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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF ARIZONA

IN RE: Bard Implanted Port Catheter Products Liability Litigation	MDL No. 3081
Judy Hicks, Individual Plaintiff, v. Becton Dickinson and Company, et al., Defendants.	No. CV-23-01703-PHX-DGC **ORDER**

This multidistrict litigation ("MDL") involves thousands of personal injury cases related to implanted port catheters ("IPCs" or "ports") designed, manufactured, and marketed by Defendants Becton Dickenson and Company, C. R. Bard, Inc., Bard Access Systems, Inc., and Bard Peripheral Vascular, Inc. (collectively, "Defendants" or "Bard"). The MDL Plaintiffs received implants of Bard IPCs and claim they were defective and caused serious injury.

The case of Plaintiff Judy Hicks has been selected for a bellwether trial in December. She received a Bard IPC in February 2021 and developed thrombosis.

Defendants have filed a motion for summary judgment. Doc. 5821. The motion is fully briefed and no party requests oral argument. *See* Docs. 6254, 6414. For reasons stated below, the Court will deny the motion.

I. Background.

An IPC is a medical device surgically implanted under the skin to provide repeated access to a patient's vascular system without the need for multiple needlesticks into peripheral veins. IPCs are used to deliver chemotherapy and immunotherapy medication, intravenous fluids, blood transfusions, and parenteral nutrition. IPCs can remain in place for weeks, months, or even years until treatment is completed.

IPCs consist of a port and a catheter. The port is a small reservoir with a self-sealing silicone center where a needle can be inserted to deliver medication. The port typically is implanted beneath the chest skin and below the collarbone. The port is attached to a catheter, which is a thin flexible tube for delivery of the medication to a vein. The catheter is tunneled under the skin to an insertion point in a central vein. Catheters vary in width and are made of silicone or polyurethane. IPCs typically are implanted by an interventional radiologist or a vascular surgeon. A nurse or other medical professional then accesses the IPC to inject the medication, which flows from the port to the catheter and into the vein.

II. Plaintiff Hicks.

On February 21, 2021, Plaintiff Hicks received a Bard X-Port IPC with a ChronoFlex polyurethane catheter at Ste. Genevieve County Memorial Hospital in Missouri for chemotherapy related to breast cancer. Dr. Theresa Cavins, a general surgeon, implanted the X-Port.

Plaintiff received multiple chemotherapy infusions through the X-Port. The device was occluded with thrombus during some of the infusions. After Plaintiff had received cancer-related surgery, the X-Port was found to be occluded at the tip of the catheter. It was surgically removed on August 3, 2022.

Plaintiff claims the X-Port caused her to suffer catheter-related thrombosis. She alleges the X-Port was defectively designed because the polyurethane used in the ChronoFlex catheter is a rough material that degrades over time and is prone to thrombus formation, and that Bard failed to make the catheter smoother or coat it with antithrombotic material. Plaintiff also alleges Bard failed to warn about and concealed the X-Port's risks.

Plaintiff asserts various claims under Missouri law.[1] Some of Plaintiff's claims have been withdrawn, and the following claims remain: design defect (Counts I and II), failure to warn (Counts III and IV), concealment (Count XI), and punitive damages. *See* Doc. 190 (short-form complaint); Doc. 1889 (master complaint, as amended). Defendants move for summary judgment on all of these claims. Doc. 5821 at 2-4.[2]

III. Summary Judgment Standard.

Summary judgment is appropriate if the moving party shows there is no genuine dispute as to any material fact and it is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(a). Summary judgment is also appropriate against a party who "fails to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial." *Celotex Corp. v. Catrett*, 477 U.S. 322, 323 (1986).

The moving party "bears the initial responsibility of informing the court of the basis for its motion, and identifying those portions of [the record] which it believes demonstrate the absence of a genuine issue of material fact." *Celotex*, 477 U.S. at 323. Only disputes over facts that might affect the outcome of the suit will preclude the entry of summary judgment, and the disputed evidence must be "such that a reasonable jury could return a verdict for the nonmoving party." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). The Court must view the evidence in the light most favorable to the nonmoving party, *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 587 (1986), and draw justifiable inferences in that party's favor, *Anderson*, 477 U.S. at 255.

