UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA

Case No. _____
State Case No. 2012 CA 25899

JAIMIE M. SIMON,

Plaintiff,

vs.

HOWMEDICA OSTEOONICS CORPORATION, a New Jersey Corporation, d/b/a STRYKER ORTHOPAEDICS, and ORTHOPEDICS SOLUTIONS, INC. d/b/a STRYKER SOUTH FLORIDA AGENCY,

Defendants.
_____ /

DEFENDANT HOWMEDICA OSTEONICS CORP.'S NOTICE OF REMOVAL

Defendant Howmedica Osteonics Corp., which has at times done business as "Stryker Orthopaedics" (hereinafter "HOC"), hereby removes this action, which is currently pending in the Circuit Court of the Seventeenth Judicial Circuit, in and for Broward County, Florida, Case No. 2012 CA 25899, to the United States District Court for the Southern District of Florida, Fort Lauderdale Division. In support of this Notice of Removal, HOC states the following:

THE REMOVED CASE

1. The removed case is a civil action filed on September 4, 2012, in the Seventeenth Judicial Circuit, in and for Broward County, Florida, and captioned *Jaimie M. Simon, Plaintiff v. Howmedica Osteonics Corp d/b/a Stryker Orthopaedics and Orthopedic Solutions, Inc. d/b/a Stryker South Florida Agency, Defendants*, Case No. 2012 CA 25899.

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2. This medical device product liability action arises out of an injury allegedly sustained by Plaintiff in connection with the implantation of an artificial hip prosthesis designed and manufactured by HOC. *See* Complaint at ¶¶ 1, 10. Plaintiff's Complaint seeks to recover damages from HOC and Orthopedic Solutions, Inc. d/b/a Stryker South Florida Agency ("Orthopedic Solutions").

PAPERS FROM REMOVED ACTION

3. Pursuant to 28 U.S.C. § 1446(a), HOC attaches to this Notice of Removal a copy of all pleadings, orders and other papers or exhibits of every kind currently on file in the state court action. *See* Exhibit 1, attached hereto.

THE REMOVAL IS TIMELY

4. Plaintiff filed this action in the aforementioned state court on September 4, 2012. HOC was served with the Complaint on September 13, 2012. This notice of removal is timely filed. *See, e.g., Murphy Brothers, Inc. v. Michetti Pipe Stringing, Inc.*, 526 U.S. 344, 355 (1999) (removal time frame triggered by receipt of *formal* service; not receipt of complaint.). Accordingly, this Notice of Removal is timely filed under Title 28 U.S.C. § 1446(b).

VENUE IS PROPER

5. Venue is proper in the Fort Lauderdale Division of this Court because this action is being removed from the Seventeenth Judicial Circuit, in and for Broward County, Florida and the acts complained of in Plaintiff's Complaint are alleged to have occurred in Broward County, Florida. *See* Complaint at ¶ 5.

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DIVERSITY OF CITIZENSHIP EXISTS BETWEEN THE PROPERLY JOINED PARTIES

6. This is a civil action that falls under the Court's original jurisdiction under 28 U.S.C. § 1332 (diversity of citizenship) and is one that may be removed to this Court based on diversity of citizenship under 28 U.S.C. §§ 1441 and 1446.

7. At all times material hereto, Plaintiff, Jaimie M. Simon, was a resident and citizen of Palm Beach County, Florida. *See* Complaint at ¶ 4.

8. At all times material hereto, Defendant HOC is and was a New Jersey corporation with its principal place of business in New Jersey. *See* Complaint at ¶ 6.

9. Defendant Orthopedic Solutions is, and was at the time this action was filed, a Florida corporation with its principal place of business in Florida. *See* Complaint at ¶ 5. As set forth in greater detail below, Orthopedic Solutions is fraudulently joined and its presence in this action does not destroy diversity jurisdiction or prevent removal to this court. Its citizenship must, therefore, be disregarded for the purposes of diversity analysis. *See Tapscott v. MS Dealer Serv. Corp.*, 77 F.3d 1353, 1360 (11th Cir. 1996). Further, its consent as a fraudulently joined defendant is not required for purposes of removal. *See Diaz v. Kaplan Univ.*, 567 F. Supp. 2d 1394, 1402 (S.D. Fla. 2008).

10. Because Plaintiff is a citizen of Florida, and HOC, the properly joined Defendant, is not, complete diversity exists under 28 U.S.C. § 1332.

ORTHOPEDIC SOLUTIONS IS FRAUDULENTLY JOINED

11. In determining whether diversity jurisdiction exists, the Court must disregard the citizenship of fraudulently joined parties. *See Tapscott*, 77 F.3d at 1360; *Cabalceta v. Standard*

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Fruit Co., 883 F.2d 1553, 1561-62 (11th Cir. 1989). Fraudulent joinder is a judicially created doctrine that allows an exception to the requirement of complete diversity. *Triggs v. John Crump Toyota, Inc.*, 154 F.3d, 1284, 1287 (11th Cir. 1998). A defendant is fraudulently joined where there is no "reasonable basis" for a claim against him. *See Crowe v. Coleman*, 113 F.3d 1536, 1542 (11th Cir. 1997).

12. The Eleventh Circuit recognizes three types of fraudulent joinder: (1) where there is no possibility that the plaintiff can prove a cause of action against the resident defendant; (2) when there is outright fraud in the plaintiff's pleading of jurisdictional facts; and (3) where the claims against the non-diverse defendant have no real connection to the claims against the diverse defendants. *Triggs,* 154 F.3d at 1287. Here, there is no possibility that the Plaintiff can prove a cause of action against Orthopedic Solutions.

13. Courts have recognized that the "no possibility" standard "cannot be taken literally." *In re Rezulin Prods. Liab. Litig.*, 133 F.Supp. 2d 272, 280 n.4 (S.D.N.Y. 2001). In fact, numerous circuits have recognized that "the standard more accurately is described as requiring a showing that there is '*no reasonable basis*' for predicting liability on the claims alleged." *Id.* (emphasis added); *see Legg v. Wyeth*, 428 F.3d 1317, 1324-25 (11th Cir. 2005) (applying "reasonable basis" test); *Crowe*, 113 F.3d at 1540 (applying "arguably a reasonable basis" test) (internal quotation omitted); *Schwartz v. State Farm Mut. Auto. Ins. Co.*, 174 F.3d 875, 879 (7th Cir. 1999) (noting that it cannot "say that there is no possibility that a state court would someday" recognize plaintiff's liability theory, but upholding removal because that currently "is not a reasonable possibility"); *see also Woods v. Firestone Tire & Rubber Co.*, 560

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F. Supp. 588, 590 (S.D. Fla. 1983) (applying "arguably reasonable basis" test); *Anderson v. Allstate Life Ins. Co.*, No. 00-0958, 2001 WL 228057, *8 (S.D. Fla. Feb. 1, 2001) (same).

14. When a defendant puts forth evidence of fraudulent joinder, the burden then shifts to the plaintiff to rebut that evidence and show that a reasonable basis for a claim exists against the fraudulently joined defendant. *See Legg*, 428 F.3d at 1323-24. Plaintiff cannot do so by merely standing on the allegations in the complaint. *See id.* at 1323.

15. Regardless of the theory which liability is predicated upon, it is axiomatic that a plaintiff must establish that it has properly identified a defendant who has actually manufactured, sold, marketed or was in some way involved with the product which caused injury. *See Rivera v. Baby Trend, Inc.,* 914 So. 2d 1102, 1104-05 (Fla. 4th DCA 2005); *Siemens Energy & Automation, Inc. v. Medina,* 719 So. 2d 312, 315 (Fla. 3d DCA 1998); *Mahl v. Dade Pipe and Plumbing Supply Co.*, 546 So. 2d 740, 741 (Fla. 3d DCA 1989).

16. In this case, Plaintiff's Complaint alleges that the subject medical device, a Rejuvenate hip implant system, was distributed by Orthopedic Solutions. However, as evidenced by the affidavit of Frank Russo, the President of Orthopedic Solutions, attached hereto as Exhibit 2, Orthopedic Solutions has never participated in any way in the retailing, distributing, marketing and/or supplying of the Rejuvenate hip implant system. Affidavit of Frank Russo at ¶ 6. Orthopedic Solutions has not placed the Rejuvenate hip implant system into the stream of commerce or acted as a distributor of that product. *Id.* In particular, Orthopedic Solutions did not participate in any way in the design, manufacture, marketing, promotion, sale, supply, retailing, and distribution of the Rejuvenate hip implant system that was purportedly implanted in Plaintiff on September 12, 2011, nor did it act as a distributor for that device or place it into

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the stream of commerce. *Id.* at ¶ 7. Finally, Orthopedic Solutions has never done business as "Stryker South Florida Agency." *Id.* at ¶ 5.

17. Accordingly, Orthopedic Solutions should not be a party in this case and has been fraudulently joined. As a result, complete diversity of citizenship exists between the parties to this suit.

THE AMOUNT IN CONTROVERSY REQUIREMENT IS SATISFIED

18. Where, as here, the jurisdictional amount is not alleged, it can nevertheless be determined when it is "facially apparent" from the Complaint itself. *Williams v. Best Buy Co.*, 269 F.3d 1316, 1319 (11th Cir. 2001) (holding that district court may consider whether jurisdictional amount is "facially apparent" from the complaint). A court may also consider the removal notice and post-removal evidence concerning the amount in controversy. *See id.*; *see also Pretka v. Kolter City Plaza II, Inc.*, 608 F.3d 744, 768 (11th Cir. 2010) (holding that "the evidence the defendant may use to establish the jurisdictional facts is not limited to that which it received from the plaintiff or the court.") "[A] removing defendant is not required to prove the amount in controversy beyond all doubt or to banish all uncertainty about it." *Pretka*, 608 F.3d at 754. This is because "[t]he law does not demand perfect knowledge or depend any less on reasonable inferences and deductions than we all do in everyday life." *Id.*

19. Plaintiff seeks compensatory damages for alleged injuries arising out of alleged defects in the Rejuvenate hip implant system manufactured by HOC. The face of the Amended Complaint makes clear that Plaintiff seeks damages in excess of $75,000, for Plaintiff alleges the following injuries/damages:

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- Significant discomfort, device loosening, infection, malposition, a large pseudotumor, and heavy metal ion contamination. Complaint at ¶¶ 22-24.
- Multiple diagnostic workups and blood testing. *Id.* at ¶¶ 23-25.
- Revision surgery. *Id.* at ¶¶ 23-25.
- Inpatient rehabilitation. *Id.* at ¶ 26.
- "[S]evere physical pain and suffering, emotional distress, mental anguish, loss of the capacity for the enjoyment of life, medical and nursing expenses, surgical expenses, lost wages and loss of earning capacity." *Id.* at ¶ 60.
- "[S]erious damage to Plaintiff including bodily injury, . . . disability, physical impairment, disfigurement, . . . inconvenience, [and] aggravation of a preexisting condition." *Id.* at ¶¶ 76, 83, 90.

20. Far less specific allegations have been held to establish, on their face, that the amount in controversy exceeds the jurisdictional requirement. *See, e.g., Gebbia v. Wal-Mart Stores, Inc.*, 233 F.3d 880, 883 (5th Cir. 2000) (slip and fall case in which plaintiff sought damages for: "medical expenses, physical pain and suffering, mental anguish and suffering, loss of enjoyment of life, loss of wages and earning capacity and permanent disability and disfigurement"); *Estevez-Gonzalez v. Kraft, Inc.*, 606 F. Supp. 127, 129 (S.D. Fla. 1985) (unspecified personal injuries; plaintiffs sought damages for "physical and mental pain, physical handicap, impairment of working ability, injuries permanent or continuing in nature, and medical expenses"); *Baker v. Firestone Tire & Rubber Co.*, 537 F. Supp. 244, 247 (S.D. Fla. 1982) (exploding tire caused "permanent and serious injuries . . . pain, disfigurement, disability, loss of wages, loss of earning capacity and loss of the capacity for the enjoyment of life, and great

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expenses for future medical treatment"); *Lee v. Altamil Corp.*, 457 F. Supp. 979, 981 (M.D. Fla. 1978) (defective machine caused "serious permanent injury, 'substantial medical expenses,' 'great pain and suffering,' and a substantial loss of income").

21. Other federal courts, moreover, have concluded that the amount in controversy exceeded $75,000 ***in similar cases***, where the plaintiffs alleged injuries related to allegedly defective hip implants. In *Milter v. Wright Med. Group, Inc.*, No. 11-cv-1153, 2011 WL 4360024, *3 (E.D. Mich. Sept. 19, 2011), the Court held that the amount in controversy had been satisfied where plaintiff alleged injuries regarding an allegedly defective hip implant that he had received, including revision surgery, hospitalization, severe lytic lesions in the area of plaintiff's femur where the device had been implanted, premature loosening around the proximal femur, the corrosion of the metal components in defendants' device allegedly resulted in the presence of "extremely elevated levels of toxic metals" in plaintiff's blood, an extended period of disability, medical expenses, lost wages, and "much physical and mental pain and suffering." *Id; see also Bloodsworth v. Smith & Nephew*, No. 2:05CV622-D, 2005 WL 3470337, *2 (M.D. Ala. Dec. 19, 2005) (in hip implant product liability case, plaintiff stipulated that amount in controversy exceed $75,000); *Askew v. DC Med., LLC*, No. 1:11-CV-1245-WSD, 2011 WL 1811433, *1 (N.D. Ga. May 12, 2011) (plaintiff did not dispute that the amount in controversy in hip implant product liability action exceeded $75,000); *Oiler v. Biomet Orthopedics, Inc.*, No. CIV.A. 02-3778, 2003 WL 22174285, *1 (E.D. La. Sept. 17, 2003) (denying remand in a hip implant product liability case where defendants had successfully argued that "it was facially apparent that the amount in controversy exceeds $75,000.00 exclusive of interest and costs").

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22. Thus, the state court action may be removed to this Court by HOC in accordance with the provisions of 28 U.S.C. § 1441(a) because (i) this action is a civil action pending within the jurisdiction of the United States District Court for the Southern District of Florida; (ii) excluding the fraudulently joined defendants, this action is between citizens of different states; (iii) the amount in controversy exceeds $75,000, exclusive of interest and costs.

FILING OF REMOVAL PAPERS

23. Pursuant to 28 U.S.C. § 1446(d), written notice of the removal of this action will be promptly served to Plaintiff's counsel.

25. Concurrent with the filing of this Notice of Removal, HOC has filed a Notice of Filing the Notice of Removal, including a true and correct copy of the Notice of Removal with the Clerk of the Circuit Court of the Seventeenth Judicial Circuit, in and for Broward County, Florida. *See* Exhibit 3, attached hereto.

26. The undersigned counsel is authorized by HOC to file this Notice of Removal, is licensed in the State of Florida and is a member in good standing of the Bar of this Court.

WHEREFORE, Defendant Howmedica Osteonics Corp. hereby removes the above-captioned action from the Circuit Court of the Seventeenth Judicial Circuit in and for Broward County, Florida, and request that further proceedings be conducted in this Court as provided by law.

Respectfully submitted,

s/ Hildy M. Sastre
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Attorneys for Defendant
Howmedica Osteonics Corp.

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on this 2nd day of October, 2012, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system and a true and correct copy was served by CM/ECF, email and U.S. Mail on all counsel of record identified below:

Jesse N. Bernheim
Florida Bar No. 0525421
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/s/ Iain L. C. Kennedy
Iain L. C. Kennedy
Florida Bar No. 96668

JS 44 (Rev. 09/11)

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
JAIMIE M. SIMON

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

(c) Attorneys *(Firm Name, Address, and Telephone Number)*
JESSE N. BERNHEIM, 101 NE THIRD AVENUE, SUITE 1410, FT. LAUDERDALE, FL 33301 (954) 573-6688

DEFENDANTS
HOWMEDICA OSTEONICS CORPORATION, a New Jersey Corporation, d/b/a STRYKER ORTHOPAEDICS, and ORTHOPEDIC SOLUTIONS, INC. d/b/a STRYKER SOUTH FLORIDA AGENCY

County of Residence of First Listed Defendant BERGEN, NEW JERSEY
(IN U.S. PLAINTIFF CASES ONLY)

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

Attorneys *(If Known)*
HILDY M. SASTRE, 201 S. BISCAYNE BLVD., SUITE 3200, MIAMI, FL 33133 (305) 358-5171 (for HOWMEDICA OSTEONICS CORP. only)

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) (For Diversity Cases Only) and One Box for Defendant)*

	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 (Excl. 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 - Med. 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
- ☐ 510 Motions to Vacate Sentence

Habeas Corpus:
- ☐ 530 General
- ☐ 535 Death Penalty
- ☐ 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/Mgmt. Relations
- ☐ 740 Railway Labor Act
- ☐ 751 Family and Medical Leave Act
- ☐ 790 Other Labor Litigation
- ☐ 791 Empl. Ret. Inc. Security Act

IMMIGRATION
- ☐ 462 Naturalization Application
- ☐ 463 Habeas Corpus - Alien Detainee (Prisoner Petition)
- ☐ 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:
Medical Device Product Liability

VII. REQUESTED IN COMPLAINT:

☐ CHECK IF THIS IS A **CLASS ACTION** UNDER F.R.C.P. 23

DEMAND $

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

VIII. RELATED CASE(S) IF ANY *(See instructions):* JUDGE _____ DOCKET NUMBER _____

DATE
10/02/2012

SIGNATURE OF ATTORNEY OF RECORD

FOR OFFICE USE ONLY

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

JS 44 Reverse (Rev. 09/11)

INSTRUCTIONS FOR ATTORNEYS COMPLETING CIVIL COVER SHEET FORM JS 44

Authority For Civil Cover Sheet

The JS 44 civil cover sheet and the information contained herein neither replaces nor supplements the filings and service of pleading or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. Consequently, a civil cover sheet is submitted to the Clerk of Court for each civil complaint filed. The attorney filing a case should complete the form as follows:

I. (a) Plaintiffs-Defendants. Enter names (last, first, middle initial) of plaintiff and defendant. If the plaintiff or defendant is a government agency, use only the full name or standard abbreviations. If the plaintiff or defendant is an official within a government agency, identify first the agency and then the official, giving both name and title.

(b) County of Residence. For each civil case filed, except U.S. plaintiff cases, enter the name of the county where the first listed plaintiff resides at the time of filing. In U.S. plaintiff cases, enter the name of the county in which the first listed defendant resides at the time of filing. (NOTE: In land condemnation cases, the county of residence of the "defendant" is the location of the tract of land involved.)

(c) Attorneys. Enter the firm name, address, telephone number, and attorney of record. If there are several attorneys, list them on an attachment, noting in this section "(see attachment)".

II. Jurisdiction. The basis of jurisdiction is set forth under Rule 8(a), F.R.C.P., which requires that jurisdictions be shown in pleadings. Place an "X" in one of the boxes. If there is more than one basis of jurisdiction, precedence is given in the order shown below.

United States plaintiff. (1) Jurisdiction based on 28 U.S.C. 1345 and 1348. Suits by agencies and officers of the United States are included here.

United States defendant. (2) When the plaintiff is suing the United States, its officers or agencies, place an "X" in this box.

Federal question. (3) This refers to suits under 28 U.S.C. 1331, where jurisdiction arises under the Constitution of the United States, an amendment to the Constitution, an act of Congress or a treaty of the United States. In cases where the U.S. is a party, the U.S. plaintiff or defendant code takes precedence, and box 1 or 2 should be marked.

Diversity of citizenship. (4) This refers to suits under 28 U.S.C. 1332, where parties are citizens of different states. When Box 4 is checked, the citizenship of the different parties must be checked. (See Section III below; federal question actions take precedence over diversity cases.)

III. Residence (citizenship) of Principal Parties. This section of the JS 44 is to be completed if diversity of citizenship was indicated above. Mark this section for each principal party.

IV. Nature of Suit. Place an "X" in the appropriate box. If the nature of suit cannot be determined, be sure the cause of action, in Section VI below, is sufficient to enable the deputy clerk or the statistical clerks in the Administrative Office to determine the nature of suit. If the cause fits more than one nature of suit, select the most definitive.

V. Origin. Place an "X" in one of the seven boxes.

Original Proceedings. (1) Cases which originate in the United States district courts.

Removed from State Court. (2) Proceedings initiated in state courts may be removed to the district courts under Title 28 U.S.C., Section 1441. When the petition for removal is granted, check this box.

Remanded from Appellate Court. (3) Check this box for cases remanded to the district court for further action. Use the date of remand as the filing date.

Reinstated or Reopened. (4) Check this box for cases reinstated or reopened in the district court. Use the reopening date as the filing date.

Transferred from Another District. (5) For cases transferred under Title 28 U.S.C. Section 1404(a). Do not use this for within district transfers or multidistrict litigation transfers.

Multidistrict Litigation. (6) Check this box when a multidistrict case is transferred into the district under authority of Title 28 U.S.C. Section 1407. When this box is checked, do not check (5) above.

Appeal to District Judge from Magistrate Judgment. (7) Check this box for an appeal from a magistrate judge's decision.

VI. Cause of Action. Report the civil statute directly related to the cause of action and give a brief description of the cause. **Do not cite jurisdictional statutes unless diversity**. Example: U.S. Civil Statute: 47 USC 553
Brief Description: Unauthorized reception of cable service

VII. Requested in Complaint. Class Action. Place an "X" in this box if you are filing a class action under Rule 23, F.R.Cv.P.

Demand. In this space enter the dollar amount (in thousands of dollars) being demanded or indicate other demand such as a preliminary injunction.

Jury Demand. Check the appropriate box to indicate whether or not a jury is being demanded.

VIII. Related Cases. This section of the JS 44 is used to reference related pending cases if any. If there are related pending cases, insert the docket numbers and the corresponding judge names for such cases.

Date and Attorney Signature. Date and sign the civil cover sheet.

JS 44 (Rev. 2/08)

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 THE REVERSE OF THE FORM.) **NOTICE: Attorneys MUST Indicate All Re-filed Cases Below.**

I. (a) PLAINTIFFS

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

(c) Attorney's (Firm Name, Address, and Telephone Number)

DEFENDANTS

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)

(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)

- ❒ 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 (Excl. 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

PERSONAL INJURY
- ❒ 362 Personal Injury - Med. Malpractice
- ❒ 365 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
- ❒ 441 Voting
- ❒ 442 Employment
- ❒ 443 Housing/ Accommodations
- ❒ 444 Welfare
- ❒ 445 Amer. w/Disabilities - Employment
- ❒ 446 Amer. w/Disabilities - Other
- ❒ 440 Other Civil Rights

PRISONER PETITIONS
- ❒ 510 Motions to Vacate Sentence

Habeas Corpus:
- ❒ 530 General
- ❒ 535 Death Penalty
- ❒ 540 Mandamus & Other
- ❒ 550 Civil Rights
- ❒ 555 Prison Condition

FORFEITURE/PENALTY
- ❒ 610 Agriculture
- ❒ 620 Other Food & Drug
- ❒ 625 Drug Related Seizure of Property 21 USC 881
- ❒ 630 Liquor Laws
- ❒ 640 R.R. & Truck
- ❒ 650 Airline Regs.
- ❒ 660 Occupational Safety/Health
- ❒ 690 Other

LABOR
- ❒ 710 Fair Labor Standards Act
- ❒ 720 Labor/Mgmt. Relations
- ❒ 730 Labor/Mgmt.Reporting & Disclosure Act
- ❒ 740 Railway Labor Act
- ❒ 790 Other Labor Litigation
- ❒ 791 Empl. Ret. Inc. Security Act

IMMIGRATION
- ❒ 462 Naturalization Application
- ❒ 463 Habeas Corpus-Alien Detainee
- ❒ 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
- ❒ 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
- ❒ 810 Selective Service
- ❒ 850 Securities/Commodities/ Exchange
- ❒ 875 Customer Challenge 12 USC 3410
- ❒ 890 Other Statutory Actions
- ❒ 891 Agricultural Acts
- ❒ 892 Economic Stabilization Act
- ❒ 893 Environmental Matters
- ❒ 894 Energy Allocation Act
- ❒ 895 Freedom of Information Act
- ❒ 900 Appeal of Fee Determination Under Equal Access to Justice
- ❒ 950 Constitutionality of State Statutes

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).

(See instructions second page): a) Re-filed Case ❒ YES ❒ NO b) Related Cases ❒ YES ❒ NO

JUDGE DOCKET NUMBER

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)**:

LENGTH OF TRIAL via _____ days estimated (for both sides to try entire case)

VIII. REQUESTED IN COMPLAINT:

❒ CHECK IF THIS IS A **CLASS ACTION** UNDER F.R.C.P. 23

DEMAND $

CHECK YES only if demanded in complaint:

JURY DEMAND: ❒ Yes ❒ No

ABOVE INFORMATION IS TRUE & CORRECT TO THE BEST OF MY KNOWLEDGE

SIGNATURE OF ATTORNEY OF RECORD DATE

FOR OFFICE USE ONLY

AMOUNT _____ RECEIPT # _____ IFP _____

EXHIBIT 1

CASE DETAIL

Broward County Case Number: **CACE12025899**
Court Type: **Civil Division - Circuit Court**
Incident Date: **N/A**
Court Location: **Central Courthouse**
Magistrate ID / Name: **N/A**

State Reporting Number: **062012CA025899AXXXCE**
Case Type: **Products Liability**
Filing Date: **09/13/2012**
Case Status: **Pending**
Judge ID / Name: **18 Singer, Michele Towbin**

Style: **Jamie Simon Plaintiff vs. Howmedica Osteonics Corp, et al Defendant**

Party(ies)	Disposition(s)	Event(s)

Expand All Collapse All

[-] **Party Detail**

Party Type	Party Name	Address (Per AOSC07-49, only the addresses of counsel can be displayed.)	Attorneys / Address ★ Denotes Lead Attorney (Per FL Bar Rule 1-3.3, the most current attorney contact information can be found on the Florida Bar website.)
Plaintiff	**Simon, Jamie M**		★ Bernheim, Jesse N Retained 3636 W Flagler St Miami, FL 33135-0000
Defendant	**Howmedica Osteonics Corp** *Doing Business As* ***Stryker Orthopaedics***		
Defendant	**Orthopedic Solutions Inc** *Doing Business As* ***Stryker South Fl Agency***		

[-] **Disposition Detail**

There is no disposition information available for this case.

[-] **Events, Hearings and Orders of the Court**

Date	Description	Additional Text
09/13/2012	**Summons Issued**	hb Party: *Defendant* Howmedica Osteonics Corp *Defendant* Orthopedic Solutions Inc
09/13/2012	**Civil Cover Sheet**	
09/13/2012	**Complaint**	
09/13/2012	**Filing Fee**	Payor: BERNHEIM, JESSE N ; Userid: CTS-dlewis ; Receipt: 20121YE1A006239; ; Amount: $401.00
09/13/2012	**Summons Issued Fee**	Payor: BERNHEIM, JESSE N ; Userid: CTS-dlewis ; Receipt: 20121YE1A006239; ; Amount: $20.00

Perform Another Search | Back

Clicking the button above, exits your paid search.

IN THE CIRCUIT COURT OF THE 17TH
JUDICIAL CIRCUIT IN AND FOR
BROWARD COUNTY, FLORIDA

GENERAL JURISDICTION DIVISION

CASE NO.: 12-25899

JAIMIE M. SIMON

Plaintiff,

vs.

HOWMEDICA OSTEOONICS CORPORATION, a New Jersey Corporation, d/b/a STRYKER ORTHOPAEDICS, and ORTHOPEDICS SOLUTIONS, INC. d/b/a STRYKER SOUTH FLORIDA AGENCY,

Defendants.
_____/

SUMMONS

18

scg
9/13/12
1:12pm
CR#795

THE STATE OF FLORIDA

To all Singular Sheriffs of the state:

YOU ARE HEREBY COMMANDED to serve this Summons and Complaint in this action on the Defendant, HOWMEDICA OSTEONICS CORPORATION d/b/a STRYKER ORTHOPAEDICS

By Serving:

CT Corporation System, as Registered Agent
1200 S. Pine Island Road
Plantation, FL 33324

Service shall be made pursuant to Florida Statute 48.081 in the following manner: On the registered agent designated by the Corporation. However, if service cannot be made on the registered Agent because of failure to keep the registered office open from 10:00 a.m. to 12:00 noon each day except Saturdays, Sundays, and legal holidays, or because the Corporation's failure to keep one or more Registered Agents on whom process may be served at the office during these hours, pursuant to Florida Statute 48.091, then service of process may be made on any employee at the corporation's place of business.

Defendant is required to serve written defenses to the Petition on Jesse N. Bernheim, Esq., Kelley, Bernheim & Dolinsky, L.L.C., 101 NE Third Avenue, Suite 1410, Ft. Lauderdale, Florida, 33301, Telephone 954-894-5900), within twenty (20) days of service of this Summons,

and to file the original of the defenses with the Clerk of the Court either before service on Plaintiff's attorneys or immediately thereafter. If a Defendant fails to do so, a default will be entered against the Defendant for relief demanded in this Petition.

SEP 13 2012

Witness my hand and official seal of this Court on this _____ day of Sep[illegible] HOWARD C. FORMAN

CLERK OF THE CIRCUIT COURT
as Clerk of said Court

By:
DEPUTY CLERK

DEBORAH A. LEWIS

A TRUE COPY
Circuit Court Seal

IN THE CIRCUIT COURT OF THE
17TH JUDICIAL CIRCUIT IN AND FOR
BROWARD COUNTY, FLORIDA

GENERAL JURISDICTION DIVISION

CASE NO. 12-25899

18

JAIMIE M. SIMON

Plaintiff,

VS.

HOWMEDICA OSTEONICS CORPORATION, a New Jersey Corporation, d/b/a STRYKER ORTHOPAEDICS, and ORTHOPEDIC SOLUTIONS, INC., d/b/a STRYKER SOUTH FLORIDA AGENCY

Defendants.

_____/

A TRUE COPY
SEP 04 2012
HOWARD C. FORMAN
CLERK OF CIRCUIT COURT
BROWARD COUNTY, FL

COMPLAINT FOR DAMAGES

COMES NOW Plaintiff, JAIMIE M. SIMON by and through the undersigned counsel, and bring their complaint against Defendant, Howmedica Osteonics Corporation, and Orthopedic Solutions, Inc. and alleges as follows:

1. This is an action for damages relating to Defendants development, testing, assembling, manufacture, packaging, labeling, preparing, distribution, marketing, supplying, and/or selling the defective product sold under the name "The Rejuvenate® System" (hereinafter "Rejuvenate" or "Defective Device").

PARTIES, JURISDICTION AND VENUE

2. That this is an action for damages in excess of $15,000.00 and this Court has jurisdiction over this matter.

3. That all conditions precedent have been performed and/or are excused.

4. At all times relevant to this cause of action, Plaintiff, JAIMIE SIMON, ("Plaintiff") is a resident of West Palm Beach, Palm Beach County, Florida and is competent to bring this action.

5. Venue in this action properly lies in the County of Broward in the State of Florida as the Defendant Orthopedic Solutions, Inc. is a Florida company organized under the laws of the state of Florida with its principle place of business in Broward County, Florida. All medical care and treatment relevant hereto took place in Broward County, Florida.

6. Defendant, Howmedica Osteonics Corporation, (hereinafter "HOWMEDICA"), d/b/a STRYKER ORTHOPAEDICS, is a corporation organized and existing under the laws of New Jersey having its principal place of business located at 325 Corporate Drive, Mahwah, New Jersey 07430 and conducts business throughout the United States including in the State Florida..

7. Defendant Orthopedic Solutions, Inc. (hereinafter "Orthopedic Solutions") d/b/a Stryker South Florida Agency, is a corporation organized and existing under the laws of the state of Florida with its principle place of business located at 505 NW 65th Court, #102, Ft. Lauderdale, FL 33309 and conducts business in the state of Florida.

8. Defendant HOWMEDICA is conclusively presumed to have been doing business in this state and is subject to Florida's long arm jurisdiction.

9. At all relevant times, Defendants expected or should have expected that its acts and omissions would have consequences within the United States and the State of Florida

THE PRODUCT

10. At all times material hereto, Defendant Howmedica developed, tested, assembled, manufactured, packaged, labeled, prepared, distributed, marketed, supplied, and/or sold the defective product sold under the name "The Rejuvenate ® System" (hereinafter "Rejuvenate System" or "Defective Device"), either directly or indirectly, to members of the general public within the the State of Florida and elsewhere, including Plaintiff, Jaimie Simon.

11. At all times material hereto, Defendant Orthopedic Solutions was engaged in the retailing, distributing, marketing and/or supplying The Rejuvenate ® System, either directly or indirectly, to members of the general public within the State of Florida, including Plaintiff.

12. Upon information and belief, in or about September 2011, Plaintiff's physician contacted the Operating Room Coordinator at Holy Cross Hospital and directed the hospital to order the Rejuvenate System for the Plaintiff's surgery.

13. Upon information and belief, in or about September 2011, the Operating Room Coordinator at Holy Cross Hospital contacted Defendant Orthopedic Solutions, distributor of Defendant Howmedica's Rejuvenate System and ordered the device for Plaintiff's surgery.

14. Upon information and belief, Defendant Orthopedic Solutions delivered the Rejuvenate System to Plaintiff's physician at Holy Cross Hospital for Plaintiff's surgery.

15. Defendants' Defective Device was placed into the stream of interstate commerce and was implanted in Plaintiff Jaimie Simon on September 12, 2011 by Dr. William Leone during total right hip replacement.

16. As a direct and proximate result of Defendant placing the Defective Product into the stream of commerce, Plaintiff Jaimie Simon has suffered and continues to suffer both injuries and damages, including but not limited to: past, present and future physical and mental pain and

suffering; and past, present and future medical, hospital, rehabilitative and pharmaceutical expenses, and other related damages.

17. On June 3, 2008, Defendant received FDA clearance to sell its Rejuvenate System in the United States. Sometime during the first week of July, 2012, the Defendant issued a voluntary worldwide recall of both the Rejuvenate and ABG II hip replacement systems.

18. The Rejuvenate System is a modular hip replacement prosthesis. It is indicated for patients requiring primary total hip arthroplasty or replacement due to painful disabling joint disease of the hip resulting from non-inflammatory degenerative arthritis.

19. Unlike most prosthetic hip implants, the Rejuvenate System is an artificial hip replacement device consisting of two basic components: a chrome cobalt neck that is inserted into a titanium stem. The System can be used with any number of bearing surface components comprised of the ball or artificial femoral head and an acetabular cup or socket.

20. The titanium stem is manufactured utilizing a proprietary titanium alloy consisting of titanium, molybdenum, zinc and iron. Their alloy was designed and patented by Defendant and is unlike any titanium alloy employed in the manufacture of other prosthetic hip implants. The Defendant claims in its promotional materials for the Rejuvenate system that their alloy is both stronger and less rigid than other titanium alloys. It also claims that the particular titanium alloy has been tested and proven by Defendant to resist the effects of corrosion and fretting.

21. At all times material hereto, the Rejuvenate stem and neck implanted in the Plaintiff Jaimie Simon was designed, manufactured, marketed, distributed and/or supplied by Defendants.

22. After the implantation of the Defective Device, Plaintiff Jaimie Simon began experiencing significant discomfort in the area of her Defective Device.

23. Diagnostic workup revealed the absence of device loosening, infection, malposition or any other explanation for the Plaintiff's symptoms.

24. Further diagnostic workup revealed the presence of pseudo tumor and the potential existence of a significant fluid collection anterior to joint adjacent to iliopsoas bursa and along the posterior superior acetabulum related to pseudobursa. Blood testing revealed the presence of heavy metal ion contamination.

25. Based upon these findings and in light of the Plaintiff's worsening symptoms, revision surgery was scheduled for September 10, 2012 at Holy Cross Hospital by Dr. William Leone. During that surgery, fretting and corrosion of the device was confirmed as was the presence of a large pseudotumor.

26. Plaintiff is currently undergoing inpatient rehabilitation.

THE STRYKER REJUVENATE HISTORY

27. In February 2009, Stryker released its Rejuvenate Modular Primary Hip System, the latest evolution in the Company's OmniFit and Secure• Fit Hip systems, which was approved for market by the FDA on June 3, 2008. The Rejuvenate Modular hip is an extension of the Stryker Modular Hip, which was approved for market by the FDA on September 13, 2007.

28. According to Stryker's materials, the Rejuvenate Modular Primary Hip System was developed to optimize anatomic restoration by providing options that offer enhanced stability, proven modularity and intra-operative flexibility. With a wide range of femoral stem and neck combinations and an extensive range of length, version and offset, the Rejuvenate

Modular Primary Hip System was marketed to enable surgeons to better personalize the implant to a patient's unique anatomy.

29. The system is comprised of separate femoral stem and neck components and offers a variety of sizing options intra-operatively. The benefit, according to Stryker, was that by allowing the surgeon to independently manage leg length, neck version, and femoral offset, the system provides surgeons the ability to better personalize the biomechanics of a patient's hip replacement.

30. The Rejuvenate System combines the material characteristics of TMZF (Ti-12Mo-6Zr-2Fc) with a plasma sprayed coating of commercially pure Ti and PureFix HA for the stem and CoCr for the neck. Defendant claims that laboratory testing demonstrates the compatibility of these materials without concern for fretting and corrosion.

31. Despite Defendants' claims, this material combination has been reported to cause corrosion. Since the 1980's medical and scientific literature has reported corrosion to be a problem when Ti and CoCr have been used at modular junctions. In its marketing and sale of the device, Stryker represented and warranted that its proprietary materials alleviate this problem.

32. The Defendant Howmedica holds two patents for modular implant devices. Currently, the Defendant has a pending application to patent a modular hip prosthesis similar to the Rejuvenate System.

URGENT SAFETY NOTICES AND RECALLS

33. In April, 2012, Defendant issued an Urgent Field Safety Notice to surgeons and hospitals in the United States.

34. In this notice, Defendant acknowledged that it had received reports of device failure due to heavy metal contamination. The Notice specifically referred to failures at the taper neck junction between the neck and stem due to corrosion and fretting.

35. This corrosion and fretting was exactly the same failure mechanism that Defendant had warranted would not occur because of the Rejuvenate's design and composition. It was also exactly the same failure mechanism that the medical and scientific community had been studying and documenting in modular device design since the 1980's.

36. The Notice went on to describe symptoms and findings identical to those experienced by Plaintiff.

37. Among those specifically mentioned in the Notice were tissue necrosis, metallosis, adverse soft tissue reaction and pseudotumor formation.

38. Almost immediately following the Notice, Defendant issued a voluntary recall of the Stryker Rejuvenate and ABGII in Canada. In the recall notice, Defendant stated that it was amending the Instructions for Use for the device to include warnings that Defendant was on notice of the issues described in the Notice above.

39. Finally, in the first week of July, 2012, Defendant issued a voluntary recall of all Stryker Rejuvenate and ABG II stems. As part of the recall notice, Defendant once again cited reports of device failure due to heavy metal fretting and corrosion.

THE FEDERAL REQUIREMENTS

40. Federal regulation states "Recall means a firm's removal or correction of a marketed product that the Food and Drug Administration considers to be in violation of the laws it administers and against which the agency would initiate legal action, e.g. seizure." See 21 CFR §7.3(g).

41. Federal regulation states: "Recall classification means the numerical designation, i.e., I, II or III, assigned by the Food and Drug Administration to a particular product recall to indicate the relative degree of health hazard presented by the product being recalled." See 21 CFR §7.3 (m).

42. Federal regulation states: "Class II is a situation in which use of, or exposure to, a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote." See 21 CFR §7.3 (m).

43. The classification of the product withdrawals and corrections of the Defendant's devices (described above) as Class II Recalls by the FDA confirms by definition that the devices were in violation of federal law and that initiation of legal action or seizure would be indicated for these devices.

44. Pursuant to federal law, a device is deemed to be adulterated if, among other things, it fails to meet established performance standards, or if the methods, facilities or controls used for its manufacture, packing, storage or installation are not in conformity with federal requirements. Sec 21 U.S.C. §351.

45. Pursuant to federal law, a device is deemed to be misbranded if, among other things, its labeling is false or misleading in any particular manner, or if it is dangerous to health when used in the manner prescribed, recommended or suggested in the labeling thereof. See 21 U.S.C. §352.

46. Pursuant to federal law, manufacturers are required to comply with FDA regulation of medical devices, including FDA requirements for records and reports, in order to prohibit introduction of medical devices that are adulterated or misbranded, and to assure the safety and effectiveness of medical devices. In particular, manufacturers must keep records and

make reports if any medical device that may have caused or contributed to death or serious injury, or if the device has malfunctioned in a manner likely to cause or contribute to death or serious injury.

47. Federal law also mandates that the FDA establish regulations requiring a manufacturer of a medical device to report promptly to FDA any correction or removal of a device undertaken to reduce a risk to health posed by the device, or to remedy a violation of federal law by which a device may present a risk to health. See 21 U.S.C. §360(i).

48. Pursuant to FDA regulation, adverse events associated with a medical device must be reported to FDA within 30 days after the manufacturer becomes aware that a device may have caused or contributed to death or serious injury, or that a device has malfunctioned and would be likely to cause or contribute to death or serious injury if the malfunction was to recur. Such reports must contain all information reasonably known to the manufacturer, including any information that can be obtained by analysis, testing, or other evaluation of the device, and any information in the manufacturer's possession. In addition, manufacturers are responsible for conducting an investigation of each adverse event, and must evaluate the cause of the adverse event. See 21 CFR §803.50.

49. Pursuant to federal regulation, manufacturers of medical devices must also describe in every individual adverse event report whether remedial action was taken in regard to the adverse event, and whether the remedial action was reported to FDA as a removal or correction of the device. See 21 CFR §803.52.

50. Pursuant to federal regulation, manufacturers must report to FDA in 5 business days after becoming aware of any reportable MDR event or events, including a trend analysis

that necessitates remedial action to prevent an unreasonable risk of substantial harm to the public health. Sec 21 CFR §803.53.

51. Pursuant to federal regulation, device manufacturers must report promptly to FDA any device corrections and removals, and maintain records of device corrections and removals. FDA regulations require submission of a written report within ten working days of any correction or removal of a device initiated by the manufacturer to reduce a risk to health posed by the device, or to remedy a violation of the ACI caused by the device, which may present a risk to health. The written submission must contain, among other things, a description of the event giving rise to the information reported and the corrective or removal actions taken, and any illness or injuries that have occurred with use of the device, including reference to any device report numbers. Manufacturers must also indicate the total number of devices manufactured or distributed which are subject to the correction or removal and provide a copy of all communications regarding the correction or removal. See 21 CFR §806.

52. Pursuant to federal regulation, manufacturers must comply with specific quality system requirements promulgated by FDA. These regulations require manufacturers to meet design control requirements, including but not limited to conducting design validation to ensure that devices conform to defined user needs and intended uses. Manufacturers must also meet quality standards in manufacture and production. Manufacturers must establish and maintain procedures for implementing corrective actions and preventive actions, and investigate the cause of nonconforming products and take corrective action to prevent recurrence. Manufacturers are also required to review and evaluate all complaints and determine whether an investigation is necessary. Manufacturers are also required to use statistical techniques where necessary to evaluate product performance. See 21 CFR §820.

53. Pursuant to federal regulation, a manufacturer must report to the FDA any new indications for use of a device, labeling changes, or changes in the performance or design specifications, circuits, components, ingredients, principle of operation or physical layout of the device. Federal regulations require that: "A PMA supplement must be submitted when unanticipated adverse effects, increases in the incidence of anticipated adverse effects, or device failures necessitate a labeling, manufacturing, or device modification."

54. Specifically, it is believed that with respect to the Rejuvenate System, Defendant failed to timely report adverse events, failed to timely conduct failure investigations and analysis, failed to timely report any and all information concerning product failures and corrections, failed to timely and fully inform FDA of unanticipated adverse effects, increases in the incidence of adverse effects, or device failures necessitating a labeling, manufacturing or device modification, failed to conduct necessary design validation, and sold a misbranded and adulterated product.

CAUSES OF ACTION

COUNT 1- NEGLIGENCE

55. Plaintiff realleges and incorporates by reference the allegations set forth above.

56. Defendants designed, manufactured, marketed, detailed, and advertised both to physicians and consumers the Rejuvenate System.

57. As a result, Defendants had a duty to perform each of these functions reasonably and with reasonable and due care for the safety and well-being of patients in whom the devices would be implanted.

58. Defendants failed to use reasonable and due care for the safety and well-being of those in whom the device would be implanted and is, therefore, negligent in the following respects:

a. Defendants failed to adequately design and manufacture the device to insure that it would not corrode, erode, deteriorate and induce severe metal toxicity in the patient. The flaws include but are not limited to:

i. The incompatibility of the TMZF titanium with other device components;

ii. Poor design of the taper neck junction between stem and neck such that micro motion was predictable;

iii. Poor manufacturing practices such that the taper neck junction between the neck and stem do not "fit" the way they were intended;

iv. A combination of the above factors leads to rapid, severe heavy metal cast off causing soft tissue and bony necrosis, pain and premature failure of the device.

b. Defendants failed to adequately test the device to insure that it would not corrode, erode, deteriorate and induce severe metal toxicity in the patient;

c. Defendants failed to conduct anything other than bench testing so that when manufactured and marketed, patients became in essence Defendant's first clinical trial;

d. Defendants made affirmative representations that the device would not fret or corrode in the human body. These representations were false and misleading to both physicians and the consumer;

e. Defendants trained its sales force to detail the device utilizing representations that the Defendants knew or should have known were false, creating in the minds of both surgeons and consumers that the device would not cause metal toxicity;

f. Defendants specifically marketed the device as a safe alternative to metal-on-metal bearing surface devices that had been widely publicized as capable of causing premature failure due to heavy metal toxicity;

g. Defendants marketed this device as a "perfect fit" for younger patients due to its modular design, creating in the minds of physicians and consumers that the device was superior to other available hip implants when, in fact, the device was so poorly designed, constructed and tested that it had to be recalled from the market only three years after it was introduced;

h. Defendants failed to manufacture the product to Defendants' own internal specifications such that the taper neck junction between the neck and stem prematurely failed causing metal debris cast-off and severe metal toxicity in patients;

i. Defendants failed to adequately test the TMZF alloy's compatibility with chrome cobalt components in an effort to prevent corrosion and fretting at the neck/stem taper neck junction of this modular device;

J. Defendants failed to promptly act upon reports of early failure such that the device continued to be implanted in unknowing patients by surgeons well after it should have been recalled;

k. Defendants chose as its predicate device a system that had known disastrous failures, had to be redesigned and is the subject of protracted litigation;

l. Defendants were on actual notice prior to marketing the Rejuvenate and ABG II that its TMZF titanium alloy performed poorly when mated with its chrome cobalt components. Defendant knew when it introduced the Rejuvenate System to the market that the Stryker

Accolade device, that was also a TMZF product, was having corrosion, fretting and failure issues at the taper neck junction between the neck and chrome cobalt head ball. Nevertheless, Defendants either suppressed or ignored the reports and marketed the Rejuvenate System anyway, knowing that these two dissimilar metals were performing poorly in the market.

59. The above conduct exhibits Defendants' failure to exercise reasonable care. It was foreseeable that such negligence would lead to premature device failure as well as severe, debilitating injuries that were permanent.

60. As a direct an proximate result of the Defendants' negligence, Plaintiff suffered severe physical pain and suffering, emotional distress, mental anguish, loss of the capacity for the enjoyment of life, medical and nursing expenses, surgical expenses, lost wages and loss of earning capacity. These damages have occurred in the past and will continue into the future.

WHEREFORE, Plaintiff respectfully requests that they be granted relief against Defendants, as contained in the Prayer For Relief.

COUNT II -BREACH OF EXPRESS WARRANTY

61. Plaintiff realleges and incorporates by reference the allegations set forth above as if set forth herein.

62. Through their public statements, their descriptions of the Rejuvenate System and their promises relating to the Rejuvenate System, Defendants expressly warranted among other things that the Rejuvenate System was efficacious and safe for its intended use; was designed and constructed of materials that would prevent fretting and corrosion; would last longer than competing acetabular devices; and was more suitable for younger adults that other devices given its purported longevity.

63. These warranties came in the form of (i) publicly made written and verbal assurances of safety; (ii) press releases and dissemination via the media of uniform promotional information that was intended to create demand for the Rejuvenate System, but which contained material misrepresentations and utterly failed to warn of the risks of the Rejuvenate System; (iii) verbal assurances made by Defendants' consumer relations personnel to the public about the safety of the Rejuvenate System and the down playing of the risks associated with the Rejuvenate System; (iv) false and misleading written information supplied by Defendants.

64. The most prominent representation made by Defendants was on its website where it expressly warranted that the design, testing and materials utilized in the Rejuvenate System would prevent fretting and corrosion

65. Plaintiff further allege that all of the aforementioned written materials are known to Defendants and in its possession, and it is Plaintiff's' reasonable belief that these materials shall be produced by Defendants and be made of record once Plaintiff is afforded the opportunity to conduct discovery.

66. When Defendants made these express warranties, Defendants knew the purpose for which Rejuvenate System was to be used and warranted it to be in all respects safe and proper for such purpose.

67. Defendants drafted the documents and/or made the statements upon which these warranty claims are based, and in so doing, defined the terms of those warranties.

68. The Rejuvenate System does not conform to Defendant's representations in that it is not safe and produces serious side effects.

69. As such, the Rejuvenate System did not conform to Defendant's promises, descriptions or affirmations of fact and was not adequately packaged, labeled, promoted or fit for the ordinary purposes for which such devices are used.

70. Defendants, therefore, breached its express warranties to Plaintiff in violation of Florida statutory and common law by manufacturing, marketing and selling the Rejuvenate System to Plaintiff causing damages as will be established at trial.

WHEREFORE, Plaintiff respectfully request that they be granted relief against Defendants, as contained in the Prayer For Relief.

COUNT III -STRICT LIABILITY -FAILURE TO WARN

71. Plaintiff realleges and incorporates by reference the allegations set forth above as if set forth herein.

72. The Rejuvenate System implanted into Plaintiff contained no warnings or, in the alternative, inadequate warnings as to the risk that the product could cause significant heavy metal toxicity.

73. The warnings that accompanied the Rejuvenate System, failed to provide that level of information that an ordinary consumer would expect when using the Rejuvenate System in a manner reasonably foreseeable to the Defendants.

74. Had Plaintiff received a proper or adequate warning as to the risks associated with using Rejuvenate System, she would not have used the product.

75. Had Plaintiff's surgeon received a proper or adequate warning as to the risks associated with using the Rejuvenate implant, he would not have recommended the device;

would have used an alternate device or at a minimum, provided Plaintiff with adequate warning and obtained her informed consent. As stated above, had Plaintiff received an adequate warning, she would not have agreed to have the Rejuvenate System implanted in her.

76. The failure to warn of the Rejuvenate System's risks caused serious damage to Plaintiff including bodily injury, pain and suffering, disability, physical impairment, disfigurement, mental anguish, inconvenience, aggravation of a preexisting condition, loss of the capacity for the enjoyment of life, the costs of medical care and expenses, loss of earnings and loss of the ability to cam money, all of which damage and losses will continue in the future.

WHEREFORE, Plaintiff respectfully requests that they be granted relief against Defendants, as contained in the Prayer For Relief.

