UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW HAMPSHIRE

IN RE: **ATRIUM MEDICAL CORP. C-QUR MESH PRODUCTS LIABILITY LITIGATION**	**MDL NO. 2753** **MDL Docket No. 1:16-md-02753-LM**

MASTER ANSWER AND JURY DEMAND OF DEFENDANT ATRIUM MEDICAL CORPORATION TO AMENDED MASTER COMPLAINT

Defendant Atrium Medical Corporation ("Atrium") submits this Answer to Plaintiffs' Amended Master Long Form Complaint, Dkt. 1172 (the "Complaint"). Throughout the Complaint, Plaintiffs refer to "Defendants" without differentiating between the Defendants. Atrium denies that Maquet Cardiovascular USA Sales, LLC ("MCV US Sales") designed, patented, manufactured, packaged, labeled, marketed, sold, or distributed C-QUR hernia mesh products, except that C-QUR mesh products were marketed and sold by MCV US Sales from January 2014 through September 2017. Whenever "Defendants" is used in the Complaint to suggest otherwise, that allegation is denied. Responding further, Atrium denies each and every allegation contained in the Complaint except as may be hereinafter admitted, qualified, or explained,[1] and states and alleges as follows:

PARTIES, JURISDICTION & VENUE

1. Atrium lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 1 of the Complaint, which are therefore denied.

[1] To the extent that the titles and headings of the Complaint are intended to be allegations directed to Atrium, they are denied. Titles and headings are re-stated herein for ease of reference only.

1. In response to the second Paragraph 1 of the Complaint, Atrium admits that it is a Delaware corporation. Atrium admits that its principal place of business is located in New Hampshire, and that its manufacturing and support facilities were previously located in Hudson, New Hampshire. Atrium admits that it is a medical device company involved in the research, development, testing, manufacture, production, marketing, promotion, and/or sale of medical devices, including C-QUR mesh.

2. Paragraph 2 contains allegations not directed to Atrium to which no response is required. To the extent a response is required, Atrium admits, on information and belief, that MCV US Sales is a limited liability corporation with its headquarters located at 45 Barbour Pond Drive, Wayne, NJ 07470, but denies that it is organized under the laws of New Jersey, denies that Atrium has operated within or as a business unit of MCV US Sales, and denies the remaining allegations of Paragraph 2 of the Complaint.

3. Denied.

4. Paragraph 4 of the Complaint states conclusions of law to which no response is required. To the extent a response is required, Atrium denies that it is liable to Plaintiffs.

5. In response to Paragraph 5 of the Complaint, Atrium admits only that it has designed, patented, manufactured, packaged, labeled, marketed, sold, and distributed C-QUR hernia mesh products; that among the intended purposes for which it designed, manufactured, marketed, and sold C-QUR mesh was for use in hernia repair; that it received clearance for those products from the U.S. Food and Drug Administration under Section 510(k) of the Food, Drug and Cosmetic Act; and that Atrium hernia mesh products were marketed and sold by MCV US Sales from January 2014 through September 2017. Atrium denies any attempt to characterize Section 510(k) of the Food, Drug and Cosmetic Act and refers the Court to the statute, implementing

regulations, and relevant legal authority for an accurate and contextual recitation of their contents. Atrium denies the remaining allegations of Paragraph 5 of the Complaint.

6. Paragraph 6 of the Complaint purports to be definitional and, therefore, does not contain allegations to which a response is a required. To the extent a response is required, Atrium admits only that it has designed and sold different C-QUR hernia mesh products; that among the intended purposes for which it designed, manufactured, marketed, and sold C-QUR mesh was for use in hernia repair; that Atrium hernia mesh products were marketed and sold by MCV US Sales from January 2014 through September 2017; and denies the remaining allegations of Paragraph 6 of the Complaint.

VENUE AND JURISDICTION

7. Admitted.

8. Atrium lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 8 of the Complaint, which are therefore denied.

9. Atrium lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 9 of the Complaint, which are therefore denied.

10. Paragraph 10 of the Complaint states conclusions of law to which no response is required. To the extent a response is required, Atrium admits only that C-QUR mesh products were manufactured and sold in New Hampshire, and that Atrium is a resident of this District. Atrium denies the remaining allegations of Paragraph 10 of the Complaint.

11. Atrium admits that, as to actions originally filed in this Court, it is subject to the personal jurisdiction of this Court because its principal place of business is in New Hampshire. Atrium admits that it conducts substantial business in New Hampshire. Atrium denies the remaining allegations of Paragraph 11 of the Complaint.

12. Atrium admits that it conducted substantial business in New Hampshire, including the development, manufacture, and sale of hernia mesh products, and denies the remaining allegations of Paragraph 12 of the Complaint.

13. Atrium admits that, as to actions originally filed in this Court, it is subject to the personal jurisdiction of this Court because its principal place of business is in New Hampshire and denies the remaining allegations of Paragraph 13 of the Complaint.

