UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA

CASE NO. 18-CIV-60095-RAR

ELMITHA PIERRE, *et al.*,

Plaintiffs,

v.

INTUITIVE SURGICAL, INC.,

Defendant.
_____/

ORDER GRANTING DEFENDANT'S MOTION FOR SUMMARY JUDGMENT

Plaintiff Elmitha Pierre claims her bowel was burned by thermal energy during her robotically-assisted hysterectomy due to an insulation defect in Defendant Intuitive Surgical, Inc.'s product—version-12 of the *Endowrist® HotShears* Monopolar Curved Scissors ("Instrument"). Pierre and her husband, Maxo Jean Jacques, aver that the Instrument was defectively designed, and maintain that Intuitive failed to warn of the alleged defects in the Instrument. As a result, Pierre claims she suffered permanent injuries, while Jacques asserts a loss of consortium claim.

This action is now before the Court upon Intuitive's Motion for Summary Judgment [ECF No. 60] ("Motion"). In its Motion, Intuitive asserts it is entitled to summary judgment because each of Plaintiffs' claims fail as a matter of law. Intuitive avers that Plaintiffs cannot prove the Instrument used in Pierre's surgery is defectively designed. And even if the Instrument has a design defect, Intuitive asserts that Plaintiffs' claims still fail because they cannot establish causation. Intuitive also argues that Plaintiffs' warning-based claims cannot survive because they are unable to prove Intuitive breached a duty to warn—or that any alleged breach of duty caused Pierre's injuries. Lastly, Intuitive maintains that Plaintiffs' loss of consortium claim fails because Plaintiffs cannot prove any other cause of action.

The Court has carefully reviewed the Motion, Plaintiffs' Response in Opposition [ECF No. 77] ("Response"), Intuitive's Reply in Support of its Motion [ECF No. 86] ("Reply"), and all the record evidence. Being otherwise fully advised in the premises, it is hereby

ORDERED AND ADJUDGED that the Motion [ECF No. 60] is **GRANTED** as set forth herein. Pursuant to Rule 58 of the Federal Rules of Civil Procedure, a final judgment will be entered by separate order.

BACKGROUND

i. The Instrument

Intuitive designs, manufactures, and sells the *da Vinci*® System, a robotic device used to assist surgeons performing laparoscopic procedures, such as hysterectomies. *See* Mot. at 2. During a robotically-assisted hysterectomy, the surgeon controls the three or four robotic arms of the *da Vinci* System to insert laparoscopic tools, like the Instrument, into the patient.

The Instrument is energized and uses monopolar energy[1] to cut and coagulate tissue. Def's. Statement of Material Facts [ECF No. 100], Pls.' Resp. to Statement of Material Facts [ECF No. 102], Def's. Reply to Statement of Material Facts [ECF No. 105] (collectively, "Def's. SOMF") ¶ 8. Two older versions of the Instrument—version-09 and version-10—developed microcracks in the insulation of the Instrument's shaft. Pls.' Counter-Statement of Material Facts [ECF No. 102], Def's. Response to Pls.' Counter-Statement of Material Facts [ECF No. 105] (collectively, "Pls.' CSMOF") ¶¶ 1, 4-7; Urgent Medical Device Recall—2955842-05-15-2013-005, at 1, May 16, 2013 [ECF No. 60-4] ("Recall"). These microcracks are particularly significant because they "*may not be visible to the user*" and may "create a pathway for electrosurgical energy to leak to tissue and potentially cause thermal injury." Recall at 1 (emphasis in original). The risk for an

[1] "Monopolar energy is a type of energy characterized by the passage of a current from a single electrode at the tip of an electrosurgical instrument to tissue and through the patient to a return pad to complete the electric current circuit." Mot. at 3 n.2 (citation omitted).

inadvertent injury increases if the Instrument has any microcracks or holes because such cracks can amplify the probability of arcing (the formation of an electric arc). Pls.' CSMOF ¶ 1. However, after these microcracks were discovered, Intuitive recalled version-09 and version-10 and designed version-12, which incorporated "new machining parameters, new process controls, [and] new inspection and testing of the [Instrument's] shafts." Def's. SOMF ¶ 10.[2]

The Instrument does not incorporate active electrode monitoring ("AEM®"), a system designed by Dr. Roger Odell that allegedly acts as a "circuit breaker, deactivating the electrosurgical unit if energy is discharged from the shaft of the monopolar instrument to non-target tissue." Def's. SOMF ¶¶ 13-14; Pls.' CSMOF ¶¶ 3, 24-25. However, the American National Standards Institute, Association for the Advancement of Medical Instrumentation, and the International Electrotechnical Commission have "never required the incorporation of . . . monitoring, such as AEM, in any monopolar electrosurgical laparoscopic instrument." Def's. SOMF ¶ 16. Notably, several other manufacturers design and sell laparoscopic instruments without incorporating AEM into their instruments. Def's. SOMF ¶ 15; Roger Odell Dep. [ECF No. 60-10] ("Odell Dep.") 47:18-25, 48:1.

ii. The Surgery

After receiving unsuccessful treatment from another doctor, Pierre visited Dr. Yat-Min Chen for a fibroid on her uterus. Dr. Chen's Dep. [ECF No. 81-17] 104:1-10. Upon confirming

[2] Although Plaintiffs' Response to Intuitive's Statement of Material Facts technically disputes this issue, Plaintiffs do not dispute that Intuitive made multiple changes to the design and manufacturing process of the Instrument before version-12 was released. Rather, Plaintiffs merely provide additional information unrelated to whether Intuitive made design and manufacturing changes to the Instrument. Moreover, Plaintiffs' additional facts are not supported by a citation to the record. Thus, the Court deems this fact admitted. *See* S.D. FLA. L. R. 56.1(b) ("All material facts . . . will be deemed admitted unless controverted by the opposing party's statement, provided that the Court finds that the movant's statement is supported by evidence in the record."); *see also Reyes v. Am. Sec. Ins. Co.*, No. 16-23978, 2017 WL 4225535, at *1 (S.D. Fla. Sept. 22, 2017) (finding local rule requires that a statement of disputed facts reference supporting evidence in the record and deeming facts disputed by plaintiff but not supported by record evidence as admitted); *Johnson v. Sch. Bd. of Broward Cty.*, No. 07-60797, 2008 WL 5427789, at *2-3 (S.D. Fla. Dec. 30, 2008) (same).

the presence of the fibroid, Dr. Chen offered Pierre two treatment plans: a hormone shot to shrink the size of the fibroid or a hysterectomy. *Id.* at 104:11-24, 105:1-8. Foregoing the hormone shot, Pierre chose to have surgery. *Id.* at 105:6-8.

