**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

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THIS DOCUMENT RELATES TO ALL CASES

# PRETRIAL ORDER # 14

(New Direct Filing Order; Master Complaint, Short Form Complaint, Amended Short Form Complaint and Master Responsive Pleadings)

On August 22, 2012, the court entered PTO # 12.[1] For reasons appearing to the court, it is **ORDERED** that PTO # 12 is **VACATED.**

To eliminate the delays associated with the transfer of cases filed in or transferred from other federal district courts to this court as part of MDL No. 2326, to promote efficiency and to accommodate plaintiffs who wish to bring claims against defendants in more than one pelvic repair system MDL, it is **ORDERED** as follows:

A. General.

(1) The attached Master Long Form Complaint and Jury Demand ("Master Complaint") against Boston Scientific Corporation ("Boston Scientific") (Exhibit A), the Short Form Complaint for new cases against Boston Scientific (Exhibit B), the Amended Short Form Complaint for existing cases (Exhibit C), and Boston Scientific's Master

[1] The court entered similar PTOs in MDLs 2325 and 2327 and they too will be vacated. The court will enter PTOs similar to the instant order in MDLs 2187, 2325 and 2327, but not MDL 2387.

Answer ("Answer") (Exhibit D) have been presented to the court, and the court **DIRECTS** that the Clerk file the same. Exhibits A and B are not new pleadings, they were attached to PTO # 12. Exhibit C differs from Exhibit B only insofar as it is titled an "Amended" Short Form Complaint. Boston Scientific recently filed Exhibit D on September 21, 2012.

(2) The court refers the parties to Exhibit E, "Amended Filing Instructions for Short Form Complaints and Amended Short Form Complaints," which is appended to this Order. **To the extent plaintiffs have questions about this Order, they are instructed to contact plaintiffs' co-liaison counsel (Harry Bell, Paul Farrell, Carl N. Frankovitch).**

(3) All factual allegations pled in the Master Complaint and all responses eventually pled in Boston Scientific's Answer are deemed pled in any previously filed Complaint and Responsive Pleading now pending in this MDL proceeding, and in any Short Form or Amended Short Form Complaint and Entry of Appearance hereafter filed; provided, however, the Master Complaint is applicable only as against Boston Scientific.

B. Directly Filed Cases.[2]

(1) Subsequent to the filing of this Order, all actions initially filed directly in the Southern District of West Virginia in MDL 2326 against Boston Scientific, the only defendant named in the attached Master Complaint, shall be filed by the Short Form Complaint. **If a Short Form Complaint is not utilized, the complaint will be struck from the docket; the plaintiff will have to file a Short Form Complaint and pay a second filing fee.**

[2] A "Directly Filed Case" is a case filed in the Southern District of West Virginia for inclusion in this MDL, but the Southern District of West Virginia does not necessarily have personal jurisdiction over the parties.

(2) Subsequent to the filing of this Order, if a plaintiff filing a new case alleges she was implanted with products manufactured or marketed by defendants in more than one MDL (i.e., plaintiff was implanted with a Boston Scientific product and a product manufactured by a defendant named in a Master Long Form Complaint in MDL Nos. 2187, 2325 or 2327) and has claims against such defendants, then the plaintiff may choose in which MDL to initially file. However, such a plaintiff must check off each applicable defendant on the Short Form Complaint.

(3) For those cases filed directly in the Southern District of West Virginia in this MDL prior to the entry of this Order, plaintiff shall file the attached **Amended** Short Form Complaint within 90 days of the entry of this Order if and only if the plaintiff names Boston Scientific (and any defendant(s) named in the Master Complaints in the three other MDLs cited above, 2187, 2325 or 2327). Even if a plaintiff intends to name the same party or parties, plaintiff must file an Amended Short Form Complaint. A plaintiff need not move to amend.

(4) If a plaintiff filed directly in the Southern District of West Virginia in this MDL prior to the entry of this Order and named defendants other than those named in Master Complaints in this or the other three MDLs cited above, direct filing was inappropriate, and the plaintiff should either dismiss the inappropriately named defendants and file an Amended Short Form Complaint within 90 days of the entry of this Order or dismiss the direct filed case without prejudice and pursue her claims in her home district with subsequent transfer to this District through the MDL Panel.

(5) This court shall not be deemed to be the "transferor court" simply by virtue of the action having been directly filed in this District in this MDL. The direct filing of

actions in MDL No. 2326 in the Southern District of West Virginia is solely for the purposes of consolidated discovery and related pretrial proceedings as provided by 28 U.S.C. § 1407; the parties submit to this court's personal jurisdiction and venue in the Southern District for those purposes only. Upon completion of all pretrial proceedings applicable to a case directly filed in the Southern District, the defendants do not intend to waive their rights to transfer any case in this MDL to a court of proper venue under 28 U.S.C. § 1406(a). At the conclusion of all pretrial proceedings, the court, pursuant to 28 U.S.C. § 1404(a), will transfer each case filed directly in the Southern District to a federal district court of proper venue as defined in 28 U.S.C. § 1391, based on the recommendations of the parties to that case, or on its own determination after briefing from the parties if they cannot agree. In an effort to avoid serial objections to venue in a single action, plaintiff shall identify in response to a defendant's venue objection, proposed alternative venues in order of preference, so that the court can consider at the same time, any objections to plaintiff's alternative choices.

C. Cases Transferred by the Judicial Panel on Multidistrict Litigation ("MDL Panel").[3]

(1) For those cases transferred to MDL No. 2326 from another Federal District Court by the MDL Panel prior to the entry of this Order, those plaintiffs, who only named defendants named in Master Complaints in this or in one or more of the other three MDLs cited above (2187, 2325, 2327), shall file an **Amended** Short Form Complaint within 90 days of the entry of this Order. For those cases transferred after the entry of this Order, any plaintiff as described in this paragraph shall file an **Amended** Short

[3] A "Case Transferred by the MDL Panel" is a case filed in a district other than the Southern District of West Virginia and subsequently transferred to the Southern District by the MDL Panel.

Form Complaint within 30 days of receipt of the member case number in MDL No. 2326. For those cases transferred to MDL No. 2326 by the MDL Panel before or after the entry of this order, wherein the plaintiff has named defendants named in Master Complaints in this or the other three MDLs noted above **AND** additional defendant(s) other than those named in Master Complaints, the plaintiff may not file an Amended Short Form Complaint, unless the plaintiff chooses to dismiss the additional defendants.

(2) Upon completion of the pretrial proceedings relating to a civil action as determined by this court, civil actions in this MDL which were transferred to this court by the MDL Panel shall be transferred for further proceedings to the District Court from which such action was transferred to this MDL.

D. All Cases.

(1) If a plaintiff in an existing case files an Amended Short Form Complaint in compliance with this Order that omits a defendant previously named in the prior complaint, the plaintiff is relieved of complying with Rule 41 of the Federal Rules of Civil Procedure in order to properly dismiss that defendant. Rather, where a plaintiff files an Amended Short Form Complaint, the court instructs the Clerk, until further notice, to add defendants named in MDLs 2187, 2325, 2326 and 2327 as indicated on the Amended Short Form Complaints and to terminate any defendant not so

indicated.[4] If a plaintiff names an additional defendant listed on a Short Form Complaint but not named in the prior complaint, the plaintiff must comply with Rule 4 as to the new defendant.

(2) To the extent any change in parties on an Amended Short Form Complaint suggests that the case should be in a different MDL, an Amended Short Form Complaint should be accompanied by a motion to transfer MDLs. Attached hereto as Exhibit F is a PDF fillable form entitled "Motion to Transfer MDL," which also can be found on the court's website. The court strongly encourages use of this form.