FACTUAL BACKGROUND

14. Atrium admits only that it has designed, patented, manufactured, packaged, labeled, marketed, sold, and distributed C-QUR mesh products, and that Atrium hernia mesh products were marketed and sold by MCV US Sales from January 2014 through September 2017. Atrium denies the remaining allegations of Paragraph 14 of the Complaint.

15. Atrium admits only that it has designed, patented, manufactured, packaged, labeled, marketed, sold, and distributed C-QUR mesh products, and that Atrium hernia mesh products were marketed and sold by MCV US Sales from January 2014 through September 2017. Atrium denies the remaining allegations of Paragraph 15 of the Complaint.

16. Atrium admits only that among the intended purposes for which it designed, manufactured, marketed, and sold C-QUR mesh was for use in hernia repair. Atrium lacks knowledge or information sufficient to form a belief regarding whether Plaintiffs' implanting surgeons implanted C-QUR mesh in Plaintiffs in accordance with the instructions for use and product specifications, which will be the subject of expert testimony, and therefore denies the remaining allegations of Paragraph 16 of the Complaint.

17. Atrium admits only that Atrium's hernia mesh products are generally intended for permanent implantation in the human body, but states that certain complications can occur with any surgical mesh, including those disclosed in the Instructions for Use that accompanied Atrium's

mesh products, and denies that the Omega 3-derived gel coating is designed to be permanent, and therefore denies the allegations set forth in Paragraph 17 of the Complaint.

18. Atrium admits only that it has marketed and distributed C-QUR surgical mesh products to the medical community; that it has accurately and appropriately represented that its surgical mesh products are safe and effective; that it has accurately presented their risks and benefits in promotional materials and Instructions for Use, and denies the remaining allegations of Paragraph 18 of the Complaint.

19. Denied.

20. Denied.

21. Atrium admits only that surgical hernia mesh manufactured by Atrium was manufactured from polypropylene, and that the C-QUR mesh product line shares the common characteristic of having an Omega 3-derived gel coating that is derived from highly purified pharmaceutical grade fish oil. Atrium lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 21 of the Complaint, which are therefore denied.

22. Atrium admits only that surgical hernia mesh manufactured by Atrium was manufactured from polypropylene, that the C-QUR mesh product line shares the common characteristic of having an Omega 3-derived gel coating that is derived from highly purified pharmaceutical grade fish oil; and that the risks and benefits of C-QUR mesh products were accurately presented in promotional materials and Instructions for Use. Atrium denies the remaining allegations of Paragraph 22 of the Complaint.

23. Denied.

24. Denied.

25. Denied.

26. Atrium denies Paragraph 26's characterization of Atrium's C-QUR mesh products and denies the remaining allegations of Paragraph 26 of the Complaint.

27. Denied.

28. Denied.

29. Denied.

30. Atrium admits only that alternative methods to treat hernias exist and that the choice of treatment or device is a medical judgment to be made by the patient's physician. Atrium otherwise denies the allegations of Paragraph 30 of the Complaint.

31. Denied.

32. Denied.

33. Denied.

34. Denied.

35. Denied.

36. Atrium denies Paragraph 36's characterization of Atrium's C-QUR mesh products and denies the remaining allegations of Paragraph 36 of the Complaint.

37. Denied.

38. Denied.

39. Denied.

40. Denied.

41. Denied.

42. Denied.

43. Atrium admits only that it has marketed and distributed C-QUR surgical mesh products to the medical community; that it has properly tested such products; that it has accurately

and appropriately represented that its surgical mesh products are safe and effective; that it has accurately presented their risks and benefits in promotional materials and Instructions for Use, and denies the remaining allegations of Paragraph 43 of the Complaint.

44. Denied.

45. Denied.

46. Denied.

47. Denied.

48. Atrium admits only that it has marketed and distributed C-QUR surgical mesh products to the medical community; that it has properly tested such products; that it has accurately and appropriately represented that its surgical mesh products are safe and effective; that it has accurately presented their risks and benefits in promotional materials and Instructions for Use, and denies the remaining allegations of Paragraph 48 of the Complaint.

49. Atrium lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 49 of the Complaint, which are therefore denied.

50. Atrium lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 50 of the Complaint, which are therefore denied.

51. Atrium lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 51 of the Complaint, which are therefore denied.

52. Denied.

53. Atrium denies Paragraph 53's characterization of Atrium's C-QUR mesh products and denies the remaining allegations of Paragraph 53 of the Complaint.

54. Atrium denies Paragraph 54's characterization of Atrium's C-QUR mesh products and denies the remaining allegations of Paragraph 54 of the Complaint.

55. Denied.

56. Atrium denies Paragraph 56's characterization of Atrium's C-QUR mesh products and denies the remaining allegations of Paragraph 56 of the Complaint.

57. Atrium denies Paragraph 57's characterization of Atrium's C-QUR mesh products and denies the remaining allegations of Paragraph 57 of the Complaint.

