UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE: DAVOL, INC./C.R. BARD, INC., POLYPROPYLENE HERNIA MESH PRODUCTS LIABILITY LITIGATION

Case No. 2:18-md-2846

JUDGE EDMUND A. SARGUS, JR.
Magistrate Judge Kimberly A. Jolson

This document relates to:
Milanesi, et al. v. C.R. Bard, Inc., et al.
Case No. 2:18-cv-01320

DISPOSITIVE MOTIONS ORDER No. 3

Defendants C.R. Bard, Inc. and Davol, Inc. seek summary judgment on each of Plaintiffs', Antonio Milanesi and Alicia Morz De Milanesi, eleven state-law tort claims. (ECF No. 57.) Defendants also raise objections to exhibits Plaintiffs cite in their response brief. (ECF No. 112.) For the reasons that follow, Defendants' motion (ECF No. 57) is **GRANTED IN PART AND DENIED IN PART**.

I. Background

Plaintiffs' case is the second bellwether trial selected from thousands of cases in this multidistrict litigation ("MDL") against Defendants. The Judicial Panel on Multidistrict Litigation described the cases in this MDL as "shar[ing] common factual questions arising out of allegations that defects in defendants' polypropylene hernia mesh products can lead to complications when implanted in patients, including adhesions, damage to organs, inflammatory and allergic responses, foreign body rejection, migration of the mesh, and infections." (No. 2:18-md-02846, ECF No. 1 at PageID #1–2.)[1] Plaintiffs raise Florida law claims against Defendants based on the implantation

[1] Docket citations are to the docket in the instant case, Case No. 18-cv-1320, unless otherwise noted.

of Defendants' Ventralex Hernia Patch in Mr. Milanesi. (ECF No. 15 at PageID #88–93.)

The Ventralex is a prescription medical device used for "umbilical and small ventral" hernia repairs. (ECF No. 57-1 at PageID #419.) The circular mesh patch is made of three layers—two of polypropylene mesh and one of permanent expanded polytetrafluoroethylene ("ePTFE"). (ECF No. 57-5 at PageID #651.) The Ventralex therefore has two sides—one of the polypropylene mesh and one of the ePTFE layer. (ECF No. 57-1 at PageID #418.) The polypropylene mesh side faces the abdominal wall, encouraging tissue to grow into the mesh, thus supporting the hernia repair. (*Id.*; ECF No. 57-2 at PageID #437.) The ePTFE side faces the intestines and is designed to be smooth with "sub-micronal porosity," minimizing tissue attachment, such as adhesions, between the intestines and other viscera and the Ventralex. (ECF No. 57-1 at PageID #418; ECF No. 57-2 at PageID #437.) Sandwiched between the two layers of polypropylene mesh is a monofilament memory coil ring, which was made of polyethylene terephthalate ("PET") when it was implanted in Mr. Milanesi.[2] (ECF No. 57-5 at PageID #651.) The ring is designed to help the patch "pop open" and then "lay flat" against the abdominal wall when the Ventralex is folded and inserted through the incision during surgical repair of the hernia. (ECF No. 57-1 at PageID #418, 422.) This feature of the Ventralex is helpful for these hernia repairs because the "pop open" feature allows for a smaller surgical incision, shorter surgeries, and less implanted foreign matter, which are considered advantageous. (ECF No. 57-2 at PageID #437.) The Ventralex patch also has straps on the first layer of polypropylene mesh so that the implanting "surgeon can gently pull on to keep the mesh centered under the hernia." (*Id.*; ECF No. 57-5 at PageID #651.) A surgeon "anchor[s]" the mesh to the repair by suturing the straps or "the patch itself" to the edges of hernia

[2] In 2013, the PET ring was replaced with a polydioxanone ring, which is a resorbable plastic. (ECF No. 57 at PageID #379 n.1.)

defect. (ECF No. 57-2 at PageID #437.)

The Ventralex comes in three sizes: small, medium, and large. (*Id.*) In their surgical "Technique Guide," Defendants recommend selecting a Ventralex size "that is approximately twice the size of the hernia defect to provide sufficient coverage." (ECF No. 57-1 at PageID #419.)

The small and medium sizes were approved for Section 510(k) premarket notification by the Food and Drug Administration ("FDA") on July 16, 2002.[3] (ECF No. 57-5 at PageID #653–56.) Defendants listed the Composix Kugel Mesh as the predicate device. (*Id.* at PageID #656.) The large size was subsequently brought to market via "a no 510(k) rationale based upon the 510(k) for the Composix Kugel product." (ECF No. 57-8 at PageID #673.) A no-510(k) rationale is when a 510(k) application does not need to be submitted because the manufacturer has made changes that do not "significantly affect the safety or effectiveness of the device." (ECF No. 57-9 at PageID #675–76 (citing 21 C.F.R. § 807.81(a)(2)).)

Mr. Milanesi underwent a surgical repair for an approximately two-centimeter umbilical hernia on July 11, 2007. (ECF No. 57-13 at PageID #857.) Dr. Karanbir Gill, Mr. Milanesi's implanting surgeon, decided to use a large Ventralex patch for the repair. (*Id.* at PageID #858.) A large Ventralex patch has an eight-centimeter diameter. (ECF No. 57-1 at PageID #431.) Dr. Gill considered a non-mesh, or primary, repair, but elected to use the Ventralex because there was "undue tension" and he "could not do a primary repair." (ECF No. 57-13 at PageID #858.)

In April 2017, about ten years after his surgery, Mr. Milanesi experienced abdominal pain, swelling or bloating, and lack of appetite. (ECF No. 57-15 at PageID #881, pp. 66–67; ECF No.

[3] The 510(k) premarket approval process has been described previously in this MDL in *In re Davol, Inc./C.R. Bard, Inc., Polypropylene Hernia Mesh Prods. Liab. Litig.*, Nos. 2:18-cv-01509, 2:18-md-2846, 2020 WL 6603657, at *7–8 (S.D. Ohio Oct. 20, 2020) (Motions in Limine Order No. 4).

57-17 at PageID #917, p. 19.) His primary care provider Dr. Miguel Gutierrez-Diaz, M.D., diagnosed him with a periumbilical hernia and an incisional hernia. (ECF No. 57-16 at PageID #910.) Dr. Guiterrez-Diaz referred him to a surgeon, Dr. Michael J. Caluda, M.D. (*Id.* at PageID #912.) On May 25, 2017, Dr. Caluda diagnosed Mr. Milanesi with a recurrent entrapped or obstructed ventral incisional hernia and recommended prompt surgery. (ECF No. 57-18 at PageID #942.) During his visual exam, Dr. Caluda noted that the area was red, firm, and swollen; he could not reduce the mass, or flatten it with manual pressure. (*Id.*)

Dr. Caluda performed surgery on Mr. Milanesi the next day. (ECF No. 57-19 at PageID #945.) He wrote in his operative notes that he had not discovered an entrapped hernia, but "purulent material" and that "[a] loop of the small bowel was densely adherent to the overlying mesh and an erosion of the bowel was evident into an abscess cavity involving a portion of the mesh, which had turned to expose the polypropylene to the bowel at some point, causing an area of adherence." (*Id.*) In his deposition, Dr. Caluda clarified that he had found a fistula, "an abnormal connection between the intestine and other structure," which eroded into the subcutaneous space through the abdominal wall, and an infection in an abscess cavity. (ECF No. 57-17 at PageID #919, p. 37; PageID #931, p. 117) Dr. Caluda went on, explaining that "[t]here was definitely an opening in the abdominal wall fascia which could be construed as a recurrent hernia but more accurately should be described as part of the infectious process in the small intestinal fistula which had eroded from the abdominal cavity into the subcutaneous space." (*Id.* at PageID #919, pp. 36–37.) The "purulent material result[ed] from intestinal contents contacting tissues where they do not belong." (*Id.* at p. 37.)

