

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW HAMPSHIRE**

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

**MASTER ANSWER AND JURY DEMAND OF
DEFENDANT GETINGE AB TO MASTER COMPLAINT**

Defendant Getinge AB (“Getinge” or “Defendant”), by and through its undersigned counsel, hereby responds to Plaintiffs’ Master Long Form Complaint and Jury Demand (“Complaint”) as follows:

PARTIES, JURISDICTION & VENUE

PLAINTIFFS

1. Defendant lacks knowledge or information sufficient to form a belief as to the truth of the matters alleged, which are therefore denied.

DEFENDANTS

1. Paragraph 1 contains allegations not directed to Getinge to which no response is required. To the extent a response is required, Getinge admits that Atrium Medical Corporation (“Atrium”) is incorporated under the laws of Delaware, and that until February/March 2015, its manufacturing and support facilities were located in Hudson, NH. Getinge further admits that Atrium 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 (hereinafter “C-QUR” or “product” or “mesh”), and denies the remaining allegations set forth in Paragraph 1.

2. Paragraph 2 contains allegations not directed to Getinge to which no response is required. To the extent a response is required, Getinge admits that Maquet Cardiovascular US Sales, LLC (“MCV US Sales”) is a limited liability company organized under the laws of New Jersey, with its principal place of business located at 45 Barbour Pond Drive, Wayne, NJ 07470, and denies the remaining allegations set forth in Paragraph 2.

3. Getinge admits that it is a Swedish corporation, organized under the laws of Sweden with its principal place of business in Sweden, and that MCV US Sales is its indirect, wholly-owned subsidiary.

4. Getinge admits that was a holding company until 2016, and denies the remaining allegations set forth in Paragraph 4.

5. Denied.

6. Getinge admits that in 2011 it indirectly acquired Atrium in a merger, and denies the remaining allegations set forth in Paragraph 6.

7. Getinge admits that since 2015, Atrium has operated as a division/business unit of Getinge, and denies the remaining allegations set forth in Paragraph 7.

8. Denied.

9. Denied.

10. Getinge admits that it is Atrium's indirect parent company, owning 100% of Atrium's shares through various subsidiaries. Getinge further admits that since 2013, MCV US Sales has sold Atrium's C-QUR mesh product line. Getinge also admits that the website www.maquet.com

lists the C-QUR mesh product line under the "biosurgery" products. Getinge denies the remaining allegations set forth in Paragraph 10.

11. Getinge admits that Atrium's website, <http://www.atriummed.com>, states that "Atrium is now part of Maquet Getinge Group," and that there exists an October 3, 2011 press release found on the website entitled "Atrium Medical Agrees to be Acquired by Getinge Group for \$680 Million." Getinge denies the remaining allegations set forth in Paragraph 11.

12. Denied.

13. Getinge admits that the C-QUR mesh products are offered on the Maquet website www.maquet.com, and that the "Contact Us" page of the www.maquet.com website states that the contact is "Vascular Systems (formerly Atrium Medical)." Getinge lacks knowledge or information sufficient to form a belief as to the truth of the matter concerning what other "publicly-available information" allegedly exists, which is therefore denied. Getinge denies the remaining allegations set forth in Paragraph 13.

14. Getinge admits that Atrium's assets and capital are subject to its indirect ownership as a function of it owning 100% of the shares of Atrium through other various subsidiaries. Getinge denies the remaining allegations set forth in Paragraph 14.

15. Denied.

16. Denied.

17. Denied.

18. Getinge admits that Atrium designed, patented, manufactured, packaged, labeled, marketed, and sold and distributed the C-QUR hernia mesh products for use in hernia repair, chest wall reconstruction, traumatic or surgical wounds, and other fascial surgical intervention procedures requiring reinforcement with a non-absorbable supportive material. Getinge also

admits that the C-QUR mesh product line shares the common characteristic of having an all natural Omega 3 gel coating that is derived from highly purified pharmaceutical grade fish oil. Getinge further admits that the C-QUR Mesh products were cleared for sale by the FDA pursuant to Section 510(k) of the Food, Drug and Cosmetic Act, and denies the remaining allegations set forth in Paragraph 18.

19. Getinge lacks knowledge or information sufficient to form a belief as to the truth of the matters alleged, insofar as the phrase “similar purposes” is undefined, which are therefore denied.

