



**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF SOUTH CAROLINA
COLUMBIA DIVISION**

JACKIE JO NEDIMYER, LEO JOSHUA	§	
NEDIMYER, GLORIA WILSON, and	§	
TABITHA WILSON,	§	
Plaintiffs,	§	
	§	
vs.	§	CIVIL ACTION NO. 3:22-1454-MGL
	§	
COOPERSURGICAL, INC., FEMCARE, LTD,	§	
<i>UK Subsidiary of Utah Medical Products, Inc.</i> ,	§	
and UTAH MEDICAL PRODUCTS, INC.,	§	
Defendants.	§	

**MEMORANDUM OPINION AND ORDER
DENYING DEFENDANTS' MOTIONS TO DISMISS
FOR LACK OF PERSONAL JURISDICTION, IMPROPER VENUE,
AND FAILURE TO STATE A CLAIM,**

I. INTRODUCTION

Plaintiffs Jackie Jo Nedimyer (J. Nedimyer), Leo Joshua Nedimyer, Gloria Wilson (G. Wilson), and Tabitha Wilson (T. Wilson) (collectively, Plaintiffs) bring this products liability lawsuit against Defendants CooperSurgical, Inc. (CooperSurgical), Femcare, Ltd, UK Subsidiary of Utah Medical Products, Inc. (Femcare), and Utah Medical Products, Inc. (Utah Medical), (collectively, Defendants).

Plaintiffs bring claims against Defendants for (1) design defect; (2) manufacturing defect; (3) failure to warn; (4) strict liability; (5) negligence; (6) violation of the South Carolina Unfair

Trade Practices Act (SCUTPA); (7) gross negligence; and (8) punitive damages. The Court has diversity jurisdiction over the matter under 28 U.S.C. § 1332.

Pending before the Court are: Utah Medical's and Femcare's motions to dismiss for lack of personal jurisdiction, under Fed. R. Civ. P. 12(b)(2), Utah Medical's and Femcare's motions to dismiss for improper venue, in accordance with Fed. R. Civ. P. 12(b)(3); and Utah Medical's, Femcare's, and CooperSurgical's motions to dismiss for failure to state a claim, pursuant to Fed. R. Civ. P. 12(b)(6).

Having carefully considered the motions, the responses, the replies, the supplements, the record, and the applicable law, it is the judgment of this Court each of Defendants' motions to dismiss will be denied.

II. FACTUAL AND PROCEDURAL HISTORY

J. Nedimyer, G. Wilson and T. Wilson “were implanted with a female birth control device known as a Filshie Clip.” Amended Complaint ¶ 16. J. Nedimyer's procedure occurred in 2005, *id.* ¶ 60, and G. Wilson and T. Wilson underwent the procedure in 2012, *id.* ¶¶ 70 and 80.

“In short, this device is intended to cause bilateral occlusion (blockage) of the fallopian tubes by applying a clip onto the fallopian tubes which then anchors and elicits tissue growth, theoretically causing a closure of the tubes.” *Id.* ¶ 16. “However,” according to Plaintiffs, “in reality, the clips migrate from the tubes wreaking havoc on the female body.” *Id.* ¶ 66.

J. Nedimyer “had a hysterectomy in February 2021 during which the Filshie clips were found to have migrated and attached to [her] intestines.” *Id.* ¶ 68.

“In July 2021, during the course of exploratory surgery [on T. Wilson], the Filshie Clips were located. The clips were not where they were supposed to be – they had migrated.” *Id.* ¶ 86. She “has to live with continued pain[;] [and] . . . had to undergo surgery [to] remove the clips.” *Id.* ¶ 89.

“On July 10, 2021, during the course of exploratory surgery [on G. Wilson], the Filshie Clips were located. The[] clips were not where they were supposed to be – they had migrated.” *Id.* ¶ 75. She “had to undergo surgery to remove the migrated clips.” *Id.* ¶ 78.

“Femcare is the manufacturer of the Filshie Clip system and it . . . obtained [Food and Drug Administration (FDA)] approval for the sale of the Filshie Clips in the United States in 1996.” *Id.* ¶ 37. “During the times relevant to this litigation and until 2019, . . . CooperSurgical imported, distributed, marketed, and sold the Filshie Clip system in the United States.” *Id.* ¶ 38. “From 2019 to the present day, . . . Utah Medical exclusively imports, sells, distributes, and markets the Filshie Clips in the United States.” *Id.* ¶ 39. Utah Medical “is the parent company of Femcare[.]” *Id.* ¶ 40.

According to Plaintiffs, “Defendants’ failure to conform with the FDA requirements prescribed in the [Premarket Approval (PMA)] and violations of relevant state and federal law form the basis of this lawsuit.” *Id.* ¶ 21. Plaintiffs state “Filshie Clips pose significant health risk, and the product has subjected untold thousands of women to significant injuries. These injuries stem from the simple fact that Filshie Clips have a propensity to migrate after being placed on the fallopian tubes.” *Id.* ¶ 48.

