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United States District Court,
N.D. New York.
Charles R. **RIEGEL** and Donna S. **Riegel**, Plaintiffs,
v.
MEDTRONIC, INC., Defendant.
No. 99-CV-0649.

Dec. 2, 2003.

Law Office of Wayne P. Smith, Schenectady NY, for Plaintiffs, Wayne P. Smith, of counsel.

Quirk and Bakalor, P.C., New York NY, for Defendant, Richard H. Bakalor, of counsel.

MEMORANDUM-DECISION and ORDER

KAHN, J.

I. INTRODUCTION

***1** Plaintiffs commenced the instant action asserting claims for negligence, strict liability, breach of express warranty, breach of implied warranty and loss of consortium arising out the eruption of an Evergreen Balloon Catheter (the "Catheter") during the course of heart treatment. By Memorandum-Decision and Order dated March 14, 2002, familiarity with which is assumed, Plaintiffs' claims sounding in strict liability, breach of implied warranty and negligence were dismissed, as well as the claim of loss of consortium to the extent that it was derivative of the dismissed claims. Plaintiffs' claims of negligent manufacturing, the loss of consortium derivative of negligent manufacturing, and breach of express warranty were not dismissed. Defendant now moves for summary judgment, pursuant to Fed.R.Civ.P. 56, seeking dismissal of the remaining claims.

II. FACTS

On May 9, 1996, Plaintiff Charles Riegel ("Riegel") underwent a medical procedure in an effort to improve his heart condition. Riegel was found to have "a diffusely diseased, heavily calcified right coronary artery which had evidence of a 95% luminal narrowing in the midportion of the right coronary artery." (Def.Ex. E.) "Because of the diffuseness of the disease, and the heavy calcification, it was felt that rotablator as the initial intervention would be the optimal intervention tool for this vessel." (*Id.*) Riegel's treating physician, Eric S. Roccario, M .D., initially used a rotablator. (*Id.*) Roccario then decided to perform "prolonged inflations of balloon angioplasty." (*Id.*) "A 2.5 Medtronic Panther 40 mm balloon was used. Several inflations were made to three atmospheres for 300 seconds. Despite these prolonged inflations the angiographic appearance appeared to be the same. Thus it was decided to tack up the intima with Cook stents." (*Id.*) Roccario then used a certain high-pressure balloon, "but because of winging of the balloon and change of the contour of the vessel, the balloon could not be advanced to [the necessary] area." (*Id.*) Accordingly, "the balloon was exchanged for a 3.0-20 mm Medtronic Evergreen [balloon catheter]." (*Id.*)

"Several inflations were made with [the Medtronic Evergreen] balloon (5) to a maximum of 10 atmospheres, a maximum of 30 seconds. An extra support guide wire 0.014 was used throughout the procedure. With the final inflation, ... the balloon had ruptured.... At that time the patient rapidly deteriorated" and is alleged to have sustained certain personal injuries (*Id*). Upon being removed from Riegel, the balloon was discarded.

Plaintiffs then commenced the instant litigation asserting the various causes of action previously listed.

III. STANDARD OF REVIEW

Federal Rule of Civil Procedure 56 provides that summary judgment is proper when "the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." FED. R. CIV. P. 56(c); *Celotex Corp. v. Catrett,* 477 U.S. 317, 322 (1986). In applying this standard, courts must " 'resolve all ambiguities, and credit all factual inferences that could rationally be drawn, in favor of the party opposing summary judgment." ' *Brown v. Henderson,* 257 F.3d 246, 251 (2d Cir.2001) (quoting *Cifra v. General Electric Co.,* 252 F .3d 205, 216 (2d Cir.2001)). Once the moving party meets its initial burden by demonstrating that no material fact exists for trial, the nonmovant "must do more than simply show that there is some metaphysical doubt as to the material facts." *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.,* 475 U.S. 574, 586 (1986) (citations omitted). Rather, the nonmovant "must come forth with evidence sufficient to allow a reasonable jury to find in her favor." *Brown,* 257 F.3d at 251 (citation omitted). Bald assertions or conjecture unsupported by evidence are insufficient to overcome a motion for summary judgment. *Carey v. Crescenzi,* 923 F.2d 18, 21 (2d Cir.1991); *Western World Ins. Co. v. Stack Oil, Inc.,* 922 F.2d 118, 121 (2d Cir.1990).

