



and ASR™ Surface Replacement femoral head component and that DePuy issued a voluntary global recall of the ASR™ XL System and ASR™ Hip Resurfacing System on August 24, 2010. Defendant denies the remaining allegations contained in Paragraph 1 and expressly denies that it is a seller of hip replacement components.

### **PARTIES AND JURISDICTION**

2. Defendant lacks knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 2 and therefore denies them.

3. Defendant admits that DeBiase is a Florida corporation with a principal place of business located at 1525-A The Greens Way, Jacksonville Beach, Florida 32250 in Duval County. Defendant denies the remaining allegations contained in Paragraph 3.

4. Defendant admits that DeBiase is a Florida corporation. Defendant denies the remaining allegations contained in Paragraph 4.

5. Defendant admits that DeBiase does business in the State of Florida as Joint Venture. Defendant denies the remaining allegations contained in Paragraph 5.

6. Defendant denies the allegations contained in Paragraph 6 as phrased and incompletely and inaccurately presented and expressly denies that it is a seller of hip replacement components.

7. Defendant lacks knowledge or information sufficient to form a belief as to what Plaintiff or her “surgeons, nurses, and hospital staff” relied on at any given time and therefore denies these allegations. Defendant denies the remaining allegations contained in Paragraph 7 and expressly denies that Bayside is a seller of hip replacement components.

8. Defendant lacks knowledge or information sufficient to form a belief as to what Plaintiff, her surgeons, nurses and hospital staff relied upon at any given time and therefore

denies those allegations. Defendant denies the remaining allegations contained in Paragraph 8.

**VENUE**

9. Defendant lacks knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 9 and therefore denies them.

**HIP REPLACEMENT COMPONENTS**

10. Defendant denies the allegations contained in Paragraph 10.

11. Defendant denies the allegations contained in Paragraph 11 as phrased and incompletely and inaccurately presented.

12. Defendant states that DePuy's "literature" speaks for itself. Defendant denies the remaining allegations contained in Paragraph 12 as phrased and incompletely presented.

13. Defendant states that DePuy's "literature" speaks for itself. Defendant denies the remaining allegations contained in Paragraph 13 as phrased and incompletely presented

14. Defendant denies the allegations contained in Paragraph 14 as interpreted, phrased and incompletely and inaccurately presented and expressly denies that it is a seller of hip replacement components.

15. Defendant denies the allegations contained in Paragraph 15 as interpreted, phrased and incompletely and inaccurately presented.

16. Defendant denies the allegations contained in Paragraph 16 as interpreted, phrased and incompletely and inaccurately presented.

17. Defendant denies the allegations contained in Paragraph 17 as interpreted, phrased and incompletely and inaccurately presented.

18. Defendant denies the allegations contained in Paragraph 18 as interpreted, phrased and incompletely and inaccurately presented.

19. Defendant denies the allegations contained in Paragraph 19 as phrased and incompletely and inaccurately presented.
20. Defendant denies the allegations contained in Paragraph 20.
21. Defendant denies the allegations contained in Paragraph 21 and expressly denies that the hip replacement components failed.
22. Defendant denies the allegations contained in Paragraph 22 as interpreted, phrased and incompletely and inaccurately presented.
23. Defendant denies the allegations contained in Paragraph 23 as interpreted, phrased and incompletely and inaccurately presented.
24. Defendant admits that in 2009, DePuy Orthopaedics, Inc. decided to discontinue the ASR™ XL System worldwide on a market-by-market basis. Defendant denies the remaining allegations contained in Paragraph 24 as phrased and incompletely presented.
25. Defendant denies the allegations contained in Paragraph 25.
26. Defendant lacks knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 26 and therefore denies them.
27. Defendant lacks knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 27 and therefore denies them.
28. Defendant lacks knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 28 and therefore denies them.
29. Defendant lacks knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 29 and therefore denies them.
30. Defendant lacks knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 30 and therefore denies them.