Plaintiffs complain “[t]he migration of the clip often requires surgical intervention to remove the Filshie Clips from the woman’s body.” *Id.* ¶ 49. According to Plaintiffs, “[t]he design was approved by the FDA without the benefit of the knowledge that Filshie Clips had a greater than .13%

risk of migration. The incidence of migration is reported at 25%, a significant increase from the .13% currently reflected in the product information sheets.” *Id.* ¶ 107.

Plaintiffs maintain “Defendants failed to properly and adequately warn and instruct the Plaintiffs and their health care providers with regard to the inadequate research and testing of the Filshie Clips, and the complete lack of a safe, effective procedure for preventing migration.” *Id.*

¶ 130. “Rather, Defendants affirmatively advertised the safety of the Filshie Clip system vis a vis the alternative methods of bilateral tubal ligation, effectively downplaying even the deminimis risk of migration or expulsion reported to the FDA for approval of the device.” *Id.*

Plaintiffs seek general and special damages.

After Plaintiff filed their lawsuit, Defendants filed various motions to dismiss, after which the Court dismissed the motions and allowed for jurisdictional discovery. Thereafter, Plaintiffs filed an amended complaint, Defendants filed their amended motions to dismiss, Plaintiffs filed their responses in opposition to the motions, and Defendants filed their replies in support. The parties have also filed several supplements.

The Court, having been fully briefed on the relevant issues, is now prepared to adjudicate Defendants’ motions.

III. UTAH MEDICAL’S AND FEMCARE’S MOTIONS TO DISMISS FOR LACK OF PERSONAL JURISDICTION

A. Standard of Review

Before the Court considers Defendants’ other motions, it must decide whether it has personal jurisdiction over each of them. *See Zenith Radio Corp. v. Hazeltine Research, Inc.*, 395 U.S. 100,

110 (1969) (“The consistent constitutional rule has been that a court has no power to adjudicate a personal claim or obligation unless it has jurisdiction over the person of the defendant.”).

Upon a defendant’s motion to dismiss for lack of personal jurisdiction, the plaintiff has the burden of showing jurisdiction exists. *In re Celotex Corp.*, 124 F.3d 619, 628 (4th Cir. 1997). Generally speaking, when a district court decides a pre-trial motion to dismiss for lack of personal jurisdiction without holding an evidentiary hearing, the plaintiff need only make a prima facie showing of personal jurisdiction and the Court is to construe the pleadings, affidavits and other supporting documents presented to the court in the light most favorable to plaintiff by assuming credibility and drawing all inferences and resolving all factual disputes in the plaintiff’s favor. *Mylan Labs., Inc., v. Akzo, N.V.*, 2 F.3d 56, 60 (4th Cir. 1993). In doing so, however, the court need not “credit conclusory allegations or draw farfetched inferences.” *Ticketmaster–New York, Inc. v. Alioto*, 26 F.3d 201, 203 (1st Cir. 1994).

Personal jurisdiction over an out-of-state defendant may be either general or specific.. “[A] court may exercise personal jurisdiction under the theory of general jurisdiction, which requires a more demanding showing of ‘continuous and systematic’ activities in the forum state” than what is required to establish specific jurisdiction. *Tire Engineering and Distribution, LLC v. Shandong Linglong Rubber Co., Ltd.*, 682 F.3d 292, 301 (4th Cir. 2012). “With respect to a corporation, the place of incorporation and principal place of business are paradigm bases for general jurisdiction.” *Daimler AG v. Bauman*, 571 U.S. 117, 137 (2014) (internal quotation marks omitted) (internal alterations omitted).

On the other hand, as to specific jurisdiction, the Court must perform a two-step analysis. The Court must first determine whether the forum state—here, South Carolina—long-arm statute

provides a basis for asserting jurisdiction over the defendant. *Young v. FDIC*, 103 F.3d 1180, 1191 (4th Cir. 1997). Then, the Court must determine the exercise of personal jurisdiction does not violate the Due Process Clause of the Fourteenth Amendment of the United States Constitution. *Id.*

South Carolina's long-arm statute has been construed to extend to the outer limits allowed by the Due Process Clause. *Foster v. Arletty 3 Sarl*, 278 F.3d 409, 414 (4th Cir. 2002). Thus, the dual jurisdictional requirements collapse into a single inquiry as to whether the defendant has "certain minimum contacts" with the forum, such that "maintenance of the suit does not offend 'traditional notions of fair play and substantial justice.'" *Int'l Shoe Co. v. Washington*, 326 U.S. 310, 316 (1945) (internal citations omitted).

