

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA**

CASE NO. 20-25308-CIV-ALTONAGA/Torres

KARINA MERINO,

Plaintiff,

v.

**ETHICON INC. and
JOHNSON & JOHNSON,**

Defendants.

ORDER

THIS CAUSE came before the Court on Defendants, Ethicon, Inc. and Johnson & Johnson’s Motion to Dismiss Plaintiff’s First Amended Complaint [ECF No. 20], filed on March 1, 2021.¹ Plaintiff, Karina Merino, filed a Response [ECF No. 23]; to which Defendants filed a Reply [ECF No. 26]. The Court has carefully considered the First Amended Complaint (the “Complaint”) [ECF No. 5], the parties’ written submissions, the record, and applicable law. For the following reasons, the Motion is granted in part.

I. BACKGROUND

This case concerns liability for injuries arising from a medical device implanted in Plaintiff. (*See generally* 1st Am. Compl.). Plaintiff is a citizen and resident of Miami-Dade County. (*See id.* ¶ 1). Johnson & Johnson and Ethicon are New Jersey corporations. (*See id.* ¶¶ 4–5). Ethicon is owned and controlled by Johnson & Johnson. (*See id.*).

Defendants’ Pelvic Mesh Products. Defendants sell pelvic mesh products, including Gynecare Tension-Free Vaginal Tape (“TVT”), designed to treat pelvic organ prolapse (“POP”)

¹ The Court uses the pagination generated by the electronic CM/ECF database, which appears in the headers of all court filings.

and stress urinary incontinence (“SUI”). (*See id.* ¶¶ 2, 10–12). The Food and Drug Administration (“FDA”) cleared Defendants’ pelvic mesh products following an abbreviated approval process. (*See id.* ¶ 20). At the time, the FDA did not require Defendants’ TVT products to undergo a formal review for safety and efficacy because Defendants falsely presented their pelvic mesh products as being similar to previously approved mesh devices. (*See id.* ¶¶ 25, 45–46). After receiving approval, Defendants aggressively marketed and sold pelvic mesh products to the medical community and patients through campaigns, brochures, medical conferences and other means. (*See id.* ¶ 22). Defendants presented exaggerated expectations regarding the safety and utility of their pelvic mesh products, especially as compared to less-risky alternatives. (*See id.* ¶ 23).

Defendants’ pelvic mesh products can cause serious harm to patients. The implanting procedure can lead to severe adverse reactions: because the products are implanted in an area of the body rich with blood vessels, nerves, and bacteria, patients are at an increased risk of developing severe infections and pain. (*See id.* ¶ 55). Moreover, these products contain polypropylene mesh, a material that promotes a severe foreign body reaction and chronic inflammatory response in a large subset of patients. (*See id.* ¶¶ 16, 42). The body’s adverse reaction to polypropylene can cause degradation, shrinkage, and contraction of the implanted mesh and of pelvic tissue, which in turn can cause patients to experience inflammation, chronic infections, significant urinary dysfunction, and vaginal deformation. (*See id.*). Defendants’ pelvic mesh products also contain collagen, which disintegrates after implantation and causes surrounding body tissue to harden. (*See id.* ¶ 17). Finally, if patients experience any of these negative side effects, effective treatment is unlikely because the implanted mesh integrates with patients’ pelvic tissue, preventing removal. (*See id.* ¶ 55).

Defendants were on notice about the potential risks posed by their TVT pelvic mesh

products. Beginning in October 2008, the FDA issued numerous notices and warnings about the dangers of pelvic mesh products used for the treatment of POP, ultimately ordering all POP device manufacturers, including Defendants, to stop selling such pelvic mesh products. (*See id.* ¶¶ 26–41). Several medical associations and consumer advocacy groups have also highlighted the products’ dangers. (*See id.* ¶¶ 34–36). The risks associated with POP-treating pelvic mesh products are similar to the risks arising from SUI-treating products — like Defendants’ TVT devices — because the same dangerous materials are used in both. (*See id.* ¶¶ 10, 37–38). Given the risks of severe complications from pelvic mesh products implanted in POP patients, the FDA mandated additional studies to investigate the risks of pelvic mesh products in SUI patients. (*See id.* ¶¶ 38–39).

Despite mounting reports of complications and complaints about TVT products, Defendants continue to market, distribute and sell TVT products to healthcare providers and patients while minimizing the serious complications associated with the device. (*See id.* ¶¶ 64–67). Defendants ignored medical studies regarding severe complications from TVT products and misrepresented the risks associated with these products. (*See id.* ¶¶ 60, 66–67). At the time Plaintiff was implanted, Defendants failed to disclose their TVT products’ propensity to shrink, degrade, and cause complications like inflammation, scarring, recurring pelvic pain, and urinary dysfunction. (*See id.* ¶ 56). Defendants suppressed information and misled the public about the safety and effectiveness of the products and the implantation procedure. (*See id.* ¶¶ 45–46, 61–63, 68).

Plaintiff’s TVT Device. Defendants marketed and sold their TVT product to Plaintiff’s healthcare providers as a safe, effective, and minimally invasive treatment for SUI. (*See id.* ¶¶ 21, 57). In May 2008, Plaintiff, who suffers from SUI, underwent surgery at Baptist Hospital in Miami

to have Dr. Ronald Sancetta implant Defendants' Gynecare TVT product. (*See id.* ¶¶ 2, 171). Plaintiff "subsequently developed complications arising from the implant of the [Gynecare TVT] product, including mesh implant complications necessitating removal, worsening mixed incontinence, pelvic pain, voiding dysfunction, dysuria, and nocturia." (*Id.* ¶ 3 (alteration added)).

Plaintiff's Complaint. Plaintiff filed her original Complaint [ECF No. 1] on December 30, 2020 and amended it on January 27, 2021. The operative Complaint asserts 15 claims against Defendants: negligence (Count I); strict liability for design defect (Count II); strict liability for manufacturing defect (Count III); strict liability for failure to warn (Count IV); strict liability for defective product (Count V); breach of express warranty (Count VI); breach of implied warranty (Count VII); fraudulent concealment (Count VIII); constructive fraud (Count IX); discovery rule, tolling and fraudulent concealment (Count X); negligent misrepresentation (Count XI); negligent infliction of emotional distress (Count XII); consumer protection (Count XIII); gross negligence (Count XIV); and unjust enrichment (Count XV). (*See generally* 1st Am. Compl.). Defendants move to dismiss all counts for failure to state claims for relief under Federal Rule of Civil Procedure 12(b)(6). (*See generally* Mot.; Reply).

