

GIBBONS P.C.

One Gateway Center
Newark, New Jersey 07102
(973) 596-4500
Attorneys for Defendant
Howmedica Osteonics Corp.

IN RE STRYKER REJUVENATE HIP STEM
AND ABG II MODULAR HIP STEM
LITIGATION

SUPERIOR COURT OF NEW JERSEY
LAW DIVISION: BERGEN COUNTY

MASTER DOCKET NO. BER-L-936-13
CASE CODE 296

**DEFENDANT HOWMEDICA
OSTEONICS CORP.'S MASTER LONG
FORM ANSWER AND JURY DEMAND
FOR REJUVENATE MODULAR
HIP STEM CASES**

Defendant Howmedica Osteonics Corp. (incorrectly named as “Howmedica Osteonics Corporation, a New Jersey corporation d/b/a Stryker Orthopaedics”) (hereinafter “Defendant” or “HOC”), by and through its counsel, Gibbons P.C., brings this Master Long Form Answer to Plaintiffs’ Master Long Form Complaint and Jury Demand for Rejuvenate Modular Hip Stem Cases (“Complaint”). In accordance with the Implementing Order dated May __, 2013, all responses and defenses pled herein are deemed pled in any previously filed Answer and in any Short Form Answer hereafter filed. Further pursuant to the Implementing Order dated May __, 2013, HOC reserves the right to assert any additional defenses which may be disclosed during the course of investigation and discovery. This Master Long Form Answer shall be subject to further Order of the Court regarding any future amendments and related motion practice.

Defendant states as follows:

1. Defendant admits that Plaintiffs purport to bring this action as indicated in the Complaint, but denies that there is any legal or factual basis for such relief. Defendant admits that HOC designed, manufactured, labeled, packaged, marketed and sold certain modular

implant components under the brand name “Rejuvenate®”. Defendant denies the remaining allegations contained in Paragraph “1” of the Complaint.

PARTIES, JURISDICTION AND VENUE

2. Defendant denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations set forth in Paragraph “2” of the Complaint, and leaves Plaintiffs to their proofs.

3. The allegations contained in Paragraph “3” of the Complaint are conclusions of law to which no response is required. To the extent a response is required, HOC admits that it is a New Jersey corporation with its principal place of business located at 325 Corporate Drive, Mahwah, Bergen County, New Jersey.

4. Regarding the allegations set forth in Paragraph “4” of the Complaint, Defendant admits that Howmedica Osteonics Corp. is a New Jersey corporation with its principal place of business located at 325 Corporate Drive, Mahwah, Bergen County, New Jersey. The remaining allegations are conclusions of law to which no response is required. To the extent a response is required, and these allegations are intended to impute liability to HOC, then Defendant denies the allegations.

5. The allegations set forth in Paragraph “5” of the Complaint do not appear to be directed at HOC. As alleged, HOC denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations. If these allegations are intended to impute liability to HOC then the allegations are denied.

THE PRODUCT

6. Defendant HOC admits that it designed, manufactured, labeled, packaged, marketed, and sold certain modular implant components under the brand name “Rejuvenate®”. Defendant denies the remaining allegations set forth in Paragraph “6” of the Complaint.

7. Defendant denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations regarding the implantation of products in Plaintiffs as set forth in Paragraph “7” of the Complaint. The remaining allegations are denied.

8. Defendant denies the allegations contained in Paragraph “8” of the Complaint.

9. Defendant admits that the Rejuvenate® Modular Hip System was cleared to market in the United States by the United States Food and Drug Administration (“FDA”). Defendant denies the remaining allegations contained in Paragraph “9” of the Complaint.

10. Regarding the allegations set forth in Paragraph “10” of the Complaint, Defendant admits that the Rejuvenate® Modular Hip System was indicated for certain patients requiring primary total hip arthroplasty or replacement.

11. Regarding the allegations set forth in Paragraph “11” of the Complaint, Defendant admits that the Rejuvenate® Modular Hip System consists of a Cobalt Chrome alloy neck component and a TMZF (Ti-12Mo-6Zr-2Fe) alloy stem component. The Rejuvenate® Modular Hip System was indicated for use in conjunction with certain other HOC total hip replacement components, which are not at issue in this litigation. Defendant denies the remaining allegations set forth in Paragraph “11” of the Complaint.

