UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA

CASE NO. 1:13-cv-20742-KING

SANDRA WITT,

Plaintiff,

vs.

HOWMEDICALL OSTEONICS CORP.,
a New Jersey corporation,
d/b/a Stryker Orthopaedics

Defendant.
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ORDER GRANTING DEFENDANT'S MOTION FOR SUMMARY JUDGMENT

THIS CAUSE comes before the Court upon Defendant's Motion for Summary Judgment (DE 70). This is an action for damages by Plaintiff Sandra Witt against Defendant Howmedical Osteonics Corp. under the theories of strict liability and negligence. Howmedical developed, manufactured, and distributed the EIUS Unicompartmental Knee System ("EIUS"). Witt allegedly sustained injuries due to a defectively designed EIUS that was surgically installed in her knee in 2008. She had the EIUS removed during a subsequent surgery in 2009, and received a total knee replacement. Witt acknowledges that both counts of her Second Amended Complaint are "premised on design defect," DE 76, at 3, as opposed to manufacturing defects, or a theory of negligent failure to warn.

I. Governing Legal Standards

"In order to hold a manufacturer liable on the theory of strict liability in tort, the user must establish the manufacturer's relationship to the product in question, the defect and unreasonably dangerous condition of the product, and the existence of the proximate causal

connection between such condition and the user's injuries or damages." *West v. Caterpillar Tractor Co.*, 336 So. 2d 80, 87 (Fla. 1976). To prove her claim for negligent design, Witt must show that Howmedical owed her a duty, that Howmedical breached the duty, that the breach was the proximate cause of her injuries, and that she suffered damages resulting from those injuries. *See Murray v. Traxxas Corp.*, 78 So. 3d 691, 693 (Fla. 2d DCA 2012). Under either theory, Witt must prove that the EIUS was defective in design, and that Howmedical's actions or omissions proximately caused her injury.

I. Standard on Motion for Summary Judgment

Summary judgment is appropriate where the pleadings and supporting materials establish that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law. *See* Fed. R. Civ. P. 56; *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986). A fact is "material" if it is may determine the outcome under the applicable substantive law. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). The nonmoving party must show specific facts to support that there is a genuine dispute. *Id.* at 256. On a motion for summary judgment, the court must view the evidence and resolve all inferences in the light most favorable to the nonmoving party. *Id.* at 255. In reviewing the record evidence, the Court may not undertake the jury's function of weighing the evidence or undertaking credibility determinations. *Latimer v. Roaring Toyz, Inc.*, 601 F.3d 1224, 1237 (11th Cir. 2010).

II. The EIUS Was Loose and Removed Easily During Witt's Explant Surgery

To show that the EIUS was defectively designed, Witt offered the testimony of only one individual, a proffered expert named Dr. Jerry Lubliner. The Court has excluded his

opinions as unreliable by separate Order (DE 86). Dr. Lubliner based his conclusion, "that there was failure in the mechanical operation of the EIUS device in the right knee of Sandra Witt," entirely on the apparent looseness and easy removability of the EIUS during Witt's explant surgery in 2009.[1] Although the Court has excluded Dr. Lubliner's opinions, the Court may still conclude, in the light most favorable to Witt, that the EIUS was loose and easily removed in 2009 during Witt's explant surgery. However, the Court is still left without a showing that the EIUS was defectively designed. Why was the EIUS loose and easily removed in 2009? Was it due to a "failure in the mechanical operation" of the device? Did Witt's surgeon negligently implant the device in 2008? Did Witt participate in extreme sports against the advice of her doctors? Is the EIUS *supposed* to be loose and easily removed one year after implanting? All of the above?

The Court acknowledges that "the 'mere existence of alternative theories for the accident [or here, the looseness and easy removability of the EIUS] cannot be the basis for taking the weighing of the evidence out of the jury's hands.'" *Moorman v. Am. Safety Equip.*, 594 So. 2d 795, 801 (Fla. 4th DCA 1992) (quoting *Zyferman v. Taylor*, 444 So. 2d 1088, 1092 (Fla. 4th DCA 1984)). But to get to the jury on her claims, Witt would have to come forward with evidence for the jury to weigh—evidence that the EIUS implanted in Witt's knee was defectively designed, and that a design defect caused her injury. She has come forward with none.[2]

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[1] The looseness and easy removability of the EIUS were not phenomena that Dr. Lubliner personally observed. He read this information in an operative report.