II. STANDARD

"To survive a motion to dismiss [under Rule 12(b)(6)], a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Iqbal*, 556 U.S. at 678 (alteration added; quoting *Twombly*, 550 U.S. at 570). Although this pleading standard "does not require 'detailed factual allegations,' . . . it demands more than an unadorned, the-defendant-unlawfully-harmed-me accusation." *Id.* (alteration added; quoting *Twombly*, 550 U.S. at 555). Pleadings must contain "more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do[.]" *Twombly*, 550 U.S. at 555 (alteration added; citation omitted). "[O]nly a complaint that states a plausible claim for relief survives a motion to

dismiss.” *Iqbal*, 556 U.S. at 679 (alteration added; citing *Twombly*, 550 U.S. at 556).

To meet this “plausibility standard,” a plaintiff must “plead[] factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.” *Id.* at 678 (alteration added; citing *Twombly*, 550 U.S. at 556). “The mere possibility the defendant acted unlawfully is insufficient to survive a motion to dismiss.” *Sinaltrainal v. Coca-Cola Co.*, 578 F.3d 1252, 1261 (11th Cir. 2009) (citation omitted), *abrogated on other grounds by Mohamad v. Palestinian Auth.*, 566 U.S. 449 (2012).

When considering a motion to dismiss, a court must construe the complaint in the light most favorable to the plaintiff and take its factual allegations as true. *See Brooks v. Blue Cross & Blue Shield of Fla., Inc.*, 116 F.3d 1364, 1369 (11th Cir. 1997) (citing *SEC v. ESM Grp., Inc.*, 835 F.2d 270, 272 (11th Cir. 1988)).

III. ANALYSIS

Defendants move to dismiss the Complaint as a shotgun pleading and argue each of Plaintiff’s 15 counts fails to state a claim for relief. (*See generally* Mot.). Plaintiff has voluntarily withdrawn Count V (defective product strict liability) and Count XIII (violation of the Florida Deceptive and Unfair Trade Practices Act). (*See* Resp. 8, 14). The Court addresses Defendants’ remaining arguments.

A. The Complaint is not a shotgun pleading.

Shotgun pleadings are routinely dismissed because they “to give the defendants adequate notice of the claims against them and the grounds upon which each claim rests.” *Weiland v. Palm Beach Cty. Sheriff’s Off.*, 792 F.3d 1313, 1323 (11th Cir. 2015) (footnote call number omitted). Two types of shotgun pleadings are at issue here: “a complaint containing multiple counts where each count adopts the allegations of all preceding counts,” and a complaint “asserting multiple claims against multiple defendants without specifying which of the defendants are responsible for

which acts or omissions, or which of the defendants the claim is brought against.” *Id.* at 1321–23 (footnote call numbers omitted). Defendants insist the Complaint is a shotgun pleading because it (1) incorporates the allegations of preceding counts, (2) describes the conduct of Defendants jointly, and (3) copies substantially from other complaints. (*See* Mot. 3–4).

1. Plaintiff does not impermissibly adopt the allegations of preceding counts.

Defendants argue the Complaint is a shotgun pleading because Plaintiff “incorporates by reference each and every paragraph” of the Complaint in each count. (*See* Mot. 3 (alteration adopted; quotation marks omitted)). Not so.

Plaintiff’s counts do not adopt the allegations of all preceding counts; rather, Plaintiff “incorporates by reference each and every *material fact* of this Complaint as if fully set forth herein.” (*E.g.*, ¶ 76 (emphasis added)). The Eleventh Circuit “has drawn a bright line of distinction between the typical shotgun pleading — where each count adopts the allegations of all preceding counts . . . — and pleadings like the [] Complaint, where each of the *factual paragraphs* are incorporated into each count regardless of their applicability to the particular count.” *Software Brokers of Am., Inc. v. Doticom Corp.*, 484 F. Supp. 3d 1205, 1213 (S.D. Fla. 2020) (emphasis added; original alterations adopted and others added; internal quotation marks omitted; citing *Woodley v. Royal Caribbean Cruises, Ltd.*, 472 F.Supp.3d 1194, 1202 (S.D. Fla. 2020)). Because the “latter is permissible,” Plaintiff’s Complaint is properly framed. *Software Brokers*, 484 F. Supp. 3d at 1213.

Defendants cite to several cases, including *Gergenti v. Ethicon, Inc.* and *Thornton v. AstraZeneca Pharms LP*, in trying to persuade that dismissal is warranted.² In each of these cases, however, the plaintiffs adopted the allegations of all preceding counts in subsequent counts. *See*,

² (*See* Mot. 4 (citing *Gergenti*, No. 2:20cv428, 2020 WL 5642001, at *2 (M.D. Fla. Sept. 22, 2020)); Reply 2 (citing *Thornton*, No. 17-cv-653, 2017 WL 2255776, at *3–4 (N.D. Ga. May 15, 2017))).

e.g., *Gergenti*, 2020 WL 5642001, at *2 (“The Complaint is a textbook shotgun pleading. Each count adopts the allegations of each proceeding [sic] count.”); *Thornton*, 2017 WL 2255776, at *3 (finding the plaintiff’s complaint plainly qualified as a shotgun pleading based, in part, on its reincorporation of allegations of preceding counts). Plaintiff avoids this error by incorporating *only* the material facts.

2. Plaintiff does not impermissibly lump Defendants together.

Next, Defendants contend the Complaint should be dismissed because it fails to distinguish each Defendant’s conduct. (*See* Mot. 3). The Court is not persuaded.

Although the Complaint does not contain individualized allegations, Plaintiff alleges (1) Ethicon is a wholly owned subsidiary of Johnson & Johnson; (2) Johnson & Johnson charged Ethicon with the design, development, promotion, marketing, testing, training, distribution, and sale of the pelvic mesh products at issue in this case; and (3) Johnson & Johnson employs Ethicon’s Company Group Chairman and Worldwide Franchise Chairman. (*See id.* ¶¶ 4–5). Together, these allegations, taken as true, explain *why* Johnson & Johnson is included with Ethicon in Plaintiff’s action — Johnson & Johnson exerted its control over Ethicon to instruct it to design and market the product at issue. Plaintiff’s claims thus do not deprive Defendants of notice of the claims against them. *See Weiland*, 792 F.3d at 1323.

