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

CHARLESTON DIVISION

IN RE: NEOMEDIC PELVIC REPAIR
SYSTEM PRODUCTS LIABILITY LITIGATION

MDL 2511

THIS DOCUMENT RELATES TO ALL CASES

PRETRIAL ORDER # 9

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

To eliminate the delays associated with the transfer of cases filed in or transferred from other federal district courts to this Court as part of MDL No. 2511, to promote efficiency and to accommodate plaintiffs who wish to bring claims against defendants in more than one pelvic repair system MDL, it is **ORDERED** as follows:

A. General.

(1) The attached Master Long Form Complaint and Jury Demand ("Master Complaint") against Desarrollo e Investigación Médica Aragonesa, S.L., ("DIMA"), Neomedic International, S.L., Neomedic Inc. and Specialties Remeex International, S.L. (sometimes collectively "Neomedic" or the "Neomedic Defendants") (Exhibit A), the Short Form Complaint for new cases against the Neomedic Defendants and others (Exhibit B), and the Amended Short Form Complaint for existing cases (Exhibit C), have been presented to the Court, and the Court **DIRECTS** that the Clerk file the same.

(2) The Neomedic Defendants shall file their Master Answers on a date to be set by the court.

(3) The Court refers the parties to Exhibit D, "Amended Filing Instructions for Short Form Complaints and Amended Short Form Complaints," which is appended to this Order.

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

B. Directly Filed Cases.[1]

(1) Subsequent to the filing of this Order, all actions initially filed directly in the Southern District of West Virginia in MDL 2511 against defendants named in the attached Master Complaint shall be filed by the Short Form Complaint. **If a Short Form Complaint is not utilized, the complaint will be struck from the docket; the plaintiff will have to file a Short Form Complaint and pay a second filing fee.**

(2) Subsequent to the filing of this Order, if a plaintiff filing a new case alleges she was implanted with pelvic repair system products manufactured or marketed by defendants in more than one MDL (i.e., plaintiff alleges that she was implanted with a Neomedic product and a product manufactured by a defendant named in a Master Long Form Complaint in MDL Nos. 2187, 2325, 2326, 2327, 2387 or 2440) and has claims against such defendants, then the plaintiff may choose in which MDL to initially file. However, such a plaintiff must check off each applicable defendant on the Short Form Complaint.

(3) For cases filed directly in MDL No. 2511 prior to the entry of this Order, each plaintiff shall file the attached Amended Short Form Complaint within ninety (90) days of entry

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

of this Order, so long as the plaintiff names only defendants named in the Master Complaint in this MDL (and any defendants named in the Master Long Form Complaints in the other MDLs identified above).

(4) If a plaintiff filed directly in the Southern District of West Virginia in this MDL prior to the entry of this Order and named defendants other than those named in Master Complaints in this or the other five MDLs cited above, direct filing was inappropriate, and the plaintiff should either dismiss the inappropriately named defendants and file an **Amended** Short Form Complaint within 90 days of the entry of this Order or dismiss the direct filed case without prejudice and pursue her claims in her home district with subsequent transfer to this District through the MDL Panel. A plaintiff need not move to amend.

(5) This Court shall not be deemed to be the "transferor court" simply by virtue of the action having been directly filed in this District in this MDL. The direct filing of actions in MDL No. 2511 in the Southern District of West Virginia is solely for the purposes of consolidated discovery and related pretrial proceedings as provided by 28 U.S.C. § 1407; the parties submit to this Court's personal jurisdiction and venue in the Southern District for those purposes only. The defendants do not intend to waive their rights to transfer any case in this MDL to a court of proper venue under 28 U.S.C. § 1406(a) upon completion of all pretrial proceedings applicable to a case directly filed in the Southern District. At the conclusion of all pretrial proceedings, the Court, pursuant to 28 U.S.C. § 1404(a), will transfer each case filed directly in the Southern District to a federal district court of proper venue as defined in 28 U.S.C. § 1391, based on the recommendations of the parties to that case, or on its own determination after briefing from the parties if they cannot agree. In an effort to avoid serial objections to venue in a single action, plaintiff shall identify in response to a defendant's venue objection, proposed alternative venues

in order of preference, so that the Court can consider at the same time, any objections to plaintiff's alternative choices.

C. Cases Transferred by the Judicial Panel on Multidistrict Litigation ("MDL Panel").[2]

(1) For those cases transferred to MDL No. 2511 from another Federal District Court by the MDL Panel **after** the entry of this Order, those plaintiffs, who only named defendants named in Master Complaints in this or in one or more of the other six MDLs cited above (2187, 2325, 2326, 2327, 2387, 2440), shall file an **Amended** Short Form Complaint within 30 days of receipt of receipt of the member case number in MDL No. 2511.

For those cases transferred to MDL No. 2511 by the MDL Panel before or after the entry of this Order, wherein the plaintiff has named defendants named in Master Complaints in this or the other five MDLs noted above **AND** additional defendant(s) other than those named in Master Complaints, the plaintiff may not file an Amended Short Form Complaint, unless the plaintiff chooses to dismiss the additional defendants.