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[1] The parties agree that Missouri substantive law governs Plaintiff's claims and Defendants' defenses. Docs. 5821 at 5-6, 6254 at 7, 11441 at 5.

[2] The master complaint sets forth claims the MDL Plaintiffs assert generally. *See* Doc. 145. Plaintiff-specific claims are contained in individual short-form complaints, profile forms, and fact sheets. *See id.*; Docs. 476, 477. The master complaint asserts seventeen claims and seeks both compensatory and punitive damages. Doc. 1889 ¶¶ 268-487. Plaintiff Hicks does not assert several of the master complaint claims — unjust enrichment, loss of consortium, wrongful death, or survival claims (Counts XIII-XVI) — and has withdrawn her claims for manufacturing defect, breach of warranty, negligent and fraudulent misrepresentation, consumer fraud, and successor liability (Counts V-X, XII, and XVII). *See* Docs. 5821 at 2, 6254 at 2 n.1, 11441 at 9 n.3.

IV. Discussion.

A. Design Defect Claims (Counts I and II).

Plaintiff asserts strict liability and negligent design defect claims. Docs. 190 ¶ 15, 1889 ¶¶ 268-300. Under Missouri law, "negligence and strict liability theories of product liability are separate and distinct theories." *Johnson v. Auto Handling Corp.*, 523 S.W.3d 452, 466 (Mo. 2017). Strict liability focuses "on the product and its condition when sold," while negligence focuses "on what the manufacturer knew rather than on the product." *Id.*

To prove strict liability design defect, a plaintiff must show that (1) the defendant sold the product in the course of its business, (2) the product was in a defective condition unreasonably dangerous when put to a reasonably anticipated use, (3) the product was used in a manner reasonably anticipated, and (4) the plaintiff was damaged as a direct result of the product's defective condition. *Id.* (citing Missouri Approved Jury Instruction (Civil) ("MAI") 25.04). "In Missouri, there is not an external standard by which to determine unreasonable danger. 'Nothing prevents the litigants from arguing that the utility of a design outweighs its risks, or that consumer expectations were violated, or any other theory of unreasonable dangerousness supported by the evidence.'" *Smith v. Brown & Williamson Tobacco Corp.*, 275 S.W.3d 748, 792 (Mo. Ct. App. 2008) (quoting *Newman v. Ford Motor Co.*, 975 S.W.2d 147, 154 (Mo. 1998)).

To prove a negligent design defect, the plaintiff must show that (1) the defendant designed the product, (2) the product had a defect, (3) the defendant failed to use ordinary care to design the product to be reasonably safe, and (4) the plaintiff was damaged as a direct result of such failure. *Johnson*, 523 S.W.3d at 466 (citing MAI 25.09). For claims involving prescription drugs and complex medical products, "ordinary care" means that degree of care, skill, and learning that an ordinarily careful expert in the defendant's business would use under the same or similar circumstances. *See* MAI 11.10; *Key v. Diamond Int'l Trucks*, 453 S.W.3d 352, 357 (Mo. Ct. App. 2015) (explaining that "MAI 11.10 is used in cases involving drug manufacturers and in cases involving 'the sophisticated nature of the engineering, dynamics, and production'" of other complex

products (quoting *Barnett v. La Societe Anonyme Turbomeca France*, 963 S.W.2d 639, 652 (Mo. Ct. App. 1997))).

Defendants argue that Plaintiff's design defect claims fail as a matter of law because the X-Port is an "unavoidably unsafe product" under comment k to Restatement (Second) of Torts § 402A. Doc. 5821 at 6-8.[3] Comment k provides an exemption from strict liability for certain "unavoidably unsafe products":

> There are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use. . . . Such a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it unreasonably dangerous.

