situated in that it was prone to fretting, corrosion or other failure.

70. Plaintiff and Class Members all have been and continue to be exposed to greater than normal background levels of the alleged defective products because all have had a defective Rejuvenate System modular neck hip stems implanted in their anatomy which are likely to fret, corrode, or otherwise fail and cause future injuries due to their defective design and manufacture.

71. The Rejuvenate System modular neck hip stems that have been implanted in Plaintiff and all Class Members are proven to be hazardous.

72. Defendant Stryker's negligent design, manufacture and/or failure to warn caused the defective Rejuvenate System modular neck hip stems to be implanted in the Plaintiff and all Class Members' anatomy.

73. As a direct and proximate result of Defendant's negligence, Plaintiff and all Class Members have a significantly increased risk of adverse local tissue reaction, metallosis and/or other serious latent diseases due to the fretting, corrosion or other failure of the subject modular neck hip stems.

74. As a further direct and proximate result of the foregoing negligence by Defendant Stryker: (a) Plaintiff and members of the Class, require regular and frequent medical monitoring for the duration of time that Defendant's modular neck hip stems remain within their bodies; and (b) Plaintiff and Class Members will be required to expend money and incur obligations to undergo tests to determine their risks and the onset of the diseases and injuries caused by the Rejuvenate System.

75. Medical monitoring tests and procedures exist which make the early detection of adverse local tissue reaction, metallosis, and other conditions that maybe caused by the failure of the subject modular neck hip stems, possible. The necessary medical monitoring includes, but is not limited to, blood tests and imaging studies such as magnetic resonance imaging.

76. The proposed medical monitoring for Plaintiff and Class Members is unnecessary for individuals who have not been implanted with Rejuvenate System modular neck hip stems, since such individuals do not have modular neck hip stems that are prone to fretting, corrosion or other failure.

77. The proposed medical monitoring program is reasonably necessary according to contemporary principles of medicine.

PRAYER FOR JUDGMENT AND RELIEF

WHEREFORE, Plaintiff Bernard G. Owen and Class Members pray for judgment against Defendant Stryker, for:

Class Certification

78. For certification of this cause as a class action suit pursuant to Rule 23(b)(2) of the Federal Rules of Civil Procedure based on the Class definition and allegations stated above.

Medical Monitoring

79. For medical monitoring, to provide Plaintiff and Class Members with periodic medical examinations and such other medical procedures as are reasonably

necessary and designed to facilitate early detection and treatment of conditions related to fretting, corrosion and/or other failure of the Rejuvenate System modular neck hip stems.

80. For medical monitoring, to provide for a court-supervised medical monitoring program managed by court-appointed court-supervised trustees, through which the Class Members will receive periodic examinations relating to the prevention, detection, and treatment of conditions related to fretting, corrosion and other failures of the Rejuvenate System modular neck hip stems.

Costs of Suit

81. For Plaintiff's costs of suit incurred herein.

Attorney's Fees

82. For Plaintiff's reasonable attorney's fees.

Other Relief

83. For such other and further relief as the Court deems just and proper.

JURY DEMAND

Plaintiff hereby demands a trial by jury of all issues which may be tried to a jury.

Dated: This 25th day of January, 2013

**FARMER, JAFFE, WEISSING,
EDWARDS, FISTOS & LEHRMAN, P.L.**

By: /s/ Steven R. Jaffe
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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 THE REVERSE OF THE FORM.) **NOTICE: Attorneys MUST Indicate All Re-filed Cases Below.**

I. (a) PLAINTIFFS Bernard G. Owen individually and on behalf of all others similarly situated, + (b) County of Residence of First Listed Plaintiff <u>West Palm Beach</u> (EXCEPT IN U.S. PLAINTIFF CASES) (c) Attorney's (Firm Name, Address, and Telephone Number) FARMER, JAFFE, WEISSING, EDWARDS, FISTOS & LEHRMAN, P.L. 425 N. Andrews Ave., Suite 2, Fort Lauderdale, Florida 33301 Telephone 954-524-2820; Facsimile 954-524-2822 +	DEFENDANTS Howmedica Osteonics Corporation a New Jersey Corporation, d/b/a Stryker Orthopedics, + County of Residence of First Listed Defendant _____ (IN U.S. PLAINTIFF CASES ONLY) NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT LAND INVOLVED. Attorneys (If Known) _____
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(d) Check County Where Action Arose: ☐ MIAMI-DADE ☐ MONROE ☒ BROWARD ☐ PALM BEACH ☐ MARTIN ☐ ST. LUCIE ☐ INDIAN RIVER ☐ OKEECHOBEE HIGHLANDS

