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SUPREME COURT OF THE STATE OF NEW YORK — NEW YORK COUNTY

PRESENT: LOBIS Justice PART 6

COLAROSSI, LISA

INDEX NO. 105865/10

MOTION DATE 6/5/12

-v-

NEW YORK-PRESBYTERIAN HEALTHCARE SYSTEM, ETAL

MOTION SEQ. NO. 01

MOTION CAL. NO. ____

The following papers, numbered 1 to 45 were read on this motion to/for dismiss

	PAPERS NUMBERED
Notice of Motion/ Order to Show Cause — Affidavits — Exhibits ...	1-28
Answering Affidavits — Exhibits	29-43; 44
Replying Affidavits	45

Cross-Motion: ☐ Yes ☑ No

Upon the foregoing papers, it is ordered that this motion

THIS MOTION IS DECIDED IN ACCORDANCE WITH THE ACCOMPANYING MEMORANDUM DECISION and Order

FILED

SEP 06 2012

NEW YORK COUNTY CLERK'S OFFICE

Dated: 9/5/12

JOAN B. LOBIS J.S.C.

Check one: ☐ FINAL DISPOSITION ☑ NON-FINAL DISPOSITION

Check if appropriate: ☐ DO NOT POST ☐ REFERENCE

☐ SUBMIT ORDER/ JUDG. ☐ SETTLE ORDER/ JUDG.

MOTION/CASE IS RESPECTFULLY REFERRED TO JUSTICE FOR THE FOLLOWING REASON(S):

SUPREME COURT OF THE STATE OF NEW YORK
NEW YORK COUNTY: IAS PART 6

----------X

LISA COLAROSSI,

Plaintiff,

Index No. 105865/2010

-against-

Decision and Order

NEW YORK-PRESBYTERIAN HEALTHCARE SYSTEM, LAWRENCE HOSPITAL CENTER, MICHAEL F. KERIN, M.D., C.R. BARD, INC., and JOHN DOES 1-5,

Defendant.

----------X

JOAN B. LOBIS, J.S.C.:

Defendant C.R. Bard, Inc. ("Bard"), which manufactured and distributed a port catheter which was implanted into plaintiff Lisa Colarossi's chest, moves, by order to show cause, for an order, pursuant to C.P.L.R. Rule 3212, granting it summary judgment dismissing Colarossi's complaint on the ground that the port catheter, a piece of which broke off and lodged in Colarossi's right ventricle, was not defective.

Colarossi was diagnosed with ovarian cancer and, after surgery, was referred for chemotherapy to an oncologist, a Dr. Provenzano, who was affiliated[1] with defendant Lawrence Hospital Center ("Lawrence Hospital"). In connection with that treatment, Dr. Provenzano referred Colarossi to a general surgeon, defendant Michael F. Kerin, M.D., for the implantation of single-lumen port catheter, which would make it easier, over the course of the chemotherapy, to infuse medication, rather than having to access a peripheral vein whenever Colarossi needed medications

[1] It is unclear whether Dr. Provenzano was a private attending or was employed by Lawrence Hospital.

or fluids, or to have her blood drawn. Dr. Kerin, aside from being Lawrence Hospital's Chief of Surgery, was evidently a private attending, and it appears that, at the time in issue, Colarossi was covered by medical insurance. She first saw Dr. Kerin in his Bronxville office, and Colarossi ultimately consented to the procedure, which took place at Lawrence Hospital on November 5, 2007.

According to Dr. Kerin, as a general matter, after such surgery would be scheduled, a port catheter would be provided by Lawrence Hospital, without input from him as to the particular make or model. Dr. Kerin had training in implanting port catheters, and before Colarossi's procedure, had implanted more than 50, of which more than 10 were the Bard port catheter involved here. Dr. Kerin had never attended any Bard-sponsored seminars or continuing medical education courses.

The port catheter in issue was approved by the FDA in 1987 as a substantial equivalent of preexisting products. The port catheter consisted of three pieces, namely, a plastic port, into which the medication would ultimately be administered, which port was implanted subcutaneously in a pocket constructed on Colarossi's chest by Dr. Kerin; a silicone catheter, which was designed to be, and was, cut to size by Dr. Kerin; and a catheter lock, which locked the catheter into place on the port's stem. The catheter was threaded into Colarossi subclavian vein on the right side of her chest. Dr. Kerin testified that he usually secured the port, which had more than two holes, with two sutures through two of those holes, on opposite sides of the port. He noticed no kinking or bending of the catheter before he concluded the procedure.

Each port catheter kit contained an approximately 30-page set of instructions for use ("IFU"), which, according to Nital Patil , a mechanical and industrial engineer who was the Director of Quality Systems for Bard Access Systems, a division of Bard, provided instructions for the implanting physician and for physicians and nurses who would later access the port. As is relevant, the IFU contained, under the bolded and large font heading "Warnings," a bolded subheading, in a smaller font, yet larger than the balance of most of the printed matter, entitled "Pinch-off Prevention." Fried aff., ex. X, at 2. Under that heading, the surgeon was advised where to place the catheter to avoid its compression between the first rib and clavicle, and that such compression could cause the catheter to fracture or sever. According to Patil, pinch-off is the term used to describe compression of the catheter between the first rib and clavicle. At placement, a radiographic study was advised to ensure that the catheter was not being so compressed. Under the same subheading, the clinical signs of pinch-off were described as difficulty drawing blood, resistance to infusion, and having to reposition the patient to successfully infuse fluids or withdraw blood. Radiologic signs of pinch-off were also described under that subheading, which recited

> "Grade 1 or 2 distortion on chest X-ray. Pinch-off should be evaluated for degree of severity prior to explantation. Patients indicating any degree of catheter distortion at the clavicle/first rib area should be followed diligently. There are grades of pinch-off that should be recognized with appropriate chest x-ray as follows:"

Id. at 3. Then the grades, severity, and recommended actions were listed. At grade 0, no distortion was seen and no actions were recommended. At grade 1, distortion was present, without luminal (see Stedman's Electronic Medical Dictionary [4th ed. 1998] [relating to the interior space of a tubular structure]) narrowing, and an x-ray was recommended every one to three months to monitor

progression to grade 2. At grade 2, distortion with luminal narrowing was present, and it was recommended that removal of the catheter be considered. Finally, at grade 3, the catheter was transected or fractured, and its prompt removal was recommended.

