UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

CONNIE SPRAGUE and JAMES SPRAGUE, *Plaintiffs*, v. MEDTRONIC, INC., MEDTRONIC USA, INC., and INTEGRA LIFESCIENCES CORPORATION, *Defendants*.	**CIVIL ACTION** Case No. _____ PLAINTIFFS DEMAND A JURY TRIAL

COMPLAINT AND JURY DEMAND

Plaintiffs Connie Sprague and James Sprague (referred to hereinafter as "Plaintiffs"), by and through their undersigned counsel, bring this Complaint against Medtronic, Inc., Medtronic USA, Inc., and Integra Lifesciences Corporation, (collectively referred to herein as "Defendants") related to the design, manufacture, marketing, distribution, and sale of Defendants' Durepair Matrix Product implanted in Plaintiff Connie Sprague. Plaintiffs make the following allegations based upon their individual personal knowledge as to their own acts, and upon information and belief, as well as upon their attorneys' investigative efforts as to Defendants' actions and misconduct and alleges as follows:

I. PARTIES

1. Plaintiffs Connie and James Sprague are citizens and residents of the State of Florida. Plaintiffs have suffered and continue to suffer significant injuries as a result of Defendants' product and the conduct alleged herein.

2. Defendant, Medtronic, Inc. is a foreign for-profit corporation organized under the laws of Ireland with its principal place of business at 710 Medtronic Pkwy NE, Minneapolis, Minnesota.

3. Defendant, Medtronic USA, Inc. is a for-profit corporation with its principal place of business at 710 Medtronic Pkwy NE, Minneapolis, Minnesota. Medtronic USA, Inc. is a wholly owned subsidiary of Medtronic, Inc.

4. Defendants Medtronic, Inc and Medtronic USA, Inc. shall be collectively referred to as "Medtronic Defendants".

5. Medtronic Defendants engage in business in the State of New Jersey, thus purposefully availing itself of the privileges and protections afforded by the State of New Jersey.

6. Defendant, Integra LifeScience Corporation is a for-profit corporation with its principal place of business at 1100 Campus Road, Princeton, New Jersey 08540.

II. JURISDICTION AND VENUE

7. That Court has jurisdiction over the subject matter presented by this Complaint pursuant to 28 U.S.C. 1332 (a)(1) because the amount in controversy exceeds $75,000.00, exclusive of interest and costs, and diversity of citizenship exists between the parties.

8. Venue is proper in this Court pursuant to 28 U.S.C. § 1391, because (a) Defendants did business in the State of New Jersey by manufacturing, selling, marketing, and/or warranting Durepair Regeneration Matrix; (b) some of the acts and transactions described herein occurred within the State of New Jersey; and (c) some of the injuries and causes of action alleged herein emanated from or occurred in the State of New Jersey.

III. FACTUAL BACKGROUND

9. At all relevant times, Defendants were in the business of developing, designing, licensing, distributing, selling, marketing, advertising, and delivering, and introducing into

interstate commerce including, *inter alia*, within the United States and, specifically, within the State of New Jersey, either directly or indirectly through third parties, subsidiaries, or related entities, Durepair Dura Regeneration Matrix ("Durepair Matrix").

10. Specifically, Medtronic's Durepair Matrix is a class II medical device developed by Defendant Medtronic, Inc, manufactured by Defendant Integra LifeSciences Corporation, and distributed, marketed and sold by Medtronic, USA, Inc.

11. At all relevant times, Durepair Matrix was used in neurosurgery to close and/or repair dural defects. This type of product has also been referred to as a "dura substitute."

12. Since obtaining FDA 510K clearance on July 6, 2004, Defendants have been developing, designing, manufacturing, licensing, distributing, selling, marketing, advertising, and delivering, and introducing into interstate commerce the Durepair Matrix.

13. However, on June 13, 2023, the FDA began the process of recalling over 65,000 Durepair Matrices from across the world due to higher-than-normal endotoxin levels found at Defendant's Boston, Massachusetts manufacturing facility.

14. In the recall notice, the FDA warned that exposure to these endotoxins may present clinically and with signs and symptoms of an acute inflammatory profess, comparable to infection.

15. On July 17, 2023, the FDA sent a warning letter to Defendant Integra LifeSciences Corporation notifying them of several violations that lead to this recall, and those violations are as follows:

a. Failure to establish and maintain procedures to control product that does not conform to specified requirements, as required by 21 CFR 820.90(a);

b. Failure to establish and maintain procedures for implementing corrective and preventive actions, including requirements for analyzing processes, work operations, concessions, quality audit reports, quality records,

service records, complaints, returned product, and other sources of quality data to identify existing and potential causes of nonconforming product, or other quality problems, as required by 21 CFR 820.100(a)(1);

c. Failure to validate with a high degree of assurance, a process whose results cannot be fully verified by subsequent inspection and test, as required by 21 CFR 820.75(a); and

d. Failure to store devices in a manner to facilitate proper stock rotation and to assess its condition as appropriate, as required by 21 CFR 820.150(a).

16. In this letter, the FDA further described Defendant Integra LifeSciences Corporation's response to the multi-month FDA investigation to be "not adequate".

IV. PLAINTIFF SPECIFIC FACTS

17. In the summer of 2022, Plaintiff Connie Sprague was diagnosed with hyperostotic intraosseous meningioma, treatment options were discussed, and the decision was made for Plaintiff to undergo surgery to remove the tumors.

18. On September 8, 2022, Plaintiff underwent a craniectomy and tumor resection with 3D cranioplasty, which required a dura excision and repair.

19. During this surgery, Plaintiff's surgeon, Dr. Todd Hollon, utilized the Medtronic Durepair Dura Regeneration Matrix Implant which is a class II medical device distributed, marketed and sold by Medtronic, USA, Inc. The "Patch" was developed by one of Medtronic's business units, Medtronic Neurosurgery and manufactured by Integra LifeSciences.