IV. DISCUSSION

a. *Breach of Express Warranty*

***2** Defendant moves to dismiss the breach of express warranty claim on the grounds that: (1) neither Plaintiffs nor their agents relied on any express warranties; and (2) any express warranties were disclaimed. Plaintiffs respond that the documentation Defendant supplied to the FDA during the product approval process is sufficient to establish an express warranty and that any disclaimers in the product's instructions are insufficient to overcome such a warranty.

"In order for an express warranty to exist, there must be an affirmation of fact or promise by the seller, the natural tendency of which is to induce the buyer to purchase. Thus, for a buyer to recover for breach of express warranty, he must show that the warranty was relied on." *Friedman v. Medtronic, Inc.,* 42 A.D.2d 185, 190 (2d Dep't 1973); *see also Clarke v. L.R. Systems,* 219 F.Supp.2d 323, 331 (E.D.N.Y.2002); *CBS, Inc. v. Ziff-Davis Pub. Co.,* 75 N.Y.2d 496, 503 (1990); *Murrin v. Ford Motor Co.,* 303 A.D.2d 475, 476 (2d Dep't 2003) (dismissing express warranty claim where there was no allegation plaintiff was aware of the alleged statements prior to purchase); *Babalola v. Crystal Chems., Inc.,* 225 A.D.2d 370, 372 (1st Dep't 1996) ; *Butler v.. Caldwell & Cook, Inc.,* 122 A.D.2d 559, 560 (4th Dep't 1986); *County of Chenango Indus. Dev. Agency v. Lockwood Greene Engineers, Inc.,* 114 A.D.2d 728, 730 (3d Dep't 1985).

Here, Plaintiffs admitted at deposition that they had no knowledge of any warranties at the time Riegel underwent the heart procedure.[FN1] Moreover, although Dr. Roccario or, potentially, the hospital, may be considered Plaintiffs' agent for purposes of the element of reliance, there is no evidence in the record from which a fair-minded trier of fact reasonably could conclude that Dr. Roccario or the hospital purchased or used the Catheter in reliance upon any express warranty. *See Friedman,* 42 A.D.2d at 190. Absent any evidence of reliance, this claim cannot stand.

FN1. At deposition, Riegel was asked the following questions and gave the following answers:

> Q. Did you rely upon any warranty for any product manufactured by ... Medtronic that was used during your ... angioplasty?
>
> A. My answer to that I believe would be I was relying on the doctor's expertise ...

> Rather than the equipment....
>
> Q. Prior to the doctor performing the angioplasty ...., did any doctor discuss with you any warranties regarding any of the equipment that would be used....
>
> A. No .....
>
> Q. Prior to the ... angioplasty procedure, did a doctor show you any warranty of a Medtronic product that would be used....
>
> A. No.
>
> Q. Have you ever seen any Medtronic warrant with respect to any of its products?
>
> A. No.
>
> (Def.'s Ex. F.)
>
> Riegel's spouse, Donna S. Riegel, similarly testified that she never had any discussions concerning a warranty with respect to the Catheter. (Def.'s Ex. F.); *see also* Rule 7.1(a)(3) Stmnt. of Mat. Facts at ¶ 8.

As Plaintiffs have conceded, even if they could establish reliance, the Catheter's Instructions for Use clearly disclaimed any express warranty. *See* Rule 7.1(a)(3) Stmnt. of Mat. Facts at ¶ 7. The Instructions for Use state in no uncertain terms that:

> [N]o representation or warranty is made that failure or cessation of function of catheters will not occur ... or that medical complications will not follow the use of catheters. Medtronic cannot warrant or guarantee Medtronic accessories because the structure of the accessories may be damaged by improper handling before or during use. Therefore, no representations or warranties are made concerning them.
>
> CATHETERS AND ACCESSORIES ARE SOLD IN AN "AS IS" CONDITION. THE ENTIRE RISK AS TO THE QUALITY AND PERFORMANCE OF CATHETERS ... IS WITH THE BUYER. MEDTRONIC DISCLAIMS ALL WARRANTIES, EXPRESS OR IMPLIED, WITH RESPECT TO CATHETERS AND ACCESSORIES.... MEDTRONIC SHALL NOT BE LIABLE TO ANY PERSON FOR ANY MEDICAL EXPENSES OR ANY DIRECT OR CONSEQUENTIAL DAMAGES RESULTING FROM THE USE OF ANY CATHETER ... OR CAUSED BY ANY DEFECT, FAILURE OR MALFUNCTION OF ANY CATHETER ... WHETHER A CLAIM FOR SUCH DAMAGES IS BASED UPON WARRANTY, CONTRACT, TORT OR OTHERWISE.
>
> ***3** (Def.'s Ex. G.)