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

D. All Cases.

(1) If a plaintiff in an existing case files an Amended Short Form Complaint in compliance with this Order that omits a defendant previously named in the prior complaint, the plaintiff is relieved of complying with Rule 41 of the Federal Rules of Civil Procedure in order

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

to properly dismiss that defendant. Rather, where a plaintiff files an Amended Short Form Complaint, the Court instructs the Clerk, until further notice, to add defendants named in MDLs 2187, 2325, 2326, 2327, 2387, 2440 and 2511 as indicated on the Amended Short Form Complaints and to terminate any defendant not so indicated. If a plaintiff names an additional defendant listed on a Short Form Complaint but not named in the prior complaint, the plaintiff must comply with Rule 4 as to the new defendant.

(2) To the extent any change in parties on an Amended Short Form Complaint suggests that the case should be in a different MDL, an Amended Short Form Complaint should be accompanied by a motion to transfer MDLs. The court will post a PDF fillable form entitled "Motion to Transfer MDL" on the Court's website. The Court strongly encourages use of this form.

(3) **Plaintiffs should not add parties to the Short Form or Amended Short Form Complaints or file versions of the Short Form or Amended Short Form Complaints that do not exactly match such complaints found on the Court's website. The Court will strike Short Form and Amended Short Form Complaints adding any party not named in a Master or Amended Master Complaint in MDLs 2187, 2325, 2326, 2327, 2387, 2440 or 2511. In the event a directly filed Short Form Complaint contains defendants not named in Master or Amended Master Complaints, the striking of such a pleading filed in a new case will require refiling and payment of a second filing fee.**

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

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

(6) The Neomedic Defendants named in the Master Complaint, DIMA, Neomedic International, S.L., Neomedic Inc. and Specialties Remeex International, S.L., are not required to file answers to Short Form or Amended Short Form Complaints. An Entry of Appearance (including an appearance entered prior to the filing of the Short Form Complaint) by an attorney representing such a defendant shall constitute a denial of all allegations in the Short Form or Amended Short Form Complaint filed against any of the defendants named in the Master Complaint and an assertion of all defenses that are included in the Master Answers of the Neomedic Defendants once they are filed.

(7) If a defendant in MDL Nos. 2187, 2325, 2326, 2327, 2387 or 2440 is named in a case in this MDL, an Entry of Appearance (including an appearance entered prior to the filing of the Short Form or Amended Short Form Complaint) by an attorney representing such a defendant shall constitute a denial of all allegations in the Short Form or Amended Short Form Complaint filed against any such defendant. In addition, the Master Responsive Pleading filed by that defendant in its designated MDL is deemed to be filed in that particular case.

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

(9) The Neomedic Defendants shall have thirty (30) days from the entry of this Order to file any motion asserting that the Master Complaint fails to state a claim upon which relief

may be granted, pursuant to Rule 12(b)(6), and plaintiffs shall have twenty (20) days thereafter to respond to the same.

The court **DIRECTS** the Clerk to file a copy of this order in 2:14-md-2511 and it shall apply to each member related case previously transferred to, removed to, or filed in this district, which includes counsel in all member cases up to and including civil action number 2:14-cv-15285. In cases subsequently filed in this district, a copy of the most recent pretrial order will be provided by the Clerk to counsel appearing in each new action at the time of filing of the complaint. In cases subsequently removed or transferred to this court, a copy of the most recent pretrial order will be provided by the Clerk to counsel appearing in each new action upon removal or transfer. It shall be the responsibility of the parties to review and abide by all pretrial orders previously entered by the court. The orders may be accessed through the CM/ECF system or the court's website at www.wvsd.uscourts.gov.

ENTER: May 29, 2014

JOSEPH R. GOODWIN
UNITED STATES DISTRICT JUDGE

Exhibit A

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

NEOMEDIC PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION

CHARLESTON DIVISION

MDL No. 2511
In Re: Neomedic Pelvic Repair System Products Liability Litigation

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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.

I. PARTIES

A. Plaintiffs

1. Plaintiffs include women who had one or more of Defendants' Pelvic Mesh Devices (defined below) inserted in their bodies to treat medical conditions, primarily pelvic organ prolapse and stress urinary incontinence.

2. Plaintiffs also include the spouses, as well as others with standing to file claims arising from Defendants' Products.

B. Defendants

3. Defendant Desarrollo e Investigación Médica Aragonesa, S.L. ("DIMA") is a corporation organized and existing under the laws of the Kingdom of Spain maintaining its principal place of business at Poligono Industrial Mediavega Parcela 2.9, Calatayud, Zaragoza, Kingdom of Spain 50300, making it a foreign citizen.

4. Defendant Neomedic International, S.L. ("Neomedic International") is a corporation organized and existing under the laws of the Kingdom of Spain maintaining its principal place of business at C/Maestrat, 41-43 Terrassa, Barcelona, Spain 08225, making it a foreign citizen. Neomedic International is registered with the FDA as a foreign exporter and specification developer of the "Needleless Sling."

5. Defendant Neomedic Inc. ("Neomedic") was a corporation organized and existing under the laws of Florida, with its principal place of business at 2655 Le Jeune Road, #810, Coral Gables, Florida, 33134, making it a citizen and resident of the State of Florida, at the time of the events giving rise to this cause of action. Defendant Neomedic Inc. was the United States headquarters of Neomedic International, S.L. at the time of the events giving rise to this cause of action.