58. Atrium denies Paragraph 58's characterization of Atrium's C-QUR mesh products and denies the remaining allegations of Paragraph 58 of the Complaint.

ESTOPPEL AND TOLLING OF STATUTE OF LIMITATIONS

59. Denied.

60. Denied.

COUNT I: NEGLIGENCE

61. In response to the allegations of Paragraph 61 of the Complaint, Atrium restates and incorporates by reference its Answer to each and every paragraph of the Complaint.

62. Atrium admits only those duties that are imposed by law, denies any breach of those duties, and otherwise denies the allegations of Paragraph 62 of the Complaint.

63. Denied.

64. Denied, including subparts.

65. Denied, including subparts.

66. Atrium denies Paragraph 66's characterization of Atrium's C-QUR mesh products and denies the remaining allegations of Paragraph 66 of the Complaint, including subparts.

67. Denied.

68. Denied.

69. Denied.

70. Denied.

70.1 Atrium denies that Plaintiffs are entitled to the relief requested in the "PRAYER" and/or the "WHEREFORE" clause following Paragraph 70, or to any relief whatsoever.

COUNT II: STRICT LIABILITY – DESIGN DEFECT

71. In response to the allegations of Paragraph 71 of the Complaint, Atrium restates and incorporates by reference its Answer to each and every paragraph of the Complaint.

72. Atrium admits only that Atrium manufactured, sold, and distributed C-QUR hernia mesh products prior to January 2014, that Atrium manufactured C-QUR mesh after January 2014, and that MCV US Sales sold and distributed C-QUR mesh from January 2014 through September 2017. Atrium denies the remaining allegations of Paragraph 72 of the Complaint.

73. Denied.

74. Atrium lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 74 of the Complaint, which will be the subject of expert testimony, and which are therefore denied.

75. Atrium lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 75 of the Complaint, which will be the subject of expert testimony, and which are therefore denied.

76. Denied.

77. Denied, including subparts.

78. Atrium lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 78 of the Complaint, which will be the subject of expert testimony, and which are therefore denied.

79. Atrium denies the first sentence of Paragraph 79 of the Complaint. Atrium denies the Atrium C-QUR mesh was defective and denies the remaining allegations of the second sentence of Paragraph 79. Atrium lacks knowledge or information sufficient to form a belief as to

the truth of the allegations of the last sentence of Paragraph 79 of the Complaint, which will be the subject of expert testimony, and which are therefore denied.

80. Denied.

81. In response to the first sentence of Paragraph 81, Atrium admits only that the Omega 3-derived gel coating was bioabsorbable. Atrium denies the remaining allegations of Paragraph 81 of the Complaint.

82. Denied.

83. Denied.

84. Atrium admits only that C-QUR mesh was designed and intended to be used in accordance with the Instructions for Use, and denies the remaining allegations of Paragraph 84 of the Complaint.

85. Atrium admits only that alternative methods to treat hernias exist and that the choice of treatment or device is a medical judgment to be made by the patient's physician. Atrium otherwise denies the allegations of Paragraph 85 of the Complaint.

86. Denied.

87. Denied.

88. Denied.

89. Denied.

89.1 Atrium denies that Plaintiffs are entitled to the relief requested in the "PRAYER" and/or the "WHEREFORE" clause following Paragraph 89, or to any relief whatsoever.

COUNT III: STRICT LIABILITY – MANUFACTURING DEFECT

90. In response to the allegations of Paragraph 90 of the Complaint, Atrium restates and incorporates by reference its Answer to each and every paragraph of the Complaint.

91. Atrium admits only that Atrium manufactured, sold, and distributed C-QUR hernia mesh products prior to January 2014, that Atrium manufactured C-QUR mesh after January 2014, and that MCV US Sales sold and distributed C-QUR mesh from January 2014 through September 2017. Atrium denies the remaining allegations of Paragraph 91 of the Complaint.

92. Denied.

93. Denied.

94. Atrium lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 94 of the Complaint, which will be the subject of expert testimony, and which are therefore denied.

95. Atrium denies the C-QUR mesh was defective and, therefore, denies the allegations of the first sentence of Paragraph 95 of the Complaint. Atrium lacks knowledge or information sufficient to form a belief as to the truth of the allegations of the second sentence of Paragraph 95 of the Complaint, which will be the subject of expert testimony, and which are therefore denied.

96. Denied.

97. Denied.

98. Denied.

99. Denied.

99.1 Atrium denies that Plaintiffs are entitled to the relief requested in the "PRAYER" and/or the "WHEREFORE" clause following Paragraph 99, or to any relief whatsoever.

COUNT IV: STRICT LIABILITY – FAILURE TO WARN

100. In response to the allegations of Paragraph 100 of the Complaint, Atrium restates and incorporates by reference its Answer to each and every paragraph of the Complaint.