31. Defendant lacks knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 31 and therefore denies them.

32. Defendant lacks knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 32 and therefore denies them.

33. Defendant lacks knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 33 and therefore denies them.

34. Defendant lacks knowledge or information sufficient to form a belief as to whether Plaintiff was implanted with ASR™ hip replacement components and therefore denies those allegations. Defendant denies the remaining allegations contained in Paragraph 34 and expressly denies that DeBiase is a seller of ASR™ hip replacement components.

35. Defendant lacks knowledge or information sufficient to form a belief as to whether Plaintiff was implanted with ASR™ hip replacement components which were “subsequently recalled by the FDA” and therefore denies those allegations. Defendant denies the remaining allegations contained in Paragraph 35.

36. Defendant lacks knowledge or information sufficient to form a belief as to Plaintiff’s alleged medical condition and therefore denies those allegations. Defendant denies the remaining allegations contained in Paragraph 36.

37. Defendant lacks knowledge or information sufficient to form a belief as to Plaintiff’s alleged medical condition and therefore denies those allegations. Defendant denies the remaining allegations contained in Paragraph 37 and expressly denies that the ASR™ hip replacement components “generated excessive metal debris.”

38. Defendant denies the allegations contained in Paragraph 38 and expressly denies that the ASR™ hip replacement components “failed”.

39. Defendant denies the allegations contained in Paragraph 39 and expressly denies that the ASR™ hip replacement components failed.

40. Defendant denies the allegations contained in Paragraph 40 and expressly denies that the ASR™ hip replacement components are “defective”.

41. Defendant denies the allegations contained in Paragraph 41 and expressly denies that the ASR™ hip replacement components are faulty or defective.

42. Defendant lacks knowledge or information sufficient to form a belief as to what Plaintiff’s physician knew or relied upon at any given time and therefore denies these allegations. Defendant denies the remaining allegations contained in Paragraph 42

#### **COUNT ONE**

43. Defendant incorporates by reference its responses to all other paragraphs of Plaintiff’s Complaint as if fully stated herein.

44. Defendant admits that DeBiase is an independent contractor of DePuy medical devices in the state of Florida but expressly denies that DeBiase is a seller of ASR™ hip replacement components. The remaining allegations contained in Paragraph 44 constitute legal statements or conclusions to which no response is required. To the extent a response is required, Defendant denies that these allegations are an accurate and complete statement of the applicable law.

45. Defendant denies the allegations contained in Paragraph 45.

46. Defendant denies the allegations contained in Paragraph 46.

47. Defendant denies the allegations contained in Paragraph 47.

#### **COUNT TWO**

48. Defendant incorporates by reference its responses to all other paragraphs of

Plaintiff's Complaint as if fully stated herein.

49. Defendant denies the allegations contained in Paragraph 49 and expressly denies that the ASR™ hip replacement components were defective, “unreasonably dangerous” or “unfit for its intended use”.

50. Defendant lacks knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 50 and therefore denies them.

51. Defendant denies the allegations contained in Paragraph 51.

52. Defendant lacks knowledge or information sufficient to form a belief as to the manner in which the ASR™ hip replacement components were being used and therefore denies these allegations. Defendant denies the remaining allegations contained in Paragraph 52 and expressly denies that the ASR™ hip replacement components were “defective, unsafe and unreasonably dangerous”.

53. Defendant denies the allegations contained in Paragraph 53.

### **COUNT THREE**

54. Defendant incorporates by reference its responses to all other paragraphs of Plaintiff's Complaint as if fully stated herein.

55. Defendant admits that DeBiase is an independent contractor of DePuy medical devices in the State of Florida. Defendant denies the remaining allegations contained in Paragraph 55 and expressly denies that it is a seller of ASR™ hip replacement components.

56. Paragraph 56 contains legal statements or conclusions to which no response is required. To the extent a response is required, the allegations are denied.