To evaluate the due process requirements for asserting personal jurisdiction, the Fourth Circuit has established a three-part test in which courts consider the following: "(1) the extent to which the defendant purposefully availed itself of the privilege of conducting activities in the State; (2) whether the plaintiffs' claims arise out of those activities directed at the State; and (3) whether the exercise of personal jurisdiction would be constitutionally reasonable." *Consulting Engineers Corp. v. Geometric Ltd.*, 561 F.3d 273, 278 (4th Cir. 2009) (citation omitted) (internal quotation marks omitted).

Courts must make a separate personal jurisdiction determination as to each defendant who raises the issue. *Rush v. Savchuk*, 444 U.S. 320, 332 (1980).

According to Plaintiffs, "[t]his Court has specific jurisdiction over . . . Defendants[.]" Amended Complaint ¶ 11. They fail to argue it has general jurisdiction. Thus, the Court will limit its discussion and analysis to the question of whether it has specific jurisdiction over Defendants.

B. Discussion and Analysis as to Utah Medical’s personal jurisdiction motion

1. Whether Utah Medical purposefully availed itself of the privilege of conducting activities in South Carolina

First, Plaintiffs must establish Utah Medical “purposefully availed itself of the privilege of conducting activities in” South Carolina. *Consulting Engineers Corp.*, 561 F.3d at 278.

Utah Medical argues “the record lacks any evidence at all that Utah Medical . . . purposefully availed itself of the privilege of conducting activities in South Carolina related to Filshie Clips when . . . Plaintiffs’ claims arose.” Utah Medical’s Memo in Support of its Motion at 7. According to Utah Medical, its CEO’s “[a]ffidavit specifically rebuts . . . Plaintiff’s allegations that Utah Medical sold or marketed Filshie Clips in South Carolina during the relevant time periods of 2005 and 2012[,]” *id.*, the dates the Filshie Clips were implanted into Plaintiffs.

Plaintiffs, however, state “Utah Medical purposefully availed itself of the privilege of conducting activities in South Carolina by currently marketing, selling, and distributing the Filshie Clip system in South Carolina, the very same product that is at issue in this litigation.” Plaintiff’s Response to Utah Medical’s Motion at 22.

“For a court to have specific personal jurisdiction over a defendant, the defendant must have purposefully established minimum contacts in the forum State such that it should reasonably anticipate being haled into court there.” *Perdue Foods LLC v. BRF S.A.*, 814 F.3d 185, 189 (4th Cir. 2016) (citation omitted) (internal quotation marks omitted) (internal alteration marks omitted).

Utah Medical admits “the fact that [it] acquired the United States distribution rights for Filshie Clips in 2019.” Utah Medical’s Memo in Support of its Motion to Dismiss at 9. Thus, it has had ongoing contacts with South Carolina since 2019, through its distribution and marketing of Filshie Clips. Utah Medical’s CEO’s Affidavit ¶¶ 8-9.

“[T]he discovery rule . . . allow[s] a claim to accrue when the litigant first knows or with due diligence should know facts that will form the basis for an action.” *Merck & Co., Inc. v. Reynolds*,

559 U.S. 633, 646 (2010) (citation omitted) (internal quotation marks omitted) (emphasis omitted). As such, as per the discovery rule, Plaintiffs' claims arose in 2021, when they realized the Filshie Clips had migrated into their bodies. Thus, their claims arose after Utah Medical's ongoing contacts with South Carolina commenced in 2019.

These post-2019 contacts with South Carolina, which entails distribution and marketing, are unquestionably relevant to Plaintiffs' post-2019 treatments, as well as their claims of negligence, gross negligence, and violation of SCUTPA. As is relates to Plaintiffs' negligence claim against Utah Medical, Plaintiffs complain it "breached [it] duty to exercise reasonable and prudent care in the . . . marketing, labeling, promotion, distribution and sale of the Filshie Clips[.]" Amended Complaint ¶ 158.

And, concerning Plaintiffs' SCUTPA claim, Plaintiffs allege Utah Medical, along with Cooper Surgical and Femcare, "have engaged in unfair competition or unfair or deceptive acts or trade practices or have made false representations in violation under the statute listed above to protect consumers against unfair, deceptive, fraudulent and unconscionable trade and business practices and false advertising, the Defendants are the suppliers, manufacturers, advertisers, and sellers, who are subject to liability under such legislation for unfair, deceptive, fraudulent and unconscionable consumer sales practices.." *Id.* ¶ 175.

According to Plaintiffs, Utah Medical was marketing the Filshie Clips as safe and effective when their claims of negligence, gross negligence, and violation of SCUTPA arose in 2021, even though the product was allegedly unsafe and ineffective.

In sum, Utah Medical, as the one with the nationwide distribution rights for Filshie Clips, and having marketed, sold, and distributed the Filshie Clips in South Carolina since 2019, has "purposefully established minimum contacts in [South Carolina] such that it should reasonably anticipate being haled into court [here]." *Perdue Foods LLC*, 814 F.3d at 189.