II. BASIS OF JURISDICTION (Place an "X" in One Box Only) <input type="checkbox"/> 1 U.S. Government Plaintiff <input type="checkbox"/> 2 U.S. Government Defendant <input type="checkbox"/> 3 Federal Question (U.S. Government Not a Party) <input checked="" type="checkbox"/> 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) <table style="width: 100%;"> <tr> <th></th> <th>PTF</th> <th>DEF</th> <th></th> <th>PTF</th> <th>DEF</th> </tr> <tr> <td>Citizen of This State</td> <td><input type="checkbox"/> 1</td> <td><input type="checkbox"/> 1</td> <td>Incorporated <i>or</i> Principal Place of Business In This State</td> <td><input type="checkbox"/> 4</td> <td><input type="checkbox"/> 4</td> </tr> <tr> <td>Citizen of Another State</td> <td><input type="checkbox"/> 2</td> <td><input type="checkbox"/> 2</td> <td>Incorporated <i>and</i> Principal Place of Business In Another State</td> <td><input type="checkbox"/> 5</td> <td><input type="checkbox"/> 5</td> </tr> <tr> <td>Citizen or Subject of a Foreign Country</td> <td><input type="checkbox"/> 3</td> <td><input type="checkbox"/> 3</td> <td>Foreign Nation</td> <td><input type="checkbox"/> 6</td> <td><input type="checkbox"/> 6</td> </tr> </table>		PTF	DEF		PTF	DEF	Citizen of This State	<input type="checkbox"/> 1	<input type="checkbox"/> 1	Incorporated <i>or</i> Principal Place of Business In This State	<input type="checkbox"/> 4	<input type="checkbox"/> 4	Citizen of Another State	<input type="checkbox"/> 2	<input type="checkbox"/> 2	Incorporated <i>and</i> Principal Place of Business In Another State	<input type="checkbox"/> 5	<input type="checkbox"/> 5	Citizen or Subject of a Foreign Country	<input type="checkbox"/> 3	<input type="checkbox"/> 3	Foreign Nation	<input type="checkbox"/> 6	<input type="checkbox"/> 6
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Citizen or Subject of a Foreign Country	<input type="checkbox"/> 3	<input type="checkbox"/> 3	Foreign Nation	<input type="checkbox"/> 6	<input type="checkbox"/> 6																				

