Before the Court is Defendant Coloplast Corporation's ("Coloplast") Motion to Dismiss. (Doc. No. 19.) Coloplast Corporation challenges the sufficiency of several causes of actions in Plaintiff Socorro Marrujo's ("Mrs. Marrujo") First Amended Complaint. (*Id.*) For the reasons stated herein, the Court **GRANTS** Coloplast's motion.

I. BACKGROUND

Mrs. Marrujo brings this products liability action against Coloplast for alleged defects in its Pelvic Mesh Products (the "Products"). (Doc. No. 18 ¶ 1.) This action arises out of the manufacturing and distribution of the Products by Coloplast, the implantation of a Product inside Mrs. Marrujo, and the subsequent damages suffered by Mrs. Marrujo and her husband, Plaintiff Roberto Marrujo (hereinafter "Mr. Marrujo" and collectively with Mrs. Marrujo "Plaintiffs"). (*Id.*)

Around August 2015, a Product was inserted in Mrs. Marrujo to treat "primary pelvic organ prolapse (POP) and stress urinary incontinence." (Id. ¶ 2.) After the implantation of the Product, Mrs. Marrujo "suffered catastrophic injuries." (Id. ¶ 43.) Plaintiffs allege that as a result of the implantation, "Mrs. Marrujo and others suffered debilitating injuries including, but not limited to, pudendal neuralgia, catastrophic pain syndrome, extreme pain, erosion, dyspareunia, urinary problems, recurrent incontinence, bowel and bladder dysfunction, loss of mobility and the need for additional surgery." (Id. ¶ 91.) Mrs. Marrujo alleges that doctors confirmed she suffered from mesh erosion and, around November 2018, she underwent her first mesh removal surgery. (Id. ¶ 2.)

Coloplast "designed, manufactured, packaged, labeled, marketed, sold, and distributed" the Products at issue. (*Id.* ¶ 16.) Plaintiffs allege that the Products "have been and continue to be marketed to the medical community and to patients as safe, effective, reliable, medical devices" despite risks and complications identified in the FDA Safety Communication and the Joint Committee Opinion from the American College of Obstetricians and Gynecologists ("ACOG") and the American Urogynecologic Society ("AUGS"). (*Id.* ¶¶ 41, 25.)

Plaintiffs allege that Coloplast has failed to disclose known risks with the Products and failed to "warn of known or scientifically knowable dangers and risks associated with the Products, including the magnitude and frequency of these risks." (*Id.* ¶ 59.) Plaintiffs assert that Coloplast "failed to provide sufficient warnings and instructions that would have put Mrs. Marrujo, her husband, and the general public on notice of the dangers and adverse effect caused by implantation of the Products." (*Id.* ¶ 60.) Plaintiffs contend that Coloplast's Products were "defective as marketed due to inadequate warning, instructions, labeling and/or inadequate testing in the presence of Defendants' knowledge of lack of safety." (*Id.* ¶ 61.)

II. LEGAL STANDARDS

A. Rule 12(b)(6)

A motion to dismiss under Rule 12(b)(6) tests the legal sufficiency of a plaintiff's

complaint. See Navarro v. Block, 250 F.3d 729, 732 (9th Cir. 2001). "[A] court may dismiss a complaint as a matter of law for (1) lack of cognizable legal theory or (2) insufficient facts under a cognizable legal claim." SmileCare Dental Grp. v. Delta Dental Plan of Cal., 88 F.3d 780, 783 (9th Cir. 1996) (citation omitted). However, a complaint will survive a motion to dismiss if it contains "enough facts to state a claim to relief that is plausible on its face." Bell Atl. Corp. v. Twombly, 550 U.S. 544, 570 (2007). In making this determination, a court reviews the contents of the complaint, accepting all factual allegations as true and drawing all reasonable inferences in favor of the nonmoving party. See Cedars-Sinai Med. Ctr. v. Nat'l League of Postmasters of U.S., 497 F.3d 972, 975 (9th Cir. 2007). Notwithstanding this deference, the reviewing court need not accept legal conclusions as true. See Ashcroft v. Igbal, 556 U.S. 662, 678 (2009). It is also improper for a court to assume "the [plaintiff] can prove facts that [he or she] has not alleged." Assoc. Gen. Contractors of Cal., Inc. v. Cal. State Council of Carpenters, 459 U.S. 519, 526 (1983). However, "[w]hen there are well-pleaded factual allegations, a court should assume their veracity and then determine whether they plausibly give rise to an entitlement to relief." Igbal, 556 U.S. at 664.