Restatement § 402A, cmt. k.[4]

Missouri courts have applied comment k to strict liability design defect claims involving prescription drugs and medical devices. *See Pollard v. Ashby*, 793 S.W.2d 394, 398-401 (Mo. Ct. App. 1990) (prescription drug Chymodiactin); *In re NuvaRing Prods. Liab. Litig.*, No. 4:08-CV-00558-RWS, 2013 WL 3716389, at *8-10 (E.D. Mo. July 12, 2013) (hormone contraceptive drug); *Racer v. Utterman*, 629 S.W.2d 387, 391-93 (Mo. Ct. App. 1981) (surgical drape); *Joyce v. Davol, Inc.*, No. 4:15-CV-468 JAR, 2016 WL 775183, at *2-3 (E.D. Mo. Feb. 29, 2016) (Bard hernia mesh plug). Missouri courts have made clear that "[c]omment k is an affirmative defense, and the manufacturer . . . bears the burden of showing that the [medical device] falls under the protection of comment k." *In re NuvaRing*, 2013 WL 3716389, at *9; *see also Joyce*, 2016 WL 775183, at *3 (explaining that "[c]omment k is generally recognized as an affirmative defense, which would require the defendants to present proof the [medical device] was incapable of being made safer"); *Pollard*, 793 S.W.2d at 400 ("comment k is an affirmative defense").

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[3] Defendants argue in passing that no reasonable jury could find that the X-Port was designed defectively (*id.* at 6), but do not develop this argument in any meaningful way. The Court will not grant summary judgment on this basis.

[4] An example of an unavoidably unsafe product "is the vaccine for the Pasteur treatment of rabies, which not uncommonly leads to very serious and damaging consequences when it is injected. Since the disease itself invariably leads to a dreadful death, both the marketing and the use of the vaccine are fully justified, notwithstanding the unavoidable high degree of risk which they involve." *Id.*

To meet its burden on this affirmative defense, a medical device manufacturer must satisfy two elements. *See Pollard*, 793 S.W.2d at 400. First, the manufacturer must show that the device's risk is unavoidable "by demonstrating that, given the current state of knowledge, no feasible alternative design exists that would accomplish the same purpose with a lesser risk." *Id.* Second, the manufacturer must show that "the overall benefit of the [device] outweighs the risk created by it." *Id.* Defendants have established neither of these elements as a matter of undisputed fact.

Defendants have not shown the undisputed absence of a feasible alternative design that would have accomplished the same purposes as the X-Port with a lesser risk of thrombosis. Defendants argue that an alternative design identified by Plaintiff — the AngioDynamics BioFlo port with Endexo antithrombotic technology — is not superior to the X-Port. Doc. 5821 at 7. Defendants rely on an alleged admission by AngioDynamics (in other litigation) that its product is not superior to Bard's, but do not explain why this admission is controlling outside of the litigation where it occurred. Nor do they address Plaintiff experts who assert that the BioFlo is superior to Plaintiff's port.

Plaintiff identifies several other alternative designs that she claims are feasible and more thrombus resistant than the X-Port, including the Bard ChronoFlex Silk port, the Orphis port with zwitterionic coating, the Zeus catheter with dextran glycoconjugate polymer technology, and Vertellus phosphorylcholine surface technology. Doc. 6254 at 9-10. Defendants dispute that these designs are feasible or comparative (Doc. 6414 at 3-6), but this only creates factual issues that must be resolved by the jury.[5]