6. Defendant Specialties Remeex International, S.L. ("SRI") is a corporation organized and existing under the laws of the Kingdom of Spain maintaining its principal place of business at C/Tren De Baix, 55 Baixos Terrassa, Barcelona, Kingdom of Spain

08223, making it a foreign citizen. Defendant SRI is registered with the FDA as the owner/operator of Neomedic International.

7. Other named Defendants against whom Plaintiffs may be making claims include: Boston Scientific Corporation ("Boston Scientific");

8. American Medical Systems, Inc. ("AMS");

9. Johnson & Johnson;

10. Ethicon, Inc.;

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

12. Sofradim Production SAS ("Sofradim");

13. Tissue Science Laboratories Limited ("TSL");

14. Mentor Worldwide LLC;

15. Coloplast Corp.;

16. Cook Incorporated;

17. Cook Biotech, Inc.;

18. Cook Medical, Inc.; and / or

19. Defendants, JOHN DOES 1-20 (fictitious names) are entities and/or persons who are liable to Plaintiffs, but who have not yet been identified despite reasonable due diligence on the part of Plaintiffs.

20. To the extent Plaintiffs have asserted claims against one or more of the named Defendants in Paragraphs 7 through 19, Plaintiffs hereby incorporate by reference as if fully set forth herein the Master Long Form Complaint of that Defendant's respective MDL.

21. All acts and omissions of the above-referenced Defendants 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.

II. JURISDICTION AND VENUE

22. 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 $75,000.00.

23. Venue and personal jurisdiction in a particular forum are alleged in each individual Short Form Complaint, and venue and personal jurisdiction are generally asserted herein. 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.

24. 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.

III. DEFENDANTS' PELVIC MESH PRODUCTS

25. At all times material to this action, Defendants have designed, patented, manufactured, packaged, labeled, marketed, sold, and distributed a line of pelvic mesh products, which are delineated below. These products were designed primarily for the purposes of treating stress urinary incontinence and pelvic organ prolapse. Each of these products was cleared for sale in the United States after the Defendants made assertions to the Food and Drug Administration of "Substantial Equivalence" under Section 510(k) of the Food, Drug and Cosmetic Act; this clearance process does not require the applicant to prove safety or efficacy. One or more of Defendants' pelvic mesh products were implanted in Plaintiff as indicated in the Short Form Complaint.

26. The products include those known as Contasure Needleless Sling System, Needleless Sling System, Remeex System/TRT Remeex System, KIM System, Uplift, and Surelift, as well as any variations of these products and any unnamed Neomedic pelvic mesh product designed and sold for similar purposes, inclusive of the instruments and procedures for implementation.

27. These products are collectively referenced as Defendants' "Pelvic Mesh Products" or "Products."

IV. FACTUAL BACKGROUND

28. 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 material derived from animal tissue. Animal 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

29. 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.

30. On October 20, 2008, the Food and Drug Administration ("FDA") issued a Public Health Notification that described over 1,000 reports of complications (otherwise known as "adverse events") that had been reported over a three year period relating to pelvic mesh products. Although the FDA notice did not identify the transvaginal mesh manufacturers by name, a review of the FDA's MAUDE database indicates that the Defendant is one of the manufacturers of the products that are the subject of the notification. In 2008, the FDA described the complications associated with pelvic mesh products as "rare."

31. 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).

32. 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).

33. 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.

34. 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."

35. 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."

36. 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).

37. 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."

38. 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."

39. 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."

40. 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.

41. 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.

42. 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.

43. 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.

44. 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.

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

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

47. 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.

48. 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.

49. 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.

50. 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.

51. 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.

52. 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.

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

54. 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.

55. 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.

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

57. 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.

58. 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.

59. 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.

60. 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.

61. 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.

62. 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.

63. 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.

64. 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.

65. 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.

66. 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.

67. 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

68. Paragraphs 1-67 of this Master Complaint are hereby incorporated by reference as if fully set forth herein.

69. 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.

70. 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 Complain.
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.

71. 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.

72. 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.

73. 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.

74. WHEREFORE, Plaintiffs demand judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and request compensatory damages, punitive damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

COUNT II: STRICT LIABILITY – DESIGN DEFECT

75. Plaintiffs incorporate by reference paragraphs 1-74 of this Complaint as if fully set forth herein.

76. 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.

77. 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.

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

79. WHEREFORE, Plaintiffs demand judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and request compensatory damages, punitive damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

COUNT III: STRICT LIABILITY – MANUFACTURING DEFECT

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

81. 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.

82. 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.

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

84. WHEREFORE, Plaintiffs demand judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and request compensatory damages, punitive damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

COUNT IV: STRICT LIABILITY – FAILURE TO WARN

85. Plaintiffs incorporate by reference paragraphs 1-84 of this Complaint as if fully set forth herein.

86. 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.

87. 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.

88. 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).

89. WHEREFORE, Plaintiffs demand judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and request compensatory damages, punitive damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

COUNT V: STRICT LIABILITY – DEFECTIVE PRODUCT

90. Plaintiffs incorporate by reference paragraphs 1-89 of this Complaint as if fully set forth herein.

91. At the time of Plaintiffs' injuries, the Defendants' Pelvic Mesh Products were defective and unreasonably dangerous to foreseeable consumers, patients, and users, including Plaintiffs, and the warnings labels, and instructions were deficient.

92. The Defendants' Pelvic Mesh Products are dangerous and defective, unfit and unsafe for their intended and reasonably foreseeable uses, and do not meet or perform to the expectations of patients and their health care providers.