B. Rule 9(b)

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Federal Rule of Civil Procedure 9(b) requires that the circumstances constituting a claim for fraud be plead with particularity. Rule 9(b) applies not just where a complaint specifically alleges fraud as an essential element of a claim, but also where the claim is "grounded in fraud" or "[sounds] in fraud." Vess v. Ciba–Geigy Corp. U.S.A., 317 F.3d 1097, 1103–04 (9th Cir. 2003). A claim is said to be "grounded in fraud" or "sounds in fraud" where a plaintiff alleges that defendant engaged in fraudulent conduct and relies on solely on that conduct to prove a claim. *Id.* "In that event, . . . the pleading of that claim as a whole must satisfy the particularity requirement of 9(b)." *Id.* However, where a plaintiff alleges claims grounded in fraudulent and non-fraudulent conduct, only the allegations of fraud are subject to heightened pleading requirements. *Id.* at 1104.

A pleading is sufficient under Rule 9(b) if it "[identifies] the circumstances

constituting fraud so that the defendant can prepare an adequate answer from the allegations." *Walling v. Beverly Enters.*, 476 F.2d 393, 397 (9th Cir. 1973). This requires that a false statement must be alleged, and that "circumstances indicating falseness" must be set forth. *In re GlenFed Sec. Litig.*, 42 F.3d 1541, 1548 (9th Cir. 1994). Thus, Rule 9(b) requires a plaintiff to identify the "who, what, when, where and how of the misconduct charged," as well as "what is false or misleading about [the purportedly fraudulent conduct], and why it is false." *Ebeid ex rel. United States v. Lungwitz*, 616 F.3d 993, 998 (9th Cir. 2010).

III. DISCUSSION

In its Motion to Dismiss, Coloplast seeks to dismiss Plaintiffs': (1) second claim based on strict products liability for a manufacturing defect; (2) fourth and fifth claims for breach of express and implied warranty; and (3) seventh, eighth, and ninth claims grounded in fraud. The Court will address each basis for dismissal below.

1. Second Claim for Strict Liability for a Manufacturing Defect

First, Coloplast argues Plaintiffs fail to meet the pleading standard for a manufacturing defect cause of action because they offer only conclusory statements instead of the underlying facts to state the claim. (Doc. No. 19 at 4.) Plaintiffs do not oppose Coloplast's motion on this claim. (Doc. No. 23 at 4.) Therefore, the Court **GRANTS** Coloplast's Motion to Dismiss this claim **WITHOUT LEAVE TO AMEND**.

2. Fourth and Fifth Claims for Breach of Express and Implied Warranty

Coloplast next argues that Plaintiffs' fourth and fifth claims for breach of express and implied warranty should be dismissed for failure to state a plausible claim for relief. (Doc. No. 19 at 6.) Coloplast alleges that Plaintiffs' claims for breach of express and implied warranty violate the *Twombly/Iqbal* pleading standard and Plaintiffs' First Amended Complaint fails to allege privity between Coloplast and Plaintiffs. (*Id.* at 6, 9.) Coloplast alleges that paragraphs 96, 97, and 99-101 of Plaintiffs' First Amended Complaint are recitations of legal conclusions and, without them, Plaintiffs have failed to provide facts that state a plausible claim for breach of express and implied warranty. (*Id.*

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at 6.) Coloplast emphasizes that the existence of an express and implied warranty is reached after an analysis of the underlying facts constituting the elements, and that those facts are absent in Plaintiffs' First Amended Complaint. (*Id.* at 7.) Additionally, Coloplast argues that privity of contract is a required element for breach of express and implied warranty and that privity does not exist between the patient and manufacturer in the implantable medical product context. (*Id.* at 9-10.)

