STATE OF SOUTH CAROLINA	)	
	)	IN THE COURT OF COMMON PLEAS
COUNTY OF CHARLESTON	)	NINTH JUDICIAL CIRCUIT
Emilio Correa and Yunny Correa,	)	Civil Action No. 2010-CP-10-9467
Plaintiffs,	)	
vs.	)	ORDER GRANTING DEFENDANT ETHICON ENDO-SURGERY, INC.'S MOTION FOR SUMMARY JUDGMENT
Bon Secours-St. Francis Xavier Hospital, Inc., Dr. Samuel Hazell, Ashley River Surgical Associates, and Ethicon Endo-Surgery, Inc.,	)	
Defendants.	)	

This matter came before the Court on Ethicon Endo-Surgery, Inc's ("Ethicon") Motion for Summary Judgment. A hearing was held on the Motion on April 3, 2013, at 10:00 a.m. and was attended by all counsel of record. After a review of the briefing, consideration of the matters that have been filed in the case, and hearing arguments from counsel, Ethicon's Motion is **GRANTED**:

FINDINGS OF FACT

Ethicon manufactures and sells surgical endocutters that can be used in multiple open or minimally invasive surgical procedures, including laparoscopic appendectomies. Endopath ETS45 Instructions for Use, Correa_EES_00028-43, at 32. The ATS45 Articulating Endocutter at issue in this case is designed as a sterile, single-patient-use instrument that is equipped with a surgical knife that cuts tissue while separately loaded staples simultaneously close the incision. *Id.* at 00032.

Ethicon's endocutters are packaged with Instructions for Use ("Instructions") that include the following warning beside the bolded word "**Caution**": Always ensure that a cartridge is

loaded before firing the instrument. If the instrument is fired without a cartridge, the instrument . . . will cut tissue without applying staples, preventing proper closure of the incision." Instructions, Correa_EES_00028-43, at 34. The Instructions include an identical warning under the bolded section "**Warnings and Precautions**." *Id.* at Correa_EES_0037. The endocutter's Instructions also provide step-by-step instructions in pictures and in words, demonstrating the steps necessary to prepare the endocutter for use during surgery. The steps are (1) remove the instrument from the package, (2) remove the reload from the package, (3) examine the reload, (4) ensure that the endocutter is in the open position, and (5) insert the new reload. *Id.* at Correa_EES_0029, 0035. Bon Secours-St. Francis Xavier Hospital, Inc. ("St. Francis") receives Ethicon endocutters in a cardboard box that contains three endocutters and a copy of the product's Instructions for Use. Anne Buck Dep. Tr., 54:3-10. Thus, every time that St. Francis purchases Ethicon endocutters, it receives Instructions for Use concerning the endocutter.

St. Francis administers a Value Analysis Program, which is a formal process by which they sought the clinically driven input of physicians, operating room personnel, and Carolinas Healthcare System concerning every product that the hospital purchased, including Ethicon's endocutter. Ferguson Dep. Tr., 14:17 to 15:17. In early 2008, when Ethicon began packaging its endocutter without a staple cartridge instead of being packaged preloaded with a staple cartridge, Ethicon's representative met with St. Francis' Materials Management department to inform the hospital about the change, coordinated with the head of staff education at St. Francis to set up an in-service training session to train the hospital employees concerning the change, and conducted the in-service before Mr. Correa's May 2008 surgery. *Id.* at 23:11-19. Neither of the operating room personnel who prepared the endocutter for use during Mr. Correa's surgery, however,

attended the in-service because they were on medical leave. Backus Dep. Tr., 56:12 to 20; Elia Dep. Tr., 62:25 to 63:6.

At 6:41 p.m. on May 29, 2008, Plaintiff Emilio Correa presented to St. Francis' Emergency Room with abdominal pain. Emilio Correa's Medical Records ("Med. Recs."), BonSecours_00019-25. Upon a CT Scan, he was diagnosed with acute appendicitis and the on-call surgeon, Defendant Dr. Samuel Hazell, was paged at 8:50 p.m. *Id.* At 9:30 p.m., Dr. Hazell called St. Francis and requested that the patient be consented for a laparoscopic appendectomy. *Id.* At 10:00 p.m., Mr. Correa was transported to St. Francis' operating room in stable condition, and the surgery began at 10:24 p.m. *Id.* at BonSecours_00019-25, 00386. Although the procedure took place at night, the operating room staff undertook all of the steps that they take for any scheduled surgery and that they had no difficulty seeing during the surgery. Backus Dep. Tr., 40:17 to 41:13; 43:15-24; Elia Dep. Tr., 31:1-5; 32:25 to 33:3; Hazell Dep. Tr., 189:10 to 190:19; 283:2 to 284:2.

When Dr. Hazell called for the endocutter, the surgical scrub who prepared the endocutter for use during surgery, did not inspect or prepare the endocutter before handing the instrument to Dr. Hazell. Backus Dep. Tr., 45:6 to 47:8. If the surgical scrub had paid attention to the jaws of the endocutter before handing the device to Dr. Hazell, she would have seen that there was no cartridge loaded. *Id.* at 47:19-25. Additionally, the surgical scrub never read the Instructions, and St. Francis did not make the Instructions available for operating room staff during surgery. Backus Dep. Tr., 66:8-10, 18-25. If the surgical scrub had followed the preparatory steps detailed in the endocutter's Instructions, then Mr. Correa's adverse event never would have occurred. Backus Dep. Tr., 69:22 to 70:1.