In the IFU's precaution section, under a subheading of "During placement," it recited that the catheter should not be used if there was "any evidence of mechanical damage or leaking." Fried aff., ex. X, at 4. That subheading also advised the surgeon not to bend the catheter at sharp angles during implantation, since that could compromise its patency. According to Patil, patency in that context referred to the ability of liquids to flow through catheters. Under the precaution section's subheading of "After placement," it was advised that the device should not be used if there was any evidence of mechanical damage or leaking, and that "[d]amage to the catheter may lead to rupture, fragmentation, possible embolism, and surgical removal." Id. at 5. Further, that subheading recited that, if signs of extravasation existed, injections should be discontinued, and immediate "appropriate medical intervention" begun. Id. According to Patil, extravasation occurs from leaks in the port catheter system, including from breaks in the catheter. See also Stedman's Electronic Dictionary (which defines "extravasate" as "[t]o exude from or pass out of a vessel into the tissues").

Under the bolded and large font heading "Possible Complications," were listed about 30 "serious complications." Fried aff., ex. X, at 6. The word "serious" was contained in a sentence below that heading in the same small font used throughout the IFU. The complications included catheter damage or breakage due to compression between the clavicle and first rib, catheter embolism, and device rotation. Patil testified that catheter embolism occurs when the catheter is

severed and "travels away from the port into [the] heart." Patil ebt, at 160. In the IFU's 10-page implantation instruction section, it advised, in small print, in the port placement subsection that, after the port was placed in the subcutaneous pocket, it should be secured by sutures, to reduce the risk of port migration and the possibility of it flipping over. That subsection also advised that there should be sufficient slack in the catheter to permit slight movement, and that the surgeon should verify that the catheter was not kinked.

The IFU then had a section on the port catheter's use and maintenance, which had a subsection on the infusion procedure, which advised that, after the infusion, the infusion site should be examined, and that if there were signs of extravasation or if the patient experienced pain, the infusion should be stopped and "appropriate intervention" should be initiated. Fried aff., ex. X, at 23. The IFU contained no section on explantation.

Dr. Kerin testified that he was familiar with the IFU, and with its warnings about pinch-off prevention, and agreed with them, including the clinical signs of pinch-off and that the catheter should not be pinched between the clavicle and first rib, but that he disagreed that the catheter had to be completely straight, since it has to bend along the vein's course. He further testified that he was familiar with the IFU's list of potential complications and agreed with them; however, when questioned about a port's flipping or twisting, he claimed never to have heard of that, and asserted, in essence, that, with the method he used to perform the procedure, the port could not move out of its location or flip in the pocket.

On the date of implantation, flouroscopy films were taken during the course of the procedure to assess whether placement was proper. A flouroscopy report indicated that the exam was "DX C ARM LESS THAN 1 HOUR." Id., ex. O. The report recited that a few images had been submitted to evaluate the port's placement in Colarossi's chest and that some kinking was noted of the catheter as it entered the subclavian vein. Dr. Kerin could not recall if he had read the flouroscopy report on the day of the procedure. According to Dr. Kerin, who was not asked what less than one hour meant, he could not tell when during the procedure the films relating to the report were taken, since multiple shots would be taken at various times during the procedure. Thus, Dr. Kerin testified that the report did not necessarily refer to the final shot, and was, therefore, insignificant.

Immediately after the port catheter's placement, an x-ray study was taken in the recovery room at Dr. Kerin's request to document positioning. The report of that study indicated that there was "slight narrowing, pinching of the catheter just above the right first rib," and that the catheter's tip appeared to be "in good position." Fried aff., ex. N. Dr. Kerin testified that, before Colarossi's discharge, he reviewed the x-ray and received and reviewed the report. He claimed that he saw nothing unusual regarding the port catheter's placement or with respect to the catheter, observed no kinking in the x-ray, found the report and x-ray to be insignificant, and believed that the port catheter had been properly placed. He, thereafter, testified that he had no recollection of having reviewed the x-ray in this case, but that it was his practice to do so after a procedure. He then testified that, since he tested the port catheter in the operating room, and it properly functioned, there could not have been any pinching. Dr. Kerin further testified that any followup would have been

with Dr. Provenzano.

On November 9, 2007, Colarossi commenced her chemotherapy sessions, which were conducted every three weeks at Lawrence Hospital. The next day, she felt unwell and called Dr. Provenzano, who told her to go to Lawrence Hospital's emergency room. Colarossi went and was admitted for two days, where she was seen by Dr. Provenzano, and diagnosed with a reaction to the medication and anxiety. A CT scan taken during that hospitalization, and compared with the chest x-ray of November 5, showed, according to the CT scan report, that the catheter tip's position had changed. Dr. Kerin, who was not involved with this hospitalization, did not see this report and was unaware of this change.

