

**IN THE UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA  
CHARLESTON DIVISION**

IN RE: BOSTON SCIENTIFIC CORP.,  
PELVIC REPAIR SYSTEM  
PRODUCTS LIABILITY LITIGATION

MDL No. 2326

---

THIS DOCUMENT RELATES TO ALL CASES

**DEFENDANT BOSTON SCIENTIFIC CORPORATION'S MASTER ANSWER  
TO PLAINTIFFS' MASTER LONG FORM COMPLAINT AND JURY DEMAND**

Defendant Boston Scientific Corporation ("Boston Scientific") hereby answers Plaintiffs' Master Long Form Complaint and Jury Demand ("Master Complaint") as follows:

By way of a general response, all allegations are denied unless specifically admitted, and any factual averment admitted is admitted only as to the specific facts and not as to any conclusions, characterizations, implications, or speculations which are contained in the averment or in the Master Complaint as a whole. Boston Scientific makes no response to the unnumbered paragraph that opens the Master Complaint because it does not allege a material fact. To the extent a response to this paragraph is deemed required, Boston Scientific admits only that Plaintiffs bring this Master Complaint by operation of Pretrial Order No. 12.

**PARTIES, JURISDICTION & VENUE**

1. Boston Scientific lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 1 and, therefore denies the same.

2. Boston Scientific admits that the entities named in Paragraph 2 have been identified as Defendants in the Short Form Complaint. Boston Scientific also admits that Plaintiffs seek to incorporate by reference the Master Long Form Complaints applicable to those entities listed in subparts (b) through (g). The remaining allegations of Paragraph 2 are denied.

3. Boston Scientific states that it is a Delaware Corporation and that its principal place of business is located in the State of Massachusetts. The remaining allegations of Paragraph 3 are denied.

4. Boston Scientific admits that federal subject matter jurisdiction is proper and that Plaintiffs are seeking damages in excess of \$75,000, but denies that Plaintiffs are entitled to any relief whatsoever. The remaining allegations of Paragraph 4 are denied.

5. Boston Scientific states that the allegations set forth in this paragraph contain conclusions of law to which no responsive pleading is required. To the extent a response is required, Boston Scientific denies the allegations in Paragraph 5.

6. Boston Scientific lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 6 and, therefore denies the same.

#### THE PELVIC MESH PRODUCTS

7. Boston Scientific admits that Paragraph 7 of the Master Complaint purports to refer to eight different pelvic mesh products collectively as “the ‘Products,’” but, to the extent such allegations purport to impute liability either directly or indirectly upon Boston Scientific, they are denied.

8. Boston Scientific admits that it designs, packages, labels, markets, sells, and distributes pelvic mesh products generally, including the Pinnacle Pelvic Floor Repair Kit, the Uphold Vaginal Support System, the Advantage Transvaginal Mid-Urethral Sling System, the Advantage Fit System, the Lynx Suprapubic Mid-Urethral Sling System, the Obtryx Transobturator Mid-Urethral Sling System, the Prefyx PPS System, and the Solyx SIS System. Boston Scientific lacks knowledge or information sufficient to form a belief as to the truth of whether any of its pelvic mesh products were implanted in any Plaintiff so indicated in a Short

Form Complaint, and therefore denies the same. The remaining allegations of Paragraph 8 are denied.

9. Boston Scientific denies the allegations of Paragraph 9.

10. The first three sentences in Paragraph 10 of Plaintiffs' Master Complaint make no allegations against Boston Scientific and, therefore, require no response by Boston Scientific. In response to the fourth and fifth sentences in Paragraph 10 of Plaintiffs' Master Complaint, Boston Scientific states that its pelvic mesh products and kits are designed, manufactured, and sold for uses consistent with their packaging and labeling. The last sentence in Paragraph 10 of Plaintiffs' Master Complaint makes no allegation against Boston Scientific and requires no response by Boston Scientific. The remaining allegations of Paragraph 10 are denied.

11. Boston Scientific admits that the pelvic mesh products at issue received FDA clearance through the FDA's 510(k) premarket notification process. Additionally, Boston Scientific states that the allegations of Paragraph 11 purport to quote, reference, interpret and/or paraphrase sections of the United States Code ("U.S.C.") and/or the Code of Federal Regulations ("C.F.R."), and that the complete and precise content of the statute or regulation can be ascertained from the statute or regulation itself. Any characterization of the statute or regulation is denied. The remaining allegations of Paragraph 11 are denied.

12. Boston Scientific states that Paragraph 12 purports to quote, characterize, reference, interpret, and/or paraphrase a document. Boston Scientific states that the complete and precise content of the document can be ascertained from the document itself. Any characterization of the document is denied. The remaining allegations of Paragraph 12 are denied.