On January 24, 2014, Dr. Chen performed a laparoscopic hysterectomy on Pierre using the *da Vinci* System and (i) the Instrument, version-12; (2) Fenestrated Bipolar Forceps ("Forceps")[3]; and (3) a metal suction irrigation tube.[4] Def's. SOMF ¶¶ 1, 4-5. Near the end of the surgery, Dr. Chen noticed that Pierre had suffered damage to her bowel. Dr. Chen's Dep. 41:10-12, 70:4-9. After realizing the damage to Pierre's bowel, Dr. Chen requested a consultation from the general surgeon on call. *Id.* at 72:17-18, 77:8-19. The surgeon looked at Pierre's tissue for approximately five minutes, determined there was not much damage, and recommended keeping her in the hospital for observation. As a result, no repairs were made to Pierre's bowel during the surgery. *Id.* at 76:13-25, 77:1-7. Six days later, Pierre began experiencing devasting physical side effects due to the damage to her bowel. *See id.* at 75:8-25, 76:1-4.

Pierre claims the injury to her bowel was caused by arcing due to an insulation defect in the shaft of the Instrument. Def's. SOMF ¶ 7. During the surgery, Dr. Chen did not witness any arcing from any of the devices used, nor did Dr. Chen see any visible defects in the Instrument. Dr. Chen's Dep. 63:25, 64:1-2, 23-25, 102:9-11, 113:20-22, 145:4-6. Nevertheless, even if arcing occurred, Dr. Chen noted that arcing, alone, does not necessarily indicate insulation failure in the Instrument because arcing may come from either the tip of the Instrument *or* the shaft of the Instrument. *Id.* at 129:19-23. And because arcing occurs quickly, it is difficult to determine whether arcing comes from the tip or the shaft of the Instrument. *Id.* at 129:25, 130:1-13.

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[3] Unlike the Instrument, the Forceps use bipolar energy. Bipolar energy is a type of energy characterized by the confinement of electrical current to the tissue between the two electrodes of the instrument. Mot. at 4 n.3.

[4] Plaintiffs do not allege any defect in either the Forceps or the metal suction irrigation tube. And Intuitive did not design or manufacture the tube.

For his own "learning experience," Dr. Chen independently asked Dr. Pitter—a now-deceased instructor who taught an advanced training course offered by Intuitive—to review Pierre's videotaped hysterectomy procedure. *Id.* at 115:7-12, 118:20-22, 131:21-24. According to Dr. Chen, Dr. Pitter concluded that the damage to Pierre's bowel was most likely due to arcing. *Id.* at 118:23-25, 119:1-25, 120:1-3, 13-16, 138:6-11. However, Dr. Chen claims that Dr. Pitter did not specify whether the alleged arcing came from the Instrument or the Forceps. Nor did Dr. Pitter tell Dr. Chen whether the Instrument used in Pierre's surgery was defective. *Id.* at 135:23-25, 136:1, 25 137:1-3, 22-25, 138:1-11.

Simply put, Dr. Chen has no conclusive evidence of a defect in the Instrument. *Id.* at 102:9-18, 141:10-14. However, Dr. Chen did notice the metal suction irrigation tube near Pierre's bowel, and believes it is "more likely" that the Forceps' energy—not the Instrument's—transferred to the tube and inadvertently conducted energy to the bowel. *Id.* at 65:15-23, 67:1-11, 86:23-25, 87:1-5, 89:6-21, 98:5-14, 125:10-25. In fact, Dr. Chen noted that he only energized the Forceps at the time of injury, and the only device near the colon was the metal suction irrigation tube. *Id.* at 89:6-21, 90:20-25, 91:1-5.

iii. The Risks of Surgery

Intuitive's User Manual at the time of Pierre's surgery contained the following warnings:

- WARNING: As with any electrosurgical device, it is possible for energy to discharge in an area other than the instrument tip. It is important to exercise caution when using an energized [Instrument or Single-Site Monopolar instrument] to help avoid unintended contact with tissue adjacent to the area to be cauterized.

- WARNING: If cracks or other flaws are observed on the instrument, do not use the instrument. Contact *Intuitive Surgical* Customer Service.

- WARNING: Failure to follow these precautions will result in electrical arcs from the wrist and alternate site burns.

Def's. SOMF ¶ 29; Intuitive Instrument and Accessories User Manual [ECF No. 86-7] at Section 4. Before and during Pierre's surgery, Dr. Chen knew the risks associated with the use of electrical energy in surgery, such as the risk of thermal damage, thermal spread, and internal damage to another organ. Dr. Chen's Dep. 25:25, 29:1-8; 58:5-25, 59:1-5. Dr. Chen was also aware of the general risks of a hysterectomy and the patient-specific factors that increase the chances of these risks. Dr. Chen's Dep. 41:13-25, 42:1-9. For example, an injury to the bowel is a recognized risk of all hysterectomies regardless if the procedure is performed open, laparoscopically, or robotically; moreover, an obese patient, such as Pierre, is more likely to suffer complications during a hysterectomy. Def's. SOMF ¶ 2.

Moreover, prior to the surgery, Dr. Chen told Pierre the benefits and risks of using the *da Vinci* system and Pierre nonetheless agreed to have the surgery. Dr. Chen's Dep. 32:2-11. Dr. Chen also discussed with Pierre the specific risks commonly associated with the surgery, such as damage to the bladder, bowel, and/or blood vessels. *Id.* at 41:13-15, 68:3-11. Pierre also signed a consent form that explicitly identifies the procedure as a "robotic laparoscopic hysterectomy" and references these known risks. *Id.* at 32:15-18.

iv. Complaint

On January 17, 2018, Plaintiffs filed their Complaint [ECF No. 1] alleging four causes of action against Intuitive. First, Plaintiffs claim that Intuitive breached its duty of care to Pierre by continuing to manufacture and distribute the Instrument after Intuitive knew or should've known of its adverse effects, and because of this alleged breach of duty, Pierre was injured. Second, Plaintiffs assert that the Instrument's insulation is defectively designed and "unreasonably dangerous."[5] Third, Plaintiffs maintain that Intuitive failed to adequately warn Pierre and/or Dr.

[5] In their Response, Plaintiffs attempt to raise a claim for manufacturing defect. *See* Resp. at 14-16. However, Plaintiffs' Complaint does not list a cause of action for manufacturing defect. *See* Compl. ¶¶ 66-78. Rather, Plaintiffs merely state—within their design defect claim—that Intuitive manufactured,

Chen about the risks associated with the Instrument, and this failure to warn caused Pierre's injuries. Lastly, Plaintiffs allege that Jacques lost the support, affection, and companionship of Pierre as a result of her injuries.