(3) **Plaintiffs should not add parties to the Short Form or Amended Short Form Complaints or file versions of the Short Form or Amended Short Form Complaints that do not exactly match such complaints found on the court's website. The court will strike Short Form and Amended Short Form Complaints adding any party not named in a Master or Amended Master Complaint in MDLs 2187, 2325, 2326 or 2327, including Coloplast and Mentor Worldwide. In the event a directly filed Short Form Complaint contains defendants not named in Master or Amended Master Complaints, the striking of such a pleading filed in a new case will require refiling and payment of a second filing fee.**

(4) **Plaintiffs must file the Amended Short Form Complaint in their member case, not in the main MDL case.**

[4] At this time, because of the posture of the fifth MDL assigned to this court, In re Coloplast Corp. Pelvic Support Systems Products Liability Litigation, MDL 2387, Coloplast and other defendants from that MDL are not included on the Short Form and Amended Short Form Complaints. Parties must file in the Coloplast MDL to name Coloplast Corp. or Mentor Worldwide or proceed through the MDL Panel until a Master Long Form Complaint and Master Answers are filed in the Coloplast MDL.

(5) In existing cases where a plaintiff filed a Short Form Complaint or Amended Short Form Complaint after the entry of PTO # 12, but prior to the entry of this Order, and it substantially complied with the provisions outlined herein, an Amended Short Form Complaint need not be refiled. The Clerk is instructed to add and terminate defendants in those cases in compliance with this Order.

(6) Each Short Form Complaint shall indicate those counts in the Master Complaint that are being asserted in the individual case and the specific consumer protection statute, if any, upon which the plaintiff relies.

(7) Boston Scientific, the only defendant named in the Master Complaint, is not required to file answers to Short Form or Amended Short Form Complaints. An Entry of Appearance (including an appearance entered prior to the filing of the Short Form Complaint) by an attorney representing Boston Scientific shall constitute a denial of all allegations in the Short Form or Amended Short Form Complaint filed against Boston Scientific and an assertion of all defenses that are included in Boston Scientific's Answer.

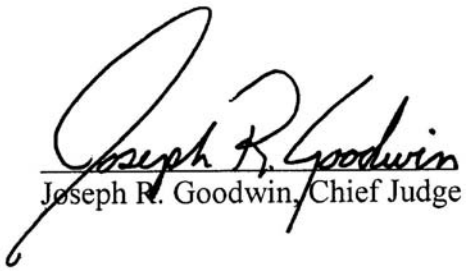
(8) If a defendant in MDL Nos. 2187, 2326 or 2327 is named in a case in this MDL, an Entry of Appearance (including an appearance entered prior to the filing of the Short Form or Amended Short Form Complaint) by an attorney representing such a defendant shall constitute a denial of all allegations in the Short Form or Amended Short Form Complaint filed against any such defendant. In addition, the Master Responsive Pleading filed by that defendant in its designated MDL is deemed to be filed in that particular case.

(9) Upon agreement of the parties, given the large number of Complaints being filed, plaintiffs' counsel will meet and confer with defendants' counsel to advise defendants before implementing any default procedures, and will provide defendants ten business days in which to cure any alleged default.

(10) Defendants shall have 30 days from the entry of this Order to file any motion asserting that the Master Complaint fails to state a claim upon which relief may be granted, pursuant to Rule 12(b)(6), and plaintiffs shall have 20 days thereafter to respond to the same.

The court **DIRECTS** the Clerk to file a copy of this order in 2:12-md-2326 and it shall apply to each member related case previously transferred to, removed to, or filed in this district, which includes counsel in all member cases up to and including civil action number 2:12-cv-05725. In cases subsequently filed in this district, a copy of the most recent pretrial order will be provided by the Clerk to counsel appearing in each new action at the time of filing of the complaint. In cases subsequently removed or transferred to this court, a copy of the most recent pretrial order will be provided by the Clerk to counsel appearing in each new action upon removal or transfer. It shall be the responsibility of the parties to review and abide by all pretrial orders previously entered by the court. The orders may be accessed through the CM/ECF system or the court's website at www.wvsd.uscourts.gov.

ENTER: September 26, 2012



**AMENDED FILING INSTRUCTIONS FOR**
**SHORT FORM COMPLAINTS AND AMENDED SHORT FORM COMPLAINTS**
**and**
**FILING INSTRUCTIONS FOR MOVING TO TRANSFER MDL**

## TO FILE AN AMENDED SHORT FORM COMPLAINT IN AN EXISTING MEMBER CASE

Abbreviated instructions to file an **Amended Short Form Complaint**, in an existing MDL member case, whether transferred to the Southern District by the MDL Panel or directly filed here, include:

- From the *CM/ECF Civil Menu*, go to *Other Documents;*
- Select one of the following events:
  C. R. BARD, INC. – Amended Short Form Complaint – C. R. BARD, INC. CASE ONLY
  AMERICAN MEDICAL – Amended Short Form Complaint – AMERICAN MEDICAL CASE ONLY
  BOSTON SCIENTIFIC – Amended Short Form Complaint – BOSTON SCIENTIFIC CASE ONLY
  ETHICON – Amended Short Form Complaint – ETHICON CASE ONLY
- Enter the civil action number for the member MDL case; **DO NOT USE THESE EVENTS IN THE MAIN CASE OR WHEN FILING A NEW CIVIL ACTION**;
- Select the party(s) filing the Amended Short Form Complaint;
- The filed date for the Amended Short Form Complaint automatically defaults to the current date at this screen; browse in the image;
- Read the cautionary notices;
- Select EACH defendant on the Amended Short Form Complaint that you wish to name; do not add defendants not listed; and
- Review the final text; if correct, press NEXT to commit the transaction.

Any changes to the style of the case will be made by designated Clerk's Office staff during the Quality Control (QC) process As stated in the PTO at paragraph D(2), to the extent any change in parties on an Amended Short Form Complaint suggests that the case should be in a different MDL, plaintiff(s) must submit a motion entitled **Motion to Transfer MDL.** Parties are directed to use the **Motion to Transfer MDL** PDF fillable form located on the Court's website for the appropriate MDL**.**

Abbreviated instructions to file a completed **Motion to Transfer MDL**, in an existing MDL member case, whether transferred to the Southern District by the MDL Panel or directly filed here, include:

- From the *CM/ECF Civil Menu*, go to *Motions and Related Filings > Motions/Applications/Petitions;*
- Select **Motion**;

- Select *Transfer between MDL Cases ***MDL Cases Only***;
- Enter the civil action number for the member MDL case -- **DO NOT USE THESE EVENTS IN THE MAIN CASE;**
- Select the party(s) filing the Motion to Transfer MDL;
- Browse in the image;
- Select the MDL case to transfer the member case FROM ;
- Select the MDL case to transfer the member case TO; and
- Review the final text; if correct, press NEXT to commit the transaction.

## TO FILE A SHORT FORM COMPLAINT AS THE INITIATING DOCUMENT IN A NEW CIVIL ACTION:

To file a new civil action via the CM/ECF system using a **Short Form Complaint** follow the instructions located on the Court's website at **CM/ECF Information > Filing New Civil Actions Electronically > Filing a Complaint**. Simply substitute a **Short Form Complaint** for a regular complaint. No special procedures are required.

*CAUTION*: Both the Pay.gov payment transaction and the CM/ECF filing transaction must be completed to finalize the filing.

