IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

CHARLESTON DIVISION

IN RE: C. R. BARD, INC., PELVIC REPAIR
SYSTEM PRODUCTS LIABILITY LITIGATION

MDL NO. 2187

THIS DOCUMENT RELATES TO ALL CASES

PRETRIAL ORDER # 31

(Master and Short Form Complaint and Master Responsive Pleadings; Direct Filing)

The attached Master Long Form Complaint and Jury Demand (Master Complaint), Short Form Complaint, and Master Responsive Pleadings have been presented to the Court, they are hereby approved, and it is ordered that the same be filed. It is further ordered that all allegations pled in the Master Complaint and all responses pled in the Master Responsive Pleadings are deemed pled in any previously filed Complaint and Responsive Pleading in this MDL proceeding, and in any Short Form Complaint and Entry of Appearance hereafter filed; provided, however, the Master Complaint is applicable only as against the defendant or defendants identified in the Short Form Complaint.

Subsequent to the filing of this Order, all future actions to be filed in this MDL proceeding shall be filed by the Short Form Complaint and may be directly filed into this Court. Defendants are not required to file answers to Short-Form or Amended Short-Form Complaints. An Entry of Appearance shall constitute a denial of all allegations in the Short-Form or Amended Short-Form Complaints except as herein provided, and an assertion of all defenses that are included in the Defendant's Master Answer. By filing an Entry of Appearance in response to

a Short Form Complaint, the Defendant waives only the defenses of insufficient process and insufficient service of process over the defendant. Should Defendant wish to raise either of those defenses in response to any Short Form Complaint, those defenses will be asserted via motion pursuant to Rule 12(b) of the Federal Rules of Civil Procedure filed at the time of the entry of appearance. As to any other defense which would cause an abatement of the action as opposed to a dismissal under Rule 12(b)(6), including lack of capacity and failure to comply with conditions precedent, defendants shall raise such issue at the time of filing of an entry of appearance if they have knowledge of such defense at that time, or if not known at that time, within a reasonable time after learning of such defense.

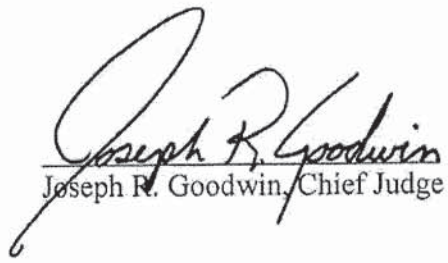
The parties have agreed that, given the large number of complaints being filed, plaintiffs' counsel will meet and confer with defendants' counsel to advise defendants before implementing any default procedures, and will provide defendants ten business days in which to cure any alleged default.

It is further ordered that Defendants shall have 60 days from the entry of this order to file any motion for failure of the Master Complaint to state a claim upon which relief may be granted pursuant to Rule 12 (b)(6) and 12 (h)(2), and Plaintiffs shall have 30 days thereafter to respond to the same.

Civil actions in this MDL were transferred to this court by the Judicial Panel on Multidistrict Litigation for coordinated or consolidated pretrial proceedings pursuant to 28 U.S.C. § 1407. Upon completion of the pretrial proceedings relating to a civil action as determined by this court, the case shall be transferred to the District Court identified in the Short Form Complaint, without prejudice to the applicable Defendants' right to contest venue in such jurisdiction prior to transfer. In the event a Defendant's objection to transfer to such jurisdiction

is sustained, ultimate venue shall be in the District chosen by the applicable Plaintiff provided the applicable Defendants are subject to jurisdiction and venue in that District.

SO ORDERED this 26th day of March, 2012.



Joseph R. Goodwin, Chief Judge

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

IN RE C. R. BARD, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION

MDL No. 2187

SOFRADIM PRODUCTION'S MASTER LONG FORM ANSWER AND AFFIRMATIVE DEFENSES TO PLAINTIFFS' MASTER LONG FORM COMPLAINT AND JURY DEMAND

Defendant Sofradim Production (hereinafter "Sofradim"), by and through its undersigned counsel, hereby files its Master Long Form Answer and Affirmative Defenses ("Master Answer") to Plaintiffs' Master Long Form Complaint and Jury Demand ("Master Complaint"). By operation of the Order of this Court, all responses and defenses pled herein are deemed pled in any previously filed Answer and in any Short Form Responsive Pleading hereafter filed. Sofradim expressly reserves any and all defenses now available or that may become available in the future. In further response to the numbered allegations contained in the Master Complaint, Sofradim states as follows:

PARTIES, JURISDICTION & VENUE

PLAINTIFFS

1.

After reasonable investigation, Sofradim lacks sufficient knowledge and information to form a belief as to the truth or falsity of the allegations contained in Paragraph 1 of the Master Complaint, and therefore denies same.

DEFENDANTS

2.

In response to the allegations contained in Paragraph 2 of the Master Complaint, Sofradim admits that the entities named therein have been identified as Defendants in the Short Form Complaint; however, to the extent the allegations purport to cast liability either directly or indirectly upon Sofradim, they are denied.

3.

The allegations in Paragraph 3 of the Master Complaint are directed to a party or entity other than Sofradim, and accordingly, no response is required. However, to the extent they purport to cast liability either directly or indirectly upon Sofradim, those allegations are denied.

4.

In response to Paragraph 4 of the Master Complaint, Sofradim admits that its legal name is "Sofradim Production" and that it is a French corporation with a principal place of business in France at 116 Avenue Du Formans, Trevoux, France 01600. The remaining allegations of Paragraph 4 are denied.

5.

The allegations in Paragraph 3 of the Master Complaint are directed to a party or entity other than Sofradim, and accordingly, no response is required. However, to the extent they purport to cast liability either directly or indirectly upon Sofradim, those allegations are denied.

JURISDICTION AND VENUE

6.

In response to the allegations contained in Paragraph 6 of the Master Complaint, Sofradim admits that Plaintiffs are seeking damages in excess of $75,000 and that subject matter jurisdiction is proper, although Sofradim denies that Plaintiffs are entitled to any recovery.

7.

The allegations contained in Paragraph 7 of the Master Complaint constitute legal conclusions to which no response is required. To the extent a response is required, Sofradim denies same.

8.

Sofradim is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 8 of the Master Complaint, and therefore denies same. Sofradim reserves the right to challenge the propriety of the venue in any particular case.

THE PELVIC MESH PRODUCTS

9.

In response to the allegations contained in Paragraph 9 of the Master Complaint, Sofradim admits that the products listed therein are various pelvic mesh products; however, to the extent the allegations purport to cast liability either directly or indirectly upon Sofradim, they are denied.

10.

The allegations in Paragraph 10 of the Master Complaint are directed to a party or entity other than Sofradim, and accordingly, no response is required; however, to the extent they purport to cast liability either directly or indirectly upon Sofradim, those allegations are denied.

11.

In response to the allegations contained in Paragraph 11 of the Master Complaint, Sofradim admits that it designed, manufactured, packaged and labeled surgical mesh products that were marketed, sold and distributed by Bard under the name Avaulta® Anterior and Posterior BioSynthetic Support Systems. However, after a reasonable investigation, Sofradim

lacks sufficient knowledge and information to form a belief as to the truth or falsity of whether any Avaulta® product was implanted in any Plaintiff so indicated in a Short Form Complaint, and therefore denies same.

12.

The allegations in Paragraph 12 of the Master Complaint are directed to a party or entity other than Sofradim, and accordingly, no response is required; however, to the extent they purport to cast liability either directly or indirectly upon Sofradim, those allegations are denied.

13.

The allegations in Paragraph 13 of the Master Complaint are directed to a party or entity other than Sofradim, and accordingly, no response is required; however, to the extent they purport to cast liability either directly or indirectly upon Sofradim, those allegations are denied.

14.

The allegations in Paragraph 14 of the Master Complaint are directed to parties or entities other than Sofradim, and accordingly, no response is required; however, to the extent they purport to cast liability either directly or indirectly upon Sofradim, those allegations are denied.

15.

The allegations in Paragraph 15 of the Master Complaint are directed to parties or entities other than Sofradim, and accordingly, no response is required; however, to the extent they purport to cast liability either directly or indirectly upon Sofradim, those allegations are denied.

16.

The allegations in Paragraph 16 of the Master Complaint are directed to parties or entities other than Sofradim, and accordingly, no response is required; however, to the extent they purport to cast liability either directly or indirectly upon Sofradim, those allegations are denied.

17.

The allegations in Paragraph 17 of the Master Complaint are directed to parties or entities other than Sofradim, and accordingly, no response is required; however, to the extent they purport to cast liability either directly or indirectly upon Sofradim, those allegations are denied.

18.

In response to the allegations contained in Paragraph 18 of the Master Complaint, Sofradim admits that it designed, manufactured, packaged and labeled surgical mesh products that were marketed, sold and distributed by Bard under the name Pelvitex® Polypropylene Mesh. However, after a reasonable investigation, Sofradim lacks sufficient knowledge and information to form a belief as to the truth or falsity of whether any Pelvitex® product was implanted in any Plaintiff so indicated in a Short Form Complaint, and therefore denies same.

19.

In response to the allegations contained in Paragraph 19 of the Master Complaint, Sofradim admits that it designed, manufactured, packaged and labeled surgical mesh products that were marketed, sold and distributed by Bard under the names Uretex® SUP Pubourethral Sling and Uretex® TO, TO2 and TO3 Trans-obturator Urethral Support Systems. However, after a reasonable investigation, Sofradim lacks sufficient knowledge and information to form a belief as to the truth or falsity of whether any Uretex® product was implanted in any Plaintiff so indicated in a Short Form Complaint, and therefore denies same.

FACTUAL BACKGROUND

20.

Sofradim denies the allegations contained in Paragraph 20 of the Master Complaint.

21.

In Response to the allegations contained in Paragraph 21 of the Master Complaint, Sofradim admits only that the products alleged herein to be manufactured by Sofradim and which have been marketed in the United States by Bard, have all been cleared by the FDA under section 510(k) of the Medical Device Amendment to the Food, Drug and Cosmetics Act. To the extent the allegations contained in Paragraph 21 of the Master Complaint contain legal conclusions, no response is required and, therefore, those conclusions are denied. The remaining allegations of Paragraph 21 of the Master Complaint are denied.

22.

In response to the allegations contained in Paragraph 22 of the Master Complaint, Sofradim responds that the publication speaks for itself. To the extent that those allegations purport to cast liability upon Sofradim, either directly or indirectly, those allegations are denied.

23.

In response to the allegations contained in Paragraph 23 of the Master Complaint, Sofradim responds that the publication speaks for itself. To the extent that those allegations purport to cast liability upon Sofradim, either directly or indirectly, those allegations are denied.

24.

In response to the allegations contained in Paragraph 24 of the Master Complaint, Sofradim responds that the publication speaks for itself. To the extent that those allegations purport to cast liability upon Sofradim, either directly or indirectly, those allegations are denied.

25.

In response to the allegations contained in Paragraph 25 of the Master Complaint, Sofradim responds that the publication speaks for itself. To the extent that those allegations purport to cast liability upon Sofradim, either directly or indirectly, those allegations are denied.

26.

Sofradim denies the allegations contained in Paragraph 26 of the Master Complaint.

27.

In response to the allegations contained in Paragraph 27 of the Master Complaint, Sofradim responds that the publication speaks for itself. To the extent that those allegations purport to cast liability upon Sofradim, either directly or indirectly, those allegations are denied.

28.

In response to the allegations contained in Paragraph 28 of the Master Complaint, Sofradim responds that the publication speaks for itself. To the extent that those allegations purport to cast liability upon Sofradim, either directly or indirectly, those allegations are denied.

29.

In response to the allegations contained in Paragraph 29 of the Master Complaint, Sofradim responds that the publication speaks for itself. To the extent that those allegations purport to cast liability upon Sofradim, either directly or indirectly, those allegations are denied.

30.

In response to the allegations contained in Paragraph 30 of the Master Complaint, Sofradim responds that the publication speaks for itself. To the extent that those allegations purport to cast liability upon Sofradim, either directly or indirectly, those allegations are denied.

31.

In response to the allegations contained in Paragraph 31 of the Master Complaint, Sofradim responds that the publication speaks for itself. To the extent that those allegations purport to cast liability upon Sofradim, either directly or indirectly, those allegations are denied.

32.

In response to the allegations contained in Paragraph 32 of the Master Complaint, Sofradim responds that the publication speaks for itself. To the extent that those allegations purport to cast liability upon Sofradim, either directly or indirectly, those allegations are denied.

33.

In response to the allegations contained in Paragraph 33 of the Master Complaint, Sofradim responds that the publication speaks for itself. To the extent that those allegations purport to cast liability upon Sofradim, either directly or indirectly, those allegations are denied.

34.

Sofradim denies the allegations contained in Paragraph 34 of the Master Complaint.

35.

Sofradim denies the allegations contained in Paragraph 35 of the Master Complaint.

36.

Sofradim denies the allegations contained in Paragraph 36 of the Master Complaint.

37.

Sofradim denies the allegations contained in Paragraph 37 of the Master Complaint.

38.

Sofradim denies the allegations contained in Paragraph 38 of the Master Complaint.

39.

Sofradim denies the allegations contained in Paragraph 39 of the Master Complaint.

40.

Sofradim denies the allegations contained in Paragraph 40 of the Master Complaint.

41.

Sofradim denies the allegations contained in Paragraph 41 of the Master Complaint, including any allegations that Sofradim markets or sells pelvic mesh products in the United States.

42.

Sofradim denies the allegations contained in Paragraph 42 of the Master Complaint, including any allegations that Sofradim advertises, promotes, markets, sells or distributes pelvic mesh products in the United States.

43.