13. Boston Scientific states that Paragraph 13 purports to quote, characterize, reference, interpret, and/or paraphrase a document. Boston Scientific states that the complete and precise content of the document can be ascertained from the document itself. Any characterization of the document is denied. The remaining allegations of Paragraph 13 are denied.

14. Boston Scientific states that Paragraph 14 purports to quote, characterize, reference, interpret, and/or paraphrase a document, and that the complete and precise content of the document can be ascertained from the document itself. Any characterization of the document is denied. The remaining allegations of Paragraph 14 are denied.

15. Boston Scientific states that Paragraph 15 purports to quote, characterize, reference, interpret, and/or paraphrase a document. Boston Scientific states that the complete and precise content of the document can be ascertained from the document itself. Any characterization of the document is denied. The remaining allegations of Paragraph 15 are denied.

16. Boston Scientific lacks knowledge or information sufficient to form a belief as to the truth of the allegations regarding the content and/or substance of information to be established in discovery and, therefore denies the same. Additionally, Boston Scientific states that the allegations of Paragraph 16 purport to reference, interpret and/or paraphrase a document, and that the complete and precise content of the document can be ascertained from the document itself. Any characterization of the document is denied. The remaining allegations of Paragraph 16 are denied.

17. Boston Scientific states that the allegations of Paragraph 17 purport to quote, reference, interpret and/or paraphrase a document, and that the complete and precise content of

the document can be ascertained from the document itself. Any characterization of the document is denied. The remaining allegations of Paragraph 17 are denied.

18. Boston Scientific states that the allegations of Paragraph 18 purport to quote, reference, interpret and/or paraphrase a document, and that the complete and precise content of the document can be ascertained from the document itself. Any characterization of the document is denied. The remaining allegations of Paragraph 18 are denied.

19. Boston Scientific states that the allegations of Paragraph 19 purport to quote, reference, interpret and/or paraphrase a document, and that the complete and precise content of the document can be ascertained from the document itself. Any characterization of the document is denied. The remaining allegations of Paragraph 19 are denied.

20. Boston Scientific states that the allegations of Paragraph 20 purport to quote, reference, interpret and/or paraphrase a document, and that the complete and precise content of the document can be ascertained from the document itself. Any characterization of the document is denied. The remaining allegations of Paragraph 20 are denied.

21. Boston Scientific states that the allegations of Paragraph 21 purport to quote, reference, interpret and/or paraphrase a document, and that the complete and precise content of the document can be ascertained from the document itself. Any characterization of the document is denied. The remaining allegations of Paragraph 21 are denied.

22. Boston Scientific states that the allegations of Paragraph 22 purport to reference, interpret and/or paraphrase a document, and that the complete and precise content of the document can be ascertained from the document itself. Any characterization of the document is denied. The remaining allegations of Paragraph 22 are denied.

23. Boston Scientific states that the allegations of Paragraph 23 purport to quote, reference, interpret and/or paraphrase a document, and that the complete and precise content of the document can be ascertained from the document itself. Any characterization of the document is denied. The remaining allegations of Paragraph 23 are denied.

24. Boston Scientific states that the allegations of Paragraph 24 purport to reference, interpret and/or paraphrase a document, and that the complete and precise content of the document can be ascertained from the document itself. Any characterization of the document is denied. The remaining allegations of Paragraph 24 are denied.

25. Boston Scientific states that the allegations of Paragraph 25 purport to reference, interpret and/or paraphrase a document, and that the complete and precise content of the document can be ascertained from the document itself. Any characterization of the document is denied. The remaining allegations of Paragraph 25 are denied.

26. Boston Scientific denies the allegations of Paragraph 26.

27. Boston Scientific denies the allegations of Paragraph 27.

28. Boston Scientific denies the allegations of Paragraph 28.

29. Boston Scientific states that Paragraph 29 purports to quote, characterize, reference, interpret, and/or paraphrase a document, and that the complete and precise content of the document can be ascertained from the document itself. Any characterization of the document is denied. The remaining allegations of Paragraph 29 are denied.

30. Boston Scientific denies the allegations of Paragraph 30.

31. Boston Scientific denies the allegations of Paragraph 31.

32. Boston Scientific denies the allegations of Paragraph 32.

33. While Boston Scientific admits that there are various treatment options for individuals with stress urinary incontinence and pelvic organ prolapse, the allegations in Paragraph 33 of Plaintiffs' Master Complaint make no allegations against Boston Scientific and, therefore, require no response by Boston Scientific. To the extent a response is required, Boston Scientific denies the allegations in Paragraph 33.