Moreover, when Dr. Hazell received the endocutter during Mr. Correa's surgery, he did not double check to ensure that the device was ready to use. Dr. Hazell Dep. Tr., 215:8-15. Even after Mr. Correa's adverse event, Dr. Hazell still does not check the instruments that he call for during surgery. Hazell Dep. Tr., 255:2-6.

Once the endocutter was inserted into Mr. Correa through the surgical trocar, Dr. Hazell cut the appendix. Because no cartridge was loaded in the endocutter, the device did not staple the incision, and stool began leaking from the incision inside Mr. Correa. *Id.* at 238:3-6. Dr. Hazell handed the endocutter back to the surgical scrub who discovered that the endocutter was not loaded with a staple cartridge. Backus Dep. Tr., 49:23 to 50:8. Dr. Hazell then converted the procedure to "open," making an incision through Mr. Correa's right lower quadrant to stop the leaking stool. Dr. Hazell Dep. Tr., 238:3-11. Mr. Correa's abdomen was cleaned, the incisions were closed, and Mr. Correa was taken to the Recovery Room. Med. Recs., BonSecours 00031-32.

SUMMARY JUDGMENT STANDARD

The South Carolina Supreme Court has found that a motion for summary judgment shall be granted where "there is no *genuine* issue as to any *material* fact . . . ." *George v. Fabri*, 345 S.C. 440, 452, 548 S.E.2d 868, 874 (2001) (emphasis in original). Summary judgment is designed to expedite disposition of cases that do not require the services of a fact finder when viewing the facts in the light most favorable to the non-moving party. *Id.* Upon a motion for summary judgment, the moving party has the initial burden of demonstrating the absence of a genuine issue of material fact. *Ellis v. Davidson*, 358 S.C. 509, 518, 595 S.E.2d 817, 821 (Ct. App. 2004). Where the nonmoving party has the burden of proof, this initial responsibility may be discharged by pointing out to the trial court that there is an absence of evidence to support the

nonmoving party's case. *Lanham v. Blue Cross & Blue Shield of S.C., Inc.*, 349 S.C. 356, 361-62, 563 S.E.2d 331, 363 (2002). Once the party moving for summary judgment meets this initial burden, the opponent cannot simply rest on mere allegations or denials contained in the pleadings. *Ellis*, at 518, 595 S.E.2d at 821. Rather, the nonmoving party must come forward with specific facts showing there is a genuine issue for trial. *Id.* at 518-19, 595 S.E.2d at 821. Moreover, such the Court is limited to consideration of "such facts as would be admissible in evidence." Rule 56(e), SCRCP; *Hall v. Fedor*, 349 S.C. 169, 175, 561 S.E.2d 654, 657 (Ct. App. 2002) ("Our appellate courts have interpreted Rule 56(e) to mean materials used to support or refute a motion for summary judgment must be those which would be admissible in evidence"). Arguments of counsel are not evidence and do not provide a factual basis for consideration upon summary judgment. *Trivelas v. South Carolina Dept. of Transp.* 348 S.C. 125, 141, 558 S.E.2d 271, 279 (Ct. App. 2001) (Howard, J., concurring in result only) (citing Rule 56(e), SCRCP).

CONCLUSIONS OF LAW

A. S.C. Code Ann. § 15-73-30, Which Legislatively Adopts Comment k of Section 402A of the Restatement (Second) of Torts, Bars Plaintiffs Strict Liability Claims and Converts Them into a Negligent Warning Claim

Comment k of Section 402A of the Restatement (Second) of Torts, legislatively adopted in South Carolina, bars strict liability claims involving "unavoidably unsafe" products. S.C. Code Ann. § 15-73-30; *Madison v. Am. Home Prods. Corp.*, 358 S.C. 449, 455 n.3, 595 S.E.2d 493, 496 n.2 (2004). As explained by the Fourth Circuit, "products, particularly ethical drugs and medical devices, often cause unwanted side effects despite the fact that they have been carefully designed and properly manufactured. In section 402A terminology, such products are deemed 'unavoidably unsafe' but are not defective or unreasonably dangerous if they are marketed with proper directions for use or include adequate warnings of potential side effects." *Brooks v. Medtronic, Inc.*, 750 F.2d 1227, 1230-31 (4th Cir. 1984). As such, South Carolina law precludes

strict liability claims in a case concerning unavoidably unsafe medical devices, and converts any such claims into a negligence inquiry as to whether the warning that accompanied the product was adequate. *See id.*; *Madison v. Am. Home Prods. Corp.*, 358 S.C. 449, 455 n.3, 595 S.E.2d 493, 496 n.3 (2004).