Sofradim denies the allegations contained in Paragraph 43 of the Master Complaint, including any allegations that Sofradim markets or sells pelvic mesh products in the United States.

44.

Sofradim denies the allegations contained in Paragraph 44 of the Master Complaint, including all subparts thereto.

45.

Sofradim denies the allegations contained in Paragraph 45 of the Master Complaint, including all subparts thereto.

46.

Sofradim denies the allegations contained in Paragraph 46 of the Master Complaint.

47.

Sofradim denies the allegations contained in Paragraph 47 of the Master Complaint.

48.

Sofradim denies the allegations contained in Paragraph 48 of the Master Complaint.

49.

Sofradim denies the allegations contained in Paragraph 49 of the Master Complaint.

50.

Sofradim lacks sufficient information to form a belief as to the truth or falsity of the allegations contained in Paragraph 50 of the Master Complaint, and therefore denies same.

51.

Sofradim denies the allegations contained in Paragraph 51 of the Master Complaint.

52.

After a reasonable investigation, Sofradim lacks sufficient knowledge and information to form a belief as to the truth or falsity of the allegations contained in Paragraph 52 of the Master Complaint, and therefore denies same.

53.

Sofradim denies the allegations contained in Paragraph 53 of the Master Complaint.

54.

Sofradim denies the allegations contained in Paragraph 54 of the Master Complaint.

55.

Sofradim denies the allegations contained in Paragraph 55 of the Master Complaint.

56.

Sofradim denies the allegations contained in Paragraph 56 of the Master Complaint.

57.

Sofradim denies the allegations contained in Paragraph 57 of the Master Complaint, including any allegations that Sofradim promoted pelvic mesh products in the United States.

58.

Sofradim denies the allegations contained in Paragraph 58 of the Master Complaint.

59.

Sofradim denies the allegations contained in Paragraph 59 of the Master Complaint.

60.

Sofradim denies the allegations contained in Paragraph 60 of the Master Complaint, including any allegations that Sofradim sells or distributes pelvic mesh products in the United States.

61.

Sofradim denies the allegations contained in Paragraph 61 of the Master Complaint.

CAUSES OF ACTION

COUNT I: NEGLIGENCE

62.

Sofradim hereby incorporates by reference its responses to Paragraphs 1-61 of the Master Complaint as if fully set forth herein. To the extent Paragraph 62 contains new allegations, Sofradim denies same.

63.

The allegations contained in Paragraph 63 of the Master Complaint constitute legal conclusions to which no response is required. To the extent a response is required, Sofradim denies same.

64.

Sofradim denies the allegations contained in Paragraph 64 of the Master Complaint, including all subparts thereto.

65.

Sofradim denies the allegations contained in Paragraph 65 of the Master Complaint, including all subparts thereto.

66.

Sofradim denies the allegations contained in Paragraph 66 of the Master Complaint, including all subparts thereto.

67.

Sofradim denies the allegations contained in Paragraph 67 of the Master Complaint.

COUNT II: STRICT LIABILITY – DESIGN DEFECT

68.

Sofradim hereby incorporates by reference its responses to Paragraphs 1-67 of the Master Complaint as if fully set forth herein. To the extent Paragraph 68 contains new allegations, Sofradim denies same.

69.

Sofradim denies the allegations contained in Paragraph 69 of the Master Complaint, including all subparts thereto.

70.

Sofradim denies the allegations contained in Paragraph 70 of the Master Complaint.

71.

The allegations contained in Paragraph 71 of the Master Complaint constitute legal conclusions to which no response is required. To the extent a response is required, Sofradim denies same.

COUNT III: STRICT LIABILITY – MANUFACTURING DEFECT

72.

Sofradim hereby incorporates by reference its responses to Paragraphs 1-71 of the Master Complaint as if fully set forth herein. To the extent Paragraph 72 contains new allegations, Sofradim denies same.

73.

Sofradim denies the allegations contained in Paragraph 73 of the Master Complaint.

74.

Sofradim denies the allegations contained in Paragraph 74 of the Master Complaint.

75.

The allegations contained in Paragraph 75 of the Master Complaint constitute legal conclusions to which no response is required. To the extent a response is required, Sofradim denies same.

COUNT IV: STRICT LIABILITY – FAILURE TO WARN

76.

Sofradim hereby incorporates by reference its responses to Paragraphs 1-75 of the Master Complaint as if fully set forth herein. To the extent Paragraph 76 contains new allegations, Sofradim denies same.

77.

Sofradim denies the allegations contained in Paragraph 77 of the Master Complaint, including all subparts thereto.

78.

Sofradim denies the allegations contained in Paragraph 78 of the Master Complaint.

79.

The allegations contained in Paragraph 79 of the Master Complaint constitute legal conclusions to which no response is required. To the extent a response is required, Sofradim denies same.

COUNT V: BREACH OF EXPRESS WARRANTY

80.

Sofradim hereby incorporates by reference its responses to Paragraphs 1-79 of the Master Complaint as if fully set forth herein. To the extent Paragraph 80 contains new allegations, Sofradim denies same.

81.

Sofradim denies the allegations contained in Paragraph 81 of the Master Complaint.

82.

Sofradim denies the allegations contained in Paragraph 82 of the Master Complaint.

83.

Sofradim denies the allegations contained in Paragraph 83 of the Master Complaint.

84.

Sofradim denies the allegations contained in Paragraph 84 of the Master Complaint.

85.

Sofradim denies the allegations contained in Paragraph 85 of the Master Complaint.

86.

Sofradim denies the allegations contained in Paragraph 86 of the Master Complaint.

COUNT VI: BREACH OF IMPLIED WARRANTY

87.

Sofradim hereby incorporates by reference its responses to Paragraphs 1-86 of the Master Complaint as if fully set forth herein. To the extent Paragraph 87 contains new allegations, Sofradim denies same.

88.

Sofradim denies the allegations contained in Paragraph 88 of the Master Complaint.

89.

Sofradim denies the allegations contained in Paragraph 89 of the Master Complaint.

90.

Sofradim denies the allegations contained in Paragraph 90 of the Master Complaint.

91.

Sofradim denies the allegations contained in Paragraph 91 of the Master Complaint.

92.

Sofradim denies the allegations contained in Paragraph 92 of the Master Complaint.

93.

Sofradim denies the allegations contained in Paragraph 93 of the Master Complaint.

COUNT VII: LOSS OF CONSORTIUM

94.

Sofradim hereby incorporates by reference its responses to Paragraphs 1-93 of the Master Complaint as if fully set forth herein. To the extent Paragraph 94 contains new allegations, Sofradim denies same.

95.

Sofradim denies the allegations contained in Paragraph 95 of the Master Complaint.

COUNT VIII: PUNITIVE DAMAGES

96.

Sofradim hereby incorporates by reference its responses to Paragraphs 1-95 of the Master Complaint as if fully set forth herein. To the extent Paragraph 96 contains new allegations, Sofradim denies same.

97.

Sofradim denies the allegations contained in Paragraph 97 of the Master Complaint, including any allegations that Sofradim sells pelvic mesh products in the United States.

98.

Sofradim denies the allegations contained in Paragraph 98 of the Master Complaint, including any allegations that Sofradim sells pelvic mesh products in the United States.

99.

Sofradim denies the allegations contained in Paragraph 99 of the Master Complaint.

100.

Sofradim denies the allegations contained in Paragraph 100 of the Master Complaint.

101.

Sofradim denies the allegations contained in Paragraph 101 of the Master Complaint.

102.

Sofradim denies the allegations contained in Paragraph 102 of the Master Complaint.

103.

Sofradim denies the allegations contained in Paragraph 103 of the Master Complaint.

104.

Sofradim denies the allegations contained in Paragraph 104 of the Master Complaint, including any allegations that Sofradim markets pelvic mesh products in the United States.

105.

Sofradim denies the allegations contained in Paragraph 105 of the Master Complaint, including any allegations that Sofradim markets, distributes or sells pelvic mesh products in the United States.

106.

Sofradim denies the allegations contained in Paragraph 106 of the Master Complaint.

107.

Sofradim denies the allegations contained in Paragraph 107 of the Master Complaint.

Furthermore, responding to the unnumbered Paragraph following Paragraph 107 of the Master Complaint beginning "WHEREFORE," Sofradim denies the allegations contained in

such Paragraph. Sofradim further denies each and every allegation not specifically admitted herein. Sofradim denies that Plaintiffs are entitled to any relief requested in the Complaint.

SOFRADIM'S AFFIRMATIVE DEFENSES

Sofradim alleges and asserts the following defenses in response to the allegations in the Master Complaint.

FIRST DEFENSE

The Master Complaint fails to state a claim or claims upon which relief can be granted under Rule 12 of the Federal Rules of Civil Procedure.

SECOND DEFENSE

This Court lacks personal jurisdiction over Sofradim such that Sofradim should be dismissed. Sofradim specifically raises this defense, makes its objections to the exercise of personal jurisdiction over Sofradim in this Court, and preserves its rights to seek dismissal by way of subsequent motion.

THIRD DEFENSE

The Master Complaint fails to state claim or claims upon which relief can be granted due to lack of adequate product identification.

FOURTH DEFENSE

The Plaintiffs may be barred from bringing some of the claims alleged in the Master Complaint because the Plaintiffs may lack standing and/or capacity to bring such claims.

FIFTH DEFENSE

The sole proximate cause of the Plaintiffs' damages, if any were sustained, was the negligence of a person or persons or entity for whose acts or omissions Sofradim was and is in no way liable.

SIXTH DEFENSE

If the Plaintiffs have been damaged, which Sofradim denies, any recovery by the Plaintiffs is barred to the extent they voluntarily exposed themselves to a known risk and/or failed to mitigate their alleged damages. To the extent the Plaintiffs have failed to mitigate their alleged damages, any recovery shall not include alleged damages that could have been avoided by reasonable care and diligence.

SEVENTH DEFENSE

The Plaintiffs failed to exercise ordinary care for their own safety such that the Plaintiffs are not entitled to recover.

EIGHTH DEFENSE

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

NINTH DEFENSE

The Plaintiffs' causes of action may be barred by the applicable statute of limitations and/or statute of repose.

TENTH DEFENSE

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

ELEVENTH DEFENSE

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

TWELFTH DEFENSE

There was no causal connection between any alleged defect in the products at issue and Plaintiffs' alleged damages with the result that Plaintiffs are not entitled to recover against Sofradim in this cause.

THIRTEENTH DEFENSE

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

FOURTEENTH DEFENSE

If the Plaintiffs have been damaged, which Sofradim denies, such damages were caused by the negligence or fault of persons and/or entities for whose conduct Sofradim is not legally responsible.

FIFTEENTH DEFENSE

If the Plaintiffs suffered any damages or injuries, which Sofradim denies, the Plaintiffs' recovery is barred, in whole or in part, or subject to reduction under the doctrine of contributory and/or comparative negligence.

SIXTEENTH DEFENSE

In the further alternative, and only in the event that it is determined that the Plaintiffs are entitled to recover against Sofradim, recovery should be reduced in proportion to the degree or percentage of negligence, fault or exposure to products attributable to the Plaintiff, any other defendants, third party defendants, or other persons, including any party immune because bankruptcy renders them immune from further litigation, as well as any party, co-defendant, or non-parties with whom the Plaintiffs have settled or may settle in the future.

SEVENTEENTH DEFENSE

If the Plaintiffs have been damaged, which Sofradim denies, the negligence or fault of the Plaintiff constitutes the sole, intervening, and superseding cause of the Plaintiffs' alleged damages.

EIGHTEENTH DEFENSE

If the Plaintiffs have been damaged, which Sofradim denies, the negligence or fault of persons and/or entities for whose conduct Sofradim is not legally responsible constitutes the sole, intervening, and superseding cause of the Plaintiffs' alleged damages.

NINETEENTH DEFENSE

If the Plaintiffs have been damaged, which Sofradim denies, the actions of persons or entities for whose conduct Sofradim is not legally responsible and the independent knowledge of these persons or entities of the risks inherent in the use of the products and other independent causes, constitute an intervening and superseding cause of the Plaintiffs' alleged damages.

TWENTIETH DEFENSE

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

TWENTY-FIRST DEFENSE

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

TWENTY-SECOND DEFENSE

Sofradim made no warranties of any kind, express or implied, including any alleged implied warranty of merchantability or implied warranty of fitness for a particular purpose, or any representations of any nature whatsoever to the Plaintiffs. To the extent applicable, the Plaintiffs' breach of warranty claims are barred by a lack of privity between the Plaintiffs and Sofradim. To the extent the Plaintiffs make warranty claims, whether express or implied, the claims are barred or limited by any and all express conditions or disclaimers, by the Plaintiffs' lack of reliance on any such warranties, and by waiver.

TWENTY-THIRD DEFENSE

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

TWENTY-FOURTH DEFENSE

To the extent the Plaintiffs assert a claim for breach of warranty, such claim is barred because the Plaintiffs did not first give notice of any alleged defect of the products to Sofradim.

TWENTY-FIFTH DEFENSE

Sofradim neither had nor breached any alleged duty to warn with respect to the products, with the result that the Plaintiffs are not entitled to recover in this cause.

TWENTY-SIXTH DEFENSE

The Plaintiff's failure to warn claims are barred by virtue of the intervention of the learned intermediary or intermediaries to whom Sofradim discharged its duties to warn.

TWENTY-SEVENTH DEFENSE

The conduct of Sofradim and the subject products at all times conformed with the Federal Food, Drug and Cosmetic Act, and other pertinent federal statute and regulations. Accordingly,

the Plaintiffs' claims are barred, in whole or in part, under the doctrine of federal preemption, and granting the relief requested would impermissibly infringe upon and conflict with federal laws, regulations, and policies in violation of the Supremacy Clause of the United States Constitution.

