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

IN RE: BOSTON SCIENTIFIC CORP., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	MDL No. 2326
TO BE FILED IN LEAD CASE:	2:13-cv-07965
THIS DOCUMENT RELATES TO CIVIL ACTION NUMBERS:	
Juana Betancourt v. Boston Scientific Corp.	Case No. 2:14-cv-11337
Margartia Dotres v. Boston Scientific Corp.	Case No. 2:13-cv-10077
Amal Eghnayem v. Boston Scientific Corp.	Case No. 2:13-cv-07965
Maria Nunez v. Boston Scientific Corp.	Case No. 2:13-cv-24346

BOSTON SCIENTIFIC CORPORATION'S MEMORANDUM OF LAW IN SUPPORT OF ITS MOTION FOR SUMMARY JUDGMENT

Defendant, Boston Scientific Corporation ("Boston Scientific"), pursuant to Fed. R. Civ. P. 56, Local Rule Civ. P. 7.1(a)(2), and Pretrial Order ("PTO") No. 91, files this Memorandum of Law in support of its Motion for Summary Judgment and states as follows:

INTRODUCTION

Plaintiffs bring these four consolidated product liability actions against Boston Scientific alleging that Boston Scientific's implantable mesh device – the Pinnacle Pelvic Floor Repair Kit ("Pinnacle") – was defective and caused them personal injuries. Plaintiffs assert causes of action for negligence, strict liability (design defect, manufacturing defect, and failure to warn), breach of express warranty, breach of implied warranty, and punitive damages.[1]

[1] As set forth in Boston Scientific's Motion for Summary Judgment on Plaintiffs' Punitive Damages Claim, which was previously filed, Plaintiffs' claims for punitive damages fail as a matter of law.

The undisputed facts establish that Boston Scientific is entitled to summary judgment because Plaintiffs' legal theories are without factual or legal support and are subject to dismissal as a matter of law:

- Plaintiffs' strict liability and negligent manufacturing claims fail for lack of evidence.
- Plaintiffs' breach of express and implied warranty claims fail for lack of privity.
- Plaintiffs' failure to warn claims are barred by Florida's learned intermediary doctrine.

For these reasons and those more fully discussed below, Boston Scientific is entitled to summary judgment on all of Plaintiffs' claims.

APPLICABLE LAW

For implantable medical device cases that originate elsewhere and are directly filed in the MDL, this Court applies the choice-of-law rules of the state in which the plaintiff was implanted with the device. *See Sanchez v. Boston Scientific Corp.*, 2:12-CV-05762, 2014 WL 202787, *4 (S.D.W. Va. Jan. 17, 2014); *see also In re Yasmin & Yaz (Drospirenone) Mktg., Sales Practices & Prods. Liab. Litig.*, MDL No. 2100, 2011 WL 1375011, *6 (S.D. Ill. Apr. 12, 2011) ("[T]he better approach is to treat foreign direct filed cases as if they were transferred from a judicial district sitting in the state where the case originated," which is "the state where the plaintiff purchased and was prescribed the subject drug.").

Here, all four Plaintiffs filed their cases directly in MDL No. 2326 pursuant to PTO 14.[2] All four Plaintiffs are Florida residents,[3] had their Pinnacle devices implanted at medical facilities in the State of Florida,[4] and identify the United States District Court for the Southern

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2 A true and correct copy of PTO 14 is attached to the Motion as Exhibit Z.

3 *See* Boston Scientific Corporation's Statement of Material Facts in Support of its Motion for Summary Judgment ("SOF"), filed concurrently herewith, at ¶¶ 1, 16, 33, 47.

4 SOF at ¶¶ 10, 26, 42, 58.

District of Florida as the proper venue absent direct filing.[5] Therefore, for choice-of-law purposes, the United States District Court for the Southern District of Florida should be considered the originating court. As a result, this Court should apply Florida's choice-of-law rules.