2. *Whether Plaintiffs' claims arise out of to Utah Medical's contacts with South Carolina*

Second, Plaintiffs must show their claims “arise out of [Utah Medical’s] activities directed at” South Carolina. *Consulting Engineers Corp.*, 561 F.3d at 278.

As the Court noted already, Utah Medical gained the nationwide distribution rights to the Filshie Clips in 2019. That is fourteen years after Nedimyer’s implantation procedure, and seven years after G. and T. Wilson’s procedures. Consequently, according to Utah Medical, Plaintiffs are unable to show their claims arise out of Utah Medical’s contacts with South Carolina.

Plaintiffs, however, cite to Utah Medical’s ongoing contacts with South Carolina by way of its marketing of Filshie Clips here. According to Plaintiffs, Utah Medical “markets the Filshie Clips as a safe and effective product and when it fails to comply with federal regulations to report adverse events to the FDA – currently and during the time when Plaintiff was suffering from the effects of the migration but had not discovered the source of their injuries.” Plaintiffs’ Response at 24.

It is indisputable Plaintiffs’ claims of negligence, gross negligence, and violation of the SCUTPA, and perhaps others, “arise out of [Utah Medical’s] activities directed at” South Carolina. *Consulting Engineers Corp.*, 561 F.3d at 278. Again, Utah Medical was marketing the Filshie Clips as safe and effective when, according to Plaintiffs, there was evidence to the contrary. And, Utah Medical’s South Carolina contacts occurred before Plaintiffs discovered their injuries allegedly caused by the Filshie Clips.

As such, Utah Medical’s contacts with South Carolina after it obtained the nationwide distribution rights to the Filshie Clips in 2019 are relevant to some of Plaintiffs’ claims. Thus, Plaintiffs have satisfied the “arise out of” requirement to establish jurisdiction over Utah Medical.

3. *Whether the exercise of personal jurisdiction over Utah Medical is constitutionally reasonable*

Third, the Court must determine “whether the exercise of personal jurisdiction [over Utah Medical] would be constitutionally reasonable.” *Consulting Engineers Corp.*, 561 F.3d at 278. “[W]here a defendant who purposefully has directed his activities at forum residents seeks to defeat jurisdiction, [it] must present a compelling case that the presence of some other considerations would render jurisdiction unreasonable.” *Burger King Corp. v. Rudzewicz*, 471 U.S. 462, 477 (1985).

When deciding whether the exercise of jurisdiction is constitutionally reasonable, the Court evaluates the following: “[1] the burden on the defendant, [2] the forum State’s interest in adjudicating the dispute, [3] the plaintiff’s interest in obtaining convenient and effective relief, [4] the interstate judicial system’s interest in obtaining the most efficient resolution of controversies, and [5] the shared interest of the several States in furthering fundamental substantive social policies.” *Christian Science Bd. of Dirs. of the First Church of Christ, Scientist v. Nolan*, 259 F.3d 209, 217 (4th Cir. 2001) (quoting *Burger King*, 471 U.S. at 477).

Utah Medical first states “defending a lawsuit in a venue where it does not employ anyone or maintain any place of business would be extremely burdensome to [it] and result in undue hardship.” Utah Medical’s Memo in Support of its Motion at 10. Second, Utah Medical contends, “without a nexus between . . . Plaintiffs’ claims and the alleged South Carolina activities of [Utah Medical], exercise of jurisdiction would not be constitutionally reasonable.” *Id.*

The first statement concerning undue hardship is conclusory, with no argument offered to support it. And, the Court rejected this second statement regarding the relationship between Plaintiffs’ claims and Utah Medical’s contacts above.

Considering the five *Nolan* factors listed above, first, Utah Medical has failed to show how it would be burdened by litigating this case in South Carolina. The Court notes Defendants are all represented by the same attorneys, who are both located here in South Carolina. Second, South

Carolina has a strong interest in protecting its citizens from harm and discouraging future violations of its laws.

Third, Plaintiffs are entitled to obtaining convenient relief in a common, accessible forum. Fourth, there is certainly an interstate interest in obtaining efficient resolution in a single forum, and Defendants have failed to establish litigating this case in South Carolina is contrary to the interests of judicial economy. Fifth and finally, South Carolina shares the interest with other states to provide a forum for efficiently litigating Plaintiffs' cause of action to further fundamental substantive social policies.

Accordingly, Utah Medical has failed to show how this Court exercising jurisdiction over it is constitutionally unreasonable such that it would "offend 'traditional notions of fair play and substantial justice.'" *Int'l Shoe Co.*, 326 U.S. at 316 (quoting *Milliken v. Meyer*, 311 U.S. 457, 463 (1940)).

To recap, Utah Medical is currently doing business in South Carolina, and was doing business in South Carolina when Plaintiff's above-mentioned claims arose. In its sharing information about the Filshie Clips purported safety and effectiveness, Utah Medical has purposefully availed itself of the privileges of doing business in South Carolina. And Utah Medical's contacts relate to some of Plaintiffs' claims, which concern allegedly misleading promotions about Filshie Clips' safety and effectiveness.