20. Dr. Hollon placed/used the Durerepair Matrix to replace excised dura, which was consistent with its marketed uses.

21. Less than a month later, Plaintiff returned to the hospital complaining of increased tenderness at the incision site and frontal pain, as well as abnormal drainage from the incision

site. On October 5, 2022, Plaintiff was rushed to surgery and underwent a cranioplasty for a suspected infected wound site.

22. During that surgery, however, no evidence of infection was found. To be safe, a sample of Plaintiff's tissue was removed and sent to pathology for testing.

23. Notably, the pathology showed no organisms on routine stains of the explanted specimen.

24. In the months following her discharge, Plaintiff had fluid accumulation on top of her incision site and also experienced a range of symptoms, including but not limited to, headaches, fatigue, brain fog, dizziness, difficulty balancing, difficulties with speech, and other cognitive and physical ailments to the point where she was unable to perform the functions of her job.

25. On February 9, 2024, Plaintiff had a follow-up appointment with Dr. Hollon and it was recommended that Plaintiff undergo an exploration of her duraplasty to replace her allograft with a 3D printed custom implant to help with the fluid accumulation.

26. On April 9, 2024, after the 3D custom implant was completed, Plaintiff was scheduled for surgery on May 8, 2024.

27. On May 8, 2024, Plaintiff underwent a revision cranioplasty and duraplasty due to a persistent pseudomeningocele and painful mesh ("the patch"). During the surgery, it was found that the Durepair Matrix has eroded and left Plaintiff's brain exposed. The eroded Durepair Matrix was then removed and replaced with a custom implant.

28. Despite this additional surgical intervention, plaintiff's headaches, head pressure, brain fog, and dizziness, among other symptoms, persisted.

29. Additionally, while the fluid accumulation initial resolved by May 24, 2024, the fluid accumulation returned in July 2024, and it was recommended that Plaintiff have a shunt placed.

30. On August 8, 2024, Plaintiff underwent yet another surgery by Dr. Hollon to place a Strata Valve Shunt system.

31. Unbeknownst to Plaintiff, the Durepair Matrix used and implanted during her September 8, 2022 surgery was included in the June 2023 FDA recall.

32. Plaintiff Connie Sprague subsequently suffered complications associated with the recalled Durepair Matrix product, including but not limited to, headaches, fatigue, brain fog, head pressure, fluid accumulation, concentration issues, slowed speech, slowed movement, issues with grip strength, and difficulty with daily activities, which ultimately required multiple surgical interventions, es described in detail above.

33. As a result of these life-altering and, in some cases, permanent injuries, Plaintiff has suffered severe emotional pain and injury and has suffered and will suffer apprehension of increased risk for injuries, infections, pain, mental anguish, discharge, and multiple corrective surgeries as a result of implantation of Durepair Matrix product.

34. As a direct and proximate result of the Durepair Matrix product, Plaintiff has incurred costs for the medical treatment required for her injuries and will continue to incur costs for her future medical treatment.

35. As a direct and proximate result of the Durepair Matrix product, Plaintiff has suffered lost wages and will continue to suffer lost wages, and a loss in earning capacity, in the future.

36. At all times material, the Durepair Matrix used during September 8, 2022 surgery was marketed, sold and/or distributed by Medtronic and/or Medtronic, USA. Further, the Dureprair Matrix used during the September 8, 2022 surgery was developed by Medtronic Neurosurgery, (a subsidiary of Medtronic and manufactured by Integra LifeSciences) in a defective and/or unreasonably dangerous condition at the time it was placed in the stream of commerce in ways which include, but are not limited to, one or more of the following**:**

a. When placed in the stream of commerce, the Dureprair Matrix contained manufacturing defects that rendered the product unreasonably dangerous;

b. When placed in the stream of commerce, the Dureprair Matrix contained abnormal endotoxin levels that rendered the product unreasonably dangerous;

c. When placed in the stream of commerce, the Dureprair Matrix deviated in its construction or quality from its specifications or planned output in a manner that rendered it unreasonably dangerous;

d. The Dureprair Matrix manufacturing defects occurred while the product was in the exclusive possession, custody and control of Defendants;

e. The subject product was not made in accordance with Medtronic Neurosurgery's specifications or performance standards; and

f. The Dureprair Matrix manufacturing defect existed before that product left the possession, custody, and control of Defedants.

37. Due to Defendants' negligence and manufacturing defect, Plaintiff is entitled to compensatory damages in a sum to be determined by the jury.

V. EQUITABLE TOLLING OF APPLICABLE STATUTE OF LIMITATIONS

38. Defendants failed to disclose a known defect and affirmatively misrepresented that Durepair Matrix was safe for its intended use. Neither Plaintiff nor Plaintiff's prescribing physicians had knowledge that Defendants were engaged in the wrongdoing alleged herein. Because of Defendants' concealment of and misrepresentations regarding the true harms ad

risks associated with Durepair Matrix, Plaintiff could not have reasonably discovered Defendants' wrongdoing at any time prior to the commencement of this action.

39. Despite diligent investigation, including consultations with Plaintiff Connie Sprague's providers, the nature of Plaintiff's injuries and damages and their relationship to the Durepair Matrix was not discovered, and though reasonable care and due diligence could not have been discovered until a date within the applicable limitations period for filing Plaintiff's claims. Plaintiff did not have actual or constructive knowledge of facts indicating to a reasonable person that she was the victim of a tort. Plaintiff was unaware of the facts upon which a cause of action rests until a date within the applicable limitations period for the filing of this action. Plaintiff's lack of knowledge was not willful, negligent, or unreasonable.

40. Thus, because Defendants fraudulently concealed the defective nature of Durepair Matrix, the running of any statute of limitations has been tolled. Likewise, Defendants are estopped from relying on any statute of limitations.

VI. CLAIMS FOR RELIEF

COUNT I
NEGLIGENCE

41. Plaintiffs incorporate each and every paragraph of this Complaint by reference as if fully stated herein and further states and alleges as follows.