Florida applies the "significant relationship test" as set forth in the Restatement (Second) of Conflict of Laws to choice of law issues arising from tort claims. *Crowell v. Clay Hyder Trucking Lines, Inc.*, 700 So. 2d 120, 122 (Fla. 2d DCA 1997) (citing *Bishop v. Florida Specialty Paint Co.*, 389 So. 2d 999 (Fla. 1980)). Under this test, the court must determine which state has the most significant contacts between the parties and the accident. *Id.* at 123. "Thus, in personal injury actions the law of the state where the injury occurred applies only when there is no other state with a more significant interest." *Id.* (citing RESTATEMENT (SECOND) CONFLICT OF LAWS § 146, 175 (1971); *State Farm Mutual Auto. Ins. Co. v. Olsen*, 406 So. 2d 1109 (Fla. 1981)).

As stated above, all four Plaintiffs are residents of Florida and had their Pinnacle devices implanted at medical facilities in Florida. Therefore, Florida has the most significant relationship to Plaintiffs' compensatory damages claims in these cases and Florida law should apply.[6]

SUMMARY JUDGMENT STANDARD

Summary judgment is proper when "there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." FED. R. CIV. P. 56; *Celotex Corp. v. Catrett*, 477 U.S. 317, 322-23 (1986). Summary judgment "is properly regarded not as a disfavored procedural shortcut, but rather as an integral part of the Federal Rules as a whole,

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[5] SOF, Ex. A at ¶ 5; Ex.G at ¶ 5; Ex. M at ¶ 5; Ex. S at ¶ 5.

[6] Indeed, in the Order consolidating these cases for discovery and trial, this Court stated "these cases implicate only Florida law." PTO 91 at 3 (attached to the Motion as Exhibit AA).

which are designed to 'secure the just, speedy and inexpensive determination of every action.'" *Celotex*, 477 U.S. at 327 (citations omitted).

Not every factual dispute between the parties will prevent summary judgment. *See Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248-49 (1986). Although the Court must review the evidence in the light most favorable to the non-moving party, the non-moving party is required to do more than show some "metaphysical doubt as to the material facts." *Matsushita Elec. Indus. Co., Ltd. v. Zenith Radio Corp.*, 475 U.S. 574, 586 (1986). Conclusory allegations or unsupported speculation is insufficient to preclude the granting of a summary judgment motion. *See Felty v. Graves-Humphreys Co.*, 818 F.2d 1126, 1128 (4th Cir. 1987); *Ross v. Commc'ns Satellite Corp.*, 759 F.2d 355, 365 (4th Cir. 1985), *abrogated on other grounds by Price Waterhouse v. Hopkins*, 490 U.S. 228 (1989).

ARGUMENT

I. SUMMARY JUDGMENT SHOULD BE ENTERED ON PLAINTIFFS' MANUFACTURING DEFECT CLAIMS

To prove a manufacturing defect under Florida law, plaintiffs must prove through expert testimony that the product (1) "does not conform to its intended design" such that it (2) "fails to perform as safely as the intended design would have performed." *Citizens Prop. Ins. Corp. v. Simkar LLC*, 813 F.Supp.2d 1356, 1363 (M.D. Fla. Sept. 26, 2011); *see also Benitez v. Synthes, Inc.*, 199 F.Supp. 2d 1339, 1344 (M.D. Fla. 2002) ("manufacturing defects are generally limited to situations where something goes wrong in the manufacturing process").

Here, Plaintiffs have provided no evidence that any of their Pinnacle devices "[did] not conform to its intended design." *Simkar LLC*, 813 F.Supp.2d at 1363. In addition, Plaintiffs have provided no evidence that their Pinnacle devices "fail[ed] to perform as safely as the intended design would have performed," because of some unspecified defect in the

manufacturing process and, therefore, Plaintiffs have provided no evidence of a manufacturing defect under Florida law. *Id.* Accordingly, the Court should grant Boston Scientific's motion for summary judgment on Plaintiffs' strict liability and negligent manufacturing claims. *See In re C.R. Bard, Inc.*, No 2:11-CV-00114, 2013 WL 5591948, at *4 (S.D. W. Va. June 4, 2013) (granting defendant's motion for summary judgment on manufacturing defect claim because plaintiff provided no evidence the product implanted in her deviated in some way "from the manufacturer's specifications or from otherwise identical units manufactured to the same manufacturing specifications"); *Savage v. Danek Med.*, 31 F. Supp. 2d 980, 983-84 (M.D. Fla. Jan. 14, 1999) (granting summary judgment for defendant medical device manufacturer on plaintiff's theories of negligence and strict liability in the design, manufacture, distribution, promotion and sale of surgical screws and noting that, as in this case, "[t]here is simply no evidence" of a manufacturing defect.).