In addition, Utah Medical has failed to establish the Court's exercise of personal jurisdiction over it is constitutionally reasonable. Therefore, for all these reasons, the Court concludes it has personal jurisdiction over Utah Medical. Therefore, it will deny Utah Medical's Rule 12(b)(2) motion to dismiss for lack of personal jurisdiction.

C. Discussion and Analysis as to Femcare's personal jurisdiction motion

1. Whether Femcare purposely availed itself of the privilege of conducting activities in South Carolina

First, Plaintiffs must demonstrate Femcare “purposefully availed itself of the privilege of conducting activities in” South Carolina. *Consulting Engineers Corp.*, 561 F.3d at 278.

Femcare “is a resident and citizen of the United Kingdom.” Femcare’s Memo in Support of its Motion at 6. “Femcare manufactures the Filshie Clip in the United Kingdom.” *Id.*

According to Femcare, it “conducts absolutely no business in South Carolina [and] . . . has never distributed the Filshie Clip in the United States, much less in South Carolina.” *Id.* (footnotes omitted). Femcare states it “did not design, research, conduct safety surveillance, develop, manufacture, test, label, package, distribute, market, or sell Filshie Clips in the State of South Carolina.” *Id.* (citation omitted) (internal quotation marks omitted) (footnotes omitted).

Femcare further maintains it:

- Does not conduct any business in South Carolina;
- Does not employ any individuals in South Carolina;
- Does not own any property in South Carolina;
- Does not own or operate any facilities in South Carolina;
- Does not maintain any place of business in South Carolina;
- Does not advertise in South Carolina; and
- Does not, and has not, directed the distribution of Filshie Clips in South Carolina.

Id. 6-7. As such, Femcare contends “[t]he record lacks any evidence suggesting [it] had purposeful Filshie Clip related contact with South Carolina when the Plaintiffs’ claims arose.” *Id.* at 7.

In response, Plaintiffs maintain “Femcare entered into an exclusive distribution agreement with defendant CooperSurgical, . . . then with its parent company, . . . Utah Medical . . . in 2019, both who exclusively sold the Filshie Clips in the U.S. stream of commerce.” Plaintiffs’ Response to Femcare’s Motion at 22 (citation omitted).

“Additionally,” according to Plaintiffs, “Femcare has access to its distributors’ information regarding which U.S. states, and even which facilities, its Filshie Clips are sold. In fact, Femcare is legally required to trace the users of its product and is currently able to locate every Filshie Clip it has ever sold in the United States.” *Id.* at 23 (footnote omitted).

Further, Plaintiffs maintain

(1) Femcare’s products were implanted in women in South Carolina; (2) Femcare was fully aware that its products were being sold and used in South Carolina; (3) Femcare did not take any actions to prevent its products from reaching South Carolina; (4) Femcare profited from the Filshie Clips sold in South Carolina; (5) Femcare continues to sell the Filshie Clips in South Carolina to this day; and (6) Femcare was and still is responsible to ensure that the Filshie Clips sold in South Carolina adhered to FDA safety guidelines and regulations.

Plaintiffs’ Response to Femcare’s Motion at 25.

“The placement of a product into the stream of commerce, without more, is not an act of the defendant purposefully directed toward the forum State.” *Asahi Metal Industry Co., Ltd. v. Superior Court of California, Solano Cnty.*, 480 U.S. 102, 112 (1987). “Additional conduct of the defendant may indicate an intent or purpose to serve the market in the forum State, for example, . . . marketing the product through a distributor who has agreed to serve as the sales agent in the forum State.” *Id.* “But a defendant’s awareness that the stream of commerce may or will sweep the product into the forum State does not convert the mere act of placing the product into the stream into an act purposefully directed toward the forum State.” *Id.*

“When a corporation purposefully avails itself of the privilege of conducting activities within the forum State, it has clear notice that it is subject to suit there[.]” *Id.* at 110 (citation omitted) (internal quotation marks omitted).

There can be no reasonable dispute as to whether Femcare purposely availed itself of the privilege of conducting activities in South Carolina. Femcare is alleged to manufacture and knowingly distribute Filshie Clips to residents of South Carolina by way of its exclusive distribution agreement with Utah Medical, who exclusively sells Filshie Clips throughout the United States without limitation, including the state of South Carolina. Thus, as the *Asahi Metal Industry Co., Ltd.* court put it, Femcare “market[ed] the product through a distributor who has agreed to serve as the

sales agent in” South Carolina. *Id.* at 112. And, three of these Filshie Clips were implanted into three of the plaintiffs in this matter: J. Nedimyer, G. Wilson, and T. Wilson.