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[5] Defendants cite no legal authority suggesting that an alternative design must be FDA-cleared or commercially available in the United States to be relevant to a design defect claim under Missouri law. *See* Doc. 6414 at 4-6; *cf. Thacker v. Ethicon, Inc.*, 47 F.4th 451, 464 (6th Cir. 2022) ("[I]t is illogical to say that an alternative design – that, by definition, was never put on the market – must have been approved by the FDA to support a design defect claim."); *In re Ethicon Inc. Pelvic Repair Sys. Prods. Liab. Litig.*, No. MDL 2327, 2020 WL 1060970, at *3 (S.D. W. Va. Feb. 13, 2020) (FDA-clearance "has no bearing on whether PVDF mesh is a safer alternative to other mesh products"). Defendants' reliance on *McMahon v. Robert Bosch Tool Corp.*, No. 4:18-CV-00583 SRC, 2019 WL 5727340 (E.D. Mo. Nov. 5, 2019), is misplaced because the proposed alternative designs in that case were "mere ideas or conceptualizations" with no testing, drawings, or prototypes. 2019 WL 5727340, at *8-9; *see also Pestel v. Vermeer Mfg. Co.*, 64 F.3d 382, 384 (8th Cir. 1995) (excluding expert testimony where "the concept of the guard was still

Defendants argue in their reply that Plaintiff fails to show her IPC was defective (Doc. 6414 at 3-4), but an inability to make that showing was not the basis of Defendants' summary judgment motion. Defendants' motion relied on comment k to Restatement § 402A. Doc. 5821 at 6-7. Plaintiff responded by showing several alternative designs which, they assert, would have made the Bard port safer, creating a factual issue on the application of comment k.

Defendants also fail to satisfy the second element of the comment k defense — that the X-Port's benefits outweigh its risks. *See Pollard*, 793 S.W.2d at 400. Defendants contend that IPCs are live-saving devices and that all IPCs carry risks of thrombosis (Doc. 5821 at 7), and they will vigorously make these assertions at trial. But Defendants' assertions do not establish that the X-Port's benefits outweigh its risks as a matter of undisputed fact. *See Lachance v. Am. Home Prods. Corp.*, No. 01-0890-CV-W-ODS, 2006 WL 89850, at *4 (W.D. Mo. Jan. 13, 2006) ("Defendants claim that because obesity is an epidemic in this country and Pondimin assists in the treatment of obesity, its benefit outweighs its risk. The issue Defendants present is one of fact, and must be decided by the jury."); *Hill v. Wyeth, Inc.*, No. 4:03CV1526 JCH, 2007 WL 674251, at *5 (E.D. Mo. Feb. 28, 2007) (same).[6]

As explained in the failure to warn section below, Defendants have also failed to show through undisputed facts that the X-Port was accompanied by proper warnings, which also precludes application of comment k. *See* Doc. 6254 at 10-11; Restatement § 402A, cmt. k ("The seller of [unavoidably unsafe] products, again with the qualification that they are properly prepared and marketed, *and proper warning is given*, . . . is not to be held to strict liability for unfortunate consequences attending their use[.]" (emphasis added));

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evolving" and the expert "had not subjected his concept to any manufacturers, academicians, or engineering professors, for scrutiny"); *Jaurequi v. Carter Mfg. Co.*, 173 F.3d 1076, 1084 (8th Cir. 1999) (same where the expert had not "attempted to construct or even draw the suggested device").

[6] Defendants assert that none of Plaintiff's experts have conducted a risk-benefit analysis (Doc. 5821 at 7), but Defendants, not Plaintiff, "bear[] the burden of showing that the [X-Port] falls under the protection of comment k." *In re NuvaRing*, 2013 WL 3716389, at *9.

Pollard, 793 S.W.2d at 399 (explaining that comment k applies to products that are "incapable of being made safe given the present state of human knowledge but which have such a high degree of social need that their use is warranted, *so long as there are sufficient warnings*" (emphasis added)).

The Court will deny Defendants' motion based on comment k to Restatement § 402A. Doc. 5821 at 6-8; *see Lemmon v. Wyeth, LLC*, No. 4:04CV01302 ERW, 2012 WL 2848161, at *15 (E.D. Mo. July 11, 2012) ("The Court finds that Defendants have not met their burden of establishing that comment k excludes their HRT products from strict liability; thus, summary judgment in their favor is not appropriate on this asserted basis.").[7]