34. Boston Scientific denies the allegations of Paragraph 34.

35. Boston Scientific denies the allegations of Paragraph 35.

36. Boston Scientific denies the allegations of Paragraph 36, including subparts (a) through (l).

37. Boston Scientific denies the allegations of Paragraph 37, including subparts (a) through (r).

38. Boston Scientific denies the allegations of Paragraph 38.

39. Boston Scientific denies the allegations of Paragraph 39.

40. Boston Scientific denies the allegations of Paragraph 40.

41. Boston Scientific denies the allegations of Paragraph 41.

42. Boston Scientific denies the allegations of Paragraph 42.

43. Boston Scientific denies the allegations of Paragraph 43.

44. Boston Scientific lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 44 and, therefore denies the same.

45. Boston Scientific lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 45 and, therefore denies the same.

46. Boston Scientific lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 46 and, therefore denies the same.

47. Boston Scientific denies the allegations of Paragraph 47.
48. Boston Scientific denies the allegations of Paragraph 48.
49. Boston Scientific denies the allegations of Paragraph 49.
50. Boston Scientific denies the allegations of Paragraph 50.
51. Boston Scientific denies the allegations of Paragraph 51.
52. Boston Scientific denies the allegations of Paragraph 52.
53. Boston Scientific denies the allegations of Paragraph 53.

CAUSES OF ACTION  
COUNT I: NEGLIGENCE

54. Boston Scientific repeats and incorporates by reference its responses set forth in Paragraphs 1-53 as though fully set forth herein.

55. The allegations set forth in Paragraph 55 constitute legal conclusions to which no response is required from Boston Scientific. To the extent a response is required, Boston Scientific denies the allegations of Paragraph 55.

56. Boston Scientific denies the allegations of Paragraph 56, including subparts (a) through (g).

57. Boston Scientific denies the allegations of Paragraph 57, including subparts (a) through (l).

58. Boston Scientific denies the allegations of Paragraph 58, including subparts (a) through (r).

59. Boston Scientific denies the allegations of Paragraph 59.

COUNT II: STRICT LIABILITY – DESIGN DEFECT

60. Boston Scientific repeats and incorporates by reference its responses to the allegations of Paragraphs 1-59 as though fully set forth herein.

61. Boston Scientific denies the allegations of Paragraph 61, including subparts (a) through (m).

62. Boston Scientific denies the allegations of Paragraph 62.

63. Boston Scientific denies the allegations of Paragraph 63.

**COUNT III: STRICT LIABILITY – MANUFACTURING DEFECT**

64. Boston Scientific repeats and incorporates by reference its responses to the allegations of Paragraphs 1-63 as though fully set forth herein.

65. Boston Scientific denies the allegations of Paragraph 65.

66. Boston Scientific denies the allegations of Paragraph 66.

67. Boston Scientific denies the allegations of Paragraph 67.

**COUNT IV: STRICT LIABILITY – FAILURE TO WARN**

68. Boston Scientific repeats and incorporates by reference its responses to the allegations of Paragraphs 1-67 as though fully set forth herein.

69. Boston Scientific denies the allegations of Paragraph 69, including subparts (a) through (s).

70. Boston Scientific denies the allegations of Paragraph 70.

71. Boston Scientific denies the allegations of Paragraph 71.

**COUNT V: BREACH OF EXPRESS WARRANTY**

72. Boston Scientific repeats and incorporates by reference its responses to the allegations of Paragraphs 1-71 as though fully set forth herein.

73. Boston Scientific denies the allegations of Paragraph 73.

74. Boston Scientific lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 74 and, therefore denies the same.

75. Boston Scientific lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 75 and, therefore denies the same.

76. Boston Scientific denies the allegations of Paragraph 76.

77. Boston Scientific denies the allegations of Paragraph 77.

78. Boston Scientific denies the allegations of Paragraph 78.

COUNT VI: BREACH OF IMPLIED WARRANTY

79. Boston Scientific repeats and incorporates by reference its responses to the allegations of Paragraphs 1-78 as though fully set forth herein.

80. Boston Scientific denies the allegations of Paragraph 80.

81. Boston Scientific lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 81 and, therefore denies the same.

82. Boston Scientific lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 82 and, therefore denies the same.

83. Boston Scientific denies the allegations of Paragraph 83.

84. Boston Scientific denies the allegations of Paragraph 84.

85. Boston Scientific denies the allegations of Paragraph 85.

COUNT VII: LOSS OF CONSORTIUM

86. Boston Scientific repeats and incorporates by reference its responses to the allegations of Paragraphs 1-85 as though fully set forth herein.

87. Boston Scientific denies the allegations of Paragraph 87.

COUNT VIII: DISCOVERY RULE, TOLLING AND FRAUDULENT CONCEALMENT

88. Boston Scientific repeats and incorporates by reference its responses to the allegations of Paragraphs 1-87 as though fully set forth herein.