Exhibit D

**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

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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 indispensible 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.
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**COUNSEL FOR DEFENDANT BOSTON SCIENTIFIC CORP.**

**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***

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**AMENDED SHORT FORM COMPLAINT**

Come now the Plaintiff(s) named below, and for Complaint against the Defendants named below, incorporate The Master Complaint in MDL No. 2326 by reference. Plaintiff(s) further show the Court as follows:

1. Female Plaintiff:

   _____

2. Plaintiff Husband (if applicable):

   _____

3. Other Plaintiff and capacity (i.e., administrator, executor, guardian, conservator):

   _____

4. State of Residence:

   _____

5. District Court and Division in which venue would be proper absent direct filing:

   _____

   _____

6. Defendants (Check Defendants against whom Complaint is made):

   ☐ A. Boston Scientific Corporation

☐ B. American Medical Systems, Inc. (“AMS”)

☐ C. American Medical Systems Holdings, Inc. (“AMS Holdings”)

☐ D. Endo Pharmaceuticals, Inc.

☐ E. Endo Health Solutions Inc. (f/k/a Endo Pharmaceuticals Holdings, Inc.)

☐ F. Johnson & Johnson

☐ G. Ethicon, Inc.

☐ H. Ethicon, LLC

☐ I. C. R. Bard, Inc. (“Bard”)

☐ J. Sofradim Production SAS (“Sofradim”)

☐ K. Tissue Science Laboratories Limited (“TSL”)

7. Basis of Jurisdiction:

☐ Diversity of Citizenship

☐ Other: _____

A. Paragraphs in Master Complaint upon which venue and jurisdiction lie:

_____

_____

_____

B. Other allegations of jurisdiction and venue:

_____

_____

_____

8. Defendants' products implanted in Plaintiff (Check products implanted in Plaintiff):

- ☐ The Uphold Vaginal Support System;
- ☐ The Pinnacle Pelvic Floor Repair Kit;
- ☐ 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;
- ☐ The Solyx SIS System; and/or
- ☐ Other

_____

_____

9. Defendants' Products about which Plaintiff is making a claim. (Check applicable products):

- ☐ The Uphold Vaginal Support System;
- ☐ The Pinnacle Pelvic Floor Repair Kit;
- ☐ 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;
- ☐ The Solyx SIS System; and/or

☐ Other

10. Date of Implantation as to Each Product:

11. Hospital(s) where Plaintiff was implanted (Including City and State):

12. Implanting Surgeon(s):

13. Counts in the Master Complaint brought by Plaintiff(s)

☐ Count I – Negligence

☐ Count II – Strict Liability – Design Defect

☐ Count III – Strict Liability – Manufacturing Defect

☐ Count IV – Strict Liability – Failure to Warn

☐ Count V - Breach of Express Warranty

☐ Count VI – Breach of Implied Warranty

☐ Count VII (by the Husband) – Loss of Consortium

☐ Count VIII – Discovery Rule, Tolling and Fraudulent Concealment

☐ Count IX – Punitive Damages

☐ Other Count _____ If Plaintiff asserts additional claims, please state the factual and legal basis for these claims below:

_____

_____

_____

☐ Other Count _____ If Plaintiff asserts additional claims, please state the factual and legal basis for these claims below:

_____

_____

_____

_____
Attorneys for Plaintiff

Address and bar information:

Exhibit B

**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***

---

**SHORT FORM COMPLAINT**

Come now the Plaintiff(s) named below, and for Complaint against the Defendants named below, incorporate The Master Complaint in MDL No. 2326 by reference. Plaintiff(s) further show the Court as follows:

1. Female Plaintiff:

_____

2. Plaintiff Husband (if applicable):

_____

3. Other Plaintiff and capacity (i.e., administrator, executor, guardian, conservator):

_____

4. State of Residence:

_____

5. District Court and Division in which venue would be proper absent direct filing:

_____

_____

6. Defendants (Check Defendants against whom Complaint is made):

☐ A. Boston Scientific Corporation

☐ B. American Medical Systems, Inc. (“AMS”)

☐ C. American Medical Systems Holdings, Inc. (“AMS Holdings”)

☐ D. Endo Pharmaceuticals, Inc.

☐ E. Endo Health Solutions Inc. (f/k/a Endo Pharmaceuticals Holdings, Inc.)

☐ F. Johnson & Johnson

☐ G. Ethicon, Inc.

☐ H. Ethicon, LLC

☐ I. C. R. Bard, Inc. (“Bard”)

☐ J. Sofradim Production SAS (“Sofradim”)

☐ K. Tissue Science Laboratories Limited (“TSL”)

7. Basis of Jurisdiction:

☐ Diversity of Citizenship

☐ Other: _____

A. Paragraphs in Master Complaint upon which venue and jurisdiction lie:

_____

_____

_____

B. Other allegations of jurisdiction and venue:

_____

_____

_____

8. Defendants' products implanted in Plaintiff (Check products implanted in Plaintiff):

- ☐ The Uphold Vaginal Support System;
- ☐ The Pinnacle Pelvic Floor Repair Kit;
- ☐ 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;
- ☐ The Solyx SIS System; and/or
- ☐ Other

_____

_____

9. Defendants' Products about which Plaintiff is making a claim. (Check applicable products):

- ☐ The Uphold Vaginal Support System;
- ☐ The Pinnacle Pelvic Floor Repair Kit;
- ☐ 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;
- ☐ The Solyx SIS System; and/or

☐ Other

10. Date of Implantation as to Each Product:

11. Hospital(s) where Plaintiff was implanted (Including City and State):

12. Implanting Surgeon(s):

13. Counts in the Master Complaint brought by Plaintiff(s)

☐ Count I – Negligence

☐ Count II – Strict Liability – Design Defect

☐ Count III – Strict Liability – Manufacturing Defect

☐ Count IV – Strict Liability – Failure to Warn

☐ Count V - Breach of Express Warranty

☐ Count VI – Breach of Implied Warranty

☐ Count VII (by the Husband) – Loss of Consortium

☐ Count VIII – Discovery Rule, Tolling and Fraudulent Concealment

☐ Count IX – Punitive Damages

☐ Other Count _____ If Plaintiff asserts additional claims, please state the factual and legal basis for these claims below:

_____

_____

_____

☐ Other Count _____ If Plaintiff asserts additional claims, please state the factual and legal basis for these claims below:

_____

_____

_____

_____
Attorneys for Plaintiff

Address and bar information:

**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**

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# MASTER LONG FORM COMPLAINT AND JURY DEMAND

Plaintiffs, by and through their counsel, bring this Master Long Form Complaint (Master Complaint) as an administrative device to set forth potential claims individual Plaintiffs may assert against Defendants in this litigation. By operation of the Order of this Court, all allegations pled herein are deemed pled in any Short Form Complaint hereafter filed.

## PARTIES, JURISDICTION & VENUE

### PLAINTIFFS

1.

Plaintiffs include women who had one or more of Defendants' Pelvic Mesh Products (the "Products") listed in Paragraph 7 of this Master Complaint inserted in their bodies to treat medical conditions, primarily pelvic organ prolapse (POP) and stress urinary incontinence (SUI), or other products as identified in Paragraphs 8 and 9 of the Short Form Complaint. Plaintiffs also include the spouses of some of said women, as well as others with standing to file claims arising from the Products.

**DEFENDANTS**

2.

Defendant(s) is/are the following or more entities as identified in the Short Form Complaint:

a) Boston Scientific Corporation (Boston Scientific);

b) American Medical Systems, Inc.;

c) Johnson & Johnson;

d) Ethicon, Inc.;

e) C. R. Bard, Inc. (Bard);

f) Sofradim Production SAS (Sofradim); and/or

g) Tissue Science Laboratories, Ltd. (TSL).

To the extent Plaintiffs have asserted claims against one of the above-named Defendant(s) in b. through g., Plaintiffs hereby incorporate by reference as if fully set forth herein the Master Long Form Complaint of that Defendant's respective MDL.

3.