Dr. Caluda excised the infected Ventralex from Mr. Milanesi's abdominal wall and resected the bowel, removing nine centimeters of Mr. Milanesi's small intestine. (*Id.* at PageID

#920, pp. 42–45.) Dr. Caluda described the explanted Ventralex as "distorted," "firm," "not pliable," and in a "buckling" shape. (ECF No. 87-2 at PageID #6672, pp. 46–47.)

Several days later, on June 1, 2017, Mr. Milanesi returned for emergency surgery because he had a high-grade post-operative small bowel obstruction. (ECF No. 57-20 at PageID #947.) This obstruction was caused by "adhesions in the right lower quadrant." (*Id.*) Dr. Caluda successfully removed the adhesions. (*Id.*)

Afterwards, Mr. Milanesi developed a recurrent incisional abdominal wall hernia near his previous surgery sites. (ECF No. 87-1 at PageID #6662.) He had "at least two areas of herniation extending laterally from the umbilicus in each direction." (*Id.*) The hernia defects were two and three centimeters. (*Id.*) Both Dr. Caluda and a surgeon from whom Mr. Milanesi sought a second opinion recommended surgical repair. (*Id.* at PageID #6663.) It does not appear that Mr. Milanesi has had this surgery.

The crux of Plaintiffs' claims is that Defendants knew of certain risks presented by the Ventralex device but marketed and sold the device despite these risks and without appropriate warnings, causing Plaintiffs' injuries. Plaintiffs point to three specific issues with the Ventralex. First, they argue that polypropylene resin oxidatively degrades *in vivo*. (ECF No. 87 at PageID #6591–92.) Defendants were aware of these risks because the Material Safety Data Sheet ("MSDS") for polypropylene noted that the material should not be used for human implantation because it can oxidize in the body. (*Id.* at PageID #6592.) Second, Plaintiffs contend that the ePTFE layer contracts more than the polypropylene, which in combination with the too-weak memory coil ring causes the device to fold or buckle or "potato chip."[4] (*Id.* at PageID #6594–95.)

[4] The technical name of this double-curved shape is a hyperbolic paraboloid. A popular potato chip packaged in tubes and horseback-riding saddles have the same shape.

The buckling leads to the Ventralex patch pulling away from the abdominal wall and curving in toward the bowel, causing the bare polypropylene side of the Ventralex to adhere to the bowel. (*Id.* at PageID #6598–99.) Plaintiffs explain that Defendants knew about this issue due to the Composix Kugel device recall for broken memory coil rings, the same rings in the Ventralex device, which Defendants used even though more buckle-resistant options were available. (*Id.* at PageID #6596–97.) Third, Plaintiffs argue that the ePTFE layer was prone to infection because of the ePTFE layer's small pore size, which is big enough for bacteria to grow in but too small for white blood cells to enter to intercept the bacteria. (*Id.* at PageID #6600–01.) This risk was known by Defendants' employees, as illustrated by internal documents. (*Id.*)

On October 26, 2018, Plaintiffs, Mr. and Ms. Milanesi, filed their complaint. (ECF No. 1 at PageID #1.) In their amended complaint, Plaintiffs raise claims for (1) defective design (strict liability), (2) failure to warn (strict liability), (3) manufacturing defect (strict liability), (4) negligence, (5) negligence per se, (6) gross negligence, (7) negligent misrepresentation, (8) fraud and fraudulent misrepresentation, (9) fraudulent concealment, (10) loss of consortium, and (11) punitive damages. (ECF No. 15 at PageID #91–92.) Defendants seek summary judgment on all claims. (ECF No. 57.) The motion is fully briefed, and Defendants have filed evidentiary objections in response to Plaintiffs' brief. (ECF Nos. 97, 111, 112.)

II. Governing Law and Legal Standard

In federal diversity actions, "state substantive law and federal procedural law apply to state claims." *Range v. Douglas*, 763 F.3d 573, 580 (6th Cir. 2014). Generally, the state law of the transferor court applies in MDLs. *See Wahl v. Gen. Elec. Co.*, 786 F.3d 491, 497–98 (6th Cir. 2015). In cases filed directly with the MDL court, MDL courts will apply the substantive state law of the "originating jurisdiction," including choice-of-law rules. *Sanchez v. Bos. Sci. Corp.*,

No. 2:12-cv-05762, 2014 WL 202787, at *4 (S.D. W. Va. Jan. 17, 2014) (quoting *In re Watson Fentanyl Patch Prods. Liab. Litig.*, MDL No. 2732, 2013 WL 4564927, at *2 (N.D. Ill. Aug. 27, 2013)). The originating jurisdiction is where the case would have been filed if the case management order permitting direct filing did not exist. *Wahl v. Gen. Elec. Co.*, 983 F. Supp. 2d 937, 943 (M.D. Tenn. 2013). In a medical device case, this is where the device was purchased, prescribed, and implanted. *E.g.*, *Sanchez*, 2014 WL 202787, at *4. There is no dispute that the action would have been filed in Florida absent Case Management Order No. 2 permitting direct filing with this Court. (ECF No. 15 at PageID #88.) Thus, Florida choice-of-law rules apply.

Under Florida choice-of-law rules, Florida law applies to this case. Florida applies the Restatement (Second) of Conflict of Laws approach, the most significant relationship analysis, to tort-law claims, including product-liability claims. *Bishop v. Fla. Specialty Paint Co.*, 389 So.2d 999, 1001 (Fla. 1980); *Tune v. Philip Morris Inc.*, 766 So.2d 350, 353 (Fla. Dist. Ct. App. 2000). Here, all pertinent events took place in Florida—Plaintiffs live there, the surgeries occurred there, and their injuries occurred there. *See* Restatement (Second) of Conflict of Laws § 145(2) (1971). The parties do not dispute the application of Florida law.

Under the Federal Rules of Civil Procedure, summary judgment is appropriate when "the movant shows that 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(a). "The moving party bears the burden of showing that no genuine issues of material fact exist." *RJ Control Consultants, Inc. v. Multiject, LLC*, 981 F.3d 446, 452 (6th Cir. 2020) (citing *Celotex Corp. v. Catrett*, 477 U.S. 317, 325 (1986)). The burden then shifts to the nonmoving party, who "must set forth specific facts showing that there is a genuine issue for trial." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 250 (1986). "In order for the non-movant to defeat a summary-judgment motion, there must be evidence on which

the jury could reasonably find for the [non-movant]." *Clabo v. Johnson & Johnson Health Care Sys., Inc.*, 982 F.3d 989, 992 (6th Cir. 2020) (alteration in original) (quoting *Bard v. Brown County*, 970 F.3d 738, 748 (6th Cir. 2020)). The court must "consider the evidence in the light most favorable to the nonmoving party and draw all reasonable inferences in that party's favor." *Johnson v. City of Saginaw*, 980 F.3d 497, 506 (6th Cir. 2020) (quoting *Quigley v. Tuong Vinh Thai*, 707 F.3d 675, 679 (6th Cir. 2013)). The ultimate question is "whether the evidence presents a sufficient disagreement to require submission to a jury or whether it is so one-sided that one party must prevail as a matter of law." *Anderson*, 477 U.S. at 251–52.