89. The allegations set forth in Paragraph 89 constitute legal conclusions to which no response is required from Boston Scientific. To the extent a response is required, Boston Scientific denies the allegations of Paragraph 89.

90. The allegations set forth in Paragraph 90 constitute legal conclusions to which no response is required from Boston Scientific. To the extent a response is required, Boston Scientific denies the allegations of Paragraph 90.

91. The allegations set forth in Paragraph 91 constitute legal conclusions to which no response is required from Boston Scientific. To the extent a response is required, Boston Scientific denies the allegations of Paragraph 91.

92. The allegations set forth in Paragraph 92 constitute legal conclusions to which no response is required from Boston Scientific. To the extent a response is required, Boston Scientific denies the allegations of Paragraph 92.

#### COUNT IX: PUNITIVE DAMAGES

93. Boston Scientific repeats and incorporates by reference its responses to the allegations of Paragraphs 1-92 as though fully set forth herein.

94. Boston Scientific denies the allegations of Paragraph 94.

95. Boston Scientific denies the allegations of Paragraph 95.

96. Boston Scientific denies the allegations of Paragraph 96.

97. Boston Scientific denies the allegations of Paragraph 97.

98. Boston Scientific denies the allegations of Paragraph 98.

99. Boston Scientific denies the allegations of Paragraph 99.

100. Boston Scientific denies the allegations of Paragraph 100.

101. Boston Scientific denies the allegations of Paragraph 101.
102. Boston Scientific denies the allegations of Paragraph 102.
103. Boston Scientific denies the allegations of Paragraph 103.
104. Boston Scientific denies the allegations of Paragraph 104.

Boston Scientific denies that Plaintiffs are entitled to the relief requested in the “WHEREFORE” clause following Paragraph 104, or to any relief whatsoever.

#### AFFIRMATIVE DEFENSES

Having answered the allegations of the Master Complaint and having denied any liability whatsoever, Boston Scientific further denies any allegations that have not been expressly admitted and asserts the following affirmative defenses:

##### FIRST AFFIRMATIVE DEFENSE

Boston Scientific is entitled to, and claims the benefit of, all defenses and presumptions set forth in or arising from any rule of law or statute in this State or any other state whose law is deemed to apply in this case.

##### SECOND AFFIRMATIVE DEFENSE

The Complaint, in whole or in part, fails to state a claim upon which relief can be granted.

##### THIRD AFFIRMATIVE DEFENSE

The Complaint, in whole or in part, fails to state a claim upon which relief can be granted due to lack of adequate product identification.

#### FOURTH AFFIRMATIVE DEFENSE

Plaintiffs' claims are barred for lack of subject matter and/or personal jurisdiction.

#### FIFTH AFFIRMATIVE DEFENSE

The Complaint must be dismissed because plaintiffs provided insufficient process and/or insufficient service of process.

#### SIXTH AFFIRMATIVE DEFENSE

Plaintiffs' claims are barred due to lack of standing and/or capacity to bring such claims.

#### SEVENTH AFFIRMATIVE DEFENSE

Plaintiffs have failed to join indispensable parties or real parties in interest necessary for the just adjudication of this matter.

#### EIGHTH AFFIRMATIVE DEFENSE

Plaintiffs' claims have been improperly joined under the applicable rules of civil procedure and the laws of the applicable state. The improper joinder of plaintiffs' causes of action violates the procedural and substantive due process rights of Boston Scientific under the Constitutions of the United States and the applicable states.

#### NINTH AFFIRMATIVE DEFENSE

Venue may be improper in any individual case in which the plaintiff does not reside in the forum or cannot otherwise establish an independent basis for venue in that forum and any such plaintiff's case should be dismissed on this basis. Plaintiffs' case may be subject to dismissal or transfer under the doctrine of forum non conveniens.

#### TENTH AFFIRMATIVE DEFENSE

Boston Scientific asserts any and all defenses available under Rule 12 of the Federal Rules of Civil Procedure.

#### ELEVENTH AFFIRMATIVE DEFENSE

Plaintiffs' claims are expressly preempted by federal law, as established by statute, including the express preemption provision of the Medical Device Amendments, 21 U.S.C. § 360k(a), to the federal Food, Drug and Cosmetic Act, 21 U.S.C. §§ 301, *et seq.* Plaintiffs' claims, if allowed, would conflict with applicable federal law and violate the Supremacy Clause of the United States Constitution.