The Fourth Circuit applying South Carolina law and courts from around the country have applied the unavoidably unsafe doctrine in a variety of medical contexts including prescription drugs, implantable medical devices, surgical tools, hospital equipment, and hand-held medical devices. *See, e.g., Brooks v. Medtronic, Inc.*, 750 F.2d 1227, 1230-31 (4th Cir. 1984) (applying South Carolina law and the unavoidably unsafe doctrine to a cardiac pacemaker); *Esposito v. I-Flow Corp.*, No. 10-cv-3883, 2011 WL 5041374 (E.D. Pa. Oct. 24, 2011) (dismissing strict liability design defect claim, finding that a hand-held medical device that delivers pain medicine intravenously was unavoidably unsafe); *Rodriguez v. Stryker Corp.*, No. 2:08-0124, 2011 WL 31462 (M.D. Tenn. Jan. 5, 2011) (same); *Geesey v. Stryker Corp.*, No. 09-2988, 2010 WL 3069630 (E.D. Pa. Aug. 4, 2010) (same); *Parkinson v. Guidant Corp.*, 315 F. Supp. 2d 741 (W.D. Pa. 2004) (finding that a guidewire, which is a surgical tool used during an angioplasty, was unavoidably unsafe and granting summary judgment as to the plaintiffs' strict liability design defect claim); *Greenberg v. Michael Reese Hospital*, 415 N.E.2d 390, 394-95 (Ill. 1980) (finding x-ray machines unavoidably unsafe and barring strict liability claims); *Racer v. Utterman*, 629 S.W.2d 387, 395 (Mo. App. 1981) (finding that a surgical drape was unavoidably unsafe and barring strict liability claim). Courts have even found that non-medical products, like commercial dry-cleaning solvent and asbestos are unavoidably unsafe. *See, e.g., Moran v. Johns-Manville Sales Corp.*, 691 F.2d 811, 814 (6th Cir. 1982) (noting that asbestos insulation is unavoidably unsafe); *Purvis v. PPG Industries, Inc.*, 502 So.2d 714 (Ala. 1987) (finding that a

commercial dry cleaning solvent was unavoidably unsafe and affirming summary judgment as to strict liability design defect claim).

The issue before the Court is whether Ethicon's endocutter is unavoidably unsafe, not whether every medical device in the country is categorically unavoidably unsafe. The Court finds that the endocutter is unavoidably unsafe because the device is equipped with a knife that is designed and intended to *cut human tissue* during surgery. Knives cannot be made safe, and therefore the endocutter is necessarily and unavoidably unsafe. Accordingly, because the South Carolina legislature and South Carolina courts have found that unavoidably unsafe products are exempt from strict liability, and Ethicon's endocutter falls within the types of products that courts across the country have found unavoidably unsafe, Plaintiffs' strict liability claims are dismissed and converted into a negligent failure to warn claim.

B. Plaintiffs Product Liability Claims Fail Because Plaintiffs Cannot Show that Ethicon's Endocutter Is Unreasonably Dangerous

In South Carolina, a plaintiff bringing a product liability claim bears the burden of proving that the product is "in a defective condition unreasonably dangerous to the user," which requires proof by consideration of "the usefulness and desirability of the product, the cost involved for added safety, the likelihood and potential seriousness of injury, and the obviousness of danger." *See Branham v. Ford Motor Co.*, 390 S.C. 203, 210, 218-19, 701 S.E.2d 5, 8, 13 (2010) (citing *Claytor v. Gen. Motors Corp.*, 277 S.C. 259, 265, 286 S.E.2d 129, 132 (1982)).

The first element of the *Claytor* test is whether Ethicon's endocutter is useful and desirable. The witnesses in this case have testified about the usefulness and desirability of Ethicon's endocutter. *See, e.g.,* Yeaton Dep. Tr., 112 to 113:4; 114:2-22 (Plaintiffs' surgical expert testifying about the benefits of laparoscopic surgery and articulating endocutters); Hazell Dep. Tr., 136:21 to 137:8 to 138:12; 147:10 to 148:14 (Plaintiffs' treating surgeon discussing the

benefits of laparoscopic surgery and articulating endocutters). The endocutter's Instructions for Use provide that the endocutters are for use as "sterile, single patient use instruments that deliver staples while simultaneously dividing tissue between rows." Instructions for Use, Correa_EES_00032. The Instructions for Use detail the need to load a staple cartridge before using the product, and thus the endocutter is intended for use only after loading a cartridge. Instructions for Use, Correa_EES_00029 (picture instructions showing the need to load a cartridge before use); 35 (under step 5 of Instructions for Use, "Insert the new reload . . . . The instrument is now loaded and ready for use."). Plaintiffs argue that the endocutter without a staple cartridge loaded is not useful or desirable, but they provide no testimony or factual basis for using the endocutter without a cartridge, and the Instructions provide that the endocutter is to be used only after a cartridge is loaded. Thus, Plaintiffs have not raised a genuine issue of material fact as to the usefulness and desirability of the endocutter.