42. Defendants had a duty to exercise reasonable care in the design, research, manufacture, marketing, advertising, supplying, promoting, packaging, sale, and distribution of Durepair Matrix, including the duty to assure that the Durepair Matrix would not cause users to suffer unreasonable, dangerous side effects.

43. Defendants failed to exercise ordinary care in the design, research, development, manufacture, marketing, supplying, promoting, advertising, packaging, sale, testing, quality

assurance, quality control, and distribution of the Durepair Matrix because Defendants knew or had reason to know that using Durepair Matrix created a high risk of unreasonable and dangerous side effects, including, but not limited to, severe erosion, exposure to abnormal endotoxin levels, infection, death and other severe personal injuries, which are permanent and lasting in nature, including, but not limited to, physical pain and mental anguish, scarring and disfigurement, diminished enjoyment of life, and any and all further medical complications, such as Plaintiff's need for life-long medical treatment and care, and fear of developing further adverse health consequences.

44. Defendants manufactured, produced, promoted, formulated, created, developed, designed, sold, and distributed Durepair Matrix without thoroughly and adequately testing them;

a. Defendants manufactured, produced, promoted, advertised, formulated, created, developed, designed, and distributed its Durepair Matrix while concealing and suppressing test results;

b. Defendants did not conduct sufficient studies and tests to determine whether its Durepair Matrix were safe for their intended use, because Defendants knew, or should have known, that its Durepair Matrix were unsafe and unfit for use by reason of the dangers to their users;

c. Defendants failed to warn Plaintiff, her physicians and her other healthcare providers, the medical and healthcare community, or the public as soon as Defendants knew, or should have known, that the dangers of the use of Durepair Matrix were much higher than the risk of adverse effects from other, safer dura substitues;

d. Defendants represented that their Durepair Matrix was safe for its intended use when Defendants knew, or should have known, that their Durepair Matrix was unsafe for its intended use. Defendants knew, or should have known, that Durepair Matrix had abnormally high levels of endotoxins that have serious and dangerous adverse health effects and consequences as a result of which Defendants' Durepair Matrix was not as safe as other dura substitutes; and

e. Defendants suppressed, concealed, and omitted information concerning warnings, recommendations, and observations about Durepair Matrix from Plaintiff Connie Sprague, her physicians, and her other healthcare providers and from the public, while knowing that Durepair Matrix is unsafe and dangerous.

45. Defendants were negligent in the design, research, development, manufacture, promotion, packaging, advertising, distribution, testing, marketing, and sale of Durepair Matrix because:

a. Defendants failed to use due care in the design, research, manufacture, and development of its Durepair Matrix so as to avoid risks to patients of serious and dangerous adverse health effects and consequences;

b. Defendants failed to design and manufacture its Durepair Matrix so as to minimize the risk of serious side effects, including, but not limited to, erosion and exposure to abnormal endotoxin levels; and

c. Defendants failed to conduct adequate testing, including pre-clinical and clinical testing, and post-marketing surveillance, to determine the safety of Durepair Matrix.

46. While Defendants knew, or should have known, that Durepair Matrix caused unreasonably dangerous side effects, Defendants nonetheless continued to market, manufacture, distribute, advertise, promote, and sell Durepair Matrix to consumers.

47. Defendants knew, or should have known, that consumers such as Plaintiff, into whom Durepair Matrix was implanted, would foreseeably suffer severe injuries as a result of Defendants' failure to exercise ordinary care, as set forth above.

48. Defendants' negligence was the proximate cause of the injuries, harm, and economic loss that Plaintiffs have suffered and will continue to suffer in the future.

49. As a direct, foreseeable, and proximate result of Defendants' aforesaid acts and omissions, and as the direct, foreseeable, and proximate result of the implantation of Defendants' Durepair Matrix into Plaintiff, Plaintiffs were caused to suffer, did suffer, and will continue to suffer from physical, emotional, economic, and other injury.

COUNT II
PRODUCT LIABILITY ACT—MANUFACTURING DEFECT
N.J. Stat. §§ 2A:58C-1 *et seq.*

50. Plaintiffs incorporate each and every paragraph of this Complaint by reference as if fully stated herein and further states and alleges as follows.

51. During the manufacturing process, Defendants' Durepair Matrix departed from its intended design due to known flaws, or flaws that Defendants should have reasonably discovered, rendering it unreasonably dangerous.

52. At all relevant times, Defendants designed, researched, developed, manufactured, tested, labeled, advertised, promoted, marketed, sold and distributed, Durepair Matrix, which was implanted into Plaintiff Connie Sprague.

53. At all relevant times, Defendants' Durepair Matrix was manufactured, designed, and labeled in an unsafe, defective, and inherently dangerous condition, which was dangerous for use by the public, and, in particular, by Plaintiff.

54. Defendants' Durepair Matrix was defective in its manufacturing, when it left Defendants' hands, the foreseeable risks exceeded the benefits allegedly associated with the design of Durepair Matrix.

55. Defendants' Durepair Matrix was manufactured defectively because it left the hands of Defendants in a defective condition and was unreasonably dangerous for the intended use for which it was designed, manufactured, and sold.

56. At all relevant times, Defendants' Durepair Matrix was in a defective condition and unsafe, and Defendants knew, or should have known, that their Durepair Matrix was defective and unsafe.

57. At the time that the Durepair Matrix device was implanted into Plaintiff, it was being used for its intended use in a manner normally intended, namely as a dura substitute. Indeed, the product was being used in its intended manner and Plaintiff was a reasonably foreseeable user of the product.

58. Defendants had a duty to create a product, to wit, its Durepair Matrix that was not unreasonably dangerous for its normal, common, intended use.

59. Defendants designed, developed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed a defective product, to wit, Durepair Matrix that

created an unreasonable risk to the health of consumers and to Plaintiff in particular, and Defendants are, therefore, strictly liable for the injuries and damages sustained by Plaintiff.