#### TWELFTH AFFIRMATIVE DEFENSE

At all relevant times, Boston Scientific was in full compliance with all applicable federal statutes and regulations, including but not limited to the Medical Device Amendments, 21 U.S.C. § 360c, *et seq.*, to the federal Food, Drug and Cosmetic Act, 21 U.S.C. §§ 301 *et seq.*, and other federal statutes and regulations, and plaintiffs' claims are accordingly barred. In the event that plaintiffs' claims are not barred, Boston Scientific is entitled to a presumption that the products at issue in this case are free from any defect or defective condition.

#### THIRTEENTH AFFIRMATIVE DEFENSE

Plaintiffs' claims are impliedly preempted by federal law.

#### FOURTEENTH AFFIRMATIVE DEFENSE

The conduct of Boston Scientific in all activities with respect to the products at issue has been and is under the supervision of the FDA. Accordingly, this action is barred by the doctrine of primary jurisdiction.

#### FIFTEENTH AFFIRMATIVE DEFENSE

At all relevant times, the devices were reasonably safe and reasonably fit for their intended use, were not defective or unreasonably dangerous, and were accompanied by proper

warnings, information, and instructions, all pursuant to generally recognized prevailing industry standards and the state-of-the-art in existence at the time.

SIXTEENTH AFFIRMATIVE DEFENSE

There was no defect in the products at issue with the result that the Plaintiffs are not entitled to recover against Boston Scientific in this case.

SEVENTEENTH AFFIRMATIVE DEFENSE

Plaintiffs' claims are subsumed and/or barred, in whole or in part, by the product liability acts and statutes enacted in each state whose law is deemed to apply in this case. Alternatively, Plaintiffs cannot prevail on their claims under the product liability acts and statutes enacted in each state whose law is deemed to apply in this case, to the extent they failed to comply with the statutory prerequisites to such claim before they filed suit.

EIGHTEENTH AFFIRMATIVE DEFENSE

Boston Scientific asserts all available defenses under the product liability acts and statutes of any state whose law is deemed to apply in this case.

NINETEENTH AFFIRMATIVE DEFENSE

The products at issue in this case are prescription medical devices that fall within "comment k" and "comment j" exceptions to strict liability, as defined in Restatement (Second) of Torts § 402A. The benefits of these products outweigh the risks, if any, which may be attendant to their use. The devices are therefore neither defective nor unreasonably dangerous.

TWENTIETH AFFIRMATIVE DEFENSE

The products at issue in this case are prescription medical devices that fall within Restatement (Third) of Torts: Products Liability § 6. Therefore, the devices are reasonably safe

in design if a reasonable healthcare provider would prescribe the devices for any class of patients knowing the foreseeable risks and therapeutic benefits.

#### TWENTY-FIRST AFFIRMATIVE DEFENSE

Plaintiffs' claims are barred, in whole or in part, because the products at issue provided a benefit to users of such products that greatly outweighed any risk associated with using such products; any risk could not have been avoided through the use of the highest standards of scientific and technical knowledge available at the time; the benefit provided to users could not be achieved in another matter with less risk; and adequate warnings concerning the risk were provided.

#### TWENTY-SECOND AFFIRMATIVE DEFENSE

The injuries allegedly resulting from plaintiffs' use of the products at issue, were not foreseeable to Boston Scientific given the state of scientific knowledge and state of the art at the time of the alleged injuries. At all times relevant, the products at issue conformed to state-of-the-art specifications and state-of-scientific knowledge for such products at that time, as well as all applicable statutes and regulations, including those of the FDA.

#### TWENTY-THIRD AFFIRMATIVE DEFENSE

Plaintiffs' claims are barred in whole or in part by plaintiffs' failure to assert a safer alternative design for any of the products at issue.

#### TWENTY-FOURTH AFFIRMATIVE DEFENSE

Without admitting that the products at issue were manufactured and/or sold by Boston Scientific, to the extent Boston Scientific had any duty with respect to the sale and/or manufacture of its products, such duty was fully discharged by the giving of adequate instructions and warnings concerning its use.

TWENTY-FIFTH AFFIRMATIVE DEFENSE

The products at issue were only available through licensed physicians who were provided complete and adequate warnings consistent with the state of medical and scientific knowledge at the time.

TWENTY-SIXTH AFFIRMATIVE DEFENSE

Plaintiffs' causes of action are barred by the learned intermediary doctrine. To the extent Plaintiffs assert that Boston Scientific failed to provide plaintiffs with adequate warnings regarding the use of the products at issue, any obligation to warn was discharged when adequate warnings were provided to Plaintiffs' treating physicians. Plaintiffs' claims are also barred by the Sophisticated User Doctrine, or other similar applicable laws.

TWENTY-SEVENTH AFFIRMATIVE DEFENSE

At all relevant times, herein, plaintiffs' prescribing physicians were in the position of a sophisticated purchaser, fully knowledgeable and informed with respect to the risks and benefits of the subject product.