93. Plaintiffs from Alaska, Arizona, California, , Florida, Hawaii, Illinois, Iowa, Maryland, Massachusetts, Minnesota, Missouri, Nebraska, Nevada, New Hampshire, , New Mexico, New York, North Dakota, Oklahoma, Oregon, Rhode Island, Utah, Vermont, Washington, D.C., West Virginia, Wisconsin, Wyoming and such other states where the common law, the Restatement of Torts (Second) and/or the Restatement of Torts (Third) are adopted, bring strict product liability claims under the common law, Section 402A of the Restatement of Torts (Second), and/or Restatement of Torts (Third)) against Defendants.

94. Plaintiffs from jurisdictions that provide a statutory cause of action for strict liability assert each of these claims against Defendants.

95. As a proximate result of the Defendants' design, manufacture, marketing, sale, and distribution of the Pelvic Mesh Products, Plaintiffs have been injured, often catastrophically, and sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort, and consortium, economic damages, and death.

96. WHEREFORE, Plaintiffs demand judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and request compensatory damages, punitive damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

COUNT VI: BREACH OF EXPRESS WARRANTY

97. Plaintiffs incorporate by reference paragraphs 1-96 of this Complaint as if fully set forth herein.

98. 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.

99. 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.

100. 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.

101. 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.

102. 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.

103. 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.

104. WHEREFORE, Plaintiffs demand judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and request compensatory damages, punitive damages, together with interest, costs of suit, attorneys’ fees, and such further relief as the Court deems equitable and just.

COUNT VII: BREACH OF IMPLIED WARRANTY

105. Plaintiffs incorporate by reference paragraphs 1-104 of this Complaint as if fully set forth herein.

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

107. 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.

108. 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.

109. 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.

110. 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.

111. 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.

112. WHEREFORE, Plaintiffs demand judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and request compensatory damages, punitive damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

COUNT VIII: FRAUDULENT CONCEALMENT

113. Plaintiffs incorporate by reference paragraphs 1-112 of this Complaint as if fully set forth herein.

114. Throughout the relevant time periods, it was known or knowable to Defendant(s) that their Pelvic Mesh Products caused large numbers of complications that were not rare. Moreover, it was known or knowable to Defendant(s) that the surgical technique and training of implanting physicians was not the cause of the adverse events associated with these devices. It was known or knowable to Defendant(s) that the safety and efficacy of its Pelvic Mesh Products had not been proven with respect to, among

other things, the product, its components, its performance and its method of insertion. It was known or knowable to Defendant(s) that there was no evidence that its Pelvic Mesh Products were safe and effective and, in fact the evidence that was known or knowable to Defendant(s) was that its Pelvic Mesh Products were not safe and effective. Defendant continued to represent that its Pelvic Mesh Products were safe and effective.

115. Despite what was known or knowable to Defendant(s) about the lack of safety and efficacy of its Pelvic Mesh Products through the relevant time periods, Defendant(s) failed to disclose this information to the plaintiffs, to their physicians or to the public at large.

116. Despite this knowledge, Defendant(s) continued to market and sell their Pelvic Mesh Products and procedures as being safe and efficacious with evidence to the contrary.

117. At all times mentioned herein, Defendants, and each of them, had the duty and obligation to disclose to Plaintiff and to her physicians, the true facts concerning the aforesaid Products, that is, that said Products were dangerous and defective, lacking efficacy for its purported use and lacking safety in normal use, and how likely it was to cause serious consequences to users including permanent and debilitating injuries. Defendants concealed these material facts prior to the time that Plaintiffs were implanted with Defendants' Pelvic Mesh Products.

118. Defendants were under a duty to Plaintiffs to disclose and warn of the defective nature of the Products because:

a. Defendants were in a superior position to know the true quality, safety and efficacy of the Defendants' Pelvic Mesh Products;
b. Defendants knowingly made false claims about the safety and quality of the Defendants' Pelvic Mesh Products in the documents and marketing materials Defendants provided to the FDA, physicians, and the general public; and
c. Defendants fraudulently and affirmatively concealed the defective nature of the Defendants' Pelvic Mesh Products from Plaintiffs.

119. The facts concealed and/or not disclosed by Defendants to Plaintiffs were material facts that a reasonable person would have considered to be important in deciding whether or not to purchase and/or use the Defendants' Pelvic Mesh Products.

120. At all times herein mentioned, Defendants, and each of them, willfully, intentionally, and maliciously concealed facts as set forth above from Plaintiffs and their physicians, and therefore, Plaintiffs, with the intent to defraud as herein alleged.

121. Defendants intentionally concealed and/or failed to disclose the true defective nature of the Products so that Plaintiffs would request and purchase the Defendants' Pelvic Mesh Products, and that her healthcare providers would dispense, prescribe, and recommend the Defendants' Pelvic Mesh Products, and Plaintiffs

justifiably acted or relied upon, to her detriment, the concealed and/or non-disclosed facts as evidenced by her purchase of the Defendants' Pelvic Mesh Products.