101. Atrium admits only that Atrium manufactured, sold, and distributed C-QUR hernia mesh products prior to January 2014, that Atrium manufactured C-QUR mesh after January 2014,

and that MCV US Sales sold and distributed C-QUR mesh from January 2014 through September 2017. Atrium denies the remaining allegations of Paragraph 101 of the Complaint.

102. Denied, including subparts.

103. Denied.

104. Denied.

105. Atrium denies that inadequate research and testing of the C-QUR mesh was done prior to C-QUR mesh being placed on the market and denies that remaining allegations of Paragraph 105 of the Complaint.

106. Denied.

107. Atrium lacks knowledge or information sufficient to form a belief as to what Plaintiffs and their physicians were aware of, but denies that C-QUR mesh was defective and denies the remaining allegations of Paragraph 107 of the Complaint.

108. In response to Paragraph 108, Atrium states that it accurately presented the risks and benefits of C-QUR surgical mesh in promotional materials and Instructions for Use, denies that Plaintiffs' physicians were not adequately warned and, therefore, denies the remaining allegations of Paragraph 108 of the Complaint.

109. In response to Paragraph 109 of the Complaint, Atrium states that it accurately presented the risks and benefits of C-QUR surgical mesh in promotional materials and Instructions for Use, denies that Plaintiffs' physicians were not adequately warned and, therefore, denies the remaining allegations of Paragraph 109 of the Complaint.

110. In response to Paragraph 110, Atrium states that it accurately presented the risks and benefits of C-QUR surgical mesh in promotional materials and Instructions for Use, denies

that Plaintiffs' physicians were not adequately warned and, therefore, denies the remaining allegations of Paragraph 110 of the Complaint.

111. In response to Paragraph 111, Atrium states that it accurately presented the risks and benefits of C-QUR surgical mesh in promotional materials and Instructions for Use, denies that Plaintiffs' physicians were not adequately warned and, therefore, denies the remaining allegations of Paragraph 111 of the Complaint.

112. In response to Paragraph 112, Atrium states that it accurately presented the risks and benefits of C-QUR surgical mesh in promotional materials and Instructions for Use, denies that Plaintiffs' physicians were not adequately warned, denies Paragraph 112's characterization of C-QUR mesh, and denies the remaining allegations of Paragraph 112 of the Complaint.

113. In response to Paragraph 113, Atrium states that it accurately presented the risks and benefits of C-QUR surgical mesh in promotional materials and Instructions for Use, denies that Plaintiffs' physicians were not adequately warned, denies Paragraph 113's characterization of C-QUR mesh, and denies the remaining allegations of Paragraph 113 of the Complaint.

114. In response to Paragraph 114, Atrium states that it accurately presented the risks and benefits of C-QUR surgical mesh in promotional materials and Instructions for Use, denies that Plaintiffs' physicians were not adequately warned and, therefore, denies the remaining allegations of Paragraph 114 of the Complaint.

115. Denied.

115.1 Atrium denies that Plaintiffs are entitled to the relief requested in the "PRAYER" and/or the "WHEREFORE" clause following Paragraph 115, or to any relief whatsoever.

COUNT V: STRICT LIABILITY – DEFECTIVE PRODUCT

116. In response to the allegations of Paragraph 116 of the Complaint, Atrium restates and incorporates by reference its Answer to each and every paragraph of the Complaint.

117. Denied.

118. Denied.

119. Atrium lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 119 of the Complaint, which are therefore denied.

120. Atrium lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 120 of the Complaint, which are therefore denied.

121. Denied.

121.1 Atrium denies that Plaintiffs are entitled to the relief requested in the "PRAYER" and/or the "WHEREFORE" clause following Paragraph 121, or to any relief whatsoever.

COUNT VI: BREACH OF EXPRESS WARRANTY

122. In response to the allegations of Paragraph 122 of the Complaint, Atrium restates and incorporates by reference its Answer to each and every paragraph of the Complaint.

123. Atrium admits only that Atrium manufactured, sold, and distributed C-QUR hernia mesh products prior to January 2014, that Atrium manufactured C-QUR mesh after January 2014, and that MCV US Sales sold and distributed C-QUR mesh from January 2014 through September 2017. Atrium denies the remaining allegations of Paragraph 123 of the Complaint.

124. Atrium admits only that it made those representations contained in the Instructions for Use that accompanied its surgical mesh products, and denies the remaining allegations of Paragraph 124 of the Complaint.

125. Atrium admits only that it made those representations contained in the Instructions for Use that accompanied its surgical mesh products, that among the intended purposes for which it designed, manufactured, marketed, and sold C-QUR Mesh was for use in hernia repair, and denies the remaining allegations of Paragraph 125 of the Complaint.

126. Atrium admits only that it made those representations contained in the Instructions for Use that accompanied its surgical mesh products. Atrium lacks knowledge or information sufficient to form a belief regarding what information Plaintiffs or their healthcare providers relied on in selecting any surgical mesh, and therefore denies such allegations of Paragraph 126 of the Complaint. Atrium denies the remaining allegations of Paragraph 126 of the Complaint.