Plaintiffs argue that their First Amended Complaint, including paragraphs 95-100, states specific allegations to meet the pleading standard for breach of express and implied warranties. (Doc. No. 23 at 4.) Plaintiffs contend that they have made specific allegations in their statement that, "Coloplast made 'express and implied warranties' to Plaintiffs and their doctors that the products at issue were 'safe, effective, fit and proper for their intended uses' [and] that those warranties were untrue." (Id.) Further, Plaintiffs argue that they have plead sufficient facts because the First Amended Complaint states that Coloplast marketed the Products "to medical professional and patients, such as Mrs. Marrujo, by making statements and representations warranting the products as 'safe, effective, reliable medical devices' and 'as safer and more effective as compared to available feasible alternative treatments of pelvic organ prolapse and stress urinary incontinence." (Id.) Plaintiffs contend that the existence of an express warranty does not have to be reached by an analysis of the underlying facts, instead the discovery process is designed to "ferret out" the underlying facts of an express warranty claim. (Id. at 5.) Further, Plaintiffs argue that, because Mrs. Marrujo purchased the product and claims to have "reasonably relied" on the implied warranty by Coloplast, the privity argument is unavailing. (*Id.* at 5-6.)

a. Breach of Express Warranty

First, when taking all factual allegations as true, Plaintiffs have failed to allege sufficient facts to state a plausible claim for relief in establishing the existence of an express warranty. An express warranty is created by: "(a) [a]ny affirmation of fact or promise made by the seller to the buyer which relates to the goods and becomes part of the basis of the bargain creates an express warranty that the goods shall conform to the affirmation or

promise," and "(b) [a]ny description of the goods which is made part of the basis of the bargain creates an express warranty that the goods shall conform to the description." Cal. Com. Code § 2313. Here, the Court need not consider legal conclusions couched as facts, and, in paragraphs 96 and 97, Plaintiffs present conclusions instead of facts to establish a claim for express warranty. (Doc. No. 18 ¶¶ 96-97.) In order to establish an express warranty Plaintiff must present enough facts to plausibly assert that Coloplast's statements formed "the basis of the bargain." But, throughout paragraphs 96 and 97, Plaintiffs summarily conclude that "Coloplast... expressly warranted" and "Plaintiffs and Plaintiffs' physicians reasonably relied," while failing to present facts that allege Mrs. Marrujo used Coloplast's statements to form the basis of her decision to use the Product or that she was ever aware of the alleged express warranties. (Doc. No. 18 ¶¶ 96-97.) Under the *Twombly/Iqbal* pleading standard, the complaint needs only enough facts to state a plausible claim for relief and, here, aside from Plaintiffs' legal conclusions, there is an inherent lack of facts to allow the Court to plausibly conclude the existence of an express warranty. (*Id.*)

Along the same rationale, Plaintiffs have failed to present facts to adequately plead privity for a breach of express warranty claim. As a general rule, "privity of contract is a required element of a breach of express warranty cause of action." *Tapia v. Davol, Inc.*, 116 F. Supp. 3d 1149, 1160 (S.D. Cal. 2015) (citing *Burr v. Sherwin Williams Co.*, 42 Cal. 2d 682, 695 (1954)). There is a clear absence of facts to plausibly conclude that Mrs. Marrujo entered into a contract with Coloplast, that she personally relied on Coloplast's specific representations in selecting the Product, and how Mrs. Marrujo's subsequent injuries were correlated to the warranties allegedly made. Therefore, the Court **GRANTS** Coloplast's Motion to Dismiss Plaintiffs' breach of express warranty claim **WITH LEAVE TO AMEND** to include specific factual allegations as to the elements of an express warranty claim.

b. Breach of Implied Warranty

Second, the Court agrees with Coloplast in that Plaintiffs have failed to present

sufficient facts to state a plausible claim for relief for breach of implied warranty and failed to allege privity between Coloplast and Plaintiffs. Plaintiffs' legal conclusions that Coloplast "impliedly warranted" that the "Products were of merchantable quality" are not supported by specific factual allegations and, thus, do not meet the *Twombly/Iqbal* pleading standard for establishing the elements of an implied warranty claim. (Doc. No. 18 ¶ 99, 101.) Further, Plaintiffs' First Amended Complaint inherently lacks factual allegations to support that Mrs. Marrujo and Coloplast were in privity with one another and, how Mrs. Marrujo read and relied upon warranties made by Coloplast, and not the judgement of her physician. *See Blanco v. Baxter Healthcare Corp.*, 70 Cal. Rptr. 3d 566, 582 (Cal. Ct. App. 2008). The Court finds persuasive similarities in *Zetz v. Bos. Sci. Corp.*, 398 F. Supp. 3d 700 (E.D. Cal. 2019), where the court further solidified that in order to establish privity in the implantable medical product context, the plaintiff must provide factual allegations that they personally relied on the representations made by the manufacturer and not the physician in selecting and using the product at issue. Indeed, in *Zetz*, the Court explained:

Plaintiffs' allegations fail to identify any specific representations made by Boston Scientific or any other specific facts that would suggest that Plaintiffs personally relied on Boston Scientific's representations when selecting and using the Product. . . . Instead, Plaintiffs' allegations only vaguely state that Plaintiffs relied in some unspecified way on some unspecified representations and unspecified 'skill, judgment and implied warranty' of Boston Scientific when selecting and using the Product. . . . This is insufficient under Rule 8 and *Iqbal* to plead the requisite privity, especially since this is a medical implant lawsuit where there is a strong presumption that Plaintiffs relied on the skill and judgment of the physician, not the manufacturer, to select and use the Product.

See Zetz, 398 F. Supp. 3d at 709.

¹ For goods to be merchantable, it "must be at least such as: (a) [p]ass without objection in the trade under the contract description; and (b) [i]n the case of fungible goods, are of fair average quality within the description; and (c) [a]re fit for the ordinary purposes for which such goods are used; and (d) [r]un, within the variations permitted by the agreement, of even kind, quality and quantity within each unit and among all units involved; and (e) [a]re adequately contained, packaged, and labeled as the agreement may require; and (f) [c]onform to the promises or affirmations of fact made on the container or label if any." Cal. Comm. Code § 2314.

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Here, Plaintiffs' paragraph 100 is identical to the paragraph in *Zetz* that was ruled insufficient to state a plausible claim for relief for breach of implied warranty. *Id.* at 712; (Doc. No. 18 ¶ 100.) Therefore, the Court **GRANTS** Coloplast's Motion to Dismiss Plaintiffs' breach of implied warranty claim **WITH LEAVE TO AMEND** to include specific factual allegations as to the elements of an implied warranty.

3. Seventh, Eighth, and Ninth Claims for Fraudulent Concealment, Fraud, and Negligent Misrepresentation

Next, Coloplast moves to dismiss Plaintiffs' claims grounded in fraud for failing to meet the heightened pleading standard required by Rule 9(b). (Doc. No. 19 at 11.) Coloplast claims that Plaintiffs have failed to plead with particularity their causes of action for fraudulent concealment, fraud,² and negligent misrepresentation³ because they have failed to allege specific factual allegations of the "who, what, when, where, and how of the misconduct charged" and, instead, allege legal conclusions. (*Id.*) Coloplast argues that Plaintiffs lump Coloplast and DOES 1-30 together and fail to identify the specific persons who they attribute the representations and omissions to. (*Id.* at 12.) Further, Coloplast argues that Plaintiffs have not satisfied an element of fraudulent concealment because they fail to present facts that establish Coloplast had a duty to disclose to Mrs. Marrujo. (*Id.* at 13.) Coloplast contends that a duty to disclose only arises in a fiduciary or transactional relationship with the plaintiff, and Plaintiffs have failed to present any facts that establish this essential relationship. (*Id.* at 14.)

Plaintiffs argue that, throughout their First Amended Complaint, they have supplied sufficient factual allegations to meet the heightened pleading standard for fraud. (Doc. No.

² The elements of a cause of action for intentional misrepresentation are (1) a misrepresentation, (2) with knowledge of its falsity, (3) with the intent to induce another's reliance on the misrepresentation, (4) actual and justifiable reliance, and (5) resulting damage." *Daniels v. Select Portfolio Servicing, Inc.*, 246 Cal. App. 4th 1150, 1166 (2016).

³ The elements of negligent misrepresentation are: "(1) a misrepresentation of a past or existing material fact, (2) without reasonable grounds for believing it to be true, (3) with intent to induce another's reliance on the fact misrepresented, (4) ignorance of the truth and justifiable reliance thereon by the party whom the misrepresentation was directed, and (5) damages." *Fox v. Pollack*, 181 Cal. App. 3d 954, 962 (1986).