60. Plaintiff, her physicians, and her other healthcare providers could not, by the reasonable exercise of care, have discovered the defects in this product or perceived its danger.

61. Defendants' Durepair Matrix was defective due to inadequate warnings and instructions, because Defendants knew or should have known that Durepair Matrix created a risk of serious and dangerous side effects, including, but not limited to, erosion and exposure to abnormal endotoxin levels, and other serious and severe personal injuries which are permanent and lasting in nature; and Defendants failed to test adequately for or to warn of these risks.

62. Defendants' Durepair Matrix was defective due to inadequate post-marketing surveillance and warnings because Defendants knew, or should have known, the risks of serious side effects, including, but not limited to, erosion, exposure to abnormal endotoxin levels, and substantial mental and physical deformity.

63. Defendants also failed to provide adequate warning for use to consumers of Durepair Matrix, and Defendants continue improperly to advertise, to market, to label, and to promote Durepair Matrix to the public and to the medical community.

64. By reason of the foregoing, Defendants are strictly liable in tort to Plaintiff.

65. The defective manufacturing of Defendants' Durepair Matrix and Defendants' over-marketing through advertisements, together with their failure to provide adequate warnings accompanying Durepair Matrix were willful, wanton, and reckless.

66. The defects in Defendants' Durepair Matrix were substantial and contributing factors in causing Plaintiff's injuries.

67. As a direct, foreseeable, and proximate result of Defendants' aforesaid acts and omissions, and as the direct, foreseeable, and proximate result of the implantation of Defendants' Durepair Matrix into Plaintiff, Plaintiffs were caused to suffer, did suffer, and will continue to suffer from physical, emotional, economic, and other injury.

COUNT III:
PRODUCT LIABILITY ACT—DESIGN DEFECT
N.J. Stat. §§ 2A:58C-1 *et seq.*

68. Plaintiffs incorporate each and every paragraph of this Complaint by reference as if fully stated herein and further states and alleges as follows.

69. At all relevant times, Defendants designed, researched, developed, manufactured, tested, labeled, advertised, promoted, marketed, sold and distributed, Durepair Matrix, which was implanted into Plaintiff Connie Sprague.

70. Defendants' Durepair Matrix was expected to, and did, reach the intended consumers, handlers, and persons coming into contact with Defendants' Durepair Matrix without substantial change in the condition in which it was produced, manufactured, sold, distributed, labeled, and marketed by Defendants.

71. At all relevant times, Defendants' Durepair Matrix was manufactured, designed, and labeled in an unsafe, defective, and inherently dangerous condition, which was dangerous for use by the public, and, in particular, by Plaintiff.

72. Defendant's Durepair Matrix was defective in its design as it was not reasonably fit, suitable, or safe for its intended or reasonably foreseeable use.

73. Defendants' Durepair Matrix was defective in design and formulation in that, when it left Defendants' hands, the foreseeable risks exceeded the benefits allegedly associated with the design of Durepair Matrix.

74. Defendants' Durepair Matrix was defective in design because, when it left the Defendants' hands, it was unreasonably dangerous, and also was more dangerous than the ordinary consumer would expect.

75. At all relevant times, Defendants' Durepair Matrix was in a defective condition and unsafe, and Defendants knew, or should have known, that their Durepair Matrix was defective and unsafe, especially when used in the manner instructed and provided by Defendants.

76. Defendants knew, or should have known, at all relevant times, that the Durepair Matrix was in a defective condition, and was and is inherently dangerous and unsafe when used in the manner instructed and provided by Defendants.

77. At the time that the Durepair Matrix device was implanted into Plaintiff, it was being used for its intended use in a manner normally intended, namely as a dura substitute. Indeed, Plaintiff and her Medical Providers were reasonably foreseeable users of Defendants' Durepair Matrix device.

78. Defendants had a duty to create a product, to wit, its Durepair Matrix that was not unreasonably dangerous for its normal, common, intended use.

79. Defendants' Durepair Matrix was manufactured defectively because it left the hands of Defendants in a defective condition and was unreasonably dangerous for the intended use for which it was designed, manufactured, and sold.

80. Defendants designed, developed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed a defective product, to wit, Durepair Matrix that created an unreasonable risk to the health of consumers and to Plaintiff in particular, and Defendants are, therefore, strictly liable for the injuries and damages sustained by Plaintiff.

81. Plaintiff, her physicians, and her other healthcare providers could not, by the reasonable exercise of care, have discovered the defects in this product or perceived its danger.

82. Defendants' Durepair Matrix was defective due to inadequate warnings and instructions, because Defendants knew or should have known that Durepair Matrix created a risk of serious and dangerous side effects, including, but not limited to, erosion and exposure to abnormal endotoxin levels, and other serious and severe personal injuries which are permanent and lasting in nature; and Defendants failed to test adequately for or to warn of these risks.

83. Defendants' Durepair Matrix was defective due to inadequate post-marketing surveillance and warnings because Defendants knew, or should have known, the risks of serious side effects, including, but not limited to, erosion, exposure to abnormal endotoxin levels, and substantial mental and physical deformity.

84. Defendants also failed to provide adequate warning for use to consumers of Durepair Matrix, and Defendants continue improperly to advertise, to market, to label, and to promote Durepair Matrix to the public and to the medical community.

85. By reason of the foregoing, Defendants are strictly liable in tort to Plaintiff.

86. The defective design of Defendants' Durepair Matrix and Defendants' over-marketing through advertisements, together with their failure to provide adequate warnings accompanying Durepair Matrix were willful, wanton, and reckless.

87. The defects in Defendants' Durepair Matrix were substantial and contributing factors in causing Plaintiff's injuries.

88. Defendant forewent a safer and more feasible alternative design that would have reduced or prevented the harm caused to Plaintiff and that would not have impaired the devices intended function.

89. As a direct, foreseeable, and proximate result of Defendants' aforesaid acts and omissions, and as the direct, foreseeable, and proximate result of the implantation of Defendants' Durepair Matrix into Plaintiff, Plaintiffs were caused to suffer, did suffer, and will continue to suffer from physical, emotional, economic, and other injury.