TWENTY-EIGHTH AFFIRMATIVE DEFENSE

Plaintiffs' claims are barred in whole or in part, because Boston Scientific acted in good faith at all relevant times and gave adequate warnings of all known or reasonably knowable risks associated with the use of its products.

TWENTY-NINTH AFFIRMATIVE DEFENSE

At all relevant times herein, the products in question were sold and distributed with proper warnings, information, cautions, and instructions in conformity with generally recognized and prevailing standards in existence at the time.

THIRTIETH AFFIRMATIVE DEFENSE

Plaintiffs' inadequate warning claims are barred because the alleged risk of which plaintiffs claim is open, obvious, and/or a matter of common knowledge.

THIRTY-FIRST AFFIRMATIVE DEFENSE

Plaintiffs' claims are barred, in whole or in part, because any labeling with respect to the subject product was not false or misleading and, therefore, constitutes protected commercial speech under the applicable provisions of the United States Constitution and the Constitutions of the 50 states.

THIRTY-SECOND AFFIRMATIVE DEFENSE

Plaintiffs' breach of warranty claims are barred because there is no privity of contract between plaintiffs and Boston Scientific; Plaintiffs failed to give timely notice of any alleged breach of warranty; Plaintiffs did not reasonably rely upon any alleged warranty; Plaintiffs failed to satisfy all conditions precedent or subsequent to the enforcement of such warranty; and the warranty was appropriately disclaimed, excluded or modified.

THIRTY-THIRD AFFIRMATIVE DEFENSE

To the extent the Plaintiffs assert a claim for breach of implied warranty, such claim must fail because the products at issue were not used for their ordinary purpose.

THIRTY-FOURTH AFFIRMATIVE DEFENSE

Boston Scientific specifically pleads all affirmative defenses under the Uniform Commercial Code ("UCC") now existing or which may arise in the future, including those defenses provided by UCC §§ 2-607 and 2-709.

THIRTY-FIFTH AFFIRMATIVE DEFENSE

Boston Scientific specifically pleads as to any claim alleging a violation of the consumer protection laws of any other state whose law is deemed to apply in this case, all affirmative defenses available to Boston Scientific under the rules and statutes of any state whose law is deemed to apply in this case, and under the common law of any state whose law is deemed to apply in this case.

THIRTY-SIXTH AFFIRMATIVE DEFENSE

Plaintiffs are not entitled to satisfaction under the consumer protection laws of any state because Plaintiffs cannot satisfy the elements of these statutes and because Plaintiffs lack standing to assert claims under these statutes.

THIRTY-SEVENTH AFFIRMATIVE DEFENSE

Plaintiffs have failed to plead fraud, misrepresentation, and any other claims sounding in fraud with the factual particularity required under Rule 9(b) of the Federal Rules of Civil Procedure, any rule or statute of any state whose law is deemed to apply in this case, or under any common law principles of any state whose law is deemed to apply in this case.

THIRTY-EIGHTH AFFIRMATIVE DEFENSE

Boston Scientific asserts all defenses available under the statutes and rules of each and every state as to any claim sounding in fraud.

THIRTY -NINTH AFFIRMATIVE DEFENSE

Plaintiffs knowingly and voluntarily assumed any and all risks associated with the use of the products at issue in this case and, thus, the “last clear chance” and assumption of the risk doctrines bar, in whole or in part, the damages plaintiffs seek to recover herein.

#### FORTIETH AFFIRMATIVE DEFENSE

The injuries and damages claimed by Plaintiffs, if any, resulted from an intervening cause or causes, and any action on the part of Boston Scientific was not the proximate or competent producing cause of Plaintiffs' alleged injuries. In the alternative, any damages that Plaintiffs might be entitled to recover against Boston Scientific must be reduced to the extent that such damages are attributable to the intervening or superseding acts and/or omissions of persons other than Boston Scientific.

#### FORTY-FIRST AFFIRMATIVE DEFENSE

Upon information and belief, there exists no proximate causation between any alleged act, omission, breach of duty, or breach of warranty (none being admitted) by Boston Scientific and Plaintiffs' alleged damages, injuries, and/or losses, and all of Plaintiffs' alleged damages, injuries, and/or losses, if any, were the result of conduct by persons other than Boston Scientific.

#### FORTY-SECOND AFFIRMATIVE DEFENSE

The injuries or damages sustained by Plaintiffs, if any, can be attributed to several causes, and accordingly, should be apportioned among the various causes according to the respective contribution of each such cause to the harm sustained.

#### FORTY-THIRD AFFIRMATIVE DEFENSE

Plaintiffs' causes of action are barred because Plaintiffs suffered no injury or damages as a result of the alleged conduct and do not have any right, standing, or competency to maintain claims for damages or other relief.