This clear, conspicuous and specific language is sufficient to disclaim any express warranties. *See Maltz v. Union Carbide Chems. & Plastics Co. Inc.*, 992 F.Supp.2d 286, 303-04 (S.D.N.Y.1998); *T.T. Exclusive Cars, Inc. v. Christie's Inc.*, 1996 WL 737204, at *2-3 (S.D.N.Y.1996); *Smith v. Fitzsimmons*, 180 A.D.2d 177, 179 (4th Dep't 1992).

For the foregoing reasons, Plaintiffs' breach of express warranty claim is dismissed.

b. *Negligent Manufacturing*

Defendant next moves to dismiss Plaintiffs' negligent manufacturing claim on the grounds that: (1) Plaintiffs do not have the actual allegedly defective balloon and, thus, do not have any direct evidence of negligent manufacture; and (2) Plaintiffs have failed to negate the possibility that causes other than the negligent manufacture may have caused the balloon to burst. Plaintiffs respond that they have negated any other possible causes.

The New York Court of Appeals recently noted that a plaintiff is not required to prove the specific defect. *Speller v. Sears, Roebuck and Co.*, 760 N.Y.S.2d 79, 81 (2003). The plaintiffs' case may be proved by circumstantial evidence. *Id.* "[T]o pro-

ceed in the absence of evidence identifying a specific flaw, a plaintiff must prove that the product did not perform as intended and exclude all other causes for the product's failure that are not attributable to defendant[ ]." *Id.* at 81-82. "[P]laintiff must establish that the product was not built to specifications or that the product, 'as constructed, deviated from any such specifications or design." ' *McArdle v. Navistar Int'l Corp.,* 293 A.D.2d 931, 932 (3d Dep't 2002) (quoting *Searle v. Suburban Propane Div. of Quantum Chem. Corp.,* 263 A.D.2d 335, 340 (3d Dep't 2000)); *see Van Deusen v. Norton Co.,* 204 A.D.2d 867 (3d Dep't 1994). The *Speller* Court continued to note that "[o]f couse, if a plaintiff's proof is insufficient with respect to either prong of this circumstantial inquiry, a jury may not infer that the harm was caused by a defective product unless plaintiff offers competent evidence identifying a specific flaw." *Id.* at 82.

There is no question here that the balloon failed. The questions are: (1) whether the product did not perform as intended; and (2) if not, why not. We do not have the benefit of the actual balloon that was used; thus, there is no direct evidence as to what may have caused it to burst. Accordingly, we are left to rely on circumstantial evidence.

Defendant contends that the cause of the burst was not due to a manufacturing defect because: (1) Dr. Roccario inflated the balloon beyond its rated burst pressure ("RBP"); (2) the use of the balloon for someone in Riegel's condition was contraindicated, as set forth in the product's instructions for use because a spicule of calcium in the artery could puncture the balloon; (3) there were metal stents used in connection with the balloon that could have punctured it; (4) a review of the manufacturing process applied to the lot from which the balloon likely was produced was in conformance with the FDA requirements and was not defective; [FN2] and (5) each balloon was inspected to ensure that it met the manufacturer's quality standards and that it conformed with the design requirements set forth in the submission approved by the FDA, including a 100% visual inspection for defects; a 100% check of the balloon outer diameter at nominal pressure, a 100% leak test at the rated burst pressure (8 atmospheres ("atm")), and two to three samples for full functional testing, including testing to failure. Because Defendant has identified several potential causes of the product's failure that are not attributable to it, Plaintiff must offer competent evidence from which a fair-minded trier of fact reasonable could conclude that "plaintiffs excluded all other causes of the fire." *Speller,* 760 N.Y.S.2d at 83.

> FN2. Because the actual balloon used for Reigel's procedure was discarded, neither Plaintiffs nor Defendant are able to identify the actual lot in which the balloon was manufactured. Based on sales records, Defendant identified a lot from which the balloon likely was manufactured. Plaintiffs have not objected to this claim.