TWENTY-EIGHTH DEFENSE

The Plaintiffs' alleged damages resulted from independent, unforeseeable, superseding, and/or intervening causes unrelated to any conduct of Sofradim.

TWENTY-NINTH DEFENSE

If the Plaintiffs recover from Sofradim, Sofradim 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.

THIRTIETH DEFENSE

The Plaintiffs' claims are or may be barred, in whole or in part, to the extent that the Plaintiff has released, settled with, entered into an accord and satisfaction, or otherwise compromised their claims. Sofradim is entitled to a set-off for the entire amount of proceeds the Plaintiffs have or may recover from all other sources.

THIRTY-FIRST DEFENSE

Should Sofradim be held liable to the Plaintiffs, which liability Sofradim specifically denies, Sofradim would be entitled to a set-off for the total of all amounts paid to the Plaintiffs from all collateral sources.

THIRTY-SECOND DEFENSE

Sofradim asserts any and all defenses, claims, credits, offsets, or remedies available to it under the Restatement (Third) of Torts and reserves the right to amend its Master Answer to file

such further pleadings as are necessary to preserve and assert such defenses, claims, credits, offsets, or remedies.

THIRTY-THIRD DEFENSE

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

THIRTY-FOURTH DEFENSE

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

THIRTY-FIFTH DEFENSE

The Plaintiffs' claims are barred because the methods, standards, warnings, and instructions used in manufacturing and/or marketing the products at issue conformed with industry custom/usage standards and/or legislative/administrative/regulatory standards.

THIRTY-SIXTH DEFENSE

The design complained of in the Master Complaint, the alleged defects of the products, and/or any alternative design claimed by the Plaintiffs were not known and, in light of the existing, reasonably-available scientific and technological knowledge, could not have been

known at the time the products at issue were designed, manufactured, and sold. Any alleged alternative design was not scientifically or technologically feasible or economically practical.

THIRTY-SEVENTH DEFENSE

Sofradim 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-EIGHTH DEFENSE

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

THIRTY-NINTH DEFENSE

To the extent the Plaintiffs assert a demand for punitive damages, Sofradim specifically incorporates by reference any and all standards of limitations regarding the determination and/or enforceability of punitive damages awards that arose in the decisions of *BMW of No. America v. Gore*, 517 U.S. 559 (1996); *Cooper Industries, Inc. v. Leatherman Tool Group, Inc.*, 532 U.S. 424 (2001); *State Farm Mut. Auto Ins. Co. v. Campbell*, 123 S. Ct. 1513 (2003); and *Exxon Shipping Co. v. Baker*, No. 07-219, 2008 U.S. LEXIS 5263 (U.S. June 25, 2008) and their progeny as well as other similar cases under both federal and state law.

FORTIETH DEFENSE

To the extent that the Plaintiffs assert a claim for punitive damages, that claim is in contravention of the rights of Sofradim under the following constitutional provisions:

1. Plaintiffs' claims for punitive or exemplary damages violate, and are therefore barred by, the Fourth, Fifth, Sixth, Eighth and Fourteenth Amendments to the Constitution of the

United States of America, and the analogous provisions of the applicable State Constitutions, on grounds including the following:

(a) it is a violation of the Due Process and Equal Protection Clauses of the Fourteenth Amendment of the United States Constitution, and the analogous provisions of the applicable State Constitutions, to impose punitive damages, which are penal in nature, against a civil defendant upon the Plaintiffs satisfying a burden of proof which is less than the "beyond a reasonable doubt" burden of proof required in criminal cases;

(b) the procedures pursuant to which punitive damages are awarded may result in the award of joint and several judgments against multiple defendants for different alleged acts of wrongdoing, which infringes upon the Due Process and Equal Protection Clauses of the Fourteenth Amendment of the United States Constitution, and the analogous provisions of the applicable State Constitutions;

(c) the procedures to which punitive damages are awarded fail to provide a reasonable limit on the amount of the award against defendant, which thereby violates the Due Process Clause of the Fourteenth Amendment of the United States Constitution, and the analogous provisions of the applicable State Constitutions;

(d) the procedures pursuant to which punitive damages are awarded fail to provide specific standards for the amount of the award of punitive damages which thereby violates the Due Process Clause of the Fourteenth Amendment of the United States Constitution, and the analogous provisions of the applicable State Constitutions;

(e) the procedures pursuant to which punitive damages are awarded result in the imposition of different penalties for the same or similar acts, and thus violate the Equal Protection Clause of the Fourteenth Amendment of the United States Constitution, and the analogous provisions of the applicable State Constitutions;

(f) the procedures pursuant to which punitive damages are awarded permit the imposition of punitive damages in excess of the maximum criminal fine for the same or similar conduct, which thereby infringes upon the Due Process Clause of the Fifth and Fourteenth Amendments and the Equal Protection Clause of the Fourteenth Amendment of the United States Constitution, and the analogous provisions of the applicable State Constitutions;

(g) the procedures pursuant to which punitive damages are awarded permit the imposition of excessive fines in violation of the Eighth Amendment of the United States Constitution, and the analogous provisions of the applicable State Constitutions;

(h) the award of punitive damages to the Plaintiffs in this action would constitute a deprivation of property without due process of law; and

(i) the procedures pursuant to which punitive damages are awarded permit the imposition of an excessive fine and penalty.

FORTY-FIRST DEFENSE

The Plaintiffs' claims are barred, in whole or in part, because Plaintiffs assumed the risks disclosed by the FDA-approved product labeling, the prescribing physicians, or other persons or entities.

FORTY-SECOND DEFENSE

There should be no recovery against Sofradim for any failure to warn or inadequacy of warning, because at all pertinent times, Plaintiffs possessed or should have possessed good and adequate knowledge which negated any need for warning.

FORTY-THIRD DEFENSE

If Plaintiffs were injured or damaged as alleged, no injury or damages being admitted, such injuries were not caused by a product manufactured by Sofradim.

FORTY-FOURTH DEFENSE

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

FORTY-FIFTH DEFENSE

The Plaintiffs' product liability claims are barred because the benefits of the products outweighed their risks.

FORTY-SIXTH DEFENSE

Venue may be improper in any individual case where the Plaintiff does not reside in the forum wherein her Complaint was filed or cannot otherwise establish an independent basis for venue in that forum and any such claims should be dismissed on this basis.

FORTY-SEVENTH DEFENSE

Plaintiffs' case may be subject to dismissal or transfer under the doctrine of forum non conveniens and/or 28 U.S.C. §§ 1404 and 1406.

FORTY-EIGHTH DEFENSE

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

FORTY-NINTH DEFENSE

The Plaintiffs have failed to plead their fraud claims with the particularity required under the applicable state's statutory and/or common law.

FIFTIETH DEFENSE

If it should be proven that any product manufactured by Sofradim was involved herein as alleged, then the state of medical and scientific knowledge or published literature or other materials reflecting the state of medical and scientific knowledge at all times relevant hereto, was such that Sofradim neither knew nor could have known that the products presented a foreseeable risk of harm in its normal and expected use.

FIFTY-FIRST DEFENSE

The damages claimed by Plaintiffs are not recoverable, in whole or in part, under the various applicable states' laws.

FIFTY-SECOND DEFENSE

Plaintiffs' claims may be barred by failure to join indispensable parties.

FIFTY-THIRD DEFENSE

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

FIFTY-FOURTH DEFENSE

Sofradim 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

Sofradim hereby requests a trial by jury on all issues so triable, and reserves the right to seek to have a trial before twelve jurors.

WHEREFORE, Sofradim avers that Plaintiffs are not entitled to the relief demanded in the Master Complaint, and Sofradim, having fully answered, prays that this action be dismissed and that it be awarded its costs in defending this action and that it be granted such other and further relief as the Court deems just and appropriate.

Dated: March 26, 2012

/s/ Deborah A. Moeller
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ATTORNEYS FOR DEFENDANT SOFRADIM PRODUCTION

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

IN RE C. R. BARD, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION

MDL No. 2187

C. R. BARD, INC.'S ANSWER AND AFFIRMATIVE DEFENSES TO PLAINTIFFS' MASTER LONG FORM COMPLAINT AND JURY DEMAND

Defendant C. R. Bard, Inc. (hereinafter "Bard"), by and through undersigned counsel, hereby files its Master Answer and Affirmative Defenses ("Master Responsive Pleading") to Plaintiffs' Master Long Form Complaint and Jury Demand ("Master Complaint"). By operation of the Order of this Court, all responses and defenses pled herein are deemed pled in any previously filed Answer and in any Entry of Appearance hereafter filed. Bard expressly reserves any and all defenses now available or that may become available in the future. In further response to the numbered allegations contained in the Master Complaint, Bard states as follows:

PARTIES, JURISDICTION & VENUE

PLAINTIFFS

1.

After reasonable investigation, Bard lacks sufficient knowledge and information to form a belief as to the truth or falsity of the allegations contained in Paragraph 1 of the Master Complaint, and therefore denies same.

DEFENDANTS

2.

In response to the allegations contained in Paragraph 2 of the Master Complaint, Bard admits that the entities named therein have been identified as Defendants in the Short Form Complaint; however, to the extent the allegations purport to cast liability either directly or indirectly upon Bard, they are denied.

3.

In response to Paragraph 3 of the Master Complaint, Bard admits that it is a New Jersey corporation with its principal place of business in New Jersey. The remaining allegations of Paragraph 3 are denied.

4.

The allegations in Paragraph 4 of the Master Complaint are directed to a party or entity other than Bard, and accordingly, no response is required. However, to the extent they purport to cast liability either directly or indirectly upon Bard, those allegations are denied.

5.

The allegations in Paragraph 5 of the Master Complaint are directed to a party or entity other than Bard, and accordingly, no response is required. However, to the extent they purport to cast liability either directly or indirectly upon Bard, those allegations are denied.

JURISDICTION AND VENUE

6.

In response to the allegations contained in Paragraph 6 of the Master Complaint, Bard admits that Plaintiffs are seeking damages in excess of $75,000 and that subject matter jurisdiction is proper, although Bard denies that Plaintiffs are entitled to any recovery.

7.

In response to the allegations contained in Paragraph 7 of the Master Complaint, Bard admits that it is subject to the personal jurisdiction of the court; however, to the extent that those allegations purport to cast liability upon Bard, either directly or indirectly, those allegations are denied. Bard further responds that it is without knowledge or information sufficient to form a belief as to the truth of those allegations as they relate to other Defendants.

8.

Bard is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 8 of the Master Complaint, and therefore denies same.

THE PELVIC MESH PRODUCTS

9.

In response to the allegations contained in Paragraph 9 of the Master Complaint, Bard admits that the products listed therein are various pelvic mesh products; however, to the extent the allegations purport to cast liability either directly or indirectly upon Bard, they are denied.

10.

In response to the allegations contained in Paragraph 10 of the Master Complaint, Bard admits that it generally designs, manufactures, and sells certain medical devices, including surgical mesh support products under the name Align® and Align® TO Urethral Support Systems. However, after a reasonable investigation, Bard lacks sufficient knowledge and information to form a belief as to the truth or falsity of whether any Align® product was implanted in any Plaintiff so indicating in a Short Form Complaint, and therefore denies same.

11.

The allegations in Paragraph 11 of the Master Complaint directed to Sofradim are directed to a party or entity other than Bard, and accordingly, no response is required; however, to the extent they purport to cast liability either directly or indirectly upon Bard, those allegations are denied. Bard admits that it marketed, sold, and distributed Avaulta® Anterior and Posterior BioSynthetic Support Systems. However, after a reasonable investigation, Bard lacks sufficient knowledge and information to form a belief as to the truth or falsity of whether any Avaulta® product was implanted in any Plaintiff so indicating in a Short Form Complaint, and therefore denies same.

12.

In response to the allegations contained in Paragraph 12 of the Master Complaint, Bard admits that it generally designs, manufactures, and sells certain medical devices, including surgical mesh support products under the name Avaulta Plus® Anterior and Posterior BioSynthetic Support Systems. However, after a reasonable investigation, Bard lacks sufficient knowledge and information to form a belief as to the truth or falsity of whether any Avaulta

Plus® product was implanted in any Plaintiff so indicating in a Short Form Complaint, and therefore denies same.

13.

In response to the allegations contained in Paragraph 13 of the Master Complaint, Bard admits that it generally designs, manufactures, and sells certain medical devices, including surgical mesh support products under the name Avaulta Solo® Anterior and Posterior BioSynthetic Support Systems. However, after a reasonable investigation, Bard lacks sufficient knowledge and information to form a belief as to the truth or falsity of whether any Avaulta Solo® product was implanted in any Plaintiff so indicating in a Short Form Complaint, and therefore denies same.

14.

The allegations in Paragraph 14 of the Master Complaint directed to TSL are directed to a party or entity other than Bard, and accordingly, no response is required; however, to the extent they purport to cast liability either directly or indirectly upon Bard, those allegations are denied. Bard admits that it marketed, sold, and distributed InnerLace® BioUrethral Support Systems. However, after a reasonable investigation, Bard lacks sufficient knowledge and information to form a belief as to the truth or falsity of whether any InnerLace® product was implanted in any Plaintiff so indicating in a Short Form Complaint, and therefore denies same.

15.

The allegations in Paragraph 15 of the Master Complaint directed to TSL are directed to a party or entity other than Bard, and accordingly, no response is required; however, to the extent they purport to cast liability either directly or indirectly upon Bard, those allegations are denied. Bard admits that it marketed, sold, and distributed the Pelvicol® Aceullar Collagen Matrix.

However, after a reasonable investigation, Bard lacks sufficient knowledge and information to form a belief as to the truth or falsity of whether any Pelvicol® product was implanted in any Plaintiff so indicating in a Short Form Complaint, and therefore denies same.

