

**UNITED STATES DISTRICT COURT
DISTRICT OF MAINE**

JANICE NOVAK,)	
)	
Plaintiff,)	
)	
v.)	Docket No. 2:17-cv-00328-NT
)	
MENTOR WORLDWIDE LLC,)	
)	
Defendant.)	

ORDER ON DEFENDANT’S MOTION FOR SUMMARY JUDGMENT

In this products liability action, Plaintiff Janice Novak (“**Ms. Novak**”) has asserted nine claims related to injuries that she allegedly sustained from a transobturator sling called ObTape (the “**ObTape**”) manufactured by Defendant Mentor Worldwide LLC (“**Mentor**”). This matter comes before me on Mentor’s motion for summary judgment. (ECF No. 5.) For the reasons set out below I **GRANT** Mentor’s motion.

PROCEDURAL BACKGROUND

Ms. Novak is one of dozens of individuals who have brought suit against Mentor for injuries allegedly caused by the ObTape. On December 3, 2008, the Panel on Multidistrict Litigation consolidated the Mentor ObTape cases before Chief Judge Land of the District Court for the Middle District of Georgia. Order, *In re Mentor Corp. ObTape Transobturator Sling Prods. Liab. Litig.* (“*In re Mentor*”), No. 4:08-md-2004-CDL (M.D. Ga. Dec. 3, 2008) (ECF No. 1). On January 14, 2016, Ms. Novak filed her Complaint in the Middle District of Georgia pursuant to a direct-filing order

issued by Chief Judge Land on December 12, 2011. Compl. ¶ 3 (ECF No. 1); *see* Stipulation and Order Regarding Direct Filing, *In re Mentor*, No. 4:08-md-2004-CDL (M.D. Ga. Dec. 12, 2011) (ECF No. 446). In her Complaint, Ms. Novak averred that but for the direct-filing order she would have filed her action in this Court. Compl. ¶ 3.

On April 24, 2017, Mentor moved for summary judgment on all of Ms. Novak's claims. Def.'s Mot. for Summ. J. 1. The parties completed briefing on Mentor's summary judgment motion on May 15, 2017. On August 16, 2017, Judge Land found that the parties' briefing raised a dispute regarding when Ms. Novak's claims accrued under Maine law. Order of Transfer 2 (ECF No. 9). Judge Land accordingly transferred Ms. Novak's action to this Court. Order of Transfer 2.

On November 28, 2017, I issued an order pursuant to Federal Rule of Civil Procedure 56(e)(4) requiring Ms. Novak to supplement the record. (ECF No. 26.) After Ms. Novak responded to that order, I permitted the parties to exchange brief memoranda regarding Ms. Novak's evidentiary submissions. Pl.'s Notice of Filing (ECF No. 27); Mot. to File Under Seal Dep. Tr. of Dr. Krishna M. Bhatta (ECF No. 28); Def.'s Resp. to Pl.'s Notice of Filing (ECF No. 32) ("**Def.'s Supp. Resp.**"); Pl.'s Reply to Def.'s Resp. to Notice of Filing (ECF No. 35) ("**Pl.'s Supp. Reply**"). I heard oral argument on Mentor's motion on February 2, 2018.

FACTUAL BACKGROUND

On November 10, 2004, Ms. Novak underwent surgery at Reddington Fairview Hospital in Skowhegan, Maine to implant an ObTape. Def.'s Separate Statement of Material Facts ¶ 1 (ECF No. 5-2) ("**DSMF**"). The ObTape was intended to treat Ms.

Novak's stress urinary incontinence. DSMF ¶ 1. Ms. Novak's surgeon, Dr. Krishna Bhatta, has testified that he cannot recall any specific representations that Mentor made to him regarding the ObTape sling, including any warnings regarding risks specific to that device. Pl.'s Additional Facts ¶ 13 (ECF No. 6-1 at 7-9) ("PSMF").¹ However, Dr. Bhatta was aware at the time of Ms. Novak's surgery that, as a general matter, implanting a foreign object into a human abdomen is associated with risks that include infection and abscess, erosion, pain during vaginal intercourse (in medical parlance, dyspareunia), postoperative pain, bleeding, irritable bowel symptoms, urgency, stress urinary incontinence, and vaginal or pelvic pain. DSMF ¶ 2. Dr. Bhatta warned Ms. Novak of these risks before he performed her ObTape surgery. Bhatta Dep. Tr. 32 (ECF No. 28-2).

¹ Mentor failed to include the language of any warning associated with the ObTape in its statement of facts or exhibits. However, Mentor's opening memorandum referred me to the following finding by Judge Land in connection with the ObTape MDL:

Every ObTape package included a Product Insert Data Sheet ("PIDS") which contained the following statement regarding "Adverse Reactions":

No undesirable effects that could be directly attributed to the polypropylene fibers have been reported in the literature. As with all foreign bodies, the ObTape is likely to trigger any existing infection, which can result in fistular formation and/or expulsion of the device. The following events have been reported *very rarely*:

Vaginal Erosion

Urethral Erosion

Infection

Patients should be monitored regularly after the device has been implanted.