VENUE AND JURISDICTION

20. Defendant lacks knowledge or information sufficient to form a belief as to the truth of the matters alleged, which are therefore denied.

21. Denied.

22. Defendant lacks knowledge or information sufficient to form a belief as to the truth of the matters alleged, which are therefore denied.

23. Denied.

24. Denied.

25. Denied.

26. Denied.

FACTUAL BACKGROUND

27. Denied.

28. Denied.

29. Denied.

30. Getinge admits that among the intended purposes for which Atrium designed, manufactured, marketed, and sold, and MCV US Sales marketed and sold C-QUR Mesh was for use in hernia repair, chest wall reconstruction, traumatic or surgical wounds, and other fascial surgical intervention procedures requiring reinforcement with a non-absorbable supportive material. Getinge lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations set forth in Paragraph 30, which are therefore denied.

31. Getinge admits that Atrium intended that the polypropylene based mesh be for permanent implantation in the human body, but the all natural Omega 3 gel coating is not designed to be permanent, and therefore denies the allegation set forth in Paragraph 31.

32. Denied.

33. Denied.

34. Denied.

35. Getinge admits Atrium manufactured the C-QUR Mesh from polypropylene, and the C-QUR Mesh has an all natural Omega 3 gel coating that is derived from highly purified pharmaceutical grade fish oil consisting of a unique blend of triglycerides and Omega 3 fatty acids. Getinge lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations set forth in Paragraph 35, which are therefore denied.

36. Denied.

37. Denied.

38. Denied.

39. Denied.

40. Denied.

41. Denied.

42. Denied.

43. Denied.

44. Denied.

45. Denied.

46. Denied.

47. Denied.

48. Denied.

49. Denied.

50. Denied.

51. Denied.

52. Denied.

53. Denied.

54. Denied.

55. Denied.

56. Denied.

57. Getinge admits that Atrium, and MCV US Sales from 2013 through the present, marketed and sold C-QUR Mesh to the medical community, but denies the remaining allegations set forth in Paragraph 57.

58. Denied.

59. Denied.

60. Denied.

61. Denied.

62. Getinge admits that Atrium and MCV US Sales markets C-QUR Mesh to the medical community as safe, effective, and reliable, but denies the remaining allegations set forth in Paragraph 62.

63. Getinge lacks knowledge or information sufficient to form a belief as to the truth of the matters alleged, which are therefore denied.

64. Getinge lacks knowledge or information sufficient to form a belief as to the truth of the matters alleged, which are therefore denied.

65. Getinge lacks knowledge or information sufficient to form a belief as to the truth of the matters alleged, which are therefore denied.

66. Denied.

67. Denied.

68. Denied.

69. Denied.

70. Denied.

71. Denied.

72. Denied.

ESTOPPEL AND TOLLING OF STATUTE OF LIMITATIONS

73. Denied.

74. Denied.

COUNT I: NEGLIGENCE

75. Defendant incorporates by reference its responses to the foregoing paragraphs as if fully set forth herein.

76. Denied.

77. Denied.

78. Defendant denies the allegations set forth in Paragraph 78 and its subparts (a)-(e).

79. Defendant denies the allegations set forth in Paragraph 79 and its subparts (a)-(d).

80. Defendant denies the allegations set forth in Paragraph 80 and its subparts (a)-(r).

81. Denied.

82. Denied.

83. Denied.

84. Denied.

Defendant denies that Plaintiffs are entitled to the relief requested in the “PRAYER” and/or the “WHEREFORE” clause following Paragraph 84, or to any relief whatsoever.

COUNT II: STRICT LIABILITY – DESIGN DEFECT

85. Defendant incorporates by reference its responses to the foregoing paragraphs as if fully set forth herein.

86. Denied.

87. Denied.

88. Denied.

89. Getinge lacks knowledge or information sufficient to form a belief as to the truth of whether the implantation of the C-QUR Mesh in Plaintiffs was medically reasonable, which is therefore denied. Getinge denies the remaining allegations set forth in Paragraph 89.

90. Denied.

91. Defendant denies the allegations set forth in Paragraph 91 and its subparts (a)-(d).

92. Defendant lacks knowledge or information sufficient to form a belief as to the truth of the matters alleged, which are therefore denied.

93. Denied.

94. Denied.

95. Getinge admits that Atrium intended the all natural Omega 3 gel coating to be absorbed into the body, and denies the remaining allegations set forth in Paragraph 95.