III. Analysis

Defendants argue that Plaintiffs fail to demonstrate genuine material fact disputes exist for trial. First, Defendants assert that Plaintiffs fail to demonstrate causation on all claims. Defendants then raise arguments for each of Plaintiffs' claims: manufacturing defect; design defect; failure to warn; negligent misrepresentation, fraud, fraudulent misrepresentation, and fraudulent concealment; negligence; negligence per se; and gross negligence/punitive damages. Plaintiffs demonstrate that summary judgment is not appropriate on their design defect, failure to warn, misrepresentation and fraud, negligence, and gross negligence/punitive damages claims.

A. Causation

Defendants argue that Plaintiffs cannot show causation for any of their claims. Specifically, Defendants explain that Plaintiffs rely on Dr. Krpata "to establish general causation for an increased risk of bowel erosion, fistula, and infection from 'buckling,' and that this 'buckling' caused Mr. Milanesi's injuries." (ECF No. 57 at PageID #387.) This is a reiteration of Defendants' arguments in their *Daubert* motion addressing Dr. Krpata. (*Compare* ECF Nos. 57 & 111 *with* ECF Nos. 63 & 121.) The Court denied Defendants' *Daubert* motion despite these

arguments. (ECF No. 166 at PageID #13583–13599.) Dr. Krpata's general and specific causation opinions regarding buckling are admissible. (*Id.* at PageID #13583–13602.) Accordingly, Plaintiffs have demonstrated a material fact dispute regarding causation.

B. Manufacturing Defect

Next, Defendants assert that Plaintiffs have not shown that the Ventralex implanted in Mr. Milanesi contained a manufacturing defect, requiring summary judgment on Plaintiffs' strict liability and negligence manufacturing defect claims. (ECF No. 57 at PageID #390.) Plaintiffs counter that they have offered evidence of a manufacturing defect and that they also are entitled to an inference of such a defect pursuant to *Cassisi v. Maytag Co.*, 396 So.2d 1140 (Fla. Dist. Ct. App. 1981). (ECF No. 87 at PageID #6633–34.) Plaintiffs do not demonstrate genuine and material fact disputes exist for their manufacturing defect claim.

Under Florida law, a plaintiff must prove the following for a strict liability products liability claim: "1) the product was defective, 2) the defect existed at the time the product left the defendant-manufacturer's control, and 3) the defect proximately caused the plaintiff's injuries." *Salinero v. Johnson & Johnson*, 400 F. Supp. 3d 1334, 1343–44 (S.D. Fla. 2019) (citing cases). To prove a manufacturing defect, the product must have "a defect that renders it unreasonably dangerous." *Tillman v. C.R. Bard, Inc.*, 96 F. Supp. 3d 1307, 1334 (M.D. Fla. 2015). A product with a manufacturing defect is one "that 'does not conform to its intended design' such that it . . . '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. 2011) (quoting *Standard Jury Instructions—Civil Cases (No. 02-2)*, 872 So.2d 893, 895 (Fla. 2004)). "Manufacturing defects are generally limited to situations where something goes wrong in the manufacturing process[.]" *Salinero*, 400 F. Supp. 3d at 1344 (quoting *Benitez v. Synthes, Inc.*, 199 F. Supp. 2d 1339, 1344

(M.D. Fla. 2002)). In other words, a manufacturing defect is an "aberrational" defect, an "unintended configuration" of the product, as opposed to a design defect which is a defect "occurring throughout an entire line of products," an "intended configuration [of the product] that may produce unintended and unwanted results." *Harduvel v. Gen. Dynamics Corp.*, 878 F.2d 1311, 1317 (11th Cir. 1989)). Accordingly, a plaintiff must show that the product had an unintended configuration or "that that [the product] did not perform properly under the circumstances" "through expert testimony." *Tillman*, 96 F. Supp. 3d at 1346 (quoting *Hall v. Sunjoy Indus. Grp., Inc.*, 764 F. Supp. 2d 1297, 1302 (M.D. Fla. 2011)). A plaintiff may show a manufacturing defect by presenting evidence of the defect or, for a strict liability claim, by showing that they are entitled to a *Cassisi* inference. *Gardener v. Ford Motor Co.*, 166 F. Supp. 3d 1261, 1266 (M.D. Fla. 2015); *Cassisi*, 396 So.2d at 1144 (discussing Restatement (Second) Torts § 402A (1965) (Strict Liability)). Plaintiffs do not demonstrate triable issues of fact exist on their manufacturing defect claim with evidence of a defect or that they are entitled to a *Cassisi* inference.

First, evidence of a defect. Plaintiffs do not show that Mr. Milanesi's Ventralex contained a manufacturing defect. Plaintiffs argue that evidence that the Ventralex did not "spring open and lie flat" is evidence of a manufacturing defect. (ECF No. 87 at PageID #6634.) The defect, they contend, is that Mr. Milanesi's Ventralex had "0.030" diameter ring as opposed to a double ring design and/or an 0.0042" ring." (*Id.*) This is not unintended deviation from the Ventralex's blueprint, but a conscious design choice—as Plaintiffs themselves argue in support of their design defect claim. (ECF No. 87 at PageID #6608.) Plaintiffs point to an unintended consequence of an intentional design, not an unintended configuration of the Ventralex. This leaves the *Cassisi* inference for Plaintiffs' strict liability manufacturing defect claim as the only possible route for Plaintiffs to survive summary judgment

A plaintiff is entitled to a legal inference of a manufacturing defect, a *Cassisi* inference, (1) when the product malfunctions (2) during its normal operation. *Cassisi*, 396 So.2d at 1148.[5] A *Cassisi* inference allows a plaintiff to present to the jury a prima facie case of a manufacturing defect. *Warner v. Sony Corp. of Am.*, 560 So.2d 399, 400 (Fla. Dist. Ct. App. 1990) (citing *Marcus v. Anderson/Gore Homes, Inc.*, 498 So.2d 1051, 1052 (Fla. Dist. Ct. App. 1981)). But "a malfunction is not established merely because a product breaks. Rather, a plaintiff 'must present evidence, through expert testimony, that [the product] did not perform properly under the circumstances." *Tillman*, 96 F. Supp. 3d at 1346 (alteration in original) (quoting *Beauregard v. Cont'l Tire N. Am., Inc.*, 435 F. App'x 877, 880 (11th Cir. 2011)). A plaintiff must provide some evidence of a malfunction, though the plaintiff need not identify the exact defect causing the malfunction or eliminate other causes of injury. *Cassisi*, 396 So.2d at 1149–52; *Edic ex rel. Edic v. Century Prods. Co.*, 364 F.3d 1276, 1285 (11th Cir. 2004) (noting expert testimony that a child's car seat malfunctioned when it ejected the child). In the medical device context, "well-known potential complications" that "are inherent in the design of the" device are insufficient to demonstrate that a device did not perform properly under the circumstances. *Tillman*, 96 F. Supp.