The second element of the *Claytor* test is consideration of the cost involved for the added safety. Plaintiffs' only evidence of the cost associated with Dr. Arslanoglu's alternative design that would have cured the purported design flaw is Dr. Arslanoglu's assertion that "I did not even have to analyze [cost]. I knew that it would be miniscule, compared to – knowing how much these devices are sold for . . . ." Arslanoglu Dep. Tr., at 144:12-15. The South Carolina Supreme Court, however, rejected almost identical testimony as inadmissible and speculative in *Watson v. Ford Motor Co.*, 389 S.C. 434, 450-51, 699 S.E.2d 169, 177 (2010), where the purported expert testified that an alternative design "was economically feasible, but offered no evidence to support this conclusion." The South Carolina Supreme Court found that the expert's "testimony lacked any scientific basis and contained no indicia of reliability." *Id.* Here, Dr. Arslanoglu's statement is further weakened by the fact that he explained the necessary steps to implement his alternative

safety measures in private industry, which would include developing a hypothesis, receiving information from the field, conducting design experiments and a feasibility analysis, evaluating and validating the results, repeating the process if the results do not match the hypothesis, conducting sterilization studies, and answering "many other questions," as well as consulting surgeons, the regulatory department, and quality departments. Arslanoglu Dep. Tr., 113:23 to 115:3; 146:9 to 148:15. Dr. Arslanoglu, however, offered no testimony about how much each of these steps would cost as applied to Ethicon's endocutter, noting "I was not tasked to look into the cost of how to make a device safer." *Id.* at 143:6-8. Just as in *Watson*, Dr. Arslanoglu's statement of cost is inadmissible, leaving Plaintiffs without admissible evidence to support the second element of the *Claytor* test.[1]

The third element of the *Claytor* test is consideration of the likelihood and potential seriousness of injury. Plaintiffs, however, have no evidence of the likelihood that an endocutter will be used unloaded during surgery. In fact, Dr. Arslanoglu admitted that he did not know the likelihood of an adverse event occurring that would be substantially similar to what happened to Mr. Correa. Dr. Arslanoglu Dep. Tr., 188:20 to 189:6. Nor can Plaintiffs support the claim that the risk of using the endocutter unloaded is higher when the device is packaged unloaded because they have no answers to three key questions: (1) What was the risk of using the preloaded endocutter without a cartridge? (2) What was the risk of using the unloaded endocutter without a cartridge? (3) What is the risk of using the unloaded endocutter packaged with a wedge in the jaws without a cartridge?[2] Plaintiffs' only piece of evidence in support of the

---

[1] Plaintiffs argue that a cost analysis is unnecessary because Ethicon could have continued to offer the endocutter preloaded or with a wedge that was subsequently incorporated. For the reasons detailed *infra* in Section D of the Court's Order, the Court finds Plaintiffs' argument insufficient to create a genuine issue of material fact.

[2] Dr. Arslanoglu, moreover, does not know the rates of user error necessary to use the device without a cartridge: He does not know the likelihood that a surgical scrub would fail to prepare the jaws of the endocutter pursuant to the Instructions for Use that accompany the endocutter (Dr. Arslanoglu Dep. Tr., at 183:3-15); he does not know the likelihood that a surgical scrub would hand a surgeon an endocutter without a cartridge loaded (*Id.* at 185:16-23); he

likelihood of injury is another purportedly similar adverse event that occurred within two months of Ethicon's transition to the unloaded endocutter, which alone is insufficient to calculate the risk of injury. The South Carolina Supreme Court, moreover, has "set forth a stringent standard for admissibility [of similar accidents]: [A] plaintiff must present a factual foundation for the court to determine that the other accidents were substantially similar to the accident at issue." *Branham v. Ford Motor Co.*, 390 S.C. 203, 230, 701 S.E.2d 5, 19 (2010) (quotations omitted). Here, Plaintiffs have failed to set forth any factual foundation for the court to determine whether the other accident involving Ethicon's endocutter was substantially similar to Mr. Correa's event. As such, Plaintiffs have not established the admissibility of the other accident, and therefore Plaintiffs may not rely on it to oppose summary judgment. Thus, Plaintiffs' only admissible evidence regarding the likelihood of injury is the fact of Mr. Correa's adverse event, which is not sufficient to create a genuine issue of material fact as to whether the endocutter was unreasonably dangerous. *See, e.g., Marchant v. Mitchell Dist. Co.*, 270 S.C. 29, 35-36, 240 S.E.2d 511, 513 (1977) ("The fact that the injury occurred . . . is not sufficient to support a finding that the [product] was unreasonably dangerous."); *Marchant II*, 272 S.C. 243, 247, 251 S.E.2d 189, 191 (1979) (a case on which Plaintiffs rely in their brief, noting that summary judgment was appropriate where the record is "barren of any competent evidence that the [product] was unreasonably dangerous absent incorporation of the safety feature"); *see also Branham*, 390 S.C. at 224, 701 S.E.2d at 16 ("[W]e do not suggest a jury question is created merely because a product can be made safer. We adhere to our longstanding approval of the principle that a product is not in a defective condition unreasonably dangerous merely because it

---

does not know the likelihood that a surgeon would fail to inspect the staple cartridge before using the device (*Id.* at 185:6-14); and he does not know the likelihood that a surgeon would use the surgical stapler without a cartridge loaded. *Id.* at 186:1-7.

'can be made more safe.'"); *Disher v. Synthes (U.S.A.)*, 371 F. Supp. 2d 764 (D.S.C. 2005) ("The law recognizes that every product could be 'made stronger' or 'more safe,' but the mere fact that the product could be 'stronger' or 'safer' does not establish a design defect or an unreasonably dangerous condition, as a matter of law.").