122. At all times herein mentioned, neither Plaintiffs nor their physicians were aware of the facts set forth above, and had they been aware of said facts, they would not have acted as they did, that is, would not reasonably relied upon said representations of safety and efficacy and utilized the Pelvic Mesh Products for treatment of stress urinary incontinence and pelvic organ prolapse. Defendants' failure to disclose this information was a substantial factor in Plaintiffs' physicians selecting defendant(s) Pelvic Mesh Products and procedures for treatment of stress urinary incontinence and pelvic organ prolapse. This failure to disclose also resulted in the provision of incorrect and incomplete information to the Plaintiff-patients.

123. As a direct and proximate result of this conduct, Plaintiffs were injured.

124. WHEREFORE, Plaintiffs demand judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and request compensatory damages, punitive damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

COUNT IX: CONSTRUCTIVE FRAUD

125. Plaintiffs incorporate by reference paragraphs 1-124 of this Complaint as if fully set forth herein.

126. Defendants are in a unique position of knowledge concerning the quality, safety and efficacy of the Defendants' Pelvic Mesh Products, which knowledge is not possessed by Plaintiffs or their physicians, and Defendants thereby hold a position of superiority over Plaintiffs and their physicians.

127. Despite their unique and superior knowledge regarding the defective nature of the Defendants' Pelvic Mesh Products, Defendants continue to suppress, conceal, omit, and/or misrepresent information to Plaintiffs, the medical community, and/or the FDA, concerning the severity of risks and the dangers inherent in the intended use of the Defendants' Pelvic Mesh Products, as compared to other products and forms of treatment.

128. For example, scientists in the recent study published in Obstetrics & Gynecology, August, 2010, found that the complication rate was so high that the clinical trial was halted early.

129. Defendants have concealed and suppressed material information, including limited clinical testing, that would reveal that the Defendants' Pelvic Mesh Products had a higher risk of adverse effects, in addition to, and exceeding those associated with alternative procedures and available devices. Instead, Defendants have misrepresented the safety and efficacy of the Products.

130. Upon information and belief, Defendants' misrepresentations are designed to induce physicians and Plaintiffs to prescribe, dispense, recommend and/or purchase the

Defendants' Pelvic Mesh Products. Plaintiffs and the medical community have relied upon Defendants' representations.

131. Defendants took unconscionable advantage of their dominant position of knowledge with regard to Plaintiffs and their medical providers and engaged in constructive fraud in their relationship with Plaintiffs and their medical providers. Plaintiffs reasonably relied on Defendants' representations.

132. As a proximate result of the Defendants' conduct, Plaintiffs have been injured, and sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort, and consortium, economic damages, and death.

133. WHEREFORE, Plaintiffs demand judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and request compensatory damages, punitive damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

COUNT X: DISCOVERY RULE, TOLLING, AND FRAUDULENT CONCEALMENT

134. Plaintiffs incorporate by reference paragraphs 1-133 of this Complaint as if fully set forth herein.

135. Plaintiffs assert all applicable state statutory and common law rights and theories related to the tolling or extension of any applicable statute of limitations,

including equitable tolling, class action tolling, delayed discovery, discovery rule, and fraudulent concealment.

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

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

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

were the direct and proximate result of the wrongful acts and omissions of the Defendant(s).

COUNT XI: NEGLIGENT MISREPRESENTATION

139. Plaintiffs incorporate by reference paragraphs 1-138 of this Complaint as if fully set forth herein.

140. Defendants had a duty to accurately and truthfully represent to the medical and healthcare community, Plaintiffs, and the public, that the Pelvic Mesh Products had not been adequately tested and found to be safe and effective for the treatment of incontinence and prolapse. The representations made by Defendants, in fact, were false.

141. Defendants failed to exercise ordinary care in the representations concerning the Pelvic Mesh Products while they were involved in their manufacture, sale, testing, quality assurance, quality control, and distribution in interstate commerce, because Defendants negligently misrepresented the Pelvic Mesh Products' high risk of unreasonable, dangerous, adverse side effects.

142. Defendants breached their duty in representing that the Defendants' Pelvic Mesh Products have no serious side effects different from older generations of similar products and/or procedures to Plaintiffs, Plaintiffs' physicians, and the medical and healthcare community.

143. As a foreseeable, direct and proximate result of the negligent misrepresentation of Defendants as set forth herein, Defendants knew, and had reason to

know, that the Pelvic Mesh Products had been insufficiently tested, or had not been tested at all, and that they lacked adequate and accurate warnings, and that they created a high risk, and/or higher than acceptable risk, and/or higher than reported and represented risk, of adverse side effects, including, erosion, pain and suffering, surgery to remove the Products, and other severe and personal injuries, which are permanent and lasting in nature.

144. As a direct and proximate result of the Defendants' conduct, Plaintiffs have been injured, and sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort, and consortium, economic damages, and death.

145. WHEREFORE, Plaintiffs demand judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and request compensatory damages, punitive damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

COUNT XII :NEGLIGENT INFLICTION OF EMOTIONAL DISTRESS

146. Plaintiffs incorporate by reference paragraphs 1-145 of this Complaint as if fully set forth herein.

147. Defendants carelessly and negligently manufactured, designed, developed, tested, labeled, marketed and sold the Defendants' Pelvic Mesh Products to Plaintiffs, carelessly and negligently concealing the harmful effects of the Defendants' Pelvic Mesh

Products from Plaintiffs, and carelessly and negligently misrepresented the quality, safety and efficacy of the Products.