II. PLAINTIFFS' BREACH OF WARRANTY CLAIMS FAIL FOR LACK OF PRIVITY

Plaintiffs cannot prevail on their breach of warranty claims because they are not in privity of contract with Boston Scientific. Under Florida law, "privity is required in order to recover damages from the seller of a product for breach of express or implied warranties." *Intergraph Corp. v. Stearman*, 555 So. 2d 1282, 1283 (Fla. 2d DCA 1990); *Kramer v. Piper Aircraft Corp.*, 520 So. 2d 37, 39 (Fla. 1988). "A warranty, whether express or implied, is fundamentally a contract. A contract cause of action requires privity." *Elizabeth N. v. Riverside Group, Inc.*, 585 So. 2d 376, 378 (Fla. 1st DCA 1990) (quotation omitted); *see also Kaiser v. Depuy Spine, Inc.*, 944 F.Supp.2d 1187, 1193 (M.D. Fla. May 14, 2013) ("it is well established in Florida that warranty-based claims . . . require privity of contract between the parties.").

Here, the Pinnacle is a medical device surgically implanted by a physician and available

only by prescription. SOF at ¶¶ 11, 28, 43, 59. Plaintiffs have not, nor could they, provide any evidence that they purchased their Pinnacle devices directly from Boston Scientific. Thus, there is no privity between Plaintiffs and Boston Scientific. As one Florida federal district court held in a case involving a prescription medical device:

> A plaintiff who purchases a product, but does not buy it directly from the defendant, is not in privity with that defendant. The complaint does not allege that the plaintiffs purchased the penile implant directly from the defendant, or that they contracted with the defendant. Because the complaint does not allege privity of contract, it fails to state a cause of action for breach of express or implied warranties.

T.W.M. v. American Medical Systems, Inc., 886 F. Supp. 842, 844 (N.D. Fla. 1995).

Because Plaintiffs are not in privity with Boston Scientific, Boston Scientific is entitled to summary judgment on Plaintiffs' breach of express and implied warranty claims. *See Timmons v. The Purdue Pharma Co, et al.*, No. 8:04-cv-1479-T-26MAP, 2006 U.S. Dist. LEXIS 3965, *15 (M.D. Fla. Feb. 2, 2006) (granting summary judgment to defendant prescription drug manufacturer on plaintiff's breach of express and implied warranty claims after finding a lack of privity between plaintiff and defendant); *Spolski Gen. Contractor, Inc. v. Jett-Aire Corporate Aviation Management of Cent. Florida, Inc.*, 637 So. 2d 968 (Fla. 5th DCA 1994) (affirming summary judgment on warranty claims where there was no privity between parties); *see also Stearman*, 555 So. 2d at 1283 (reversing final judgment for plaintiff on his breach of warranty claims because "there was a complete absence of privity" between the parties); *T.W.M*, 886 F. Supp. at 844 (granting medical device manufacturer's motion to dismiss on plaintiff's breach of express and implied warranty claims because "the law of Florida is that to recover for the breach of a warranty, either express or implied, the plaintiff must be in privity of contract with the defendant"); *Kaiser*, 944 F.Supp.2d at 1193 (denying plaintiff's request to amend his complaint

to add a breach of warranty claim concerning a prescription medical device because "a breach of warranty claim fails where plaintiff did not purchase the product from the defendant.").