Boston Scientific is a Delaware corporation with its corporate headquarters in Massachusetts. All acts and omissions of Boston Scientific as described herein were done by its agents, servants, employees and/or owners, acting in the course and scope of their respective agencies, services, employments and/or ownership.

## JURISDICTION AND VENUE

4.

Federal subject matter jurisdiction in the constituent actions is based upon 28 U.S.C. § 1332(a), in that in each of the constituent actions there is complete diversity among Plaintiffs and Defendant(s) and the amount in controversy exceeds $75,000.

5.

Defendant(s) have significant contacts with the federal judicial district identified in the Short Form Complaint such that they are subject to the personal jurisdiction of the court in said district.

6.

A substantial part of the events and omissions giving rise to Plaintiffs' causes of action occurred in the federal judicial district identified in the Short Form Complaint. Pursuant to 28 U.S.C. § 1391(a), venue is proper in said district.

## THE PELVIC MESH PRODUCTS

7.

Defendant Boston Scientific's Pelvic Mesh Products (the "Products") include, at least, the following:

a) The Uphold Vaginal Support System;

b) The Pinnacle Pelvic Floor Repair Kit;

c) The Advantage Transvaginal Mid-Urethral Sling System;

d) The Advantage Fit System;

e) The Lynx Suprapubic Mid-Urethral Sling System;

f) The Obtryx Transobturator Mid-Urethral Sling System;

g) The Prefyx PPS System; and

h) The Solyx SIS System.

8.

Boston Scientific designed, manufactured, packaged, labeled, marketed, sold, and distributed the following Pelvic Mesh Products, including that which was implanted in any Plaintiff so indicated in a Short Form Complaint: Pinnacle Pelvic Floor Repair Kit, Uphold Vaginal Support System, Advantage Transvaginal Mid-Urethral Sling System, Advantage Fit System, Lynx Suprapubic Mid-Urethral Sling System, Obtryx Transobturator Mid-Urethral Sling System, Prefyx PPS System, Solyx SIS System, and/or Other.

## FACTUAL BACKGROUND

9.

Defendants' Pelvic Mesh Products contain monofilament polypropylene mesh and/or collagen. Despite claims that polypropylene is inert, the scientific evidence shows that this material as implanted in the relevant female Plaintiff set forth in the Short Form Complaint is biologically incompatible with human tissue and promotes a negative immune response in a large subset of the population implanted with the Products. This negative response promotes inflammation of the pelvic tissue and can contribute to the formation of severe adverse reactions to the mesh. Furthermore, Defendants' collagen products cause hyper-inflammatory responses leading to problems including chronic pain and fibrotic reaction. Defendants' collagen products disintegrate after implantation in the female pelvis. The collagen products cause adverse tissue reactions, and are causally related to infection, as the collagen is a foreign material derived from animal and/or human tissue. The collagen is harsh upon the female pelvic tissue. When mesh is

inserted in the female body according to the manufacturers' instructions, it creates a non-anatomic condition in the pelvis leading to chronic pain and functional disabilities.

10.

Surgical mesh products have been used to repair abdominal hernias since the 1950s. In the 1970s, gynecologists began using surgical mesh products that were designed for hernia repair for abdominal repair to surgically repair prolapsed organs. In the 1990s, gynecologists began using this surgical mesh for the surgical treatment of POP and SUI. Manufacturers, including Boston Scientific, began to modify the mesh used in hernia repair to be used as products specifically intended to correct POP and/or SUI. Today, Boston Scientific sells pelvic mesh "kits" which can include not only the surgical mesh, but also tissue fixation anchors and insertion tools. The Products manufactured by Defendants are considered Class II medical devices.

11.

Defendants sought and obtained FDA clearance to market the Products under Section 510(k) of the Medical Device Amendment to the Food, Drug and Cosmetics Act. Section 510(k) provides for marketing of a medical device if the device is deemed "substantially equivalent" to other predicate devices marketed prior to May 28, 1976. No formal review for safety or efficacy is required, and no formal review for safety or efficacy was ever conducted by Boston Scientific with regard to the Products.

12.

On July 13, 2011, the FDA issued a Safety Communication wherein the FDA stated that "serious complications associated with surgical mesh for transvaginal repair of POP are **not rare**" (emphasis in the original).

13.

The FDA Safety Communication also stated, "*Mesh contraction* (shrinkage) is a *previously unidentified risk* of transvaginal POP repair with mesh that has been reported in the published scientific literature and in adverse event reports to the FDA. Reports in the literature associate mesh contraction with vaginal shortening, vaginal tightening and vaginal pain." (emphasis in original).

14.

In a December 2011 Joint Committee Opinion, the American College of Obstetricians and Gynecologists (ACOG) and the American Urogynecologic Society (AUGS) also identified physical and mechanical changes to the mesh inside the body as a serious complication associated with vaginal mesh, stating:

> There are increasing reports of vaginal pain associated with changes that can occur with mesh (contraction, retraction, or shrinkage) that result in taut sections of mesh . . . Some of these women will require surgical intervention to correct the condition, and some of the pain appears to be intractable.

15.

The ACOG/AUGS Joint Committee Opinion also recommended, among other things, that "[p]elvic organ prolapse vaginal mesh repair should be reserved for high-risk individuals in whom the benefit of mesh placement may justify the risk."

16.

The injuries of the female Plaintiff, as will be more fully established in Discovery, are reported in the FDA Safety Communication and in the ACOG/AUGS Joint Committee Opinion.

17.

The FDA Safety Communication further indicated that the benefits of using transvaginal mesh products instead of other feasible alternatives did not outweigh the associated risks. Specifically, the FDA Safety Communication stated: "it is not clear that transvaginal POP repair with mesh is more effective than traditional non-mesh repair in all patients with POP and it may expose patients to greater risk."

18.

Contemporaneously with the Safety Communication, the FDA released a publication titled "Urogynecologic Surgical Mesh: Update on the Safety and Effectiveness of Transvaginal Placement for Pelvic Organ Prolapse" (the White Paper). In the White Paper, the FDA noted that the published, peer-reviewed literature demonstrates that "[p]atients who undergo POP repair with mesh are subject to mesh-related complications that are not experienced by patients who undergo traditional surgery without mesh."

19.

The FDA summarized its findings from its review of the adverse event reports and applicable literature stating that it "has NOT seen conclusive evidence that using transvaginally placed mesh in POP repair improves clinical outcomes any more than traditional POP repair that does not use mesh, and it may expose patients to greater risk." (emphasis in original).

20.

The FDA White Paper further stated that "these products are associated with serious adverse events . . . compounding the concerns regarding adverse events are performance data that fail to demonstrate improved clinical benefit over traditional non-mesh repair."

21.

In its White Paper, the FDA advises doctors to, *inter alia*, "[r]ecognize that in most cases, POP can be treated successfully without mesh thus avoiding the risk of mesh-related complications." The FDA concludes its White Paper by stating that it "has identified serious safety and effectiveness concerns over the use of surgical mesh for the transvaginal repair of pelvic organ prolapse."

22.

As is known to the Defendants, the risks associated with POP repair are the same as SUI repair. However, the data regarding the magnitude and frequency of these known risks are not as developed as the data on POP repair. The FDA recognized this, as demonstrated by its Section 522 Orders issued to manufacturers of pelvic mesh products used to treat SUI in January of 2012.

23.

In September 2011, the FDA acknowledged the need for additional data and noted in "Surgical Mesh For Treatment of Women with Pelvic Organ Prolapse and Stress Urinary Incontinence" that the literature and information developing on SUI repair with mesh "indicates that serious complications can occur . . . [and] a case can be made for additional premarket and/or post market studies to better address the risk/benefit of all mesh products used for SUI."

