

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

Case No. 16-60471-CIV-GAYLES

DENNIS GODELIA and
STERLING YOUMAS,

Plaintiffs,

v.

ZOLL SERVICES, LLC,

Defendant.

ORDER

THIS CAUSE comes before the Court upon Defendant's Motion for Summary Judgment [ECF No. 64]. The Court has carefully reviewed the Motion and the record and is otherwise fully advised. For the reasons set forth below, the Motion is denied.

BACKGROUND

Defendant Zoll Services, Inc. ("Defendant") designs, manufactures, and markets the LifeVest, a wearable defibrillator for patients at risk for sudden cardiac arrest. The LifeVest is made to detect life-threatening heart rhythms and automatically deliver a shock to restore normal rhythm. The LifeVest is a Class III medical device, initially approved for sale in 2001 by the Food and Drug Administration ("FDA").

In November 2013, after recovering from a cardiac operation, Debra Godelia began using the LifeVest. On November 18, 2013, Mrs. Godelia experienced a defibrillation event (the "Event")¹ and lost consciousness. Although the parties dispute why, it is undisputed that Mrs. Godelia's LifeVest did not administer the requisite shock. After realizing that the LifeVest was

¹ A defibrillation event is either ventricular tachycardia ("VT") (150 beats per minute) or ventricular fibrillation ("VF") (200 beats per minute).

not administering a shock, Mrs. Godelia's son called 911. Emergency personnel performed CPR on Mrs. Godelia and transported her to the hospital. Mrs. Godelia remained unconscious until she died in the hospital on November 20, 2013.

Plaintiffs Dennis Godelia and Sterling Youmas ("Plaintiffs"), relying on their expert, Richard J. Daken, and other record evidence,² argue that the LifeVest failed to deliver the shock to Mrs. Godelia because the cable connecting the rear therapy electrode set to the LifeVest's distribution network ("DN") was separated from the circuit board within the DN and that this separation was the result of defective soldering. Defendant does not dispute that the cable is currently separated from the LifeVest's circuit board. However, Defendant argues, through its own experts and record evidence, that the cable could not have been separated at the time of the Event and that it must have disconnected from the circuit board after the Event.

Plaintiffs also argue that Zoll failed to implement regulatory-required processes to ensure that its manufacturing of the LifeVest, and in particular, the soldering at issue, was non-defective and that the soldering defect was a direct result of Zoll's failure to implement such manufacturing processes.

Plaintiffs assert claims for strict products liability based on a manufacturing defect; negligence based on a manufacturing defect; fraudulent misrepresentation; fraudulent marketing and promotion; breach of express warranty; and negligent misrepresentation.³ Defendant has moved for summary judgment arguing that (1) Plaintiffs' manufacturing defect claims fail because Plaintiffs cannot establish a product defect or that Defendant's failure to comply with federal

² The Court denied Defendant's motion to exclude Mr. Daken's opinions, finding them to be admissible under Federal Rule of Evidence 702. [ECF No. 145].

³ The Second Amended Complaint lists eight counts, however, Plaintiffs dropped their claim for fraudulent omission and the Eleventh Circuit affirmed the Court's dismissal of Plaintiffs' claim for negligent infliction of emotional distress.

regulations caused the defect, and (2) Plaintiffs' remaining claims fail because they incorporate the same product defect as the manufacturing defect claims and because Plaintiffs cannot establish that they detrimentally relied on Defendant's representations.

ANALYSIS

Summary judgment, pursuant to Federal Rule of Civil Procedure 56(a), "is appropriate only if 'the movant shows that there is no genuine issue as to any material fact and the movant is entitled to judgment as a matter of law.'" *Tolan v. Cotton*, 134 S. Ct. 1861, 1866 (2014) (per curiam) (quoting Fed. R. Civ. P. 56(a)). "By its very terms, this standard provides that the mere existence of some alleged factual dispute between the parties will not defeat an otherwise properly supported motion for summary judgment; the requirement is that there be no *genuine* issue of *material* fact." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 247–48 (1986). An issue is "genuine" when a reasonable trier of fact, viewing all of the record evidence, could rationally find in favor of the nonmoving party in light of his burden of proof. *Harrison v. Culliver*, 746 F.3d 1288, 1298 (11th Cir. 2014). And a fact is "material" if, "under the applicable substantive law, it might affect the outcome of the case." *Hickson Corp. v. N. Crossarm Co.*, 357 F.3d 1256, 1259–60 (11th Cir. 2004).