[5] This rule is "founded upon strong policy considerations that aid a plaintiff in meeting his burden of proof when direct proof of . . . product defectiveness is wanting." *Cassisi*, 396 So.2d. at 1149 (footnotes omitted) (discussing the parallels between the doctrine of *res ipsa loquitor* and what would become the *Cassisi* rule). Often, applications of the *Cassisi* rule apply where the allegedly defective product has been destroyed, badly damaged, or eliminated by the malfunction. *Id.* at 1149–50. However, a destroyed or lost product it is not a prerequisite for the *Cassisi* inference to apply. *Id.* at 1151. "Cases applying the [*Cassisi*] inference frequently involve evidentiary facts comprising both an expert's inspection of the product as well as proof of its malfunction, coupled with evidence of normal use." *Id.* When the product is unavailable or when the plaintiff faces an information asymmetry, these "'practical evidentiary problems,' the burden shifts to the manufacturer—the one most familiar with the product—to prove that its product was defect-free at the time of injury, or that the defect was not the cause of the injury." *Miller v. Allstate Ins. Co.*, 573 So.2d 24, (Fla. Dist. Ct. App. 1990) (quoting *Cassisi*, 396 So.3d at 1147–51).

3d at 1346–47; *Ocasio v. C.R. Bard, Inc.*, No. 8:13-cv-1962-T-36AEP, 2015 WL 3496062, at *8 (M.D. Fla. 2015). In *Tillman*, for example, the injuries that the plaintiff suffered were "well-known complications" of a filter device, including tilt, perforation, and migration of the device within the body. 96 F. Supp. 3d at 1346–47. And without evidence of an "intervening manufacturing defect," the plaintiff did not demonstrate that the filter in her inferior vena cava filter malfunctioned, and she was thus not entitled to the *Cassisi* inference. *Id.* at 1347.

Plaintiffs do not provide sufficient evidence justifying the application of the *Cassisi* inference. Plaintiffs do not point to expert testimony that Mr. Milanesi's Ventralex did not perform properly. Indeed, Dr. Krpata agreed during his deposition that he was not offering an opinion that Mr. Milanesi's Ventralex deviated from specifications or did not perform properly. (ECF No. 57-10 at PageID #790, p. 279.) Plaintiffs also do not provide any other evidence that shows that Mr. Milanesi's injuries—fistula, adhesions, and bowel erosion—were caused by an intervening malfunction, as opposed to being well-known complications inherent to the Ventralex's design. (*See, e.g.*, ECF No. 57-17 at PageID #929, p. 107.) For these reasons, Plaintiffs fail to demonstrate a triable issue of fact remains for their manufacturing defect claim.

C. Design Defect

Defendants next turn to Plaintiffs' design defect claims, arguing that Plaintiffs have no admissible evidence of a design defect, that Plaintiffs have no evidence that the Ventralex's design caused Mr. Milanesi's injuries, that as a matter of law the benefits of the Ventralex design outweighed the risks, and that as a matter of law the Ventralex was a state-of-the-art design in 2007. (ECF No. 57 at PageID #390–400.) A reasonable jury could find that the Ventralex contained a design defect that caused Plaintiffs' injuries, and summary judgment is inappropriate on Defendants' state-of-the-art defense.

Again, a plaintiff must show the following to succeed on a strict-liability product defect claim: "(1) a defect existed in the product, (2) the defect caused the injury, and (3) the defect in the product existed at the time the product left the possession of the manufacturer." *Cooper v. Old Williamsburg Candle Corp.*, 653 F. Supp. 2d 1220, 1223 (M.D. Fla. 2009). To prove a design defect, a plaintiff may offer evidence under either the consumer expectations test or the risk utility test. *Aubin v. Union Carbide Corp.*, 177 So.3d 489, 511 (Fla. 2015). Here, Plaintiffs proceed under the consumer expectations test, "which considers whether a product is unreasonably dangerous in design because it failed to perform as safely as an ordinary consumer would expect when used as intended or in a reasonably foreseeable manner." *Id.* at 503 (citing Restatement (Second) of Torts § 402A (1965)).

Plaintiffs show that the Ventralex has design defects and that those defects caused Mr. Milanesi's injuries. Given the evidence that Plaintiffs have put forth regarding the Ventralex's buckling, the design of the memory recoil ring, and the unavoidable technique errors, as discussed in the Court's *Daubert* opinion addressing Dr. Krpata's opinions (ECF No. 166 at PageID #13583–13599.), a jury could find that the Ventralex does not perform as safely as the average consumer or their learned intermediary would expect when used in a manner foreseeable or as intended by Defendants. Dr. Krpata's opinions that the design defects in the Ventralex caused Mr. Milanesi's injuries are also admissible. (*Id.* at PageID #13599–13603.) Defendants' arguments to the contrary were addressed in the Court's opinion and order addressing the admissibility of Dr. Krpata's opinions. (*Id.* at PageID #13583–13603.)

Defendants counter that Plaintiffs must satisfy the risk-utility test for design defect claims in medical device cases which they have not done. (ECF No. 57 at PageID #392.) But the Florida Supreme Court has held otherwise. In *Aubin v. Union Carbide Corp.*, the Florida Supreme Court

"adhere[d] to the consumer expectations test . . . and reject[ed] the categorical adoption of the Third Restatement," which sets forth the risk-utility test for design defects. 177 So.3d at 510. The Court was emphatically clear that its refusal to categorically adopt the risk-utility test was because the test undermines Florida's reasons for adopting strict liability for products in the first place, primarily that the risk utility test "[i]ncreases the burden for injured consumers." *Id.*; *see also id.* at 502–04 (discussing those reasons in depth). Although a plaintiff may offer evidence relevant to the risk-utility test, including evidence of an alternative design, the Florida Supreme Court refused to require such evidence. *Id.* at 511. Importantly, the Florida Supreme Court declined to modify the standard jury instructions permitting use of the consumer expectations or risk utility test. *Id.* at 512; *see also In re Std. Jury Instr. In Civ. Cases—Report No. 13-01*, 160 So.3d 869, 871 (Fla. 2015). In medical device cases, courts have interpreted the holding in *Aubin* as permitting a plaintiff to "prevail by proving either" the consumer expectation test or the risk utility test. *Pierre v. Intuitive Surgical, Inc.*, 476 F. Supp. 3d 1260, 1270 (S.D. Fla. 2020) (quoting *Anderson v. Techtronic Indus. N. Am., Inc*, No. 13-1571, 2015 WL 12843836, at *3 (M.D. Fla. Apr. 14, 2015)). Nothing in the Florida Supreme Court's rationale justifies a different approach to complex medical device cases, and so the Court concludes that the Florida Supreme Court would not require plaintiffs to follow the risk-utility test.