Defendants again rely on *Gergenti* for support. (*See* Mot. 4; Reply 3 (citing *Gergenti*, 2020 WL 5642001, at *2)). But the *Gergenti* complaint contained another fatal error. *See Gergenti*, 2020 WL 5642001, at *2 (finding the plaintiff’s complaint to be a shotgun pleading where, in addition to adopting all preceding allegations into each count, the complaint “mixe[d] several claims against the two [d]efendants without specifying which [d]efendant is responsible for which acts or omissions.” (alterations added)). Plaintiff’s Complaint does not contain aggravating factors, presenting Defendants with sufficient notice as to the claims brought against them.

Dismissal on this basis is thus unwarranted.

3. *The Complaint contains enough Plaintiff-specific facts.*

Defendants urge the Court to dismiss the Complaint as a “generic one size fits all pleading” that “virtually mirrors numerous other [c]omplaints” and fails to set forth facts tailored to Plaintiff’s case. (Mot. 1, 4 (alteration added; quotation marks omitted); Reply 2 (“Of [] 174 paragraphs . . . only the first three bare-bones paragraphs are unique and specific to Plaintiff.”)). Plaintiff insists *her Complaint mirrors others* because *her case mirrors others* — those of other women who have been injured by Defendants’ pelvic mesh products — and the context provided by the facts common to other pelvic mesh cases is relevant to her case. (*See* Resp. 4–5). The Court agrees with Plaintiff.

To support dismissal, Defendants cite *Minton v. Ethicon, Inc.*, No. 20-cv-251 (N.D. Fla. Apr. 1, 2021). (*See* Notice of Suppl. Auth. [ECF No. 31]). In *Minton*, the court determined a pelvic mesh patient’s complaint was defective for several reasons: it failed to identify which of the defendants’ products caused the plaintiff’s injuries, it incorporated preceding counts’ allegations in subsequent counts, and it made allegations regarding the defendants’ products generally rather than the specific product that caused the plaintiff’s health issues. *See id.* at *2–3. Defendants also point to *Thornton*, where the court found a complaint was a shotgun pleading because the plaintiff adopted preceding allegations in each count, named a litany of third parties as defendants, and failed to show specific causation. *See* 2017 WL 2255776, at *3–4.

The Complaint may not be entirely original, but it contains enough Plaintiff-specific information to put Defendants on notice; it does not suffer from the vagueness present in *Minton* or *Thornton*. Plaintiff alleges (1) she was implanted with Defendants’ Gynecare TVT device; (2) the TVT device was meant to treat Plaintiff’s SUI; (3) Dr. Ronald Sancetta implanted the product on May 28, 2008 at Baptist Hospital in Miami; and (4) Plaintiff subsequently suffered

complications from the device's implant, including mesh removal surgery, worsening incontinence, and pelvic pain. (*See* 1st Am. Compl. ¶¶ 1–3, 104). Plaintiff states which product she was implanted with; identifies two Defendants, one of whom is owned and controlled by the other; and alleges that her implanted TVT product, because of certain defects, caused her severe complications related to the area of the body where the device was implanted.

Plaintiff thus provides the requisite notice to Defendants of the claims against them. *See Weiland*, 792 F.3d at 1323. In sum, the Complaint is not a shotgun pleading.

B. Count I: Negligence

Count I states a negligence claim against Defendants. (*See* 1st Am. Compl. ¶¶ 69–75). To state a claim of negligence, Plaintiff must allege facts supporting a duty of care. *See Holguin v. Celebrity Cruises, Inc.*, No. 10-20215-Civ, 2010 WL 1837808, at *1 (S.D. Fla. May 4, 2010). Plaintiff alleges Defendants had a duty “to use reasonable care in designing, researching, manufacturing, marketing, labeling, packaging, supplying, distributing and selling the TVT product[;]” which was dangerous and defective. (1st Am. Compl. ¶ 70 (alteration added)).

Defendants argue Plaintiff's negligence claim should be dismissed to the extent the underlying theories of design defect, manufacturing defect, and failure to warn are dismissed. (*See* Mot. 12). The Court will not “strike alleged duties from the Complaint[] in line-item fashion.” *Holguin*, 2010 WL 1837808, at *1; *see also Havana Docks Corp. v. Carnival Corp.*, No. 19-cv-21724, 2020 WL 5517590, at *12 (S.D. Fla. Sept. 14, 2020) (“[C]ourts routinely refuse to excise ‘in line-item fashion’ portions of a complaint where the claim at hand is otherwise adequately stated.” (alteration added; citations omitted)). For the reasons explained in Sections III.C and III.E, Plaintiff states a negligence claim based on design defect and failure-to-warn theories, alleging Defendants had a duty to use reasonable care in designing the Gynecare TVT device or ensuring

adequate warnings were provided to treating physicians.

The Court thus denies the Motion as to Count I.

C. Count II: Design Defect

Counts II asserts a strict liability claim against Defendants based on defective design. (*See* 1st Am. Compl. ¶¶ 76–79). “To state a claim in Florida for strict products liability based on a design or manufacturing defect, a plaintiff must plead three elements: (1) a relationship between the defendant and the product; (2) a defect which caused the product to be unreasonably dangerous; and (3) causation between the defect and the harm suffered by the user.” *Dye v. Covidien LP*, 470 F. Supp. 3d 1329, 1334 (S.D. Fla. 2020) (internal quotation marks and citations omitted). “The complaint must contain factual allegations about what was in fact defective about the product.” *Shapiro v. NuVasive, Inc.*, No. 19-23163-Civ, 2019 WL 5742159, at *2 (S.D. Fla. Nov. 5, 2019) (internal quotation marks and citations omitted). Defendants argue Plaintiff fails to plead (1) a defect and (2) causation. (*See* Mot. 4–6).

Defendants contend Plaintiff fails to plead a defect because her allegations (1) are not tailored to the specific device implanted in Plaintiff and (2) do not pinpoint a specific defect. (*See* Mot. 5–6). Neither argument is persuasive.

1. Plaintiff plausibly alleges a defect.

Plaintiff alleges Defendants’ TVT products, which include the Gynecare TVT device, suffer from several defects: the use of polypropylene and collagen in the device; a risky implanting procedure; the difficulty in achieving the product’s removal; and the tendency of the device to degrade, shrink, and fragment. (*See* 1st Am. Compl. ¶ 55). Plaintiff buttresses her allegations by stating the materials used in Defendants’ pelvic mesh products are found to trigger serious complications in patients (*see id.* ¶¶ 15, 16, 17), citing to FDA and other health advisory warnings that confirm such complications (*see id.* ¶¶ 28, 29, 35). This is sufficient to plausibly allege a

defect in the Gynecare TVT device, making the device unreasonably dangerous.