No undesirable effects directly attributed to materials used in the Introducer Needles have been reported in the literature.

Order at 4-5, No. 4:08-md-2004-CDL (M.D. Ga. Apr. 22, 2010) (ECF No. 241) (cited in Def.'s Mem in Support of Mot. for Summ. J. 1 (ECF No. 5-1)).

Ms. Novak claims that she experienced several of these symptoms as a result of her ObTape. DSMF ¶ 3. Shortly after her ObTape surgery, Ms. Novak began experiencing lower abdominal pain. DSMF ¶ 4. Between eight months to one year after the surgery—toward the end of 2005—Ms. Novak began experiencing pain during sexual intercourse. DSMF ¶ 5; PSMF ¶ 4. And sometime before the end of 2006, Ms. Novak began to experience vaginal leaking and vaginal bleeding. DSMF ¶ 6; PSMF ¶ 5.

Within two years of her surgery—before the end of 2006—Ms. Novak went back to Dr. Bhatta and told him that she was experiencing abdominal pain. PSMF ¶ 2. Dr. Bhatta did not know what was causing Ms. Novak’s pain and ordered several tests. PSMF ¶ 2. Ms. Novak underwent one inconclusive round of testing but she did not complete the tests because she found them embarrassing. *See* Novak Dep. Tr. 7-8 (ECF No. 7-1). Ultimately, Dr. Bhatta did not provide Ms. Novak with a diagnosis. PSMF ¶¶ 2, 3. Ms. Novak later consulted her regular physician, Dr. Michael MacDonald, who also did not offer an opinion on the cause of her abdominal pain. PSMF ¶ 3.

It was not until 2013 that Ms. Novak first attributed her abdominal pain, dyspareunia, and vaginal leaking and bleeding to the ObTape. PSMF ¶ 10. On April 24, 2014, Ms. Novak underwent surgery at Broward Outpatient Center in Pompano Beach, Florida, during which Dr. Earle Pescatore removed part of her ObTape. DSMF ¶ 7.

LEGAL STANDARD

Summary judgment is appropriate when there is no genuine dispute of material fact and the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(a). A dispute is genuine where a reasonable jury could resolve the point in favor of either party. *Oahn Nguyen Chung v. StudentCity.com, Inc.*, 854 F.3d 97, 101 (1st Cir. 2017). A fact is material where it could influence the outcome of the litigation. *Id.* The moving party may establish that there is no genuine dispute of material fact by “affirmatively produc[ing] evidence that negates an essential element of the non-moving party’s claim,” or by “using ‘evidentiary materials already on file . . . [to] demonstrate that the non-moving party will be unable to carry its burden of persuasion at trial.’ ” *Ocasio-Hernandez v. Fortuño-Burset*, 777 F.3d 1, 4-5 (1st Cir. 2015) (citation omitted). This burden “may be discharged by ‘showing’—that is, pointing out to the district court—that there is an absence of evidence to support the nonmoving party’s case.” *Celotex Corp. v. Catrett*, 477 U.S. 317, 325 (1986).

On a motion for summary judgment, courts must construe the record in the light most favorable to the non-movant and resolve all reasonable inferences in the non-movant’s favor. *Burns v. Johnson*, 829 F.3d 1, 8 (1st Cir. 2016). Conversely, “neither conclusory allegations, improbable inferences, and unsupported speculation, nor brash conjecture coupled with earnest hope that something concrete will materialize, is sufficient to block summary judgment.” *J. Geils Band Emp. Benefit Plan v. Smith Barney Shearson, Inc.*, 76 F.3d 1245, 1251 (1st Cir. 1996) (marks and citations omitted); *see also Griggs-Ryan v. Smith*, 904 F.2d 112, 115 (1st Cir. 1990)

“A genuine issue of material fact does not spring into being simply because a litigant claims that one exists.”).

DISCUSSION

Mentor has moved for summary judgment on all of Ms. Novak’s claims, advancing three principal arguments: 1) that Ms. Novak’s claims for negligence, defective design, manufacturing defects, failure-to-warn, breach of implied warranties, breach of express warranties, and negligent misrepresentation (Counts I-VI, IX) are time-barred under Maine’s statute of limitations; 2) that Ms. Novak’s “failure-to-warn” claims (part of Count I and Counts IV, VII-IX) fail because she has not adduced evidence of causation, which is an essential element of those claims; and 3) that Ms. Novak’s fraudulent misrepresentation, fraudulent concealment, and negligent misrepresentation claims (Counts VII-IX) fail because she has not provided evidence that she suffered a pecuniary loss, which is an essential element of all three claims.