LEGAL STANDARD

Summary judgment is appropriate where "the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." FED. R. CIV. P. 56(c). In making this assessment, the Court "must view all the evidence and all factual inferences reasonably drawn from the evidence in the light most favorable to the nonmoving party," *Stewart v. Happy Herman's Cheshire Bridge, Inc.*, 117 F.3d 1278, 1285 (11th Cir. 1997) (citation omitted), and "must resolve all reasonable doubts about the facts in favor of the non-movant," *United of Omaha Life Ins. Co. v. Sun Life Ins. Co. of Am.*, 894 F.2d 1555, 1558 (11th Cir. 1990) (citation omitted). "The mere existence of some factual dispute will not defeat summary judgment unless that factual dispute is material to an issue affecting the outcome of the case." *Chapman v. Al Transport*, 229 F.3d 1012, 1023 (11th Cir. 2000) (citation omitted). And "[a] genuine issue of material fact does not exist unless there is sufficient evidence favoring the nonmoving party for a reasonable jury to return a verdict in its favor." *Id.*

The movant's initial burden on a motion for summary judgment "consists of a responsibility to inform the court of the basis for its motion and to identify those portions of the

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designed, and promoted "products" that were defective in design and manufacture. *Id.* at ¶ 67. Intuitive asserts that Plaintiffs are wrongfully attempting to introduce a new theory of litigation at the summary judgment phase, and the Court agrees. Reply at 7. It is unreasonable to conclude that Plaintiffs intended to bring a manufacturing claim against Intuitive from one sentence in the Complaint in a section titled "Count II Product Liability—Design Defect." Moreover, all other causes of action are appropriately titled and listed as separate counts. Therefore, the Court will not entertain an argument on manufacturing defect at this posture. *See Witt v. Stryker Corp. of Michigan*, 648 F. App'x 867, 874-75 (11th Cir. 2016) ("Both parties clearly understood that [plaintiff's] action turned on an alleged defective *design*. The fact that [plaintiff] simply alleged in her operative complaint that [defendant] was the manufacturer of the [] device is not sufficient to state a claim for defective manufacture.") (emphasis in original).

pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, which it believes demonstrate the absence of a genuine issue of material fact." *Fitzpatrick v. City of Atlanta*, 2 F.3d 1112, 1115 (11th Cir. 1993) (alterations and internal quotation marks omitted) (citing *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986)). Once the moving party has shouldered its initial burden, the burden shifts to the non-moving party to "'set forth specific facts showing that there is a genuine issue for trial,' not just to 'rest upon the mere allegations or denials of the adverse party's pleading.'" *United States v. Lawrence*, 276 F.3d 193, 197 (5th Cir. 2001) (quoting *Resolution Trust Corp. v. Camp*, 965 F.2d 25, 29 (5th Cir. 1992)).

ANALYSIS[6]

I. Strict Product Liability—Design Defect

"Under Florida law, a strict product liability action based upon design defect requires the plaintiff to prove that (1) a product (2) produced by a manufacturer (3) was defective or created an unreasonably dangerous condition (4) that proximately caused (5) injury." *Pinchinat v. Graco Children's Products, Inc.*, 390 F. Supp. 2d 1141, 1148 (M.D. Fla. 2005) (citing *McCorvey v. Baxter Healthcare Corp.*, 298 F.3d 1253, 1257 (11th Cir. 2002)).

"The burden to show that a defective design exists is on the plaintiff." *Farias v. Mr. Heater, Inc.*, 757 F. Supp. 2d 1284, 1293 (S.D. Fla. 2010) (citation omitted). To satisfy this burden, plaintiff must provide "more than a mere scintilla of evidence of a defect" and cannot "simply [rely] on legal conclusions or evidence which would be inadmissible at trial." *Ojeda v. Louisville Ladder Inc.*, 410 F. App'x 213, 215 (11th Cir. 2010) (citation omitted); *Ojeda v. Louisville Ladder Inc.*, No. 08-20690, 2009 WL 10697444, at *6 n.15 (S.D. Fla. Sept. 15, 2009) ("*Ojeda I*") (citation

[6] As part of its analysis, the Court will often refer to Dr. Odell's testimony and Dr. Chen's testimony—two disclosed experts for Plaintiffs. However, in doing so, the Court considers their testimony in a limited capacity and only to determine whether a genuine dispute of material fact prevents the entry of summary judgment. By referring to their testimony, the Court makes no determination as to whether Odell or Dr. Chen would withstand challenges under *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993).

omitted). Plaintiff must also provide expert testimony to prove a design defect, and failure to provide such testimony is fatal to plaintiff's claim. *Cooper v. Old Williamsburg Candle Corp.*, 653 F. Supp. 2d 1220, 1225 (M.D. Fla. 2009). Lastly, plaintiff does not satisfy this burden by merely indicating that a manufacturer failed to produce a "fail-safe product." *Hernandez v. Altec Environmental Products, LLC*, 903 F. Supp. 2d 1350, 1359 (S.D. Fla. 2012) ("Products liability does not make the manufacturer an insurer of all foreseeable accidents which involve its product . . . . An action is not maintainable in products liability merely because the design used was not the safest possible."); *Pinchinat*, 390 F. Supp. 2d at 1148 ("[A] manufacturer does not have to make a product accident proof.").

The parties do not dispute that Intuitive designed and produced the Instrument. Rather, the parties only dispute whether the Instrument was defective and/or unreasonably dangerous and if so, whether such defect proximately caused Pierre's injuries. The Court will address each of the parties' arguments in turn by explaining—and applying—the different design defect "tests" required under Florida law before summarizing its analysis in the context of summary judgment.

A. Defect

"[T]he definition of design defect is in a state of flux in Florida." [7] *In re Standard Jury Instructions in Civil Cases—Report No. 09–10 (Prods. Liab.)*, 91 So. 3d 785, 789 (Fla. 2012) (Pariente, J., concurring). Courts commonly use at least one of the following three "tests" to determine whether a product is defectively designed: (1) the consumer expectation test; (2) the risk utility test; and (3) the reasonable alternative design test. *Anderson v. Techtronic Industries North America, Inc.*, No. 13-1571, 2015 WL 12843836, at *5-6 (M.D. Fla. Apr. 14, 2015); *Tillman v. C.R. Bard, Inc.*, 96 F. Supp. 3d 1307, 1338-39 (M.D. Fla. 2015). "A plaintiff may prevail by

[7] A federal court sitting in diversity jurisdiction must apply substantive state law; in doing so, federal courts must "decide the case the way it appears the state's highest court would." *Bravo v. United States*, 577 F.3d 1324, 1325 (11th Cir. 2009).

proving either theory." *Anderson*, 2015 WL 12843836, at *3 (citation omitted). "Thus, at present, the proper definition of design defect, and whether that definition varies depending on the type of product involved remains unclear in Florida law." *Id.* Although not *explicitly* stated in their Response, Plaintiffs assert that the insulation in version-12 of the Instrument is defectively designed under all three tests.[8]

i. Consumer Expectation Test

A product is defectively designed under the consumer expectation test if "the product fails to perform as safely as an ordinary consumer would expect when used as intended or in a manner reasonably foreseeable by the manufacturer." *Tillman*, 96 F. Supp. 3d at 1338-39; RESTATEMENT (SECOND) OF TORTS § 402A. According to the Florida Supreme Court, the consumer expectation test—as opposed to the risk utility test—is an "essential part of determining a design defect" and "best vindicates the purposes underlying the doctrine of strict liability." *Aubin v. Union Carbide Corp.*, 177 So. 3d 489, 494 (Fla. 2015). However, this does not prevent plaintiff from introducing evidence indicating that the product's risks outweigh the benefits—or evidence of a reasonable alternative design. *Id.* at 511. Nor is defendant precluded from rebutting plaintiff's claim by demonstrating the contrary. *Id.* Simply put, the consumer expectation test is *generally* a necessary theory courts must consider; however, it is not the only factor in a design defect analysis.