Defendants take issue with Plaintiff's allegations for "generically addressing the alleged design of numerous pelvic mesh products[]" rather than singling out the Gynecare TVT device. (Mot. 5 (alteration added)). But while Plaintiff describes defects with all of Defendants' TVT products, she also states one of those TVT products was implanted inside her. (*See* 1st Am. Compl. ¶¶ 2, 55). Logically, the risks present in *all* of Defendants' TVT products must be present in the *specific* product implanted in Plaintiff. Moreover, the Court infers the risks associated with POP are similar to those associated with SUI because Plaintiff alleges Defendants' products, which are used to treat both conditions, contain the same defective design. (*See id.* ¶¶ 12–17, 37). Drawing all reasonable inferences in Plaintiff's favor, as the Court must, Plaintiff plausibly alleges a defect in the Gynecare TVT product.

Defendants also contend Plaintiff's claim fails because Plaintiff does not pinpoint a particular defect in Defendants' Gynecare TVT device. At the pleading stage, Plaintiff may allege several defects without specification. *See Bailey v. Janssen Pharmaceutica, Inc.*, 288 F. App'x 597, 605 (11th Cir. 2008) (overturning a lower court's dismissal of a design defect claim where the plaintiff identified several possible and alternate defects because the "very nature of a products liability action — where the cause or source of the defect is not obvious to the consumer — would make it difficult for an appellant to pinpoint a specific source of defect").

In sum, Plaintiff plausibly alleges a design defect.

2. Plaintiff sufficiently alleges causation.

Defendants next insist Plaintiff fails to allege causation because the Complaint "pleads no facts whatsoever that would plausibly link her injuries to the alleged defect(s)." (Mot. 6). The Court disagrees.

Plaintiff alleges (1) she was implanted with Defendant's Gynecare TVT product (*see* 1st

Am. Compl. ¶ 2); (2) she subsequently suffered complications in her pelvic area, including implant removal surgery, worsened SUI, pelvic pain, and voiding dysfunction (*see id.* ¶ 3); (3) Defendants’ pelvic mesh products are known to cause patients to experience pelvic pain and significant urinary dysfunction (*see id.* ¶¶ 16–18, 55); and (4) “[a]s a direct and proximate result of the product’s aforementioned defects” Plaintiff “under[went] medical treatment[,] [] will likely undergo future medical treatment and procedures, [and] has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, lost income, and other damages” (*id.* ¶ 78 (alterations added)). This sufficiently pleads injuries caused by Defendants’ product.

The out-of-circuit authority Defendants provide in support of their causation argument is unconvincing. (*See* Mot. 6 & n.5). For example, Defendants urge the Court to apply the reasoning of a district court in Minnesota, dismissing a similar complaint for lack of causation because the plaintiff did not detail “which of the numerous enumerated design defects [the plaintiff] claims caused her injury, whether she was pain-free before the implantation of the [TVT product], what outcome [the plaintiff] anticipated, or what other factors may have contributed to [the plaintiff]’s injuries.” (Mot. 6 (quoting *Dolan v. Bos. Sci. Corp.*, No. 20-cv-1827, 2021 WL 698777, at *2 (D. Minn. Feb. 23, 2021) (alterations added; footnote call number omitted))).³

Such particularity, however, is not required here. “Under Florida law, plaintiffs are not

³ In a footnote, Defendants include numerous cases supporting dismissal for plaintiffs’ failures to adequately plead design defects. (*See* Mot. n.5 (citing *Meredith v. Medtronic, Inc.*, No. 3:18-cv-00127, 2019 WL 6330677, at *4 (S.D. Iowa Oct. 25, 2019) (dismissing a complaint because the plaintiff did not distinguish complications arising from a defective hernia-repair product from complications arising from the hernia surgery itself); *Moore v. C.R. Bard, Inc.*, 217 F. Supp. 3d 990, 995-96 (E.D. Tenn. 2016) (plaintiff did not describe how the alleged defect caused the plaintiff’s injuries); *Pellegrin v. C.R. Bard*, Civ. A. No. 17-12473, 2018 WL 3046570, at *5 (E.D. La. June 20, 2018) (plaintiff failed to allege how the defect contributed to her specific injuries or what other alternative designs existed at the time of surgery); *Nowell v. Medtronic Inc.*, 273 F. Supp. 3d 1166, 1249-50 (D.N.M. 2019) (plaintiff did not allege the precise defect in the defendants’ mesh product); *Baca v. Johnson & Johnson*, No. CV-20-01036, 2020 WL 6450294, at *4 (D. Ariz. Nov. 2, 2020) (plaintiff failed to describe how the defective product caused the plaintiff’s injuries); *Hernandez v. Johnson & Johnson*, No. 4:20-cv-05136, 2021 WL 320612, at *3 (E.D. Wash. Jan. 8, 2021) (plaintiff did not plausibly allege the device’s design defect itself caused the plaintiff’s damages))).

required to set forth [in the complaint] the precise chemical, biological, or other process by which the defective product causes the alleged harm [to defeat] a motion to dismiss.” *Dye*, 470 F. Supp. 3d at 1336 (alterations added; internal quotation marks omitted; citing *Small v. Amgen*, 2 F. Supp. 3d 1292, 1297 (M.D. Fla. 2014), and *Godelia v. Doe I*, 881 F.3d 1309, 1318 (11th Cir. 2018)). Instead, “plaintiffs need only place defendants on notice of the type of harm allegedly caused by the design defect.” *Id.* (internal quotation marks and citation omitted).

As stated, Plaintiff’s allegations sufficiently plead causation — indeed, “[i]t would be unreasonable for the Court to require Plaintiff to plead exactly *how* the implanted [p]roduct is defective and *how* it caused [her] alleged injuries when Plaintiff has not yet been afforded discovery or the benefit of expert testimony.” *Id.* (alterations added; emphasis in original; citation omitted).

Plaintiff adequately pleads a strict liability design defect claim; the Motion is denied as to Count II.

D. Count III: Manufacturing Defect

Count III asserts a strict liability manufacturing defect claim against Defendants. (*See* 1st Am. Compl. ¶¶ 80–83). Defendants contend Plaintiff’s manufacturing defect claim must fail because Plaintiff does not plead any facts pertaining to a manufacturing defect. (*See* Mot. 7–8 (“Plaintiff, however, does not allege *how* her TVT deviated from Ethicon[’s] [] design and manufacturing specifications[.]” (emphasis in original; alteration added))). The Court agrees.