Accordingly, the Court is unable to conclude Femcare’s contacts with South Carolina were random, fortuitous, or the result of a third party’s unilateral activity. *See Walden v. Fiore*, 571 U.S. 277, 286 (2014) (holding, in the context of intentional torts, it is insufficient to rely on a defendant’s random, fortuitous, or attenuated contacts or on the unilateral activity of a plaintiff to establish personal jurisdiction over a defendant. “A forum State’s exercise of jurisdiction over an out-of-state intentional tortfeasor must be based on intentional conduct by the defendant that creates the necessary contacts with the forum.”).

Instead, Femcare’s contacts with South Carolina are the result of Femcare’s decision to sell its Filshie Clips throughout the United States, including South Carolina, through its distributors: first, CooperSurgical and now, Utah Medical. A manufacturer such as Femcare should be able to reasonably expect its medical device, Filshie Clips, would be sold in South Carolina when it entered into its exclusive distribution agreements with CooperSurgical and Utah Medical for the purpose of distributing its Filshie Clips throughout the United States. Those agreements failed to exclude South Carolina from the territories where its Filshie Clips would be sold.

Therefore, the Court concludes Plaintiffs have established Femcare purposely availed itself of the privilege of conducting activities in South Carolina.

2. *Whether Plaintiffs’ claims arise out of to Femcare’s contacts with South Carolina*

Second, Plaintiffs must establish their claims “arise out of [Femcare’s] activities directed at” South Carolina. *Consulting Engineers Corp.*, 561 F.3d at 278.

Femcare insists it “did not design, manufacture, distribute or sell Filshie Clips in South Carolina, and did not create any other contacts in the State. Any distribution in South Carolina by third party CooperSurgical does not fit the requirement that the relationship must arise out of

contacts that the defendant [itself] creates with the forum State.” Femcare’s Memo in Support of its Motion to Dismiss at 7 (citation omitted) (internal quotation marks omitted).

Plaintiffs maintain, however, that “Femcare has sufficient minimum contacts in South Carolina and is, therefore, subject to personal jurisdiction of this Court as [their claims] arise[] out of injuries from a product Femcare manufactured and knowingly had distributed to the residents of South Carolina.” Plaintiffs’ Response to Femcare’s Motion at 22.

“[I]f the sale of a product of a manufacturer or distributor . . . is not simply an isolated occurrence, but arises from the efforts of the manufacturer or distributor to serve directly or indirectly, the market for its product in other States, it is not unreasonable to subject it to suit in one of those States if its allegedly defective merchandise has there been the source of injury to its owner or to others.” *World-Wide Volkswagen Corp. v. Woodson*, 444 U.S. 286, 297 (1980) “The forum State does not exceed its powers under the Due Process Clause if it asserts personal jurisdiction over a corporation that delivers its products into the stream of commerce with the expectation that they will be purchased by consumers in the forum State.” *Id.* at 297-98.

Citing to this precedent, the Federal Circuit held the Virginia district court had personal jurisdiction over two foreign defendant manufacturers where “the accused [infringing device] arrived in Virginia through defendants’ purposeful shipment . . . through an established distribution channel.” *Beverly Hills Fan Co. v. Royal Sovereign Corp.*, 21 F.3d 1558, 1565 (Fed. Cir. 1994) (citing *World-Wide Volkswagen Corp.*, 444 U.S. at 297).

The Court is presented with the same fact pattern here. The Filshie Clips “arrived in [South Carolina] through [Femcare’s] purposeful shipment . . . through an established distribution channel.” *Id.* And, there is no dispute the Filshie Clips allegedly caused Plaintiffs’ purported injuries. Therefore, in light of the case law above, the Court easily concludes Plaintiffs’ claims arise out of to Femcare’s contacts with South Carolina.

3. ***Whether the exercise of personal jurisdiction over Femcare is constitutionally reasonable***

Third, the Court must decide “whether the exercise of personal jurisdiction [over Femcare] would be constitutionally reasonable.” *Consulting Engineers Corp.*, 561 F.3d at 278.

Femcare makes the same argument as to this requirement that Utah Medical made: “defending a lawsuit in a venue (and country) where it does not employ anyone or maintain any place of business would be extremely burdensome to Femcare and result in significant undue hardship.” Femcare’s Memo in Support of its Motion at 10. And, “without a nexus between . . . Plaintiffs’ claims and the alleged South Carolina activities of Femcare, exercise of jurisdiction would not be constitutionally reasonable” *Id.*

As before, the first statement concerning undue hardship is conclusory, with no argument offered to support it. And, the Court has already rejected this second statement regarding the relationship between Plaintiffs’ claims and Femcare’s contacts above. Further, the Court’s consideration of the five *Nolan* factors in the same here as it was for Utah Medical. Thus, it will refrain from repeating the discussion a second time here.

Consequently, Femcare has neglected to establish how this Court exercising jurisdiction over it is constitutionally unreasonable such that it would “offend ‘traditional notions of fair play and substantial justice.’” *Int’l Shoe Co.* 326 U.S. at 316 (quoting *Milliken*, 311 U.S. at 463).