Intuitive argues that the Court should depart from the consumer expectation test in circumstances such as here, where the product is "too complex for the ordinary consumer to have any expectations concerning their proper operation." Reply at 1-2; *Rydzewski v. DePuy Orthopaedics, Inc.*, No. 11-80007, 2012 WL 7997961, at *2 (S.D. Fla. Aug. 14, 2012); *see also*

[8] *See* Resp. at 10, 13 n.2, 14 ("Florida law provides that a product is unreasonably dangerous because of its design if the product fails to perform as safely as an ordinary consumer would expect . . . . A product may also be unreasonably dangerous because of its design where the risk of danger in the design outweighs the benefits . . . . [H]ad [AEM®] technology been incorporated to the Pierre [Instrument], she would not have been injured . . . . [T]he arcing during Ms. Pierre's surgery could have been prevented by AEM[®] . . . .") (emphasis added).

Tillman, 96 F. Supp. 3d at 1339; *Schenone v. Zimmer Holdings, Inc.*, No. 12-1046-J-39, 2014 WL 12576790, at *6-7 (M.D. Fla. Aug. 7, 2014); *Force v. Ford Motor Co.*, 879 So. 2d 103, 109 (Fla. 5th DCA 2004). However, the aforementioned cases cited by Intuitive were decided before *Aubin*, and there, the Florida Supreme Court reversed an appellate court decision for requiring plaintiff to provide evidence of a reasonable alternative design and adopting the risk utility test to the exclusion of the consumer expectation test. 177 So. 3d at 510-12. In its decision, the Florida Supreme Court emphasized the role manufacturers play "in crafting the image of a product and establishing the consumers' expectations for that product, a portrayal which in turn motivates consumers to purchase that particular product." *Id.* at 511. And because of this, the consumer expectation test—as opposed to the risk utility test—rightfully places the burden on manufacturers, not injured consumers. *Id.* at 510-11. Furthermore, the Florida Supreme Court has "rejected applying legal principles that are inconsistent with [this] general philosophy . . . ." *Id.* at 503.

The parties do not cite—nor is the Court aware of—any case post-*Aubin* that does not utilize the consumer expectation test for medical devices. However, Intuitive's argument is not without merit. Medical device manufacturers generally do not market their products to "ordinary consumers." Rather, medical device manufacturers promote and advertise their products to intermediaries, such as hospitals, physicians, and other trained medical professionals. However, 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. Therefore, the Court must consider the ordinary consumer's expectation in its design defect analysis.

Here, Plaintiffs assert that the insulation in the Instrument was defective in design because arcing occurred; therefore, the Instrument did not perform to Pierre's or Dr. Chen's expectations.

Resp. at 14. However, Plaintiffs have not demonstrated that arcing actually occurred during Pierre's surgery. Dr. Chen did not witness any arcing during the surgery; he merely assumed arcing occurred because of inadmissible hearsay[9] from Dr. Pitter. And aside from Plaintiffs' conclusory allegations and Dr. Chen's inadmissible testimony, there is no direct evidence indicating the Instrument did not perform as expected during Pierre's surgery.[10]

ii. Risk Utility Test

A product is considered unreasonably dangerous under the risk utility test if the risk of danger in the design outweighs the benefits. *Tillman*, 96 F. Supp. 3d at 1339. Plaintiffs allege that version-12 of the Instrument is more susceptible to causing injury—and therefore, unreasonably dangerous—because of its "long history of inadequate insulation."[11] Resp. at 14. In support of this allegation, Plaintiffs rely on several performance tests conducted by Intuitive that found microcracks on version-09 and version-10 of the Instrument, as well as the consequential recall. Resp. at 6. Plaintiffs also rely on medical articles indicating that version-09 and version-10 were prone to stray electrical currents and "loss of insulator integrity" at the end of the Instrument's "life cycle." *Id.* However, Plaintiffs' reliance is misplaced. It is illogical and unreasonable to conclude that the insulation in version-12 of the Instrument was defective in design—or more susceptible to risks—simply because version-09 and version-10 were defective and subject to a recall. *See Gardner*, 166 F. Supp. 3d at 1271-72 ("[T]he idea that defects . . . in other vehicles

[9] *See infra* Causation, Section I.B.

[10] Because Plaintiffs cannot establish whether arcing occurred during Pierre's surgery, they ask the Court to consider unrelated, past circumstances where physicians reported arcing from version-12 of the Instrument during surgeries. Resp. at 7; *see also* MedWatch Reports [ECF No. 81-24, 81-47, 81-49]. However, it is inappropriate for the Court to consider an unrelated surgery with possibly an entirely different set of circumstances to establish whether an unintended consequence occurred in Pierre's surgery. *See Gardner v. Ford Motor Co.*, 166 F. Supp. 3d 1261, 1271-72 (M.D. Fla. 2015).

[11] Although this argument is not explicitly cited as part of Plaintiffs' risk utility theory, it does fall somewhat within that analysis.

can establish a defect or fire in the [vehicle at issue], without specific evidence . . . is speculative and therefore unable to create a genuine issue of material fact."); *see also Hughes v. Stryker Sales Corp.*, No. 08-0655, 2010 WL 1961051, at *4 (S.D. Ala. May 13, 2010), *aff'd*, 423 F. App'x 878 (11th Cir. 2011) (finding that "it would be an unreasonable and unsupportable inferential leap for a finder of fact to conclude" that a product recall, alone, gives rise "to [an] inference that the actual device implanted in [plaintiff] had a defect"). This is especially true when it is undisputed that version-12 of the Instrument incorporated new changes to repair the alleged past defects found in version-09 and version-10.