127. Denied.

128. Atrium admits only that it made those representations contained in the Instructions for Use that accompanied its surgical mesh products, and denies the remaining allegations of Paragraph 128 of the Complaint, including subparts.

129. Denied.

130. Denied.

131. Denied.

131.1 Atrium denies that Plaintiffs are entitled to the relief requested in the "PRAYER" and/or the "WHEREFORE" clause following Paragraph 131, or to any relief whatsoever.

COUNT VII: BREACH OF IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS OF PURPOSE

132. In response to the allegations of Paragraph 132 of the Complaint, Atrium restates and incorporates by reference its Answer to each and every paragraph of the Complaint.

133. Atrium admits only that Atrium manufactured, sold, and distributed C-QUR hernia mesh products prior to January 2014, that Atrium manufactured C-QUR mesh after January 2014, and that MCV US Sales sold and distributed C-QUR mesh from January 2014 through September 2017. Atrium denies the remaining allegations of Paragraph 133 of the Complaint.

134. Atrium admits only that it provided such implied warranties as may be imposed by applicable law, denies any violation of such warranties, and denies the remaining allegations of Paragraph 134 of the Complaint.

135. Atrium admits only that it provided such implied warranties as may be imposed by applicable law, denies any violation of such warranties, and denies the remaining allegations of Paragraph 135 of the Complaint.

136. Atrium lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 136 of the Complaint, which will be the subject of expert testimony, and which are therefore denied.

137. Atrium admits only that C-QUR mesh was designed and intended to be used in accordance with the Instructions for Use, and lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 137 of the Complaint, which will be the subject of expert testimony, and which are therefore denied.

138. Atrium admits only that that it has accurately presented the indications, risks and benefits of C-QUR surgical mesh products in Instructions for Use, that it lacks knowledge or information sufficient to form a belief regarding whether Plaintiffs' implanting surgeons implanted C-QUR mesh in Plaintiffs in accordance with the Instructions for Use and product specifications, which will be the subject of expert testimony, and denies the remaining allegations of Paragraph 138 of the Complaint.

139. In response to the first sentence of Paragraph 139 of the Complaint, Atrium admits only that C-QUR mesh was designed and intended to be used in accordance with the Instructions for Use, and lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of the first sentence of Paragraph 139 of the Complaint, which will be the

subject of expert testimony, and which are therefore denied. In response to the remaining allegations of Paragraph 139 of the Complaint, Atrium admits only that it provided such implied warranties as may be imposed by applicable law, denies any violation of such warranties, and denies the remaining allegations of Paragraph 139 of the Complaint, including subparts.

140. Atrium lacks knowledge or information sufficient to form a belief regarding what information Plaintiffs or their healthcare providers relied on in selecting any surgical mesh, and therefore denies such allegations of Paragraph 140 of the Complaint.

141. Atrium admits only that that it has accurately presented the indications, risks and benefits of C-QUR surgical mesh products in Instructions for Use, that it lacks knowledge or information sufficient to form a belief regarding whether Plaintiffs' implanting surgeons implanted C-QUR mesh in Plaintiffs in accordance with the Instructions for Use and product specifications, which will be the subject of expert testimony, and denies the remaining allegations of Paragraph 141 of the Complaint.

142. Denied.

143. Denied.

144. Denied.

145. Denied.

145.1 Atrium denies that Plaintiffs are entitled to the relief requested in the "PRAYER" and/or the "WHEREFORE" clause following Paragraph 145, or to any relief whatsoever.

COUNT VIII: FRAUDULENT CONCEALMENT

146. In response to the allegations of Paragraph 146 of the Complaint, Atrium restates and incorporates by reference its Answer to each and every paragraph of the Complaint.

147. Denied.

148. Denied.

149. Denied.

150. Denied, including subparts.

151. Denied.

152. Denied.

153. Denied.

154. Denied.

155. Denied.

155.1 Atrium denies that Plaintiffs are entitled to the relief requested in the "PRAYER" and/or the "WHEREFORE" clause following Paragraph 155, or to any relief whatsoever.

COUNT IX: CONSTRUCTIVE FRAUD

156. In response to the allegations of Paragraph 156 of the Complaint, Atrium restates and incorporates by reference its Answer to each and every paragraph of the Complaint.

157. Denied.

158. Denied.

159. Denied.

160. Denied.

161. Denied.

162. Denied.

162.1 Atrium denies that Plaintiffs are entitled to the relief requested in the "PRAYER" and/or the "WHEREFORE" clause following Paragraph 162, or to any relief whatsoever.

COUNT X: DISCOVERY RULE, TOLLING, AND FRAUDULENT CONCEALMENT

163. In response to the allegations of Paragraph 163 of the Complaint, Atrium restates and incorporates by reference its Answer to each and every paragraph of the Complaint.

164. Atrium acknowledges that Plaintiffs desire to assert "state statutory and common law rights and theories," but denies that Plaintiffs are entitled to toll or extend any applicable statute of limitations.