After the first session, Lavern Redway, became Colaraossi's infusion nurse. Before Nurse Redway was permitted to administer chemotherapy to patients, she was required to take a training session provided by Lawrence Hospital, and then received hands-on training and periodic refresher courses sponsored by the hospital and, on occasion, by drug manufacturers. The initial training session course dealt with the types of drugs, how they were administered, their side-effects, and how to respond to certain unspecified occurrences and access different ports. Nurse Redway did not recall whether she had ever received any literature. It is unclear whether she had any training regarding potential complications involving the catheter portion of the port catheter, since she testified that she was unaware that, below the skin, the port was attached to a catheter, and she had only seen a picture of a port.

According to Nurse Redway, during Colarossi's second chemotherapy session of November 30, an alarm sounded indicating that the medication administration had been disrupted. She checked everything, including the tubing attached to an IVAC machine, which evidently supplied the medication which flowed into the port, to ensure that the machine's tubing did not contain an air bubble or was not kinked. Since the tubing was fine, Nurse Redway had Colarossi shift her position, which solved the problem. Nurse Redway testified that Colarossi's position should not have created any issue, but that the fact that a change of position remedied the problem, demonstrated that her position caused the problem. Nurse Redway then wrote an entry on Colarossi's chart indicating that the port catheter had been temperamental.

It appears that, about a month after the port catheter was placed in Colarossi's chest, and at least before her third chemotherapy session on December 21, 2007, Colarossi felt the port flipping and bulging sideways in her chest[2] for the first time when she bent down to pick up her son's clothing off the floor, and that it then began "flipping around constantly" (Colarossi ebt, at 149, 131-32), most commonly when she was bending over, but also, at times, when she was standing. The flipping would last for seconds and then the port would flatten out. She claims that she called Dr. Provenzano's office on the day that it first flipped, and that, when he called back, she informed him

[2] The likelihood is that the port first flipped after the second session. Colarossi testified that she thought that she had informed the nurse of the flipping at her second chemotherapy session, during which session Colarossi claimed that the port had not functioned, and that, therefore, the chemotherapy had to be administered via a peripheral line. Later in her testimony, Colarossi indicated that the port stopped being used at her third session. That the port first flipped after the second session is supported by Nurse Redway's chart entry of the third session, that the peripheral line had to be used at that session and that Colarossi had informed her about the flipping, and by the absence of such notations during the second session.

that it was always flipping. Colarossi claims that he informed her that he would see her at her next chemotherapy appointment, but that, at the next session, he "just pop[ped] in" and spoke only to the infusion nurse. Id. at 113, 130. Colarossi testified that, in response to being informed about the flipping, Dr. Provenzano ordered no imaging studies, nor did she believe that Dr. Provenzano told her to see Dr. Kerin. Colarossi also did not believe that she ever called Dr. Kerin about the flipping.

When she next saw Nurse Redway at the third session, Colarossi informed her of the flipping, and Nurse Redway documented that the port had been twisting. By all accounts, at the third session, the port was not twisted. While Nurse Redway's recollection as to the specific timing of events that day was somewhat hazy, she testified, after reviewing her chart entries of December 21, that, when she examined the area of the port, before beginning the premedications through it, she observed a curved raised area that she described as looking, for lack of a better term, like a large artery beneath Colarossi's skin, just above the port. She then contacted Dr. Kerin, who examined Colarossi, determined that the port was operative, and authorized the infusion of chemotherapy through the port. At some time after the premedication was commenced, Colarossi complained of burning, and Nurse Redway observed that gauze was absorbing fluid due to a leakage problem. According to Colarossi, Nurse Redway called in several other nurses, including her supervisor, who unsuccessfully attempted to access the port. Nurse Redway was unsure of whether she called Dr. Kerin and advised him of this development or whether he came again, but Nurse Redway then, possibly on her own initiative, established a peripheral line and administered the chemotherapy through it, rather than through the port. Colarossi claimed that she did not see Dr. Provenzano

during the third chemotherapy session.

After that session, Colarossi asserted that she saw Dr. Provenzano at his office and told him that, if the port catheter was not working, she wanted it removed. Although Colarossi's testimony was somewhat inconsistent on this point, she claimed that Dr. Provenzano agreed that the port should be removed since it was not working.

Dr. Kerin testified that he could not recall any interactions with Colarossi after he implanted the port catheter, that he did not recall her ever showing him that the port would flip, and that his next involvement with her, after the implantation, was his having been advised by someone, although he could not recall who, that the port catheter was not working properly and needed to be removed. Dr. Kerin could not recall Dr. Provenzano ever having advised him that the port had been flipping.

Dr. Kerin performed the explantation procedure at Lawrence Hospital on January 7, 2008, without the assistance of any radiological studies. He testified that the port and catheter, at the time of removal, were in the same places where he had originally implanted them, and that the two sutures used to secure the port were still there. He further testified that the port catheter looked fine when he extracted it. Dr. Kerin's surgical report for that procedure recited that Colarossi had been referred for the surgery because of a malfunctioning port catheter. The report's pre- and post-surgical diagnoses were a malfunctioning port catheter. The port catheter was sent to the hospital's pathology lab for examination. The pathology report did not indicate any irregularities, and the port

catheter was discarded, apparently by the hospital. Following explantation, the balance of Colarossi's course of chemotherapy was administered uneventfully using peripheral lines.

In December 2009, Colarossi was seen at Northern Dutchess Hospital for abdominal cramping and right-sided pleuritic chest pain. A chest x-ray and CT scan revealed an approximately 7-8 cm catheter fragment lodged in Colarossi's right cardiac ventricle. An ultimately futile procedure to snare that fragment was conducted a few days later at New-York Presbyterian Hospital. Colarossi was advised that open-heart surgery was her only option for retrieval of the fragment.