16.

The allegations in Paragraph 16 of the Master Complaint directed to TSL are directed to a party or entity other than Bard, and accordingly, no response is required; however, to the extent they purport to cast liability either directly or indirectly upon Bard, those allegations are denied. Bard admits that it marketed, sold, and distributed the PelviLace® and PelviLace® TO Transobturator BioUrethral Support Systems. However, after a reasonable investigation, Bard lacks sufficient knowledge and information to form a belief as to the truth or falsity of whether any PelviLace® product was implanted in any Plaintiff so indicating in a Short Form Complaint, and therefore denies same.

17.

The allegations in Paragraph 17 of the Master Complaint directed to TSL are directed to a party or entity other than Bard, and accordingly, no response is required; however, to the extent they purport to cast liability either directly or indirectly upon Bard, those allegations are denied. Bard admits that it marketed, sold, and distributed the PelviSoft® Acellular Collagen BioMesh. However, after a reasonable investigation, Bard lacks sufficient knowledge and information to form a belief as to the truth or falsity of whether any PelviSoft® product was implanted in any Plaintiff so indicating in a Short Form Complaint, and therefore denies same.

18.

The allegations in Paragraph 18 of the Master Complaint directed to Sofradim are directed to a party or entity other than Bard, and accordingly, no response is required; however,

to the extent they purport to cast liability either directly or indirectly upon Bard, those allegations are denied. Bard admits that it marketed, sold, and distributed the Pelvitex® Polypropylene Mesh. However, after a reasonable investigation, Bard lacks sufficient knowledge and information to form a belief as to the truth or falsity of whether any Pelvitex® product was implanted in any Plaintiff so indicating in a Short Form Complaint, and therefore denies same.

19.

The allegations in Paragraph 19 of the Master Complaint directed to Sofradim are directed to a party or entity other than Bard, and accordingly, no response is required; however, to the extent they purport to cast liability either directly or indirectly upon Bard, those allegations are denied. Bard admits that it marketed, sold, and distributed the Uretex® SUP Pubourethral Sling and Uretex® TO, TO2 and TO3 Trans-obturator Urethral Support Systems. However, after a reasonable investigation, Bard lacks sufficient knowledge and information to form a belief as to the truth or falsity of whether any Uretex® product was implanted in any Plaintiff so indicating in a Short Form Complaint, and therefore denies same.

FACTUAL BACKGROUND

20.

Bard denies the allegations contained in Paragraph 20 of the Master Complaint.

21.

Bard denies the allegations contained in Paragraph 21 of the Master Complaint.

22.

In response to the allegations contained in Paragraph 22 of the Master Complaint, Bard responds that the publication speaks for itself. To the extent that those allegations purport to cast liability upon Bard, either directly or indirectly, those allegations are denied.

23.

In response to the allegations contained in Paragraph 23 of the Master Complaint, Bard responds that the publication speaks for itself. To the extent that those allegations purport to cast liability upon Bard, either directly or indirectly, those allegations are denied.

24.

In response to the allegations contained in Paragraph 24 of the Master Complaint, Bard responds that the publication speaks for itself. To the extent that those allegations purport to cast liability upon Bard, either directly or indirectly, those allegations are denied.

25.

In response to the allegations contained in Paragraph 25 of the Master Complaint, Bard responds that the publication speaks for itself. To the extent that those allegations purport to cast liability upon Bard, either directly or indirectly, those allegations are denied.

26.

Bard denies the allegations contained in Paragraph 26 of the Master Complaint.

27.

In response to the allegations contained in Paragraph 27 of the Master Complaint, Bard responds that the publication speaks for itself. To the extent that those allegations purport to cast liability upon Bard, either directly or indirectly, those allegations are denied.

28.

In response to the allegations contained in Paragraph 28 of the Master Complaint, Bard responds that the publication speaks for itself. To the extent that those allegations purport to cast liability upon Bard, either directly or indirectly, those allegations are denied.

29.

In response to the allegations contained in Paragraph 29 of the Master Complaint, Bard responds that the publication speaks for itself. To the extent that those allegations purport to cast liability upon Bard, either directly or indirectly, those allegations are denied.

30.

In response to the allegations contained in Paragraph 30 of the Master Complaint, Bard responds that the publication speaks for itself. To the extent that those allegations purport to cast liability upon Bard, either directly or indirectly, those allegations are denied.

31.

In response to the allegations contained in Paragraph 31 of the Master Complaint, Bard responds that the publication speaks for itself. To the extent that those allegations purport to cast liability upon Bard, either directly or indirectly, those allegations are denied.

32.

In response to the allegations contained in Paragraph 32 of the Master Complaint, Bard responds that the publication speaks for itself. To the extent that those allegations purport to cast liability upon Bard, either directly or indirectly, those allegations are denied.

33.

In response to the allegations contained in Paragraph 33 of the Master Complaint, Bard responds that the publication speaks for itself. To the extent that those allegations purport to cast liability upon Bard, either directly or indirectly, those allegations are denied.

34.

Bard denies the allegations contained in Paragraph 34 of the Master Complaint.

35.

Bard denies the allegations contained in Paragraph 35 of the Master Complaint.

36.

Bard denies the allegations contained in Paragraph 36 of the Master Complaint.

37.

Bard denies the allegations contained in Paragraph 37 of the Master Complaint.

38.

Bard denies the allegations contained in Paragraph 38 of the Master Complaint.

39.

Bard denies the allegations contained in Paragraph 39 of the Master Complaint.

40.

Bard denies the allegations contained in Paragraph 40 of the Master Complaint.

41.

Bard denies the allegations contained in Paragraph 41 of the Master Complaint.

42.

Bard denies the allegations contained in Paragraph 42 of the Master Complaint.

43.

Bard denies the allegations contained in Paragraph 43 of the Master Complaint.

44.

Bard denies the allegations contained in Paragraph 44 of the Master Complaint, including all subparts thereto.

45.

Bard denies the allegations contained in Paragraph 45 of the Master Complaint, including all subparts thereto.

46.

Bard denies the allegations contained in Paragraph 46 of the Master Complaint.

47.

Bard denies the allegations contained in Paragraph 47 of the Master Complaint.

48.

Bard denies the allegations contained in Paragraph 48 of the Master Complaint.

49.

Bard denies the allegations contained in Paragraph 49 of the Master Complaint.

50.

Bard denies the allegations contained in Paragraph 50 of the Master Complaint.

51.

Bard denies the allegations contained in Paragraph 51 of the Master Complaint.

52.

After a reasonable investigation, Bard lacks sufficient knowledge and information to form a belief as to the truth or falsity of the allegations contained in Paragraph 52 of the Master Complaint, and therefore denies same.

53.

Bard denies the allegations contained in Paragraph 53 of the Master Complaint.

54.

Bard denies the allegations contained in Paragraph 54 of the Master Complaint.

55.

Bard denies the allegations contained in Paragraph 55 of the Master Complaint.

56.

Bard denies the allegations contained in Paragraph 56 of the Master Complaint.

57.

Bard denies the allegations contained in Paragraph 57 of the Master Complaint.

58.

Bard denies the allegations contained in Paragraph 58 of the Master Complaint.

59.

Bard denies the allegations contained in Paragraph 59 of the Master Complaint.

60.

Bard denies the allegations contained in Paragraph 60 of the Master Complaint.

61.

Bard denies the allegations contained in Paragraph 61 of the Master Complaint.

CAUSES OF ACTION

COUNT I: NEGLIGENCE

62.

Bard hereby incorporates by reference its responses to Paragraphs 1-61 of the Master Complaint as if fully set forth herein.

63.

The allegations contained in Paragraph 63 of the Master Complaint constitute legal conclusions to which no response is required. To the extent a response is required, those allegations are denied.

64.

Bard denies the allegations contained in Paragraph 64 of the Master Complaint, including all subparts thereto.

65.

Bard denies the allegations contained in Paragraph 65 of the Master Complaint, including all subparts thereto.

66.

Bard denies the allegations contained in Paragraph 66 of the Master Complaint, including all subparts thereto.

67.

Bard denies the allegations contained in Paragraph 67 of the Master Complaint.

COUNT II: STRICT LIABILITY – DESIGN DEFECT

68.

Bard hereby incorporates by reference its responses to Paragraphs 1-67 of the Master Complaint as if fully set forth herein.

69.

Bard denies the allegations contained in Paragraph 69 of the Master Complaint, including all subparts thereto.

70.

Bard denies the allegations contained in Paragraph 70 of the Master Complaint.

71.

Bard denies the allegations contained in Paragraph 71 of the Master Complaint.

COUNT III: STRICT LIABILITY – MANUFACTURING DEFECT

72.

Bard hereby incorporates by reference its responses to Paragraphs 1-71 of the Master Complaint as if fully set forth herein.

73.

Bard denies the allegations contained in Paragraph 73 of the Master Complaint.

74.

Bard denies the allegations contained in Paragraph 74 of the Master Complaint.

75.

Bard denies the allegations contained in Paragraph 75 of the Master Complaint.

COUNT IV: STRICT LIABILITY – FAILURE TO WARN

76.

Bard hereby incorporates by reference its responses to Paragraphs 1-75 of the Master Complaint as if fully set forth herein.

77.

Bard denies the allegations contained in Paragraph 77 of the Master Complaint, including all subparts thereto.

78.

Bard denies the allegations contained in Paragraph 78 of the Master Complaint.

79.

Bard denies the allegations contained in Paragraph 79 of the Master Complaint.

COUNT V: BREACH OF EXPRESS WARRANTY

80.

Bard hereby incorporates by reference its responses to Paragraphs 1-79 of the Master Complaint as if fully set forth herein.

81.

Bard denies the allegations contained in Paragraph 81 of the Master Complaint.

82.

Bard denies the allegations contained in Paragraph 82 of the Master Complaint.

83.

Bard denies the allegations contained in Paragraph 83 of the Master Complaint.

84.

Bard denies the allegations contained in Paragraph 84 of the Master Complaint.

85.

Bard denies the allegations contained in Paragraph 85 of the Master Complaint.

86.

Bard denies the allegations contained in Paragraph 86 of the Master Complaint.

COUNT VI: BREACH OF IMPLIED WARRANTY

87.

Bard hereby incorporates by reference its responses to Paragraphs 1-86 of the Master Complaint as if fully set forth herein.

88.

Bard denies the allegations contained in Paragraph 88 of the Master Complaint.

89.

Bard denies the allegations contained in Paragraph 89 of the Master Complaint.

90.

Bard denies the allegations contained in Paragraph 90 of the Master Complaint.

91.

Bard denies the allegations contained in Paragraph 91 of the Master Complaint.

92.

Bard denies the allegations contained in Paragraph 92 of the Master Complaint.

93.

Bard denies the allegations contained in Paragraph 93 of the Master Complaint.

COUNT VII: LOSS OF CONSORTIUM

94.

Bard hereby incorporates by reference its responses to Paragraphs 1-93 of the Master Complaint as if fully set forth herein.

95.

Bard denies the allegations contained in Paragraph 95 of the Master Complaint.

COUNT VIII: PUNITIVE DAMAGES

96.

Bard hereby incorporates by reference its responses to Paragraphs 1-95 of the Master Complaint as if fully set forth herein.

97.

Bard denies the allegations contained in Paragraph 97 of the Master Complaint.

98.

Bard denies the allegations contained in Paragraph 98 of the Master Complaint.

99.

Bard denies the allegations contained in Paragraph 99 of the Master Complaint.

100.

Bard denies the allegations contained in Paragraph 100 of the Master Complaint.

101.

Bard denies the allegations contained in Paragraph 101 of the Master Complaint.

102.

Bard denies the allegations contained in Paragraph 102 of the Master Complaint.

103.

Bard denies the allegations contained in Paragraph 103 of the Master Complaint.

104.

Bard denies the allegations contained in Paragraph 104 of the Master Complaint.

105.

Bard denies the allegations contained in Paragraph 105 of the Master Complaint.

106.

Bard denies the allegations contained in Paragraph 106 of the Master Complaint.

107.

Bard denies the allegations contained in Paragraph 107 of the Master Complaint.

Furthermore, responding to the unnumbered Paragraph following Paragraph 107 of the Master Complaint beginning "WHEREFORE," Bard denies the allegations contained in such Paragraph. Bard further denies each and every allegation not specifically admitted herein. Bard denies that Plaintiffs are entitled to any relief requested in the Complaint.

BARD'S AFFIRMATIVE DEFENSES

Bard alleges and asserts the following defenses in response to the allegations in the Master Complaint.

FIRST DEFENSE

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

SECOND DEFENSE

The Master Complaint fails to state claim or claims upon which relief can be granted due to lack of adequate product identification.

THIRD DEFENSE

The Plaintiffs may be barred from bringing some of the claims alleged in the Master Complaint because the Plaintiffs may lack standing and/or capacity to bring such claims.

FOURTH DEFENSE

The sole proximate cause of the Plaintiffs' damages, if any were sustained, was the negligence of a person or persons or entity for whose acts or omissions Bard was and is in no way liable.

FIFTH DEFENSE

If the Plaintiffs have been damaged, which Bard denies, any recovery by the Plaintiffs is barred to the extent they voluntarily exposed themselves to a known risk and/or failed to mitigate their alleged damages. To the extent the Plaintiffs have failed to mitigate their alleged damages,

any recovery shall not include alleged damages that could have been avoided by reasonable care and diligence.

SIXTH DEFENSE

The Plaintiffs failed to exercise ordinary care for their own safety such that the Plaintiffs are not entitled to recover.

SEVENTH DEFENSE

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

EIGHTH DEFENSE

The Plaintiffs' causes of action may be barred by the applicable statute of limitations and/or statute of repose.