I. Whether Counts I-VI and IX are Time-Barred under Maine’s Statute of Limitations

The parties do not dispute that Maine law applies to Ms. Novak’s claims. Def.’s Mem. in Support of Mot. for Summ. J. 3 (ECF No. 5-1) (“**Def.’s Mem.**”); Pl.’s Opp’n to Def.’s Mot. for Summ. J. 3-7 (ECF No. 6) (“**Pl.’s Opp’n**”). Under Maine’s limitations statute, “[a]ll civil actions shall be commenced within 6 years after the cause of action accrues and not afterwards.” 14 Me. Rev. Stat. § 752; *see also Johnston v. Dow & Coulombe, Inc.*, 686 A.2d 1064, 1065 n.1 (Me. 1996).

Under the general rule in Maine, a cause of action accrues “at the time a judicially cognizable injury is sustained.” *Dugan v. Martel*, 588 A.2d 744, 746 (Me. 1991). In tort actions, the cause of action is said to accrue when “a wrongful act produces an injury for which a potential plaintiff is entitled to seek judicial vindication.” *Id.* Under this date-of-injury rule, “mere ignorance of a cause of action does not prevent the statute of limitations from running.” *Id.*; *see also Descoteau v. Analogic Corp.*, 696 F. Supp. 2d 138, 140 (D. Me. 2010) (under Maine’s statute of limitations, “[i]t is irrelevant whether the plaintiff is aware of his injury and/or the extent of his damages”). While the rule may seem harsh, statutes of limitations represent public policy decisions by state legislatures that balance several competing interests. As the Law Court has explained:

First, parties injured by the actions of others must be afforded an opportunity to pursue their meritorious claims and seek relief in the courts. On the other hand, potential defendants are entitled to eventual repose and to protection from being required to meet claims which could have been addressed more effectively if asserted more promptly. Difficulties in defending stale claims are caused by faded memories, dead or otherwise unavailable witnesses, and lost or destroyed evidence. Additionally, several courts have attributed to statutes of limitations the function of filtering out those claims which are spurious, inconsequential, and unfounded, because meritorious claims are not usually allowed to remain neglected. The intended effect, then, of statutes of limitations is to stimulate activity and to punish negligence and slumber.

Myrick v. James, 444 A.2d 987, 994 (Me. 1982) (citations omitted) *superseded by statute on other grounds* by P.L. 1985, ch. 804, §§ 13, 22 (effective Aug. 1, 1988) (codified at 24 Me. Rev. Stat. § 2902 (2011)), *as recognized in Choroszy v. Tso*, 647 A.2d 803, 807 (Me. 1994); *see also Erlich v. Ouellette, Labonte, Roberge & Allen, P.A.*, 637 F.3d 32, 37 (1st Cir. 2011) (“Departures from Maine’s date-of-injury rule are rare.

They have involved careful balancing between competing interests of fairness and repose, and the opinions have not always been unanimous.”).

On rare occasions, Maine courts apply a “discovery rule” exception to the general date-of-injury rule.² Under the discovery rule exception, a claim does not accrue until the plaintiff discovers the defendant’s misconduct. The Law Court has strictly limited the discovery rule’s application to “three discrete areas: legal malpractice, foreign object and negligent diagnosis medical malpractice, and asbestosis.” *Johnston*, 686 A.2d at 1066. When it has applied the discovery rule, the Law Court has been moved by situations in which the plaintiff did not and could not know of her injury. For example in *Anderson v. Neil*, the court adopted a discovery rule exception in actions for negligent title search, a form of legal malpractice. 428 A.2d 1189, 1192 (Me. 1981). The Law Court has since described its holding in *Anderson* as follows:

[A]pplication of the discovery rule is appropriate only when there exists a fiduciary relationship between the plaintiff and defendant, the plaintiff must rely on the defendant’s advice as a fiduciary, and the cause of action was virtually undiscoverable absent an independent investigation that would be destructive of the fiduciary relationship.

Nevin v. Union Tr. Co., 726 A.2d 694, 699 (Me. 1999). Likewise in *Myrick v. James*, the Law Court found it appropriate to apply a discovery rule exception in foreign object malpractice actions³ because a patient necessarily places complete trust in her

² The Maine Legislature has also enacted laws that have applied the discovery rule to certain limited causes of action, none of which are advanced here. *See, e.g.*, 14 Me. Rev. Stat. § 751–E (2003) (claims for damages based on profits of crime accrue when loss is discovered).

³ The Maine Legislature later codified the discovery rule for foreign object malpractice actions and simultaneously foreclosed any further judicial expansion of the discovery rule in the area of

surgeon, and because “the presence of the foreign-object and thus the plaintiff’s awareness of an act asserted to be negligent remained *unknown and unknowable* until” after the statute of limitations period had run. 444 A.2d 987, 995 (Me. 1982).