***4** Plaintiffs respond that: (1) Defendant's own literature states that one in every one thousand balloons will burst; (2) Dr. Roccario removed any calcium spicules with a rotablator before using the Catheter; (3) Dr. Roccario denies that a stent could have ruptured the balloon; (4) the balloon ruptured radially as opposed to longitudinally (which it was designed to do); and (5) it was routine to inflate the balloon beyond its rated burst pressure.

It is undisputed that Dr. Roccario inflated the balloon to 10 atms, which is 2 atms and approximately 29.4 pounds per square inch ("psi") beyond the rated burst pressure. (*See* Rule 7.1(a)(3) Stmnt. of Mat. Facts at ¶¶ 25, 27.) It also is undisputed that the "Warnings/Precautions" section of the Catheter's Instructions for Use state that "[b]alloon pressure should not exceed the Rated Burst Pressure." (*Id.* at ¶ 26.) Moreover, the use of the balloon is contraindicated for "diffuse or calcified stenosis" and is indicated only for "single-vessel atherosclerotic coronary disease that is ... noncalcified." (Def.'s Ex. G.) It is Defendant's position that inflating the balloon beyond its rated burst pressure either alone or together with the use on Riegel, who presented with

diffuse disease and calcification, was outside the product's intended use and could have caused product failure.

Plaintiffs respond, through the affidavit of Dr. Roccario, that "exceeding the maximum recommended atmospheres of eight (8) to ten (10) atmospheres was not outside the window of its testing in laboratory settings as shown by its own literature on failure rates, and inflation to ten (10) atmospheres was based upon my past experience with the product and was called for under the circumstances herein presented in order to attempt to obtain the angiographic appearance that I desired rather than what I was presented with at the time and instead of reintroducing still another balloon." (Roccario Aff. at ¶ 20.) Plaintiffs also contend that the literature submitted with the balloon shows a chart depicting the diameter of the balloon at pressures up to thirteen atm, thereby evidencing that the product was intended to be used up to that pressure. Finally, Plaintiffs argue that the use of the rotoblader was intended to remove any calcification.

The language in the Instructions for Use is unequivocal. It clearly states that the balloon pressure should not exceed the rated burst pressure. (Def. Ex. G at 000003.) The instructions further recommend using a pressure indicating inflation device. (*Id.*) In the section discussing balloon inflation, the literature similarly instructs the user to "inflate the balloon to gradually increasing pressures up to the Rated Burst Pressure." (*Id.* at 000004.) Although the Instructions for Use do contain charts indicating various diameters from the balloon from pressures ranging from 4 atm to 13 atm, just above the charts it is written that "Rated Burst Pressure is 8 atm." (*Id.* at 000006.) The Instructions for Use clearly state that the product is indicated for noncalcified artery disease and is contraindicated for diffuse or calcified stenosis. Because Dr. Roccario inflated the balloon beyond 8 atm and used it on a patient who presented with heavy calcification and an apparently significantly diffuse disease, it appears that the balloon was not intended for uses above 8 atm and certainly not for uses above 8 atm for a patient with calcification. *See David v.. Makita, U.S.A., Inc.,* 233 A.D.2d 145 (1st Dep't 1996).

***5** Although Dr. Roccario states that "the procedures followed were specifically chosen to avoid having the calcified areas be left in such a manner so as to cause a rupture in the balloon and this is why I chose the 1.75 mm rotational atherectomy burr in a 2.5 mm vessel," (Roccario Aff., at ¶ 17), Dr. Roccario does not state that no calcification remained (or that no calcification could have remained) following the use of the Rotoblator that could have caused the balloon to rupture. (*See id.*) Dr. Roccario admitted to knowingly exceeding the rated burst pressure and having done so upon a balance of the risk of a burst balloon against introducing another balloon. (*See* Roccario Aff. at ¶ 20.) Moreover, while Dr. Roccario does state that "the probable cause of the rupture of the balloon catheter did *not* come about due to procedural decisions that I made ... during the operative procedure," Dr. Roccario does not state that it is his belief that a calcium spicule, either alone, or together with the inflation of the balloon beyond the rated burst pressure, did not cause the balloon to burst. (*See generally id.*) Significantly, Dr. Roccario, who had the opportunity to observe the burst balloon, offers no opinion as to how the balloon burst and does not state his belief that it was caused by a manufacturing defect.