The fourth element of the *Claytor* test is consideration of the obviousness of danger. In their briefing, Plaintiffs have not disputed the obviousness of the danger in using an unloaded endocutter and cite testimony of surgery experts that the endocutter should never be introduced into a patient unloaded. During oral argument, however, Plaintiffs argued that the fact that Mr. Correa was injured is evidence that the danger was not obvious. Plaintiffs' argument, however, does not create an issue of material fact, because as discussed above the fact of the Plaintiffs' injury alone is insufficient to withstand summary judgment.

Accordingly, Plaintiffs have not demonstrated a genuine issue of material fact that Ethicon's endocutter was unreasonably dangerous, and Ethicon is entitled to summary judgment as to Plaintiffs' product liability claims.

C. Plaintiffs Product Liability Claims Fail Because Plaintiffs Cannot Show that Ethicon's Endocutter, at the Time of the Accident, Was in Essentially the Same Condition as When It Left Ethicon's Possession

Under South Carolina law, plaintiffs bringing product liability claims must establish "that the product, at the time of the accident, was in essentially the same condition as when it left the hands of the defendant . . . ." *Branham v. Ford Motor Co.*, 390 S.C. 203, 210, 701 S.E.2d 5, 8 (2010) (quoting *Madden v. Cox*, 284 S.C. 574, 579, 328 S.E.2d 108, 112 (Ct. App. 1985)). Endocutters leave Ethicon and are shipped to a third party vendor; they are shipped from the third party vendor to St. Francis, where they are stored in St. Francis' inventory; then they are sent to the operating room. Moreover, despite the fact that Ethicon packages the endocutters as "sterile, single patient use instruments," Instructions, Correa_EES_00032, several St. Francis

witnesses testified that after the endocutters are used during surgery, they are reprocessed. Oliver Dep. Tr., 64:8-13; Elia Dep. Tr., 40:14-19; 40:24 to 41:7. Plaintiffs have offered no evidence of the endocutter's condition at the time it left Ethicon's possession nor at the time that it was used during Plaintiff's surgery. Plaintiffs have not cited any deposition testimony about the condition of the endocutter during Mr. Correa's surgery or regarding whether the device was previously reprocessed at St. Francis. Moreover, Plaintiffs have no evidence of the lot number of the endocutter that could trace its path from Ethicon through the chain of custody to St. Francis. Finally, the endocutter was discarded after Mr. Correa's surgery so it cannot be examined. Therefore, Plaintiffs' claim that the product was in the same condition during Mr. Correa's surgery as when it left Ethicon is speculative, and Plaintiffs have no admissible testimony to support this element of their product liability claims, and summary judgment is appropriate. *See, e.g., Gastineau v. Murphy*, 331 S.C. 565, 570, 503 S.E.2d 712, 714 (1998) (noting that circumstantial evidence is sufficient to warrant the finding of a fact only when the circumstances lead to a reasonably certain conclusion, not mere speculation) (citation omitted).

D. Plaintiffs' Design Defect Claim Fails Because They Have No Admissible Evidence of an Alternative Feasible Design To Cure the Purported Defect

In *Branham v. Ford Motor Co.*, 390 S.C. 203, 701 S.E.2d 5 (2010), the South Carolina Supreme Court adopted the risk-utility test when considering claims of design defect, which requires Plaintiffs to offer evidence of the following:

- an alternative design that would have prevented the product from being unreasonably dangerous;
- reasonable costs of the alternative design;

- reasonable safety of the alternative design; and
- reasonable functionality of the alternative design.

Id. at 225, 701 S.E.2d at 16.

Plaintiffs' proffered expert, Dr. Arslanoglu, opines that Ethicon's endocutter is unreasonably dangerous because it always could, and still can, cut if no cartridge is loaded. Dr. Arslanoglu Dep. Tr., 101:23 to 104:23; 122:21 to 123:15; 125:16 to 126:15. Dr. Arslanoglu testified that the alternative design necessary to prevent the endocutter from being unreasonably dangerous would have both a lockout mechanism in the staple cartridge and a second lockout feature that would prevent the endocutter from cutting if no cartridge is present. *Id.* at 128:8-15. Dr. Arslanoglu, however, has not developed the specifications of an alternative design that would cure this alleged design flaw. *Id.* at 128:16-18. Moreover, Dr. Arslanoglu has not prepared any specifications for his alternative designs; he has not developed anything in writing as to how he would implement the alternative designs; he has not chosen any materials for use in implementing his alternative designs; and he has not developed any prototypes or tested any of the alternative designs. *Id.* at 111:12-18; 115:14-19; 116:7-15; 128:16 to 129:6. Such superficial analysis is insufficient to satisfy the alternative design requirement of the risk-utility test. *See, e.g., Disher v. Synthes (U.S.A.)*, 371 F. Supp. 2d 764, 771 (D.S.C. 2005) (Norton, J.) (granting defendant medical device company's motion for summary judgment on design defect claim, finding that the plaintiff's expert's "untested hypothetical suppositions" concerning an alternative design of a bone screw was insufficient to establish the alternative design requirement of the risk-utility test; and finding that failure to perform the risk-utility analysis discussed by the South Carolina Supreme Court in Claytor and discussed in Branham was fatal to the plaintiff's design-defect claim); *Bragg v. Hi-Ranger, Inc.*, 319 S.C. 531, 546, 462 S.E.2d 321, 330 (Ct. App. 1995) (affirming a directed verdict dismissing plaintiff's design defect claims where the plaintiff's

expert designed a non-defective alternative product but where the alternative product was for demonstration purposes only).