96. Denied.

97. Denied.

98. Denied.

99. Denied.

100. Denied.

101. Denied.

102. Denied.

103. Denied.

Defendant denies that Plaintiffs are entitled to the relief requested in the “PRAYER” and/or the “WHEREFORE” clause following Paragraph 103, or to any relief whatsoever.

COUNT III: STRICT LIABILITY – MANUFACTURING DEFECT

104. Defendant incorporates by reference its responses to the foregoing paragraphs as if fully set forth herein.

105. Denied.

106. Denied.

107. Denied.

108. Denied.

109. Denied.

110. Denied.

111. Denied.

112. Denied.

113. Denied.

Defendant denies that Plaintiffs are entitled to the relief requested in the “PRAYER” and/or the “WHEREFORE” clause following Paragraph 113, or to any relief whatsoever.

COUNT IV: STRICT LIABILITY – FAILURE TO WARN

114. Defendant incorporates by reference its responses to the foregoing paragraphs as if fully set forth herein.

115. Denied.

116. Defendant denies the allegations set forth in Paragraph 116 and its subparts (a)-(u).

117. Denied.

118. Denied.

119. Denied.

120. Denied.

121. Denied.

122. Denied.

123. Denied.

124. Denied.

125. Denied.

126. Denied.

127. Denied.

128. Denied.

129. Denied.

Defendant denies that Plaintiffs are entitled to the relief requested in the “PRAYER” and/or the “WHEREFORE” clause following Paragraph 129, or to any relief whatsoever.

COUNT V: STRICT LIABILITY – DEFECTIVE PRODUCT

130. Defendant incorporates by reference its responses to the foregoing paragraphs as if fully set forth herein.

131. Denied.

132. Denied.

133. Defendant lacks knowledge or information sufficient to form a belief as to the truth of the matters alleged, which are therefore denied.

134. Defendant lacks knowledge or information sufficient to form a belief as to the truth of the matters alleged, which are therefore denied.

135. Denied.

Defendant denies that Plaintiffs are entitled to the relief requested in the “PRAYER” and/or the “WHEREFORE” clause following Paragraph 135, or to any relief whatsoever.

COUNT VI: BREACH OF EXPRESS WARRANTY

136. Defendant incorporates by reference its responses to the foregoing paragraphs as if fully set forth herein.

137. Denied.

138. Denied.

139. Denied.

140. Denied.

141. Denied.

142. Defendant denies the allegations set forth in Paragraph 142 and its subparts (A)-(C).

143. Denied.

144. Denied.

145. Denied.

Defendant 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 VII: BREACH OF IMPLIED WARRANTIES
OF MERCHANTABILITY AND FITNESS OF PURPOSE**

146. Defendant incorporates by reference its responses to the foregoing paragraphs as if fully set forth herein.

147. Denied.

148. Denied.

149. Denied.

150. Defendant lacks knowledge or information sufficient to form a belief as to the truth of the matters alleged, which are therefore denied.

151. Denied.

152. Denied.

153. Defendant denies the allegations set forth in Paragraph 153 and its subparts (A)-(C).

154. Denied.

155. Denied.

156. Denied.

157. Denied.

158. Denied.

159. Denied.

Defendant denies that Plaintiffs are entitled to the relief requested in the “PRAYER” and/or the “WHEREFORE” clause following Paragraph 159, or to any relief whatsoever.

COUNT VIII: FRAUDULENT CONCEALMENT

160. Defendant incorporates by reference its responses to the foregoing paragraphs as if fully set forth herein.

161. Denied.

162. Denied.

163. Denied.

164. Defendant denies the allegations set forth in Paragraph 164 and its subparts (a)-(c).

165. Denied.

166. Denied.

167. Denied.

168. Denied.

169. Denied.

Defendant denies that Plaintiffs are entitled to the relief requested in the “PRAYER” and/or the “WHEREFORE” clause following Paragraph 169, or to any relief whatsoever.

COUNT IX: CONSTRUCTIVE FRAUD

170. Defendant incorporates by reference its responses to the foregoing paragraphs as if fully set forth herein.

171. Denied.

172. Denied.

173. Denied.

174. Denied.

175. Denied.

176. Denied.

Defendant denies that Plaintiffs are entitled to the relief requested in the “PRAYER” and/or the “WHEREFORE” clause following Paragraph 176, or to any relief whatsoever.