B. Failure to Warn Claims (Counts III and IV).

Plaintiff asserts strict liability and negligent failure to warn claims. *See* Docs. 190 ¶ 15, 1889 ¶¶ 301-341. To prove strict liability failure to warn under Missouri law, the plaintiff must show that (1) the defendant sold the product at issue in the course of its business, (2) the product was unreasonably dangerous when put to a reasonably anticipated use without knowledge of its characteristics, (3) the defendant did not give an adequate warning of the danger, (4) the product was used in a manner reasonably anticipated, and (5) the plaintiff was damaged as a direct result of the product being sold without an adequate warning. *See* MAI 25.05; *Moore*, 332 S.W.3d at 756. "Missouri law recognizes that 'a product may be rendered unreasonably dangerous and therefore actionable because of the absence of a warning concerning use or misuse, or because the warning that has been given is informationally deficient.'" *Moore*, 332 S.W.3d at 756 (quoting *Nesselrode v. Exec. Beechcraft, Inc.*, 707 S.W.2d 371, 382 (Mo. 1986)).

[7] Defendants' motion addresses only strict liability and cites no legal authority suggesting that comment k is a defense to a claim of negligence. *See* Docs. 5821 at 6-7, 6254 at 11; Restatement § 402A, cmt. a ("The rule [in this Section] is one of strict liability, making the seller subject to liability to the user or consumer even though he has exercised all possible care in the preparation and sale of the product. . . . The rule stated here is not exclusive, and does not preclude liability based upon the alternative ground of negligence of the seller[.]"); *Lemmon*, 2012 WL 2848161, at *14 (explaining that comment k "addresses the application of strict liability to unavoidably unsafe products").

To prove negligent failure to warn, a plaintiff must show that (1) the defendant manufactured or designed the product, (2) the product was defective or hazardous, (3) the defendant failed to use ordinary care to adequately warn of the risk of harm from the defect or hazard, and (4) the plaintiff was damaged as a direct result of such failure. *See* MAI 25.09; *Ameer v. Lyft, Inc.*, 711 S.W.3d 534, 543 (Mo. Ct. App. 2025); *see also Johnson*, 523 S.W.3d at 462 (explaining that the MAIs require "claims of strict liability for failure to adequately warn be submitted under MAI 25.05, and claims of negligent manufacture, design, or failure to warn be submitted under MAI 25.09").

In the context of failure to warn claims involving prescription drugs and medical devices, "Missouri courts adhere to the learned intermediary doctrine." *Doe v. Alpha Therapeutic Corp.*, 3 S.W.3d 404, 419 (Mo. Ct. App. 1999) (citations omitted). "The learned intermediary doctrine provides that a manufacturer of prescription drugs or medical devices has a duty to warn a physician of the risks involved with its product. The physician then acts as a 'learned intermediary' between the manufacturer and the patient so that any warning given to the physician is deemed a warning to the patient." *Chole v. Bos. Sci. Corp.*, No. 4:19-CV-02976 JAR, 2020 WL 1853266, at *6 (E.D. Mo. Apr. 13, 2020) (citing *Doe*, 3 S.W.3d at 419; *Kirsch v. Picker Int'l, Inc.*, 753 F.2d 670, 671 (8th Cir. 1985)). The learned intermediary doctrine further provides that "the failure of [the] manufacturer to provide the physician with an adequate warning of the risks associated with a prescription product is 'not the proximate cause of a patient's injury if the prescribing physician had independent knowledge of the risk that the adequate warnings should have communicated.'" *Doe*, 3 S.W.3d at 420 (citation omitted); *see also Chole*, 2020 WL 1853266, at *6 ("Because the defective aspect of the product must cause the injury, the plaintiff must show that a proper warning would have changed the decision of the treating physician, i.e., that but for the inadequate warning, the treating physician would not have used or prescribed the product.").

Defendants argue that summary judgment is warranted on the failure to warn claims because (1) the warnings provided in the X-Port's Instructions for Use ("IFU") are

adequate as a matter of law, and (2) the learned intermediary doctrine forecloses the claims. Doc. 5821 at 8-11.