Plaintiffs also allege that the "numerous adverse event reports" and returned instruments with microcracks sufficiently indicate an insulation defect in version-12. *See generally* MedWatch Reports. Intuitive fails to directly address these allegations. For example, Intuitive does not dispute Plaintiffs' claims, nor does Intuitive assert that version-12 of the Instrument is an exceptional medical device with benefits far outweighing these alleged risks. Rather, Intuitive merely relies on Plaintiffs' lack of specific evidence indicating an insulation defect in the Instrument used in Pierre's surgery. This, according to Intuitive, is fatal to Plaintiffs' design defect claim.

In support of this argument, Intuitive relies on *Hernandez*,[12] where the court granted summary judgment because plaintiff failed to introduce evidence of a design defect. 903 F. Supp. 2d at 1360. However, this interpretation of *Hernandez* is incomplete. In *Hernandez*, it was "*undisputed* that the wood chipper as designed was not dangerous"; instead, plaintiff alleged the

[12] Intuitive also cites to *Ojeda I* to support this proposition. There, plaintiff was attempting to establish a design defect pursuant to *Cassisi v. Maytag Co.*, 396 So. 2d 1140 (Fla. 1st DCA 1981), which triggers an inference of defectiveness (an issue not currently before the Court), using only plaintiff's own affidavit. *Ojeda I*, 2009 WL 10697444, at *4-5. However, plaintiff's affidavit in *Ojeda I* was devoid of any facts regarding his "normal operation" of the ladder—a required element for a *Cassisi* inference—and therefore, the court granted summary judgment. Because Plaintiffs are not relying on *Cassisi*, *Ojeda I* is factually distinguishable and inapplicable.

product was unreasonably dangerous simply because "it didn't work the way it was supposed to[.]" *Id.* at 1359 (emphasis added). Therefore, the issue in *Hernandez* was not whether the wood chipper was defectively designed, but whether a manufacturer could be strictly liable for a "foreseeable misuse of a product" or for a reasonably designed product that simply functions in "an allegedly unsatisfactory or inefficient manner." *Id.* The court determined that a manufacturer could not be held strictly liable for design defect under these circumstances. *Id.* at 1360.

There is a critical difference between this case and *Hernandez*. Here, the parties dispute whether the product was defectively designed and/or unreasonably dangerous. And although Plaintiffs have not demonstrated with absolute certainty an actual design defect in the Instrument used in Pierre's surgery, Plaintiffs have provided evidence of allegedly unreasonable risks associated with the version-12 design. *See generally* MedWatch Reports; *see also* Odell Dep. 62:7-12, 79:15-20 (plaintiff's expert stating there *may* have been insulation failure in the Instrument used in Pierre's surgery and he saw evidence of cracked Instruments post-recall) (emphasis added).[13] Moreover, the three tests used to define a design defect under Florida law do not mandate that Plaintiffs present evidence of the *actual* defect in the Instrument used in Pierre's surgery.

iii. Reasonable Alternative Design

A design is defective under the reasonable alternative design test if "the foreseeable risks of harm posed by the product could have been reduced or avoided by the adoption of a reasonable alternative design . . . and the omission of the alternative design renders the product not reasonably safe." *Anderson*, 2015 WL 12843836, at *5 (internal quotations omitted) (citing RESTATEMENT

[13] Intuitive claims the Court should not consider Odell's testimony because Odell did not inspect the Instrument used in Pierre's surgery and cannot confirm whether the Instrument actually suffered from insulation failure; therefore, Intuitive asserts Odell's testimony is merely speculative. However, at this posture, the Court must view the evidence and give all reasonable inferences in the light most favorable to Plaintiffs. Therefore, the Court will not ignore Odell's testimony.

(THIRD) OF TORTS: PRODUCTS LIABILITY § 2(b)). Plaintiffs maintain that version-12 of the Instrument is unreasonably dangerous because it failed to incorporate AEM® or other similar technology and consequently, Intuitive failed to reduce foreseeable risks of harm associated with version-12.

Intuitive asserts it is entitled to summary judgment because Plaintiff has not established that version-12 is "not reasonably safe" without AEM® or other similar technology. Mot. at 11; *see also Scheman-Gonzalez v. Saber Mfg. Co.*, 816 So. 2d 1133, 1141 (Fla. 4th DCA 2002) (citation omitted) ("[W]here a product is reasonably safe, the fact that there may be a better alternative design is not grounds for product liability."). Intuitive highlights the lack of peer-reviewed studies comparing the risk of thermal injury in surgeries conducted with AEM® or other similar technology to those without such features. Intuitive also focuses on the standards of various independent, nonprofit organizations that do not require coaxial shielding and monitoring and claims the ECRI Institute—an independent nonprofit organization that investigates the safety of medical products—has "never issued an opinion or conclusion that monopolar electrosurgical laparoscopic instruments [without] AEM® are defective or unsafe to use." Mot. at 11; Def's. SOMF ¶ 17.

However, Plaintiffs' expert concluded that version-12 of the Instrument is defectively designed because "it did not incorporate AEM® or coaxial shielding and monitoring of the shaft of the device." Odell Decl. [ECF No. 60-9] at 2. In addition, Plaintiffs' expert indicates that incorporating AEM® or other similar technology is feasible and reasonably possible. *Id.* at 4. Odell also testified he is aware of studies that indicate patients are safer when monopolar electrosurgical devices incorporate coaxial shielding and monitoring. Odell Dep. 57:11-25. And generally, Odell repeatedly discusses the "unreasonable" dangers, such as insulation failure and

stray electrosurgical energy, often associated with devices failing to incorporate AEM® or coaxial shielding and monitoring of the shaft of the device (i.e., version-12). Odell Decl. at 3.

iv. Defect Summary

Plaintiffs cannot prevail under a consumer expectation test because there is no admissible evidence—other than Plaintiffs' own conclusory allegations—indicating the Instrument did not perform as expected by the ordinary consumer. But Plaintiffs and their expert do allege the risks of insulation failure and the dangerous consequences of the microcracks sometimes found in the insulation of version-12. Plaintiffs and their expert have also provided evidence of a reasonable alternative design and alleged that failure to incorporate this alternative design makes version-12 of the Instrument "not reasonably safe."

Although Intuitive raises persuasive arguments, the Court must, at this posture, resolve all reasonable inferences in favor of Plaintiffs. Because of this, the evidence presented by Plaintiffs is sufficient to create a genuine issue of material fact as to whether the Instrument used in Pierre's surgery was defectively designed under Florida law. Reasonable minds could differ as to whether the risks of version-12 outweigh the benefits or whether version-12 is "not reasonably safe" without AEM® or other similar technology. Therefore, whether the Instrument used in Pierre's surgery was defectively designed is a question of fact and cannot be decided as a matter of law.