12. Regarding the allegations set forth in Paragraph “12” of the Complaint, Defendant admits that the Rejuvenate® Modular Hip System includes a stem that was manufactured with HOC’s proprietary and patented titanium alloy known as “TMZF.” Defendant denies the remaining allegations set forth in Paragraph “12” of the Complaint.

13. Defendant denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations set forth in Paragraph “13” of the Complaint, and leaves Plaintiffs to their proofs.

14. Defendant denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations set forth in Paragraph “14” of the Complaint. To the extent the allegations in Paragraph “14” seek to impute liability to Defendant, they are denied.

15. Defendant denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations set forth in Paragraph “15” of the Complaint. To the extent the allegations in Paragraph “15” seek to impute liability to Defendant, they are denied.

16. Defendant denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations set forth in Paragraph “16” of the Complaint. To the extent the allegations in Paragraph “16” seek to impute liability to Defendant, they are denied.

THE STRYKER REJUVENATE HISTORY

17. Regarding the allegations set forth in Paragraph “17” of the Complaint, Defendant admits that the Rejuvenate® Modular Hip System was cleared to market in the United States by the FDA. Defendant denies the remaining allegations contained in Paragraph “17” of the Complaint.

18. Regarding the allegations set forth in Paragraph “18” of the Complaint, Plaintiffs fail to identify the “materials” allegedly summarized in the allegations. Accordingly, Defendant lacks knowledge or information sufficient to form a belief as to the truth or falsity of these allegations, and leaves Plaintiffs to their proofs. To the extent these allegations seek to impute liability to Defendant, they are denied.

19. Regarding the allegations set forth in Paragraph “19” of the Complaint, Defendant admits that the Rejuvenate® Modular Hip System consists of neck and stem components available in a range of sizes that were designed to attempt to optimize anatomic restoration. The remaining allegations are denied.

20. Regarding the allegations set forth in Paragraph “20” of the Complaint, Defendant admits that the Rejuvenate® Modular Hip System stem bodies are made of TMZF (Ti-12Mo-

6Zr-2Fe) alloy with a plasma sprayed coating of commercially pure (CP) titanium and PureFix HA. HOC further admits that the necks are made of a Cobalt Chrome (CoCr) alloy. The remaining allegations are denied.

21. Defendant denies the allegations contained in Paragraph “21” of the Complaint.

22. Regarding the allegations set forth in Paragraph “22” of the Complaint, Plaintiffs fail to identify the “devices” and “patents” referenced therein. Accordingly, Defendant lacks knowledge or information sufficient to form a belief as to the truth or falsity of these allegations, and leaves Plaintiffs to their proofs. The content of the documents referenced therein speak for themselves, and, therefore, no answer is required. If an answer is deemed required, and these allegations are intended to impute liability to HOC, then Defendant denies the allegations.

URGENT SAFETY NOTICES AND RECALLS

23. Regarding the allegations set forth in Paragraph “23” of the Complaint, Defendant HOC admits that on or about April 25, 2012, the company issued a Product Correction Bulletin to surgeons and healthcare providers regarding the Rejuvenate® Modular Hip System. The remaining allegations are denied.

24. Regarding the allegations set forth in Paragraph “24” of the Complaint, the content of the Product Correction Bulletin issued by HOC in April 2012 speaks for itself, and, therefore, no answer is required. If an answer is deemed required, and these allegations are intended to impute liability to HOC, then Defendant denies the allegations.

25. Defendant denies the allegations contained in Paragraph “25” of the Complaint.

26. Regarding the allegations set forth in Paragraph “26” of the Complaint concerning the content of the Product Correction Bulletin issued by HOC in April 2012, the content of the document speaks for itself, and, therefore, no answer is required. Regarding the remaining allegations regarding Plaintiffs’ symptoms, Defendant denies knowledge or information

sufficient to form a belief as to the truth or falsity of the allegations and leaves Plaintiffs to their proofs.

27. Regarding the allegations set forth in Paragraph “27” of the Complaint, the content of the Product Correction Bulletin issued by HOC in April 2012 speaks for itself, and, therefore, no answer is required. If an answer is deemed required, and these allegations are intended to impute liability to HOC, then Defendant denies the allegations.