In sum, Femcare is subject to this Court’s jurisdiction. It has purposefully availed itself of the privilege of conducting activities within South Carolina. It placed its product, the Filshie Clips, in the stream of commerce with the intent it reach the state of South Carolina; and it continues to conduct substantial business in South Carolina.

Further, Plaintiffs' claims arise out of Femcare's contacts with South Carolina. And, Femcare is unable to show the Court's exercise of personal jurisdiction over it would be constitutionally unreasonable. Accordingly, Femcare is subject to this Court's jurisdiction.

IV. UTAH MEDICAL'S AND FEMCARE'S MOTIONS TO DISMISS FOR IMPROPER VENUE

A. Standard of Review

Where grounds for a motion to dismiss include lack of personal jurisdiction, improper venue, and failure to state a claim upon which relief could be granted, the Court should have pass on jurisdiction and venue issues, in that order, before considering whether Plaintiffs stated a claim. *Arrowsmith v. United Press Intern.*, 320 F.2d 219, 221 (2nd Cir. 1963).

"A plaintiff is obliged . . . to make only a prima facie showing of proper venue . . . to survive a motion to dismiss." *Aggarao v. MOL Ship Mgmt. Co., Ltd.*, 675 F.3d 355, 366 (4th Cir.2012) (citation omitted). "In assessing whether there has been a prima facie venue showing, [the Court will] view the facts in the light most favorable to the plaintiff." *Id.*

"This question—whether venue is 'wrong' or 'improper'—is generally governed by 28 U.S.C. § 1391." *Atlantic Marine Const. Co., Inc. v. U.S. Dist. Court for Western Dist. of Texas*, 571 U.S. 49, 55 (2013). As per that statute, "[e]xcept as otherwise provided by law . . . this section shall govern the venue of all civil actions brought in district courts of the United States." § 1391(a)(1).

"When venue is challenged, the [C]ourt must determine whether the case falls within one of the three categories set out in § 1391(b). If it does, venue is proper; if it does not, venue is improper, and the case must be dismissed or transferred under § 1406(a)." *Atlantic Marine Const. Co., Inc.*, 571 U.S. at 56.

As per § 1391(b), "[a] civil action may be brought in—(1) a judicial district in which any defendant resides, if all defendants are residents of the State in which the district is located; (2) a judicial district in which a substantial part of the events or omissions giving rise to the claim

occurred, or a substantial part of property that is the subject of the action is situated; or (3) if there is no district in which an action may otherwise be brought as provided in this section, any judicial district in which any defendant is subject to the court's personal jurisdiction with respect to such action.”

B. Discussion and Analysis as to Utah Medical's and Femcare's improper venue motions

Both Utah Medical and Femcare argue they “do[] not reside in this district. Further, no events or omissions giving rise to any claim against [them] occurred in this district. Therefore, venue is improper in this Court[.]” Utah Medical's Memo in Support of its Motion to Dismiss at 31; and Femcare's Memo in Support of its Motion to Dismiss at 26.

In response, Plaintiffs state “[i]f this Court were to find that it has jurisdiction over Defendant[s], then venue is proper under 28 U.S.C. § 1391.” Plaintiffs' Response to Utah Medical's Motion at 35 n.62; and Plaintiffs' Response to Femcare's Motion at 31 n.41.

As the Court has held above, “a substantial part of the events or omissions giving rise to [Plaintiffs'] claim[s] occurred” in South Carolina, § 1391(b)(2). Therefore, inasmuch as “the case falls within one of the three categories set out in § 1391(b)[,],” *Atlantic Marine Const. Co., Inc.*, 571 U.S. at 56, “venue is proper[.]” *Id.*

Consequently, the Court will decline to grant Utah Medical's and Femcare's motions to dismiss for improper venue. Nevertheless, the Court will entertain a motion for change of venue, in accordance with 28 U.S.C. § 1404, if any of the parties wish to file one.

V. UTAH MEDICAL'S, FEMCARE'S, AND COOPERSURGICAL'S MOTIONS TO DISMISS FOR FAILURE TO STATE A CLAIM

A. Standard of Review.

“The purpose of a Rule 12(b)(6) motion is to test the sufficiency of a complaint.” *Edwards v. City of Goldsboro*, 178 F.3d 231, 243 (4th Cir. 1999). When considering a motion to dismiss for

failure to state a claim, a plaintiff's well-pled allegations are taken as true, and the complaint and all reasonable inferences are liberally construed in the plaintiff's favor. *Mylan Laboratories, Inc. v. Matkari*, 7 F.3d 1130, 1134 (4th Cir.1993).

The Court may consider only the facts alleged in the complaint, which may include any documents either attached to or incorporated in the complaint, and matters of which the court may take judicial notice. *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 322 (2007). Although the Court must accept the plaintiff's factual allegations as true, any conclusory allegations are not entitled to an assumption of truth, and even those allegations pled with factual support need only be accepted to the extent "they plausibly give rise to an entitlement to relief." *Ashcroft v. Iqbal*, 556 U.S. 662, 679 (2009).