Defendants point to several counter authorities, but none persuade. With the exception of one case, every authority precedes *Aubin*, and thus provides little persuasive guidance. (ECF No. 57 at PageID # 391–92.) Only one Florida court has required plaintiffs bringing design defect claims in medical device cases to satisfy the risk-utility test, simply distinguishing *Aubin* by noting that it did not address medical devices or the learned intermediary doctrine. *Cavanaugh v. Stryker Corp.*, 308 So.3d 149, 155 (Fla. Dist. Ct. App. 2020). But "this, alone, does not warrant departure

from the consumer expectation test. Merely relying on who a manufacturer markets its products to does not overcome one of the main policy justifications in *Aubin*—maintaining the burden on the manufacturer as opposed to the injured consumer." *Pierre*, 476 F. Supp. 3d at 1271 (considering whether the device performed to plaintiff's or his doctor's expectations). Most courts interpreting *Aubin* have concluded, without much ado, that the consumer expectations test applies to medical device cases. *Geery v. Ethicon, Inc.*, No. 6:20-cv-1975-RBD-LRH, 2021 WL 2580144, at *5 (M.D. Fla. Apr. 9, 2021); *Davis v. Bos. Sci. Corp.*, No. 2:17–cv–682–FTM–38CM, 2018 WL 2183885, at *4 (M.D. Fla. May 11, 2018); *Douse v. Bos. Sci. Corp.*, 314 F. Supp. 3d 1251, 1260 (M.D. Fla. 2018); *see Kendall v. Bos. Sci. Corp.*, No. 6:17-cv-1888-Orl-37GJK, 2018 WL 3910883, at *4 (M.D. Fla. Apr. 17, 2018).

Finally, Defendants also contend that summary judgment is appropriate on Plaintiffs' design defect claim because the Ventralex was state of the art in 2007. (ECF No. 57 at PageID #398.) The state-of-the-art argument is an affirmative defense. Fla. Stat. § 768.1257; *Eghnayem v. Bos. Sci. Corp.*, No. 1:14–cv–024061, 2016 WL 4051311, at *4 (S.D. Fla. Mar. 17, 2016). This means that Defendants bear the burden of persuasion at trial, and thus Defendants' "initial" burden as the movant on summary judgment "is 'higher in that it must show that the record contains evidence satisfying the burden of persuasion and that the evidence is so powerful that no reasonable jury would be free to disbelieve it.'" *Surles v. Andison*, 678 F.3d 452, 455–56 (6th Cir. 2012) (quoting *Cockrel v. Shelby Cnty. Sch. Dist.*, 270 F.3d 1036, 1056 (6th Cir. 2001)). Specifically, the moving party "must lay out the elements of its claims." 10A Mary Kay Kane, Federal Practice & Procedure § 2727.1 (4th ed.) (Westlaw Update Oct. 2020).

Defendants do not satisfy this burden. In two instances they refer to the state of the art in 2007. (ECF No. 57 at PageID #398 ("[C]onsidering the other devices that were available in 2007

to repair Mr. Milanesi's hernia, the Ventralex was clearly state of the art[.]"), 400 ("Considering the devices that were available in 2007 to repair Mr. Milanesi's hernia, the Ventralex was clearly state of the art[.]").) This is insufficient. Accordingly, summary judgment on Plaintiffs' design defect claim is inappropriate.

D. Failure to Warn

Next, Defendants argue that Plaintiffs fail to show that a reasonable jury could conclude that Defendants' instructions for use ("IFU") were inadequate warnings. (ECF No. 57 at PageID #400.) Under Florida law, "[s]trict liability and negligent failure to warn cases boil down to three elements that Plaintiff must prove: 1) that the warnings accompanying the item were inadequate; 2) that the inadequacy of the warnings proximately caused Plaintiff's injury; and 3) that Plaintiff in fact suffered an injury by using the product." *Colville v. Pharmacia & Upjohn Co. LLC*, 565 F. Supp. 2d 1314, 1320 (N.D. Fla. 2008) (collecting Florida cases). Specifically, Defendants contend that the Ventralex's IFU contains adequate warnings as a matter of law and that Plaintiffs cannot show that an inadequate warning proximately caused Mr. Milanesi's injuries. (*Id.* at PageID #400–04.) Plaintiffs show genuine fact disputes exist as to the adequacy of the warnings and proximate causation, and Defendants do not show that the warnings are adequate as a matter of law.

1. Adequacy of Warning

In medical device cases, "the issue is whether the warning provided to the physician is adequate." *Rounds v. Genzyme Corp.*, 440 F. App'x 753, 755 (11th Cir 2011); *see also Beale v. Biomet, Inc.*, 492 F. Supp. 2d 1360, 1366 (S.D. Fla. 2007). This is because the learned intermediary doctrine applies under Florida law. *Beale*, 492 F. Supp. 2d at 1335. Therefore, "the duty to warn is directed to physicians rather than patients under the 'learned intermediary' doctrine." *Hoffmann-La Roche Inc. v. Mason*, 27 So.3d 75, 77 (Fla. Dist. Ct. App. 2009). "[T]o

warn adequately, the product label must make apparent the potential harmful consequences. The warning should be of such intensity as to cause a reasonable man to exercise for his own safety caution commensurate with the potential danger." *Scheman-Gonzalez v. Saber Mfg. Co.*, 816 So.2d 1133, 1139 (Fla. Dist. Ct. App. 2002) (quoting *Am. Cyanamid Co. v. Roy*, 466 So.2d 1079, 1082 (Fla. Dist. Ct. App. 1984)). But "[w]hen a warning is designed to inform a 'learned intermediary,' it is somewhat easier to establish the adequacy of the warning because it will be read and considered by a trained expert." *Hayes v. Spartan Chem. Co., Inc.*, 622 So.2d 1352, 1354 (Fla. Dist. Ct. App. 1993).

Typically, a plaintiff must provide expert testimony to demonstrate that a defendant's warnings were in adequate; otherwise, summary judgment on plaintiff's failure to warn claim is appropriate. *Nunez v. Coloplast Corp.*, 461 F. Supp. 3d 1260, 1266 (S.D. Fla. 2020); *see also Upjohn Co. v. MacMurdo*, 562 So.2d 680, 683 (Fla. 1990) ("Therefore, the adequacy or inadequacy of the warning to inform a physician must, except in the more obvious situations, be proved by expert testimony."). On the other hand, "[t]he sufficiency and reasonableness of the warnings are questions of fact best left for the jury unless the warnings are accurate, clear, and unambiguous." *Thomas v. Bombardier Recreational Prods, Inc.*, 682 F. Supp. 2d 1297, 1300 (M.D. Fla. 2010) (citing *Scheman-Gonzalez*, 816 So.2d at 1139–40). In other words, "the adequacy of the warnings can be resolved as a matter of law if they are 'accurate, clear, and unambiguous.'" *Nunez*, 461 F. Supp. 3d at 1260 (quoting *Farias v. Mr. Heater, Inc.*, 757 F. Supp. 2d 1284, 1293 (S.D. Fla. 2010)). Plaintiffs' failure to warn claims survive in relation to post-implantation buckling.

Plaintiffs have shown that questions of fact remain as to the adequacy of the Ventralex's IFU with regard to the risk of buckling, contracture, and ePTFE-related infections. The IFU notes

the possibility that polypropylene causes adhesions and that the polypropylene mesh side of the Ventralex should not be placed against the bowel during implantation and that if the ring is damaged during the initial surgery to place the Ventralex, bowel perforation is possible. (ECF No. 57-6 at PageID #658.) It also lists adverse reactions, including fistula. (*Id.*) Dr. Gill testified that these warnings are insufficient because they do not include information about the Ventralex's alleged propensity to buckle after implantation. (ECF No. 57-4 at PageID #573, pp. 64–65.) He also stated that he was not warned that the ePTFE would contract more quickly than polypropylene, which is part of the buckling mechanism, or that ePTFE has a particular risk of infection. (*Id.* at PageID #581–82, 586, p.p. 97–98, 114.) He went on, explaining that the IFU gives no indication that after the Ventralex is "la[id] right next to the abdominal," subsequent buckling and adhesions and inflammation can result. (*Id.* at PageID#573, p. 65.) And in response to counsel's questioning about buckling and subsequent bowel puncture, Dr. Gill confirmed that there was no mention of such post-implantation risks.[6] (*Id.* at p. 64.) Dr. Krpata offers a similar opinion. (ECF No. 57-22 at PageID #977–78.)