Moreover, the South Carolina Supreme Court described evidence of a cost-benefit analysis as "the essence of the risk-utility test" and that the "presentation of an alternative design must include consideration of the costs [and] safety . . . associated with the alternative design," *Branham*, 390 S.C. at 225, 701 S.E.2d at 17. Dr. Arslanoglu, however, has not conducted a cost analysis of any of his alternative designs, noting that "I was not tasked to look into the cost of how to make a device safer." *Id.* at 142:20 to 143:20. Dr. Arslanoglu's assertion that the cost of the alternative safety measures would be "miniscule" is insufficient to meet Plaintiffs' burden, as the Supreme Court found in *Watson v. Ford Motor Co.*, 389 S.C. 434, 450-51, 699 S.E.2d 169, 177 (2010) (finding that an expert's "testimony lacked any scientific basis and contained no indicia of reliability" where the expert testified that an alternative design "was economically feasible, but offered no evidence to support this conclusion"). Additionally, Dr. Arslanoglu's identifying another product's design on the market does not eliminate the requirement that Plaintiffs conduct a cost analysis. *Branham*, 390 S.C. at 219, 701 S.E.2d at 14 (discussing that identifying an alternative design on the market still required evidence that the alternative design would not have increased costs). Finally, Dr. Arslanoglu has not evaluated any potential risks that would be associated with his "alternative designs," testifying "that would be the task of the design engineers implementing those changes . . . ." *Id.* at 150:1 to 151:23. Because the risk-utility test requires proof of cost and safety risks associated with proposed alternative designs, and because Dr. Arslanoglu has not undertaken any such analysis, Plaintiffs have insufficient evidence to survive summary judgment on their design claim.

Plaintiffs claim that they are not required to satisfy the elements of the risk-utility test because Ethicon's preloaded endocutter constitutes an alternative design, and because Ethicon's subsequent incorporation of a wedge in the jaws of the endocutter (which is inadmissible as a subsequent remedial measure and therefore inappropriate for consideration at summary judgment) constitutes an alternative design. The Court finds Plaintiffs' argument insufficient to create an issue of material fact because neither the preloaded endocutter nor the endocutter packaged with a wedge in the jaws cures the alleged design defect because under either scenario the endocutter could still cut without a cartridge. For instance, when a spent staple cartridge is removed during surgery, the device has the ability to cut before a new cartridge is loaded; similarly, when the wedge is removed from the jaws of the endocutter, the device has the ability to cut before a staple cartridge is loaded. Thus, neither the presence of a staple cartridge nor the wedge render the endocutter unable to cut if no cartridge is loaded. Accordingly, Plaintiffs' claim that Ethicon could have packaged the endocutter preloaded or with a wedge in the jaws does not satisfy the first element of the risk-utility test, which requires that the alternative design cure the alleged design defect. As such, Plaintiffs' design defect claim fails.

E. Plaintiffs' Warning Claims Fail Because Ethicon Did Not Have a Duty to Warn Them; Ethicon's Warnings Were Adequate as a Matter of Law; and Plaintiffs Have No Evidence that a Different Warning Would Have Prevented Their Injuries

A manufacturer has no duty to warn patients of potential risks or dangers associated with their products when the product is distributed to a "sophisticated user" who is in a position to understand and assess the risks associated with the product. *Bragg v. Hi-Ranger, Inc.*, 319 S.C. 531, 549, 462 S.E.2d 321, 331-32 (Ct. App. 1995). St. Francis administers a Value Analysis

Program, which is a formal process by which they sought the clinically driven input of physicians, operating room personnel, and Carolinas Healthcare System concerning every product that the hospital purchased, including Ethicon's endocutter. Ferguson Dep. Tr., 14:17 to 15:17. Plaintiffs have not disputed that Ethicon was reasonable in assuming that St. Francis would understand the risks attendant to use of medical devices in their hospital, including Ethicon's endocutter. *See Bragg v. Hi-Ranger, Inc.*, 319 S.C. 531, 551, 462 S.E.2d 321, 332 (Ct. App. 1995) (finding that the jury correctly received an instruction concerning the sophisticated user doctrine where the plaintiff's employer, an electrical contractor, used and was familiar with aerial bucket trucks and the plaintiff was injured while working on an aerial bucket truck). Therefore, the undisputed evidence is that St. Francis constitutes a sophisticated user, and Ethicon's duty to warn therefore did not run to the Plaintiffs, which entitles Ethicon to summary judgment.