III. PLAINTIFFS' FAILURE TO WARN CLAIMS ARE BARRED BY THE LEARNED INTERMEDIARY DOCTRINE

To prevail on their failure to warn claims, whether the claims sound in negligence or strict liability, Plaintiffs must prove: (1) the warnings accompanying the Pinnacle were inadequate; (2) the inadequacy of the warnings proximately caused Plaintiffs' injury; and (3) Plaintiffs in fact suffered an injury from the use the device. *Colville v. Pharmacia & Upjohn Co.*, 565 F. Supp. 2d 1314, 1320 (N.D. Fla. 2008). Here, summary judgment is warranted on all four Plaintiffs' failure to warn claims under the learned intermediary doctrine because Boston Scientific provided adequate warnings of the risks associated with the Pinnacle device to Plaintiffs' treating physicians. In addition, Boston Scientific is entitled to summary judgment on Plaintiff Juana Betancourt's failure to warn claims because her treating physician testified that he was aware of the risks for which she seeks recovery at the time of her Pinnacle placement.

A. Boston Scientific Did Not Owe a Duty to Warn Plaintiffs Directly.

To the extent Plaintiffs allege that Boston Scientific owed and breached a duty to warn them directly of the potential risks associated with use of the Pinnacle, that claim fails as a matter of law because in cases involving prescription medical devices, such as the Pinnacle, a manufacturer has no duty to warn the patient directly of the risks that may be associated with the device's use. *See, e.g. Christopher v. Cutter Labs.*, 53 F.3d 1184, 1192 (11th Cir. 1995); *Buckner v. Allergan Pharm., Inc.*, 400 So. 2d 820, 822 (Fla. 5th DCA 1981), *rev. denied*, 407 So. 2d 1102 (Fla. 1981). Rather, pursuant to the learned intermediary doctrine, a manufacturer of a prescription medical device has a duty to warn only the prescribing physicians, *i.e., the learned intermediaries*, of potential risks associated with the device's use. *Upjohn Co. v. MacMurdo*,

562 So. 2d 680, 683 (Fla. 1990) (the "manufacturer's duty to warn of the drug's dangerous side effects is directed to the physician rather than the patient."); *Beale v. Biomet, Inc.*, 492 F. Supp. 2d 1360, 1368 (S.D. Fla. 2007) ("under Florida law, the learned intermediary doctrine applies to prescription medical devices."). The prescribing physician is responsible for communicating those risks to the patient during the course of medical treatment. *Id.* at 1365-70. Accordingly, to the extent Plaintiffs are alleging that Boston Scientific failed to warn them directly of the potential risks of the Pinnacle device, Plaintiffs' claims fail as a matter of law.

B. Boston Scientific Provided Adequate Warnings of the Risks Associated With the Pinnacle Device.

Boston Scientific provided an adequate warning of the risks associated with the Pinnacle device to all four Plaintiffs' treating physicians. In Florida, a prescription medical device manufacturer discharges its duty to warn when its labeling adequately informs the learned intermediary of the device's risks. *See Upjohn*, 562 So. 2d at 683. "When a manufacturer gives a warning regarding its product, the issue is whether the warning provided to the physician is adequate." *Beale*, 492 F. Supp. 2d at 1368. Under Florida law, the adequacy of warnings can become a question of law where the warning is accurate, clear, and unambiguous. *Rounds v. Genzyme Corp.*, 440 Fed. Appx. 753, 756 (11th Cir. 2011).

In *Rounds*, the plaintiff filed suit arguing that the defendant manufacturer failed to provide proper training to the treating physician regarding Carticel, the defendant's prescription biologic product used to repair cartilage injuries. *Id.* at 754. The defendant moved to dismiss the complaint on the basis of the learned intermediary doctrine and attached the product's labeling which contained information on warnings and precautions. *Id.* The Florida federal district court granted defendant's motion to dismiss finding the learned intermediary doctrine barred plaintiff's claims. *Id.* On appeal, the Eleventh Circuit affirmed finding "the package insert specifically

advised [the physician] of the likelihood of the very injury of which the [plaintiffs] complain: the need for subsequent medical treatment and surgeries following the use of Carticel." *Id.* The court concluded "Genzyme satisfied the learned intermediary doctrine in this case by informing [the physician] of the risks associated with Carticel by providing him the package insert which contained clear, unambiguous language about how to identify Carticel patients and about the risk of the injury suffered by [plaintiff]." *Id.* at 756.