COUNT IV
PRODUCT LIABILITY ACT—FAILURE TO WARN
N.J. STAT. §§ 2A:58C-1 *et seq.*

90. Plaintiffs incorporate each and every paragraph of this Complaint by reference as if fully stated herein and further states and alleges as follows.

91. Defendants researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold, and otherwise released Durepair Matrix into the stream of commerce within the State of New Jersey and elsewhere, and directly advertised and marketed within the State of New Jerswey and elsewhere, Durepair Matrix to consumers or persons responsible for consumers, and, therefore, had a duty to warn of the risks associated with the use of Durepair Matrix.

92. Defendants' Durepair Matrix was under the exclusive control of Defendants and was not accompanied by adequate warnings regarding adverse side effects and complications associated with the use of Durepair Matrix, or by adequate warnings regarding the comparative severity, duration, and extent of the risk of injuries associated with use of Durepair Matrix.

93. Defendants failed to timely and reasonably to warn of material facts regarding the safety and efficacy of Durepair Matrix; no healthcare provider would have prescribed — and no consumer would have used — Durepair Matrix had the facts concerning the safety and efficacy of Durepair Matrix been made known to such healthcare providers and consumers.

94. Defendants' Durepair Matrix device lacked these adequate warnings when the product left Defendants' control. Without these warnings, Defendants' Durepair Matrix device was defective as it was not reasonable fit, suitable, or safe for its intended purpose.

95. Defendants' advertising campaign for Durepair Matrix did *not* advise either consumers or healthcare providers that Durepair Matrix presented multiple and dangerous medical risks, including but not limited to erosion and exposure to abnormal endotoxin levels.

96. Defendants failed to perform or otherwise facilitate adequate testing; such testing would have demonstrated that Durepair Matrix posed serious and potentially life-threatening side effects and complications with respect to which full and proper warning accurately and fully reflecting the symptoms, scope and severity should have been made to healthcare providers, to the FDA, and to consumers, including Plaintiff Connie Sprague. Indeed, Plaintiff and her Medical Providers were reasonably foreseeable users of Defendants' Durepair Matrix Device.

97. Durepair Matrix was defective due to inadequate post-marketing warnings and instructions because, after Defendants knew, or should have known, of the risk of serious and potentially life-threatening side effects and complications from the use of Durepair Matrix, Defendants failed to provide adequate warnings to healthcare providers or to the consuming public, including Plaintiff Connie Sprague, and instead continued to advertise and market Durepair Matrix aggressively.

98. As a direct, foreseeable, and proximate result of Defendants' foregoing conduct, Plaintiffs have suffered and will continue to suffer serious and permanent physical and emotional injuries, has incurred medical expenses, has suffered, and will continue to suffer economic loss, and has otherwise been physically, emotionally, and economically injured.

COUNT V
BREACH OF EXPRESS WARRANTY

99. Plaintiffs incorporate each and every paragraph of this Complaint by reference as if fully stated herein and further states and alleges as follows.

100. At all relevant times, Defendants manufactured, compounded, portrayed, distributed, recommended, merchandised, advertised, promoted, and sold Durepair Matrix to be used to repair and replace dura during neurosurgical procedures.

101. Defendants expressly warranted that their Durepair Matrix was safe and fit for use by consumers, was of merchantable quality, did not produce dangerous side effects, and was adequately tested and fit for its intended use.

102. At the time of Defendants' aforesaid express warranties, Defendants knew or should have known, that their Durepair Matrix did not conform to these express warranties because their Durepair Matrix was not safe and had numerous serious side effects, about which Defendants did not adequately warn.

103. As a direct, foreseeable, and proximate result of Defendants' breach of their express warranties, Plaintiffs suffered and will continue to suffer severe and permanent personal injuries, harm, and economic loss.

104. Plaintiff relied on Defendants' express warranties with respect to their Durepair Matrix.

105. Members of the medical community, including Plaintiff Connie Sprague's physicians and other healthcare providers, relied upon Defendants' representations and warranties in connection with the use, recommendation, description, and implantation of Durepair Matrix.

106. Defendants breached the express warranties because their Durepair Matrix was, and is, defective and unreasonably unsafe for its intended use.

107. Defendants expressly represented to Plaintiff, her physicians and her other healthcare providers that its Durepair Matrix (i) was safe and fit for the purposes intended, (ii) was of merchantable quality, (iii) did not produce any dangerous side effects in excess of those risks associated with the use of dura substitutes, (iv) the side effects it produced were accurately reflected in the warnings, and (v) it was adequately tested and fit for its intended use.

108. Defendants knew, or should have known, that their aforesaid representations and warranties were false, misleading, and untrue because its Durepair Matrix was not safe and fit for its intended use and caused its users serious injuries of which Defendants did not adequately warn.

109. As a direct, foreseeable, and proximate result of Defendants' foregoing acts and omissions, Plaintiffs were caused to suffer and did suffer serious and grievous personal injuries, including erosion and abnormal exposure to endotoxins, as well as other grievous personal injuries, including, but not limited to, physical pain and mental anguish, permanently diminished enjoyment of life, and any and all additional life implications and complications, such as Plaintiff's need for life-long medical treatment and medical monitoring, and perpetual fear of developing additional adverse health consequences.

110. As a direct, foreseeable, and proximate result of Defendants' foregoing conduct, Plaintiffs have suffered and will continue to suffer serious and permanent physical and emotional injuries, has incurred medical expenses, has suffered and will continue to suffer economic loss, and has otherwise been physically, emotionally, and economically injured.

COUNT VI
BREACH OF IMPLIED WARRANTY

111. Plaintiffs incorporate each and every paragraph of this Complaint by reference as if fully stated herein and further states and alleges as follows.

112. At all relevant times, Defendants manufactured, compounded, portrayed, distributed, recommended, merchandised, advertised, promoted, and sold Durepair Matrix to be used to repair and replace dura during neurosurgical procedures.