28. Regarding the allegations contained in Paragraph “28” of the Complaint, Defendant admits that the Rejuvenate® and ABG™ II Modular Hip Systems were voluntarily recalled in Canada on or about April 2012 relating to an amendment to the Instructions for Use. With respect to the content of the Notice, the document speaks for itself, and therefore, no answer is required. If an answer is deemed required, and these allegations are intended to impute liability to HOC, then Defendant denies the allegations.

29. Regarding the allegations contained in Paragraph “29” of the Complaint, Defendant admits that a voluntary product recall of the Rejuvenate® and ABG™ II Modular Hip Systems was initiated by HOC in June 2012. Regarding the allegations concerning the content of the “recall notice,” the document speaks for itself, and, therefore, no answer is required. If an answer is deemed required, and these allegations are intended to impute liability to HOC, then Defendant denies the allegations.

THE FEDERAL REQUIREMENTS

30. The allegations contained in Paragraph “30” of the Complaint are conclusions of law to which no response is required. Also, the content of the referenced regulation speaks for itself. To the extent a response is required, and these allegations are intended to impute liability to HOC, then Defendant denies the allegations.

31. The allegations contained in Paragraph “31” of the Complaint are conclusions of law to which no response is required. Also, the content of the referenced regulation speaks for

itself. To the extent a response is required, and these allegations are intended to impute liability to HOC, then Defendant denies the allegations.

32. The allegations contained in Paragraph “32” of the Complaint are conclusions of law to which no response is required. Also, the content of the referenced regulation speaks for itself. To the extent a response is required, and these allegations are intended to impute liability to HOC, then Defendant denies the allegations.

33. The allegations contained in Paragraph “33” of the Complaint are conclusions of law to which no response is required. To the extent a response is required, and these allegations are intended to impute liability to HOC, then Defendant denies the allegations.

34. The allegations contained in Paragraph “34” of the Complaint are conclusions of law to which no response is required. Also, the content of the referenced section of the United States Code speaks for itself. To the extent a response is required, and these allegations are intended to impute liability to HOC, then Defendant denies the allegations.

35. The allegations contained in Paragraph “35” of the Complaint are conclusions of law to which no response is required. Also, the content of the referenced section of the United States Code speaks for itself. To the extent a response is required, and these allegations are intended to impute liability to HOC, then Defendant denies the allegations.

36. The allegations contained in Paragraph “36” of the Complaint are conclusions of law to which no response is required. Also, the content of the referenced section of the United States Code speaks for itself. To the extent a response is required, and these allegations are intended to impute liability to HOC, then Defendant denies the allegations.

37. The allegations contained in Paragraph “37” of the Complaint are conclusions of law to which no response is required. Also, the content of the referenced regulation speaks for itself. To the extent a response is required, and these allegations are intended to impute liability to HOC, then Defendant denies the allegations.

38. The allegations contained in Paragraph “38” of the Complaint are conclusions of law to which no response is required. Also, the content of the referenced regulation speaks for itself. To the extent a response is required, and these allegations are intended to impute liability to HOC, then Defendant denies the allegations.

39. The allegations contained in Paragraph “39” of the Complaint are conclusions of law to which no response is required. Also, the content of the referenced regulation speaks for itself. To the extent a response is required, and these allegations are intended to impute liability to HOC, then Defendant denies the allegations.

40. The allegations contained in Paragraph “40” of the Complaint are conclusions of law to which no response is required. Also, the content of the referenced regulation speaks for itself. To the extent a response is required, and these allegations are intended to impute liability to HOC, then Defendant denies the allegations.

41. The allegations contained in Paragraph “41” of the Complaint are conclusions of law to which no response is required. Also, the content of the referenced regulation speaks for itself. To the extent a response is required, and these allegations are intended to impute liability to HOC, then Defendant denies the allegations.

42. The allegations contained in Paragraph “42” of the Complaint are conclusions of law to which no response is required. Also, the content of the referenced regulation speaks for itself. To the extent a response is required, and these allegations are intended to impute liability to HOC, then Defendant denies the allegations.