23 at 8.) Further, Plaintiffs provide specific facts in their Opposition that they claim meets the "who, what, when, where, and how" standard. (*Id.* at 9-10.) Plaintiffs contend that a duty to disclose did exist because a physician stands in the shoes of the plaintiff in the case of implants and Coloplast had exclusive and superior knowledge of the defects and failed to disclose. (*Id.* at 11.)

a. Plaintiffs Fail to Comply With Rule 9(b)

To plead with particularity under Rule 9(b), a party must plead the "who, what, when, where, and how of the misconduct charged." *Cooper v. Pickett*, 137 F.3d 616, 627 (9th Cir. 1997). In other words, "the pleader must state the time, place and specific content of the false representations as well as the identities of the parties to the misrepresentation." *Alan Neuman Prods., Inc. v. Albright*, 862 F.2d 1388, 1392-93 (9th Cir. 1988). "Rule 9(b) does not allow a complaint to merely lump multiple defendants together but require[s] plaintiffs to differentiate their allegations when suing more than one defendant . . . and inform each defendant separately of the allegations surrounding his alleged participation in the fraud." *Swartz v. KPMG LLP*, 476 F.3d 756, 764-65 (9th Cir. 2007).

Plaintiffs have failed to include facts in their First Amended Complaint that assert the "who, when, where, and how" of the fraud, negligent misrepresentation, and fraudulent concealment claims. Plaintiffs' Opposition provides facts as to *how* the misrepresentations were disseminated through "documents, patients brochures, and internet websites as well as in-person at medical conferences, hospitals, and private offices" but these facts cannot be found in the First Amended Complaint. (Doc. No. 23 at 10); *Schwenk v. Chula Vista Police Dep't*, No. 11-CV-2069-L JMA, 2012 WL 1354055, at *2 n.1 (S.D. Cal. Apr. 18, 2012) (holding that any factual allegations found in the opposition but not in the complaint will not be considered) (citing *Farr v. United States*, 990 F.2d 451, 454 (9th Cir. 1993)). Also, Plaintiffs do not provide any facts or allegations as to *when* any of the allegedly fraudulent behavior took place in their First Amended Complaint. In Plaintiffs' First Amended Complaint, the "*who*" in paragraph 180, "Defendants, their sales wholesalers, distributors representatives, detail persons and other authorized agents," and the "*where*"

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in paragraph 12, "a substantial part of the events and omissions giving rise to Plaintiffs' causes of action occurred in San Diego County, California," do not provide clarity as to who perpetuated the different fraudulent claims, where they occurred, and, importantly, how it relates to Mrs. Marrujo and her injuries. (Doc. No. 18 ¶¶ 180, 12.) Further, Plaintiffs fail to differentiate between each party's participation in the fraud by lumping together Coloplast and DOES 1-30. (*Id.* ¶¶ 108-184.)

Therefore, although Plaintiffs allege compelling scenarios for fraudulent behavior, for example, Coloplast touting their products as "FDA approved" instead of "cleared," they have included insufficient facts as to the "who, when, where, and how" of each fraudulent activity to meet the heightened pleading standard under 9(b). (Doc. No. 18 ¶ 128.)

b. Plaintiffs Fail to Plead the Elements of Fraudulent Concealment,Fraud, and Negligent Misrepresentation

Additionally, Plaintiffs have failed to plead with particularity facts that support the elements of fraud and negligent misrepresentation. Specifically, Plaintiffs do not adequately plead that (1) Coloplast acted with intent to induce reliance on the misrepresentations, (2) justifiable reliance on Plaintiffs' part, and (3) damages. In their First Amended Complaint, Plaintiffs repeat statements in pages 29-47 to plead fraud claims but assert legal conclusions in several paragraphs including but not limited to: 110-112; 114-115; 135; 138; 151; 157; 166; 169. (Doc. No. 18.) Plaintiffs fail to allege facts that suggest Mrs. Marrujo was ever aware of or influenced by misrepresentations in Coloplast's documents, patient brochures, or websites. Nowhere in Plaintiffs' First Amended Complaint do they specify what product was implanted in Mrs. Marrujo and how Coloplast's alleged fraudulent behavior was related to the actual product that caused Mrs. Marrujo's injuries. Throughout Plaintiffs' First Amended Complaint, they use the plural form of "Products" to describe what was implanted in Mrs. Marrujo, "Mrs. Marrujo had the Products inserted into her body," but in Plaintiffs' Opposition they clarify that, "one such product, Coloplast's Aris Urethral Vaginal Sling . . . was implanted in Mrs. Marrujo" (Doc. No. 18 ¶ 2; Doc. No. 23 at 1.) Thus, there is a significant lack of particularity