Plaintiff alleges (1) the Gynecare TVT product was defective “with respect to its manufacture, in that it deviated materially from Defendant[s’] . . . design and manufacturing specifications in such a manner as to pose unreasonable risks of serious bodily harm to []

These cases are not controlling, and the Court does not find them persuasive here, where Plaintiff sufficiently pleads defects and causation.

Plaintiff[;]” and (2) “[a]s a direct and proximate result of the products’ aforementioned defects . . . Plaintiff has experienced significant mental and physical pain[.]” (1st Am. Compl. ¶¶ 81–82 (alterations added)). Aside from these conclusory statements, Plaintiff’s claim lacks any facts describing how Defendants deviated from manufacturing specifications; indeed, Plaintiff only provides facts pertaining to defective design or inadequate warnings. (*See id.* ¶ 55 (describing the TVT products’ defects, among others, as “the use of polypropylene, . . . the design of the products to be inserted into and through an area of the body that . . . lead[s] to excessive blood loss and vascular damage, . . . [and] biomechanical issues with the design[.]” (alterations added)); *id.* ¶ 56 (“The TVT products are also defective due to Defendants’ failure to adequately warn or instruct the Plaintiff[.]” (alteration added))).

In *Kuchenbecker v. Johnson & Johnson*, the court dismissed a similar manufacturing defect claim for failure to state a claim for relief. *See* No. 19-61712-Civ, 2019 WL 4416079, at *2 (S.D. Fla. Sept. 16, 2019). In that case, as here, the “closest [the p]laintiffs c[ame] to alleging a manufacturing defect [wa]s the allegation that Defendants failed to manufacture the Gynecare TVT [product] so as to avoid an unreasonable risk of harm[.]” and “the only factual allegations offered to support th[at] conclusion relate[d] to the defective design and defective warning claims.” *Id.* (alterations added; citations omitted). Without facts describing “how the device implanted in the [p]laintiff deviated from manufacturing specifications[.]” the *Kuchenbecker* plaintiffs’ manufacturing defect claim was essentially duplicative of the design defect claim. *Id.* (alterations added). As such, the court dismissed the *Kuchenbecker* plaintiffs’ manufacturing defect claim. *See id.*

Kuchenbecker is on all fours with the present case. Because Plaintiff fails to state a manufacturing defect claim, Count III is dismissed.

E. Count IV: Failure to Warn

Count IV asserts a strict liability failure-to-warn claim against Defendants. (*See* 1st Am. Compl. ¶¶ 84–89). “Under Florida law, when strict liability is based on a medical product’s insufficient warnings, [the] plaintiff must allege all of the following: (1) that the warnings accompanying the item were inadequate; (2) that the inadequacy of the warnings proximately caused [the p]laintiff’s injury; and (3) that [the p]laintiff in fact suffered an injury by using the product. Plaintiff must also plead the content of the warning label or otherwise describe the manner in which the warning was inadequate.” *Dye*, 470 F. Supp. 3d at 1338 (original alterations adopted; other alterations added; internal quotation marks and citations omitted).

Defendants contend Plaintiff’s failure-to-warn claim should be dismissed because it fails to plead the first two elements: (1) inadequate warnings and (2) causation. (*See* Mot. 10).

1. Plaintiff pleads Defendants’ warnings were inadequate.

Defendants argue Plaintiff “does not adequately plead how [the] TVT’s warnings were inadequate because it [(A)] does not address what was contained in that product’s warnings and [(B)] only generally discusses all pelvic mesh products allegedly manufactured by Defendants.” (Mot. 10 (alteration added)). This argument fails to persuade.

First, Plaintiff alleges Defendants inadequately warned of numerous risks, including the following:

[T]he risk of chronic inflammation resulting from the products; [] the risk of chronic infections resulting from the products; [] the risk of permanent vaginal or pelvic scarring as a result of the products; [] the risk of de novo urinary dysfunction; [] the risk of de novo dyspareunia or painful sexual relations; [] the risk of recurrent, intractable pelvic pain and other pain resulting from the products; [] the need for corrective or revision surgery to adjust or remove the products which in some cases is not feasible nor possible; [and] the severity of complications that could arise as a result of implantation of the products[.]

(1st Am. Compl. ¶ 56 (alterations added)). By describing the risks Defendants’ allegedly omitted

to warn about, Plaintiff sufficiently pleads how the warnings were inadequate. *See Dye*, 470 F. Supp. 3d at 1338 (stating a plaintiff may plead “the content of the warning label *or* otherwise describe the manner in which the warning was inadequate.” (emphasis added; citations omitted)).

Second, Defendants’ attack on Plaintiff’s generalized language is not persuasive. As noted, the Court can plausibly infer that Plaintiff’s TVT device suffers from the same inadequate warnings applicable to all of Defendants’ TVT devices. (*See* 1st Am. Compl. ¶¶ 2, 55). Plaintiff therefore pleads the first element of her failure-to-warn claim.

2. Plaintiff draws a causal link between the inadequate warnings and Plaintiff’s injuries.

Defendants also insist Plaintiff fails to show causation because the Complaint omits facts showing “how the [] implanting surgeon acted in reliance on deficiencies in Ethicon’s warnings[.]” (Mot. 10 (alterations added)). Because “Florida has adopted the learned intermediary doctrine[,] . . . the duty to warn flows from the medical product manufacturer to the physician, not the ultimate consumer, and [the] plaintiff must assert the warnings given to [her] physician were inadequate.” *Dye*, 470 F. Supp. 3d at 1338 (original alterations adopted; other alterations added; emphasis, internal quotation marks, and citations omitted). “If the manufacturer properly warns the physician regarding the known risks, the learned intermediary doctrine applies and the manufacturer’s duty to warn the consumer is discharged.” *Dimieri v. Medicis Pharm. Corp.*, No. 14-cv-176, 2014 WL 3417364, at *2 (M.D. Fla. July 14, 2014) (citing *Christopher v. Cutter Labs*, 53 F.3d 1184, 1192 (11th Cir. 1995)).

Plaintiff, however, alleges “Defendants provided incomplete, insufficient and misleading training and information to physicians . . . leading to the dissemination of inadequate and misleading information to patients, including Plaintiff.” (1st Am. Compl. ¶ 51 (alteration added)). She clarifies that “while some problems associated with the TVT products were made known to

physicians, *the magnitude and frequency of these problems were not disclosed and were hidden from physicians.*” (*Id.* ¶ 53 (emphasis added)). The Court infers from these allegations that implanting physicians — like Plaintiff’s — relied upon the limited information provided by Defendants in selecting Defendants’ devices for treatment and would have made different treatment recommendations had they known the true magnitude and frequency of the risks associated with Defendants’ TVT products.