43. Defendant denies the allegations contained in Paragraph “43” of the Complaint.

CAUSES OF ACTION

COUNT I - NEGLIGENCE

44. In response to Paragraph “44” of Count I of the Complaint, Defendant repeats each and every response to the allegations set forth in Paragraphs “1” through “43” of the Complaint as if set forth at length herein.

45. Regarding Paragraph “45” of Count I of the Complaint, Defendant HOC admits that it designed, manufactured, and marketed the Rejuvenate® Modular Hip System. The remaining allegations are denied.

46. As Paragraph “46” of Count I of the Complaint alleges a legal conclusion, no answer is required. To the extent the allegations in Paragraph “46” seek to impute liability to Defendant, the allegations are denied.

47. Defendant denies the allegations contained in Paragraph “47” of Count I of the Complaint (including all of the sub-paragraphs).

48. Defendant denies the allegations contained in Paragraph “48” of Count I of the Complaint

49. Defendant denies the allegations contained in Paragraph “49” of Count I of the Complaint.

WHEREFORE, Defendant demands judgment in its favor and against Plaintiffs, dismissing Count I of the Complaint with prejudice, together with costs of suit and such other relief as the Court deems equitable and just.

COUNT II - NEGLIGENCE PER SE

50. In response to Paragraph “50” of Count II of the Complaint, Defendant repeats each and every response to the allegations set forth in Paragraphs “1” through “49” of the Complaint as if set forth at length herein.

51. As Paragraph “51” of Count II of the Complaint alleges a legal conclusion, no answer is required. To the extent the allegations in Paragraph “51” seek to impute liability to Defendant, the allegations are denied.

52. Defendant denies the allegations contained in Paragraph “52” of Count II of the Complaint.

WHEREFORE, Defendant demands judgment in its favor and against Plaintiffs, dismissing Count II of the Complaint with prejudice, together with costs of suit and such other relief as the Court deems equitable and just.

COUNT III - STRICT PRODUCTS LIABILITY - DEFECTIVE DESIGN

53. In response to Paragraph “53” of Count III of the Complaint, Defendant repeats each and every response to the allegations set forth in Paragraphs “1” through “52” of the Complaint as if set forth at length herein.

54. The allegations in Paragraph “54” of Count III of the Complaint amount to a declarative statement about what type of case Plaintiffs believe is alleged in the Complaint, and Defendant admits that Plaintiffs have so averred. If these allegations are intended to impute liability to HOC, then Defendant denies the allegations.

55. Defendant denies the allegations contained in Paragraph “55” of Count III of the Complaint.

56. Defendant denies the allegations contained in Paragraph “56” of Count III of the Complaint.

57. Defendant denies the allegations contained in Paragraph “57” of Count III of the Complaint.

58. Defendant denies the allegations contained in Paragraph “58” of Count III of the Complaint.

59. Defendant denies the allegations contained in Paragraph “59” of Count III of the Complaint.

WHEREFORE, Defendant demands judgment in its favor and against Plaintiffs dismissing Count III of the Complaint with prejudice, together with costs of suit and such other relief as the Court deems equitable and just.

COUNT IV - STRICT PRODUCTS LIABILITY - MANUFACTURING DEFECT

60. In response to Paragraph “60” of Count IV of the Complaint, Defendant repeats each and every response to the allegations set forth in Paragraphs “1” through “59” of the Complaint as if set forth at length herein.

61. The allegations in Paragraph “61” of Count IV of the Complaint amount to a declarative statement about what type of case Plaintiffs believe is alleged in the Complaint, and Defendant admits that Plaintiffs have so averred. If these allegations are intended to impute liability to HOC, then Defendant denies the allegations.

62. Regarding the allegations contained in Paragraph “62” of Count IV of the Complaint, Defendant admits that the components of the Rejuvenate® Modular Hip System are indicated for use in the human body. The remaining allegations are denied.

63. Defendant denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations set forth in Paragraph “63” of Count IV of the Complaint regarding the need for removal of Plaintiffs’ implants. Defendant denies the remaining allegations in Paragraph “63.”