Colarossi commenced this action against Bard, Dr. Kerin, Lawrence Hospital, and New York-Presbyterian Healthcare System, of which Lawrence Hospital was alleged to have been a member. Also named were various John Does. As against Bard, Colarossi asserted causes of action sounding in negligence in the design, manufacture, testing, assembly, and sale (evidently including the marketing and warnings) of the port catheter (fourth cause of action); strict products liability predicated on design and manufacturing defects and the lack of adequate warnings (fifth cause of action); breach of implied warranty (sixth cause of action), evidently of merchantability (see U.C.C. § 2-314), since there is no allegation that Bard knew of the particular purpose for which the multipurpose port catheter was required (see U.C.C. § 2-315); express warranty (seventh cause of action); and strict products liability based on a defective design (eighth cause of action). Bard, in lieu of a demand for a bill of particulars, served Colarossi with interrogatories. Colarossi served responses and supplemental responses to the interrogatories.

Colarossi asserted in her supplemental responses, that the port catheter had to be removed because it was inoperable and temperamental, had been leaking interstitially, causing fluid to accumulate and a burning sensation under her skin near the port site, it had become twisted and kinked, causing a U-shaped bulge under her skin, and because the catheter had migrated out of the subclavian vein. In her supplemental interrogatory responses, Colarossi added that the catheter fractured either before or during the procedure to remove the port catheter. As to the deficiencies in its warnings, Colarossi asserted that Bard, as a result of continuous adverse incident reports, going back to at least 2002 and relating to failures similar to those experienced by Colarossi, knew of the problems relating to the port catheter and failed to provide adequate warnings.

Colarossi's supplemental responses recited that Bard's IFU should have contained framed and bolded warnings indicating that mechanical friction can cause fracture and the migration of the catheter fragment into the right heart and pulmonary artery; that fracture most commonly occurs when shoulder joint movements cause a hammer/anvil effect of the first rib and clavicle; and that a diagnostic study is recommended right after port catheter placement. Also claimed as a necessary bolded and framed warning was that the port catheter needed to be secured to prevent rotation, which could lead to kinking and fracture, and that a diagnostic study was highly recommended if kinking was suspected. Finally, Colarossi's supplemental responses recited that the IFU should have contained the framed and bolded warning that leakage during medicine administration through the port is a sign of kinking, which could cause fracture, and that, if leakage occurs, a chest x-ray is strongly recommended.

Bard, which did not provide an affidavit from an expert on this application, and relies instead primarily on its IFU, a brochure it issued on catheter pinch-off and fracture, and the deposition transcripts in this case, asserts that it is entitled to summary judgment because Colarossi has provided no evidence refuting Bard's alleged proof that, had the port catheter been properly placed during installation, so that it was not in a pinch-off position, the catheter would not have fractured. While Bard seemed to be urging that plaintiff's injuries were due solely to Dr. Kerin's alleged malpractice, on reply, Bard made it clear that it was not seeking summary judgment on any such basis.

Bard urges that the port catheter was properly designed, and that, because port catheters from the lot number in issue passed post-manufacture testing, as testified to by Patil, the port catheter was properly manufactured. Additionally, Bard maintains that, since Colarossi never examined the exemplar (from a different lot number) which it made available, and, since she has never had the opportunity to examine the port catheter which was removed from her body, she cannot demonstrate that the port catheter was defective.

Bard also claims that it provided comprehensive warnings of the risks and signs of pinch-off under its IFU's warning section and, that, under the possible complications section, it listed catheter embolism among its "serious" complications. Fried aff., ex. X, at 6. Bard also observes that Dr. Kerin, as the learned intermediary, had been furnished with the port catheter's IFU, and was aware of the possible complications associated with implantation, including the risk of pinch-off if the port catheter was improperly placed. Bard further asserts that Nurse Redway was provided with

training from drug and device manufacturers on the administration of chemotherapy and accessing ports. Bard maintains that it has established the adequacy of its warnings and, in light of Dr. Kerin's knowledge of the pinch-off risk and other complications, that Colarossi's injuries were not proximately caused by any deficiency in its warnings, and that Colarossi has failed to rebut this prima facie showing.

Bard asserts that Colarossi's breach of express warranty claim must be dismissed because she admitted in her interrogatory responses that she was unaware of any such warranty. As to her implied warranty claim, Bard maintains that the port catheter was fit for its expected purpose because Bard claims that it has demonstrated that the port catheter was adequately designed; its lot passed post-manufacturing testing; Bard conveyed adequate warnings to the learned intermediaries, such as Dr. Kerin; Dr. Kerin knew that improper placement, at the time of its installation, could result in a pinch-off; and because allegedly neither he, nor any other medical professional, ever found the port catheter to have been inoperable. Bard asserts that Colarossi's negligence cause of action must be dismissed based on its arguments in support of the dismissal of her other claims.

In response, Colarossi claims that Bard's motion must be denied because she has presented enough evidence to support her negligence, strict products liability, and breach of implied warranty causes of action, since Bard's warnings were inadequate. To support this assertion, Colarossi provides the affidavit of Ted Milo, an electrical engineer, with claimed expertise in medical instruments, who was involved in product development for pharmaceutical and disease research facilities, has experience with product design, labeling and warnings, and who purports to

be familiar with Bard chemotherapy ports, such as the one in issue. Milo adds that the qualifications which allow him to opine with respect to the issues here, are also set forth in his attached resume, which indicates, among other things, that he worked for about 14 years as the Director of Research and Development for a medical device manufacturer, where he managed a group of 55 engineers. His duties there consisted of managing technical support functions, including mechanical and electrical design, technology research, and generating specifications for new products. Milo's resume further indicates his familiarity with various arterial, heart, and blood pressure devices, medical tubing, catheter fracture and failure, and venous access port failure. In his affidavit Milo indicates that he has researched various relevant FDA databases regarding Bard's port catheter, and is relying on his own background, training, education, and skill, as well as on industry standards, FDA requirements, and the relevant medical and scientific literature.