The Law Court has also acknowledged the continuing tort doctrine, which provides plaintiffs with another possible refuge from the harshness of the date-of-injury rule. Courts have applied Maine’s continuing tort doctrine where “no single incident in a chain of [tortious] activity can fairly or realistically be identified as the cause of significant harm.” *Frontier Commc’ns Corp. v. Barrett Paving Materials, Inc.*, 631 F. Supp. 2d 110, 115 (D. Me. 2009) (quoting *McLaughlin v. Superintending Sch. Comm. of Lincolnville*, 832 A.2d 782, 789 n.6 (Me. 2003)) (applying continuing tort doctrine where complaint described a series of incidents spanning 20 years during which contaminants were allegedly spilled onto the ground or into the river near a rail yard). “In such cases, the breach of duty is regarded as a single continuing wrong that terminates when the exposure to the harm terminates.” *Id.* (quoting *McLaughlin*, 832 A.2d at 789 n.6). The Law Court has yet to apply the continuing tort doctrine outside of an action involving a continuing trespass or nuisance. It has also refused to apply the doctrine when the cause of a plaintiff’s injuries was a single act of negligence. *See Dugan*, 588 A.2d at 745-46 (plaintiff’s claim was time-barred where

medical malpractice. *Choroszy v. Tso*, 647 A.2d 803, 807 (Me. 1994) (discussing history of 24 Me. Rev. Stat. § 2902 (2003)).

Ms. Novak’s claims are not the same as claims for foreign object malpractice, which arise when a doctor unintentionally leaves an object in a patient’s body. In fact, when Maine’s legislature codified the discovery rule for foreign object malpractice actions they expressly excluded cases like Ms. Novak’s. 24 Me. Rev. Stat. § 2902 (foreign object malpractice discovery rule does not apply where “[an] object [was] intentionally implanted or permitted to remain in the patient’s body as a part of the health care or professional services”).

defendant's negligent installation of insulation caused walls to rot and cellulose dust to leak into home continuously and was not saved by the facts that harms were continuing in nature or that plaintiff did not become aware of the scope of the injury until later). In *Dugan*, the Law Court found that the ongoing nature of the harm did not toll the statute of limitations because—unlike, for example, an action alleging a pattern or practice of discriminatory behavior—the plaintiff's injuries were caused “only by [the defendant's] single negligent installation job in October of 1981, not by separate and discrete acts on his part occurring afterward.” *Id.* at 746; *see also Kelleher v. Boise Cascade Corp.*, 676 F. Supp. 22, 25 (D. Me. 1988) (claim time-barred where plaintiff “had notice of his injuries immediately after his exposure to the hazardous substance. . . . His right to seek recovery for that injury was not prejudiced by his inability to determine the exact scope of his injuries.”).

Here, Mentor asserts that Maine's six-year limitations period applies to bar Ms. Novak's claims for negligence, defective design, manufacturing defects, failure-to-warn, breach of implied warranties, breach of express warranties, and negligent misrepresentation. Def.'s Mem. 1. As Ms. Novak filed suit on January 14, 2016, those claims are time-barred if they accrued before January 14, 2010. Def.'s Mem. 6-7. Mentor claims that it is undisputed that Ms. Novak began to experience the same symptoms that she has attributed to the ObTape—abdominal pain, vaginal bleeding, vaginal leaking, and dyspareunia—no later than two years after her initial ObTape surgery on November 11, 2004. PSMF ¶¶ 1, 4, 6, 8. Mentor argues that because Ms. Novak therefore sustained an injury for which she could have sought judicial

vindication no later than November 11, 2006, that is the latest date on which her claims could have accrued.

In response, Ms. Novak initially argued that Maine's date-of-injury rule does not apply to this action because the "Obtape was a condition . . . which caused continuous harm to Ms. Novak for the entire time that the device remained implanted." Pl.'s Opp'n 5. She claimed that the ObTape's presence in her body therefore constituted a continuing tort and that the statute of limitations was tolled until she had the ObTape removed in 2014. Pl.'s Opp'n 7.⁴ In her supplemental brief Ms. Novak raised a new claim that a genuine dispute exists regarding when the ObTape first caused her injuries. Pl.'s Supp. Reply 1. Ms. Novak asserts that Mentor has produced no evidence that her symptoms in late 2006 were caused by the ObTape. Pl.'s Supp. Reply 1. Although she complains of the same symptoms now, she argues, essentially, that her early symptoms may have had a different cause.

Ms. Novak's claim does not fall within the bounds of Maine's continuing tort doctrine. She has not alleged that Mentor took repeated wrongful actions that, in aggregate or in unidentifiable part, ultimately caused her harm. Instead, she has alleged that there was some finite act or set of acts (manufacture, design, inadequate warning, or misrepresentation) that led to her injuries.⁵ This case aligns most closely

⁴ Ms. Novak relied in part on a pair of decisions by the Federal District Courts of Georgia, both of which applied a version of the continuing tort doctrine followed under Georgia law. Pl.'s Opp'n 5-6 (citing *Wheeler v. Novartis Pharm. Corp.*, 944 F. Supp. 2d 1344 (S.D. Ga. 2013); *Carr v. Ethicon*, No. 11 Civ. 2217, 2011 WL 4424457 (N.D. Ga. Sept. 20, 2011)). At oral argument, Ms. Novak's counsel conceded that Georgia applies a very different accrual rule from the rules applicable in Maine. These cases are accordingly inapposite.