113. At the time Defendants marketed, sold, and distributed Durepair Matrix for implantation into Plaintiff, Defendants knew of the intended use of Durepair Matrix, and impliedly warranted Durepair Matrix to be of merchantable quality and safe and fit for such intended use.

114. Defendants impliedly represented and warranted to Plaintiff, her physicians and other healthcare providers, and to the general public, that Durepair Matrix was safe and of merchantable quality and fit for the ordinary purpose for which Durepair Matrix was to be used.

115. Defendants' representations and warranties were false, misleading, and inaccurate because Durepair Matrix was unsafe, unreasonably dangerous, improper, not of merchantable quality and otherwise defective.

116. Plaintiff Connie Sprague, her physicians, and her other healthcare providers relied on Defendants' superior skill and judgment, as to whether Durepair Matrix was of merchantable quality and safe and fit for their intended use, and as to whether Durepair Matrix was fit for this particular use.

117. Defendants put Durepair Matrix into the stream of commerce within the State of New Jersey and elsewhere, in a defective, unsafe, and inherently dangerous condition, and

Durepair Matrix was expected by Defendants to and did reach Plaintiff without substantial change in the condition in which Durepair Matrix was sold.

118. Defendants breached their implied warranty because Durepair Matrix was not fit for its intended use and purpose.

119. As a direct, foreseeable, and proximate result of Defendants' aforesaid acts and omissions within the State of New Jersey, Plaintiffs were caused to suffer, and did suffer, serious and dangerous side effects exposure of the mesh, including but not limited to erosion and exposure to abnormal endotoxin levels, difficulty with daily activities, and permanent and substantial mental and physical deformity, and has undergone and/or will have to undergo corrective surgeries and may need further corrective surgery. Plaintiffs have suffered other grievous personal injuries, including, but not limited to, physical pain and mental anguish, permanently diminished enjoyment of life, and any and all additional life implications and complications, such as Plaintiff's need for life-long medical treatment and care, medical monitoring, and perpetual fear of developing additional adverse health consequences.

120. As a direct, foreseeable, and proximate result of Defendants' foregoing conduct, Plaintiffs have suffered and will continue to suffer serious and permanent physical and emotional injuries, has incurred medical expenses, has suffered and will continue to suffer economic loss, and has otherwise been physically, emotionally, and economically injured.

COUNT VII
UNJUST ENRICHMENT

121. Plaintiffs incorporate each and every paragraph of this Complaint by reference as if fully stated herein and further states and alleges as follows.

122. Defendants are, and at all times were, the manufacturer, seller, and/or supplier of Durepair Matrix.

123. Plaintiff paid for Durepair Matrix for the purpose of repairing and/or replacing her dura.

124. Defendants accepted payment from Plaintiffs for the purchase of Durepair Matrix.

125. Plaintiff has not received the safe and effective Durepair Matrix for which she paid. Defendants have voluntarily accepted and retained these profits and benefits, derived from Plaintiff, with full knowledge and awareness that, as a result of Defendants' fraud and other conscious and intentional wrongdoing, Plaintiffs were not receiving a product of the quality, nature or fitness that had been represented by Defendants or that Plaintiff, as a reasonable consumer, expected.

126. By virtue of the conscious wrongdoing alleged above, Defendants have been unjustly enriched at the expense of Plaintiff, who is entitled to in equity, and hereby seeks, the disgorgement and restitution of Defendants' wrongful profits, revenues, and benefits, to the extent and in the amount deemed appropriate by the Court; and such other relief as the Court deems just and proper to remedy the Defendants' unjust enrichment.

COUNT VIII
COMMON LAW FRAUD

127. Plaintiffs incorporate each and every paragraph of this Complaint by reference as if fully stated herein and further states and alleges as follows.

128. Defendants falsely and fraudulently represented to Plaintiff Connie Sprague, her physicians, and her other healthcare providers, to the medical and healthcare communities, and to the public that Durepair Matrix had been tested and had been determined to be a safe and effective dura substitute.

129. When Defendants made their aforesaid representations, Defendants knew that those representations were false, and Defendants willfully, wantonly, and recklessly disregarded

the falsity of their representations as well as the dangers and health risks to users of Durepair Matrix, including Plaintiff.

130. Defendants made the aforesaid representations with the intent of defrauding and deceiving Plaintiff, her physicians and her other healthcare providers, the medical and healthcare communities, and the public, and to induce Plaintiff, her physicians, and her other healthcare providers, the medical and healthcare communities, and the public, to recommend, purchase, and implant Durepair Matrix as a dura substitute, all of which evinced a callous, reckless, willful, and depraved indifference to the health, safety, and welfare of Plaintiff and other consumers.

131. In representations to Plaintiff, her physicians, and her other healthcare providers, Defendants fraudulently concealed and intentionally omitted the following material information:

a. Durepair Matrix was exposed to higher than normal endotoxin levels;

b. The risk of adverse events with Durepair Matrix was not adequately tested and was known by Defendants;

c. Defendants deliberately failed to follow up on the adverse results from clinical studies and buried and misrepresented those results;

d. Defendants were aware at all times of the dangers in Durepair Matrix;

e. Durepair Matrix was defective, and caused dangerous and adverse side effects, including, but not limited to, erosion and exposure to abnormal endotoxin levels;

f. Durepair Matrix was manufactured negligently;

g. Durepair Matrix was manufactured defectively; and,

h. Durepair Matrix was designed negligently and defectively.

132. Defendants had a duty to disclose to Plaintiff, her physicians, and her other healthcare providers, the defective nature of Durepair Matrix, including, but not limited to, the fact that Durepair Matrix had heightened risks of dangerous side effects.

133. Defendants had sole access to the facts concerning the defective nature of Durepair Matrix and its propensity to cause serious and dangerous side effects and hence, cause dangerous injuries and damage to persons into whom Durepair Matrix was implanted, including Plaintiff.