Here, Boston Scientific discharged its duty to warn under Florida's learned intermediary doctrine by providing accurate, clear, and unambiguous language about the possible risks of the Pinnacle device in the accompanying Directions for Use ("DFU"). In fact, the Pinnacle DFU advises physicians of the very injuries for which Plaintiffs seek recovery:

- Plaintiff Mania Nunez alleges she has suffered "pain, erosion, bleeding, bowel problems, dyspareunia, fistulas and infections." SOF at ¶ 15. The DFU that accompanied her Pinnacle device warned her treating physician of each of these risks. SOF at ¶ 12.
- Plaintiff Amal Eghnayem alleges she has suffered "chronic pelvic and vaginal area pain requiring pain medication and sleeping pills[,] as well as severe urinary problems, erosion, vaginal bleeding, and discharge, pain during intercourse and the need for additional surgery." SOF at ¶ 32. The DFU that accompanied her Pinnacle device warned her treating physician of each of these risks. SOF at ¶ 29.
- Plaintiff Margarita Dotres alleges she has suffered from "dyspareunia with bleeding and urination during intercourse," "difficulty with bowel movements," "constant symptoms of a urinary tract infection," "vaginal discharge and pain in her lower back and hip," and "a burning sensation in her vagina that is always present." SOF at ¶ 47.

The DFU that accompanied her Pinnacle device warned her treating physician of each of these risks. SOF at ¶ 44.

- Plaintiff Juana Betancourt alleges she has suffered from "vaginal pain, irritation, erosion, mesh exposure, and dyspareunia." SOF at ¶ 67. The DFU that accompanied her Pinnacle device warned her treating physician of each of these risks. SOF at ¶ 60.

Because Boston Scientific provided accurate, clear, and unambiguous warnings concerning the potential risks and complications of the Pinnacle device, including the exact potential complications for which these four Plaintiffs seek recovery, Boston Scientific discharged its duty to warn under the learned intermediary doctrine. *See Rounds*, 440 Fed. Appx. at 756. Accordingly, this Court should grant summary judgment on Plaintiffs' failure to warn claims.

C. All Four Plaintiffs' Treating Physicians Were Aware of the Potential Risks of the Pinnacle Device For Which They Seek Recovery.

Boston Scientific is further entitled to summary judgment on Plaintiffs' failure to warn claims because Plaintiffs cannot show that any allegedly inadequate warning proximately caused their injuries. Where, as here, the prescribing physician has knowledge of a risk that an allegedly adequate warning should have communicated, the allegedly inadequate warning cannot be the proximate cause of a plaintiff's injury. *Beale*, 492 F.Supp. 2d at 1365 ("the causal link between a patient's injury and the alleged failure to warn is broken when the prescribing physician had 'substantially the same' knowledge as an adequate warning from the manufacturer should have communicated to him"). And, where the risks are generally known in the medical community absent a warning, a failure to warn claim cannot succeed and summary judgment is appropriate. *Timmons,* 2006 U.S. Dist. LEXIS 3965 at *12-14; *Colville*, 565 F. Supp. 2d at 1322 (awarding summary judgment because the plaintiff's prescribing physician was aware of the drug's risks);

Felix v. Hoffman-LaRoche, Inc., 540 So. 2d 102, 104 (Fla. 1989) ("any inadequacy in the [drug's] warning could not have been the proximate cause of the [alleged injury]" where "the prescribing physician testified that he fully understood the warnings and also had prior knowledge of the teratogenic propensity of [the drug]").