On the other hand, Defendant's expert, James Slater, M.D., states in his affidavit that "[i]t is well known among interventional cardiologists that, even if you use a Rotoblator in an attempt to clear the vessel of calcium so as to attempt to avoid a balloon burst, it is improbable, if not impossible, to clear the vessel of all calcium spicules." (Slater Reply Aff. at pp. 3-4.) He further states that "[i]n my opinion, with a reasonable degree of medical certainty, even after the use of the Rotoblator with the 1.75 burr, calcium spicules had to have been left in the vessel and one of these calcium spicules, on its own or on conjunction with the metal stent,

caused the balloon to burst." (*Id.*)

The lack of a manufacturing defect as a cause of the injury is substantiated by the affidavit of Kaushik Patel who stated that, upon review of the information pertaining to the likely lot from which the balloon at issue here was manufactured, there is no evidence of any quality deficiencies and that each balloon was tested up to the 8 atm rated burst pressure. (Patel Aff. at ¶¶ 14-19.)

Based on the foregoing, there is insufficient evidence in the record upon which a fair-minded trier of fact reasonably could conclude that the balloon did not burst because of a calcium spicule, either alone or together with the inflation of the balloon beyond the 8 atm rated burst pressure.

Plaintiffs also submit the report of their expert, Ted Milo, an engineer, who asserts that the balloon was designed to fail longitudinally, but that, based on the nature of Riegel's injury, it must have failed radially.[FN3] While Mr. Milo does make this statement in his supplemental report, (*see* April 19, 2003 Milo Aff., Ex. C), this conclusion is not supported or substantiated by any medical or other proof. Mr. Milo does not explain how Riegel's particular injury likely was caused by a radial failure, how he came to this conclusion or what methodologies or medical evidence substantiate his opinion in this regard. *Daubert v. Merrell Dow Pharmaceuticals,* 509 U.S. 579, 590 (1993); *see also Amorgianos v. Nat'l R.R. Passenger Corp.,* 303 F.3d 256, 265 (2d Cir.2002).

> FN3. It is questionable whether the conclusion that the balloon failed radially should be considered in the first instance because it was not contained in any of Plaintiff's discovery disclosures. This theory first appears in Milo's April 2003 supplemental expert report, which was prepared after the close of discovery and apparently in opposition to Defendant's motion for summary judgment. Milo's initial report, which is based upon the same information, made no mention of the possibility of a radial failure.

***6** In fact, the evidence submitted as Exhibit B to the Milo affidavit supports no such conclusion. While the reports submitted in Exhibit B evidence some situations where a balloon burst resulted in no complications to the patient, that evidence also reveals situations in which a vessel was apparently dissected from a burst balloon. Upon review of Exhibit B, this Court has not located a single report indicating that a vessel was dissected from a radial failure. Even assuming the reports identify either no or minor complications resulting from longitudinal failures, it is too great a leap to conclude that, because numerous longitudinal failures did not have any significant negative patient outcomes, Riegel's somewhat serious problem must have been caused by a radial rupture. Moreover, Milo fails to address the situation that the more serious injury may be caused by pinhole perforations or jetstream leaks. It further appears from the reports in Exhibit B that non-longitudinal ruptures are caused by non-manufacturing related issues such as overpressurizing a balloon that has damage to its surface or punctures caused by a calcified lesion.

Defendant's expert Slater's affidavit states that: (1) Milo's opinion was not confirmed by Dr. Roccario, who was in a position to examine the balloon and note whether it failed radially (but did not do so); (2) based on the condition of Riegel's vessel, "the nature of the injury sustained ... after the balloon burst cannot be related to the manner in which the balloon failed," (May 19, 2003 Slater Aff. at p. 5); (3) "to determine in what manner the balloon failed based on the nature of the injury is to come to a conclusion based on pure speculation," (*Id.*); and (4) "[i]t is my belief, with a reasonable degree of medical certainty, that either a longitudinal failure of the balloon or a radial failure of the balloon could have caused the same injury." *Id.* at p. 6.

Defendant's other expert, Kaushik Patel, an engineer, stated that

> balloon failure mode (longitudinal or radial) has no impact on the patient outcome from the point of view of vessel injury. Balloons bursting both longitudinally or radially can cause injury to the vessel. On the other hand, balloons can burst either longitudinally or radially and not cause injury to the vessel. There is no way to tell which way a balloon burst based on the injury to the vessel itself.... Mr. Milo's opinion that the balloon bursted radially because of the injury suffered by Mr. Riegel is nothing more than speculation and is not based on any scientific fact. Mr. Milo does not indicate that he did any testing on these types of balloons.