1. Adequacy of the Warning.

Defendants contend that the IFU for Plaintiff's X-Port identifies the risks and injuries Plaintiff experienced. *Id.* at 9. The IFU lists catheter occlusion and vascular thrombosis as possible complications. Doc. 5821-3 at 9-10.

In determining the adequacy of a warning, Missouri courts consider "the placement of the warning, its language and how it may or may not impress the average user." *Brown v. Bay State Abrasives*, 821 S.W.2d 531, 533 (Mo. Ct. App. 1991). "In evaluating these factors, the dangerous nature of the product, the form in which it is used, the burden to be imposed by requiring warnings and the likelihood that the particular warning will be adequately communicated to those who will foreseeably use the product must also be considered." *Id.*; *see also Johnson v. Medtronic, Inc.*, 365 S.W.3d 226, 235 (Mo. Ct. App. 2012) (same). Defendants address none of these considerations. *See* Doc. 5821 at 8-11.

Plaintiff presents evidence that Defendants' warnings were inadequate because the X-Port's IFU merely lists catheter occlusion and vascular thrombosis among more than 30 possible complications, with no information about frequency, severity, or product-specific risk. Doc. 6254 at 13 (citing Doc. 6254-1 ¶¶ 160-65, 167, 169-72). Plaintiff also presents evidence that the IFU omits information Defendants possessed, including high thrombus rates, particularly for chemotherapy patients (up to 18%), thrombogenic material properties and degradation, and safer alternatives. *Id.* (citing Doc. 6254-1 ¶¶ 63-64, 69-77, 80-118, 122-123, 138-177).

Plaintiff's evidence creates a question of fact on whether Defendants adequately warned about the scope of the danger and harm that could result from use of the X-Port. *See Moore*, 332 S.W.3d at 756 (explaining that a warning may be inadequate where it is "informationally deficient"); *Barron v. Abbott Lab'ys, Inc.*, 529 S.W.3d 795, 800 (Mo. 2017) ("[T]he contents of a warning [must] be complete and accurate, so as to not mislead. . . . As Depakote's label did not reflect this relevant information [about higher risks of

birth defects], a reasonable inference could be drawn from this evidence that Abbott's warning was not complete and accurate and, therefore, did not adequately warn."); *Brown v. Bay State Abrasives*, 821 S.W.2d 531, 534 (Mo. Ct. App. 1991) ("This court will not open up a gaping loophole in failure to warn cases by permitting manufacturers to rely on general language that provides just enough information for the user to . . . research the dangers of a product themselves. The manufacturer possesses the most access to such information and it is in the best position to see to it that adequate warnings are given.").[8]

The Court will deny Defendants' motion based on the adequacy of the X-Port's warnings.

2. Learned Intermediary Doctrine.

Defendants argue that summary judgment is warranted under the learned intermediary doctrine because Dr. Cavins testified that she was aware all vascular access devices carry a risk of thrombosis and occlusion. Doc. 5821 at 11 (citing Doc. 5821-1 ¶¶ 38-39). But this testimony shows only that Dr. Cavins had general knowledge of the risk of thrombosis and occlusion, not that she knew the specific information Plaintiff claims Bard failed to provide regarding increased risks associated with the ChronoFlex catheter.

Dr. Cavins testified that she believed there was only a "small incidence" of port-related complications, and that she was not aware of any issues specific to the X-Port and would expect Bard to inform surgeons of any "unusual, specific defects or problems with the device." Doc. 6254-49 at 13, 17, 68. She also testified that in order to make an informed decision about whether to implant an X-Port, she "absolutely . . . would want to know" if the ChronoFlex catheter material could degrade in a patient's body and increase the risk of thrombus formation, including the percentage of patients who experienced this complication. *Id.* at 18-24. She further testified that she would want to know if the X-Port

[8] Defendants rely on *Bader Farms, Inc. v. Monsanto Co.*, No. 1:16-CV-299 SNLJ, 2017 WL 1315792 (E.D. Mo. Apr. 10, 2017), but the plaintiffs in that case presented no evidence of an inadequate warning and their only response to the defendant's use of the warning labels was "a cursory, one-phrase declaration that 'the adequacy of the warning is for the jury.'" 2017 WL 1315792, at *4; *see also* Doc. 6254 at 12-13.

should not stay implanted longer than necessary due to an increased risk of thrombosis and other complications. *Id.* at 23-24.