⁵ Ms. Novak also invokes the continuing treatment doctrine, which tolls the statute of limitations for medical malpractice claims until the end of a physician/patient relationship. Pl.'s Opp'n

with *Dugan*,⁶ where the Law Court refused to apply the continuing tort doctrine despite ongoing harm and found that the statute of limitations began to run when cracks appeared in the siding and nails began to protrude three days after the contractor finished the job. In this case, Ms. Novak first began to experience symptoms of abdominal pain shortly after the operation in 2004, and pain during sexual intercourse, vaginal leaking, and vaginal bleeding began all before the end of 2006. By that time, at the latest, the statute of limitations had begun to run.⁷

5-6. Similar to the continuing tort doctrine, the Law Court has found that the continuing treatment doctrine may apply if a plaintiff's claim "arises from two or more related acts or omissions by a single health care provider or practitioner where each act or omission deviated from the applicable standard of care and, to at least some demonstrable degree, proximately caused the harm complained of." *Baker v. Farrand*, 26 A.3d 806, 816 (Me. 2011). As discussed above, however, this case does not involve repeated tortious actions that continued into the limitations period, and the continuing treatment doctrine does not save Ms. Novak's claims.

⁶ At oral argument, Ms. Novak's counsel pressed the point that *Dugan* is distinguishable and that the continuing tort doctrine should apply here because Ms. Novak's ObTape degenerated over time and Mentor can therefore point to no one, critical moment when Ms. Novak's injury began. Counsel directed my attention to *Wilcox v. City of Portland*, No. CV-06-444, 2008 WL 6630061 (Me. Super. Ct. Sept. 10, 2008). In *Wilcox*, the plaintiffs claimed to have suffered various illnesses after being exposed to airborne biotoxins in Portland's former International Marine Terminal. *Id.* at 1. Most of the plaintiffs had worked in the terminal for at least two days during the statute of limitations period. *Id.* at 10. The court first found that it was not necessary to apply the continuing tort doctrine to save those plaintiffs' claims. The court noted that the defendant had not eliminated the possibility that the plaintiffs' exposures during the limitations period caused them additional medical harms. *Id.* at 12. Therefore, the court considered the plaintiffs' final day of exposure to be their date of injury under Maine's ordinary accrual rule. *Id.* After observing that the plaintiffs' injuries during those final exposures might well be negligible, the court went on to find that it would be appropriate to apply the continuing tort doctrine to the case at bar, "where the harm is caused by the cumulative effect of the mold conditions for which the [defendant] allegedly bears responsibility, where no single incident can realistically be identified as the cause of significant harm, and where the result is a continuing wrong that terminates when the exposure to the harm terminates." *Id.* at 12 n.16.

Wilcox is inapposite. Unlike the *Wilcox* plaintiffs, Ms. Novak underwent only one, readily-identifiable exposure to the ObTape (her surgery), and all of Mentor's allegedly tortious conduct took place before that point. Like the contractor-defendant and the plaintiff's home in *Dugan*, Mentor's wrongful conduct may have caused the ObTape to deteriorate, which in turn may have caused injuries over time. However, once those injuries had manifested, the fact that their full scope remained unknown did not stop the statute of limitations from running. *See Dugan*, 588 A.2d at 746.

⁷ Ms. Novak's argument that her early symptoms were "too isolated or inconsequential to trigger the running of the Statute of Limitations," Pl.'s Supp. Reply 4, is unavailing. The case on which Ms. Novak relies for this proposition was decided under New York law and applied that state's discovery rule. *See Grill v. Philip Morris USA, Inc.*, 653 F. Supp. 2d 481 (S.D.N.Y. 2009). As discussed above, no

The Plaintiff's additional claim—raised in her supplemental briefing—that there is a genuine dispute over whether her 2004–2006 symptoms were caused by the ObTape also is without merit. Mentor has provided evidence that the ObTape caused her early symptoms, and Ms. Novak has been unable to point to any contradictory evidence that would establish a genuine dispute. As Mentor explained in its opening brief, Def.'s Mem. 6, Ms. Novak's own expert, Dr. Christopher Walker, reported that Ms. Novak experienced bleeding, dyspareunia, and pelvic pain “[s]hortly after her implant,” and that in his medical opinion Ms. Novak's symptoms “are complications of her ObTape implant.” Walker Report 3 (ECF No. 5-8). Dr. Walker's report therefore serves as evidence that the symptoms Ms. Novak experienced shortly after her surgery were caused by her ObTape.⁸ The only evidence that Ms. Novak offers to dispute her own expert's opinion is the fact that neither Dr. Bhatta nor Dr.

similar rule applies here. To the contrary, under Maine law the statute of limitations begins to run even if the plaintiff could only access nominal damages at the time of their initial injury. *Rared Manchester NH, LLC v. Rite Aid of N.H., Inc.*, 693 F.3d 48, 52 (1st Cir. 2012); *see also Williams v. Ford Motor Co.*, 342 A.2d 712, 716 (Me. 1975) (“[A] cause of action arises when a wrongful act is coupled with an injury, no matter how slight.”).