[2] The Court notes that even if Dr. Lubliner's testimony had not been excluded, it would be no help to Witt here. His one-sentence opinion on the EIUS's alleged defect was "that there was failure in the mechanical operation of the EIUS device in the right knee of Sandra Witt."

III. Howmedical's Notice of Loosening Problems and the Recall of the EIUS

Witt argues that she has shown evidence to support her claims based on design defect because (1) Howmedical had notice of the EIUS's propensity to loosen, and (2) the EIUS was recalled after Witt's surgery. These portions of Witt's argument are supported only by scant and dubious citations to the record—to apparently internal Howmedical documents such as a "Design and Development Plan," internal memoranda, a "Risk Analysis Report," a "Non-Conformance Report," and a "Manufacturer Product Hold Notice."[3] Defendant objects that these documents are unauthenticated (and not self-authenticating). They are not even explained or put in context by competent testimony in the form of affidavit, deposition, or otherwise. The Court is therefore unable to ascribe them any significance, or construe them as providing evidentiary support for Witt's claims. For example, Witt states as follows:

> [A Risk Analysis Report completed in January 1998] identified loosening in both the femoral and tibial components of the Minimally Invasive Surgery Unicompartmental Knee (MIS UNI) as key areas of concern in the product design. . . . By 2003 HOC was focused on design changes to the tibial component, and there was notation that these changes began to affect the femoral component. This reporting was disregarded because they were not considered related to the project underway, the EIUS All Poly Tibial Component Project, project 0874.

DE 76, at 6. First, without corroborating or even explanatory testimony, the Court is unable to conclude that the technical documents Witt relies on either (a) support the assertions for which she cites them, or (b) provide evidentiary support for her claims. Even when

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Even if the Court credited this *ipse dixit* for summary judgment purposes, Witt's claims would nevertheless be plagued by the same deficiencies. Witt has presented no evidence that the "failure in the mechanical operation" was due to the EIUS's defective design, as opposed to the negligence of Witt's surgeon, Witt's own actions, etc.

[3] Witt filed an unopposed motion for leave to file these documents under seal (DE 82). That motion is GRANTED. The Court has reviewed and considered these restricted-access documents (which Witt attached to her motion for leave to file under seal).

generously construed, Witt's assertions at most show that Howmedical was aware of loosening as an "area of concern" in the EIUS design at some unidentified stage(s) in its development. None of Witt's assertions support her claim that the EIUS implanted in her knee was defectively designed, or that a defect therein caused her injury.

Other of Witt's assertions are wholly unsupported. For example, Witt states that "Howmedical recalled the device on January 11, 2012, including the exact part and lot number explanted in April 2009, the Femoral Component implant device inserted into Plaintiff on April 18, 2008 was on the list. Catalog Number 6636-2-011 EIUS UNI XS FEM RM/LL." DE 76, at 7. Witt cites her own Second Amended Complaint as support for this statement.[4] Witt has failed to come forward with evidence sufficient to show a design defect in the EIUS.[5] Her claims, both premised on design defects, must fail as a matter of law.

IV. Conclusion

Therefore, it is **ORDERED, ADJUDGED, and DECREED** that Defendant's Motion for Summary Judgment **(DE 70)** be, and the same is, hereby **GRANTED**.

DONE and ORDERED in Chambers at the James Lawrence King Federal Justice Building and United States Courthouse, Miami, Florida, this 20th day of April, 2015.

JAMES LAWRENCE KING
UNITED STATES DISTRICT JUDGE
SOUTHERN DISTRICT OF FLORIDA

cc: All Counsel of Record

[4] There is a pending Defendant's motion to exclude evidence of, *inter alia*, the recall as inadmissible under Federal Rule of Evidence 407 (Subsequent Remedial Measures). Witt did not respond to the motion. *See* DE 52. It is unnecessary for the Court to resolve it because Witt has failed to provide evidentiary support for her claims in any event.

[5] The Court does not address Howmedical's "Government Rules Defense."