64. Defendant denies the allegations contained in Paragraph “64” of Count IV of the Complaint.

65. Defendant denies the allegations contained in Paragraph “65” of Count IV of the Complaint.

66. Defendant denies the allegations contained in Paragraph “66” of Count IV of the Complaint.

WHEREFORE, Defendant demands judgment in its favor and against Plaintiffs dismissing Count IV of the Complaint with prejudice, together with costs of suit and such other relief as the Court deems equitable and just.

COUNT V - STRICT PRODUCTS LIABILITY - FAILURE TO WARN

67. In response to Paragraph “67” of Count V of the Complaint, Defendant repeats each and every response to the allegations set forth in Paragraphs “1” through “66” of the Complaint as if set forth at length herein.

68. Regarding the allegations set forth in Paragraph “68” of Count V of the Complaint about the content of the labeling, Instructions for Use, and warnings related to the implant at issue, the documents speak for themselves, and, therefore, no answer is required. The remaining allegations are denied.

69. Defendant denies the allegations contained in Paragraph “69” of Count V of the Complaint.

70. Defendant denies the allegations contained in Paragraph “70” of Count V of the Complaint.

71. Defendant denies the allegations contained in Paragraph “71” of Count V of the Complaint.

72. Defendant denies the allegations contained in Paragraph “72” of Count V of the Complaint.

WHEREFORE, Defendant demands judgment in its favor and against Plaintiffs dismissing Count V of the Complaint with prejudice, together with costs of suit and such other relief as the Court deems equitable and just.

COUNT VI - BREACH OF EXPRESS WARRANTY

73. In response to Paragraph “73” of Count VI of the Complaint, Defendant repeats each and every response to the allegations set forth in Paragraphs “1” through “72” of the Complaint as if set forth at length herein.

74. Defendant denies the allegations contained in Paragraph “74” of Count VI of the Complaint.

75. Defendant denies the allegations contained in Paragraph “75” of Count VI of the Complaint.

76. Defendant denies the allegations contained in Paragraph “76” of Count VI of the Complaint.

77. Regarding the allegations contained in Paragraph “77” of Count VI of the Complaint, rather than actual allegations, the content of Paragraph “77” appears to be an improper statement of Plaintiffs’ position regarding written discovery. Therefore, no response is required. To the extent the allegations seek to impute liability to Defendant, they are denied.

78. Defendant denies the allegations contained in Paragraph “78” of Count VI of the Complaint.

79. As Paragraph “79” of Count VI of the Complaint alleges a legal conclusion, no answer is required. To the extent the allegations in Paragraph “79” seek to impute liability to Defendant, they are denied.

80. Defendant denies the allegations contained in Paragraph “80” of Count VI of the Complaint.

81. Defendant denies the allegations contained in Paragraph “81” of Count VI of the Complaint.

82. Defendant denies the allegations contained in Paragraph “82” of Count VI of the Complaint.

83. Defendant denies the allegations contained in Paragraph “83” of Count VI of the Complaint.

WHEREFORE, Defendant demands judgment in its favor and against Plaintiffs, dismissing Count VI of the Complaint with prejudice, together with costs of suit and such other relief as the Court deems equitable and just.

COUNT VII - BREACH OF WARRANTY AS TO MERCHANTABILITY

84. In response to Paragraph “84” of Count VII of the Complaint, Defendant repeats each and every response to the allegations set forth in Paragraphs “1” through “83” of the Complaint as if set forth at length herein.

85. As Paragraph “85” of Count VII of the Complaint alleges a legal conclusion, no answer is required. To the extent the allegations in Paragraph “85” seek to impute liability to Defendant, they are denied.

86. Defendant denies the allegations contained in Paragraph “86” of Count VII of the Complaint.

87. Defendant denies the allegations contained in Paragraph “87” of Count VII of the Complaint.

88. As Paragraph “88” of Count VII of the Complaint alleges a legal conclusion, no answer is required. To the extent the allegations in Paragraph “88” seek to impute liability to Defendant, they are denied.

89. Defendant denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations set forth in Paragraph “89” of Count VII of the Complaint. To

the extent the allegations in Paragraph “89” seek to impute liability to Defendant, they are denied.