⁸ Were there any doubt as to whether Dr. Walker's report was addressing Ms. Novak's early symptoms, Ms. Novak's own testimony would dispel it: Dr. Walker attributed Ms. Novak's dyspareunia to her ObTape even though Ms. Novak admittedly had not had sex for “eight [or] nine years” as of her February 9, 2017 deposition. Novak Dep. Tr. 5 (ECF No. 5-5). Ms. Novak's own testimony therefore suggests that she first experienced symptoms that her own medical expert has specifically attributed to the ObTape no later than February of 2009—well before the January 2010 accrual cutoff.

This evidence also differentiates this action from *Sturgeon v. Marois Bros.*, on which Ms. Novak relies. 511 A.2d 1065 (Me. 1986); *see* Pl.'s Supp. Reply 2. In that case, the only “evidence” that the same negligent conduct had caused two injuries occurring years apart was the plaintiff's belief that the two events were related. 511 A.2d at 1066. Ms. Novak's reliance on *Townsend v. Chute Chem. Co.*, 691 A.2d 199 (Me. 1997), is similarly misplaced. *Townsend* reversed a trial court's grant of judgment as a matter of law to the defendant because, unlike Ms. Novak, the *Townsend* plaintiff had offered testimony about the accrual date of her injury that contradicted other evidence in the record. *Id.* at 202.

MacDonald drew any connection between her symptoms and the ObTape when she saw them in 2006. Pl.'s Supp. Reply 3.

The question before me is whether, on this evidence, a reasonable juror could find that the symptoms Ms. Novak experienced before January 14, 2010 were caused by something other than the ObTape.⁹ Even drawing all reasonable inferences in Ms. Novak's favor, I find that conclusion to be unsupported. There is no evidence that Dr. Bhatta or Dr. MacDonald made any finding that contradicted Dr. Walker's later determination that Ms. Novak's symptoms were caused by the ObTape. Instead, the evidence shows that Dr. Bhatta's initial testing on Ms. Novak was inconclusive, and that she refused to return for further tests. *See* Novak Dep. Tr. 7-8 (ECF No. 7-1). As to Dr. MacDonald, there is no evidence in the record regarding his treatment of Ms. Novak beyond Ms. Novak's testimony that she spoke to him about her lower abdominal pain and that Dr. MacDonald prescribed Detrol to help with her vaginal leaking. Novak Dep. Tr. 9. On this record, a jury could not infer that something other than the ObTape caused Ms. Novak's symptoms without engaging in complete speculation. In such instances, summary judgment is appropriate. *J. Geils Band Emp. Benefit Plan*, 76 F.3d at 1251.¹⁰

⁹ Ms. Novak argues that to succeed on its motion Mentor must establish a specific accrual date as a matter of law. Pl.'s Supp. Reply 4. Ms. Novak cites no authority for this assertion and even a cursory search of the caselaw reveals that Maine's courts do not require such exactitude. *See, e.g., Halliday v. Henry*, 116 A.3d 1270, 1272 (Me. 2015) (granting summary judgment where the record established that plaintiff's claims accrued "no later than 2005").

¹⁰ Ms. Novak has given me no reason to push against the boundaries of Maine's statute of limitations jurisprudence. Ms. Novak was informed of the possible risks of her implantation surgery. When within two years she experienced symptoms similar to those of which she had been warned, Ms. Novak went back to her surgeon. And when Ms. Novak's surgeon told her that she would need to undergo certain tests for a diagnosis, she refused additional testing. On these facts, Ms. Novak cannot claim the "blameless ignorance" that has supported application of the discovery rule. *See Myrick*, 444

For the foregoing reasons, I find that Counts I-VI and IX of Ms. Novak's Complaint are barred by Maine's statute of limitations, and I grant Mentor's motion for summary judgment on those counts.

II. Whether Ms. Novak Has Presented Evidence of Causation Sufficient to Support her Failure-to-Warn Claims (Counts I, IV, VII-IX)

Mentor asserts that it is entitled to summary judgment on Ms. Novak's claims that are "premised on a failure to warn" because Ms. Novak has failed to develop any evidence that Mentor's failure to warn of the ObTape's risks proximately caused Ms. Novak's injuries.¹¹ Def.'s Mem. 7. Specifically, Mentor argues that Ms. Novak has no evidence that an alternative warning or representation would have changed Dr. Bhatta's decision to use the ObTape to treat her. Def.'s Mem. 8.

To survive a motion for summary judgment on a failure-to-warn claim, a plaintiff must show that an "inadequate warning proximately caused the plaintiff's

A.2d at 995; *see also Erlich*, 637 F.3d at 37 ("Applying a discovery rule in these circumstances would represent a significant step in expanding Maine law that we decline to take.").