B. Causation

"To prove causation under a strict products liability theory, a plaintiff must prove that the product defect proximately caused his injury." *Rink v. Cheminova, Inc.*, 400 F.3d 1286, 1295 (11th Cir. 2005). "Regarding . . . proof of causation, in complex cases where a jury is asked to assess complex medical or scientific issues outside the scope of a layperson's knowledge, an expert's testimony is required." *Small v. Amgen, Inc.*, 723 F. App'x 722, 726 (11th Cir. 2018) (citing *Guinn v. AstraZeneca Pharm. LP*, 602 F.3d 1245, 1256 (11th Cir. 2010)). "Without expert

testimony, the plaintiff's claim fails as a matter of law." *Id.* However, expert testimony indicating the "mere possibility" of causation is insufficient. *Guinn*, 602 F.3d at 1256 (quoting *Gooding v. Univ. Hosp. Bldg., Inc.*, 445 So. 2d 1015, 1018 (Fla. 1984)). Therefore, if the matter is "one of pure speculation or conjecture, or the probabilities are at best evenly balanced, it becomes the duty of the court to direct a verdict for the defendant." *Id.*

Intuitive claims it is entitled to summary judgment because Plaintiffs do not have admissible expert testimony to prove causation.[14] Intuitive asserts that any testimony provided by Dr. Chen based on his discussions with Dr. Pitter is inadmissible for two reasons: (1) as a percipient expert witness, Dr. Chen cannot rely on another physician's opinion; and (2) the testimony is hearsay. Mot. at 14; Def's. Reply to Statement of Material Facts ¶¶ 19-20. Plaintiffs do not address Intuitive's claims in their Response. Rather, Plaintiffs only rely on Dr. Chen's testimony and other circumstantial evidence to support a theory of causation based on differential diagnosis.[15]

As discussed below, the Court will first analyze Intuitive's expert witness and hearsay concerns regarding Dr. Chen's testimony before turning to differential diagnosis as an alternative theory. The Court will then conclude with a summary of issues regarding causation.

i. Percipient Expert

Dr. Chen was disclosed by Plaintiffs as an expert under Rule 26(a)(2)(C) of the Federal Rules of Civil Procedure. *See* Not. of Service Expert Disclosures [ECF No. 60-7] ("Disclosure"). Unlike retained experts under Rule 26(a)(2)(B), disclosed witnesses under (2)(C) are not required to produce a written expert report. *See* FED. R. CIV. P. 26(a)(2)(B), (C); *Pringle v. Johnson & Johnson*, No. 13-81022, 2019 WL 6723822, at *2 (S.D. Fla. Dec. 11, 2019). To qualify for the

[14] Odell did not provide an admissible opinion on causation. *See* Order Granting Intuitive's Expedited Motion to Strike Plaintiffs' Expert Opinion [ECF No. 52]. Dr. Chen is the only other person permitted to testify as an expert. Therefore, Dr. Chen is Plaintiffs only disclosed expert who opines as to causation.

[15] "Differential diagnosis is a process by which a physician systematically eliminates possible causes of a patient's ailment to arrive at its most probable cause." *Rink*, 400 F.3d at 1294 n.8.

"less burdensome disclosure obligations," a treating physician may only offer an opinion based on personal observations made while treating the plaintiff. *Id.* (citation omitted); *see also Sweat v. United States*, No. 14-888, 2015 WL 8270434, at *2 (M.D. Fla. Dec. 8, 2015) (citation omitted) ("[I]f a treating physician acquired the opinions that are the subject of the testimony directly through treatment of the plaintiff, the treating physician cannot be forced to file a written report required by Rule 26(a)(2)(B)."") (alteration in original); *Blakely v. Safeco Insur. Co. of Illinois*, 13–796, 2014 WL 1118071, at *3 (M.D. Fla. Mar. 20, 2014) (same). However, if a treating physician's opinion is based on information *outside* of his or her personal observations, the treating physician's opinion is inadmissible unless the physician provides a written expert report in compliance with Rule 26(a)(2)(B). *Williams v. Mast Biosurgery USA, Inc.*, 644 F.3d 1312, 1317-18 (11th Cir. 2011); *see also Blakely*, 2014 WL 1118071, at *3 ("[I]f a health care professional is asked to give any additional opinions, beyond those procured directly from treatment, then for those additional opinions to be admissible, Plaintiff must first provide the full written disclosures required by Rule 26(a)(2)(B).")

Here, the Disclosure noted that Dr. Chen would opine "to a reasonable degree of medical probability [that] the thermal injury [Pierre] sustained during [her] hysterectomy resulted from unintended arcing of electricity due to an insulation failure or defect [in the Instrument used]." *Id.* However, the Disclosure inaccurately represents Dr. Chen's actual testimony. Rather, Dr. Chen's testimony made four facts abundantly clear: (1) the injury "most likely" occurred from thermal energy transferred to the metal suction tube; (2) he was only firing the Forceps at the time of Pierre's injury; (3) he did not observe any defect in the Instrument used or witness any arcing during surgery; and (4) even if arcing occurred, it does not necessarily indicate an insulation defect.

And although Dr. Chen did testify that Pierre's injury likely resulted from arcing, *see* Dr. Chen Dep. 126:1-10, his opinion was conjectural, not based on personal observations made during

Pierre's treatment, and was not necessary or critical to Pierre's treatment. Therefore, this opinion is inadmissible without a written expert report in compliance with Rule 26(a)(2)(B).[16]

ii. Hearsay

Assuming Dr. Chen did not need to provide a written expert report, his opinion is nevertheless inadmissible to the extent it relies on statements from Dr. Pitter because it is hearsay.

Generally, inadmissible hearsay—an out-of-court statement, presented for the truth of the matter asserted, that does not fall within an exception to the hearsay rule—cannot be considered on a motion for summary judgment. *Macuba v. Deboer*, 193 F.3d 1316, 1322 (11th Cir. 1999) (citation omitted). However, a "district court may consider a hearsay statement in passing on a motion for summary judgment if the statement could be reduced to admissible evidence at trial or reduced to admissible form." *Id.* at 1323 (citation and internal quotations omitted). "For example, the statement might be admissible [if] it falls within an exception to the hearsay rule, or does not constitute hearsay at all (because it is not offered to prove the truth of the matter asserted), or is used solely for impeachment purposes (and not as substantive evidence)." *Id.* (citation and footnotes omitted).

As previously mentioned, Plaintiffs do not address whether Dr. Chen's testimony is hearsay or if it is, whether it is subject to a hearsay exception. However, Plaintiffs' Response, their Response to Defendant's Statement of Material Facts, and their Counter-Statement of Material Facts, often refer to Dr. Pitter's alleged statements to indicate that Pierre's injury was caused by arcing. *See* Resp at 6; Resp. to Statement of Material Facts ¶¶ 19, 20; Pls.' Counter-Statement of Material Facts ¶¶ 10, 19. Therefore, Plaintiffs likely intend to use Dr. Pitter's statements for the truth of the matter asserted.