Construed in the light most favorable to Plaintiff, this evidence presents a triable issue as to whether Dr. Cavins knew the information Defendants allegedly failed to provide and whether she would have acted differently if Defendants had provided additional warnings. *See Tune v. Synergy Gas Corp.*, 883 S.W.2d 10, 14 (Mo. 1994) (explaining that "[i]f there is sufficient evidence from which a jury could find that the plaintiff did not already know the danger, there is a presumption that a warning will be heeded" (citing *Arnold v. Ingersoll-Rand Co.*, 834 S.W.2d 192, 194 (Mo. 1992))). The Court will deny Defendants' motion based on the learned intermediary doctrine. Doc. 5821 at 8-11.

C. Fraudulent Concealment Claim (Count XI).

Plaintiff alleges that Defendants fraudulently concealed material facts about the X-Port from Plaintiff and her healthcare providers, including that the device was unsafe and not fit for its intended purpose, that it posed dangerous health risks greater than those associated with other IPCs, and that it was not adequately tested to withstand normal placement within the human body. *See* Doc. 1889 ¶ 428. Plaintiff further alleges that Defendants had a duty to disclose this information due to their superior knowledge of and sole access to the information, and that the information would have been material to her doctor's decision to use the X-Port. *Id.* ¶ 429.

Defendants argue that fraudulent concealment is not a separate tort in Missouri and ask the Court to grant summary judgment on Plaintiff's concealment claim. Doc. 5821 at 14 (citing *Hess v. Chase Manhattan Bank USA, N.A.*, 220 S.W.3d 758, 765 (Mo. 2007)). This appears to be largely a matter of semantics.

In *Hess*, the Missouri Supreme Court said that it "has not recognized a separate tort of fraudulent nondisclosure, such as Hess asserts here." *Id.* But this does not mean that plaintiffs in Missouri cannot sue for material nondisclosures. *Hess* went on to say that in nondisclosure cases, "a party's silence in the face of a legal duty to speak replaces the first element [of a fraudulent misrepresentation claim]: the existence of a representation." *Id.*

Other cases applying Missouri law speak of "fraudulent concealment" claims, but make clear that the elements are the same as fraudulent misrepresentation, with this first element being changed to silence in the face of a legal duty to speak. *See, e.g.*, *Collins v. Metro. Life Ins. Co.*, 117 F.4th 1010, 1018 (8th Cir. 2024) ("Under Missouri and Illinois law, fraudulent concealment has the same requirements as fraud, except that a party's silence is not fraudulent absent a legal duty to speak."); *Tucker v. Ethicon, Inc.*, No. 4:20-CV-1543 RLW, 2021 WL 410058, at *7 (E.D. Mo. Feb. 5, 2021) ("Under Missouri law, a common law claim for fraudulent non-disclosure or concealment falls under the rubric of fraudulent misrepresentation." (citations omitted)); *Doe v. Ratigan*, 481 S.W.3d 36, 45 (Mo. Ct. App. 2015) ("In Missouri, fraudulent nondisclosure is not a separate tort. . . . [F]ailing to speak when the law imposes a duty to do so replaces the essential element of a "false, material representation" in a fraudulent misrepresentation case." (cleaned up)).

Thus, Plaintiff can sue Defendants under Missouri law for fraudulently concealing a material fact. Whether this claim is presented to the jury as a separate claim or a variation of fraudulent misrepresentation can be decided in jury instruction. The Court will not grant summary judgment on Plaintiff's concealment claim.