IV. NATURE OF SUIT (Place an "X" in One Box Only)							
CONTRACT <input type="checkbox"/> 110 Insurance <input type="checkbox"/> 120 Marine <input type="checkbox"/> 130 Miller Act <input type="checkbox"/> 140 Negotiable Instrument <input type="checkbox"/> 150 Recovery of Overpayment & Enforcement of Judgment <input type="checkbox"/> 151 Medicare Act <input type="checkbox"/> 152 Recovery of Defaulted Student Loans (Excl. Veterans) <input type="checkbox"/> 153 Recovery of Overpayment of Veteran's Benefits <input type="checkbox"/> 160 Stockholders' Suits <input type="checkbox"/> 190 Other Contract <input type="checkbox"/> 195 Contract Product Liability <input type="checkbox"/> 196 Franchise	TORTS <table style="width: 100%;"> <tr> <td style="vertical-align: top;"> PERSONAL INJURY <input type="checkbox"/> 310 Airplane <input type="checkbox"/> 315 Airplane Product Liability <input type="checkbox"/> 320 Assault, Libel & Slander <input type="checkbox"/> 330 Federal Employers' Liability <input type="checkbox"/> 340 Marine <input type="checkbox"/> 345 Marine Product Liability <input type="checkbox"/> 350 Motor Vehicle <input type="checkbox"/> 355 Motor Vehicle Product Liability <input checked="" type="checkbox"/> 360 Other Personal Injury </td> <td style="vertical-align: top;"> PERSONAL INJURY <input type="checkbox"/> 362 Personal Injury - Med. Malpractice <input type="checkbox"/> 365 Personal Injury - Product Liability <input type="checkbox"/> 368 Asbestos Personal Injury Product Liability PERSONAL PROPERTY <input type="checkbox"/> 370 Other Fraud <input type="checkbox"/> 371 Truth in Lending <input type="checkbox"/> 380 Other Personal Property Damage <input type="checkbox"/> 385 Property Damage Product Liability </td> </tr> </table>	PERSONAL INJURY <input type="checkbox"/> 310 Airplane <input type="checkbox"/> 315 Airplane Product Liability <input type="checkbox"/> 320 Assault, Libel & Slander <input type="checkbox"/> 330 Federal Employers' Liability <input type="checkbox"/> 340 Marine <input type="checkbox"/> 345 Marine Product Liability <input type="checkbox"/> 350 Motor Vehicle <input type="checkbox"/> 355 Motor Vehicle Product Liability <input checked="" type="checkbox"/> 360 Other Personal Injury	PERSONAL INJURY <input type="checkbox"/> 362 Personal Injury - Med. Malpractice <input type="checkbox"/> 365 Personal Injury - Product Liability <input type="checkbox"/> 368 Asbestos Personal Injury Product Liability PERSONAL PROPERTY <input type="checkbox"/> 370 Other Fraud <input type="checkbox"/> 371 Truth in Lending <input type="checkbox"/> 380 Other Personal Property Damage <input type="checkbox"/> 385 Property Damage Product Liability	FORFEITURE/PENALTY <input type="checkbox"/> 610 Agriculture <input type="checkbox"/> 620 Other Food & Drug <input type="checkbox"/> 625 Drug Related Seizure of Property 21 USC 881 <input type="checkbox"/> 630 Liquor Laws <input type="checkbox"/> 640 R.R. & Truck <input type="checkbox"/> 650 Airline Regs. <input type="checkbox"/> 660 Occupational Safety/Health <input type="checkbox"/> 690 Other	BANKRUPTCY <input type="checkbox"/> 422 Appeal 28 USC 158 <input type="checkbox"/> 423 Withdrawal 28 USC 157 PROPERTY RIGHTS <input type="checkbox"/> 820 Copyrights <input type="checkbox"/> 830 Patent <input type="checkbox"/> 840 Trademark	OTHER STATUTES <input type="checkbox"/> 400 State Reapportionment <input type="checkbox"/> 410 Antitrust <input type="checkbox"/> 430 Banks and Banking <input type="checkbox"/> 450 Commerce <input type="checkbox"/> 460 Deportation <input type="checkbox"/> 470 Racketeer Influenced and Corrupt Organizations <input type="checkbox"/> 480 Consumer Credit <input type="checkbox"/> 490 Cable/Sat TV <input type="checkbox"/> 810 Selective Service <input type="checkbox"/> 850 Securities/Commodities/Exchange <input type="checkbox"/> 875 Customer Challenge 12 USC 3410 <input type="checkbox"/> 890 Other Statutory Actions <input type="checkbox"/> 891 Agricultural Acts <input type="checkbox"/> 892 Economic Stabilization Act <input type="checkbox"/> 893 Environmental Matters <input type="checkbox"/> 894 Energy Allocation Act <input type="checkbox"/> 895 Freedom of Information Act <input type="checkbox"/> 900 Appeal of Fee Determination Under Equal Access to Justice <input type="checkbox"/> 950 Constitutionality of State Statutes	REAL PROPERTY <input type="checkbox"/> 210 Land Condemnation <input type="checkbox"/> 220 Foreclosure <input type="checkbox"/> 230 Rent Lease & Ejectment <input type="checkbox"/> 240 Torts to Land <input type="checkbox"/> 245 Tort Product Liability <input type="checkbox"/> 290 All Other Real Property
PERSONAL INJURY <input type="checkbox"/> 310 Airplane <input type="checkbox"/> 315 Airplane Product Liability <input type="checkbox"/> 320 Assault, Libel & Slander <input type="checkbox"/> 330 Federal Employers' Liability <input type="checkbox"/> 340 Marine <input type="checkbox"/> 345 Marine Product Liability <input type="checkbox"/> 350 Motor Vehicle <input type="checkbox"/> 355 Motor Vehicle Product Liability <input checked="" type="checkbox"/> 360 Other Personal Injury	PERSONAL INJURY <input type="checkbox"/> 362 Personal Injury - Med. Malpractice <input type="checkbox"/> 365 Personal Injury - Product Liability <input type="checkbox"/> 368 Asbestos Personal Injury Product Liability PERSONAL PROPERTY <input type="checkbox"/> 370 Other Fraud <input type="checkbox"/> 371 Truth in Lending <input type="checkbox"/> 380 Other Personal Property Damage <input type="checkbox"/> 385 Property Damage Product Liability						
CIVIL RIGHTS <input type="checkbox"/> 441 Voting <input type="checkbox"/> 442 Employment <input type="checkbox"/> 443 Housing/Accommodations <input type="checkbox"/> 444 Welfare <input type="checkbox"/> 445 Amer. w/Disabilities Employment <input type="checkbox"/> 446 Amer. w/Disabilities Other <input type="checkbox"/> 440 Other Civil Rights	PRISONER PETITIONS <input type="checkbox"/> 510 Motions to Vacate Sentence Habeas Corpus: <input type="checkbox"/> 530 General <input type="checkbox"/> 535 Death Penalty <input type="checkbox"/> 540 Mandamus & Other <input type="checkbox"/> 550 Civil Rights <input type="checkbox"/> 555 Prison Condition	LABOR <input type="checkbox"/> 710 Fair Labor Standards Act <input type="checkbox"/> 720 Labor/Mgmt. Relations <input type="checkbox"/> 730 Labor/Mgmt. Reporting & Disclosure Act <input type="checkbox"/> 740 Railway Labor Act <input type="checkbox"/> 790 Other Labor Litigation <input type="checkbox"/> 791 Empl. Ret. Inc. Security Act IMMIGRATION <input type="checkbox"/> 462 Naturalization Application <input type="checkbox"/> 463 Habeas Corpus-Alien Detainee <input type="checkbox"/> 465 Other Immigration Actions	SOCIAL SECURITY <input type="checkbox"/> 861 HIA (1395ff) <input type="checkbox"/> 862 Black Lung (923) <input type="checkbox"/> 863 DIWC/DIWW (405(g)) <input type="checkbox"/> 864 SSID Title XVI <input type="checkbox"/> 865 RSI (405(g)) FEDERAL TAX SUITS <input type="checkbox"/> 870 Taxes (U.S. Plaintiff or Defendant) <input type="checkbox"/> 871 IRS—Third Party 26 USC 7609				