[16] To the extent Dr. Chen relies on Dr. Pitter's alleged statements to form his opinion, such testimony is also inadmissible without a written expert report because the opinion would not be based on his own personal observations made during Pierre's treatment.

Despite Plaintiffs' failure to address this alleged hearsay issue, the Court will conduct a brief analysis of some relevant issues and possible exceptions. First, the Court must determine whether Dr. Pitter's statements are hearsay. Because Plaintiffs claim Dr. Pitter was teaching a course offered by Intuitive when he made the alleged statements, it may be argued that Dr. Pitter is an agent or employee of Intuitive and therefore, his statements are not hearsay under Rule 801(d)(2) of the Federal Rules of Evidence. *See City of Tuscaloosa v. Harcros Chemicals, Inc.*, 158 F.3d 548, 557 (11th Cir. 1998) (citation and internal quotations omitted) ("A statement by [a] party's agent or servant concerning a matter within the scope of the agency or employment, made during the existence of the relationship, however, is deemed an admission by a party opponent and is excluded from the definition of hearsay.") (alteration in original).

However, there is nothing in the record to suggest an agency relationship between Dr. Pitter and Intuitive. And even if there was such evidence, there is no indication the statement related to a matter within the scope of the agency. *See Wilkinson v. Carnival Cruise Lines, Inc.*, 920 F.2d 1560, 1566 (11th Cir. 1991) (citations and internal quotations omitted) ("It is well established that Rule 801(d)(2)(D) requires the *proffering party* to lay a foundation to show that an otherwise excludible statement relates to a matter within the scope of the agent's employment.") (emphasis in original). Therefore, without any evidence to the contrary, it is likely that Dr. Pitter's statements are hearsay.

Assuming Dr. Pitter's statements are hearsay, the Court must determine whether a possible hearsay exception applies. After careful review of the hearsay exceptions listed under Rule 803 and 804 of the Federal Rules of Evidence, the Court finds no exception applies to Dr. Pitter's statements. Thus, Dr. Pitter's statements are inadmissible hearsay and cannot be reduced to admissible evidence at trial.

iii. Differential Diagnosis

Assuming Dr. Chen's testimony is otherwise admissible, Plaintiffs rely on Dr. Chen's testimony and other circumstantial evidence to establish causation through differential diagnosis. However, differential diagnosis, alone, is simply insufficient to create a genuine issue of material fact. *See Rink*, 400 F.3d at 1295 (citation omitted) ("[D]ifferential diagnoses alone [is] still . . . legally insufficient to meet their burden on causation. While numerous federal courts have found differential diagnosis sufficiently reliable to be admissible under *Daubert*, we have found in the context of summary judgment that differential diagnosis evidence by itself does not suffice for proof of causation.").

iv. Causation Summary

Odell—Plaintiffs' retained expert—failed to provide an opinion on causation. Therefore, Plaintiffs' remaining expert is Dr. Chen. Because Dr. Chen's opinion as to the cause of Pierre's injury is purely conjectural and not based on his own observations during the course of Pierre's treatment, it is inadmissible without an expert report. To the extent Dr. Chen's opinion is based on Dr. Pitter's statement, it is also inadmissible for the same reason. Moreover, Dr. Pitter's statements are inadmissible hearsay and cannot be considered on a motion for summary judgment. And lastly, even assuming Dr. Chen's testimony is admissible without an expert report, Plaintiffs cannot establish causation through differential diagnosis. Therefore, Plaintiffs have not produced sufficient admissible evidence to create a genuine issue of material fact as to causation—a necessary element of Plaintiffs' design defect claim. Because of this, Intuitive is entitled to summary judgment as to Plaintiffs' claim for design defect.

II. Negligence

The Court need not consider whether Intuitive negligently designed version-12 of the Instrument because Plaintiffs have not produced sufficient admissible evidence to create a genuine

issue of material fact as to causation—a necessary element of Plaintiffs' negligent design claim. *See Cooper*, 653 F. Supp. 2d at 1226 ("To prove any products liability claim sounding in negligence, . . . a *plaintiff* must establish (1) that the defendant owed a duty of care toward the plaintiff, (2) that the defendant breached that duty, (3) that the breach was the proximate cause of the plaintiff's injury, and (4) that the product was defective or unreasonably dangerous.") (emphasis added); *Kilpatrick v. Breg, Inc.*, No. 08-10052, 2009 WL 2058384 (S.D. Fla. June 25, 2009) (finding plaintiff's "failure to proffer sufficient evidence of causation, an element critical to all of his claims, [is] necessarily fatal to his efforts to avoid summary judgment").

III. Failure to Warn

"Under Florida law, to succeed on a failure to warn claim a plaintiff must show (1) that the product warning was inadequate; (2) that the inadequacy proximately caused her injury; and (3) that she in fact suffered an injury from using the product." *Eghnayem v. Bos. Sci. Corp.*, 873 F.3d 1304, 1321 (11th Cir. 2017) (citing *Hoffmann-La Roche Inc. v. Mason*, 27 So. 3d 75, 77 (Fla. 1st DCA 2009)). The parties dispute whether Intuitive provided adequate warnings and if not, whether the inadequate warnings caused Pierre's injuries. The Court will address each of these arguments in turn, beginning with the adequacy of the warnings before addressing proximate cause and concluding with a summary of the failure to warn analysis.

i. Adequacy of Warnings

Intuitive claims it is entitled to summary judgment because it provided adequate warnings and nonetheless, Plaintiffs failed to provide expert testimony on the adequacy or inadequacy of Intuitive's warnings. Plaintiffs do not address their lack of expert testimony; however, Plaintiffs claim Intuitive's warnings are inadequate because they do not warn of potential cracks in the insulation nor do they warn of the increased risks of thermal energy due to these potential cracks.

"While in many instances the adequacy of warnings . . . is a question of fact, . . . it can be resolved as a question of law where the warning is accurate, clear, and unambiguous." *Farias*, 684 F.3d at 1233 (citations and internal quotations omitted). "To warn adequately, the product label must make apparent the potential harmful consequences. The warning must be of such intensity as to cause a reasonable man to exercise for his own safety caution commensurate with the potential danger." *Id.*

For medical products, "a . . . manufacturer's duty to warn is satisfied if it gives an adequate warning to the physician who prescribes the drug" pursuant to Florida's learned intermediary doctrine. *Small v. Amgen, Inc.*, 134 F. Supp. 3d 1358, 1367 (M.D. Fla. 2015) ("*Small I*"). "This is so because the prescribing physician, acting as a 'learned intermediary' between the manufacturer and the consumer, weighs the potential benefits against the dangers in deciding whether to recommend the product to meet the patient's needs." *Wilson v. Danek Medical, Inc.*, No. 1999 WL 1062129, at *3 (M.D. Fla. Mar. 29, 1999) (citation omitted); *see also Eghnayem*, 873 F.3d at 1321. "[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." *Eghnayem*, 873 F.3d at 1321-22 (citation omitted).