#### FORTY-FOURTH AFFIRMATIVE DEFENSE

Plaintiffs' causes of action are barred, in whole or in part, by the applicable statutes of limitations and statutes of repose.

FORTY-FIFTH AFFIRMATIVE DEFENSE

Plaintiffs' causes of action are barred, in whole or in part, by the doctrines of waiver, estoppel, and laches.

FORTY-SIXTH AFFIRMATIVE DEFENSE

Plaintiffs' alleged injuries occurred, if at all, because of circumstances and conditions beyond the control of Boston Scientific.

FORTY-SEVENTH AFFIRMATIVE DEFENSE

Plaintiffs may not recover on the claims pleaded in the Complaint because the damages sought are too speculative and remote.

FORTY-EIGHTH AFFIRMATIVE DEFENSE

If Plaintiffs sustained injuries or incurred expenses as alleged, such injuries or expenses resulted from pre-existing or unrelated medical, genetic, or environmental conditions, diseases or illnesses of the Plaintiffs.

FORTY-NINTH AFFIRMATIVE DEFENSE

If Plaintiffs sustained injuries or incurred expenses as alleged by operation of nature or idiosyncratic and/or allergic reaction to the products at issue, used either alone or in combination with any other drug, Boston Scientific is not liable.

FIFTIETH AFFIRMATIVE DEFENSE

Upon information and belief, the injuries, damages, and/or losses sustained by Plaintiffs, if any, were directly and proximately caused by and contributed to by Plaintiffs' own negligence and comparative fault, and therefore any recovery should be diminished, reduced, offset, or barred in accordance with the principles of comparative fault and/or contributory negligence.

FIFTY-FIRST AFFIRMATIVE DEFENSE

All or part of the damages, injuries, and/or losses alleged by Plaintiffs were caused by the abuse and/or misuse by Plaintiffs, or others, of Boston Scientific's products, which were not reasonable foreseeable, thereby barring Plaintiffs from any recovery against Boston Scientific.

FIFTY-SECOND AFFIRMATIVE DEFENSE

All or part of the damages sustained by Plaintiffs, if any, are due to Plaintiffs' failure to mitigate their damages and therefore may not be recovered by Plaintiffs.

FIFTY-THIRD AFFIRMATIVE DEFENSE

Plaintiffs' claims are barred, in whole or in part, by their failure to comply with conditions precedent to their right to recover.

FIFTY-FOURTH AFFIRMATIVE DEFENSE

Plaintiffs' claims for equitable relief are barred because equitable relief is not available under any of the alleged causes of action.

FIFTY-FIFTH AFFIRMATIVE DEFENSE

Plaintiffs' claims for equitable relief are barred because Plaintiffs have an adequate remedy at law.

FIFTY-SIXTH AFFIRMATIVE DEFENSE

Plaintiffs are not entitled to the equitable relief requested in the Complaint because the hardship that would be imposed on Boston Scientific by the relief is greatly disproportionate to any hardship that Plaintiffs might suffer in its absence.

FIFTY-SEVENTH AFFIRMATIVE DEFENSE

Plaintiffs are not entitled to the equitable relief requested in the Complaint because the Court lacks any sufficiently certain, non-speculative basis for fashioning such relief.

FIFTY-EIGHTH AFFIRMATIVE DEFENSE

No act or omission of Boston Scientific was malicious, willful, wanton, reckless, grossly negligent, or intentional and, therefore, any award of punitive damages is barred.

FIFTY-NINTH AFFIRMATIVE DEFENSE

Punitive damages are not appropriate in this case and any claim for punitive damages contravenes the rights of Boston Scientific under each of the following constitutional provisions: the Due Process Clause and the Double Jeopardy Clause of the Fifth Amendment of the United States Constitution; the Excessive Fines Clause of the Eighth Amendment of the United States Constitution; the Equal Protection Clause and Due Process Clause of the Fourteenth Amendment of the United States Constitution; the Constitutions of the 50 states; and the law, statutes, rules and policies of the 50 states given the circumstances of this litigation, including but not limited to:

- (a) imposition of punitive damages by a jury which
  - (1) is not provided with standards of sufficient clarity for determining the appropriateness, and the appropriate size, of a punitive damages award;
  - (2) is not adequately and clearly instructed on the limits on punitive damages imposed by the principles of deterrence and punishment;
  - (3) is not expressly prohibited from awarding punitive damages, or determining the amount of an award thereof, in whole or in part, on the basis of invidiously discriminatory characteristics, including the corporate status, or state of residence of Boston Scientific;
  - (4) is permitted to award punitive damages under a standard for determining liability for such damages which is vague and arbitrary and does not

define with sufficient clarity the conduct or mental state which makes punitive damages permissible; and