NINTH DEFENSE

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

TENTH DEFENSE

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

ELEVENTH DEFENSE

There was no causal connection between any alleged defect in the products at issue and Plaintiffs' alleged damages with the result that Plaintiffs are not entitled to recover against Bard in this cause.

TWELFTH DEFENSE

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

THIRTEENTH DEFENSE

If the Plaintiffs have been damaged, which Bard denies, such damages were caused by the negligence or fault of persons and/or entities for whose conduct Bard is not legally responsible.

FOURTEENTH DEFENSE

If the Plaintiffs suffered any damages or injuries, which are denied, the Plaintiffs' recovery is barred, in whole or in part, or subject to reduction under the doctrine of contributory and/or comparative negligence.

FIFTEENTH DEFENSE

In the further alternative, and only in the event that it is determined that the Plaintiffs are entitled to recover against Bard, recovery should be reduced in proportion to the degree or percentage of negligence, fault or exposure to products attributable to the Plaintiff, any other defendants, third party defendants, or other persons, including any party immune because bankruptcy renders them immune from further litigation, as well as any party, co-defendant, or non-parties with whom the Plaintiffs have settled or may settle in the future.

SIXTEENTH DEFENSE

If the Plaintiffs have been damaged, which Bard denies, the negligence or fault of the Plaintiff constitutes the sole, intervening, and superseding cause of the Plaintiffs' alleged damages.

SEVENTEENTH DEFENSE

If the Plaintiffs have been damaged, which Bard denies, the negligence or fault of persons and/or entities for whose conduct Bard is not legally responsible constitutes the sole, intervening, and superseding cause of the Plaintiffs' alleged damages.

EIGHTEENTH DEFENSE

If the Plaintiffs have been damaged, which Bard denies, the actions of persons or entities for whose conduct Bard is not legally responsible and the independent knowledge of these persons or entities of the risks inherent in the use of the products and other independent causes, constitute an intervening and superseding cause of the Plaintiffs' alleged damages.

NINETEENTH DEFENSE

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

TWENTIETH DEFENSE

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

TWENTY-FIRST DEFENSE

Bard made no warranties of any kind, express or implied, including any alleged implied warranty of merchantability or implied warranty of fitness for a particular purpose, or any representations of any nature whatsoever to the Plaintiffs. To the extent applicable, the Plaintiffs' breach of warranty claims are barred by a lack of privity between the Plaintiffs and

Bard. To the extent the Plaintiffs make warranty claims, whether express or implied, the claims are barred or limited by any and all express conditions or disclaimers, by the Plaintiffs' lack of reliance on any such warranties, and by waiver.

TWENTY-SECOND DEFENSE

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

TWENTY-THIRD DEFENSE

To the extent the Plaintiffs assert a claim for breach of warranty, such claim is barred because the Plaintiffs did not first give notice of any alleged defect of the products to Bard.

TWENTY-FOURTH DEFENSE

Bard neither had nor breached any alleged duty to warn with respect to the products, with the result that the Plaintiffs are not entitled to recover in this cause.

TWENTY-FIFTH DEFENSE

The Plaintiffs' claims are barred by the learned intermediary doctrine.

TWENTY-SIXTH DEFENSE

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

TWENTY-SEVENTH DEFENSE

The Plaintiffs' alleged damages resulted from independent, unforeseeable, superseding, and/or intervening causes unrelated to any conduct of Bard.

TWENTY-EIGHTH DEFENSE

If the Plaintiffs recover from Bard, it 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.

TWENTY-NINTH DEFENSE

The Plaintiffs' claims are or may be barred, in whole or in part, to the extent that the Plaintiff has released, settled with, entered into an accord and satisfaction, or otherwise compromised their claims. Bard is entitled to a set-off for the entire amount of proceeds the Plaintiffs have or may recover from all other sources.

THIRTIETH DEFENSE

Should Bard be held liable to the Plaintiffs, which liability is specifically denied, Bard would be entitled to a set-off for the total of all amounts paid to the Plaintiffs from all collateral sources.

THIRTY-FIRST DEFENSE

Bard asserts any and all defenses, claims, credits, offsets, or remedies available to it under the Restatement (Third) of Torts and reserves the right to amend its Answer to file such further pleadings as are necessary to preserve and assert such defenses, claims, credits, offsets, or remedies.

THIRTY-SECOND DEFENSE

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

THIRTY-THIRD DEFENSE

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

THIRTY-FOURTH DEFENSE

The Plaintiffs' claims are barred because the methods, standards, warnings, and instructions used in manufacturing and/or marketing the products at issue conformed with industry custom/usage standards and/or legislative/administrative/regulatory standards.

THIRTY-FIFTH DEFENSE

The design complained of in the Master Complaint, the alleged defects of the products, and/or any alternative design claimed by the Plaintiffs were not known and, in light of the existing, reasonably-available scientific and technological knowledge, could not have been known at the time the products at issue were designed, manufactured, and sold. Any alleged alternative design was not scientifically or technologically feasible or economically practical.

THIRTY-SIXTH DEFENSE

Bard 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-SEVENTH DEFENSE

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

THIRTY-EIGHTH DEFENSE

To the extent the Plaintiffs assert a demand for punitive damages, Bard specifically incorporates by reference any and all standards of limitations regarding the determination and/or enforceability of punitive damages awards that arose in the decisions of *BMW of No. America v. Gore*, 517 U.S. 559 (1996); *Cooper Industries, Inc. v. Leatherman Tool Group, Inc.*, 532 U.S. 424 (2001); *State Farm Mut. Auto Ins. Co. v. Campbell*, 123 S. Ct. 1513 (2003); and *Exxon Shipping Co. v. Baker*, No. 07-219, 2008 U.S. LEXIS 5263 (U.S. June 25, 2008) and their progeny as well as other similar cases under both federal and state law.

THIRTY-NINTH DEFENSE

To the extent that the Plaintiffs assert a claim for punitive damages, that claim is in contravention of the rights of Bard under the following constitutional provisions:

1. Plaintiffs' claims for punitive or exemplary damages violate, and are therefore barred by, the Fourth, Fifth, Sixth, Eighth and Fourteenth Amendments to the Constitution of the United States of America, and the analogous provisions of the applicable State Constitutions, on grounds including the following:

(a) it is a violation of the Due Process and Equal Protection Clauses of the Fourteenth Amendment of the United States Constitution, and the analogous provisions of the applicable State Constitutions, to impose punitive damages, which are penal in nature, against a civil defendant upon the Plaintiffs satisfying a burden of proof which is less than the "beyond a reasonable doubt" burden of proof required in criminal cases;

(b) the procedures pursuant to which punitive damages are awarded may result in the award of joint and several judgments against multiple defendants for different alleged acts of wrongdoing, which infringes upon the Due Process and Equal Protection Clauses of the Fourteenth Amendment of the United States Constitution, and the analogous provisions of the applicable State Constitutions;

(c) the procedures to which punitive damages are awarded fail to provide a reasonable limit on the amount of the award against defendant, which thereby violates the Due Process Clause of the Fourteenth Amendment of the United States Constitution, and the analogous provisions of the applicable State Constitutions;

(d) the procedures pursuant to which punitive damages are awarded fail to provide specific standards for the amount of the award of punitive damages which thereby violates the Due Process Clause of the Fourteenth Amendment of the United States Constitution, and the analogous provisions of the applicable State Constitutions;

(e) the procedures pursuant to which punitive damages are awarded result in the imposition of different penalties for the same or similar acts, and thus violate the

Equal Protection Clause of the Fourteenth Amendment of the United States Constitution, and the analogous provisions of the applicable State Constitutions;

(f) the procedures pursuant to which punitive damages are awarded permit the imposition of punitive damages in excess of the maximum criminal fine for the same or similar conduct, which thereby infringes upon the Due Process Clause of the Fifth and Fourteenth Amendments and the Equal Protection Clause of the Fourteenth Amendment of the United States Constitution, and the analogous provisions of the applicable State Constitutions;

(g) the procedures pursuant to which punitive damages are awarded permit the imposition of excessive fines in violation of the Eighth Amendment of the United States Constitution, and the analogous provisions of the applicable State Constitutions;

(h) the award of punitive damages to the Plaintiffs in this action would constitute a deprivation of property without due process of law; and

(i) the procedures pursuant to which punitive damages are awarded permit the imposition of an excessive fine and penalty.

FORTIETH DEFENSE

The Plaintiffs' claims are barred, in whole or in part, because Plaintiffs assumed the risks disclosed by the FDA-approved product labeling, the prescribing physicians, or other persons or entities.

FORTY-FIRST DEFENSE

There should be no recovery against Bard for any failure to warn or inadequacy of warning, because at all pertinent times, Plaintiffs possessed or should have possessed good and adequate knowledge which negated any need for warning.

FORTY-SECOND DEFENSE

If Plaintiffs were injured or damaged as alleged, no injury or damages being admitted, such injuries were not caused by a product manufactured by Bard.

FORTY-THIRD DEFENSE

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

FORTY-FOURTH DEFENSE

The Plaintiffs' product liability claims are barred because the benefits of the products outweighed their risks.

FORTY-FIFTH DEFENSE

Venue may be improper in any individual case where the Plaintiff does not reside in the forum wherein her Complaint was filed or cannot otherwise establish an independent basis for venue in that forum and any such claims should be dismissed on this basis.

FORTY-SIXTH DEFENSE

Plaintiffs' case may be subject to dismissal or transfer under the doctrine of forum non conveniens.

FORTY-SEVENTH DEFENSE

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

FORTY-EIGHTH DEFENSE

The Plaintiffs have failed to plead their fraud claims with the particularity required under the applicable state's statutory and/or common law.

FORTY-NINTH DEFENSE

If it should be proven that any product distributed by Bard was involved herein as alleged, then the state of medical and scientific knowledge or published literature or other materials reflecting the state of medical and scientific knowledge at all times relevant hereto, was such that Bard neither knew nor could have known that the products presented a foreseeable risk of harm in its normal and expected use.

FIFTIETH DEFENSE

The damages claimed by Plaintiffs are not recoverable, in whole or in part, under the various applicable states' laws.

FIFTY-FIRST DEFENSE

Plaintiffs' claims may be barred by failure to join indispensable parties.

FIFTY-SECOND DEFENSE

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

FIFTY-THIRD DEFENSE

Bard hereby gives notice that it intends to rely upon and incorporates by reference any affirmative defenses that may be asserted by any co-defendant in this lawsuit.

JURY DEMAND

Bard hereby requests a trial by jury on all issues so triable, and reserves the right to seek to have a trial before twelve jurors.

WHEREFORE, Bard avers that Plaintiffs are not entitled to the relief demanded in the Complaint, and Bard, having fully answered, prays that this action against it be dismissed and that it be awarded its costs in defending this action and that it be granted such other and further relief as the Court deems just and appropriate.

Dated: March 19, 2012

/s/Richard B. North, Jr.
Richard B. North, Jr.
Georgia Bar No. 545599

Nelson Mullins Riley & Scarborough LLP
Atlantic Station
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Attorneys for C. R. Bard, Inc.

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

CHARLESTON DIVISION

IN RE: C.R. Bard, Inc.,
Pelvic Repair System Products Liability Litigation.
MDL no. 2187

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. 2187 by reference. Plaintiff(s) further show the court as follows:

1. Female Plaintiff

   _____

2. Plaintiff Husband

   _____

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

   _____

4. State of Residence

   _____

5. District Court and Division in which action is to be filed upon transfer from the MDL.

   _____

   _____

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

   ( )A. C. R. Bard, Inc. ("Bard")

   ( )B. Sofradim Production SAS ("Sofradim")

( )C. Tissue Science Laboratories Limited ("TSL")

( )D. Other defendants

_____

_____

7. Basis of Jurisdiction

Diversity of Citizenship

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

_____

_____

_____

B. Other allegations of jurisdiction and venue

_____

_____

_____

_____

9. Defendants' products implanted in Plaintiff (Check products implanted in Plaintiff)

( )A. The Align Urethral Support System;

( )B. The Align TO Urethral Support System;

( )C. The Avaulta Anterior BioSynthetic Support System;

( )D. The Avaulta Posterior BioSynthetic Support System;

( )E. The Avaulta Plus Anterior BioSynthetic Support System;

( )F. The Avaulta Plus Posterior BioSynthetic Support System;

( )G. The Avaulta Solo Anterior Synthetic Support System;

( )H. The Avaulta Solo Posterior Synthetic Support System;

( )I. The InnerLace BioUrethral Support System;

( )J. The Pelvicol Acellular Collagen Matrix;

( )K. The PelviLace BioUrethral Support System;

( )L. The PelviLace TO Trans-obturator BioUrethral Support System;

( )M. The PelviSoft Acellular Collagen BioMesh;

( )N. The Pelvitex Polypropylene Mesh;

( )O. The Uretex SUP Pubourethral Sling;

( )P. The Uretex TO Trans-obturator Urethral Support System;

( )Q. The Uretex TO2 Trans-obturator Urethral Support System; and

( )R. The Uretex TO3 Trans-obturator Urethral Support System.

( )S. Other

_____

_____

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

( )A. The Align Urethral Support System;

( )B. The Align TO Urethral Support System;

( )C. The Avaulta Anterior BioSynthetic Support System;

( )D. The Avaulta Posterior BioSynthetic Support System;

( )E. The Avaulta Plus Anterior BioSynthetic Support System;

( )F. The Avaulta Plus Posterior BioSynthetic Support System;

( )G. The Avaulta Solo Anterior Synthetic Support System;

( )H. The Avaulta Solo Posterior Synthetic Support System;

( )I. The InnerLace BioUrethral Support System;

( )J. The Pelvicol Acellular Collagen Matrix;

( )K. The PelviLace BioUrethral Support System;

( )L. The PelviLace TO Trans-obturator BioUrethral Support System;

( )M. The PelviSoft Acellular Collagen BioMesh;

( )N. The Pelvitex Polypropylene Mesh;

( )O. The Uretex SUP Pubourethral Sling;

( )P. The Uretex TO Trans-obturator Urethral Support System;

( )Q. The Uretex TO2 Trans-obturator Urethral Support System; and

( )R. The Uretex TO3 Trans-obturator Urethral Support System.