To determine whether a warning is adequate or inadequate to inform a physician of the risks of injury, expert testimony is generally required. *Id.* (citation omitted). Because version-12 of the Instrument is a complex medical device, an expert is needed to determine the adequacy of Intuitive's warnings. This is not a circumstance where a jury could readily observe the possible consequences of the device. Here, it is undisputed that Plaintiffs failed to provide expert testimony on the adequacy or inadequacy of Intuitive's warnings. Therefore, this, alone, is fatal to Plaintiffs' failure to warn claim.

However, even if failure to provide expert testimony were not deemed fatal to Plaintiffs' claim, Intuitive provided the following warnings:

> - WARNING: As with any electrosurgical device, it is possible for energy to discharge in an area other than the instrument tip. It is important to exercise caution when using an energized [Instrument or Single-Site Monopolar instrument] to help avoid unintended contact with tissue adjacent to the area to be cauterized.
>
> - WARNING: If cracks or other flaws are observed on the instrument, do not use the instrument. Contact *Intuitive Surgical* Customer Service.
>
> - WARNING: Failure to follow these precautions will result in electrical arcs from the wrist and alternate site burns.

Plaintiffs assert that Intuitive failed to provide adequate warnings because Intuitive did not warn physicians of possible cracks in the insulation and the increased risks of thermal injury when those cracks are present. However, to provide adequate warnings, Intuitive need only reasonably warn physicians of the injury alleged from failure to use the product in the prescribed manner, not the specific way(s) the alleged injury may occur. *See Farias*, 684 F.3d at 1233 ("To warn adequately, the product label must make apparent the potential harmful consequences."); *Small I*, 134 F. Supp. 3d at 1372 ("[M]anufacturers are only required to warn the prescribing physician of the possibility that the drug may cause the injury alleged by the plaintiff."); *Brito v. County of Palm Beach*, 753 So. 2d 109, 112 (Fla. 4th DCA 1998) ("A warning should contain some wording directed to the significant dangers arising from failure to use the product in the prescribed manner, such as the risk of serious injury or death.").

Here, Intuitive's warnings provide that "it is possible for energy to discharge in an area other than the instrument tip" and "failure to follow . . . precautions *will* result in electrical arcs . . . ." Although Intuitive does not explicitly warn of the risks of thermal burns, a trained medical expert like Dr. Chen could reasonably decipher the possible dangerous consequences (i.e.,

thermal burn of surrounding tissue) of unintended energy discharge and/or arcing. *See* Dr. Chen Dep. 29:9-21 ("Q: And thermal spread, can that occur for reasons having nothing to do with a defect in the instrument? . . . A: . . . . But for the damage I heard about the arcing, the electric arc, and damage to the tissue."); *Id.* at 141:18-25 ("Q: Is arcing supposed to happen during *da Vinci* surgery? . . . A: We don't want arcing [to] happen during the surgery. Q: Why not? A: You can damage anything, you don't see it . . . "). Therefore, Intuitive's warnings are clear, unambiguous, and adequate to inform a medical physician of the risks of version-12.

ii. Proximate Cause

However, even assuming that Intuitive provided inadequate warnings, Plaintiffs failure to warn claim still fails because they cannot establish that the inadequacy caused Pierre's injuries. "[T]o satisfy the causation element, a plaintiff must show that her treating physician would not have used the product had adequate warnings been provided." *Eghnayem*, 873 F.3d at 1321 (citation omitted). And furthermore, even if a manufacturer provides inadequate warnings, the manufacturer will not be liable "if the plaintiff's physician independently knew of the risks and failed to advise the plaintiff." *Wilson*, 1999 WL 1062129, at *4; *Felix v. Hoffmann-LaRoche, Inc.*, 540 So. 2d 102, 104 (Fla. 1989).

Plaintiffs have not provided any evidence indicating Dr. Chen would not have used version-12 of the Instrument had he known of the risk of thermal injury to surrounding organs. Moreover, Dr. Chen's own testimony contradicts this point. Dr. Chen knew that version-12 (and the use of electrical surgical energy generally) came with risks—specifically the risk of thermal damage and internal damage to another organ—and explained these risks to Pierre. *See* Dr. Chen Dep. at 28:25, 29:1-8, 23-25, 30:1, 17-25, 31:1-17, 32:2-14, 46:24-25, 47:1-2, 48:10-17, 21-25, 67:17-25. In fact, Pierre signed a consent form that explained these possible risks. Thus, even if

Intuitive's warnings were somehow inadequate, Dr. Chen independently knew of the risks and went so far as to inform Pierre of these risks. Consequently, the causal link is broken.

iii. Failure to Warn Summary

Plaintiffs' lack of expert testimony to support the alleged inadequacy of Intuitive's warnings is fatal. But even if expert testimony were not required, Intuitive's warnings reasonably notify a trained physician of the risks of arcing and cracks, and a physician can reasonably decipher the potential consequences of these risks. And nonetheless, Dr. Chen knew of the risks associated with version-12 of the Instrument and electrical surgical energy generally, and informed Pierre of these risks. Because of this, the Court must grant summary judgment in favor of Intuitive as to Plaintiffs' failure to warn claim.

IV. Loss of Consortium

Because all other causes of action fail, Intuitive claims Jacques' loss of consortium claim must also fail. The Court agrees. *See In re Engle* Cases, 767 F.3d 1082, 1087 (11th Cir. 2014) (citing *Faulkner v. Allstate Ins. Co.*, 367 So. 2d 214, 217 (Fla. 1979)) ("[U]nder Florida law, a loss of consortium claim is derivative in nature and wholly dependent on [the injured party's] ability to recover[.]"); *see also Gomez v. Pfizer, Inc.*, 675 F. Supp. 2d 1159, 1164 (S.D. Fla. 2009) (citation omitted) (dismissing loss of consortium claim because it is a derivative action and wife did not have a viable claim). Notably, Plaintiffs do not address this argument in their Response.

CONCLUSION

For the foregoing reasons, the Court concludes that Intuitive is entitled to summary judgment on each of Plaintiffs' claims. Accordingly, it is hereby

ORDERED AND ADJUDGED that Defendant's Motion for Summary Judgment [ECF No. 60] is **GRANTED**. Pursuant to Rule 58 of the Federal Rules of Civil Procedure, a final judgment will be entered by separate order.

DONE AND ORDERED in Fort Lauderdale, Florida, this 6th day of March, 2020.

RODOLFO A. RUIZ II
UNITED STATES DISTRICT JUDGE