24.

Defendants did not, and have not, adequately studied the extent of the risks associated with the Products. In January 2012, the FDA recognized the risk to women and mandated additional studies to further investigate these risks.

25.

Defendant(s) knew or should have known about the Products' risks and complications identified in the FDA Safety Communication and the ACOG/AUGS Joint Committee Opinion.

26.

Defendants knew or should have known that the Products unreasonably exposed patients to the risk of serious harm while conferring no benefit over available feasible alternatives that do not involve the same risks.

27.

The scientific evidence shows that the material from which the Products are made is biologically incompatible with human tissue and promotes a negative immune response in a large subset of the population implanted with the Products, including the female Plaintiff named in the Short Form Complaint.

28.

This negative response promotes inflammation of the pelvic tissue and contributes to the formation of severe adverse reactions to the mesh, such as those experienced by the female Plaintiff named in the Short Form Complaint.

29.

The FDA defines both "degradation" and "fragmentation" as "device problems" to which the FDA assigns a specific "device problem code." "Material Fragmentation" is defined as an "[i]ssue associated with small pieces of the device breaking off unexpectedly" and "degraded" as an "[i]ssue associated with a deleterious change in the chemical structure, physical properties, or appearance in the materials that are used in device construction." The Products were unreasonably susceptible to degradation and fragmentation inside the body.

30.

The Products were unreasonably susceptible to shrinkage and contraction inside the body. Defendants should have known of this serious risk and warned physicians and patients.

31.

The Products were unreasonably susceptible to "creep" or the gradual elongation and deformation when subject to prolonged tension inside the body.

32.

To this day, the Products have been and continue to be marketed to the medical community and to patients as safe, effective, reliable, medical devices, implanted by safe and effective, minimally invasive surgical techniques, and as safer and more effective as compared to available feasible alternative treatments of pelvic organ prolapse and stress urinary incontinence, and other competing products.

33.

A woman who elects to have her SUI or POP surgically treated has several options. SUI can be corrected through traditional abdominal surgery using sutures to attach the urethra to a ligament in the pelvis (known as the "Burch procedure"). SUI can also be surgically addressed using synthetic materials placed under the urethra to provide support. POP can be corrected through abdominal or transvaginal surgery and using biologic, composite, or synthetic materials.

34.

Defendants omitted and downplayed the risks, dangers, defects, and disadvantages of the Products, and advertised, promoted, marketed, sold and distributed the Products as safe medical devices when Defendants knew or should have known that the Products were not safe for their intended purposes, and that the Products would cause, and did cause, serious medical problems,

and in some patients, including the female Plaintiff named in the Short Form Complaint, catastrophic injuries. Further, while some of the problems associated with the Products were made known to physicians, the magnitude and frequency of these problems were not disclosed and were hidden from physicians.

35.

Contrary to Defendants' representations and marketing to the medical community and to the patients themselves, the Products have high rates of failure, injury, and complications, fail to perform as intended, require frequent and often debilitating re-operations, and have caused severe and irreversible injuries, conditions, and damage to a significant number of women, including the female Plaintiff named in the Short Form Complaint, making them defective under the law.

36.

The specific nature of the Products' defects includes, but is not limited to, the following:

a) The use of polypropylene and collagen in the Products and the immune reactions that result from such material, causing adverse reactions and injuries;

b) The design of the Products to be inserted into and through an area of the body with high levels of bacteria that can adhere to the mesh causing immune reactions and subsequent tissue breakdown and adverse reactions and injuries;

c) Biomechanical issues with the design of the Products, including, but not limited to, the propensity of the Products to contract or shrink inside the body, that in turn cause surrounding tissue to be inflamed, become fibrotic, and contract, resulting in injury;

d) The use and design of arms and anchors in the Products, which, when placed in the women, are likely to pass through contaminated spaces and that can injure major nerve routes in the pelvic region;

e) The propensity of the Products for "creep," or to gradually elongate and deform when subject to prolonged tension inside the body;

f) the inelasticity of the Products, causing them to be improperly mated to the delicate and sensitive areas of the vagina and pelvis where they are implanted, and causing

pain upon normal daily activities that involve movement in the pelvic region (e.g., intercourse, defecation, walking);

g) The propensity of the Products for degradation or fragmentation over time, which causes a chronic inflammatory and fibrotic reaction, and results in continuing injury over time;

h) The hyper-inflammatory responses to collagen leading to problems including chronic pain and fibrotic reaction;

i) The propensity of the collagen products to disintegrate after implantation in the female pelvis, causing pain and other adverse reactions;

j) The adverse tissue reactions caused by the products, which are causally related to infection, as the mesh is a foreign organic material from animals and/or human cadavers;

k) The harshness of collagen upon the female pelvic tissue, and the hardening of the product in the body; and

l) The creation of a non-anatomic condition in the pelvis leading to chronic pain and functional disabilities when the mesh is implanting according to the manufacturers' instructions.

37.

The Products are also defective due to Defendants' failure to adequately warn or instruct the female Plaintiff named in the Short Form Complaint and/or her health care providers of subjects including, but not limited to, the following:

a) The Products' propensities to contract, retract, and/or shrink inside the body;

b) The Products' propensities for degradation, fragmentation and/or creep;

c) The Products' inelasticity preventing proper mating with the pelvic floor and vaginal region;

d) The frequency and manner of mesh erosion or extrusion;

e) The risk of chronic inflammation resulting from the Products;

f) The risk of chronic infections resulting from the Products;

g) The risk of permanent vaginal or pelvic scarring as a result of the Products;

h) The risk of recurrent, intractable pelvic pain and other pain resulting from the Products;

i) The need for corrective or revision surgery to adjust or remove the Products;

j) The severity of complications that could arise as a result of implantation of the Products;

k) The hazards associated with the Products;

l) The Products' defects described herein;

m) Treatment of pelvic organ prolapse and stress urinary incontinence with the Products is no more effective than feasible available alternatives;

n) Treatment of pelvic organ prolapse and stress urinary incontinence with the Products exposes patients to greater risk than feasible available alternatives;

o) Treatment of pelvic organ prolapse and stress urinary incontinence with the Products makes future surgical repair more difficult than feasible available alternatives;

p) Use of the Products puts the patient at greater risk of requiring additional surgery than feasible available alternatives;

q) Removal of the Products due to complications may involve multiple surgeries and may significantly impair the patient's quality of life; and

r) Complete removal of the Products may not be possible and may not result in complete resolution of the complications, including pain.

38.

Defendants under reported and continues to underreport information about the propensity of the Products to fail and cause injury and complications, and have made unfounded representations regarding the efficacy and safety of the Products through various means and media.

39.

Defendants failed to perform proper and adequate testing and research in order to determine and evaluate the nature, magnitude and frequency of the risks attendant to the Products.

40.

Defendant(s) failed to design and establish a safe, effective procedure for removal of the Products, or to determine if a safe, effective procedure for removal of the Products exists.

41.

Feasible and suitable alternatives to the Products have existed at all times relevant that do not present the same frequency or severity of risks as do the Products.

42.

The Products were at all times utilized and implanted in a manner foreseeable to Defendants, as Defendants generated the instructions for use, created the procedures for implanting the devices, and trained the implanting physician.

43.

Defendants knowingly provided incomplete and insufficient training and information to physicians regarding the use of the Products and the aftercare of patients implanted with the Products.

44.

The Products implanted in the female Plaintiff named in the Short Form Complaint were in the same or substantially similar condition as they were when they left Defendants' possession, and in the condition directed by and expected by Defendants.

45.