COUNT X: DISCOVERY RULE, TOLLING, AND FRAUDULENT CONCEALMENT

177. Defendant incorporates by reference its responses to the foregoing paragraphs as if fully set forth herein.

178. Defendant 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.

179. Denied.

180. Denied.

181. Denied.

COUNT XI: NEGLIGENT MISREPRESENTATION

182. Defendant incorporates by reference its responses to the foregoing paragraphs as if fully set forth herein.

183. Denied.

184. Denied.

185. Denied.

186. Denied.

187. Denied.

Defendant denies that Plaintiffs are entitled to the relief requested in the “PRAYER” and/or the “WHEREFORE” clause following Paragraph 187, or to any relief whatsoever.

COUNT XII: NEGLIGENT INFLICTION OF EMOTIONAL DISTRESS

188. Defendant incorporates by reference its responses to the foregoing paragraphs as if fully set forth herein.

189. Denied.

190. Denied.

191. Denied.

192. Denied.

193. Denied.

194. Denied.

Defendant denies that Plaintiffs are entitled to the relief requested in the “PRAYER” and/or the “WHEREFORE” clause following Paragraph 194, or to any relief whatsoever.

COUNT XIII: VIOLATION OF CONSUMER PROTECTION LAWS

195. Defendant incorporates by reference its responses to the foregoing paragraphs as if fully set forth herein.

196. Denied.

197. Denied.

198. Defendant denies the allegations set forth in Paragraph 198 and its subparts (a)-(c).

199. Denied.

200. Denied.

- 201. Denied.
- 202. Denied.
- 203. Denied.
- 204. Denied.
- 205. Denied.
- 206. Denied.
- 207. Denied.
- 208. Denied.
- 209. Denied.
- 210. Denied.
- 211. Denied.
- 212. Denied.

Defendant denies that Plaintiffs are entitled to the relief requested in the “PRAYER” and/or the “WHEREFORE” clause following Paragraph 212, or to any relief whatsoever.

COUNT XIV: GROSS NEGLIGENCE

213. Defendant incorporates by reference its responses to the foregoing paragraphs as if fully set forth herein.

214. Denied.

215. Denied.

216. Defendant lacks knowledge or information sufficient to form a belief as to the truth of the matters alleged, which are therefore denied.

217. Denied.

Defendant denies that Plaintiffs are entitled to the relief requested in the “PRAYER” and/or the “WHEREFORE” clause following Paragraph 217, or to any relief whatsoever.

COUNT XV: UNJUST ENRICHMENT

218. Defendant incorporates by reference its responses to the foregoing paragraphs as if fully set forth herein.

219. Denied.

220. Denied.

221. Denied.

222. Denied.

223. Denied.

Defendant denies that Plaintiffs are entitled to the relief requested in the “PRAYER” and/or the “WHEREFORE” clause following Paragraph 223, or to any relief whatsoever.

COUNT XVI: LOSS OF CONSORTIUM

224. Defendant incorporates by reference its responses to the foregoing paragraphs as if fully set forth herein.

225. Denied.

Defendant 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.

COUNT XVII: PUNITIVE OR ENHANCED COMPENSATORY DAMAGES

226. Defendant incorporates by reference its responses to the foregoing paragraphs as if fully set forth herein.

227. Denied.

228. Denied.

- 229. Denied.
- 230. Denied.
- 231. Denied.
- 232. Denied.
- 233. Denied.
- 234. Denied.
- 235. Denied.
- 236. Denied.
- 237. Denied.
- 238. Denied.
- 239. Denied.

Defendant denies that Plaintiffs are entitled to the relief requested in the “PRAYER” and/or the “WHEREFORE” clause following Paragraph 239, including its subparts (i)-(x), or to any relief whatsoever.

PRAYER FOR RELIEF

Defendant denies that Plaintiffs are entitled to the relief enumerated in the “PRAYER FOR RELIEF”, or to any relief whatsoever.

JURY DEMAND

Pursuant to Rule 38(b) of the Federal Rules of Civil Procedure, Defendant demands a trial by jury on all issues so triable.

STATEMENT OF AFFIRMATIVE DEFENSES

FIRST DEFENSE

The Court lacks personal jurisdiction over Getinge.