Additionally, an adequate warning under South Carolina law requires only a warning "which, if followed, makes the product safe for use." *Allen v. Long Mfg. NC, Inc.*, 332 S.C. 422, 427, 505 S.E.2d 354, 357 (Ct. App. 1998). St. Francis receives Ethicon endocutters in a cardboard box that contains three endocutters and a copy of the product's Instructions for Use. Anne Buck Dep. Tr., 54:3-10. Thus, every time that St. Francis purchases Ethicon endocutters, it receives Instructions for Use concerning the endocutter. The Instructions for Use provide step-by-step written and picture instructions concerning the preparation of the endocutter. Instructions for Use, Correa_EES_00028-43, at 35. The steps are (1) remove the instrument from the package, (2) remove the reload from the package, (3) examine the reload, (4) ensure that the endocutter is in the open position, and (5) insert the new reload. *Id.* If the surgical scrub had

followed these steps during Mr. Correa's surgery, his adverse event never would have happened. (Backus Dep. Tr., 69:22 to 70:1.)

Moreover, the Instructions contained several warnings concerning the consequences of using the endocutter without first loading a staple cartridge. Beside the bolded word "**Caution**" and under the bolded section "**Warnings and Precautions,**" Ethicon warned, "Always ensure that a cartridge is loaded before firing the instrument. If the instrument is fired without a cartridge, the instrument will cut tissue without applying staples preventing proper closure of the incision." Thus, the consequences of using the endocutter without a cartridge are clear. *Id.* at 67:17 to 68:2.

Plaintiffs contend that the word "warning" should have appeared on the box, that instructions should have been packaged in each box instead of each carton, and that the medical experts do not read the instructions such that the instructions cannot be adequate. Plaintiffs, however, have cited no case law or expert testimony to support any of these arguments. Rather, they argue that the issue is a question for the jury.[3] The Court finds Plaintiffs' argument does not create an issue of material fact because Ethicon provided multiple warnings that, if followed, would have prevented Mr. Correa's injury. Thus, because the Instructions for Use, if followed, made the endocutter safe for use, the warning was adequate as a matter, *Allen*, *supra*, and Ethicon is entitled to summary judgment.

Finally, South Carolina law requires proof that an alternate warning would have made a difference in the conduct of the person warned and would have prevented the plaintiff's injury.

[3] Plaintiffs cite *Allen* for the proposition that the adequacy of the warning is a question for the jury. In *Allen*, however, the expert offered specific testimony as to how and why the warning that accompanied a portable grain auger was inadequate to warn users that the center of gravity could shift and fall. 332 S.C. 422, 429-30, 505 S.E.2d 354, 358 (Ct. App. 1998). Here, Plaintiffs have offered no such testimony. Rather, their expert and the surgical scrub both testified that if Ethicon's Instructions were followed, the device would have used safely and effectively. Therefore, no issue of material fact exists, and *Allen* is inapplicable.

Odom v. G.D. Searle & Co., 979 F.2d 1001 (4th Cir. 1992) (affirming summary judgment where the plaintiff offered no evidence that an alternative warning would have caused a different medical device to be used thereby preventing her alleged injury); *Allen v. Long Mfg. NC, Inc.*, 332 S.C. 422, 432, 505 S.E.2d 354, 359 (Ct. App. 1998). Plaintiffs have offered no evidence, however, that a different warning would have prevented Mr. Correa's injuries. Rather, their expert agreed that if Ethicon's Instructions were followed, the endocutter would have been used with a cartridge present, such that Mr. Correa's injury never would have occurred. Arslanoglu Dep. Tr., 240:15-21. Plaintiffs' expert and the surgical scrub who prepared the endocutter for use during Mr. Correa's surgery agreed that the endocutter could be used safely and effectively if the steps in the Instructions were followed. *Id.* at 251:10-23; Backus Dep. Tr., 47:19-25; 69:22-70:1. Finally, the surgical scrub who prepared the endocutter for use during Mr. Correa's surgery never read the Instructions, and St. Francis did not make the Instructions available for operating room staff for use during surgery. Backus Dep. Tr., 66:8-10, 18-25. As such, a different warning would not have prevented Mr. Correa's injuries because there is no evidence that the surgical scrub or Dr. Hazell would have read them. *See Sauls v. Wyeth Pharms. Inc.*, 846 F. Supp. 2d 499 (D.S.C. 2012) (finding that the burden is on the plaintiff to demonstrate that a different warning would have been heeded). Accordingly, Plaintiffs have failed to offer evidence that a different warning would have prevented their injuries, and Ethicon is entitled to summary judgment.

F. Plaintiffs' Negligence Claim Fails Because Plaintiffs Have Offered Nothing To Prove that Ethicon Had a Duty To Personally Warn Plaintiffs' Physician and To Conduct an In-Service; Plaintiffs Have No Proof or Authority Regarding Any Standard of Care Even if Such Duties Existed and Thus Have No Evidence of Breach; and Plaintiffs Have No Evidence that Any Breach Caused Their Injuries

A cause of action for negligence requires Plaintiffs to offer proof that (1) Ethicon owed a duty of care to them, (2) that Ethicon breached the duty by a negligent act or omission, (3) that

the breach was the actual and proximate cause of their injury, and (4) that Plaintiffs suffered an injury. *Madison ex rel. Bryant v. Babcock Ctr., Inc.*, 371 S.C. 123, 135, 638 S.E.2d 650, 656 (2006). As an initial matter, Plaintiffs have abandoned any negligent design or manufacturing claim and argue only that Ethicon failed to properly notify Dr. Hazell of the change to the endocutter and failed to properly conduct an in-service at St. Francis.