90. Defendant denies the allegations contained in Paragraph “90” of Count VII of the Complaint.

WHEREFORE, Defendant demands judgment in its favor and against Plaintiffs, dismissing Count VII of the Complaint with prejudice, together with costs of suit and such other relief as the Court deems equitable and just.

COUNT VIII - BREACH OF IMPLIED WARRANTIES

91. In response to Paragraph “91” of Count VIII of the Complaint, Defendant repeats each and every response to the allegations set forth in Paragraphs “1” through “90” of the Complaint as if set forth at length herein.

92. Regarding Paragraph “92” of Count VIII of the Complaint, Defendant HOC admits that it designed, manufactured, and marketed the Rejuvenate® Modular Hip System. The remaining allegations are denied.

93. Defendant denies the allegations contained in Paragraph “93” of Count VIII of the Complaint.

94. As Paragraph “94” of Count VIII of the Complaint alleges a legal conclusion, no answer is required. To the extent the allegations in Paragraph “94” seek to impute liability to Defendant, they are denied.

95. As Paragraph “95” of Count VIII of the Complaint alleges a legal conclusion, no answer is required. To the extent the allegations in Paragraph “95” seek to impute liability to Defendant, they are denied.

96. Defendant denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations set forth in Paragraph “96” of Count VIII of the Complaint. To

the extent the allegations in Paragraph “96” seek to impute liability to Defendant, they are denied.

97. Defendant denies the allegations contained in Paragraph “97” of Count VIII of the Complaint (including all of the sub-paragraphs).

98. Defendant denies the allegations contained in Paragraph “98” of Count VIII of the Complaint.

99. Defendant denies the allegations contained in Paragraph “99” of Count VIII of the Complaint.

100. Defendant denies the allegations contained in Paragraph “100” of Count VIII of the Complaint.

101. Defendant denies the allegations contained in Paragraph “101” of Count VIII of the Complaint.

WHEREFORE, Defendant demands judgment in its favor and against Plaintiffs, dismissing Count VIII of the Complaint with prejudice, together with costs of suit and such other relief as the Court deems equitable and just.

**COUNT IX - CONSUMER FRAUD AND/OR UNFAIR
AND DECEPTIVE TRADE PRACTICES UNDER STATE LAW**

102. In response to Paragraph “102” of Count IX of the Complaint, Defendant repeats each and every response to the allegations set forth in Paragraphs “1” through “101” of the Complaint as if set forth at length herein.

103. The allegations in Paragraph “103” of Count IX of the Complaint amount to a declarative statement about what type of case Plaintiffs may allege in the Complaint, and Defendant admits that Plaintiffs have so averred, but denies that there is any legal or factual basis for such relief.

104. The allegations in Paragraph “104” of Count IX of the Complaint amount to a declarative statement about what type of case Plaintiffs may allege in the Complaint, and Defendant admits that Plaintiffs have so averred, but denies that there is any legal or factual basis for such relief.

WHEREFORE, Defendant demands judgment in its favor and against Plaintiffs, dismissing Count IX of the Complaint with prejudice, together with costs of suit and such other relief as the Court deems equitable and just.

COUNT X - GROSS NEGLIGENCE/MALICE

105. In response to Paragraph “105” of Count X of the Complaint, Defendant repeats each and every response to the allegations set forth in Paragraphs “1” through “104” of the Complaint as if set forth at length herein.

106. Defendant denies the allegations contained in Paragraph “106” of Count X of the Complaint.

107. Defendant denies the allegations contained in Paragraph “107” of Count X of the Complaint.

108. The allegations in Paragraph “108” of Count X of the Complaint amount to a declarative statement about what type of case Plaintiffs may allege in the Complaint, and Defendant admits that Plaintiffs have so averred, but denies that there is any legal or factual basis for such relief.

109. Defendant denies the allegations contained in Paragraph “109” of Count X of the Complaint.

WHEREFORE, Defendant demands judgment in its favor and against Plaintiffs, dismissing Count X of the Complaint with prejudice, together with costs of suit and such other relief as the Court deems equitable and just.

COUNT XI - LOSS OF CONSORTIUM

110. In response to Paragraph “110” of Count XI of the Complaint, Defendant repeats each and every response to the allegations set forth in Paragraphs “1” through “109” of the Complaint as if set forth at length herein.