The injuries, conditions, and complications suffered by numerous women around the world who have been implanted with the Products include, but are not limited to, erosion, mesh contraction, infection, fistula, inflammation, scar tissue, organ perforation, dyspareunia (pain during sexual intercourse), blood loss, neuropathic and other acute and chronic nerve damage and pain, pudendal nerve damage, pelvic floor damage, and chronic pelvic pain.

46.

In many cases, including the female Plaintiff named in the Short Form Complaint, women have been forced to undergo extensive medical treatment including, but not limited to, operations to locate and remove mesh, operations to attempt to repair pelvic organs, tissue, and nerve damage, the use of pain control and other medications, injections into various areas of the pelvis, spine, and the vagina, and operations to remove portions of the female genitalia.

47.

The medical and scientific literature studying the effects of the Products, like that of the product(s) implanted in the relevant female Plaintiff named in the Short Form Complaint, has examined each of these injuries, conditions, and complications, and has reported that they are causally related to the Products.

48.

Removal of contracted, eroded and/or infected mesh can require multiple surgical interventions for removal of mesh and results in scarring on fragile compromised pelvic tissue and muscles.

49.

At all relevant times herein, Defendants continued to promote the Products as safe and effective even when no clinical trials had been done supporting long- or short-term efficacy or safety.

50.

In doing so, Defendants failed to disclose the known risks and failed to warn of known or scientifically knowable dangers and risks associated with the Products, including the magnitude and frequency of these risks.

51.

At all relevant times herein, Defendants failed to provide sufficient warnings and instructions that would have put the female Plaintiff named in the Short Form Complaint and the general public on notice of the dangers and adverse effects caused by implantation of the Products.

52.

The Products as designed, manufactured, distributed, sold and/or supplied by Defendants were defective as marketed due to inadequate warnings, instructions, labeling and/or inadequate testing in the presence of Defendants' knowledge of lack of safety.

53.

As a result of having the Products implanted in her, the female Plaintiff named in the Short Form Complaint has experienced significant mental and physical pain and suffering, has sustained permanent injury, has undergone medical treatment and will likely undergo further medical treatment and procedures, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, and/or lost income, and other damages.

## CAUSES OF ACTION

## COUNT I: NEGLIGENCE

54.

All previous paragraphs of this Master Complaint are hereby incorporated by reference as if fully set forth herein.

55.

Defendants had a duty to individuals, including the female Plaintiff named in the Short Form Complaint, to use reasonable care in designing, manufacturing, marketing, labeling, packaging and selling the Products.

56.

Defendants were negligent in failing to use reasonable care as described herein in designing, manufacturing, marketing, labeling, packaging and selling the Products. Defendant(s) breached their aforementioned duty by, among other things:

a) Failing to design the Products so as to avoid an unreasonable risk of harm to women in whom the Products were implanted, including the female Plaintiff named in the Short Form Complaint;

b) Failing to manufacture the Products so as to avoid an unreasonable risk of harm to women in whom the Products were implanted, including the female Plaintiff named in the Short Form Complaint;

c) Failing to use reasonable care in the testing of the Products so as to avoid an unreasonable risk of harm to women in whom the Products were implanted, including the female Plaintiff named in the Short Form Complaint;

d) Failing to use reasonable care in inspecting the Products so as to avoid an unreasonable risk of harm to women in whom the Products were implanted, including the female Plaintiff named in the Short Form Complaint;

e) Failing to use reasonable care in the training and instruction to physicians for the safe use of the Products;

f) Failing to use reasonable care in studying the Products to evaluate their safety and to determine the nature, magnitude, and frequency of serious, life threatening complications that were known or knowable; and

g) Otherwise negligently or carelessly designing, manufacturing, marketing, labeling, packaging and/or selling the Products.

57.

The reasons that Defendants' negligence caused the Products to be unreasonably dangerous and defective include, but are not limited to:

a) The use of polypropylene and/or collagen material in the Products and the immune reaction that results from such material, causing adverse reactions and injuries;

b) The design of the Products to be inserted into and through an area of the body with high levels of bacteria that adhere to the mesh causing immune reactions and subsequent tissue breakdown and adverse reactions and injuries;

c) Biomechanical issues with the design of the Products, including, but not limited to, the propensity of the Products to contract or shrink inside the body, that in turn cause surrounding tissue to be inflamed, become fibrotic, and contract, resulting in injury;

d) The use and design of arms and anchors in the Products, which, when placed in the women, are likely to pass through contaminated spaces and injure major nerve routes in the pelvic region;

e) The propensity of the Products for "creep," or to gradually elongate and deform when subject to prolonged tension inside the body;

f) The inelasticity of the Products, causing them to be improperly mated to the delicate and sensitive areas of the pelvis where they are implanted, and causing pain upon normal daily activities that involve movement in the pelvis (e.g., intercourse, defecation);

g) The propensity of the Products for degradation or fragmentation over time, which causes a chronic inflammatory and fibrotic reaction, and results in continuing injury over time;

h) The hyper-inflammatory responses to collagen leading to problems including chronic pain and fibrotic reaction;

i) The propensity of the collagen products to disintegrate after implantation in the female pelvis, causing pain and other adverse reactions;

j) The adverse tissue reactions caused by the collagen products, which are causally related to infection, as the collagen is a foreign organic material from animals;

k) The harshness of collagen upon the female pelvic tissue; and

l) The creation of a non-anatomic condition in the pelvis leading to chronic pain and functional disabilities when the mesh is implanting according to the manufacturers' instructions.

58.

Defendants also negligently failed to warn or instruct the female Plaintiff named in the Short Form Complaint and/or her health care providers of subjects including, but not limited to, the following:

a) The Products' propensities to contract, retract, and/or shrink inside the body;

b) The Products' propensities for degradation, fragmentation and/or creep;

c) The Products' inelasticity preventing proper mating with the pelvic floor and vaginal region;

d) The rate and manner of mesh erosion or extrusion;

e) The risk of chronic inflammation resulting from the Products;

f) The risk of chronic infections resulting from the Products;

g) The risk of permanent vaginal or pelvic scarring as a result of the Products;

h) The risk of recurrent, intractable pelvic pain and other pain resulting from the Products;

i) The need for corrective or revision surgery to adjust or remove the Products;

j) The severity of complications that could arise as a result of implantation of the Products;

k) The hazards associated with the Products;

l) The Products' defects described herein;

m) Treatment of pelvic organ prolapse and stress urinary incontinence with the Products is no more effective than feasible available alternatives;

n) Treatment of pelvic organ prolapse and stress urinary incontinence with the Products exposes patients to greater risk than feasible available alternatives;

o) Treatment of pelvic organ prolapse and stress urinary incontinence with the Products makes future surgical repair more difficult than feasible available alternatives;

p) Use of the Products puts the patient at greater risk of requiring additional surgery than feasible available alternatives;

q) Removal of the Products due to complications may involve multiple surgeries and may significantly impair the patient's quality of life; and

r) Complete removal of the Products may not be possible and may not result in complete resolution of the complications, including pain.

59.

As a direct and proximate result of Defendants' negligence, the female Plaintiff named in the Short Form Complaint has experienced significant mental and physical pain and suffering, has sustained permanent injury, has undergone medical treatment and will likely undergo further medical treatment and procedures, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, lost income, and other damages.

**COUNT II: STRICT LIABILITY – DESIGN DEFECT**

60.

All previous paragraphs of this Master Complaint are hereby incorporated by reference as if fully set forth herein.

61.