in what product is at issue and how Coloplast's fraudulent behavior surrounding that product is correlated to Mrs. Marrujo's injuries.

Finally, the Court agrees with Coloplast that Plaintiffs have failed to allege facts that establish a fiduciary or transactional relationship that would impose a duty to disclose on Coloplast for fraudulent concealment.4 "There are four circumstances in which nondisclosure or concealment may constitute actionable fraud: (1) when the defendant is in a fiduciary relationship with the plaintiff; (2) when the defendant had exclusive knowledge of material facts not known to the plaintiff; (3) when the defendant actively conceals a material fact from the plaintiff; and (4) when the defendant makes partial representations but also suppresses some material facts." See Deteresa v. Am. Broad. Cos., 121 F.3d 460, 467 (9th Cir. 1997) (citation omitted). "The first circumstance requires a fiduciary relationship; each of the other three presupposes the existence of some other relationship between the plaintiff and defendant in which a duty to disclose can arise." *Id*. "Such relationships are created by transaction between parties from which a duty to disclose can arise." Id. Examples of transactional relationships are "seller and buyer, employer and prospective employee, doctor and patient, or parties entering into any kind of contractual agreement" but, here Plaintiffs fail to provide facts that allege any of these relationships. Id.

Therefore, the Court **GRANTS** Coloplast's Motion to Dismiss Plaintiffs' claims for fraudulent concealment, fraud, and negligent misrepresentation **WITH LEAVE TO AMEND** to include specific facts as to the "who, when, where, and how" of the fraud claims and facts that support a duty to disclose for fraudulent concealment.

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⁴ The elements of a cause of action for fraudulent concealment are: "(1) the defendant must have concealed or suppressed a material fact, (2) the defendant must have been under a duty to disclose the fact to the plaintiff, (3) the defendant must have intentionally concealed or suppressed the fact with the intent to defraud the plaintiff, (4) the plaintiff must have been unaware of the fact and would not have acted as he did if he had known of the concealed or suppressed fact, and (5) as a result of the concealment or suppression of the fact, the plaintiff must have sustained damage." *Mktg. W., Inc. v. Sanyo Fisher (USA) Corp.*, 6 Cal. App. 4th 326, 336-37 (1997).

V. CONCLUSION

For the reasons stated herein, the Court **GRANTS** Coloplast's Motion to Dismiss. (Doc. No. 19.) The Court **DISMISSES WITHOUT LEAVE** to amend Plaintiffs' second cause of action for manufacturing defect. The Court **DISMISSES WITH LEAVE TO AMEND** Plaintiffs' fourth and fifth claims for breach of express and implied warranty to include specific factual allegations to plausibly assert the elements of each claim. The Court also **DISMISSES WITH LEAVE TO AMEND** Plaintiffs' seventh, eighth, and ninth fraud-based claims to include facts that support the "who, when, where, and how" of the fraud allegations and to assert facts that establish a fiduciary or transactional relationship for a duty to disclose. *See Foman v. Davis*, 371 U.S. 178, 182 (1962) (stating that leave to amend should be freely given in the absence of an apparent reason such as, "undue delay, bad faith or dilatory motive on the part of the movant, repeated failure to cure deficiencies by amendment previously allowed, undue prejudice to the opposing party by virtue of allowance of the amendment, futility of amendment, etc.").

Plaintiffs must file an Amended Complaint addressing the deficiencies noted herein by **July 27, 2020**.

IT IS SO ORDERED.

Dated: July 6, 2020

Hon. Anthony J. Battaglia
United States District Judge