111. Defendant denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations set forth in Paragraph “111” of Count XI of the Complaint regarding the Plaintiffs’ marital status. Defendant denies the remaining allegations.

WHEREFORE, Defendant demands judgment in its favor and against Plaintiffs dismissing Count XI of the Complaint with prejudice, together with costs of suit and such other relief as the Court deems equitable and just.

**COUNT XII - PUNITIVE DAMAGES UNDER COMMON LAW,
PUNITIVE DAMAGES ACT (N.J.S.A. 2A:15-5.9 et seq.) and PRODUCT LIABILITY
ACT (N.J.S.A. 2A:58C-1 et seq.)**

112. In response to Paragraph “112” of Count XII of the Complaint, Defendant repeats each and every response to the allegations set forth in Paragraphs “1” through “111” of the Complaint as if set forth at length herein.

113. Defendant denies the allegations contained in Paragraph “113” of Count XII of the Complaint.

114. Defendant denies the allegations contained in Paragraph “114” of Count XII of the Complaint.

115. Defendant denies the allegations contained in Paragraph “115” of Count XII of the Complaint.

116. Defendant denies the allegations contained in Paragraph “116” of Count XII of the Complaint.

117. Defendant denies the allegations contained in Paragraph “117” of Count XII of the Complaint.

118. Defendant denies the allegations contained in Paragraph “118” of Count XII of the Complaint.

119. Defendant denies the allegations contained in Paragraph “119” of Count XII of the Complaint.

120. Defendant denies the allegations contained in Paragraph “120” of Count XII of the Complaint.

121. Defendant denies the allegations contained in Paragraph “121” of Count XII of the Complaint.

122. Defendant denies the allegations contained in Paragraph “122” of Count XII of the Complaint.

123. Defendant submits that the allegations contained in Paragraph “123” of Count XII of the Complaint are improper and contrary to the existence of binding precedent regarding punitive damages. Defendant denies the allegations.

WHEREFORE, Defendant demands judgment in its favor and against Plaintiffs dismissing Count XII of the Complaint with prejudice, together with costs of suit and such other relief as the Court deems equitable and just.

COUNT XIII - MEDICAL MONITORING

124. In response to Paragraph “124” of Count XIII of the Complaint, Defendant repeats each and every response to the allegations set forth in Paragraphs “1” through “123” of the Complaint as if set forth at length herein.

125. Regarding Paragraph “125” of Count XIII of the Complaint, Defendant HOC admits that it designed, manufactured, and marketed the Rejuvenate® Modular Hip System. The remaining allegations are denied.

126. As Paragraph “126” of Count XIII of the Complaint alleges a legal conclusion, no answer is required. To the extent the allegations in Paragraph “126” seek to impute liability to Defendant, they are denied.

127. Defendant denies the allegations contained in Paragraph “127” of Count XIII of the Complaint (including all of the sub-paragraphs).

128. Defendant denies the allegations contained in Paragraph “128” of Count XIII of the Complaint (including all of the sub-paragraphs).

129. Defendant denies the allegations contained in Paragraph “129” of Count XIII of the Complaint.

130. Regarding the allegations set forth in Paragraph “130” of Count XIII of the Complaint, as with the implantation and use of all medical devices of this type, the implantation and use of the Rejuvenate® Modular Hip System has attendant risks. To the extent these allegations are intended to impute liability to HOC, then Defendant denies the allegations.

131. Defendant denies the allegations contained in Paragraph “131” of Count XIII of the Complaint.

132. Defendant denies the allegations contained in Paragraph “132” of Count XIII of the Complaint.

133. Defendant denies the allegations contained in Paragraph “133” of Count XIII of the Complaint.

134. As Paragraph “134” of Count XIII of the Complaint alleges a legal conclusion and requires expert opinion evidence, no answer is required. To the extent the allegations in Paragraph “134” seek to impute liability to Defendant, they are denied.

135. The allegations set forth in Paragraph “135” of Count XIII of the Complaint are unintelligible so no response to the actual allegations is possible. To the extent these allegations are intended to impute liability to HOC, then Defendant denies the allegations.