Defendants contend that there is no evidence that Dr. Cavins relied on any material omission by Defendants in deciding to implant the X-Port. Doc. 5821 at 14. But Dr. Cavins testified that while she did not review the X-Port's IFU on a regular basis, she was familiar with its contents and used it as a reference in making treatment decisions. Doc. 6254-49 at 6-7. And as explained above on the failure to warn claims, Dr. Cavins also testified that before implanting the X-Port, she would have wanted to know if the catheter material could increase the risk of thrombosis and other complications. *Id.* at 18-24.

Construed in the light most favorable to Plaintiff, the evidence presents a triable issue on the fraudulent concealment claim. The Court will deny Defendants' motion on the claim.[9]

[9] Defendants make a new argument in their reply brief – that Plaintiff has not identified a legal duty that required Defendants to speak. Doc. 6414 at 11. The Court will not address an argument made for this first time in a reply brief.

D. Punitive Damages.

Plaintiff seeks punitive damages. Docs. 190 ¶ 15, 1889 ¶¶ 484-87. Defendants rely on Mo. Rev. Stat. § 510.261.1, which provides that punitive damages shall not be awarded unless the plaintiff "proves by clear and convincing evidence that the defendant intentionally harmed the plaintiff without just cause or acted with a deliberate and flagrant disregard for the safety of others." Doc. 5821 at 15.[10] Defendants argue that Plaintiff has no evidence that they deliberately harmed her or acted with deliberate and flagrant disregard for the safety of her or others. Doc. 5821 at 16.

Plaintiff presents evidence that Defendants have known for more than 20 years that they needed to fix problems with their ports, including the need for antithrombotic technology. Doc. 6254 at 16 (citing Doc. 6254-1 ¶ 58). This includes evidence that Defendants knew the risk of thrombus formation was as high as 18% and that thrombosis was a serious and deadly problem, rating 10 out of 10 on internal risk assessments. *Id.* (citing Doc. 6254-1 ¶¶ 59-60, 63-64). Plaintiff further asserts that despite knowing about the increased thrombosis rate, Defendants refused to fully develop and sell a more thrombus-resistant port. *Id.* at 17 (citing Doc. 6254-1 ¶¶ 80-123, 142-67).

This evidence, if believed by a jury, could reasonably support a finding that Defendants acted with a deliberate and flagrant disregard for the safety of Plaintiff and

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[10] MAI 10.0 states that punitive damages may be awarded where the conduct of defendant was "outrageous because of defendant's evil motive or reckless indifference to the rights of others[.]" Other MAIs state that punitive damages may be awarded where the conduct of the defendant showed "complete indifference to or conscious disregard for the safety of others[.]" MAI 10.02 (negligence); 10.04 and 10.05 (strict liability product defect and/or failure to warn); 10.06 (negligence and strict liability). The Committee's comment to the punitive damages instructions notes that § 510.261.1 "purports to effect changes to the law of punitive damages[.]" MAI 10.00. The Committee took no position, however, because [c]ase law will determine the extent of those changes and the impact on jury instructions[.]" *Id.* Missouri courts have not yet decided whether the punitive damages instructions in the MAIs are inconsistent with § 510.261.1. *See Reyna Hotel Corp. v. Lotus Hosp. Mgmt., LLC*, 714 S.W.3d 423, 443 (Mo. Ct. App. 2025) ("Rather than prove the punitive damages instructions submitted to the jury misstated the law, Defendants simply ask this Court to presume reversible error occurred based on their unsupported interpretation of the language in the instruction and section 510.261.1. As a result, we find Defendants have failed to carry their burden on appeal to establish reversible error.").

other patients who received X-Port IPCs. The Court will deny Defendants' motion on punitive damages. Doc. 5821 at 15-16.[11]

IT IS ORDERED that Defendants' motion for summary judgment (Doc. 5821) is **denied**.

Dated this 26th day of October, 2026.

David G. Campbell
Senior United States District Judge

[11] Defendants note that Plaintiff's medical experts continue to place Bard IPCs and that none of the experts opine that the risks of Bard IPCs outweigh their benefits. *Id.* at 16. Defendants will be free to make these arguments to the jury, but they are not sufficient for summary judgment.