(5) is not subject to trial court and appellate judicial review for reasonableness and the furtherance of legitimate purposes on the basis of objective standards;

(b) imposition of such punitive damages, and determination of the amount of an award thereof, where applicable state law is impermissibly vague, imprecise, or inconsistent;

(c) imposition of such punitive damages, and determination of the amount of an award thereof, without bifurcating the trial and trying all punitive damages issues only if and after the liability of Boston Scientific has been found on the merits;

(d) imposition of such punitive damages, and determination of the amount of an award thereof, based on anything other than Boston Scientific's conduct in connection with the sale of the products alleged in this litigation, or in any other way subjecting Boston Scientific to impermissible multiple punishment for the same alleged wrong.

#### SIXTIETH AFFIRMATIVE DEFENSE

Any claim for punitive damages in this case cannot be sustained to the extent it seeks to punish Boston Scientific for alleged harm to non-parties and/or persons who are not before the Court. Imposition of punitive damages under such circumstances would violate Boston Scientific's procedural and substantive due process rights and equal protection rights under the Fifth and Fourteenth Amendments to the United States Constitution and Boston Scientific's due process and equal protection rights under cognate provisions of the Constitutions of the 50 states, and would be improper under the common law and public policies of the United States and the 50 states.

SIXTY-FIRST AFFIRMATIVE DEFENSE

Boston Scientific specifically incorporates by reference all standards of limitations regarding the determination and enforceability of any punitive damages award.

SIXTY-SECOND AFFIRMATIVE DEFENSE

Boston Scientific specifically pleads all defenses available to it under the rules and statutes of each and every state with respect to any claims for punitive damages.

SIXTY-THIRD AFFIRMATIVE DEFENSE

Boston Scientific asserts the provisions of all applicable statutory caps on damages of any sort under the laws of each and every state whose law is deemed to apply in this case.

SIXTY-FOURTH AFFIRMATIVE DEFENSE

Boston Scientific is entitled to credit for any settlement of claims for alleged injuries and damages made by Plaintiffs with any other person or entity.

SIXTY-FIFTH AFFIRMATIVE DEFENSE

If Plaintiffs recover from Boston Scientific, Boston Scientific is entitled to contribution, set-off, and/or indemnification, either in whole or in part, from all persons or entities whose negligence or fault proximately caused or contributed to cause the Plaintiffs' alleged damages.

SIXTY-SIXTH AFFIRMATIVE DEFENSE

The damages claimed by Plaintiffs are not recoverable, in whole or in part, under the laws each and every state whose law is deemed to apply in this case.

SIXTY-SEVENTH AFFIRMATIVE DEFENSE

To the extent the claims asserted in the Complaint are based on a theory providing for liability without proof of defect and proof of causation, the claims violate Boston Scientific's

rights under the United States Constitution and analogous provisions of Constitutions of the 50 states.

SIXTY-EIGHTH AFFIRMATIVE DEFENSE

Plaintiffs' claims are barred, in whole or in part, by the Commerce Clause of the United States Constitution because they purport to regulate interstate commerce and impermissibly place an undue burden on interstate commerce.

SIXTY-NINTH AFFIRMATIVE DEFENSE

Plaintiffs are not entitled to an award of attorneys' fees in the absence of a contract, statute, or law authorizing such fees.

SEVENTIETH AFFIRMATIVE DEFENSE

Boston Scientific expressly reserves the right to amend this Answer to assert additional defenses or to make additional claims for relief as discovery in this action should warrant. Additionally, Boston Scientific hereby gives notice that it intends to rely upon and incorporate by reference any affirmative defenses that may be asserted by any co-defendant in this lawsuit.

JURY DEMAND

Boston Scientific hereby requests a jury trial as to all claims triable in this action.

PRAYER FOR RELIEF

WHEREFORE, Boston Scientific prays for relief from judgment from Plaintiffs as follows:

1. Plaintiffs take nothing by reason of their Master Complaint;
2. Boston Scientific recovers its costs, and attorneys' fees incurred herein;
3. For a trial by jury on all issues so triable; and
4. For such further and other relief as the Court deems proper.

Dated: September 21, 2012

Respectfully submitted,

By: /s/ Jon A. Strongman  
Robert T. Adams  
Jon A. Strongman  
Bryan T. Pratt  
SHOOK, HARDY & BACON L.L.P.  
2555 Grand Boulevard  
Kansas City, Missouri 64108  
Telephone: 816.474.6550  
Facsimile: 816.421.5547  
rtadams@shb.com  
jstrongman@shb.com  
bpratt@shb.com

**COUNSEL FOR DEFENDANT  
BOSTON SCIENTIFIC CORP.**