The Court must determine whether the law recognizes a particular duty, and if not, then the defendant is entitled to a judgment. *Madison ex rel. Bryant v. Babcock Ctr., Inc.*, 371 S.C. 123, 135-36, 638 S.E.2d 650, 656 (2006). Plaintiffs carry the burden of proof, and have cited no South Carolina or other authority to support their argument that Ethicon owed a duty to them to inform Dr. Hazell personally of the change from preloaded endocutter to unloaded endocutter. Likewise, Plaintiffs have cited no South Carolina or other authority to support their argument that Ethicon owed a duty to them to conduct an in-service presentation at St. Francis regarding the change from preloaded endocutter to unloaded endocutter. Because the record is void of any evidence or authority that Ethicon owed them a duty to personally warn Dr. Hazell or to conduct an in-service presentation at St. Francis, Plaintiffs have failed to meet their burden of proof, and Ethicon is entitled to summary judgment on Plaintiffs' negligence claim.

In South Carolina, the relevant standard of care "may be established and defined by the common law, statutes, administrative regulations, industry standards, or a defendant's own policies and guidelines." *Madison*, 371 S.C. at 140, 638 S.E.2d at 659. If Ethicon had either or both duties that Plaintiffs claim, however, Plaintiffs still have cited no South Carolina or other authority to establish and define the relevant standard of care regarding personally warning physicians and conducting in-service presentations. Without establishing the standard of care, Plaintiffs cannot demonstrate that Ethicon breached the standard of care. As such, Plaintiffs

have failed to meet their burden of proof, and Ethicon is entitled to summary judgment on Plaintiffs' negligence claim.

Finally, Plaintiffs have offered no evidence that any breach of duty was the actual and proximate cause of their injuries, and the undisputed evidence is to the contrary. If Dr. Hazell were personally notified of the change from preloaded endocutter to unloaded endocutter, his behavior would have been the same. Hazell Dep. Tr., 255:2-6 ("Q. So you'd agree that since that has happened [being handed an incorrect instrument during surgery], that it's -- it's important that you check to make sure that the instrument that's been handed to you is the instrument that you have called for? A. No, no."). Moreover, if Ethicon had conducted a different in-service, Plaintiffs' injuries would have been the same because the operating room staff who prepared the endocutter for use during Mr. Correa's surgery were on medical leave at the time of the in-service and did not attend. Backus Dep. Tr., 56:12-20; Elia Dep. Tr., 62:25 to 63:6. Accordingly, Plaintiffs have failed to meet their burden of proof, and Ethicon is entitled to summary judgment on Plaintiffs' negligence claim.

CONCLUSION

Based on the foregoing, Ethicon's Motion for Summary Judgment is granted on the Plaintiffs' claims of strict liability, product liability, design defect, warnings, and negligence and are hereby dismissed with prejudice.

AND IT IS SO ORDERED.

The Honorable Kristi L. Harrington
Circuit Court Judge for the Ninth Judicial Circuit

April 26, 2013

Charleston, South Carolina

MotleyRice®
LLC
ATTORNEYS AT LAW
www.motleyrice.com

28 Bridgeside Blvd.
Mt. Pleasant, SC 29464
o. 843.216.9000 f. 843.216.9450

Carmen S. Scott
Licensed in SC
direct: 843.216.9160
cscott@motleyrice.com

May 29, 2013

Clerk of Court
South Carolina Court of Appeals
P.O. Box 11629
Columbia, SC 29211

RE: *Emilio Correa and Yunni Correa v. Bon Secours St. Francis Xavier Hospital, Inc., Dr. Samuel Hazell, Ashley River Surgical Associates, and Ethicon Endo-Surgery, Inc.*
Appellate Case No. 2013-001070

Dear Clerk of Court:

Enclosed please find copies of the Order Granting Defendant Ethicon Endo-Surgery, Inc's Motion for Summary Judgment and Order Granting Defendant Ethicon Endo-Surgery, Inc's Motion to Exclude Testimony of Ruhi Arslanoglu, Ph.D. These documents are the subject of the Notices of Appeal previously filed with the Court and assigned appellate case number 2013-001070.

Please let me know if there is anything else you need from me. Thank you.

Sincerely,

Carmen Scott BJdR3

Carmen Scott
Motley Rice LLC
28 Bridgeside Blvd.
Mt. Pleasant, SC 29464
(843) 216-9160
Attorney for Appellant

cc: Jane Thompson Davis
Nelson Mullins Riley & Scarborough LLP
151 Meeting St./Sixth Floor
Charleston, SC 29401
Attorney for Respondent

Joseph J. Tierney
Young Clement Rivers LLP
P.O. Box 993
Charleston, SC 29402
Attorney for Bon Secours St. Francis Xavier Hospital, Inc.

Hugh W. Buyck
Buyck and Sanders Law Firm LLC
P.O. Box 2424
Mt. Pleasant, SC 29464-2424
Attorney for Dr. Samuel Hazell and Ashley River Surgical Associates