To the extent that Plaintiffs argue that the IFU provides inadequate warnings without relation to subsequent buckling, the Court concludes they fail to demonstrate a material fact dispute. Plaintiffs argue that a "generic laundry listing of adverse reactions" that are "possible" is inadequate (ECF No. 87 at PageID #6615–16), but the IFU is clear that the Ventralex cannot be placed against the bowels during implantation. (ECF No. 57-6 at PageID #658.) With regard to adhesions specifically, the IFU states, "[d]o not place the mesh surface against the bowel" (*id.*), which is adequate, *see Zanzuri v. G.D. Searle & Co.*, 748 F. Supp. 1511, 1516–17 (S.D. Fla. 1990)

[6] Although fact disputes exist, Dr. Gill's broad, unspecific assertions that he "expect[s] the company to give me complete information," which Plaintiffs cite, do not create material fact disputes. (ECF No. 87 at PageID #6616.)

(distinguishing the case at hand from Florida precedent by noting that lack of an express statement where a device should not be placed).

Defendants raise two counterarguments. First, Defendants argue that the risks of adhesions, fistula, and bowel erosion are clearly warned of in the IFU, meaning that the Court can determine that as a matter of law, the warnings are adequate. (ECF No. 57 at PageID #402.) The warnings are unambiguous, accurate, and clear with regard to the risks such as adhesions if the Ventralex's polypropylene side is exposed to bowel during implantation. (ECF No. 57-6 at PageID #658.) But the IFU does not address buckling that leads to polypropylene exposure after apparently appropriate implantation and associated risks. Defendants provide no authority for the proposition that incomplete but clear warnings are adequate as a matter of law. As always, the question on summary judgment is whether a reasonable jury could find for the nonmoving party under these specific circumstances, and Florida's precedent on adequate warnings as a matter of law is simply another way of stating this well-worn standard.

Second, Defendants contend that a manufacturer need only warn of a possible injury—not the defect or mechanism that caused the injury, such as buckling. (ECF No. 57 at PageID #403; ECF No. 111 at PageID #10609–11.) There is no indication that Florida state courts would so narrowly construe the issue of the adequacy of warnings so as to take this issue away from the jury. Florida precedent sets the scope of injury relatively broadly, instructing courts to look at whether the "warnings were adequate to warn a physician of the possibility that [the device] might be causing the condition experienced." *MacMurdo*, 562 So.2d at 683. Florida courts also describe a warning as adequate if it warns of "the dangers" of a drug, *Mason*, 27 So.3d at 77, and "the potential harmful consequences," *Scheman–Gonzalez*, 816 So.2d at 1139.

The Supreme Court of Florida also frequently turns to the Restatement (Second) of Torts

for guidance, *e.g.*, *Aubin*, 177 So.3d at 512; *United States v. Stevens*, 994 So.2d 1062, 1067 (Fla. 2008), which indicates the court would not limit the scope of injury as Defendants urge. An "injury" is "the invasion of any legally protected interest," while "harm" is "the existence of loss or detriment in fact of any kind to a person resulting from any cause." Restatement (Second) of Torts § 7(1)–(2) (1965). "The most usual form of injury is the infliction of some harm; but there may be an injury although no harm is done." *Id.* cmt. a. Restatement also defines "bodily harm" as "any physical impairment of the condition of another's body, or physical pain or illness." *Id.* at § 15. This suggests that Florida courts do not view injury as synonymous with bodily harm.

Indeed, courts applying Florida law often discuss the defect or mechanism of an injury in relation to the bodily harm a plaintiff has suffered to examine the adequacy of the warning. In *Thomas v. Bombardier Recreational Products, Inc.*, the court did not only look at whether a warning label noted the risk of internal injuries associated with a personal watercraft, but also relied on the fact that the label noted that these internal injuries "can occur if the water is forced into body cavities as a result of falling into water or being near jet thrust nozzle." 682 F. Supp. 2d at 1300. This vivid description is without a doubt a mechanism of an injury. The same is true in medical device cases. In *Humleker v. Bostic Scientific Corp.*, material fact disputes existed when an expert opined that a warning was inadequate because it failed to state the risk of "shrinkage due to contraction and scarring." No. 6:19-cv-121-Orl-31EJK, 2020 WL 6870852, at *14 (M.D. Fla. Oct. 2, 2020). In an even clearer example, *Barrow v. Bristol-Myers Squibb*, the court found during a bench trial that the defendant's warnings were inadequate because they failed to warn of silica gel bleeds from breast protheses, which caused the plaintiff to suffer from autoimmune and neurological disease. No. 96–689–CIV–ORL–19B, 1998 WL 812318, at *1 & 25 (M.D. Fla. Oct. 28, 1998). *But see Pierre*, 476 F. Supp. 3d at 1279 (concluding that a warning must adequately

warn of the injury, "not the specific way(s) that the alleged injury may occur").

Whether a label is clear and unambiguous as a matter of law depends on the circumstances of the case, specifically the injuries claimed. On the facts that Plaintiffs point to, the risks presented by the Ventralex buckling are distinct from the risks of placing the Ventralex's polypropylene side next to the bowels. Accordingly, the IFU is not so unambiguous in relation to the risks presented by the Ventralex buckling that no reasonable jury could conclude the IFU was inadequate with regard to buckling and the attendant risks.

2. Causation

Defendants also argue that even if the warnings are inadequate, Plaintiffs cannot show that the inadequate warnings in the Ventralex's IFU caused Plaintiffs' injuries. (ECF No. 57 at PageID #404.) Whether a product liability claim is based on strict liability or negligence, the proximate causation standard from negligence claims governs causation. *West v. Caterpillar Tractor Co., Inc.*, 336 So.2d 80, 90 (Fla. 1976). In the learned intermediary context, there is no proximate causation between the defendant's failure to warn and the plaintiff's injury if the "learned intermediary has actual knowledge of the substance of the alleged warning and would have taken the same course of action even with the information the plaintiff contends should have been provided." *Beale*, 492 F. Supp. 2d at 1371 (quoting *Ellis v. C.R. Bard, Inc.*, 311 F.3d 1272, 1283 n.8 (11th Cir. 2002)).

Plaintiffs show that the Ventralex's IFU's inadequate warnings were the proximate cause of Mr. Milanesi's injuries. Dr. Gill testified that had he known about the Ventralex's risk of buckling, which includes ePTFE contraction and memory coil ring issues, and the ePTFE-specific risk of infection, he would not have used the Ventralex device for Mr. Milanesi's hernia repair. (ECF No. 57-4 at PageID #581, pp. 96–97; 585–86, pp. 113–15.) This is sufficient to survive

summary judgment. Defendants focus on Dr. Gill's statements that he would want information about "excessive" risks (ECF No. 111 at PageID #10613), but what Dr. Gill means when he says "excessive" does not help the Defendants. Most importantly, when the Court views his testimony in the light most favorable to Plaintiffs and draws all inferences in their favor, Dr. Gill's characterization of the unaddressed risks does not override the point of his deposition testimony that he would have used a different device had he known about the risks described to him during the deposition. That his testimony may be subject to different interpretations is an issue of witness credibility for the jury.