The Products implanted in the female Plaintiff named in the Short Form Complaint were not reasonably safe for their intended uses and were defective as described herein with respect to their design. As previously stated, the Products' design defects include, but are not limited to:

a) The use of polypropylene and/or collagen material in the Products and the immune reaction that results from such material, causing adverse reactions and injuries;

b) The design of the Products to be inserted into and through an area of the body with high levels of bacteria that adhere to the mesh causing immune reactions and subsequent tissue breakdown and adverse reactions and injuries;

c) Biomechanical issues with the design of the Products, including, but not limited to, the propensity of the Products to contract or shrink inside the body, that in turn cause surrounding tissue to be inflamed, become fibrotic, and contract, resulting in injury;

d) The use and design of arms and anchors in the Products, which, when placed in the women, are likely to pass through contaminated spaces and injure major nerve routes in the pelvic region;

e) The propensity of the Products for "creep," or to gradually elongate and deform when subject to prolonged tension inside the body;

f) The inelasticity of the Products, causing them to be improperly mated to the delicate and sensitive areas of the pelvis where they are implanted, and causing pain upon normal daily activities that involve movement in the pelvis (e.g., intercourse, defecation);

g) The propensity of the Products for degradation or fragmentation over time, which causes a chronic inflammatory and fibrotic reaction, and results in continuing injury over time;

h) The hyper-inflammatory responses to collagen leading to problems including chronic pain and fibrotic reaction;

i) The propensity of the collagen products to disintegrate after implantation in the female pelvis, causing pain and other adverse reactions;

j) The adverse tissue reactions caused by the collagen products, which are causally related to infection, as the collagen is a foreign organic material from animals and/or human cadavers;

k) The harshness of collagen upon the female pelvic tissue, and the hardening of the product in the body;

l) The creation of a non-anatomic condition in the pelvis leading to chronic pain and functional disabilities when the mesh is implanting according to the manufacturers' instructions, and

m) The use of polypropylene material in the products and the failure to provide adequate directions for use (DFU) and training.

62.

As a direct and proximate result of the Products' aforementioned defects as described herein, the female Plaintiff named in the Short Form Complaint has experienced significant mental and physical pain and suffering, has sustained permanent injury, has undergone medical treatment and will likely undergo future medical treatment and procedures, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, lost income, and other damages.

63.

Defendants are strictly liable to the female Plaintiff named in the Short Form Complaint for designing, manufacturing, marketing, labeling, packaging and selling a defective product(s).

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

64.

All previous paragraphs of this Master Complaint are hereby incorporated by reference as if fully set forth herein.

65.

The Products implanted in the female Plaintiff named in the Short Form Complaint were not reasonably safe for their intended uses and were defective as described herein as a matter of law with respect to their manufacture, in that they deviated materially from Defendants' design and manufacturing specifications in such a manner as to pose unreasonable risks of serious bodily harm to the female Plaintiff named in the Short Form Complaint.

66.

As a direct and proximate result of the Products' aforementioned defects as described herein, the female Plaintiff named in the Short Form Complaint has experienced significant

mental and physical pain and suffering, has sustained permanent injury, has undergone medical treatment and/or corrective surgery and hospitalization, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, and/or lost income, and other damages.

67.

Defendants are strictly liable to the female Plaintiff named in the Short Form Complaint for designing, manufacturing, marketing, labeling, packaging and selling defective products.

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

68.

All previous paragraphs of this Master Complaint are hereby incorporated by reference as if fully set forth herein.

69.

The Products implanted in the female Plaintiff named in the Short Form Complaint were not reasonably safe for their intended uses and were defective as described herein as a matter of law due to their lack of appropriate and necessary warnings. Specifically, Defendants did not provide sufficient or adequate warnings regarding, among other subjects:

a) The Products' propensities to contract, retract, and/or shrink inside the body;

b) The Products' propensities for degradation, fragmentation, disintegration and/or creep;

c) The Products' inelasticity preventing proper mating with the pelvic floor and vaginal region;

d) The rate and manner of mesh erosion or extrusion;

e) The risk of chronic inflammation resulting from the Products;

f) The risk of chronic infections resulting from the Products;

g) The risk of permanent vaginal or pelvic scarring as a result of the Products;

h) The risk of recurrent, intractable pelvic pain and other pain resulting from the Products;

i) The need for corrective or revision surgery to adjust or remove the Products;

j) The severity of complications that could arise as a result of implantation of the Products;

k) The hazards associated with the Products;

l) The Products' defects described herein;

m) Treatment of pelvic organ prolapse and stress urinary incontinence with the Products is no more effective than feasible available alternatives;

n) Treatment of pelvic organ prolapse and stress urinary incontinence with the Products exposes patients to greater risk than feasible available alternatives;

o) Treatment of pelvic organ prolapse and stress urinary incontinence with the Products makes future surgical repair more difficult than feasible available alternatives;

p) Use of the Products puts the patient at greater risk of requiring additional surgery than feasible available alternatives;

q) Removal of the Products due to complications may involve multiple surgeries and may significantly impair the patient's quality of life;

r) Complete removal of the Products may not be possible and may not result in complete resolution of the complications, including pain; and

s) The nature, magnitude and frequency of complications that could arise as a result of implantation of the Products.

70.

As a direct and proximate result of the Products' aforementioned defects as described herein, the female Plaintiff named in the Short Form Complaint has experienced significant mental and physical pain and suffering, has sustained permanent injury, has undergone medical treatment and will likely undergo further medical treatment and procedures, has suffered

financial or economic loss, including, but not limited to, obligations for medical services and expenses, and/or lost income, and other damages.

71.

Defendants are strictly liable to the female Plaintiff named in the Short Form Complaint for designing, manufacturing, marketing, labeling, packaging and selling a defective product(s).

**COUNT V: BREACH OF EXPRESS WARRANTY**

72.

All previous paragraphs of this Master Complaint are hereby incorporated by reference as if fully set forth herein.

73.

Defendants made assurances as described herein to the general public, hospitals and health care professionals that the Products were safe and reasonably fit for their intended purposes.

74.

The female Plaintiff named in the Short Form Complaint and/or her healthcare provider chose the Products based upon Defendants' warranties and representations as described herein regarding the safety and fitness of the Products.

75.

The female Plaintiff named in the Short Form Complaint, individually and/or by and through her physician, reasonably relied upon Defendants' express warranties and guarantees that the Products were safe, merchantable, and reasonably fit for their intended purposes.

76.

Defendants breached these express warranties because the Products implanted in the female Plaintiff named in the Short Form Complaint were unreasonably dangerous and defective as described herein and not as Defendant(s) had represented.

77.

Defendants' breach of their express warranties resulted in the implantation of an unreasonably dangerous and defective products in the body of the female Plaintiff named in the Short Form Complaint, placing said Plaintiff's health and safety in jeopardy.

78.

As a direct and proximate result of Defendants' breach of the aforementioned express warranties, the female Plaintiff named in the Short Form Complaint has experienced significant mental and physical pain and suffering, has sustained permanent injury, has undergone medical treatment and will likely undergo further medical treatment and procedures, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, and/or lost income, and other damages.

**COUNT VI: BREACH OF IMPLIED WARRANTY**

79.

All previous paragraphs of this Master Complaint are hereby incorporated by reference as if fully set forth herein.

80.

Defendants impliedly warranted that the Products were merchantable and were fit for the ordinary purposes for which they were intended.

81.

When the Products were implanted in the female Plaintiff named in the Short Form Complaint to treat her pelvic organ prolapse and/or stress urinary incontinence, the Products were being used for the ordinary purposes for which they were intended.

82.

The female Plaintiff named in the Short Form Complaint, individually and/or by and through her physician, relied upon Defendants' implied warranties of merchantability in consenting to have the Products implanted in her.

83.

Defendants breached these implied warranties of merchantability because the Products implanted in the female Plaintiff named in the Short Form Complaint were neither merchantable nor suited for their intended uses as warranted.

84.