The Court need not accept unsupported legal allegations, *Revene v. Charles Cnty. Comm'rs*, 882 F.2d 870, 873 (4th Cir.1989), legal conclusions couched as factual allegations, *Papasan v. Allain*, 478 U.S. 265, 286 (1986), or conclusory factual allegations devoid of any reference to specific acts, dates, or policies, *United Black Firefighters v. Hirst*, 604 F.2d 844, 847 (4th Cir 1979).

In sum, factual allegations must be enough to raise a right to relief above the speculative level, on the assumption all the allegations in the complaint are true (even if doubtful in fact). *Bell Atlantic Corporation v. Twombly*, 550 U.S. 544, 555 (2007).

B. Discussion and Analysis as to Defendants' failure-to-state-a-claim motions

Defendants all make the same argument in their motion to dismiss for failure to state a claim: "[a]ll . . . Plaintiffs' claims are preempted, both because Plaintiffs contend the product should have been designed and labeled in a manner that is different from that approved by the FDA (express preemption) and because their claims all rely on the alleged failure to provide accurate information to the FDA (implied preemption)." Utah Medical's Memo in Support of its Motion to Dismiss at

15; Femcare's Memo in Support of its Motion to Dismiss at 10-11; and CooperSurgical's Memo in Support of its Motion to Dismiss at 15-16.

Defendants also all contend the learned intermediary doctrine bars Plaintiffs' claims. Utah Medical's Memo in Support of its Motion to Dismiss at 28-29; Femcare's Memo in Support of its Motion to Dismiss at 23-24; and CooperSurgical's Memo in Support of its Motion to Dismiss at 14-15.

Plaintiffs, unsurprisingly, disagree.

The Court concurs with those other courts holding it best to decide the preemption question after discovery. *See eg., Shook v. Boston Scientific Corp.*, No. 1:20-cv-242-MOC-WCM, 2021 WL 1093637, at *3 (W.D.N.C. May 22, 2021) ("The Court has determined that, in light of the lenient pleading standards of *Iqbal* and *Twombly*, the Court will deny the motion to dismiss and allow the parties to proceed with discovery. In so holding, the Court makes no determination on federal preemption at this time. Rather, the Court has determined that Plaintiff has merely sufficiently pleaded enough facts to overcome a motion to dismiss as to the preemption issue.").

Concerning the learned intermediary doctrine, "[u]nder this doctrine, the manufacturer's duty to warn extends only to the prescribing physician, who then assumes responsibility for advising the individual patient of risks associated with the drug or device." *Odom v. G.D. Searle & Co.*, 979 F.2d 1001, 1003 (4th Cir. 1992). As per the doctrine, "the burden remains on the plaintiff to demonstrate the additional non-disclosed risk was sufficiently high that it would have changed the treating physician's decision to prescribe the product for the plaintiff." *Id.*

Discovery is necessary for Plaintiffs to attempt to meet this burden. As such, it would be inappropriate for the Court to decide the learned intermediation issue at this stage.

Accordingly, the Court will deny Defendants' motion to dismiss for failure to state a claim.

VI. CONCLUSION

Based on the foregoing discussion and analysis, it is the judgment of the Court Utah Medical's and Femcare's motions to dismiss for lack of personal jurisdiction are **DENIED**; Utah Medical's and Femcare's motions to dismiss for improper venue are **DENIED**; and Utah Medical's, Femcare's, and CooperSurgical's motions to dismiss for failure to state a claim are **DENIED**.

The Court disfavors footnotes. *See* <https://scholarship.law.missouri.edu/cgi/viewcontent.cgi?article=1905&context=facpubs> (last accessed August 30, 2023) (“Justice Stephen G. Breyer has sworn off footnotes in his opinions because judges write ‘to explain as clearly as possible and as simply as possible . . . the reasons’ for the decision. ‘[E]ither a point is sufficiently significant to make, in which case it should be in the text,’ says Justice Breyer, ‘or it is not, in which case, don’t make it.’”))

And, in regards to citations in footnotes, as Judge Richard A. Posner correctly stated, “[t]he obvious objection to [putting citations in] footnotes is that they force the reader to interrupt the reading of the text with glances down to the bottom of the page.” <https://digitalcommons.unl.edu/cgi/viewcontent.cgi?article=1193&context=ajacourtreview> (last accessed on August 30, 2023). Therefore, going forward, the Court requires citations appear in the body of the parties’ submissions, not in footnotes.

Not later than September 14, 2023, the parties shall confer and then draft and submit to the Court a proposed consent scheduling order.

IT IS SO ORDERED.

Signed this 7th day of September, 2023, in Columbia, South Carolina.

/s/ Mary Geiger Lewis
MARY GEIGER LEWIS
UNITED STATES DISTRICT JUDGE