(May 19, 2003 Patel Aff. at ¶¶ 10-12.)

Patel further stated that the "primary reason for designing the balloon to fail longitudinally is to make sure that, in case the balloon were to fail for any reason, it could be removed safely from the vessel without leaving a piece of the balloon material behind in the patient which could potentially cause emboli." (*Id.* at ¶ 9.) This conclusion is substantiated by the report of Defendant's other expert, Scott Solano, an engineer, which states that the concern with pinhole rupture (as distinguished from a radial rupture where there is a tear around the circumference of the balloon) is that pressure released from pinhole rupture may impact the surrounding vessel, whereas the concern from a radial tear is that "the balloon [might] snag on the guide catheter and cause the entire system to have to be removed." (Def.'s Ex. L.)

*7 Milo substantiates his opinion that there was a manufacturing defect with a statement in Defendant's Premarket Approval Process ("PMA") documents that:

> The balloon inflation test employed a comprehensive protocol to study balloon burst strength, distensibility and fatigue. Burst test data were analyzed statistically to show with 95% confidence that 99 .9% of the balloons will not burst below the recommended maximum inflation pressure (rmip) of 90 psi.

According to Milo, this statement is an admission by Defendant that "one (1) in every thousand (1000) balloons *will* burst at pressures below the maximum rated burst pressure." (Milo. Aff. Ex. C (emphasis supplied)).

The reliability of this statement from a scientific perspective is questionable because, as Patel notes in his reply affidavit, "[t]he reliability of 99.9% in the balloon burst pressure means that statistically there is a possibility that one out of one thousand ballon[s] *could* fail below RBP, not that one out of one thousand *will* fail below the RBP." (Patel Aff., ¶ 17 (emphasis in original)). In any event, the evidence in the record is that the balloon did not burst until it exceeded the rated burst pressure.[FN4] Thus, this evidence does not tend to suggest a manufacturing defect or otherwise tend to show that the balloon burst for a reason not attributable to Defendant.

> FN4. This "admission" that one in every one thousand balloon will burst leads Milo to conclude that there should be 100% testing. The undisputed evidence in the record, however, is that Defendant does test every balloon up to the 8 atm rated burst pressure. Milo believes that Defendant should test every balloon beyond 8 atm. The product's specifications call for a rated burst pressure of 8 atm. Because the balloon did not burst until it was inflated beyond 8 atm, nothing in Milo's report tends to suggest that the balloon was not properly manufactured to meet specifications and does not provide evidence from which it reasonably may be concluded that the balloon burst due to reasons not attributable to Defendant.

For these reasons, Milo's conclusion that the nature of the injury must have been caused by a radially ruptured balloon is based on sheer surmise and conjecture rather than on any scientific basis. Milo

failed to demonstrate any grounds for his conclusion that the balloon likely failed radially. *Amorgianos,* 303 F.3d at 265. Based on the foregoing, Milo's conclusion in this regard is not sufficiently substantiated to be admissible as expert testimony and, thus, cannot be used as a basis for demonstrating a manufacturing defect.

In light of the undisputed facts that: (1) Riegel presented with "heavy calcification;" (2) the use of the balloon was contraindicated for his condition (at least until after the use of a Rotoblator to clear the calcium spicules); (3) a Rotoblator is unable to remove all calcium spicules; and (4) the balloon was inflated beyond the rated burst pressure on a patient known to have heavy calcification, and given the lack of any evidence from which it reasonably can be concluded that the balloon ruptured radially, Plaintiff has failed to submit sufficient evidence from which a fair-minded trier of fact reasonably conclude that Plaintiff excluded all other causes of the burst. Accordingly, Defendant's motion to dismiss the negligent manufacture claim must be granted.

V. CONCLUSION

For the foregoing reasons, it is hereby

ORDERED, that Defendant's motion for summary judgment is GRANTED in its entirety; and it is further

ORDERED, that Plaintiffs' claims for breach of express warranty, negligent manufacture and loss of consortium are DISMISSED; and it is further

***8** ORDERED, that the Clerk of the Court is instructed to close the file in this matter; and it is further

ORDERED, that the Clerk serve a copy of this order on all parties by regular mail.

IT IS SO ORDERED.

N.D.N.Y.,2003.
Riegel v. Medtronic, Inc.
Not Reported in F.Supp.2d, 2003 WL 25556778 (N.D.N.Y.)

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