148. Plaintiffs were directly impacted by Defendants' carelessness and negligence, in that Plaintiffs have sustained and will continue to sustain emotional distress, severe physical injuries and/or death, economic losses, and other damages as a direct result of being implanted with the Pelvic Mesh Products sold and distributed by Defendants and/or because of the nature of their relationship to the individual implanted with the Pelvic Mesh Products.

149. As a direct and proximate result of the Defendants' conduct, Plaintiffs have been injured, and sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort, and consortium, economic damages, and death.

150. WHEREFORE, Plaintiffs demand judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and request compensatory damages, punitive damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

COUNT XIII: VIOLATION OF CONSUMER PROTECTION LAWS

151. Plaintiffs incorporate by reference paragraphs 1-150 of this Complaint as if fully set forth herein.

152. Plaintiffs purchased and used the Defendants' Pelvic Mesh Products primarily for personal use and thereby suffered ascertainable losses as a result of Defendants' actions in violation of the consumer protection laws.

153. Had Defendants not engaged in the deceptive conduct described herein, Plaintiffs would not have purchased and/or paid for the Defendants' Pelvic Mesh Products, and would not have incurred related medical costs and injury.

154. Defendants engaged in wrongful conduct while at the same time obtaining, under false pretenses, monies from Plaintiffs for the Pelvic Mesh Products that would not have been paid had Defendants not engaged in unfair and deceptive conduct.

155. Unfair methods of competition or deceptive acts or practices that were proscribed by law, including the following:

156. Representing that goods or services have characteristics, ingredients, uses benefits or quantities that they do not have;

157. Advertising goods or services with the intent not to sell them as advertised; and,

158. Engaging in fraudulent or deceptive conduct that creates a likelihood of confusion or misunderstanding.

159. Plaintiffs were injured by the cumulative and indivisible nature of Defendants' conduct. The cumulative effect of Defendants' conduct directed at patients,

physicians and consumers was to create demand for and sell the Defendants' Pelvic Mesh Products. Each aspect of Defendants' conduct combined to artificially create sales of the Defendants' Pelvic Mesh Products.

160. Defendants have a statutory duty to refrain from unfair or deceptive acts or trade practices in the design, labeling, development, manufacture, promotion, and sale of the Defendants' Pelvic Mesh Products.

161. Had Defendants not engaged in the deceptive conduct described above, Plaintiffs would not have purchased and/or paid for the Products, and would not have incurred related medical costs.

162. Defendants' deceptive, unconscionable, or fraudulent representations and material omissions to patients, physicians and consumers, including Plaintiffs, constituted unfair and deceptive acts and trade practices in violation of the state consumer protection statutes listed below.

163. Defendants' actions, as complained of herein, constitute unfair competition or unfair, unconscionable, deceptive or fraudulent acts, or trade practices in violation of state consumer protection statutes, as listed below.

164. Defendants have engaged in unfair competition or unfair or deceptive acts or trade practices or have made false representations in violation of the statutory provisions of the Plaintiffs' respective states.

165. Under the applicable statutes to protect consumers against unfair, deceptive, fraudulent and unconscionable trade and business practices and false advertising, Defendants are the suppliers, manufacturers, advertisers, and sellers, who are subject to liability under such legislation for unfair, deceptive, fraudulent and unconscionable consumer sales practices.

166. Defendants violated the statutes that were enacted in these states to protect consumers against unfair, deceptive, fraudulent and unconscionable trade and business practices and false advertising, by knowingly and falsely representing that the Defendants' Pelvic Mesh Products were fit to be used for the purpose for which they were intended, when in fact they were defective and dangerous, and by other acts alleged herein. These representations were made in marketing and promotional materials.

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

168. Defendants had actual knowledge of the defective and dangerous condition of the Defendants' Pelvic Mesh Products and failed to take any action to cure such defective and dangerous conditions.

169. Plaintiffs and the medical community relied upon Defendants' misrepresentations and omissions in determining which product and/or procedure to undergo and/or perform (if any).

170. Defendants' deceptive, unconscionable or fraudulent representations and material omissions to patients, physicians and consumers, constituted unfair and deceptive acts and practices.

171. By reason of the unlawful acts engaged in by Defendants, and as a direct and proximate result thereof, Plaintiffs have suffered ascertainable losses and damages.

172. As a direct and proximate result of Defendants' violations of the states' consumer protection laws, Plaintiffs have sustained economic losses, injuries and other damages and are entitled to statutory and compensatory damages in an amount to be proven at trial.

173. WHEREFORE, Plaintiffs demand judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and request restitution and disgorgement of profits, together with interest, cost of suit, attorneys' fees, and all such other and further relief as this Court deems just and proper.

COUNT XIV: GROSS NEGLIGENCE

174. Plaintiffs incorporate by reference paragraphs 1-173 of this Complaint as if fully set forth herein.

175. The wrongs done by Defendants were aggravated by the kind of malice, fraud, and grossly negligent disregard for the rights of others, the public, and Plaintiffs for which the law would allow, and which Plaintiffs will seek at the appropriate time under governing law for the imposition of exemplary damages, in that Defendants' conduct, including the failure to comply with applicable federal standards: was specifically intended to cause substantial injury to Plaintiffs; or when viewed objectively from Defendants' standpoint at the time of the conduct, involved an extreme degree of risk, considering the probability and magnitude of the potential harm to others, and Defendants were actually, subjectively aware of the risk involved, but nevertheless proceeded with conscious indifference to the rights, safety, or welfare of others; or included a material representation that was false, with Defendants, knowing that it was false or with reckless disregard as to its truth and as a positive assertion, with the intent that the representation is acted on by Plaintiffs.