"Where the material facts are undisputed and all that remains are questions of law, summary judgment may be granted." *Eternal Word Television Network, Inc. v. Sec'y of U.S. Dep't of Health & Human Servs.*, 818 F.3d 1122, 1138 (11th Cir. 2016). The Court must construe the evidence in the light most favorable to the nonmoving party and draw all reasonable inferences in that party's favor. *SEC v. Monterosso*, 756 F.3d 1326, 1333 (11th Cir. 2014). However, to prevail on a motion for summary judgment, "the nonmoving party must offer more than a mere scintilla of evidence for its position; indeed, the nonmoving party must make a showing sufficient to permit the jury to reasonably find on its behalf." *Urquilla-Diaz v. Kaplan Univ.*, 780 F.3d 1039, 1050 (11th Cir. 2015).

Here, the Court finds that genuine issues of material fact exist on all of Plaintiffs' claims. Indeed, there are clear factual disputes as to whether the cable connecting the rear therapy electrode was detached at the time of the Event and whether this separation was due to defective soldering. Moreover, there is a genuine issue of material fact as to whether the soldering defect—if one existed—was the result of Defendant's failure to implement regulatory-required processes. These disputes are for a jury to resolve.⁴

The Court also finds that there are genuine issues of material fact as to whether Mrs. Godelia detrimentally relied on Defendant's representations about the LifeVest. Defendant argues that Mrs. Godelia could not have detrimentally relied on the representations because there were no alternative options to the LifeVest. The Court disagrees. While there might not have been any other appropriate external or internal defibrillation device for Mrs. Godelia, she might have chosen, as an alternative option, to not wear the defibrillation device at all and seek another form of treatment. Without the LifeVest, her family, who had been instructed by Defendant to stay away from Mrs. Godelia while the LifeVest sounded an alarm, might have attempted CPR the minute she fell to the ground. As with the questions surrounding the detached cable, questions about Mrs. Godelia's reliance on Defendant's representations are for a jury.⁵

4 Although Mr. Daken will be able to offer his expert opinion as to the detached cable and soldering to the jury, the Court also finds that Plaintiff is entitled to a *Cassisi* inference that the LifeVest malfunctioned during normal operations. See *Cassisi v. The Maytag Co*, 396 So. 2d 1140 (Fla. 1st DCA 1981) (holding that a product may be deemed defective at the time of injury and at the time of sale if it malfunctions during normal operations). However, even "where a *Cassisi* inference is appropriate, the inference does not establish defectiveness, as a matter of law, but only permits a Plaintiff to submit the case to the jury to consider the inference when determining whether there is a defect in the product." *Pantages v. Cardinal Health 200, Inc.*, 508-CV-116-OC-GRJ, 2009 WL 2244536, at *2 (M.D. Fla. July 27, 2009).

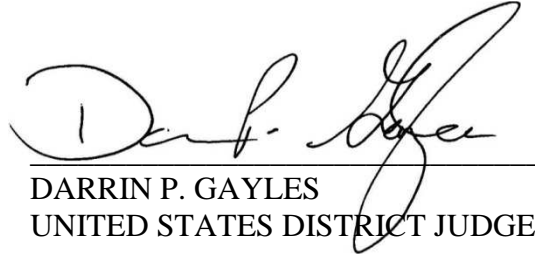
5 Defendant also argues that, without a product defect, Plaintiffs cannot seek noneconomic damages on their misrepresentation claims. As the Court finds that the question of whether the LifeVest was defective must go to the jury, it need not address Defendant's arguments regarding the availability of damages for Plaintiffs' fraud and misrepresentation claims at this time.

CONCLUSION

Based on the foregoing, it is

ORDERED AND ADJUDGED that Defendant's Motion for Summary Judgment [ECF No. 64] is **DENIED**.

DONE AND ORDERED in Chambers at Miami, Florida, this 13th day of August, 2019.



DARRIN P. GAYLES
UNITED STATES DISTRICT JUDGE