57. Defendant lacks knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 57 and therefore denies them.

58. Defendant denies the allegations contained in Paragraph 58.

59. Defendant denies the allegations contained in Paragraph 59.

60. Defendant denies the allegations contained in Paragraph 60.

#### **COUNT FOUR**

61. Defendant incorporates by reference its responses to all other paragraphs of Plaintiff's Complaint as if fully stated herein.

62. Paragraph 62 contains legal statements or conclusions to which no response is required. To the extent a response is required, the allegations are denied.

63. Defendant denies the allegations contained in Paragraph 63.

64. Defendant denies the allegations contained in Paragraph 64 and expressly denies any "false and deceptive" advertising.

65. Defendant denies the allegations contained in Paragraph 65.

66. Defendant denies the allegations contained in Paragraph 66.

67. Defendant denies the allegations contained in Paragraph 67.

68. Defendant denies the allegations contained in Paragraph 68. As to the unnumbered paragraph following Paragraph 68, Defendant denies that Plaintiff is entitled to relief of any kind.

69. Defendant denies that Plaintiff is entitled to damages of any kind

#### **DEFENSES**

##### **FIRST DEFENSE**

Plaintiff knowingly and voluntarily assumed any and all risks associated with the use of the product at issue in this case and such assumption of the risks bars in whole or in part the damages Plaintiff seeks to recover herein.

## **SECOND DEFENSE**

At all times mentioned herein, Plaintiff was negligent, careless, and at fault, and conducted herself so as to contribute substantially to her alleged injuries and damages. Said negligence, carelessness, and fault of Plaintiff bar in whole or in part the damages that Plaintiff seeks to recover herein.

## **THIRD DEFENSE**

Plaintiff's alleged injuries and damages attributable to the use of the product at issue in this case, if any, were not legally caused by the product at issue, but instead were legally caused by intervening and superseding causes or circumstances.

## **FOURTH DEFENSE**

Plaintiff's alleged damages, if any, are barred in whole or in part by Plaintiff's failure to mitigate such damages.

## **FIFTH DEFENSE**

Plaintiff's causes of action are barred by the applicable statutes of limitation, statutes of repose, and the doctrine of laches.

## **SIXTH DEFENSE**

Defendant did not make to Plaintiff, nor did it breach, any implied warranties and/or breach any warranties created by law. To the extent that Plaintiff relies on any theory of breach of warranty, such claims are barred by applicable law, and for lack of privity with Defendant and/or for failure of Plaintiff, or Plaintiff's representatives, to give timely notice to Defendant of any alleged breach of warranty. Defendant further specifically pleads as to any breach of warranty claim all defenses under the Uniform Commercial Code existing and which may arise in the future as enacted in the State of Florida and any other state whose law is deemed to apply

in this case.

**SEVENTH DEFENSE**

At the time of sale or delivery, the product conformed to the state-of-the-art for such products at that time.

**EIGHTH DEFENSE**

Plaintiff's claims should be diminished in whole or in part in the amount paid to Plaintiff by any party or non-party with whom Plaintiff has settled or may settle.

**NINTH DEFENSE**

Plaintiff's damages, if any, are barred or limited by the payments received from collateral sources.

**TENTH DEFENSE**

Plaintiff's causes of action are barred by the learned intermediary doctrine.

**ELEVENTH DEFENSE**

Plaintiff's claims are barred by the doctrines of informed consent, release, and waiver.

**TWELFTH DEFENSE**

Defendant is entitled to, and claim the benefits of, all defenses and presumptions set forth in or arising from any rule of law or statute in the state of Florida, Plaintiff's alleged state of citizenship and residence, including but not limited to sections 768.1256 and 768.1257, Florida Statutes, and any other state whose law is deemed to apply in this case. Defendant reserves the right to assert any additional defenses in which may be disclosed during the course of additional investigation and discovery.

**THIRTEENTH DEFENSE**

The injuries and damages claimed by Plaintiff, if any, were caused in whole or in part by

the acts or omissions of persons over whom Defendant has no control or right of control.

#### **FOURTEENTH DEFENSE**

Plaintiff's claims are barred by the equitable doctrine of estoppel.