134. Defendants' aforesaid concealment and omissions of material fact concerning the safety of Durepair Matrix were made intentionally, willfully, wantonly, and recklessly to mislead, to cause Plaintiff's physicians, and her other healthcare providers to purchase and to implant Durepair Matrix, and to mislead Plaintiff into reliance and to cause Plaintiff to permit Durepair Matrix to be implanted into her.

135. At the time that Defendants made these representations, and at the time Durepair Matrix was implanted into Plaintiff, Plaintiff was unaware of the falsehood of Defendants' aforesaid representations, reasonably believed them to be true, and relied upon them.

136. Defendants knew that Durepair Matrix could and would cause severe and grievous personal injury to women into whom they were implanted, and that Durepair Matrix was inherently dangerous in a manner that exceeded any purported benefit from the use of Durepair Matrix and any warnings gave concerning Durepair Matrix.

137. In reasonable reliance upon Defendants' false representations, Plaintiff Connie Sprague was induced to, and did permit Durepair Matrix to be implanted into her, thereby sustaining severe and permanent personal injuries and damages. Defendants knewthat Plaintiff, her physicians, and her other healthcare providers had no way to determine that Defendants

concealed and omitted facts necessary to make the statements Defendants made about Durepair Matrix true.

138. Plaintiff, her physicians, and her other healthcare providers reasonably relied on Defendants' statements and representations which suppressed and concealed facts that were critical to understanding the dangers inherent in the use of Durepair Matrix.

139. As a result of Defendants' research, clinical trials, testing, or lack thereof, Defendants intentionally distributed false information and made false statements and representations, including, but not limited to, assuring Plaintiff, her physicians, and her other healthcare providers, and the public that Durepair Matrix was safe to use as a dura substitute.

140. Defendants had a duty when disseminating information to the public, including Plaintiff, to disseminate truthful information; and Defendants had a parallel duty not to deceive the public, Plaintiff, Plaintiff's physicians, and Plaintiff's other healthcare providers.

141. The information Defendants distributed to Plaintiff, her physicians and her other healthcare providers, to the public, and to the medical community, included, but was not limited to, reports, press releases, advertising campaigns, television commercials, print advertisements, billboards and other commercial media containing representations, which were materially false and misleading, and which contained material omissions of the truth about the dangers of the use of Durepair Matrix.

142. Defendants misrepresented Plaintiff, her physicians, and other healthcare providers, to the healthcare and medical communities, and to the public, the material facts that Durepair Matrix did not have dangerous or serious adverse health safety concerns, and that Durepair Matrix was as safe as other dura substitutes.

143. Defendants' intent in making these misrepresentations was to deceive and defraud and to gain the confidence of Plaintiff, her physicians and other healthcare providers, the medical community, and the public, and to induce Plaintiff, her physicians and other healthcare providers, the healthcare and medical communities, and the public to request, recommend, and implant Durepair Matrix into patients, including Plaintiff.

144. Defendants made claims and representations in reports to the public and to healthcare professionals and in advertisements that Durepair Matrix did not present serious health risks.

145. Defendants' aforesaid representations were knowingly false when made and werewithout regard to the true facts.

146. Defendants' aforesaid representations were made with the intention of deceiving and defrauding Plaintiff, her physicians and her other healthcare providers and other members of the healthcare and medical communities, were made in order to induce Plaintiff, her physicians and her other healthcare providers to dispense, recommend, and implant Durepair Matrix into Plaintiff.

147. Defendants intentionally concealed, omitted, and misrepresented the dangerous and serious health and safety concerns inherent in the use of Durepair Matrix for the purpose of influencing the sales of a product known to Defendants to be dangerous and defective, and certainly not as safe as other dura substitute alternatives.

148. Defendants willfully and intentionally failed to disclose the truth, failed to disclose material facts, and made false representations, for the purpose of deceiving Plaintiff, her physicians, and her other healthcare providers, into a false sense of security, to induce Plaintiff's

physicians and other healthcare providers to recommend, dispense, and implant Durepair Matrix into Plaintiff, and to induce Plaintiff to permit Durepair Matrix to be implanted into her.

149. Plaintiff and her healthcare providers relied to their detriment on Defendants' misrepresentations and omissions. Had Plaintiff known the truth about the dangers and serious health and safety risks of Durepair Matrix, Plaintiff would not have permitted Durepair Matrix to be implanted into her.

150. Defendants' fraud and deceit was perpetrated willfully, wantonly, and purposefully on Plaintiff.

151. As a direct, foreseeable and proximate result of Defendants' aforesaid acts and omissions Plaintiff was caused to suffer, and did suffer, the serious and dangerous side effects of permanent and substantial physical deformity, has undergone corrective surgeries and will likely require further corrective surgery, and suffered further grievous personal injuries, including, but not limited to, physical pain and mental anguish, permanently diminished enjoyment of life, and any and all additional life implications and complications, such as Plaintiff's need for life-long medical treatment and care, medical monitoring and perpetual fear of developing additional adverse health consequences.

152. As a direct, foreseeable, and proximate result of Defendants' foregoing conduct, Plaintiff has suffered and will continue to suffer serious and permanent physical and emotional injuries, has incurred medical expenses, has suffered and will continue to suffer economic loss, and has otherwise been physically, emotionally, and economically injured.

COUNT IX
NEGLIGENT MISREPRESENTATION

153. Plaintiffs incorporate each and every paragraph of this Complaint by reference as if fully stated herein and further states and alleges as follows.

154. Defendants had the duty to accurately and truthfully represent to the medical and healthcare communities, to Plaintiff, her physicians, and her other healthcare providers, and to the public, that Durepair Matrix had been tested and had been determined to be a safe and effective dura substitute. Defendants' representations of safety and effectiveness of Durepair Matrix were false.

155. Defendants failed to exercise ordinary care in their representations concerning Durepair Matrix because Defendants negligently concealed, omitted and misrepresented Durepair Matrix's high risk of unreasonable, dangerous, adverse side effects.