Defendants counter that Dr. Gill had independent knowledge of the applicable risks of the Ventralex, severing any causal connection between the IFU and Mr. Milanesi's injuries. (ECF No. 404–06.) But Dr. Gill is clear that he associated the buckling and ePTFE risks with features or issues unique to the Ventralex device. (ECF No. 57-4 at PageID #581, pp. 96–97; 585–86, pp. 113–15.) The more general knowledge about hernia mesh devices that Defendants point to only demonstrates a factual issue of whether Dr. Gill in fact did not have independent knowledge of the applicable risks in light of his previous experience—which is a jury question.

Defendants also contend that Plaintiffs do not offer an adequate alternative warning from an expert. (ECF No. 57 at PageID #405.) However, "[t]here is no requirement that an expert produce an alternative warning for his testimony to be admissible." *Mizrahi v. Yamaha Motor Corp., U.S.A.*, No. 17-24484-CIV-SCOLA/TORRES, 2019 WL 3318527, at *11 (S.D. Fla. 2019).

Finally, Defendants argue that Dr. Gill's statements that he would not have used the Ventralex had he known about the risks discussed above are discounted because the questions he was asked were "hypothetical." According to Defendants, Dr. Gill has not acknowledged these risks as real, and he was not shown any reliable evidence of these risks during his deposition. (ECF

No. 57 at PageID #406.) Defendants urge the Court to weigh Dr. Gill's testimony by evaluating how seriously he assessed the questions, which it cannot do. For this reason, the Court need not address the parties' dispute about Dr. Gill's review of the MSDS during his deposition and how it impacts his retrospective assessment of whether he would have taken a different route with adequate warnings. (ECF No. 57 at PageID #406–07; ECF No. 87 at PageID #6620; ECF No. 111 at PageID #10614–15.)

E. Negligent Misrepresentations, Fraud, Fraudulent Misrepresentation, and Fraudulent Concealment

Defendants next contend that Plaintiffs' negligent misrepresentation, fraud, and fraudulent concealment/misrepresentation claims do not survive summary judgment. (ECF No. 57 at PageID #411.) Primarily, they contend that these claims are subsumed by Plaintiffs' failure to warn claim. (*Id.*) Plaintiffs' misrepresentation and fraud claims are not subsumed by their failure to warn claim, and they show that a reasonable jury could find that Defendants made misrepresentative or fraudulent statements.

At the outset, it is necessary to address whether Plaintiffs' fraud and misrepresentation claims collapse into their failure to warn claims. In an effort to prevent a run-around the learned intermediary doctrine in failure-to-warn claims, some courts have concluded that the learned intermediary doctrine also applies to fraud-based claims. *E.g.*, *Beale*, 492 F. Supp. 3d at 1372–73; *Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 736, 743–44 (S.D.W. Va. 2014) (collecting cases). In effect, this means that a plaintiff cannot raise fraud claims on the basis of the defendant's representations made to the plaintiff, as opposed to her doctor. *Huskey*, 29 F. Supp. 3d at 744 ("Here, the plaintiffs' fraud-based claims and warranty claims are simply repackaged failure-to-warn claims. The plaintiffs appear to concede that their fraud-based claims are based solely on representations made by Ethicon to Ms. Huskey."); *Bellew v. Ethicon, Inc.*, No. 2:13–cv–22473,

2014 WL 6886129, at *5–6 (S.D.W. Va. 2014). Contrary to Defendants' contention, this line of cases does not stand for the proposition that all fraud-based claims are "repackaged" failure-to-warn claims if they address the same conduct; the operative issue is whether Plaintiffs are attempting to do an end-run around the learned intermediary doctrine by focusing on Defendants' statements to Mr. Milanesi, not Dr. Gill. Plaintiffs point to only the representations Defendants made to Dr. Gill—not Mr. Milanesi—and they do not argue that the learned intermediary rule does not apply. (ECF No. 87 at PageID #6632.) Accordingly, there is no indication that the Court should treat Plaintiffs' fraud-based claims as part of their failure to warn claims. No authority that Defendants provide stand for the proposition that failure-to-warn claims and fraud-based claims cannot encompass the same conduct.[7]

For negligent misrepresentation, a plaintiff must demonstrate that "(1) the defendant made a misrepresentation of material fact that he believed to be true but which was in fact false; (2) the defendant was negligent in making the statement because he should have known the representation was false; (3) the defendant intended to induce the plaintiff to rely and [sic] on the misrepresentation; and (4) injury resulted to the plaintiff acting in justifiable reliance upon the misrepresentation." *Specialty Marine & Indus. Supplies, Inc. v. Venus*, 66 So.3d 306, 309 (Fla. Dist. Ct. App. 2011) (alteration in original) (quoting *Simon v. Celebration Co.*, 883 So.2d 826, 832 (Fla. Dist. Ct. App. 2004)). For fraudulent concealment or misrepresentation, a plaintiff must show

> (1) a misrepresentation of material fact or suppression of the truth; (2) [a] knowledge of the representor of the misrepresentation, or [b] representations made by the representor without knowledge as to either the truth or falsity, or [c] representations made under circumstances in which the representor ought to have known, if he did not know, of the falsity thereof; (3) an intention that the representor

[7] Defendants point to *Nunez*, but it is unclear from the opinion if the plaintiff's fraud-based claims were premised on representations made to the plaintiff and thus whether the plaintiff was attempting to evade the learned-intermediary rule. 461 F. Supp. 3d at 1267. The court in *Nunez* relied on *Huskey* and *Bellew*, and so this Court does so here as well.

> induce another to act on it; and (4) resulting injury to the party acting in justifiable reliance on the representation.

Dugas v. 3M Co., 101 F. Supp. 3d 1246, 1254 (M.D. Fla. 2015) (alterations in original) (quoting *Jones v. Gen. Motors Corp.*, 24 F. Supp. 2d 1335, 1339 (M.D. Fla. 1998)). Defendants dispute two elements of Plaintiff's misrepresentation and fraud claims: whether there were in fact misrepresentations and whether Dr. Gill relied on those statements. (ECF No. 57 at PageID #412.)

Plaintiffs make the requisite showings on these elements to survive summary judgment. First, they show that Defendants made misrepresentations of and/or concealed aspects of the safety and performance of the Ventralex, which are material facts. As discussed above, Defendants did not disclose in the Ventralex's IFU the possibility that that the Ventralex would buckle after implantation, which encompasses ePTFE contracture and ring resilience issues. *Supra* Part III.D.

Second, Plaintiffs demonstrate that Dr. Gill relied on these misrepresentations and/or omissions in selecting the Ventralex for Mr. Milanesi's hernia repair surgery. As noted above, Dr. Gill testified that he would have considered alternate devices had he been aware of these risks, including the risk that the Ventralex would buckle. *Id.* Defendants argue that Plaintiffs have not shown that the Ventralex buckles or that there are issues with the ring, and that Dr. Gill was aware of the risks (ECF No. 111 at PageID #10620), but these arguments have been addressed, *supra* Part III.B & D.