Milo maintains, based on Patil's testimony and reports to the FDA, that Bard had knowledge of catheter pinch-off and fracture, that, although Bard did warn of catheter pinch-off, Bard's warnings to the physicians who used the device, including those who implanted them, were inadequate in a number of respects. Milo asserts that Bard was aware that movement of the port in its pocket was another cause of catheter damage and fracture, yet left it to the surgeon to decide how to secure the port. According to Milo, securing a port with two sutures would prevent lateral, but not rotational movement. Milo opines that the IFU should have had a bold warning indicating that at least three of the port's holes needed to be sutured to avoid rotational movement and the possibility of flipping, which can affect the degree of pinch-off and lead to fracture and migration into the heart or pulmonary artery. Milo maintains that if such warning had been provided, the

catheter would have remained in place, and not have become compressed and fractured. Alternatively, Milo claims that, if such warning had been provided, Dr. Kerin, once advised of the port's rotation, would have considered the possibility of fracture.

Milo further urges that Bard should have added a bold warning that diagnostic studies should be performed if pinch-off signs, such as difficulty infusing medications, or the inability to infuse medications with pain or swelling, were present. Also, he claims that a warning that leakage during medicine infusion is a sign of kinking, which could lead to catheter fracture, and that an x-ray is strongly recommended in that case. Milo claims that a warning, that early detection of catheter fracture may prevent catheter embolization into the heart or pulmonary artery, was also needed.

Milo asserts that had the foregoing warnings been added, Dr. Kerin would have monitored the port, ordered radiological tests, and seen evidence of a pinch-off or fracture, and "acted accordingly" (Milo aff., ¶ 44). Further, observing that Patil testified that, if the catheter was incompletely fractured, explantation could cause a complete severance, Milo opines that, Bard should have added warnings that, prior to explanting a malfunctioning port, a diagnostic study was strongly recommended. Milo also claims that warnings should have been added indicating that the catheter should be measured (evidently both before implantation and after explantation) and that its end should be examined for signs of fracture to ensure that the entire catheter has been removed. Additionally, Milo asserts that the IFU should have contained a warning that, after explantation, a study of the heart or flouroscopy is recommended to visualize any catheter fragment. Milo claims that had Dr. Kerin measured the catheter, inspected it, and taken an x-ray after explantation,

fragmentation would have immediately been discovered, instead of a year later, which may have facilitated the fragment's prompt removal. Milo opines that Bard's failure to provide appropriate warnings proximately caused Colarossi's injuries. He also claims that the port catheter was unfit for its intended purpose because Bard's warnings were inadequate and that Bard's manufacturing techniques were deficient because it did not report Colarossi's catheter's fracture and migration to the FDA (but see Wallace v. Sitma U.S.A., Inc., 77 A.D.3d 918 [2d Dep't 2010] [manufacturing defect claims are predicated on what happens before the product leaves the manufacturer's control]).

In reply, Bard adds that, because Dr. Kerin was independently aware of the pinch-off risk, Bard cannot have proximately caused Colarossi's injuries, and that, since the IFU adequately warned the medical community, including Dr. Kerin, of the risks of pinch-off between the first rib and clavicle, and all potential dangers of the port catheter, it is entitled to summary judgment. Bard further maintains that Milo, as an electrical engineer, lacks the qualifications to opine about the port catheter, since it is not an electrical device, and since Milo allegedly has no training in anatomy, surgery, interventional radiology, or in non-electrical implantable medical devices. Bard adds that, even were Milo qualified to offer an opinion, his affidavit is replete with speculation about what Dr. Kerin would have done if provided with the warnings claimed to have been necessary. Further, Bard claims that, because Milo never examined the subject catheter or the proffered exemplar, his opinion lacks weight.

At oral argument, Colarossi's counsel conceded that plaintiff was only pursuing its causes of action to the extent that they are based on the failure to provide adequate warnings.

Irrespective of a plaintiff's burden at trial, on summary judgment, the movant bears the initial burden of prima facie establishing that party's entitlement to the requested relief, by eliminating all material allegations raised by the pleadings. Alvarez v. Prospect Hosp., 68 N.Y.2d 320 (1986); Winegrad v. New York Univ. Med. Ctr., 64 N.Y.2d 851 (1985); Kuri v. Bhattacharya, 44 A.D.3d 718 (2d Dep't 2007). The failure to do so requires the denial of the application, "regardless of the sufficiency of the opposing papers." Winegrad, 64 N.Y.2d at 853. If the movant makes the necessary showing, the burden shifts to the other side to demonstrate the existence of a material fact. Ferluckaj v. Goldman Sachs & Co., 12 N.Y.3d 316, 320 (2009). Additionally, "the remedy of summary judgment is a drastic one, which should not be granted where there is any doubt as to the existence of a triable issue or where the issue is even arguable, since it serves to deprive a party of his day in court." Gibson v. American Export Isbrandtsen Lines, 125 A.D.2d 65, 74 (1st Dep't 1987) (internal citations omitted). Moreover, a defendant does not meet its prima facie burden on a summary judgment motion by pointing to gaps in a plaintiff's case. Bryan v. 250 Church Assoc., LLC, 60 A.D.3d 578 (1st Dep't 2009).