176. Plaintiffs relied on the representation and suffered injury as a proximate result of this reliance.

177. Plaintiffs therefore will seek to assert claims for exemplary damages at the appropriate time under governing law in an amount within the jurisdictional limits of the Court.

178. Plaintiffs also allege that the acts and omissions of named Defendants, whether taken singularly or in combination with others, constitute gross negligence that proximately caused the injuries to Plaintiffs. In that regard, Plaintiffs will seek exemplary

damages in an amount that would punish Defendants for their conduct and which would deter other manufacturers from engaging in such misconduct in the future.

179. WHEREFORE, Plaintiffs demand judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and request compensatory damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

COUNT XV: UNJUST ENRICHMENT

180. Plaintiffs incorporate by reference paragraphs 1-179 of this Complaint as if fully set forth herein.

181. Plaintiffs paid for the Defendants' Pelvic Mesh Products for the purpose of treatment of stress urinary incontinence and/ or pelvic organ prolapse or other similar conditions.

182. Defendants have accepted payment by Plaintiffs and others on Plaintiffs' behalf for the purchase of the Defendants' Pelvic Mesh Products.

183. Plaintiffs have not received the safe and effective medical devices for which they paid.

184. It would be inequitable for Defendants to keep this money since Plaintiffs did not in fact receive a safe and effective medical device as represented by Defendants.

185. WHEREFORE, Plaintiffs demand judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and request compensatory damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

COUNT XVI: LOSS OF CONSORTIUM

186. Plaintiffs incorporate by reference paragraphs 1-185 of this Complaint as if fully set forth herein.

187. 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.

188. WHEREFORE, Plaintiffs demand judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and request compensatory damages, punitive damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

COUNT XVII: PUNITIVE DAMAGES

189. Plaintiffs incorporate by reference paragraphs 1-188 of this Complaint as if fully set forth herein.

190. 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.

191. 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.

192. 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.

193. 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.

194. 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.

195. 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.

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

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

198. 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.

199. 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.

200. 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.

PRAYER FOR RELIEF

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

1. Compensatory damages to Plaintiffs for past, present, and future damages, including, but not limited to, pain and suffering for severe and permanent personal injuries sustained by Plaintiffs, health and medical care costs, together with interest and costs as provided by law;

2. Restitution and disgorgement of profits;

3. Reasonable attorneys' fees;

4. The costs of these proceedings;

5. All ascertainable economic damages;

6. Medical monitoring damages;

7. Punitive damages;

8. Survival damages (if applicable);

9. Wrongful death damages (if applicable); and

10. Such other and further relief as this Court deems just and proper.

Dated: May 16, 2014

Respectfully submitted,

/s/ Derek H. Potts
Derek H. Potts
Patricia L. Campbell
The Potts Law Firm, LLP
908 Broadway, 3rd Floor
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816-931-2230
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Email: dpotts@potts-law.com
Email: pcampbell@potts-law.com
LEAD ATTORNEY

/s/ Riley Burnett, Jr.
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Burnett Law Firm
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Houston, TX 77007
832-413-4410
Fax: 832-900-2120
Email: rburnett@rburnettlaw.com.
LEAD ATTORNEY

DEMAND FOR JURY TRIAL

Plaintiffs hereby demand a trial by jury as to all issues.

Dated: May 16, 2014

Respectfully submitted,

/s/ Derek H. Potts
Derek H. Potts
Patricia L. Campbell
The Potts Law Firm, LLP
908 Broadway, 3rd Floor
Kansas City, MO 64108
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Email: rburnett@rburnettlaw.com.
LEAD ATTORNEY

Exhibit B

PRINT FORM RESET FORM

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA

CHARLESTON DIVISION

In Re: Neomedic Pelvic Repair System Products Liability
MDL No. 2511
Civil Action No.

SHORT FORM COMPLAINT

Come now the Plaintiff(s) named below, and for their Complaint against the Defendants named below, incorporate the Master Complaint in MDL No. 2511 by reference. Plaintiff(s) further show the court as follows:

1. Female Plaintiff

2. Plaintiff Spouse (if applicable)

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

4. State of Residence

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

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

   ☐ A. Desarrollo e Investigación Médica Aragonesa, S.L. ("DIMA")

   ☐ B. Neomedic International, S.L.

☐ C. Neomedic Inc.

☐ D. Specialties Remeex International, S.L.

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

☐ F. Ethicon, Inc.

☐ G. Johnson & Johnson

☐ H. Boston Scientific Corporation

☐ I. C. R. Bard, Inc. (“Bard”)

☐ J. Sofradim Production SAS (“Sofradim”)

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

☐ L. Mentor Worldwide LLC

☐ M. Coloplast Corp.

☐ N. Cook Incorporated

☐ O. Cook Biotech, Inc.

☐ P. Cook Medical, Inc.