At the same time, Plaintiffs do not demonstrate that Dr. Gill relied on any other statements from Defendants or that these statements are connected to this case, however. Plaintiffs point to a representation in a newsletter from Defendants that the Ventralex would "pop open and lay flat." (ECF No. 87 at PageID #6632.) But in his deposition, Dr. Gill never stated that he saw and relied on this statement; he only testified that he may have seen information like this in a brochure. (See ECF No. 57-4 at PageID #564–65, pp. 29–33.) Plaintiffs also point to a statement that the

Ventralex was "easy to use." (ECF No. 87 at PageID #6632.) But these representations have no connection to this case because Dr. Gill did not state that he found the device difficult to use, *i.e.,* implantation. Moreover, Mr. Milanesi's injuries did not occur during implantation.

For these reasons, Plaintiffs' misrepresentation and fraud claims survive summary judgment.

F. Other Negligence Claims

Next, Defendants argue that summary judgment is appropriate on Plaintiffs' other negligence claims to the extent that they raise negligence claims distinct from their design defect, manufacturing defect, and failure to warn claims, and on Plaintiff's negligence per se claim. (ECF No. 57 at PageID #408–09.) Plaintiffs do not appear to raise negligence claims apart from their product liability claims, though Plaintiffs fail to make an adequate showing as to their negligence per se claim.

First, Defendants point to a number of allegations from Plaintiffs' initial complaint, arguing that any other negligence claims are "subsumed" under Plaintiffs' products liability claim based on negligence. (*Id.* at PageID #408–09.) There is no indication that Plaintiffs intend to raise other negligence claims. Accordingly, Defendants' motion for summary judgment is moot in this regard.[8]

Second, Plaintiffs do not meet their burden on summary judgment for their negligence per se claim. Under Florida a law, violation of a statute or regulation is negligence per se "where a statute imposes strict liability designed to protect a particular class of persons unable to protect

[8] Plaintiffs treat Defendants' argument as one that Plaintiffs' negligence claims are subsumed by their strict liability claims. (ECF No. 87 at PageID #6623–24.) The Court does not read Defendants' motion this way. It is also indisputable that Florida treats products liability claims arising under negligence and strict liability as distinct from the other. *E.g.*, *see West v. Caterpillar Tractor Co.,* 336 So.2d 80, 90 (Fla. 1976)

themselves" or where a plaintiff is a member of the class that the statute was intended to protect, suffered the type of injury the statute was designed to prevent, and the violation of the statute was the proximate cause of the injury. *Vitrano v. Fla. Power & Light Co.*, 190 So.3d 89, 92 (Fla. Dist. Ct. App. 2015). Otherwise, violation of a statute or regulation is simply evidence of negligence. *Id.* Plaintiffs do not make any showing that they are members of the class that any statute or regulation was designed to protect, that they suffered the injury the statute or regulation was designed to prevent, or that Defendants' violation of this statute or regulation caused their injuries. (ECF No. 87 at PageID #6623.) Plaintiffs contend that statutory and regulatory violations are evidence of negligence (*id.*), but as set forth above, this does not demonstrate negligence per se. Accordingly, summary judgment is appropriate on Plaintiffs' negligence per se claim.

G. Gross Negligence and Punitive Damages

For Plaintiffs' gross negligence claim, which can give rise to punitive damages, Defendants argue that Plaintiffs have not proffered evidence that the Ventralex's risks were greater than those posed by other devices (ECF No. 57 at PageID #410) or evidence that Defendants had knowledge of these risks (ECF No. 111 at PageID #10621). Regardless, Plaintiffs show genuine issues of material fact remain for trial as to their gross negligence and punitive damages claims.

Gross negligence consists of three elements: "(1) circumstances constituting an imminent or clear and present danger amounting to a more than normal or usual peril, (2) knowledge or awareness of the imminent danger on the part of the tortfeasor, and (3) an act or omission that evinces a conscious disregard of the consequences." *Moradiellos v. Gerelco Traffic Ctrls., Inc.*, 176 So.3d 329, 335 (Fla. Dist. Ct. App. 2015) (quoting *Vallejos v. Lan Cargo S.A.*, 116 So.3d 545, 552 (Fla. Dist. Ct. App. 2013)). A plaintiff must prove these elements by clear and convincing evidence. *Nunez*, 461 F. Supp. 3d at 1268.

Plaintiffs have met their burden of production. As described at length above, Plaintiffs have demonstrated that the Ventralex contained defects that made the Ventralex prone to buckle and expose bare polypropylene to viscera. A reasonable jury could find the following. First, the ePTFE layer contracted more rapidly than the polypropylene side, and this contracture away from the abdominal wall was worsened by the fact that the memory coil ring could not withstand this buckling. Second, the ePTFE layer was also prone to infection. Third, Plaintiffs have also shown material fact disputes on whether the Defendants knew about these risks at the time Mr. Milanesi received his Ventralex. Fourth, Defendants received complaints prior to Mr. Milanesi's surgery that noted infection in the Ventralex. (ECF No. 87-1 at PageID #6653.) Defendants received other reports that the Ventralex and Composix Kugel did not lie flat after implantation and that the Large Ventralex buckled. (*Id.* at PageID #6653–54.) Viewing the record in the light most favorable to Plaintiffs, that Defendants then continued to market the Ventralex indicates that Defendants acted with conscious disregard.

Defendants argue that the first prong requires a showing that the Ventralex presented more risks than other devices. (ECF No. 57 at PageID #410.) There is no legal support for this focus. Gross negligence does not require a comparative risk assessment; it requires a global assessment of the likelihood of risk. In *Moradiellos*, the court explained this clearly: "[S]imple negligence is that course of conduct which a reasonable and prudent man would know *might possibly* result in injury to persons or property whereas gross negligence is that course of conduct which a reasonable and prudent man would know would *probably and most likely* result in injury to persons or property." 176 So.3d at 335 (alteration in original) (emphasis added). The question at hand here is not whether the Ventralex posed more risks than other device, but the degree of probability of those risks, of which Defendants should have been aware. Plaintiffs' claim thus survives

summary judgment.

IV. Loss of Consortium

In their motion, Defendants argue that summary judgment is appropriate on Plaintiffs' loss of consortium claim because it is a derivative claim, and no other claims remain. (ECF No. 57 at PageID #413.) Plaintiffs' design defect, failure to warn, negligent misrepresentation, and fraudulent misrepresentation/concealment claims remain for jury adjudication. Accordingly, summary judgment on this basis is inappropriate.

V. Objections

Defendants also raise objections to nineteen exhibits cited in Plaintiffs' response brief under Federal Rule of Civil Procedure 56(c)(2). (ECF No. 112 at PageID #10707.) The Court did not rely on any of these exhibits in its summary judgment opinion. Thus, there is no need at this time to resolve Defendants' objections that "the material cited to support or dispute a fact cannot be presented in a form that would be admissible in evidence." Fed. R. Civ. P. 56(c)(2).

VI. Conclusion

For the reasons set forth above, Defendants' motion for summary judgment (ECF No. 57) is **GRANTED IN PART AND DENIED IN PART**.

IT IS SO ORDERED.

10/5/2021
DATE

s/Edmund A. Sargus, Jr.
EDMUND A. SARGUS, JR.
UNITED STATES DISTRICT JUDGE