165. Atrium acknowledges that Plaintiffs desire to assert that the statute of limitations should be tolled, but denies that Plaintiffs are entitled to toll or extend any applicable statute of limitations.

166. Denied.

167. Denied.

COUNT XI: NEGLIGENT MISREPRESENTATION

168. In response to the allegations of Paragraph 168 of the Complaint, Atrium restates and incorporates by reference its Answer to each and every paragraph of the Complaint.

169. Denied.

170. Denied.

171. Denied.

172. Denied.

173. Denied.

173.1 Atrium denies that Plaintiffs are entitled to the relief requested in the "PRAYER" and/or the "WHEREFORE" clause following Paragraph 173, or to any relief whatsoever.

COUNT XII: NEGLIGENT INFLICTION OF EMOTIONAL DISTRESS

174. In response to the allegations of Paragraph 174 of the Complaint, Atrium restates and incorporates by reference its Answer to each and every paragraph of the Complaint.

175. Denied.

176. Denied.

177. Denied.

178. Denied.

179. Denied.

180. Denied.

180.1 Atrium denies that Plaintiffs are entitled to the relief requested in the "PRAYER" and/or the "WHEREFORE" clause following Paragraph 180, or to any relief whatsoever.

COUNT XIII: VIOLATION OF CONSUMER PROTECTION LAWS

181. In response to the allegations of Paragraph 181 of the Complaint, Atrium restates and incorporates by reference its Answer to each and every paragraph of the Complaint.

182. Paragraph 182 contains legal conclusions to which no response is required. To the extent a response is required, Atrium denies the allegations of Paragraph 182 of the Complaint.

183. Denied.

184. Denied, including subparts.

185. Denied.

186. Paragraph 186 contains legal conclusions to which no response is required. To the extent a response is required, Atrium admits only that it has such duties as may be imposed by applicable law, denies any breach of such duties, and denies the remaining allegations of Paragraph 186 of the Complaint.

187. Denied.

188. Denied.

189. Denied.

190. Denied.

191. Paragraph 191 contains legal conclusions to which no response is required. To the extent a response is required, Atrium admits only that it has such duties as may be imposed by

applicable law, denies any breach of such duties, and denies the remaining allegations of Paragraph 191 of the Complaint.

192. Denied.

193. Denied.

194. Atrium denies that C-QUR mesh was in a defective or dangerous condition and denies the remaining allegations of Paragraph 194 of the Complaint.

195. Denied.

196. Denied.

197. Denied.

198. Denied.

198.1 Atrium denies that Plaintiffs are entitled to the relief requested in the "PRAYER" and/or the "WHEREFORE" clause following Paragraph 198, or to any relief whatsoever.

COUNT XIV: GROSS NEGLIGENCE

199. In response to the allegations of Paragraph 199 of the Complaint, Atrium restates and incorporates by reference its Answer to each and every paragraph of the Complaint.

200. Denied.

201. Denied.

202. Atrium lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 202 of the Complaint, which are therefore denied.

203. Denied.

203.1 Atrium denies that Plaintiffs are entitled to the relief requested in the "PRAYER" and/or the "WHEREFORE" clause following Paragraph 203, or to any relief whatsoever.

COUNT XV: UNJUST ENRICHMENT

204. In response to the allegations of Paragraph 204 of the Complaint, Atrium restates and incorporates by reference its Answer to each and every paragraph of the Complaint.

205. Atrium admits only that it has manufactured, sold, and supplied C-QUR mesh products, and that Atrium hernia mesh products were marketed and sold by MCV US Sales from January 2014 through September 2017. Atrium denies the remaining allegations of Paragraph 205 of the Complaint.

206. Denied.

207. Denied.

208. Denied.

209. Denied.

209.1 Atrium denies that Plaintiffs are entitled to the relief requested in the "PRAYER" and/or the "WHEREFORE" clause following Paragraph 209, or to any relief whatsoever.

COUNT XVI: LOSS OF CONSORTIUM

210. In response to the allegations of Paragraph 210 of the Complaint, Atrium restates and incorporates by reference its Answer to each and every paragraph of the Complaint.

211. Denied.

211.1 Atrium denies that Plaintiffs are entitled to the relief requested in the "PRAYER" and/or the "WHEREFORE" clause following Paragraph 211, or to any relief whatsoever.

COUNT XVII: PUNITIVE OR ENHANCED COMPENSATORY DAMAGES

212. In response to the allegations of Paragraph 212 of the Complaint, Atrium restates and incorporates by reference its Answer to each and every paragraph of the Complaint.

213. Atrium denies Paragraph 213's characterization of Atrium's C-QUR mesh products and denies the remaining allegations of Paragraph 213 of the Complaint.

214. Atrium denies Paragraph 214's characterization of Atrium's C-QUR mesh products and denies the remaining allegations of Paragraph 214 of the Complaint.