( )S. Other

_____

_____

11. Date of Implantation as to Each Product

_____

_____

_____

12. Hospital(s) where Plaintiff was implanted (including City and State)

_____

_____

13. Implanting Surgeon(s)

_____

_____

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

( ) Count I

( ) Count II

( ) Count III

( ) Count IV

( ) Count V

( ) Count VI

( ) Count VII (by the Husband)

( ) Count VIII

_____

Attorneys for Plaintiff

_____

_____

Address and bar information:

_____

_____

_____

_____

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

CHARLESTON DIVISION

IN RE: C.R. Bard, Inc.,
Pelvic Repair System Products Liability Litigation.
MDL no. 2187

MASTER LONG FORM COMPLAINT AND JURY DEMAND

Plaintiffs, by and through their counsel, bring this Master Long Form 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 previously filed Complaint and 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 9 of this Master Complaint inserted in their bodies to treat medical conditions, primarily pelvic organ prolapse (POP)and stress urinary incontinence. 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.

Defendants are one or more of the following entities as identified in the Short Form Complaint:

a. C. R. Bard, Inc. ("Bard");

b. Sofradim Production SAS ("Sofradim"); and

c. Tissue Science Laboratories Limited ("TSL").

3.

Bard is a New Jersey corporation with its principal place of business in New Jersey. All acts and omissions of Bard 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.

4.

Sofradim is a French company with its principal place of business at 116 Avenue Du Formans, Trevoux, France 01600. All acts and omissions of Sofradim 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.

5.

TSL is a British private limited company with its principal place of business in the United Kingdom. All acts and omissions of TSL 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

6.

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 Defendants and the amount in controversy exceeds $75,000.

7.

Defendants 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.

8.

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

9.

Defendants' Pelvic Mesh Products (the "Products")are as follows:

a. The Align Urethral Support System;

b. The Align TO Urethral Support System;

c. The Avaulta Anterior BioSynthetic Support System;

d. The Avaulta Posterior BioSynthetic Support System;

e. The Avaulta Plus Anterior BioSynthetic Support System;

f. The Avaulta Plus Posterior BioSynthetic Support System;

g. The Avaulta Solo Anterior Synthetic Support System;

h. The Avaulta Solo Posterior Synthetic Support System;

i. The InnerLace BioUrethral Support System;

j. The Pelvicol Acellular Collagen Matrix;

k. The PelviLace BioUrethral Support System;

l. The PelviLace TO Trans-obturator BioUrethral Support System;

m. The PelviSoft Acellular Collagen BioMesh;

n. The Pelvitex Polypropylene Mesh;

o. The Uretex SUP Pubourethral Sling;

p. The Uretex TO Trans-obturator Urethral Support System;

q. The Uretex TO2 Trans-obturator Urethral Support System; and

r. The Uretex TO3 Trans-obturator Urethral Support System.

10.

Bard designed, manufactured, packaged, labeled, marketed, sold, and distributed the Align and Align TO Urethral Support Systems, including that which was implanted in any Plaintiff so indicating in a Short Form Complaint.

11.

Sofradim designed, manufactured, packaged and labeled the Avaulta Anterior and Posterior BioSynthetic Support Systems, including that which was implanted in any Plaintiff so indicating in a Short Form Complaint. Bard marketed, sold, and distributed the Avaulta Anterior and Posterior BioSynthetic Support Systems, including that which was implanted in any Plaintiff so indicating in a Short Form Complaint.

12.

Bard designed, manufactured, packaged, labeled, marketed, sold, and distributed the Avaulta Plus Anterior and Posterior BioSynthetic Support Systems, including that which was implanted in any Plaintiff so indicating in a Short Form Complaint.

13.

Bard designed, manufactured, packaged, labeled, marketed, sold, and distributed the Avaulta Solo Anterior and Posterior BioSynthetic Support Systems, including that which was implanted in any Plaintiff so indicating in a Short Form Complaint.

14.

TSL designed, manufactured, packaged and labeled the InnerLace BioUrethral Support System, including that which was implanted in any Plaintiff so indicating in a Short Form Complaint. Bard marketed, sold, and distributed the InnerLace BioUrethral Support System, including that which was implanted in any Plaintiff so indicating in a Short Form Complaint.

15.

TSL designed, manufactured, packaged and labeled the Pelvicol Acellular Collagen Matrix, including that which was implanted in any Plaintiff so indicating in a Short Form Complaint. Bard marketed, sold, and distributed the Pelvicol Acellular Collagen Matrix, including that which was implanted in any Plaintiff so indicating in a Short Form Complaint.

16.

TSL designed, manufactured, packaged and labeled the PelviLace and PelviLace TO Trans-obturator BioUrethral Support Systems, including that which was implanted in any Plaintiff so indicating in a Short Form Complaint. Bard marketed, sold, and distributed the

PelviLace and PelviLace TO Trans-obturator BioUrethral Support Systems, including that which was implanted in any Plaintiff so indicating in a Short Form Complaint.

17.

TSL designed, manufactured, packaged and labeled the PelviSoft Acellular Collagen BioMesh, including that which was implanted in any Plaintiff so indicating in a Short Form Complaint. Bard marketed, sold, and distributed the PelviSoft Acellular Collagen BioMesh, including that which was implanted in any Plaintiff so indicating in a Short Form Complaint.

18.

Sofradim designed, manufactured, packaged and labeled the Pelvitex Polypropylene Mesh, including that which was implanted in any Plaintiff so indicating in a Short Form Complaint. Bard marketed, sold and distributed the Pelvitex Polypropylene Mesh, including that which was implanted in any Plaintiff so indicating in a Short Form Complaint.

19.

Sofradim designed, manufactured, packaged and labeled the Uretex SUP Pubourethral Sling, and Uretex TO, TO2, and TO3 Trans-obturator Urethral Support Systems, including that which was implanted in any Plaintiff so indicating in a Short Form Complaint. Bard marketed, sold and distributed the Uretex SUP Pubourethral Sling, and Uretex TO, TO2, and TO3 Trans-obturator Urethral Support Systems, including that which was implanted in any Plaintiff so indicating in a Short Form Complaint.

FACTUAL BACKGROUND

20.

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 Defendants' Pelvic Mesh 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 organic material from animals. Cross linked collagen is harsh upon the female pelvic tissue. It hardens in the body. 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.

21.

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 with regard to the Products.

22.

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).

23.

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).

24.

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.

25.

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."

26.

The injuries of the female Plaintiff as will be more fully set forth in the Plaintiff's Fact Sheet to be served in this civil action are reported in the FDA Safety Communication and in the ACOG/AUGS Joint Committee Opinion.

27.

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.

28.

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.”

29.

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.”

30.

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).

31.

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.”

32.

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."

33.

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."

34.

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

35.

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.

36.

The scientific evidence shows that the material from which Defendants' 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.

37.

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.

38.

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.

39.

The Products were unreasonably susceptible to shrinkage and contraction inside the body.

40.

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

41.

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.

42.

Defendants omitted 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.

43.

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.

44.

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

a. the use of polypropylene and collagen material 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); and

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 cross linked 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.

45.

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 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.

46.

Defendants have underreported 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.

47.

Defendants failed to perform proper and adequate testing and research in order to determine and evaluate the risks and benefits of the Products.

48.

Defendants 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.

49.

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.

50.

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

51.

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

52.

The Product or 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.

53.

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.

54.

In many cases, including the female Plaintiff named in the Short Form Complaint, the 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.

55.

The medical and scientific literature studying the effects of Defendants' mesh 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.

56.

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.

57.

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.

58.

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.

59.

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.

60.

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 Defendant's knowledge of lack of safety.

61.

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

62.

Paragraphs 1-61 of this Master Complaint are hereby incorporated by reference as if fully set forth herein.

63.

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.

64.

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

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

65.

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 material 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); and

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 cross linked 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.

66.

Defendant 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.

67.

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

68.

Plaintiffs incorporate by reference paragraphs 1-67 of this Complaint 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 with respect to their design. As previously stated, the Products' design defects include, but are not limited to:

a. the use of polypropylene material 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); and

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 cross linked 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.

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 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.

71.

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

COUNT III: STRICT LIABILITY – MANUFACTURING DEFECT

72.

Plaintiffs incorporate by reference paragraphs 1-71 of this Complaint as if fully set forth herein.

73.

The Product(s) 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.

74.

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.

75.

Defendant is strictly liable to the female Plaintiff named in the complaint for designing, manufacturing, marketing, labeling, packaging and selling a defective product(s).

COUNT IV: STRICT LIABILITY – FAILURE TO WARN

76.

Plaintiffs incorporate by reference paragraphs 1-75 of this Complaint as if fully set forth herein.

77.

The Product(s) 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; and

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

78.

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.

79.

Defendant is 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

80.

Plaintiffs incorporate by reference paragraphs 1-79 of this Complaint as if fully set forth herein.

81.

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.

82.

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.

83.

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.

84.

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

85.

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

86.

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

87.

Plaintiffs incorporate by reference paragraphs 1-86 of this Complaint as if fully set forth herein.

88.

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

89.

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.

90.

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.

91.

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

92.

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.

93.

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

94.

Plaintiffs incorporate by reference paragraphs 1-93 of this Complaint as if fully set forth herein.

95.

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 husband named in the Short Form Complaint has suffered a loss of his wife's consortium, companionship, society, affection, services and support.

COUNT VIII: PUNITIVE DAMAGES

96.

Plaintiffs incorporate by reference paragraphs 1-95 of this Complaint as if fully set forth herein.

97.

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.

98.

Defendants sold the Products to the female Plaintiff named in the Short Form Complaint's 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.

99.

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, Defendants chose instead to continue to market and sell the Products as safe and effective.

100.

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.

101.

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.

102.

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.

103.

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

104.

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

105.

Defendants knew of the Products' defective and unreasonably dangerous nature, but continued 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.

106.

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.

107.

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 named in the Short Form Complaint demand a trial by jury, judgment against Defendants for compensatory and punitive damages in an amount exceeding $75,000, as well as costs, attorney fees, interest, or any other relief, monetary or equitable, to which they are entitled.

PLAINTIFFS DEMAND A TRIAL BY JURY.

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Attorneys for Plaintiff(s)

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

IN RE C. R. BARD, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION

MDL No. 2187

TISSUE SCIENCE LABORATORIES LIMITED'S MASTER LONG FORM ANSWER AND AFFIRMATIVE DEFENSES TO PLAINTIFFS' MASTER LONG FORM COMPLAINT AND JURY DEMAND

Defendant Tissue Science Laboratories Limited (hereinafter "TSL"), by and through its undersigned counsel, hereby files its Master Long Form Answer and Affirmative Defenses ("Master Answer") to Plaintiffs' Master Long Form Complaint and Jury Demand ("Master Complaint"). By operation of the Order of this Court, all responses and defenses pled herein are deemed pled in any previously filed Answer and in any Short Form Responsive Pleading hereafter filed. TSL expressly reserves any and all defenses now available or that may become available in the future. In further response to the numbered allegations contained in the Master Complaint, TSL states as follows:

PARTIES, JURISDICTION & VENUE

PLAINTIFFS

1.

After reasonable investigation, TSL lacks sufficient knowledge and information to form a belief as to the truth or falsity of the allegations contained in Paragraph 1 of the Master Complaint, and therefore denies same.

DEFENDANTS

2.

In response to the allegations contained in Paragraph 2 of the Master Complaint, TSL admits that the entities named therein have been identified as Defendants in the Short Form Complaint; however, to the extent the allegations purport to cast liability either directly or indirectly upon TSL, they are denied.

3.

The allegations in Paragraph 3 of the Master Complaint are directed to a party or entity other than TSL, and accordingly, no response is required. However, to the extent they purport to cast liability either directly or indirectly upon TSL, those allegations are denied.

4.

The allegations in Paragraph 4 of the Master Complaint are directed to a party or entity other than TSL, and accordingly, no response is required. However, to the extent they purport to cast liability either directly or indirectly upon TSL, those allegations are denied.

5.

In response to Paragraph 5 of the Master Complaint, TSL admits that it is a British private limited company with a principal place of business in the United Kingdom. The remaining allegations of Paragraph 5 are denied.

JURISDICTION AND VENUE

6.

In response to the allegations contained in Paragraph 6 of the Master Complaint, TSL admits that Plaintiffs are seeking damages in excess of $75,000 and that subject matter jurisdiction is proper, although TSL denies that Plaintiffs are entitled to any recovery.

7.

The allegations contained in Paragraph 7 of the Master Complaint constitute legal conclusions to which no response is required. To the extent a response is required, TSL denies same.

8.

TSL is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 8 of the Master Complaint, and therefore denies same. TSL reserves the right to challenge the propriety of the venue in any particular case.

THE PELVIC MESH PRODUCTS

9.

In response to the allegations contained in Paragraph 9 of the Master Complaint, TSL admits that the products listed therein are various pelvic mesh products; however, to the extent the allegations purport to cast liability either directly or indirectly upon TSL, they are denied.

10.

The allegations in Paragraph 10 of the Master Complaint are directed to a party or entity other than TSL, and accordingly, no response is required; however, to the extent they purport to cast liability either directly or indirectly upon TSL, those allegations are denied.