In *Colville,* the plaintiff alleged that she developed osteoporosis as a result of using a prescription medication and asserted negligent and strict liability failure to warn claims against the drug's manufacturer. *Colville*, 565 F. Supp. 2d at 1316. The plaintiff alleged that neither she nor her doctors were warned that use of the medication could cause osteopenia. *Id.* at 1317. However, the plaintiff's prescribing physician testified that at the time she prescribed the drug to the plaintiff, she understood there was a risk of the drug causing osteoporosis – the injury for which plaintiff was seeking damages. *Id.* at 1318. Accordingly, the United States District Court for the Northern District of Florida held that the plaintiff had "failed to show that the inadequacy of the manufacturer's warnings was a proximate cause of her osteopenia diagnosis" and entered summary judgment in favor of the defendant drug manufacturer. *Id.* at 1322.

Likewise, in *Hoffman-LaRoche Inc. v. Mason*, 27 So. 3d 75, 76 (Fla. 1st DCA 2009), the plaintiff alleged that he developed inflammatory bowel disease ("IBD") as a result of taking a prescription drug. The plaintiff asserted strict liability and negligent failure to warn claims against the manufacturer alleging that the drug's label inadequately warned his prescribing physician about the risk of developing IBD. *Id.* However, plaintiff's prescribing physician testified that he was aware of the possibility that the drug could cause IBD and that he would have prescribed the drug even if the label stated that the drug could cause IBD. *Id.* Florida's First District Court of Appeal held that the defendant manufacturer was entitled to a directed

verdict because the plaintiff failed to establish that the alleged inadequate warning proximately caused his injuries. *Id.* at 77.

As set forth below, like the manufacturer defendants in *Colville* and *Mason*, Boston Scientific is entitled to summary judgment on all four Plaintiffs' failure to warn claims because their treating physicians were aware of the risks for which they seek recovery prior to performing their surgeries.

1. Plaintiff Juana Betancourt Cannot Prove Proximate Causation

Dr. Emilio Gomez-Madrazo, the physician who performed Ms. Betancourt's Pinnacle procedure, was aware of the risks of vaginal pain, irritation, erosion, mesh exposure, and dyspareunia – the same potential complications for which Ms. Betancourt seeks recovery – prior to performing her procedure:

Q: Now, there's a section, Doctor, on this DFU, still on page 4, that lists adverse events. Do you see that?

A: Yes.

Q. And it starts with Potential adverse reactions that may be associated with surgically implanted materials include. Do you see that?

A: Yes.

Q. And then there's list of potential adverse reactions; right?

A. Yes.

Q: And you were aware of those potential adverse reactions prior to Ms. Betancourt's procedure; right?

MS. HUTSON: Object to the form.

A. Yes.

Q. And I know we've talked about this, so I'm going to go through it pretty quickly, but listed under Adverse Events, you would agree constipation is one of them; right?

A. Yes.

Q. And **dyspareunia**?

A. Yes.

Q. **Erosion** and **extrusion**?

A. Yes.

Q. Fistula formation?

A. Yes.

Q. **Pain**, discomfort, **irritation** is listed?

A. Yes.

Q. And recurrent prolapse is listed?

A. Yes.

Deposition of Emilio Gomez-Madrazo, M.D., June 16, 2014, at 81:2 – 82:9 (emphasis added) (relevant excerpts attached to the Motion as Exhibit BB). In addition, Dr. Gomez-Madrazo testified that he had no criticisms of the Pinnacle DFU that was in place at the time of Ms. Betancourt's procedure and agreed that all of these potential complications were well known to the medical community:

Q. Doctor, do you have any criticisms about this DFU that we just reviewed?

MS. HUTSON: Object to the form.

A. No.

Q. Would you agree with me, Doctor, that the complications that we just reviewed in the DFU are well known?

MR. DANIEL: Form.

MS. HUTSON: Object to the form.

A. Yes.

Id. at 83:1-11. Because Plaintiff Juana Betancourt's treating physician testified that he was aware of the risks for which Plaintiff seeks recovery prior to her Pinnacle placement, Ms. Betancourt cannot prove any alleged failure to warn proximately caused her injuries. Therefore, Boston Scientific is entitled to summary judgment on her strict liability and negligent failure to warn claims.