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 the Plaintiffs have been damaged, which the Defendant denies, any recovery by the Plaintiffs are barred to the extent Plaintiffs voluntarily exposed themselves to a known risk and/or failed to mitigate their alleged damages. To the extent the Plaintiffs have failed to mitigate their 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 the Plaintiffs may be due to the operation of nature or idiosyncratic reaction(s) and/or pre-existing condition(s) in the Plaintiffs over which Defendant had no control or knowledge.

SIXTH DEFENSE

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

SEVENTH DEFENSE

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 Defendant in this cause.

EIGHTH DEFENSE

If the Plaintiffs have been damaged, which the Defendant denies, such damages were caused by the negligence or fault of the Plaintiffs.

NINTH DEFENSE

If the Plaintiffs suffered any damages or injuries, which Defendant denies, the Plaintiffs' recovery is barred, in whole or in part, or subject to reduction under the doctrines of contributory and/or comparative negligence and/or last clear chance or assumption of the risk.

TENTH DEFENSE

Recovery against the Defendant, if any, should be reduced in proportion to the degree or percentage of negligence, fault or exposure to products attributable to the Plaintiff or any other party or non-party to this case, including any party immune because bankruptcy renders them immune from further litigation, as well as any parties or non-parties with whom the Plaintiff has settled or may settle in the future under the law of all states that allow such a reduction. *See, e.g., DeBenedetto v. CLD Consulting Engineers, Inc.*, 153 N.H. 793 (2006); *Nilsson v. Bierman*, 150 N.H. 393 (2003).

ELEVENTH DEFENSE

If the Plaintiffs have been damaged, which the Defendant denies, such damages were caused by unforeseeable, independent, intervening, and/or superseding events for which the Defendant is not legally responsible.

TWELFTH DEFENSE

If the Plaintiffs have been damaged, which the Defendant denies, such damages were caused by abuse, misuse, user error and/or modification, alteration or other substantial change of the product at issue for which the Defendant was and is in no way liable.

THIRTEENTH DEFENSE

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

FOURTEENTH DEFENSE

The subject product at all times conformed with the Federal Food, Drug and Cosmetic Act and other pertinent federal statute and regulations. Accordingly, the Plaintiffs' claims are barred, in whole or in part, under the doctrine of federal preemption, and granting the relief requested would impermissibly infringe upon and conflict with federal laws, regulations and policies in violation of the Supremacy Clause of the United States Constitution.

FIFTEENTH 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 the Plaintiffs were legally adequate.

SIXTEENTH DEFENSE

The 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.

SEVENTEENTH DEFENSE

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

EIGHTEENTH DEFENSE

Getinge asserts that Plaintiff's claims are barred by any applicable safe harbor doctrine to the extent that federal law permits the packaging, labeling and marketing practices alleged in the Complaint.

NINETEENTH DEFENSE

To the extent the Plaintiff's 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).

TWENTIETH DEFENSE

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

TWENTY-FIRST DEFENSE

To the extent the Plaintiff asserts a demand for punitive damages, Getinge specifically incorporates by reference any and all standards of limitations regarding the determination and/or enforceability of punitive damages awards that arose in the decisions of *BMW of No. America v. Gore*, 517 U.S. 559 (1996); *Cooper Industries, Inc. v. Leatherman Tool Group, Inc.*, 532 U.S. 424 (2001); *State Farm Mut. Auto Ins. Co. v. Campbell*, 123 S. Ct. 1513 (2003); and *Exxon*

Shipping Co. v. Baker, No. 07-219, 2008 U.S. LEXIS 5263 (U.S. June 25, 2008) and their progeny as well as other similar cases under both federal and state law.

TWENTY-SECOND DEFENSE

No reasonable notice was given of any alleged breach of implied warranty.

TWENTY-THIRD DEFENSE

Defendant is entitled to and claims the benefits of all defenses and presumptions set forth in 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. Defendant reserves the right to assert that the law of a state other than New Hampshire applies to this action, including the laws of Sweden.

TWENTY-FOURTH DEFENSE

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

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

Dated: June 6, 2017

Respectfully submitted,

GETINGE AB

/s/ Hugh J. Turner Jr.

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Counsel for Defendant

CERTIFICATE OF SERVICE

I hereby certify that on this 6th day of June, 2017, I electronically transmitted the foregoing document to the Clerk's Office using the CM/ECF System for filing and transmittal of a Notice of Electronic Filing to the following CM/ECF participant:

/s/Hugh J. Turner Jr.
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