A party injured as a result of a defective product, may seek to recover against a manufacturer based on theories of a breach of a promise express or implied, negligence, or strict products liability. Voss v. Black & Decker Mfg. Co., 59 N.Y.2d 102, 106 (1983). Since Colarossi was never able to provide Bard, in response to its interrogatories, with any express warranty it allegedly made, and since Colarossi's counsel advised the court that she is only pursuing her claims to the extent that they are based on a failure to provide adequate warnings, the express warranty cause of action (seventh cause of action), the design defect cause of action (eighth cause of action),

and all claims set forth in Colarossi's fourth, fifth, and sixth causes of action predicated on design and manufacturing defects, as opposed to the failure to provide adequate warnings, are dismissed. This leaves the branches of Bard's motion, which seek an order granting it summary judgment dismissing Colarossi's negligence, strict products liability, and breach of implied warranty causes of action, to the extent that they are based on inadequate warnings.

Negligence and strict products liability causes of action may be predicated on a claim that a product is defective because of a failure to adequately warn of its risks and dangers. See, e.g., Bazerman v. Gardall Safe Corp., 203 A.D.2d 56 (1st Dep't 1994). A medical device manufacturer has a duty to warn of all possible risks of which it knows or should know, using measures that are reasonably needed to bring such "knowledge to the attention of the medical profession." Glucksman v. Halsey Drug Co., Inc., 160 A.D.2d 305, 307 (1st Dep't 1990); see also Martin v. Hacker, 83 N.Y.2d 1, 8 (1993). That obligation, is owed, not directly to the patient but to the medical community, which acts as the informed intermediaries between the patient and the manufacturer. Glucksman v. Halsey Drug Co., Inc., 160 A.D.2d at 307. On summary judgment, a manufacturer meets its burden of demonstrating that it warnings were adequate where it establishes that it provided the patient's healthcare providers with "specific detailed information on the risks of the [product]." Id. While the adequacy of warnings presents an issue for the trier of fact, except in "the most unusual circumstances" (Montufar v. Shiva Automation Serv., 256 A.D.2d 607, 608 [2d Dep't 1998] [internal quotation marks and citation omitted]), the determination of whether the adequacy of a warning presents a jury issue, requires an analysis of the warning's language (Martin v. Hacker, 83 N.Y.2d at 10). Among the factors to be considered are "whether the warning is accurate, clear,

consistent on its face, and whether it portrays with sufficient intensity the risk involved." Id. "For a warning to be accurate it must be correct, fully descriptive and complete." Id. at 11. The "greater the potential hazard ... , the more extensive must be the manufacturer's efforts to make that hazard known to the medical profession." Baker v. St. Agnes Hosp., 70 A.D.2d 400, 406 (2d Dep't 1979). Although the intensity of the warning's language is a factor to consider, another factor is the prominence with which the warning is displayed. Johnson v. Johnson Chem. Co., 183 A.D.2d 64, 70 (2d Dep't 1992).

Even if a manufacturer's warnings are inadequate, where the manufacturer shows that the healthcare provider is independently aware of the risks, the manufacturer meets its burden on summary judgment of prima facie establishing a lack of causation. Glucksman v. Halsey Drug Co., Inc., 160 A.D.2d at 307; cf. Montufar v. Shiva Automation Serv., 256 A.D.2d at 607-08 (manufacturer not entitled to summary judgment where it failed to show that its warnings were adequate or that they "would have been superfluous" because plaintiff or his employer was aware of the hazards). Further, in a strict products liability case a defendant may be granted summary judgment where it establishes that actions of those other than itself were the sole proximate cause of plaintiff's injuries. Yun Tung Chow v. Reckitt & Colman, Inc., 17 N.Y.3d 29, 34 (2011); see also Mincieli v. Pequa Indus., Inc., 56 A.D.3d 627, 628 (2d Dep't 2008) (defendant on summary judgment application in products liability case required to prima facie show that "product was not defective or that there were other causes of the accident not attributable to it"); Mulhall v. Hannafin, 45 A.D.3d 55, 60-61 (1st Dept 2007) (where, on summary judgment motion, manufacturer of medically implanted product demonstrates that plaintiff's injuries were not caused by failure to warn,

plaintiff must show causation).

Turning first to the threshold issue of Milo's competency to offer any opinion in this case, an individual is qualified to offer an expert opinion if that individual is "possessed of the requisite skill, training, education, knowledge or experience from which it can be assumed that the information imparted or the opinion rendered is reliable (internal quotation marks and citations omitted)." O'Boy v. Motor Coach Indus., Inc., 39 A.D.3d 512, 513-14 (2d Dep't 2007). One may be qualified based upon "[l]ong observation, actual experience and/or study. No precise rule has been formulated and applied as to the exact manner in which such skill and experience must be acquired." Steinbuch v. Stern, 2 A.D.3d 709, 710 (2d Dep't 2003) (internal quotation marks and citations omitted). In addition, one is not required to have a medical license to opine on medical questions. Id.; Karasik v. Bird, 98 A.D.2d 359, 361-363 (1st Dept 1984); cf. Bickom v. Bierwagen, 48 A.D.3d 1247 (4th Dep't 2008).