136. Defendant denies the allegations contained in Paragraph “136” of Count XIII of the Complaint.

WHEREFORE, Defendant demands judgment in its favor and against Plaintiffs dismissing Count XIII of the Complaint with prejudice, together with costs of suit and such other relief as the Court deems equitable and just.

PRAYER FOR RELIEF

In response to Plaintiffs’ Paragraph and subparts entitled “Prayer for Relief,” Defendant denies all statements that Plaintiffs are entitled to any relief and/or damages whatsoever against Defendant.

SEPARATE DEFENSES

FIRST SEPARATE DEFENSE

Plaintiffs’ claims are preempted by the Medical Device Amendments to the Food, Drug & Cosmetic Act of 1938.

SECOND SEPARATE DEFENSE

Plaintiffs’ claims are barred in whole or in part by the applicable statute of limitations.

THIRD SEPARATE DEFENSE

Any and all acts complained of and the alleged damages resulting therefrom were the result of Plaintiffs’ assumption of the risk.

FOURTH SEPARATE DEFENSE

Plaintiffs' claims are barred, in whole or in part, because of the doctrine of informed consent.

FIFTH SEPARATE DEFENSE

The imposition of punitive damages against Defendant would violate Defendant's rights under the Due Process clauses in the Fifth and Fourteenth Amendments to the Constitution of the United States, the Excessive Fines clause in the Eighth Amendment to the Constitution of the United States, the Double Jeopardy clause in the Fifth Amendment to the Constitution of the United States, the equal protection clause of the Fourteenth Amendment to the Constitution of the United States, and the Sixth Amendment to the Constitution of the United States, in several regards, including but not limited to the following:

- a. imposition of punitive damages by a jury which is inadequately instructed regarding the rationale behind punitive damages, the standards/criteria governing such an award of damages, and/or the limits of such damages;
- b. imposition of punitive damages where applicable law is impermissibly vague, imprecise, or inconsistent;
- c. imposition of punitive damages that employs a burden of proof that is less than clear and convincing evidence;
- d. imposition of punitive damages without bifurcating the trial and trying all punitive damages issues separately, only if and after a finding on the merits of the liability of Defendant;
- e. imposition of punitive damages without any predetermined limit on any such award;

f. imposition of punitive damages which allows multiple punishment for the same alleged act(s) or omission(s); and

g. imposition of punitive damages without consistent appellate standards of review of such an award.

SIXTH SEPARATE DEFENSE

The Complaint fails to state a cause of action upon which relief can be granted under applicable law.

SEVENTH SEPARATE DEFENSE

HOC reserves the right to assert any additional defenses which may be disclosed during the course of investigation and discovery as permitted by applicable law and by this Court's Implementing Order dated May __, 2013.

WHEREFORE, Defendant demands judgment in its favor and against Plaintiffs, dismissing Plaintiffs' Complaint with prejudice, together with the costs of suit and such other relief as the Court deems equitable and just.

GIBBONS P.C.
One Gateway Center
Newark, New Jersey 07102
(973) 596-4500
Attorneys for Defendant
Howmedica Osteonics Corp.

Dated: May __, 2013

By: _____
Kim M. Catullo

DEMAND FOR A TRIAL BY JURY

Defendant demands a trial by jury of twelve of all claims triable as of right by jury.

GIBBONS P.C.
One Gateway Center
Newark, New Jersey 07102
(973) 596-4500
Attorneys for Defendant
Howmedica Osteonics Corp.

By: _____
Kim M. Catullo

Dated: May __, 2013

CERTIFICATION PURSUANT TO N.J. COURT RULE 4:5-1

I hereby certify that this case has been identified as a case that has been assigned for centralized case management to the Honorable Brian R. Martinotti, J.S.C., Superior Court, Law Division, Bergen County, by Order dated January 15, 2013, and captioned "In Re Stryker Rejuvenate Hip Stem and ABGII Modular Hip Stem Litigation," Case No. 296. The undersigned further certifies that I am unaware of the identities of any other persons or entities who should be joined in the within action.

GIBBONS P.C.
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COUNSEL DESIGNATION

Pursuant to Rule 4:25-4, Kim M. Catullo is hereby designated as New Jersey trial counsel for Defendant Howmedica Osteonics Corp.

GIBBONS P.C.

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