Taken together, these allegations show inadequate warnings provided to Plaintiff’s physician, who relied on them in deciding to implant Plaintiff with Defendants’ product. *See Dimieri*, 2014 WL 3417364, at *3 (stating a plaintiff can succeed on a failure-to-warn claim by alleging “the physician did not have substantially the same information as the manufacturer due to the inadequate warnings” (citing *Chase v. Novartis Pharm. Corp.*, 740 F. Supp. 2d 1295, 1297 (M.D. Fla. 2006))).

Plaintiff sufficiently pleads an inadequate warning claim in Count IV.

F. Counts VI & VII: Breach of Express and Implied Warranties

Plaintiff asserts breach-of-express-warranty (Count VI) and breach-of-implied-warranty (Count VII) claims against Defendants. (*See* 1st Am. Compl. ¶¶ 95–101, 102–108). Defendants argue Plaintiff (1) pleads insufficient facts regarding the warranties; and (2) lacks privity with Defendants. (*See* Mot. 14–15). The Court considers each argument.

1. Plaintiff pleads enough facts about Defendants’ warranties.

Defendants argue Plaintiff fails to plead enough facts regarding Defendants’ alleged warranties. (*See* Mot. 15; Reply 4). “Any affirmation of fact or promise” from the seller to the buyer “creates an express warranty that the goods shall conform to the affirmation or promise.” Fla. Stat. §§ 672.313(a)–(b). “It is not necessary to the creation of an express warranty that the seller use formal words such as ‘warrant’ or ‘guarantee’ . . . to make a warranty.” *State Farm Ins.*

v. Nu Prime Roll-A-Way of Miami, Inc., 557 So. 2d 107, 108 (Fla. 3d DCA 1990) (alteration added; citation omitted). Additionally, a contract for the sale of goods — made by a merchant with respect to those goods — implies a warranty that the goods are “fit for the ordinary purposes for which such goods are used[.]” Fla. Stat. § 672.314 (alteration added).

Plaintiff alleges Defendants made express and implied assurances to physicians that Defendants’ TVT products were safe and fit for their intended use. (*See* 1st Am. Compl. ¶¶ 96, 103). In support, Plaintiff states Defendants (1) circulated written brochures and information online “offering exaggerated and misleading expectations as to the safety and utility” of their pelvic mesh devices (*id.* ¶¶ 23, 52); (2) “misrepresented, omitted and downplayed the known risks, dangers, adverse events, contraindications, defects and disadvantages of [Defendants’] products” (*id.* ¶ 53 (alteration added)); and “promoted [the TVT products] to physicians and patients as an innovative, minimally invasive procedure with minimal local tissue reactions, minimal tissue trauma and minimal pain while correcting [SUI]” (*id.* ¶ 12 (alterations added)).

These factual allegations show Defendants made warranties by describing the goods as safe, and Defendants sold the products to physicians implying the products would be fit for their ordinary use. *See State Farm*, 557 So. 2d at 108 (“A seller’s representations in [] advertisements, catalogues, circulars, etc., may . . . constitute an express warranty for breach of which the seller will be liable for damages to one who, in making the purchase, relies thereon to his injury.” (alterations added; citations omitted)). Plaintiff sufficiently alleges Defendants made express and implied warranties.

2. Plaintiff alleges privity as a third-party beneficiary.

Defendants next contend Plaintiff fails to establish privity with Defendants. (*See* Mot. 14; Reply 4). Although Plaintiff did not purchase the TVT device directly from Defendants, Plaintiff maintains she establishes privity as a third-party beneficiary because she was the intended

consumer of Defendants' product and the intended beneficiary of Defendants' warranties. (*See* Resp. 11).

“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) (citations omitted). “Florida law recognizes that, in some situations, a person who is not a party to a contract can enforce the terms of the contract if the provisions of the contract primarily and directly benefit the third party or a class of persons of which the third party is a member.” *Weiss v. Gen. Motors LLC*, 418 F. Supp. 3d 1173, 1182 (S.D. Fla. 2019) (alteration adopted; citation omitted); *see also Aprigliano v. Am. Honda Motor Co.*, 979 F. Supp. 2d 1331, 1340 (S.D. Fla. 2013) (“Florida courts have relaxed the contractual privity requirement where the express warranty was intended to benefit subsequent owners.” (citations omitted)).

Plaintiff alleges she chose Defendants' TVT product based on Defendants' warranties to her or her physician and relied on those warranties in consenting to the implant procedure. (*See* 1st Am. Compl. ¶¶ 46, 98, 105). Plaintiff contends Defendants' warranties were made to benefit her as a patient — not the physician or the hospital Defendants sold their TVT products to — and insists as a patient she is the “intended consumer” of the TVT device. (*See* Resp. 11). Construing the facts in the light most favorable to Plaintiff, the Court finds Plaintiff minimally alleges she is a third-party beneficiary of Defendants' warranties.⁴ *Cf. Weiss*, 418 F. Supp. 3d at 1183 (inferring a car manufacturer who sells its products through dealerships intends its vehicle warranties to

⁴ Defendants cite several Florida cases dismissing breach-of-warranty claims pursued against drug or medical device manufacturers due to a lack of privity. (*See* Reply 4 (citing *T.W.M. v. Am. Med. Sys., Inc.*, 886 F. Supp. 842, 844 (N.D. Fla. 1995) (dismissing breach of warranty claim for lack of privity); *Witt v. Howmedica Osteonics Corp.*, No. 13-cv-20742, 2013 WL 6858395, at *3 (S.D. Fla. Dec. 30, 2013) (same); and *Fields v. Mylan Pharm., Inc.*, 751 F. Supp. 2d 1257, 1259 (N.D. Fla. Dec. 11, 2009) (same))). These authorities are inapposite; unlike Plaintiff, the plaintiffs in these cases did not allege they were third-party beneficiaries of the manufacturers' warranties.

benefit end-users, not dealerships).

Plaintiff satisfies the third-party beneficiary exception to privity and sufficiently describes the warranties breached, stating claims for breach of express and implied warranties. The Motion is denied as to Counts VI and VII.