While Milo's affidavit is a bit thin, I find that, for purposes of this summary judgment application, "where there is no opportunity to fully explore the scope of [his] expertise" (DaRonco v. White Plains Hosp. Ctr., 215 A.D.2d 339, 340 [1st Dep't 1995]; cf. Limmer v. Rosenfeld, 92 A.D.3d 609 [1st Dep't 2012]), Milo is competent to offer an opinion, at least on the issue of whether the warnings were adequate and on the potential of the catheter to fracture, since he claims, through study and his employment history to be experienced in the areas of product labeling and warnings, including FDA requirements, and to be familiar with various circulatory system-related devices, medical tubing, catheter fracture, and Bard port catheters, including the one in issue, and had, for

many years, been involved in supervising those involved in mechanical medical device design. Milo further claimed to have familiarized himself with the relevant medical and scientific literature. See generally Mustello v. Berg, 44 A.D.3d 1018, 1018-19 (2d Dep't 2007).

It may be difficult for Colarossi to establish exactly when the catheter severed, including that it severed at explantation, a complication which Patil conceded could occur due to the "trauma" of withdrawing of a broken catheter (Patil ebt, at 153), or that studies immediately before or after explantation or measuring the catheter at explantation would have avoided the catheter fragment's lodging in her ventricle or facilitated retrieval. Nonetheless, here, where Colarossi and Nurse Redway's testimony support that port rotation occurred and where Colarossi claimed that such rotation continued over an extended period before the port catheter's removal, Patil's testimony is adequate to support Milo's position so as to raise issues at least as to whether the IFU adequately explained the risks associated with the port's movement and rotation, and should have warned that the port needed to be secured in at least three places to avoid such movement and its associated risks.

Patil testified that, before November 2007, Bard had notice of catheter fracture and that there were causes of catheter fracture other that pinch-off, including "where the port moves in the pocket a little too much and [the] catheter is secure on top and it causes flexural fatigue." Patil ebt, at 121, 161. While that latter statement was followed by "[i]n other words, a nick with a scalpel, it's not realized during placing and eventually, it tears off," that statement does not seem to be an interpretation of what preceded it. Id. Further, Patil testified that a catheter, if it stayed bent at a sharp angle or corner for an extended period of time, could break or sever with movement.

Additionally, Patil indicated that, while the port had a number of suture holes, the IFU did not specify a minimum number of sutures needed, and left that up to the physician. He also testified that if the port had only been secured by one suture, he could see it flipping over in the pocket, but if a port had "multiple" sutures anchoring it down, the chance of its flipping would be diminished. Id. at 180.

In light of Patil's concession regarding the known danger of a moving port, and the potential serious ramifications of flexural fatigue, there is an issue as to whether Bard should have warned implanting surgeons of the need to secure the port with sutures through at least three holes to avoid rotational movement, which could lead to catheter fracture and, consequently, catheter embolism. Even if Dr. Kerin should have known that, to prevent rotational movement, three sutures were needed, there is an issue as to whether he was apprised of the serious consequences of a rotating port, and, hence, the need to ensure that it was adequately secured. Additionally, although there is no evidence that Dr. Kerin was ever apprised of the port's having turned on its side, Colarossi testified that she notified Dr. Provenzano of the flipping and the continuous nature of it soon after she first experienced it, allegedly about a month after its November 5, 2007 implantation. Further, Nurse Redway was notified of the port's flipping on December 21, 2007. However, the port, despite the continuous flipping, was not removed until January 7, 2008.

The IFU, while containing, in its warning section, the serious ramifications of a pinch-off, i.e., fracture and severance, did not indicate in that section that a rotating port could also lead to the same serious consequences. The IFU's potential complications section did not even indicate

the consequences of a flipping port, and it only listed one cause of catheter breakage ... pinch-off. That another complication, catheter embolism, which presumably can only happen with catheter severance, was set forth in that list, does not avail Bard on this motion, since catheter embolism was not explicitly linked with rotation. Cf. Forte v. Weiner, 200 A.D.2d 421, 422 (1st Dep't 1994) (adequacy of warnings not established where, among other things, drug package insert set forth potentially fatal hepatic lesion as a risk but failed to link it to any increased risk due to patient's age or dosage). Moreover, the complication of a flipping port was buried among about 30 other complications, and the word "serious," which was ascribed to all the complications as a whole, was not contained in the large and bolded heading, but in smaller print. See, e.g., Johnson v. Johnson Chem. Co., 183 A.D.2d at 70 (less intense warning prominently displayed in block letters on front label may be more effective than more intense warning unobtrusively displayed "in small letters in the middle of a 10-page package insert"). Indeed, Dr. Kerin claimed never to have heard of a twisting or flipping port. Also, although the IFU indicated in its precaution section that the port catheter should not be used if there was evidence of mechanical damage or leaking, it is unclear whether a healthcare provider would have understood mechanical damage to include port rotation. Under the foregoing circumstances, it cannot be said that Bard has established, as a matter of law, that its warnings were "fully descriptive and complete" (Martin v. Hacker, 83 N.Y.2d at 11) and adequate. Montufar v. Shiva Automation Serv., 256 A.D.2d at 607; Fox v. Wyeth Labs., 129 A.D.2d 611, 612 (2d Dep't 1987).

On the issue of causation, although there is evidence, including the November 5, 2007 x-ray and flouroscopy reports' results, the CT scan report from the November 10 hospitalization, and

the need to reposition Colaraossi during her second chemotherapy session, suggesting that a pinch-off occurred due to negligence on Dr. Kerin's part on the day of the implantation procedure, Bard has specifically indicated that its motion is not premised on his alleged malpractice, and Bard has provided no expert's affidavit demonstrating that he or any other healthcare provider was negligent or that they caused Colarossi's injuries. Even if Dr. Kerin or another healthcare provider had committed malpractice, that would not exclude any contributory wrongdoing by Bard.