11.

The allegations in Paragraph 11 of the Master Complaint are directed to parties or entities other than TSL, and accordingly, no response is required; however, to the extent they purport to cast liability either directly or indirectly upon TSL, those allegations are denied.

12.

The allegations in Paragraph 12 of the Master Complaint are directed to a party or entity other than TSL, and accordingly, no response is required; however, to the extent they purport to cast liability either directly or indirectly upon TSL, those allegations are denied.

13.

The allegations in Paragraph 13 of the Master Complaint are directed to a party or entity other than TSL, and accordingly, no response is required; however, to the extent they purport to cast liability either directly or indirectly upon TSL, those allegations are denied.

14.

In response to the allegations contained in Paragraph 14 of the Master Complaint, TSL admits that it designed, manufactured, packaged and labeled surgical mesh products that were marketed, sold and distributed by Bard under the name InnerLace® BioUrethral Support System. However, after a reasonable investigation, TSL lacks sufficient knowledge and information to form a belief as to the truth or falsity of whether any InnerLace® product was implanted in any Plaintiff so indicated in a Short Form Complaint, and therefore denies same.

15.

In response to the allegations contained in Paragraph 15 of the Master Complaint, TSL admits that it designed, manufactured, packaged and labeled surgical mesh products that were marketed, sold and distributed by Bard under the name Pelvicol® Acellular Collagen Matrix. However, after a reasonable investigation, TSL lacks sufficient knowledge and information to form a belief as to the truth or falsity of whether any Pelvicol® product was implanted in any Plaintiff so indicated in a Short Form Complaint, and therefore denies same.

16.

In response to the allegations contained in Paragraph 16 of the Master Complaint, TSL admits that it designed, manufactured, packaged and labeled surgical mesh products that were marketed, sold and distributed by Bard under the names PelviLace® and PelviLace® TO Transobturator BioUrethral Support Systems. However, after a reasonable investigation, TSL lacks sufficient knowledge and information to form a belief as to the truth or falsity of whether any PelviLace® product was implanted in any Plaintiff so indicated in a Short Form Complaint, and therefore denies same.

17.

In response to the allegations contained in Paragraph 17 of the Master Complaint, TSL admits that it designed, manufactured, packaged and labeled surgical mesh products that were marketed, sold and distributed by Bard under the name PelviSoft® Acellular Collagen BioMesh. However, after a reasonable investigation, TSL lacks sufficient knowledge and information to form a belief as to the truth or falsity of whether any PelviSoft® product was implanted in any Plaintiff so indicated in a Short Form Complaint, and therefore denies same.

18.

The allegations in Paragraph 18 of the Master Complaint are directed to parties or entities other than TSL, and accordingly, no response is required; however, to the extent they purport to cast liability either directly or indirectly upon TSL, those allegations are denied.

19.

The allegations in Paragraph 19 of the Master Complaint are directed to parties or entities other than TSL, and accordingly, no response is required; however, to the extent they purport to cast liability either directly or indirectly upon TSL, those allegations are denied.

FACTUAL BACKGROUND

20.

TSL denies the allegations contained in Paragraph 20 of the Master Complaint.

21.

In Response to the allegations contained in Paragraph 21 of the Master Complaint, TSL admits only that the products alleged herein to be manufactured by TSL and which have been marketed in the United States by Bard, have all been cleared by the FDA under section 510(k) of the Medical Device Amendment to the Food, Drug and Cosmetics Act. To the extent the allegations contained in Paragraph 21 of the Master Complaint contain legal conclusions, no response is required and, therefore, those conclusions are denied. The remaining allegations of Paragraph 21 of the Master Complaint are denied.

22.

In response to the allegations contained in Paragraph 22 of the Master Complaint, TSL responds that the publication speaks for itself. To the extent that those allegations purport to cast liability upon TSL, either directly or indirectly, those allegations are denied.

23.

In response to the allegations contained in Paragraph 23 of the Master Complaint, TSL responds that the publication speaks for itself. To the extent that those allegations purport to cast liability upon TSL, either directly or indirectly, those allegations are denied.

24.

In response to the allegations contained in Paragraph 24 of the Master Complaint, TSL responds that the publication speaks for itself. To the extent that those allegations purport to cast liability upon TSL, either directly or indirectly, those allegations are denied.

25.

In response to the allegations contained in Paragraph 25 of the Master Complaint, TSL responds that the publication speaks for itself. To the extent that those allegations purport to cast liability upon TSL, either directly or indirectly, those allegations are denied.

26.

TSL denies the allegations contained in Paragraph 26 of the Master Complaint.

27.

In response to the allegations contained in Paragraph 27 of the Master Complaint, TSL responds that the publication speaks for itself. To the extent that those allegations purport to cast liability upon TSL, either directly or indirectly, those allegations are denied.

28.

In response to the allegations contained in Paragraph 28 of the Master Complaint, TSL responds that the publication speaks for itself. To the extent that those allegations purport to cast liability upon TSL, either directly or indirectly, those allegations are denied.

29.

In response to the allegations contained in Paragraph 29 of the Master Complaint, TSL responds that the publication speaks for itself. To the extent that those allegations purport to cast liability upon TSL, either directly or indirectly, those allegations are denied.

30.

In response to the allegations contained in Paragraph 30 of the Master Complaint, TSL responds that the publication speaks for itself. To the extent that those allegations purport to cast liability upon TSL, either directly or indirectly, those allegations are denied.

31.

In response to the allegations contained in Paragraph 31 of the Master Complaint, TSL responds that the publication speaks for itself. To the extent that those allegations purport to cast liability upon TSL, either directly or indirectly, those allegations are denied.

32.

In response to the allegations contained in Paragraph 32 of the Master Complaint, TSL responds that the publication speaks for itself. To the extent that those allegations purport to cast liability upon TSL, either directly or indirectly, those allegations are denied.

33.

In response to the allegations contained in Paragraph 33 of the Master Complaint, TSL responds that the publication speaks for itself. To the extent that those allegations purport to cast liability upon TSL, either directly or indirectly, those allegations are denied.

34.

TSL denies the allegations contained in Paragraph 34 of the Master Complaint.

35.

TSL denies the allegations contained in Paragraph 35 of the Master Complaint.

36.

TSL denies the allegations contained in Paragraph 36 of the Master Complaint.

37.

TSL denies the allegations contained in Paragraph 37 of the Master Complaint.

38.

TSL denies the allegations contained in Paragraph 38 of the Master Complaint.

39.

TSL denies the allegations contained in Paragraph 39 of the Master Complaint.

40.

TSL denies the allegations contained in Paragraph 40 of the Master Complaint.

41.

TSL denies the allegations contained in Paragraph 41 of the Master Complaint, including any allegations that TSL markets or sells pelvic mesh products in the United States.

42.

TSL denies the allegations contained in Paragraph 42 of the Master Complaint, including any allegations that TSL advertises, promotes, markets, sells or distributes pelvic mesh products in the United States.

43.

TSL denies the allegations contained in Paragraph 43 of the Master Complaint, including any allegations that TSL markets or sells pelvic mesh products in the United States.

44.

TSL denies the allegations contained in Paragraph 44 of the Master Complaint, including all subparts thereto.

45.

TSL denies the allegations contained in Paragraph 45 of the Master Complaint, including all subparts thereto.

46.

TSL denies the allegations contained in Paragraph 46 of the Master Complaint.

47.

TSL denies the allegations contained in Paragraph 47 of the Master Complaint.

48.

TSL denies the allegations contained in Paragraph 48 of the Master Complaint.

49.

TSL denies the allegations contained in Paragraph 49 of the Master Complaint.

50.

TSL lacks sufficient information to form a belief as to the truth or falsity of the allegations contained in Paragraph 50 of the Master Complaint, and therefore denies same.

51.

TSL denies the allegations contained in Paragraph 51 of the Master Complaint.

52.

After a reasonable investigation, TSL lacks sufficient knowledge and information to form a belief as to the truth or falsity of the allegations contained in Paragraph 52 of the Master Complaint, and therefore denies same.

53.

TSL denies the allegations contained in Paragraph 53 of the Master Complaint.

54.

TSL denies the allegations contained in Paragraph 54 of the Master Complaint.

55.

TSL denies the allegations contained in Paragraph 55 of the Master Complaint.

56.

TSL denies the allegations contained in Paragraph 56 of the Master Complaint.

57.

TSL denies the allegations contained in Paragraph 57 of the Master Complaint, including any allegations that TSL promoted pelvic mesh products in the United States.

58.

TSL denies the allegations contained in Paragraph 58 of the Master Complaint.

59.

TSL denies the allegations contained in Paragraph 59 of the Master Complaint.

60.

TSL denies the allegations contained in Paragraph 60 of the Master Complaint, including any allegations that TSL sells or distributes pelvic mesh products in the United States.

61.

TSL denies the allegations contained in Paragraph 61 of the Master Complaint.

CAUSES OF ACTION

COUNT I: NEGLIGENCE

62.

TSL hereby incorporates by reference its responses to Paragraphs 1-61 of the Master Complaint as if fully set forth herein. To the extent Paragraph 62 contains new allegations, TSL denies same.

63.

The allegations contained in Paragraph 63 of the Master Complaint constitute legal conclusions to which no response is required. To the extent a response is required, TSL denies same.

64.

TSL denies the allegations contained in Paragraph 64 of the Master Complaint, including all subparts thereto.

65.

TSL denies the allegations contained in Paragraph 65 of the Master Complaint, including all subparts thereto.

66.

TSL denies the allegations contained in Paragraph 66 of the Master Complaint, including all subparts thereto.

67.

TSL denies the allegations contained in Paragraph 67 of the Master Complaint.

COUNT II: STRICT LIABILITY – DESIGN DEFECT

68.

TSL hereby incorporates by reference its responses to Paragraphs 1-67 of the Master Complaint as if fully set forth herein. To the extent Paragraph 68 contains new allegations, TSL denies same.

69.

TSL denies the allegations contained in Paragraph 69 of the Master Complaint, including all subparts thereto.

70.

TSL denies the allegations contained in Paragraph 70 of the Master Complaint.

71.

The allegations contained in Paragraph 71 of the Master Complaint constitute legal conclusions to which no response is required. To the extent a response is required, TSL denies same.

COUNT III: STRICT LIABILITY – MANUFACTURING DEFECT

72.

TSL hereby incorporates by reference its responses to Paragraphs 1-71 of the Master Complaint as if fully set forth herein. To the extent Paragraph 72 contains new allegations, TSL denies same.

73.

TSL denies the allegations contained in Paragraph 73 of the Master Complaint.

74.

TSL denies the allegations contained in Paragraph 74 of the Master Complaint.

75.

The allegations contained in Paragraph 75 of the Master Complaint constitute legal conclusions to which no response is required. To the extent a response is required, TSL denies same.

COUNT IV: STRICT LIABILITY – FAILURE TO WARN

76.

TSL hereby incorporates by reference its responses to Paragraphs 1-75 of the Master Complaint as if fully set forth herein. To the extent Paragraph 76 contains new allegations, TSL denies same.

77.

TSL denies the allegations contained in Paragraph 77 of the Master Complaint, including all subparts thereto.

78.

TSL denies the allegations contained in Paragraph 78 of the Master Complaint.

79.

The allegations contained in Paragraph 79 of the Master Complaint constitute legal conclusions to which no response is required. To the extent a response is required, TSL denies same.

COUNT V: BREACH OF EXPRESS WARRANTY

80.

TSL hereby incorporates by reference its responses to Paragraphs 1-79 of the Master Complaint as if fully set forth herein. To the extent Paragraph 80 contains new allegations, TSL denies same.

81.

TSL denies the allegations contained in Paragraph 81 of the Master Complaint.

82.

TSL denies the allegations contained in Paragraph 82 of the Master Complaint.

83.

TSL denies the allegations contained in Paragraph 83 of the Master Complaint.

84.

TSL denies the allegations contained in Paragraph 84 of the Master Complaint.

85.

TSL denies the allegations contained in Paragraph 85 of the Master Complaint.

86.

TSL denies the allegations contained in Paragraph 86 of the Master Complaint.

COUNT VI: BREACH OF IMPLIED WARRANTY

87.

TSL hereby incorporates by reference its responses to Paragraphs 1-86 of the Master Complaint as if fully set forth herein. To the extent Paragraph 87 contains new allegations, TSL denies same.

88.

TSL denies the allegations contained in Paragraph 88 of the Master Complaint.

89.

TSL denies the allegations contained in Paragraph 89 of the Master Complaint.

90.

TSL denies the allegations contained in Paragraph 90 of the Master Complaint.

91.

TSL denies the allegations contained in Paragraph 91 of the Master Complaint.

92.

TSL denies the allegations contained in Paragraph 92 of the Master Complaint.

93.

TSL denies the allegations contained in Paragraph 93 of the Master Complaint.

COUNT VII: LOSS OF CONSORTIUM

94.

TSL hereby incorporates by reference its responses to Paragraphs 1-93 of the Master Complaint as if fully set forth herein. To the extent Paragraph 94 contains new allegations, TSL denies same.

95.

TSL denies the allegations contained in Paragraph 95 of the Master Complaint.

COUNT VIII: PUNITIVE DAMAGES

96.

TSL hereby incorporates by reference all responses to Paragraphs 1-95 of the Master Complaint as if fully set forth herein. To the extent Paragraph 96 contains new allegations, TSL denies same.

97.

TSL denies the allegations contained in Paragraph 97 of the Master Complaint, including any allegations that TSL sells pelvic mesh products in the United States.

98.

TSL denies the allegations contained in Paragraph 98 of the Master Complaint, including any allegations that TSL sells pelvic mesh products in the United States.

99.