V. ORIGIN (Place an "X" in One Box Only)
☒ 1 Original Proceeding ☐ 2 Removed from State Court ☐ 3 Re-filed- (see VI below) ☐ 4 Reinstated or Reopened ☐ 5 Transferred from another district (specify) _____ ☐ 6 Multidistrict Litigation ☐ 7 Appeal to District Judge from Magistrate Judgment

VI. RELATED/RE-FILED CASE(S).	a) Re-filed Case <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO b) Related Cases <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO (See instructions second page): JUDGE _____ DOCKET NUMBER _____
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VII. CAUSE OF ACTION	Cite the U.S. Civil Statute under which you are filing and Write a Brief Statement of Cause (Do not cite jurisdictional statutes unless diversity): Rule 23 F.R.C.P (Medical Monitoring) LENGTH OF TRIAL via _____ days estimated (for both sides to try entire case)
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VIII. REQUESTED IN COMPLAINT:	<input checked="" type="checkbox"/> CHECK IF THIS IS A CLASS ACTION UNDER F.R.C.P. 23	DEMAND \$ _____ CHECK YES only if demanded in complaint: JURY DEMAND: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
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ABOVE INFORMATION IS TRUE & CORRECT TO THE BEST OF MY KNOWLEDGE	SIGNATURE OF ATTORNEY OF RECORD /s/ Steven R. Jaffe	DATE January 25, 2013
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FOR OFFICE USE ONLY

AMOUNT _____	RECEIPT # _____	IFP _____
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UNITED STATES DISTRICT COURT

for the

Southern District of Florida

BERNARD G. OWEN,

Plaintiff(s)

v.

HOWMEDICA OSTEONICS CORPORATION, d/b/a
STRYKER ORTHOPEDICS,

Defendant(s)

Civil Action No.

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* HOWMEDICA OSTEONICS CORPORATION,
d/b/a STRYKER ORTHOPEDICS,
THOUGH ITS REGISTERED AGENT, CT CORPORATION SYSTEM
1200 S. PINE ISLAND ROAD
PLANTATION FL 33324 US

A lawsuit has been filed against you.

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

Steven R. Jaffe, Esq.
FARMER, JAFFE, WEISSING, et al.
425 N. Andrews Ave., Suite 2
Fort Lauderdale, Florida 33301
Tel: 954-524-2820; Fax: 954-524-2822
Email: steve@pathtojustice.com

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

CLERK OF COURT

Date: _____

Signature of Clerk or Deputy Clerk

Civil Action No. _____

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

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

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

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

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

☐ I returned the summons unexecuted because _____ ; or

☐ Other *(specify)*: _____

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

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

Date: _____

Server's signature

Printed name and title

Server's address

Additional information regarding attempted service, etc: