**UNITED STATES DISTRICT COURT**
**DISTRICT OF MINNESOTA**

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Cheryl Helder and
Dan Helder,

Plaintiffs,

v.

Howmedica Osteonics Corp., d/b/a
Stryker Orthopaedics,

Defendant.

**Civil Case No.:** _____

**COMPLAINT AND DEMAND FOR JURY TRIAL**

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Plaintiffs Cheryl and Dan Helder, for their causes of action against the above-named Defendant, allege and state upon information and belief as follows:

## PARTIES, JURISDICTION & VENUE

1. Plaintiffs Cheryl Helder and Dan Helder are residents of Stewartville, Minnesota and, at all times material herein, have resided together as husband and wife.

2. Defendant Howmedica Osteonics Corp. d/b/a Stryker Orthopaedics ("Stryker") is a corporation organized and existing under the laws of New Jersey, with its principal place of business in Mahwah, New Jersey. Defendant does business throughout the United States, including in the State of Minnesota.

3. This action is properly before the Court because complete diversity of citizenship between Plaintiffs and Defendant exists. In addition, the amount in controversy claimed by Plaintiffs exceeds $75,000.00. As a result, this Court has jurisdiction over this matter pursuant to 28 U.S.C. § 1332(a).

4. Defendants are subject to the *in personam* jurisdiction of this Court, and venue is therefore proper herein pursuant to 28 U.S.C. § 1391, because Defendant did

(and does) business within the State of Minnesota, has had continuous and systematic contacts with the State of Minnesota, has consented to jurisdiction in the State of Minnesota, and/or has committed a tort in whole or in part in the State of Minnesota against Plaintiffs as more fully set-forth herein. On information and belief, Defendants also advertised in this district, made material omissions and representations in this district, and breached warranties in this district.

## THE PRODUCT

5. At all times material hereto, Stryker developed, tested, assembled, manufactured, packaged, labeled, prepared, distributed, marketed, supplied, and/or sold a defective product sold under the name "The Rejuvenate® System" ("Rejuvenate®"), either directly or indirectly, to members of the general public within the State of Minnesota and elsewhere, including Plaintiff Cheryl Helder.

6. On June 3, 2008, Stryker received FDA clearance to sell its Rejuvenate® system in the United States. During the first week of July 2012, Defendant issued a voluntary worldwide recall of both the Rejuvenate® and ABG II hip replacement systems.

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

8. 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 Rejuvenate® system can be used interchangeably with any number of Stryker bearing surface components which comprise

the ball and an acetabular cup or socket. The bearing surface system or components are unrelated to the Rejuvenate® system's method of failure.

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

10. At all times material hereto, the Rejuvenate® stem and neck implanted in the Plaintiff were designed, manufactured, marketed, retailed, distributed, and/or supplied by Stryker.

11. On August 12, 2010, Plaintiff Cheryl Helder underwent right total hip arthroplasty using the Rejuvenate® system. On October 31, 2011, Plaintiff underwent left total hip arthroplasty using the Rejuvenate® system.

12. Subsequent to implantation of the bilateral Rejuvenate® systems, Plaintiff Cheryl Helder began experiencing significant bilateral hip pain and discomfort.

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

14. Further diagnostic workup revealed one or more of the following findings: the presence of pseudotumor formation, the existence of a significant fluid collection about the hip prosthesis, and/or blood testing indicating the presence of heavy metal ion contamination.

15. Based upon these findings and worsening symptoms, Plaintiff Cheryl Helder underwent a revision of the right hip components on November 23, 2012. For these same reasons, Plaintiff underwent a revision of the left hip components on January 2, 2013.

16. As a direct and proximate result of Stryker placing the Rejuvenate® system into the stream of commerce, Plaintiff 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.

## THE STRYKER REJUVENATE HISTORY

17. In February 2009, Stryker released its Rejuvenate® Modular Primary Hip System, the latest evolution in the Defendant'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 Sept 13, 2007.

18. According to Defendant'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 each patient's unique anatomy.

19. The Rejuvenate® system is comprised of separate femoral stem and neck components and offers a variety of sizing options intraoperatively. 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 each patient's hip replacement implant.

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

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

22. Stryker holds two patents for modular implant devices. Currently, Defendant has a pending application to patent a modular hip prosthesis similar to the Rejuvenate® system.

## URGENT SAFETY NOTICES AND RECALLS

23. In April of 2012, Stryker issued an Urgent Field Safety Notice to surgeons and hospitals in the United States regarding the Rejuvenate® system.

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

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

26. The Urgent Field Safety Notice went on to describe symptoms and findings identical to those experienced by Plaintiff Cheryl Helder.

27. Among those symptoms and findings specifically mentioned in the Urgent Field Safety Notice were tissue necrosis, metallosis, adverse soft tissue reaction, and pseudotumor formation.

28. Almost immediately following the Urgent Field Safety Notice, Stryker issued a voluntary recall of the Stryker Rejuvenate® and ABG II in Canada. In the Canadian recall notice, Stryker stated that it was amending the Instructions for Use for the Rejuvenate® system to include warnings that Defendant was on notice of the issues described in the Urgent Field Safety Notice above.

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

## THE FEDERAL REQUIREMENTS

30. 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).

31. 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).

32. 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).

33. 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.

34. 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. *See* 21 U.S.C. §351.

35. 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.

36. 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 of its medical devices may have caused or contributed to death or serious injury, or if the devices have malfunctioned in a manner likely to cause or contribute to death or serious injury. 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).

37. 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) a device may have caused or contributed to death or serious injury, or (b) 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.

38. Pursuant to federal regulations, manufacturers of medical devices must also describe in every individual adverse event report whether remedial action was taken

with 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.

39. Pursuant to federal regulations, manufacturers must report 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, to the FDA within 5 business days after becoming aware of such event or events. *See* 21 CFR §803.53.

40. Pursuant to federal regulations, device manufacturers must report promptly to FDA any device corrections and removals and must also 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 Act 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, 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.

41. Pursuant to federal regulations, 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 of the devices. 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. Further, Manufacturers are required to use statistical techniques, where necessary, to evaluate product performance. *See* 21 CFR §820.

42. Pursuant to federal regulations, 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 its devices. 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." *See* 21 CFR §814.

43. Specifically, it is believed that with respect to the Rejuvenate® system, Stryker failed to timely report adverse events; failed to timely conduct failure investigations and analyses; 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.

## FIRST CAUSE OF ACTION

**(Negligence)**

44. Plaintiffs incorporate by reference all preceding paragraphs as if fully set forth herein and further state and allege as follows:

45. Stryker designed, manufactured, marketed, detailed, and advertised, both to physicians and consumers, the Rejuvenate® system.

46. As a result, Stryker 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, including Plaintiff Cheryl Helder.

47. Stryker failed to use reasonable and due care for the safety and well-being of those in whom the device would be implanted, including Plaintiff Cheryl Helder, and is therefore negligent in the following respects:

a. Defendant 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 the following:

i. Incompatibility of the TMZF titanium alloy 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; and

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

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

d. Defendant 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, including Plaintiff Cheryl Helder;

e. Defendant trained its sales force to detail the device utilizing representations that Defendant 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. Defendant 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. Defendant 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. Defendant failed to manufacture the product to FDA-cleared and/or Defendant's 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. Defendant 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. Defendant 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 or sales suspended;

k. Defendant chose as its predicate device a hip implant system that had known, disastrous failures in the past; had to be redesigned due to design flaws; and has been the subject of protracted litigation filed by patients who have been harmed by defects in the predicate modular device; and

l. Defendant was on actual knowledge prior to marketing the Rejuvenate System and ABG II that its TMZF titanium alloy performed poorly when mated with chrome cobalt components.

Defendant also knew when it introduced the Rejuvenate® system to the market that the Stryker Accolade as well as other Stryker devices that were also made of TMZF alloy were experiencing corrosion, fretting, and failure issues at the taper neck junction between the neck and chrome cobalt head or ball. Nevertheless, Defendant either suppressed or ignored these reports and marketed the Rejuvenate® system anyway, knowing that these two dissimilar metals when utilized in various hip implant devices were performing poorly in the market and causing harm to patients.

48. The above conduct illustrates Stryker's failure to exercise reasonable care. It was foreseeable that such negligence would lead to premature device failure as well as severe, permanent, debilitating injury to patients, including Plaintiff Cheryl Helder.

49. As a direct and proximate result of Stryker's negligence, Plaintiff has suffered, and will continue to suffer, injury, emotional distress, harm and economic loss as alleged herein.

## SECOND CAUSE OF ACTION

### (Breach of Express Warranty)

50. Plaintiffs incorporate by reference all preceding paragraphs as if fully set forth herein and further state and allege as follows:

51. Through their public statements, their descriptions of the Rejuvenate® system, and Defendant's promises relating to the Rejuvenate® system, Stryker expressly warranted, among other things, that the Rejuvenate® system was effective and safe for its intended use; was designed and constructed of materials that would prevent fretting and

corrosion; would last longer that competing hip implant devices; and was more suitable for younger adults than other devices given its purported longevity.

52. 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 Defendant's consumer relations personnel to the public about the safety of the Rejuvenate® system that also downplayed the risks associated with the Rejuvenate® system; and (iv) false and misleading written information supplied by Stryker.

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

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

55. When Stryker made these express warranties, it knew the purpose for which the Rejuvenate® system was to be used, and warranted it to be in all respects safe and proper for such purpose.

56. Stryker 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.

57. The Rejuvenate® system does not conform to Stryker's representations in that these devices are not safe and produce serious side effects.

58. As such, the Rejuvenate® system did not conform to Stryker'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.

59. As a direct and proximate result of Stryker's breach of express warranties, Plaintiff has suffered, and will continue to suffer, injury, emotional distress, harm and economic loss as alleged herein.

## THIRD CAUSE OF ACTION

**(Breach of Implied Warranty)**

60. Plaintiff incorporates by reference all preceding paragraphs as if fully set forth herein and further alleges as follows:

61. At the time Stryker marketed, sold, and distributed the Rejuvenate® system, Defendant knew of the use for which this system was intended and impliedly warranted the product to be of merchantable quality, safe, fit and effective for such use.

62. Stryker knew, or had reason to know, that Plaintiff and her physicians would rely on the Defendant's judgment and skill in providing the Rejuvenate® system for its intended use.

63. Plaintiff and her physicians reasonably relied upon the skill and judgment of Stryker as to whether the Rejuvenate® system was of merchantable quality, safe, fit, and effective for its intended use.

64. Contrary to such implied warranty, the Rejuvenate® system was not of merchantable quality or safe or fit or effective for its intended use, because the product

was, and is, unreasonably dangerous, defective, unfit and ineffective for the ordinary purposes for which the Rejuvenate® system was used.

65. As a direct and proximate result of the breach of implied warranty, Plaintiff has suffered, and will continue to suffer, injury, emotional distress, harm and economic loss as alleged herein.

## FOURTH CAUSE OF ACTION

### (Strict Liability – Failure to Warn)

66. Plaintiffs incorporate by reference all preceding paragraphs as if fully set forth herein and further state and allege as follows:

67. 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. Similar, although still inadequate, warnings were added in 2012 by Defendant.

68. The warnings that accompanied the Rejuvenate® system failed to provide that level of information that an ordinary consumer would expect when using the implant in a manner reasonably foreseeable to Stryker.

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

70. Had Plaintiff's surgeon received a proper or adequate warning as to the risks associated with using the Rejuvenate® system, he would not have recommended the device; would have used an alternate device; or, at a minimum, would have provided Plaintiff with adequate warning and obtained informed consent.

71. As a direct and proximate result of Stryker's failure to warn, Plaintiff has suffered, and will continue to suffer, injury, emotional distress, harm and economic loss as alleged herein.

## FIFTH CAUSE OF ACTION

### (Strict Liability – Design Defect)

72. Plaintiffs incorporate by reference all preceding paragraphs as if fully set forth herein and further state and allege as follows:

73. This is an action for strict liability based upon design defect against Defendant Stryker.

74. Stryker's Rejuvenate® system is designed in such a way that, when used as intended, it causes serious, permanent, and devastating damage to patients in whom the devices are implanted. The damage and mechanism of injury have been previously described herein.

75. Stryker's Rejuvenate® system does not perform as safely as an ordinary consumer would expect when used as intended or in a manner reasonably foreseeable to Defendant.

76. The risks of using Stryker's Rejuvenate® system outweigh the benefits of using the devices.

77. The Rejuvenate® systems installed bilaterally in Plaintiff's hips were defectively designed.

78. As a direct and proximate result of the Rejuvenate®'s defective design, Plaintiff has suffered, and will continue to suffer, injury, emotional distress, harm and economic loss as alleged herein.

## SIXTH CAUSE OF ACTION

### (Strict Liability – Manufacturing Defect)

79. Plaintiffs incorporate by reference all preceding paragraphs as if fully set forth herein and further state and allege as follows:

80. This is an action for strict liability based on a manufacturing defect.

81. The Rejuvenate® system is designed for implantation into the human body and to last for fifteen or more years. The Rejuvenate® system was also designed to be compatible with human tissue and bone.

82. The Rejuvenate® systems implanted in Plaintiff failed and were removed within a short period of time after the original date of implantation.

83. The Rejuvenate® systems installed in Plaintiff's hips were not compatible with human tissue and bone. Through a process of fretting and corrosion, the Rejuvenate® system released heavy metals into the Plaintiff's body causing severe and permanent destruction of bone and tissue. Stryker failed to manufacture the Rejuvenate® system in a manner that prevented fretting and corrosion.

84. The Rejuvenate® systems implanted in Plaintiff's hips contained a manufacturing defect.

85. As a direct and proximate result of Stryker's manufacturing defect, Plaintiff has suffered, and will continue to suffer, injury, emotional distress, harm and economic loss as alleged herein.

## SEVENTH CAUSE OF ACTION

**(Violation of State Deceptive Acts and Practices, Unfair Trade Practices, Consumer Protection, Merchandising Practices, and False Advertising Acts)**

86. Plaintiffs incorporate by reference all preceding paragraphs as if fully set forth herein and further state and allege as follows:

87. By reason of the conduct as alleged herein, and by inducing Plaintiff and her physicians to use the Rejuvenate® system through the use of deception, fraud, false advertising, false pretenses, misrepresentations, unfair and/or deceptive practices and the concealment and suppression of material facts, including but not limited to fraudulent statements, concealments and misrepresentations identified herein and above, Stryker violated the provisions of Minn. Stat. §§ 325F.67, 325F.69, 325D.13, and 325D.44.

88. As a direct and proximate result of Defendants' statutory violations, Plaintiff was implanted with bilateral Rejuvenate® systems, which would not have occurred had Stryker not used deception, fraud, false advertising, false pretenses, misrepresentations, unfair and/or deceptive practices and the concealment and suppression of material facts to induce Plaintiff and her physicians to use the product.

89. By reason of such violations and pursuant to Minn. Stat. § 8.31, subd. 3a, and §§ 325D.44, 325F.67, and 325F.68-70, Plaintiff is entitled to recover all of the monies paid for the product; to be compensated for the cost of the medical care arising out of the use of the product; and to recover any and all consequential damages recoverable under the law including, but not limited to, both past and future medical expenses, past wage loss, loss of future earning capacity, past and future pain, suffering, disability, and emotional distress. Plaintiff is entitled to seek compensatory damages, attorneys fees, injunctive and equitable relief, and other remedies as determined by the

Court pursuant to Minn. Stat. § 8.31, subd. 3a, and §§ 325D.44, 325F.67, and 325F.68-70.

## EIGHTH CAUSE OF ACTION

**(Loss of Consortium)**

90. Plaintiffs incorporate by reference all preceding paragraphs as if fully set forth herein and further state and allege as follows:

91. As a further direct result of defendants' breach of duties as described and alleged above, Plaintiff Dan Helder has lost, and will in the future lose, his wife's companionship, aid, comfort, society, services, protection and consortium, all to his damage in an amount greater than $75,000.00.

## PRAYER FOR RELIEF

WHEREFORE, Plaintiffs seek judgment in their favor as follows:

1. Awarding actual damages to Plaintiffs incidental to the purchase and use of the Rejuvenate® system in an amount to be determined at trial;

2. Awarding the past and future costs of treatment for Plaintiff's injuries caused by the Rejuvenate® system;

3. Awarding injunctive relief, including disgorgement of all profits made from and monies paid for the Rejuvenate® system;

4. Awarding damages for Plaintiff's physical pain and suffering;

5. Awarding damages for Plaintiff's mental and emotional anguish;

6. Awarding pre-judgment and post-judgment interest to Plaintiff;

7. Awarding, if the Court allows an amended complaint on Plaintiff's motion, for punitive damages;

8. Awarding the costs and expenses of this litigation to Plaintiff;

9. Awarding reasonable attorneys' fees and costs to Plaintiff as provided by law; and

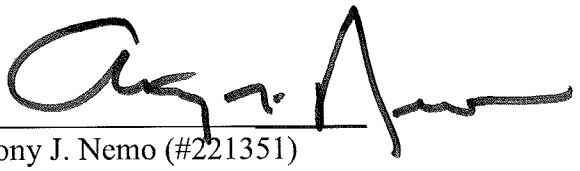
10. For such further relief as this Court deems necessary, just and proper.

**JURY DEMAND**

Plaintiff hereby requests a trial by jury, pursuant to Rule 38 of the Federal Rules of Civil Procedure, on all claims and issues so triable.

Dated: January 17, 2013

MESHBESHER & SPENCE, LTD.

By 

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JS 44 (Rev. 09/11)

# CIVIL COVER SHEET

The JS 44 civil coversheet and the information contained herein neither replace nor supplement the filing and service of pleadngs 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 inSeptember 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**
Cheryl Helder and Dan Helder

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

**(c)** Attorneys *(Firm Name, Address, and Telephone Number)*
Anthony J. Nemo, Meshbesher & Spence, Ltd., 1616 Park Avenue, Minneapolis, MN 55404 (612) 339-9121

**DEFENDANTS**
Howmedica Osteonics Corp. d/b/a Stryker Orthopaedics

County of Residence of First Listed Defendant
*(IN U.S. PLAINTIFF CASES ONLY)*
NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.

Attorneys *(If Known)*

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

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

**III. CITIZENSHIP OF PRINCIPAL PARTIES** *(Place an "X" in One Box for Plaintiff) (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. sec. 1332
Brief description of cause:
Defective hip implant resulting in personal injury

**VII. REQUESTED IN COMPLAINT:**
☐ CHECK IF THIS IS A CLASS ACTION UNDER F.R.C.P. 23
DEMAND $ 75,000.00
CHECK YES only if demanded in complaint:
JURY DEMAND: ☑ Yes ☐ No

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

DATE 01/17/2013

SIGNATURE OF ATTORNEY OF RECORD

**FOR OFFICE USE ONLY**

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