TSL denies the allegations contained in Paragraph 99 of the Master Complaint.

100.

TSL denies the allegations contained in Paragraph 100 of the Master Complaint.

101.

TSL denies the allegations contained in Paragraph 101 of the Master Complaint.

102.

TSL denies the allegations contained in Paragraph 102 of the Master Complaint.

103.

TSL denies the allegations contained in Paragraph 103 of the Master Complaint.

104.

TSL denies the allegations contained in Paragraph 104 of the Master Complaint, including any allegations that TSL markets pelvic mesh products in the United States.

105.

TSL denies the allegations contained in Paragraph 105 of the Master Complaint, including any allegations that TSL markets, distributes or sells pelvic mesh products in the United States.

106.

TSL denies the allegations contained in Paragraph 106 of the Master Complaint.

107.

TSL denies the allegations contained in Paragraph 107 of the Master Complaint.

Furthermore, responding to the unnumbered Paragraph following Paragraph 107 of the Master Complaint beginning "WHEREFORE," TSL denies the allegations contained in such Paragraph. TSL further denies each and every allegation not specifically admitted herein. TSL denies that Plaintiffs are entitled to any relief requested in the Complaint.

TSL'S AFFIRMATIVE DEFENSES

TSL alleges and asserts the following defenses in response to the allegations in the Master Complaint.

FIRST DEFENSE

The Master Complaint fails to state a claim or claims upon which relief can be granted under Rule 12 of the Federal Rules of Civil Procedure.

SECOND DEFENSE

This Court lacks personal jurisdiction over TSL such that TSL should be dismissed. TSL specifically raises this defense, makes its objections to the exercise of personal jurisdiction over TSL in this Court, and preserves its rights to seek dismissal by way of subsequent motion.

THIRD DEFENSE

The Master Complaint fails to state claim or claims upon which relief can be granted due to lack of adequate product identification.

FOURTH DEFENSE

The Plaintiffs may be barred from bringing some of the claims alleged in the Master Complaint because the Plaintiffs may lack standing and/or capacity to bring such claims.

FIFTH DEFENSE

The sole proximate cause of the Plaintiffs' damages, if any were sustained, was the negligence of a person or persons or entity for whose acts or omissions TSL was and is in no way liable.

SIXTH DEFENSE

If the Plaintiffs have been damaged, which TSL denies, any recovery by the Plaintiffs is barred to the extent they voluntarily exposed themselves to a known risk and/or failed to mitigate

their alleged damages. To the extent the Plaintiffs have failed to mitigate their alleged damages, any recovery shall not include alleged damages that could have been avoided by reasonable care and diligence.

SEVENTH DEFENSE

The Plaintiffs failed to exercise ordinary care for their own safety such that the Plaintiffs are not entitled to recover.

EIGHTH DEFENSE

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

NINTH DEFENSE

The Plaintiffs' causes of action may be barred by the applicable statute of limitations and/or statute of repose.

TENTH DEFENSE

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

ELEVENTH DEFENSE

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

TWELFTH DEFENSE

There was no causal connection between any alleged defect in the products at issue and Plaintiffs' alleged damages with the result that Plaintiffs are not entitled to recover against TSL in this cause.

THIRTEENTH DEFENSE

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

FOURTEENTH DEFENSE

If the Plaintiffs have been damaged, which TSL denies, such damages were caused by the negligence or fault of persons and/or entities for whose conduct TSL is not legally responsible.

FIFTEENTH DEFENSE

If the Plaintiffs suffered any damages or injuries, which TSL denies, the Plaintiffs' recovery is barred, in whole or in part, or subject to reduction under the doctrine of contributory and/or comparative negligence.

SIXTEENTH DEFENSE

In the further alternative, and only in the event that it is determined that the Plaintiffs are entitled to recover against TSL, recovery should be reduced in proportion to the degree or percentage of negligence, fault or exposure to products attributable to the Plaintiff, any other defendants, third party defendants, or other persons, including any party immune because bankruptcy renders them immune from further litigation, as well as any party, co-defendant, or non-parties with whom the Plaintiffs have settled or may settle in the future.

SEVENTEENTH DEFENSE

If the Plaintiffs have been damaged, which TSL denies, the negligence or fault of the Plaintiff constitutes the sole, intervening, and superseding cause of the Plaintiffs' alleged damages.

EIGHTEENTH DEFENSE

If the Plaintiffs have been damaged, which TSL denies, the negligence or fault of persons and/or entities for whose conduct TSL is not legally responsible constitutes the sole, intervening, and superseding cause of the Plaintiffs' alleged damages.

NINETEENTH DEFENSE

If the Plaintiffs have been damaged, which TSL denies, the actions of persons or entities for whose conduct TSL is not legally responsible and the independent knowledge of these persons or entities of the risks inherent in the use of the products and other independent causes, constitute an intervening and superseding cause of the Plaintiffs' alleged damages.

TWENTIETH DEFENSE

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

TWENTY-FIRST DEFENSE

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

TWENTY-SECOND DEFENSE

TSL made no warranties of any kind, express or implied, including any alleged implied warranty of merchantability or implied warranty of fitness for a particular purpose, or any representations of any nature whatsoever to the Plaintiffs. To the extent applicable, the Plaintiffs' breach of warranty claims are barred by a lack of privity between the Plaintiffs and

TSL. To the extent the Plaintiffs make warranty claims, whether express or implied, the claims are barred or limited by any and all express conditions or disclaimers, by the Plaintiffs' lack of reliance on any such warranties, and by waiver.

TWENTY-THIRD DEFENSE

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

TWENTY-FOURTH DEFENSE

To the extent the Plaintiffs assert a claim for breach of warranty, such claim is barred because the Plaintiffs did not first give notice of any alleged defect of the products to TSL.

TWENTY-FIFTH DEFENSE

TSL neither had nor breached any alleged duty to warn with respect to the products, with the result that the Plaintiffs are not entitled to recover in this cause.

TWENTY-SIXTH DEFENSE

The Plaintiff's failure to warn claims are barred by virtue of the intervention of the learned intermediary or intermediaries to whom TSL discharged its duties to warn.

TWENTY-SEVENTH DEFENSE

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

TWENTY-EIGHTH DEFENSE

The Plaintiffs' alleged damages resulted from independent, unforeseeable, superseding, and/or intervening causes unrelated to any conduct of TSL.

TWENTY-NINTH DEFENSE

If the Plaintiffs recover from TSL, TSL 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.

THIRTIETH DEFENSE

The Plaintiffs' claims are or may be barred, in whole or in part, to the extent that the Plaintiff has released, settled with, entered into an accord and satisfaction, or otherwise compromised their claims. TSL is entitled to a set-off for the entire amount of proceeds the Plaintiffs have or may recover from all other sources.

THIRTY-FIRST DEFENSE

Should TSL be held liable to the Plaintiffs, which liability TSL specifically denies, TSL would be entitled to a set-off for the total of all amounts paid to the Plaintiffs from all collateral sources.

THIRTY-SECOND DEFENSE

TSL asserts any and all defenses, claims, credits, offsets, or remedies available to it under the Restatement (Third) of Torts and reserves the right to amend its Master Answer to file such further pleadings as are necessary to preserve and assert such defenses, claims, credits, offsets, or remedies.

THIRTY-THIRD DEFENSE

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

THIRTY-FOURTH DEFENSE

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

THIRTY-FIFTH DEFENSE

The Plaintiffs' claims are barred because the methods, standards, warnings, and instructions used in manufacturing and/or marketing the products at issue conformed with industry custom/usage standards and/or legislative/administrative/regulatory standards.

THIRTY-SIXTH DEFENSE

The design complained of in the Master Complaint, the alleged defects of the products, and/or any alternative design claimed by the Plaintiffs were not known and, in light of the existing, reasonably-available scientific and technological knowledge, could not have been known at the time the products at issue were designed, manufactured, and sold. Any alleged alternative design was not scientifically or technologically feasible or economically practical.

THIRTY-SEVENTH DEFENSE

TSL 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-EIGHTH DEFENSE

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

THIRTY-NINTH DEFENSE

To the extent the Plaintiffs assert a demand for punitive damages, TSL specifically incorporates by reference any and all standards of limitations regarding the determination and/or enforceability of punitive damages awards that arose in the decisions of *BMW of No. America v. Gore*, 517 U.S. 559 (1996); *Cooper Industries, Inc. v. Leatherman Tool Group, Inc.*, 532 U.S. 424 (2001); *State Farm Mut. Auto Ins. Co. v. Campbell*, 123 S. Ct. 1513 (2003); and *Exxon Shipping Co. v. Baker*, No. 07-219, 2008 U.S. LEXIS 5263 (U.S. June 25, 2008) and their progeny as well as other similar cases under both federal and state law.

FORTIETH DEFENSE

To the extent that the Plaintiffs assert a claim for punitive damages, that claim is in contravention of the rights of TSL under the following constitutional provisions:

1. Plaintiffs' claims for punitive or exemplary damages violate, and are therefore barred by, the Fourth, Fifth, Sixth, Eighth and Fourteenth Amendments to the Constitution of the United States of America, and the analogous provisions of the applicable State Constitutions, on grounds including the following:

(a) it is a violation of the Due Process and Equal Protection Clauses of the Fourteenth Amendment of the United States Constitution, and the analogous provisions of the applicable State Constitutions, to impose punitive damages, which are penal in nature, against a civil defendant upon the Plaintiffs satisfying a burden of proof which is less than the "beyond a reasonable doubt" burden of proof required in criminal cases;

(b) the procedures pursuant to which punitive damages are awarded may result in the award of joint and several judgments against multiple defendants for different alleged acts of wrongdoing, which infringes upon the Due Process and Equal Protection Clauses of the Fourteenth Amendment of the United States Constitution, and the analogous provisions of the applicable State Constitutions;

(c) the procedures to which punitive damages are awarded fail to provide a reasonable limit on the amount of the award against defendant, which thereby violates the Due Process Clause of the Fourteenth Amendment of the United States Constitution, and the analogous provisions of the applicable State Constitutions;

(d) the procedures pursuant to which punitive damages are awarded fail to provide specific standards for the amount of the award of punitive damages which thereby violates the Due Process Clause of the Fourteenth Amendment of the United States Constitution, and the analogous provisions of the applicable State Constitutions;

(e) the procedures pursuant to which punitive damages are awarded result in the imposition of different penalties for the same or similar acts, and thus violate the

Equal Protection Clause of the Fourteenth Amendment of the United States Constitution, and the analogous provisions of the applicable State Constitutions;

(f) the procedures pursuant to which punitive damages are awarded permit the imposition of punitive damages in excess of the maximum criminal fine for the same or similar conduct, which thereby infringes upon the Due Process Clause of the Fifth and Fourteenth Amendments and the Equal Protection Clause of the Fourteenth Amendment of the United States Constitution, and the analogous provisions of the applicable State Constitutions;

(g) the procedures pursuant to which punitive damages are awarded permit the imposition of excessive fines in violation of the Eighth Amendment of the United States Constitution, and the analogous provisions of the applicable State Constitutions;

(h) the award of punitive damages to the Plaintiffs in this action would constitute a deprivation of property without due process of law; and

(i) the procedures pursuant to which punitive damages are awarded permit the imposition of an excessive fine and penalty.

FORTY-FIRST DEFENSE

The Plaintiffs' claims are barred, in whole or in part, because Plaintiffs assumed the risks disclosed by the FDA-approved product labeling, the prescribing physicians, or other persons or entities.

FORTY-SECOND DEFENSE

There should be no recovery against TSL for any failure to warn or inadequacy of warning, because at all pertinent times, Plaintiffs possessed or should have possessed good and adequate knowledge which negated any need for warning.

FORTY-THIRD DEFENSE

If Plaintiffs were injured or damaged as alleged, no injury or damages being admitted, such injuries were not caused by a product manufactured by TSL.

FORTY-FOURTH DEFENSE

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

FORTY-FIFTH DEFENSE

The Plaintiffs' product liability claims are barred because the benefits of the products outweighed their risks.

FORTY-SIXTH DEFENSE

Venue may be improper in any individual case where the Plaintiff does not reside in the forum wherein her Complaint was filed or cannot otherwise establish an independent basis for venue in that forum and any such claims should be dismissed on this basis.

FORTY-SEVENTH DEFENSE

Plaintiffs' case may be subject to dismissal or transfer under the doctrine of forum non conveniens and/or 28 U.S.C. §§ 1404 and 1406.

FORTY-EIGHTH DEFENSE

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

FORTY-NINTH DEFENSE

The Plaintiffs have failed to plead their fraud claims with the particularity required under the applicable state's statutory and/or common law.

FIFTIETH DEFENSE

If it should be proven that any product manufactured by TSL was involved herein as alleged, then the state of medical and scientific knowledge or published literature or other materials reflecting the state of medical and scientific knowledge at all times relevant hereto, was such that TSL neither knew nor could have known that the products presented a foreseeable risk of harm in its normal and expected use.

FIFTY-FIRST DEFENSE

The damages claimed by Plaintiffs are not recoverable, in whole or in part, under the various applicable states' laws.

FIFTY-SECOND DEFENSE

Plaintiffs' claims may be barred by failure to join indispensable parties.

FIFTY-THIRD DEFENSE

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

FIFTY-FOURTH DEFENSE

TSL 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

TSL hereby requests a trial by jury on all issues so triable, and reserves the right to seek to have a trial before twelve jurors.

WHEREFORE, TSL avers that Plaintiffs are not entitled to the relief demanded in the Master Complaint, and TSL, having fully answered, prays that this action be dismissed and that it be awarded its costs in defending this action and that it be granted such other and further relief as the Court deems just and appropriate.

Dated: March 26, 2012

/s/ Deborah A. Moeller
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