215. Atrium denies Paragraph 215's characterization of Atrium's C-QUR mesh products and denies the remaining allegations of Paragraph 215 of the Complaint.

216. Denied.

217. Denied.

218. Denied.

219. Atrium denies Paragraph 219's characterization of Atrium's C-QUR mesh products and denies the remaining allegations of Paragraph 219 of the Complaint.

220. Atrium denies Paragraph 220's characterization of Atrium's C-QUR mesh products and denies the remaining allegations of Paragraph 220 of the Complaint.

221. Denied.

222. Atrium denies Paragraph 222's characterization of Atrium's C-QUR mesh products and denies the remaining allegations of Paragraph 222 of the Complaint.

223. Atrium denies Paragraph 223's characterization of Atrium's C-QUR mesh products and denies the remaining allegations of Paragraph 223 of the Complaint.

224. Atrium denies Paragraph 224's characterization of Atrium's C-QUR mesh products and denies the remaining allegations of Paragraph 224 of the Complaint.

225. Denied.

225.1 Atrium denies that Plaintiffs are entitled to the relief requested in the "PRAYER" and/or the "WHEREFORE" clause following Paragraph 225, or to any relief whatsoever.

PLAINTIFFS' PRAYER FOR RELIEF

226. Atrium denies that Plaintiffs are entitled to the relief requested in the "PRAYER FOR RELIEF," or to any relief whatsoever.

DEFENSES

Atrium reserves the right to rely upon any of the following or additional defenses to claims asserted by Plaintiffs to the extent that such defenses are supported by information developed through discovery or evidence at trial. By asserting the following defenses, Atrium does not allege or admit that it has the burden of proof or the burden of persuasion with respect to any of these matters. Moreover, nothing stated herein is intended or shall be construed as an acknowledgement that any particular issue or subject necessarily is relevant to Plaintiffs' allegations. Atrium asserts all available defenses, including:

FIRST DEFENSE

Atrium reserves the right to assert that this Court lacks personal jurisdiction over it as to actions not originally filed in this Court.

SECOND DEFENSE

The Complaint fails to state a claim or claims upon which relief can be granted.

THIRD DEFENSE

The Plaintiffs' claims are barred by the applicable statute of limitations and/or statute of repose.

FOURTH DEFENSE

If Plaintiffs have been damaged, which Atrium denies, any recovery by Plaintiffs is barred to the extent any Plaintiff voluntarily exposed himself or herself to a known risk and/or failed to mitigate his or her alleged damages. To the extent any Plaintiff has failed to mitigate his or her alleged damages, any recovery shall not include alleged damages that could have been avoided by reasonable care and diligence.

FIFTH DEFENSE

The injuries and damages allegedly sustained by Plaintiffs may be due to the operation of nature, or idiosyncratic reaction(s), and/or pre-existing condition(s) in Plaintiffs over which Atrium had no control or knowledge.

SIXTH DEFENSE

The Plaintiffs' claims are barred, in whole or in part, by the doctrines of laches, waiver, and/or estoppel.

SEVENTH DEFENSE

If any Plaintiff suffered any damages or injuries, which Atrium denies, there was no causal connection between any alleged defect in the product at issue and Plaintiffs' alleged damages; thus, Plaintiffs are not entitled to recover against Atrium.

EIGHTH DEFENSE

If any Plaintiff suffered any damages or injuries, which Atrium denies, such damages were caused by the negligence or fault of Plaintiffs.

NINTH DEFENSE

If any Plaintiff suffered any damages or injuries, which Atrium denies, Plaintiffs' recovery is barred, in whole or in part, or is subject to reduction under the doctrine of comparative fault.

TENTH DEFENSE

If any Plaintiff suffered any damages or injuries, which Atrium denies, such damages were caused by unforeseeable, independent, intervening, and/or superseding events for which Atrium is not legally responsible.

ELEVENTH DEFENSE

Plaintiffs' failure to warn claims are barred by virtue of the intervention of the learned intermediary or intermediaries to whom Atrium discharged its duties to warn. At all relevant times herein, the Plaintiffs' prescribing physicians were in the position of learned intermediaries and/or sophisticated purchasers.

TWELFTH DEFENSE

The product at issue is neither defective nor unreasonably dangerous because the product is a medical device falling within what is commonly known as Comments (j) and (k), Restatement (Second) of Torts § 402A, and comparable provisions of the Restatement (Third) of Torts (Products Liability), in that the product at issue was, at all times material to the Complaint, reasonably safe and reasonably fit for its intended use, and the warnings and instructions accompanying the product at the time of the occurrence or injuries alleged by Plaintiffs were legally adequate.

THIRTEENTH DEFENSE

Plaintiffs' claims are barred because the methods, standards, warnings, and instructions used in manufacturing and/or marketing the product at issue conformed with the generally recognized, reasonably available, and reliable state of knowledge when the product was manufactured and marketed.