7. Basis of Jurisdiction

☐ Diversity of Citizenship

☐ Other: _____

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

_____

_____

_____

B. Other allegations of jurisdiction and venue

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

- ☐ A. Needleless System;
- ☐ B. Contasure Needleless Sling;
- ☐ C. Remeex Systern/TRT Remeex System;
- ☐ D. KIM System;
- ☐ E. Surelift;
- ☐ F. Uplift;
- ☐ G. Other

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

- ☐ A. Needleless System;
- ☐ B. Contasure Needleless Sling;
- ☐ C. Remeex Systern/TRT Remeex System;
- ☐ D. KIM System;
- ☐ E. Surelift;
- ☐ F. Uplift;

☐ G. Other

10. Date of Implantation as to Each Product

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

12. Implanting Surgeon(s)

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

☐ Count I - Negligence

☐ Count II - Strict Liability - Design Defect

☐ Count III - Strict Liability- Manufacturing Defect

☐ Count IV - Strict Liability - Failure to Warn

☐ Count V - Strict Liability - Defective Product

☐ Count VI – Breach of Express Warranty/

☐ Count VII - Breach of Implied Warranty

☐ Count VIII - Fraudulent Concealment

☐ Count IX - Constructive Fraud

☐ Count X - Discovery Rule, Tolling and Fraudulent Concealment

☐ Count XI - Negligent Misrepresentation

☐ Count XII - Negligent Infliction of Emotional Distress

☐ Count XIII - Violation of Consumer Protection Laws

☐ Count XIV - Gross Negligence

☐ Count XV - Unjust Enrichment

☐ Count XVI - (By the Spouse)- Loss of Consortium

☐ Count XVII - Punitive Damages

☐ Other (please state the facts supporting this Count in the space, immediately below)

s/

Attorney(s) for Plaintiff

Address, phone number, email address and bar information:

Exhibit C

PRINT FORM RESET FORM

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA

CHARLESTON DIVISION

In Re: Neomedic Pelvic Repair System Products Liability
MDL No. 2511
Civil Action No.

AMENDED SHORT FORM COMPLAINT

Come now the Plaintiff(s) named below, and for their Complaint against the Defendants named below, incorporate the Master Complaint in MDL No. 2511 by reference. Plaintiff(s) further show the court as follows:

1. Female Plaintiff

2. Plaintiff Spouse (if applicable)

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

4. State of Residence

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

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

   ☐ A. Desarrollo e Investigación Médica Aragonesa, S.L. ("DIMA")

   ☐ B. Neomedic International, S.L.

☐ C. Neomedic Inc.

☐ D. Specialties Remeex International, S.L.

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

☐ F. Ethicon, Inc.

☐ G. Johnson & Johnson

☐ H. Boston Scientific Corporation

☐ I. C. R. Bard, Inc. (“Bard”)

☐ J. Sofradim Production SAS (“Sofradim”)

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

☐ L. Mentor Worldwide LLC

☐ M. Coloplast Corp.

☐ N. Cook Incorporated

☐ O. Cook Biotech, Inc.

☐ P. Cook Medical, Inc.

7. Basis of Jurisdiction

☐ Diversity of Citizenship

☐ Other: _____

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

_____

_____

_____

B. Other allegations of jurisdiction and venue

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

- ☐ A. Needleless System;
- ☐ B. Contasure Needleless Sling;
- ☐ C. Remeex Systern/TRT Remeex System;
- ☐ D. KIM System;
- ☐ E. Surelift;
- ☐ F. Uplift;
- ☐ G. Other

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

- ☐ A. Needleless System;
- ☐ B. Contasure Needleless Sling;
- ☐ C. Remeex Systern/TRT Remeex System;
- ☐ D. KIM System;
- ☐ E. Surelift;
- ☐ F. Uplift;

☐ G. Other

10. Date of Implantation as to Each Product

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

12. Implanting Surgeon(s)

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

☐ Count I - Negligence

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☐ Count III - Strict Liability- Manufacturing Defect

☐ Count IV - Strict Liability - Failure to Warn

☐ Count V - Strict Liability - Defective Product

☐ Count VI – Breach of Express Warranty/

☐ Count VII - Breach of Implied Warranty

☐ Count VIII - Fraudulent Concealment

☐ Count IX - Constructive Fraud

☐ Count X - Discovery Rule, Tolling and Fraudulent Concealment

☐ Count XI - Negligent Misrepresentation

☐ Count XII - Negligent Infliction of Emotional Distress

☐ Count XIII - Violation of Consumer Protection Laws

☐ Count XIV - Gross Negligence

☐ Count XV - Unjust Enrichment

☐ Count XVI - (By the Spouse)- Loss of Consortium

☐ Count XVII - Punitive Damages

☐ Other (please state the facts supporting this Count in the space, immediately below)

s/

Attorney(s) for Plaintiff

Address, phone number, email address and bar information:

Exhibit D

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

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

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

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

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

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

- From the *CM/ECF Civil Menu*, go to *Motions and Related Filings > Motions/Applications/Petitions;*
- Select **Motion**;
- Select *Transfer between MDL Cases ***MDL Cases Only***;
- Enter the civil action number for the member MDL case -- **DO NOT USE THESE EVENTS IN THE MAIN CASE;**
- Select the party(s) filing the Motion to Transfer MDL;
- Browse in the image;
- Select the MDL case to transfer the member case FROM ;
- Select the MDL case to transfer the member case TO; and
- Review the final text; if correct, press NEXT to commit the transaction.

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

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

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