G. Counts VIII, IX & XI: Fraudulent Concealment, Constructive Fraud, and Negligent Misrepresentation

Plaintiff asserts fraudulent concealment (Count VIII), constructive fraud (Count IX), and negligent misrepresentation (Count XI) claims against Defendants. (*See* 1st Am. Compl. ¶¶ 109–27, 133–40). Defendants argue Plaintiff (1) falls short of pleading the heightened standard of particularity required for fraud claims; and (2) fails to allege the elements of each claim. (*See* Mot. 16–18). According to Plaintiff, she properly pleads each claim with the requisite particularity. (*See* Resp. 12–13). Alternatively, she requests leave to amend her claims to conform to the heightened standard. (*See id.*).

A heightened standard of particularity applies to claims of fraudulent concealment, constructive fraud, and negligent misrepresentation. *See* Fed. R. Civ. P. 9(b) (“In alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake.”); *Lamm v. State St. Bank & Tr.*, 749 F.3d 938, 951 (11th Cir. 2014) (“Rule 9(b)’s heightened pleading standard applies to negligent misrepresentation claims.” (citation omitted)). This rule ensures defendants are alerted to the precise misconduct alleged and protects against “spurious charges of immoral and fraudulent behavior.” *Ziembra v. Cascade Int’l, Inc.*, 256 F.3d 1194, 1202 (11th Cir. 2001) (internal quotation marks and citations omitted).

Under Rule 9(b), claims of fraud must state “precisely what statements were made in what documents or oral representations[,] [] what omissions were made,” “the time and place of each such statement[,] [] the person responsible[,]” “the content of such statements[,] [] the manner in

which they misled the plaintiff,” and “what the defendants obtained as a consequence of the fraud.” *Id.* at 1203 (alterations added; citation omitted). In sum, “[Rule 9(b)] requires the plaintiff to plead the who, what, when, where, and how of the allegedly fraudulent statements or omissions, though the specific facts related to the defendant’s specific state of mind when the allegedly fraudulent statements were made need only be alleged generally.” *Aprigliano*, 979 F. Supp. 2d at 1342 (internal quotation marks omitted; citing *Brooks*, 116 F.3d at 1369).

Plaintiff’s claims simply do not detail the “who, what, when, where, and how” of the fraud she alleges. *Aprigliano*, 979 F. Supp. 2d at 1342 (internal quotation marks omitted; citing *Brooks*, 116 F.3d at 1369). Indeed, Plaintiff frames her allegations in generalized language, avoiding specificity. (*See, e.g.*, 1st Am. Compl. ¶ 138 (stating “misrepresentations would have been made to Plaintiff’s implanting physician at his practice, at the hospital where Plaintiff was implanted with the TVT, and/or at any other forum”); *id.* ¶ 115 (describing facts as “concealed and/or not disclosed”); *id.* ¶¶ 109–20, 121–27, 133–40 (referring to Defendants generally without identifying the specific persons responsible for misrepresentations)). Without more particularity, Plaintiff’s allegations are too bare and imprecise to meet the heightened pleading standard of Rule 9(b).

Plaintiff fails to satisfy the heightened pleading standard for fraud or negligent misrepresentations. Counts VII, IX, and XI are dismissed.⁵

Plaintiff includes in her March 8, 2021 Response a request to further amend her Complaint in the event the Court determines her fraud allegations fall short of the required particularity. (*See* Resp. 13). However, on February 17, 2021, the Court entered a Scheduling Order [ECF No. 15] setting a deadline for the parties to amend pleadings: March 31, 2021. Plaintiff — on notice as to the various deficiencies raised by Defendants in the present Motion — could have amended prior

⁵ Because Plaintiff’s fraud and misrepresentation claims are subject to dismissal for failing to satisfy Rule 9(b), the Court declines to address Defendants’ Rule 12(b)(6) arguments.

to that deadline. Plaintiff instead elected to stand by the Amended Complaint, risking that the March 31, 2021 pleading amendment deadline would pass. It has done so. The Court denies Plaintiff's request to file a third pleading to shore up deficiencies she could have cured earlier.

H. Count X: Discovery Rule, Tolling and Fraudulent Concealment

Count X states a claim for “Discovery Rule, Tolling and Fraudulent Concealment.” (1st Am. Compl. ¶¶ 128–32). Defendants argue the claim is not a recognized cause of action. (*See* Mot. 20). Nevertheless, Plaintiff insists that “discovery rule, tolling and fraudulent concealment are all viable legal theories” and “[w]hether these theories are pleaded under a subheading . . . or elsewhere in the body of Plaintiff's [Complaint], is of no legal significance.” (Resp. 16 (alterations added)). The Court agrees with Defendants.

Plaintiff (1) “asserts all applicable state statutory and common law rights and theories related to the tolling or extension of any applicable statute of limitations, including equitable tolling, delayed discovery, discovery rule, and fraudulent concealment[;]” and (2) “pleads [] the discovery rule should be applied to toll the running of the statute of limitations until Plaintiff knew, or . . . should have known, of facts indicating that Plaintiff had been injured, the cause of the injury, the unreasonable and dangerous conditions of the TVT, and the tortious nature of the wrongdoing that caused the injury.” (1st Am. Compl. ¶¶ 129–30 (alterations added)). These allegations are pre-emptive attacks on Defendants' potential affirmative defenses — not an independent cause of action. *See Kuchenbecker*, 2019 WL 4416079, at *4 (dismissing a claim nearly identical to Plaintiff's because it was not a distinct cause of action).

Count X is dismissed.

I. Count XII: Negligent Infliction of Emotional Distress

Plaintiff brings a claim of negligent infliction of emotional distress in Count XII. (*See* 1st Am. Compl. ¶¶ 141–144). Under Florida law, “a plaintiff can recover damages for emotional

distress caused by the negligence of another, [but] the emotional distress suffered must flow from physical injuries the plaintiff sustained [as a result of the negligence].” *Fla. Dep’t of Corr. v. Abril*, 969 So. 2d 201, 206 (Fla. 2007) (alterations added; citations omitted).

Defendants maintain Plaintiff pleads too few facts to sustain her claim. (*See* Mot. 12–13). The Court agrees. Plaintiff alleges she (1) “has sustained and will continue to sustain emotional distress, severe physical injuries, economic losses, and other damages as a direct result of being implanted with the TVT pelvic mesh product”; and (2) “[a]s a direct and proximate result of [] Defendant[s]’ conduct, Plaintiff has been injured, and sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort, and economic damages.” (1st Am. Compl. ¶¶ 143–44 (alterations added)).