2. Plaintiffs Margarita Dotres and Mania Nunez Cannot Prove Proximate Causation

Dr. Emery Salom, the treating physician for both Ms. Nunez and Ms. Dotres,[7] was aware of the potential complications listed in the Pinnacle DFU prior to performing Ms. Nunez's surgery and considered these complications when he was treating Ms. Nunez:

Q: Do you see on the third page of that document the list of complications?

A: Yes.

Q: And the warnings that were listed by Boston Scientific in their directions for use?

A: Yes.

Q: Are these the complications that were presented to you by Boston Scientific in 2008?

A: Yes.

Q: Did you rely upon these complications as listed in this DFU and as presented to you by Boston Scientific the complications that you took into account when discussing the complications with Ms. Nunez in 2008?

A: Yes, it's fair to say.

Deposition of Emery Salom, M.D., July 19, 2014, at 41:17-42:10 (relevant excerpts attached to the Motion as Exhibit CC). As discussed *supra* in section III.B., Boston Scientific's accurate, clear, and unambiguous warnings in the Pinnacle DFU warned of the exact complications for which Plaintiffs seek recovery. Because Dr. Salom was aware of the risks listed in the Pinnacle DFU prior to treating Ms. Nunez and Ms. Dotres and, thus, the risks for which Ms. Nunez and Ms. Dotres seek recovery, these Plaintiffs cannot prove any alleged failure to warn proximately caused their injuries. Therefore, Boston Scientific is entitled to summary judgment on Ms. Nunez's and Ms. Dotres' strict liability and negligent failure to warn claims.

3. Plaintiff Amal Eghnayem Cannot Prove Proximate Causation

Dr. William Porter, the physician who performed Ms. Eghnyaem's Pinnacle procedure, was aware of the potential risks of pain, erosion, dyspareunia, and the need for additional

[7] Dr. Salom performed Ms. Nunez's Pinnacle surgery on August 27, 2008, followed by Ms. Dotres' Pinnacle surgery on October 8, 2008. SOF ¶¶ 5, 41.

surgeries – complications for which Ms. Eghnayem seeks recovery - prior to performing her procedure:

> Q: Okay. And you would have - - well, when you explained to her the various options, would you have explained to her that the option of mesh would have include certain risks that would have include[d] erosion and dyspareunia and extrusion?
>
> A: Yes.
>
> Q: Okay. It would have included the risks of possible infection, possibly needing to have some parts of the mesh removed. Would that have been discussed with her?
>
> A: Yes, I have a separate consent form, and I - - I don't see it in the record, but - - for that. And I've been using it for ten years.
>
> ***
>
> Q: [referring to the Pinnacle DFU] – there's a reference to a foreign body reaction. Is that - - I don't know if that's something that you would state in those terms or whether that's more of a science term. Is that - - would you go into detail about foreign body response with the paint?
>
> A: I wouldn't say foreign body reaction, but we would have reactions, anesthesia reaction. We would have reactions. We have mesh erosion. We'd have pain.

Deposition of William Porter, M.D., July 22, 2014, at 52:2-18, 67:21-68:5 (relevant excerpts attached to the Motion as Exhibit DD). Because Dr. Porter was aware of the risks of pain, erosion, dyspareunia, and the need for additional surgeries prior to Ms. Eghnayem's procedure, she cannot prove any alleged failure to warn was the proximate cause of her injuries. Accordingly, Boston Scientific is entitled to summary judgment on her failure to warn claims.

CONCLUSION

For the foregoing reasons, Boston Scientific respectfully requests that the Court grant summary judgment in its favor with respect to all of Plaintiffs' manufacturing defect, breach of warranty, and failure to warn claims.

Dated: August 15, 2014.

Respectfully submitted,

By: /s/ Jon A. Strongman

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CERTIFICATE OF SERVICE

I hereby certify that on August 15, 2014, a true and correct copy of the foregoing was electronically filed with the Clerk of the Court using CM/ECF system, which will send notifications of such filing to the CM/ECF participants registered to receive service in this matter:

Dated: August 15, 2014

Respectfully submitted,

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