COUNT IV -STRICT LIABILITY -DESIGN DEFECT

77. Plaintiff realleges and incorporates by reference the allegations set forth above as if set forth herein.

78. This is an action based upon design defect against Defendants.

79. Defendants' Rejuvenate System is designed in such a way that, when used as intended, they cause serious, permanent and devastating damage to patients in whom they are implanted. The damage and mechanism of injury have been previously described.

80. Defendants' Rejuvenate System did not perform as safely as an ordinary consumer would expect when used as intended or in a manner reasonably foreseeable to Defendants.

81. The risks of using Defendants' Rejuvenate System outweigh the benefits of using them.

82. The Rejuvenate System installed in Plaintiff's hip was defectively designed.

83. The design defect in Defendant's Rejuvenate System caused serious damage to Plaintiff including bodily injury, pain and suffering, disability, physical impairment, disfigurement, mental anguish, inconvenience, aggravation of a preexisting condition, loss of the capacity for the enjoyment of life, the costs of medical care and expenses, loss of earnings and loss or the ability to earn money, all of which damage and losses will continue in the future.

WHEREFORE, Plaintiff respectfully requests that they be granted relief against Defendants, as contained in the Prayer For Relief.

COUNT V -STRICT LIABILITY -MANUFACTURING DEFECT

84. Plaintiff realleges and incorporates by reference the allegations set forth above as if set forth herein.

85. This is an action based on a manufacturing defect against both Defendants.

86. The Rejuvenate System is designed for implantation into the human body and to last fifteen or more years. It is also designed to be compatible with human tissue and bone.

87. The Rejuvenate System implanted in the Plaintiff's right hip failed and was removed in less than one year.

88. The Rejuvenate System installed in Plaintiff's hip was not compatible with human tissue and bone. Through a process of fretting and corrosion it released heavy metals into the Plaintiff's body causing severe and permanent destruction of bone and tissue. Defendants failed to manufacture the product in a manner that prevented fretting and corrosion and, in fact, manufactured the product such that it caused fretting and corrosion.

89. The Rejuvenate System installed in Plaintiff's hip contained a manufacturing defect.

90. The manufacturing defect in the Rejuvenate System caused serious damage to Plaintiff including bodily injury, pain and suffering, disability, physical impairment, disfigurement, mental anguish, inconvenience, aggravation of a preexisting condition, loss of the capacity for the enjoyment of life, the costs of medical care and expenses, loss of earnings and loss of the ability to cam money, all of which damage and losses will continue in the future.

WHEREFORE, Plaintiff respectfully requests that they be granted relief against Defendants, as contained in the Prayer For Relief.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for judgment against the Defendants as follows:

a. Awarding compensatory damages resulting from Defendants violation of the Florida Law;
b. Awarding compensatory damages resulting from Defendants breach of implied and express warranty, negligence, design defect, failure to warn and for strict liability;
c. Awarding actual damages to the Plaintiff incidental to Plaintiff's purchase and use of The Rejuvenate System in an amount to be determined at trial;
d. Awarding pre-judgment and post-judgment interest to the Plaintiff;
e. Awarding the costs and expenses of their litigation to the Plaintiff;
f. Awarding reasonable attorneys' fees and costs to the Plaintiff as provided by law; and

g. Granting all such other relief as the Court deems necessary, just and proper.

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BY:_____
JESSE N. BERNHEIM, ESQ.
FBN: 0525421

EXHIBIT 2

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA

Case No.

JAIMIE M. SIMON,

Plaintiff,

vs.

HOWMEDICA OSTEONICS CORPORATION, a New Jersey Corporation, d/b/a STRYKER ORTHOPAEDICS, and ORTHOPEDIC SOLUTIONS, INC. d/b/a STRYKER SOUTH FLORIDA AGENCY,

Defendants.
_____ /

AFFIDAVIT OF FRANK RUSSO

FRANK RUSSO, being duly sworn, hereby deposes and says:

1. I am over twenty-one years of age, of sound mind and competent to make this Affidavit, and have personal knowledge of the facts set forth herein.

2. I am President of Orthopedic Solutions, Inc. ("Orthopedic Solutions"). I have held this position since at least 2001. In this position, I am familiar with the business conducted by and operations of Orthopedic Solutions.

3. I have read the Complaint filed in this case, and I am aware that Plaintiff, Jaimie M. Simon, alleges that he was injured by a Rejuvenate hip implant system, designed and manufactured by Howmedica Osteonics Corporation d/b/a Stryker Orthopaedics ("HOC"), that was distributed or placed into the stream of interstate commerce by Orthopedic Solutions, d/b/a Stryker South Florida Agency, in or about September 2011.

4. Orthopedic Solutions is not now nor has it ever been an agent of HOC.

5. Orthopedic Solutions has never done business as "Stryker South Florida Agency."

6. Orthopedic Solutions has never participated in any way in the retailing, distributing, marketing and/or supplying of the Rejuvenate hip implant system. Orthopedic Solutions has not placed any Rejuvenate hip implant system into the stream of commerce and has never acted as a distributor of that product.

7. Orthopedic Solutions did not participate in any way in the retailing, distributing, marketing and/or supplying of the Rejuvenate hip implant system that was purportedly implanted in Plaintiff on September 12, 2011. Orthopedic Solutions did not place the Rejuvenate hip implant system that was purportedly implanted in Plaintiff on September 12, 2011, into the stream of commerce or act as a distributor of that product.

FURTHER AFFIANT SAYETH NOT.

I declare under penalty of perjury that the foregoing is true and correct.

EXECUTED ON: October 2nd, 2012

Frank Russo

SWORN TO AND SUBSCRIBED before me this 2nd day of October 2012, by Frank Russo, who is personally known to me or who produced _____ as identification.

ARLENE KELLER
MY COMMISSION # EE 107244
EXPIRES: August 24, 2015
Bonded Thru Notary Public Underwriters

Arlene Keller
Printed Name

Notary Public, State of Florida

My commission expires: August 24, 2015

EXHIBIT 3

IN THE CIRCUIT COURT OF THE 17TH JUDICIAL CIRCUIT IN AND FOR BROWARD COUNTY, FLORIDA

GENERAL JURISDICTION DIVISION

JAIMIE M. SIMON

Plaintiff,

vs.

HOWMEDICA OSTEONICS CORPORATION, a New Jersey Corporation, d/b/a STRYKER ORTHOPAEDICS, and ORTHOPEDIC SOLUTIONS, INC. d/b/a STRYKER SOUTH FLORIDA AGENCY,

Defendants.

CASE NO.: 12-25899

NOTICE OF FILING NOTICE OF REMOVAL

Defendant Howmedica Osteonics Corp., which has at times done business as "Stryker Orthopaedics" (hereinafter "HOC") hereby file the attached copy of their Notice of Removal, filed in the United States District Court for the Southern District of Florida on October 2, 2012. Pursuant to 28 U.S.C. § 1446(d), the filing of this notice effects the removal of this case, and this Court shall proceed no further unless the case is remanded from the federal court.

LAW OFFICES
SHOOK, HARDY & BACON L.L.P.
MIAMI CENTER, SUITE 3200, 201 SOUTH BISCAYNE BOULEVARD, MIAMI, FLORIDA 33131-4332 •TELEPHONE (305) 358-5171

Respectfully submitted,

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By: _____
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CERTIFICATE OF SERVICE

WE HEREBY CERTIFY that a true and correct copy of the foregoing has been served by E-mail and U.S. Mail this 2nd day of October, 2012 to all parties on the below service list:

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