Defendants' breach of their implied warranties resulted in the implantation of unreasonably dangerous and defective products in the body of the female Plaintiff named in the Short Form Complaint, placing said Plaintiff's health and safety in jeopardy.

85.

As a direct and proximate result of Defendants' breach of the aforementioned implied warranties, the female Plaintiff named in the Short Form Complaint has experienced significant mental and physical pain and suffering, has sustained permanent injury, has undergone medical treatment and will likely undergo further medical treatment and procedures, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, and/or lost income, and other damages.

## COUNT VII: LOSS OF CONSORTIUM

86.

All previous paragraphs of this Master Complaint are hereby incorporated by reference as if fully set forth herein.

87.

As a direct and proximate result of the above-described injuries sustained by the female Plaintiff named in the Short Form Complaint, where applicable, her spouse named in the Short Form Complaint has suffered a loss of consortium, companionship, society, affection, services and support.

## COUNT VIII: DISCOVERY RULE, TOLLING AND FRAUDULENT CONCEALMENT

88.

All previous paragraphs of this Master Complaint are hereby incorporated by reference as if fully set forth herein.

89.

Plaintiffs assert all applicable state statutory and common law rights and theories related to the tolling or extension of any applicable statute of limitations, including equitable tolling, class action tolling, delayed discovery, discovery rule, and fraudulent concealment.

90.

Plaintiffs plead that the discovery rule should be applied to toll the running of the statute of limitations until Plaintiffs knew, or through the exercise of reasonable care and diligence should have known, of facts indicating that Plaintiffs had been injured, the cause of the injury, and the tortious nature of the wrongdoing that caused the injury.

91.

Despite diligent investigation by Plaintiffs, including the female Plaintiff named in Plaintiff's Short-Form Complaint, into the cause of their injuries, including consultations with Plaintiffs' medical providers, the nature of Plaintiffs' injuries and damages, and their relationship to the Products was not discovered, and through reasonable care and due diligence could not have been discovered, until a date within the applicable statute of limitations for filing Plaintiffs' claims. Therefore, under appropriate application of the discovery rule, Plaintiffs' suit was filed well within the applicable statutory limitations period.

92.

The running of the statute of limitations in this cause is tolled due to equitable tolling. Defendants are estopped from asserting a statute of limitations defense due to Defendants' fraudulent concealment, through affirmative misrepresentations and omissions, from Plaintiffs and Plaintiffs' physicians of the true risks associated with the Products. As a result of Defendants' fraudulent concealment, Plaintiffs and Plaintiffs' physicians were unaware, and could not have known or have learned through reasonable diligence that Plaintiffs had been exposed to the risks alleged herein and that those risks were the direct and proximate result of the wrongful acts and omissions of the Defendants.

**COUNT IX: PUNITIVE DAMAGES**

93.

All previous paragraphs of this Master Complaint are hereby incorporated by reference as if fully set forth herein.

94.

Defendants sold their Products to the healthcare providers of the Plaintiff named in the Short Form Complaint and other healthcare providers in the state of implantation and throughout the United States without doing adequate testing to ensure that the Products were reasonably safe for implantation in the female pelvic area.

95.

Defendants sold the Products to Plaintiffs', including the female Plaintiff named in the Short Form Complaint, health care providers and other health care providers in the state of implantation and throughout the United States in spite of their knowledge that the Products can shrink, disintegrate and/or degrade inside the body, and cause the other problems heretofore set forth in this complaint, thereby causing severe and debilitating injuries suffered by the Plaintiff named in the Short Form Complaint and numerous other women.

96.

Defendants ignored reports from patients and health care providers throughout the United States and elsewhere of the Products' failures to perform as intended, which lead to the severe and debilitating injuries suffered by the Plaintiff named in the Short Form Complaint and numerous other women. Rather than doing adequate testing to determine the cause of these injuries, or to rule out the Products' designs or the processes by which the Products are manufactured as the cause of these injuries, Defendant(s) chose instead to continue to market and sell the Products as safe and effective.

97.

Defendants knew the Products were unreasonably dangerous in light of their risks of failure, pain and suffering, loss of life's enjoyment, remedial surgeries and treatments in an effort

to cure the conditions proximately related to the use of the Products, as well as other severe and personal injuries which were permanent and lasting in nature.

98.

Defendants withheld material information from the medical community and the public in general, including the female Plaintiff named in the Short Form Complaint, regarding the safety and efficacy of the Products.

99.

Defendants knew and recklessly disregarded the fact that the Products caused debilitating and potentially life altering complications with greater frequency than feasible alternative methods and/or products used to treat pelvic organ prolapse and stress urinary incontinence.

100.

Defendants misstated and misrepresented data and continue to misrepresent data so as to minimize the perceived risk of injuries caused by the Products.

101.

Notwithstanding the foregoing, Defendants continue to aggressively market the Products to consumers, without disclosing the true risks associated with the Products.

102.

Defendants knew of the Products' defective and unreasonably dangerous nature, but continued to mislead physicians and patients and to manufacture, market, distribute, and sell the Products so as to maximize sales and profits at the expense of the health and safety of the public, including the female Plaintiff named in the Short Form Complaint.

103.

Defendants continue to conceal and/or fail to disclose to the public, including the Plaintiff named in the Short Form Complaint, the serious complications associated with the use of the Products to ensure continued and increased sales of the Products.

104.

Defendants' conduct as described herein shows willful misconduct, malice, fraud, wantonness, oppression, or that entire want of care which raises the presumption of conscious indifference to consequences, thereby justifying an award of punitive damages.

WHEREFORE, the Plaintiffs demand judgment against Defendants, and each of them, individually, jointly and severally, and request compensatory damages, together with interest, cost of suit, attorneys' fees, and all such other relief as the Court deems just and proper as well as:

- Compensatory damages to Plaintiffs for past, present, and future damages, including but not limited to, pain and suffering for severe and permanent personal injuries sustained by Plaintiffs, emotional distress, mental anguish, physical disfigurement and impairment; health and medical care costs, together with pre- and post-judgment interest and costs as provided by law;
- Restitution and disgorgement of profits;
- Reasonable attorneys' fees;
- The costs of these proceedings;
- All ascertainable economic damages;
- Punitive damages;
- Survival damages (if applicable);
- Wrongful death damages (if applicable); and
- Such other and further relief as this Court deems just and proper.

PLAINTIFFS DEMAND A TRIAL BY JURY.

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Exhibit F

**UNITED STATES DISTRICT COURT**
**SOUTHERN DISTRICT OF WEST VIRGINIA**
**CHARLESTON DIVISION**

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

MDL No. 2326
Honorable Joseph R. Goodwin

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**Plaintiff(s),**

v. **CASE NO.**

**Defendant(s).**

**MOTION TO TRANSFER MDL**

**COME NOW** the plaintiff(s), by and through the undersigned counsel, and move the court to transfer this member case from MDL 2326, In re: Boston Scientific Corp. Pelvic Repair System Products Liability Litigation, to:

MDL Select One:

Plaintiff(s) herein filed a Complaint or Short Form Complaint in MDL 2326 against Boston Scientific Corp. and others. Plaintiff(s) later filed an Amended Complaint that no longer included Boston Scientific Corp. in that litigation; included instead, among others, were the following parties from MDL _____:

Because Boston Scientific Corp. is no longer a named defendant in this member case, Plaintiff(s) respectfully request that the Court: 1) **GRANT** the Plaintiff(s) motion to transfer this civil action from MDL 2326 to _____; and 2) direct the Clerk to disassociate this civil action as a member case in MDL 2326 and re-associate it with MDL _____ .

_____

**CERTIFICATE OF SERVICE**

I hereby certify that on _____, I electronically filed the foregoing with the Clerk of Court using the CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this member case.

_____