These threadbare allegations are insufficient to state a claim for negligent infliction of emotional distress. The Complaint is devoid of non-conclusory factual allegations supporting Plaintiff’s claim of *emotional* distress. Indeed, Plaintiff’s only allegation listing her specific harm caused by Defendants’ device includes only *physical* injuries and symptoms. (*See id.* ¶ 3).

Count XII is thus dismissed for failing to state a claim. *See, e.g., Kuchenbecker*, 2019 WL 4416079, at *3 (dismissing a similar emotional distress claim).

J. Count XIV: Gross Negligence

Count XIV seeks punitive damages against Defendants for gross negligence. (*See* 1st Am. Compl. ¶¶ 164–68). “‘Gross negligence’ means that the defendant’s conduct was so reckless or wanting in care that it constituted a conscious disregard or indifference to the life, safety, or rights of persons exposed to such conduct.” Fla. Stat. § 768.72(2)(b). Defendants argue (1) Plaintiff fails to allege Defendants’ conduct was reckless enough to be grossly negligent; and (2) the Court should dismiss the claim to the same extent it dismisses her strict liability claims of design defect,

manufacturing defect, and failure to warn. (*See* Mot. 12–14).

1. Plaintiff alleges Defendants consciously disregarded patients’ health.

Defendants contend Plaintiff fails to allege the “extreme and outrageous conduct” required to show gross negligence.⁶ (Mot. 13–14). The Court disagrees.

Plaintiff alleges Defendants showed utter indifference and conscious disregard for Plaintiff and the public’s safety because Defendants knew their TVT products were unreasonably dangerous considering the severe and permanent complications associated with the product. (*See* 1st Am. Compl. ¶¶ 42, 44–45, 61, 66, 165). Notwithstanding this knowledge, Defendants continued to sell the products to maximize profits at the expense of patients’ health. (*See id.*). These allegations sufficiently state the requisite level of recklessness for a gross negligence claim.

2. The Court will not carve out theories from Plaintiff’s gross negligence claim.

Defendants also argue the Court should dismiss Plaintiff’s gross negligence claim to the same extent it dismisses her strict liability manufacturing defect claim. (*See* Mot. 12). As stated, the Court will not carve out individual theories of liability from an otherwise adequately pleaded claim. *See, e.g., Holguin*, 2010 WL 1837808, at *1; *Havana Docks Corp.*, 2020 WL 5517590, at *12. Because Plaintiff’s design defect and failure-to-warn claims survive (*see infra* Sections III.C, III.E); so, too, does her gross negligence claim — as it is predicated, in part, on those theories of liability. The Motion is denied as to Count XIV.

K. Count XV: Unjust Enrichment

Count XV asserts an unjust enrichment claim against Defendants. (*See* 1st Am. Compl. ¶¶ 169–74). Defendants argue Plaintiff’s claim should be dismissed because (1) her remedy lies in

⁶ Defendants also contend Plaintiff’s claim should fail because gross negligence “is not a valid stand-alone claim under Florida law.” (Mot. 13). Courts have considered such standalone claims, without comment, indicating their validity. *See, e.g., Lamm State St.*, 749 F.3d at 947 (reviewing a gross negligence claim on appeal of an order granting dismissal); *King v. Bencie*, 806 F. App’x 873, 875 (11th Cir. 2020) (same).

tort and, alternatively, (2) her allegations are conclusory and deficient. (*See* Mot. 19–20; Reply 5–6).

1. Plaintiff’s unjust enrichment claim is not barred by her tort claims.

Defendants argue Plaintiff’s claim should be dismissed because her remedy lies in tort. (*See* Mot. 19). Plaintiff maintains her unjust enrichment claim, although rooted in products liability, is proper as an alternate claim. (*See* Resp. 14–15). The Court agrees: Plaintiff may plead unjust enrichment as an alternative to her product liability claims. *See Kuchenbecker*, 2019 WL 4416079, at *4.

2. Plaintiff sufficiently pleads her unjust enrichment claim.

To state an unjust enrichment claim, a plaintiff must allege three elements: “(1) plaintiff has conferred a benefit on the defendant, who has knowledge thereof; (2) defendant voluntarily accepts and retains the conferred benefit; and (3) the circumstances are such that it would be inequitable for the defendant to retain the benefit without paying the value thereof to the plaintiff.” *Sierra Equity Grp., Inc. v. White Oak Equity Partners, LLC*, 650 F. Supp. 2d 1213, 1229 (S.D. Fla. 2009) (citations omitted). Defendants insist Plaintiff fails to state a claim because her claim is predicated on the theory that Defendants’ product was unsafe and ineffective, which Plaintiff fails to show. (*See* Mot. 20; Reply 5–6). The Court is unpersuaded.

Plaintiff sufficiently pleads the elements of unjust enrichment: (1) Plaintiff paid for Defendants’ Gynecare TVT product, conferring a benefit on Defendants (*see* 1st Am. Compl. ¶ 171); (2) Defendants “accepted payment by Plaintiff and/or others on Plaintiff’s behalf” for Defendants’ product (*id.* ¶ 172); and (3) inequity resulted from Defendants’ retention of Plaintiff’s money, as “Plaintiff [did] not receive[] the safe and effective TVT medical device for which she paid” (*id.* ¶¶ 173–74 (alterations added)). Plaintiff alleges the product caused her severe complications and worsened her SUI (*see id.* ¶ 3), allowing the Court to reasonably infer

Defendants' product was unsafe and ineffective. Plaintiff pleads enough facts to plausibly state an unjust enrichment claim.

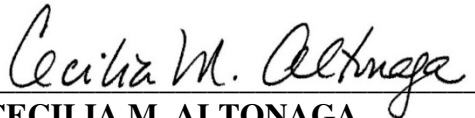
Consequently, Count XV survives dismissal.

IV. CONCLUSION

For the foregoing reasons, it is **ORDERED AND ADJUDGED** as follows:

1. Defendants, Ethicon, Inc. and Johnson & Johnson's Motion to Dismiss Plaintiff's First Amended Complaint [ECF No. 20] is **GRANTED in part**. Counts III, VIII, IX, X, XI, and XII are dismissed without prejudice.
2. Defendants must respond to the operative complaint by **May 18, 2021**.
4. Plaintiff's pre-emptively filed Motion for Leave to File Her Second Amended Complaint [ECF No. 23] is **DENIED**.

DONE AND ORDERED in Miami, Florida, this 4th day of May, 2021.


CECILIA M. ALTONAGA
UNITED STATES DISTRICT JUDGE

cc: counsel of record