

**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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