¹¹ These include Ms. Novak's strict liability failure-to-warn, fraudulent misrepresentation, fraudulent concealment, and negligent misrepresentation claims, and a portion of her negligence claim. Mentor's motion treats this set of claims collectively, and Ms. Novak has not objected to this characterization. Moreover this appears to be a reasonable reading of Ms. Novak's theories of liability. Count I, Ms. Novak's negligence count, alleges in part that Mentor breached "a duty to Plaintiff to adequately warn her and her treating physicians, of the risks associated with the Ob/Tape." Compl. ¶ 24 (ECF No. 1). Count IV is a straightforward failure-to-warn claim. Compl. ¶¶ 44-56. Count VII—Fraudulent Misrepresentation—alleges that Mentor falsely represented that the ObTape had been tested and found to be safe for treatment of female urinary incontinence. Compl. ¶¶ 75-76. Count VIII—Fraudulent Concealment—alleges that Mentor misrepresented that the ObTape was safe for its intended use. Compl. ¶ 86. And Count IX—Negligent Misrepresentation—alleges that Mentor negligently misrepresented the ObTape's "high risk of unreasonable, dangerous side effects." Compl. ¶ 98. In light of the foregoing, I have adopted the parties' joint treatment of these counts as "predicated on a failure to warn." *See Doe v. Solvay Pharm., Inc.*, 350 F. Supp. 2d 257, 262, 274 & nn.7, 12 (D. Me. 2004) (on defendant's motion for summary judgment, considering plaintiff's claims for deceptive trade practices, failure to warn, and fraudulent misrepresentation collectively because those counts were "premised on a failure to warn"), *aff'd Doe v. Solvay Pharm., Inc.*, 153 F. App'x 1 (1st Cir. 2005).

injury.” *Pottle v. Up-Right, Inc.*, 628 A.2d 672, 675 (Me. 1993). Under Maine law, “[p]roximate cause is generally a question of fact for the jury, but the court has a duty to direct a verdict for the defendant if the jury’s deliberation [would] rest[] only on speculation or conjecture.” *Merriam v. Wanger*, 757 A.2d 778, 781 (Me. 2000); *see also Koken v. Black & Veatch Const., Inc.*, 426 F.3d 39, 49 (1st Cir. 2005) (applying Maine law and granting summary judgment to the defendant on plaintiff’s failure-to-warn claim because there was no evidence regarding the possible consequences of the plaintiff’s proposed alternative warning).

In *Merriam v. Wanger*, a medical malpractice action, the Law Court vacated a judgment in favor of the plaintiff because the court found that the plaintiff had failed to present any evidence of proximate cause. 757 A.2d at 782. The court noted that while the plaintiff’s experts had testified to the foreseeable risks caused by the defendant doctor’s failure to properly diagnose the plaintiff, “neither expert testified that [the plaintiff’s] damages would have been avoided had [the defendant] acted properly, and neither was directly asked that question.” *Id.* The court further explained that “[a]llowing a jury to infer causation on complex medical facts without the aid of expert testimony on the subject and without some showing that Wanger’s conduct was ‘more likely than not’ a cause of Merriam’s injury, stretches the jury’s role beyond its capacity.” *Id.*

“It is generally accepted that in a case involving medical products prescribed or used by a physician or trained medical personnel, the warning runs to the physician not the patient.” *Knowlton v. Deseret Med., Inc.*, 930 F.2d 116, 120 n.2 (1st

Cir. 1991). That is, a manufacturer fulfills its duty to warn a consumer of the dangers inherent in a product when the manufacturer has adequately warned the consumer's physician. *See Garside v. Osco Drug, Inc.*, 976 F.2d 77, 80 (1st Cir. 1992). The parties agreed during oral argument that this "learned intermediary" rule applies here.¹² Where the learned intermediary rule applies, "to create a jury question, the evidence must be of sufficient weight to establish . . . at least some reasonable likelihood that an adequate warning would have prevented the plaintiff from receiving the [medical product]." *Doe v. Solvay Pharm., Inc.*, 350 F. Supp. 2d 257, 273 (D. Me. 2004) (quoting *Thomas v. Hoffman-LaRoche, Inc.*, 949 F.2d 806, 812 (5th Cir. 1992)).

The parties do not dispute that when Dr. Bhatta performed Ms. Novak's surgery, he was aware of various risks inherent in the implantation of any foreign object into the human body. DSMF ¶ 2. Mentor argues that Ms. Novak's claimed injuries are simply the manifestation of those known risks, and that Ms. Novak has no evidence that an additional warning would have altered Dr. Bhatta's decision to implant the ObTape.