#### **FIFTEENTH DEFENSE**

Upon information and belief, if the injuries referred to in the Complaint were caused by Defendant's product, which is denied, the injuries are the result of an idiosyncratic reaction to the product.

#### **SIXTEENTH DEFENSE**

Plaintiff's alleged injuries are a result of a pre-existing and/or unrelated medical condition for which Defendant is not responsible.

#### **SEVENTEENTH DEFENSE**

To the extent Plaintiff's claims are based on alleged misrepresentations or omissions made to the FDA, such claims are barred pursuant to *Buckman Co. v. Plaintiff's Legal Comm.*, 531 U.S. 341 (2001).

#### **EIGHTEENTH DEFENSE**

If Defendant's products are unsafe in any way, they are unavoidably unsafe. Plaintiff's purported action is, therefore, barred by Comment k of § 402A of the Restatement (Second) of Torts and/or other applicable law.

#### **NINETEENTH DEFENSE**

Plaintiff's injuries and damages, if any, were proximately caused by the negligence or fault of Plaintiff, or persons or parties whose identities are unknown at this time, and such comparative negligence or fault is sufficient to proportionately reduce or bar Plaintiff's recovery. Thus, Defendant is entitled to have its liability to the Plaintiff, if any, reduced as a result of the

negligence or fault of said persons or entities, pursuant to the provisions of section 768.81, Florida Statutes. To the extent any recovery is permitted in this case, pursuant to sections 768.31 and 768.81, Florida Statutes, judgment must be entered on the basis of Defendant's percentage of fault, taking into account the percentage of fault attributable to all other persons, whether or not a party hereto, and not on the basis of joint and several liability. The persons or entities referred to in this paragraph that are presently unknown to Defendant will be identified in a timely manner consistent with Nash v. Wells Fargo, 678 So. 2d 1262 (Fla. 1996).

#### **TWENTIETH DEFENSE**

Plaintiff's claims are barred in whole or in part under sections 4, 6(c), and 6(d) of the Restatement (Third) of Torts: Products Liability.

#### **TWENTY-FIRST DEFENSE**

Defendant asserts all defenses available under the Florida Deceptive and Unfair Trade Practices Act, §501.201, *et seq.*

#### **TWENTY-SECOND DEFENSE**

To the extent that Plaintiff relies on any misrepresentation-based theory, such claims are not stated with particularity as required by Rule 1.120, Florida Rules of Civil Procedure. To the extent that Plaintiff's claims are based upon alleged representations by Defendant, those claims are barred as there was no reliance upon such representations.

#### **TWENTY-THIRD DEFENSE**

Plaintiff fails to state a cause of action against Defendant upon which relief may be granted.

#### **TWENTY-FOURTH DEFENSE**

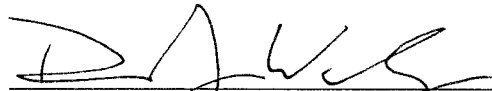
Plaintiff's Complaint has failed to name necessary and indispensable parties.

**TWENTY-FIFTH DEFENSE**

Defendant reserves its right to raise such further and additional defenses as may be available upon the facts to be developed in discovery and under other applicable substance of law.

**JURY DEMAND**

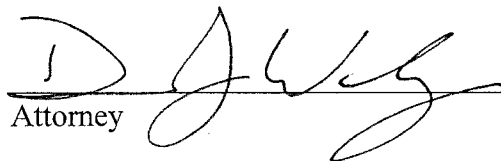
Defendant Mark DeBiase, Inc. d/b/a Joint Venture requests a trial by jury composed of the maximum number of jurors allowed by law, on all issues so triable.



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**CERTIFICATE OF SERVICE**

I CERTIFY that a copy of this pleading was mailed to Altom M. Maglio, Maglio, Christopher & Toale, 1751 Mound Street, Second Floor, Sarasota, FL 34236 and Brian Franciskato, Nash & Franciskato Law Firm, 2300 Main Street, Kansas City, MO 64108, this 26th day of October, 2011.



Attorney