156. Defendants knew, or should have known, that Durepair Matrix had been insufficiently tested, or had not been tested at all, lacked adequate and accurate warnings, and created a high risk, or higher than acceptable risk, or higher than reported and represented risk, of adverse side effects, including, but not limited to, erosion and exposure to abnormal levels of endotoxins.

157. As a direct, foreseeable and proximate result of Defendants' wrongful acts and omissions, Plaintiffs have suffered and will continue to suffer serious and permanent physical and emotional injuries, has incurred medical expenses, has suffered and will continue to suffer economic loss, and has otherwise been physically, emotionally, and economically injured.

COUNT X
VIOLATIONS OF NEW JERSEY CONSUMER FRAUD ACT
N.J. Stat. §§ 56:8-1, *et seq.*

158. Plaintiffs incorporate each and every paragraph of this Complaint by reference as if fully stated herein and further states and alleges as follows.

159. Defendants have a statutory duty to refrain from engaging in unconscionable commercial practices, deception, fraud, false pretense, misrepresentation, or the knowing concealment or omission of material facts with the intent that others rely on those actions.

160. Had the Defendants not engaged in the deceptive conduct described herein, Plaintiffs would not have purchased and/or paid for the defective product referenced herein and would not have incurred related medical costs and injury.

161. Defendants engaged in wrongful conduct while at the same time obtaining, under false pretenses, substantial sums of money from Plaintiff for the defective product that would not have been paid had Defendants not engaged in unfair and deceptive conduct.

162. Plaintiff was injured by the cumulative and indivisible nature of Defendants' conduct. The cumulative effect of Defendants' conduct directed at patients, physicians and consumers was to create demand for and sell the defective product. Each aspect of Defendants' conduct combined to artificially create sales of the defective product.

163. Defendants are liable to Plaintiffs jointly and severally for all general, special, and injunctive relief to which Plaintiffs are entitled by law. Under statutes enacted in New Jersey to protect consumers against unfair, deceptive, fraudulent, and unconscionable trade and business practices, Plaintiff is a consumer who purchased Defendants' Durepair Matrix products pursuant to a consumer transaction for personal use and is therefore subject to protection under such legislation.

164. Under statutes enacted in New Jersey to protect consumers against unfair, deceptive, fraudulent, and unconscionable trade and business practices, Defendants are the suppliers, manufacturers, advertisers, and sellers, who are subject to liability under such legislation for unfair, deceptive, fraudulent, and unconscionable consumer sales practices.

165. Defendants violated the statutes enacted in New Jersey to protect consumers against unfair, deceptive, fraudulent, and unconscionable trade and business practices and false advertising, by knowingly and falsely representing that the Durepair Matrix products were fit to be used for the purpose for which it was intended, when in fact the Durepair Matrix Products were defective and dangerous.

166. The actions and omissions of Defendants alleged herein are uncured or incurable deceptive acts under the statutes enacted in New Jersey to protect consumers against unfair, deceptive, fraudulent, and unconscionable trade and business practices.

167. Defendants had actual knowledge of the defective and dangerous condition of the Durepair Matrix Products and failed to take any action to cure such defective and dangerous conditions.

168. Plaintiff and the medical community relied upon Defendants' misrepresentations and omissions in determining which Durepair Matrix Products to utilize.

169. Defendants' deceptive, unconscionable, or fraudulent representations and material omissions to patients, physicians, and consumers, including Plaintiff, constituted unfair and deceptive acts and practices in violation of New Jersey's Consumer Fraud Act (CFA), N.J. Stat. §56:8.

170. Because of the unlawful acts engaged in by Defendants, and as a direct and proximate result thereof, Plaintiff has suffered ascertainable loss and damages.

171. As a direct and proximate result of Defendants' violations of New Jersey's Consumer Fraud Act (CFA), N.J. Stat. §56:8, Plaintiff Connie Sprague has sustained economic losses and other damages and is entitled to statutory, compensatory, injunctive, and declaratory relief in an amount to be proven at trial.

COUNT XI
LOSS OF CONSORTIUM

172. Plaintiffs hereby incorporate each and every paragraph of this Complaint by reference as if fully stated herein and further state and allege as follows.

173. As a result of the negligence of Defendants, Plaintiff Connie Sprague has suffered a substantial reduction in her capacity to enjoy life and participate in her usual activities.

174. Plaintiff Connie Sprague has permanent injuries, pain, and physical disabilities which have limited, and will limit in the future, her ability to receive and enjoy services, companionship, and intimacy from her husband, Plaintiff James Sprague.

175. Because of Plaintiff's permanent injuries and disability, she has been unable to provide the normal household services and chores which she previously performed for herself and her husband, Plaintiff James Sprague.

176. As a direct and proximate result of Defendants' wrongful conduct, Plaintiffs have sustained and will continue to sustain loss of companionship and society, severe emotional distress, mental anguish, economic losses, and other damages for which they are entitled to statutory, compensatory, injunctive, equitable, and declaratory relief in an amount to be proven at trial.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs Connie and James Sprague pray for relief against Defendants, jointly and severally, as follows:

A. Judgment in favor of Plaintiffs and against Defendants, for damages in such amounts as may be proven at trial;

B. Compensation for both economic and non-economic losses, including but not limited to medical expenses, disfigurement, pain and suffering, mental anguish and emotional distress, in such amounts as may be proven at trial;

C. Compensation for Punitive Damages;

D. Restitution and disgorgement of all revenue that Defendant has obtained through the manufacture, marketing, sale and administration of the Durepair Matrix Products;

E. Attorneys' fees and costs where applicable;

F. Pre-and post-judgment interest; and

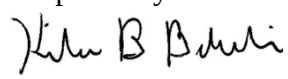
G. Any and all further relief, both legal and equitable, that the Court may deem just and proper.

JURY DEMAND

Plaintiffs hereby demand a jury trial on all claims so triable in this action.

Dated: October 6, 2025

Respectfully submitted,



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