Ms. Novak initially responded by asserting that Dr. Bhatta "may very well have decided not to use the ObTape if he had been informed about the foreseeable risks associated with the device, such as ObTape's greater risk of erosion as compared

¹² While the Law Court has yet to adopt the learned intermediary rule, the First Circuit has repeatedly found that the Law Court would likely apply the rule in medical products liability actions. *E.g. Violette v. Smith & Nephew Dyonics, Inc.*, 62 F.3d 8, 13 (1st Cir. 1995); *Doe v. Solvay Pharm., Inc.*, 153 F. App'x 1, 3 (1st Cir. 2005); *see also Tardy v. Eli Lilly & Co.*, CV-03-538, 2004 WL 1925536, *2 (Me. Super. Ct. 2004) (following an "overwhelming majority" of jurisdictions" and applying the learned intermediary rule).

to other slings.” Pl.’s Resp. 7-8.¹³ Ms. Novak’s unsupported assertion of fact and speculation regarding what a witness might say at trial are, of course, not evidence. I therefore permitted Ms. Novak an opportunity to submit evidence into the record to support her otherwise bald assertion. In response, Ms. Novak produced a set of academic articles that discuss the ObTape and Dr. Bhatta’s complete deposition transcript.

Even with this additional evidence, Ms. Novak has failed to establish a genuine issue of fact regarding proximate cause. The articles that Ms. Novak has submitted do suggest that the ObTape is associated with higher rates of certain complications than other sling products, including vaginal erosion and impaired vaginal healing. *See, e.g.*, Pl.’s Notice of Filing 5 (ECF No. 27-3) (concluding that the ObTape “is effective in curing or improving stress incontinence; however, a troubling incidence of impaired vaginal healing and mesh extrusion has been recognized”). However, Ms. Novak has offered no evidence whatsoever that this information would have changed Dr. Bhatta’s decision to treat Ms. Novak using the ObTape. The information presented in Ms. Novak’s supplemental exhibits is not so one-sided that a lay jury could reasonably assume, without any further context, that it would have altered Dr. Bhatta’s assessment of the ObTape’s risks. And Dr. Bhatta’s deposition transcript reflects that Ms. Novak’s counsel failed to ask him whether additional information

¹³ Ms. Novak’s counsel advanced a different theory at oral argument, claiming that Dr. Bhatta was not aware of a risk that the ObTape could degrade inside a patient’s body. This discussion of degradation appears nowhere in Ms. Novak’s briefing on proximate cause. Moreover, counsel could provide no record support for the proposition that if Dr. Bhatta had been made aware of the risk of degradation, he would not have proceeded with Ms. Novak’s surgery.

would have altered his decision to go ahead with Ms. Novak's ObTape surgery. *See generally* Bhatta Dep. Tr.¹⁴

Ms. Novak's counsel conceded at oral argument that there is a "paucity" of evidence in the record to support the proposition that Dr. Bhatta would have changed his decision to treat Ms. Novak using the ObTape if Mentor had warned him of additional risks. Counsel further conceded that to put such evidence into the record, they would need to submit an additional declaration or to question Dr. Bhatta at trial. Neither route is available to Ms. Novak. While Ms. Novak might have presented an additional declaration during summary judgment briefing, her counsel failed to do so even after I offered them an opportunity to supplement the record and despite having been on notice of this evidentiary gap since the day they received Mentor's opening brief. Nor is waiting until trial to develop evidence an option for a party faced with a motion for summary judgment. *See Celotex Corp.*, 477 U.S. at 322.

Absent any evidence of how Dr. Bhatta would have responded to an additional or different warning, I find that Ms. Novak has failed to satisfy her burden to establish that a genuine issue of material fact exists regarding proximate cause on

¹⁴ Contrary to Ms. Novak's supposition, Pl.'s Opp'n 8, it was her burden to develop evidence sufficient to make out her own claims. She cannot, therefore, avoid summary judgment by suggesting that Mentor ought to have asked Mr. Bhatta this question instead. *See Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986) ("The plain language of Rule 56(c) mandates the entry of summary judgment, after adequate time for discovery and upon motion, 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."); *see also Beane v. Util. Trailer Mfg. Co.*, 934 F. Supp. 2d 871, 883 n.36 (W.D. La. 2013) ("[The plaintiff] bears the burden of proving the elements of her [products liability] claim at trial. Thus, assertions that [the defendant's] claims fail because it did not ask about certain issues in a deposition improperly place the burden on [the defendant].").

her failure-to-warn claims. *Merriam*, 757 A.2d at 782; *Koken*, 426 F.3d at 50. I therefore grant Mentor's motion for summary judgment on Counts VII-IX.¹⁵

CONCLUSION

For the reasons stated above, the Court **GRANTS** the Defendant's motion for summary judgment.

SO ORDERED.

/s/ Nancy Torresen
United States Chief District Judge

Dated this 14th day of February, 2018.

¹⁵ Mentor argues that Ms. Novak's fraudulent misrepresentation, negligent misrepresentation, and fraudulent concealment claims fail for the additional reason that she has not developed evidence that she suffered a pecuniary loss. Def.'s Mem. 8. Because I find that summary judgment is appropriate on those Counts for the reasons set out above, I need not address this additional argument.