FOURTEENTH DEFENSE

Plaintiffs' claims are barred, in whole or in part, because at all relevant times, Atrium complied with all applicable laws and regulations.

FIFTEENTH DEFENSE

Plaintiffs' claims are barred by any applicable safe harbor doctrine to the extent that federal or state law permits the packaging, labeling, and marketing practices alleged in the Complaint.

SIXTEENTH DEFENSE

Plaintiffs' claims are barred by the doctrines of informed consent and release, or assumption of the risk.

SEVENTEENTH DEFENSE

If any Plaintiff suffered any damages or injuries, which Atrium denies, Plaintiffs' claims may be barred, in whole or in part, to the extent Plaintiffs' injuries were caused, in whole or in part, by negligence, fault, or wrongful conduct of third parties. Plaintiffs' claims should be dismissed, reduced, offset, or barred in accordance with the principles of comparative negligence, equitable indemnity, and comparative contribution.

EIGHTEENTH DEFENSE

The methods, standards, and techniques utilized with respect to the design, manufacture, marketing, promotion and sale of Atrium's hernia mesh, including but not limited to adequate warnings and instructions with respect to the product's use, conformed to the applicable state of the art and the state of scientific and medical knowledge available at the time.

NINETEENTH DEFENSE

Plaintiffs' claims are barred because the product at issue was designed, manufactured, and marketed in accordance with the state of the art and when the product left the control of Atrium, no practical and technically feasible alternative design was available that would have prevented the harm for which Plaintiffs seek to recover without substantially impairing the safety, efficacy, or usefulness of the product for its intended use.

TWENTIETH DEFENSE

To the extent any Plaintiff relies on any theory of breach of warranty, such claims are barred by applicable law, and for lack of privity with Atrium and/or for failure of Plaintiffs, or Plaintiffs' representatives, to give timely notice to Atrium of any alleged breach of warranty. Atrium further specifically pleads as to any breach of warranty claim, all affirmative defenses under the Uniform Commercial Code existing and which may arise in the future.

TWENTY-FIRST DEFENSE

Atrium is entitled to and claims the benefits of all defenses and presumptions of or arising from any rule of law or statute in this State and any other state whose law is deemed to apply in this case. Atrium reserves the right to assert that the law of a state other than New Hampshire applies to this action.

TWENTY-SECOND DEFENSE

To the extent the Plaintiffs' claims are based on alleged misrepresentations made to the FDA, such claims are barred pursuant to *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001).

TWENTY-THIRD DEFENSE

Plaintiffs fail to plead fraud with particularity.

TWENTY-FOURTH DEFENSE

Plaintiffs' claims may be barred because of Plaintiffs' failure to join necessary and indispensable parties.

TWENTY-FIFTH DEFENSE

Plaintiffs' damages, if any, may be barred, limited, or offset in the amount of any reimbursement received by Plaintiffs as a result of any insurance or other health benefits plan, or any amounts paid by any insurance or other health benefits plan.

TWENTY-SIXTH DEFENSE

The Complaint fails to state a claim against Atrium for punitive damages or enhanced compensatory damages, and Atrium incorporates by reference herein and hereby invokes, without waiver of the other defenses, Atrium's Constitutional and other objections under any applicable provisions of any state law.

TWENTY-SEVENTH DEFENSE

To the extent Plaintiffs seek punitive damages, multiples of actual damages, or enhanced compensatory damages, Atrium specifically incorporates by reference any and all standards or limitations regarding the determination and enforceability of punitive and exemplary damage awards which arose in the decisions of *TXO Products Corp. v. Alliance Resources Corp.*, 509 U.S. 443 (1993); *BMW of North America Inc. v. Gore*, 517 U.S. 559 (1996); *Cooper Industries, Inc. v. Leatherman Tool Group*, 532 U.S. 424 (2001); *State Farm Mutual Automobile Insurance Co. v. Campbell*, 538 U.S. 408 (2003); *Philip Morris USA v. Williams*, 549 U.S. 346 (2007); and *Exxon Shipping Co. v. Baker*, 554 U.S. 471 (2008), and their progeny, as well as other similar cases under both federal and state law.

RESERVATION OF RIGHT TO AMEND

Atrium intends to rely upon any additional defenses that become available during the course of investigation and/or discovery and reserves the right to amend its Answer to assert these defenses.

JURY TRIAL DEMANDED

Atrium hereby demands a trial by jury on all issues so triable.

WHEREFORE, Atrium respectfully requests that the Court: (1) enter judgment for Atrium on all counts of the Complaint; (2) award Atrium its attorneys' fees and expenses and costs; and (3) award Atrium additional relief as the Court may deem appropriate and just.

Dated: January 9, 2020

Respectfully submitted,

/s/ Katherine Armstrong

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CERTIFICATE OF SERVICE

I hereby certify that on January 9, 2020, the foregoing was filed via the Court's CM/ECF system, which will automatically serve and send notification of such filing to all registered attorneys of record.

/s/ Katherine Armstrong
Katherine Armstrong