Bard's claim, that it has met its burden of demonstrating a lack of causation and that it is, therefore, entitled to summary judgment because Dr. Kerin was allegedly aware of the risk of pinch-off and the port catheter's potential complications, is without merit. Aside from the fact that there is no evidence that Dr. Kerin was aware of the risks of port rotation and that Bard has failed to show that its warnings were adequate, this is not simply a product, such as an artificial hip, which a surgeon implants and generally requires no further medical intervention. As recognized by Patil, the port catheter was, after implantation, to be accessed by other medical professionals, in this case, Dr. Provenzano and the nurses administering the medication. Thus the IFU, in particular those portions dealing, not with the product's implantation instructions, but with its use, and any other materials or training provided by Bard had to be geared toward them as well. See Patil ebt, at 95-96, 108; cf. id. at 27. Other than referring to the IFU, and to other materials and seminars, which other materials Bard did not indicate were provided to those involved in Colarossi's care, Bard's motion is silent as to how it provided warnings to those other individuals, or what Dr. Provenzano knew. Bard does not explain how placing warnings in a kit used by the surgeon would be adequate to apprise those who later accessed the port. While Patil indicated that Bard also published a brochure on catheter

pinch-off and fracture, upon which its counsel seeks to rely on this motion, Patil only testified that such brochure was "sometimes" handed out by Bard's salespeople to "some" facilities which asked for or needed it, and was also given out to facilities once Bard confirmed that a pinch-off incident had occurred. Id. at 102, 111-115. Bard has presented no evidence that it provided this brochure to Lawrence Hospital or to any of the individuals involved in Colarossi's care prior to the incident. Further, it is not even clear whether the brochure was sent to the hospital after Bard learned of the incident in this case, since Patil testified that Bard never concluded that Colarossi's case involved a pinch-off. Also, even had this brochure been provided to Lawrence Hospital before the incident, it is not apparent how that would have added to Dr. Provenzano or Dr. Kerin's knowledge if they were private attending physicians. Bard has also set forth no evidence that anyone involved in Colarossi's care attended any Bard seminar or training session, or that it provided any training at Lawrence Hospital. Contrary to Bard's assertion, Nurse Redway only testified that some seminars were provided by drug manufacturers, not by device manufacturers. In light of all of the foregoing, Bard's application to dismiss the balance of the negligence (fourth) and strict products liability (fifth) causes of action must be, and hereby is, denied.

As to the implied warranty cause of action, such a claim may be asserted where a product is "not reasonably fit for the ordinary purposes for which such goods are used," a claim which "focuses on the expectations for the performance of the product when used in the customary, usual and reasonably foreseeable manners" (internal quotation marks and citation omitted)." Denny v. Ford Motor Co., 87 N.Y.2d 248, 258-59 (1995); see also U.C.C. § 2-314 (2)(c). While at trial, a plaintiff can recover on such a claim by showing "that the product was not minimally safe for its

expected purpose" (Denny v. Ford Motor Co., 87 N.Y.2d at 259), on summary judgment, the manufacturer bears the initial burden of demonstrating that the product "was reasonably safe for the ordinary purposes for which it is used" (Lauber v. Sears, Roebuck & Co., 273 A.D.2d 922, 922 [4th Dep't 2000]).

In view of Bard's claims that the port catheter was fit because its warnings were adequate and were conveyed to the learned intermediaries, and because Dr. Kerin was allegedly aware of the relevant risks, and since, as just indicated, Bard has not demonstrated that this is so, it has failed to meet its burden of showing its entitlement to dismissal of this cause of action. Further, Bard's claim, that the catheter was fit because there is no evidence that it malfunctioned, is undercut by Nurse Redway's testimony, including that, at the second session, Colarossi had to be repositioned, a sign of pinch-off according to the IFU's warning section, and that, during the third session, the port catheter leaked and caused burning, leading Nurse Redway to abandon the port catheter and establish a peripheral line. The malfunctioning is also supported by Colarossi's testimony that three nurses tried unsuccessfully to use the port catheter, at the third session, and by Dr. Kerin's testimony that he removed the port catheter because he was informed that it was malfunctioning, as well as by his surgical report. Finally, that the port catheter's lot passed certain post-manufacturing tests, does not, standing alone without any expert's affidavit, demonstrate that the port catheter was fit, here where Patil conceded that it could fracture if the port experienced too much movement, and where there is an issue as to whether the port catheter met the intermediaries' expectations for performance considering the warnings which accompanied it. Accordingly, the branch of Bard's motion seeking an order granting it summary judgment dismissing the balance of the implied warranty cause of

action is denied.

Accordingly, it is hereby

ORDERED that the branch of C.R. Bard, Inc.'s summary judgment motion which seeks an order dismissing plaintiff's breach of express warranty cause of action (seventh cause of action) is granted, and that cause of action is dismissed as to C.R. Bard, Inc.; and it is further

ORDERED that the branch of C.R. Bard, Inc.'s summary judgment motion which seeks an order dismissing plaintiff's design defect cause of action (eighth cause of action) is granted, and that cause of action is dismissed as to C.R. Bard, Inc.; and it is further

ORDERED that, to the extent that the Amended Complaint's fourth (negligence), fifth (strict products liability), and sixth (implied warranty) causes of action are based on claims of defective design and manufacturing, those claims are dismissed as to C.R. Bard, Inc., but, to the extent that C.R. Bard, Inc., seeks an order granting it summary judgment dismissing plaintiff's claims under the fourth, fifth, and sixth causes of action, which are predicated on the warnings and instructions provided, C.R. Bard's summary judgment motion is denied; and it is further

ORDERED that the claims and causes of action, to the extent that they are dismissed against C. R. Bard, Inc., are severed, and the balance of the action shall continue; and it is further

ORDERED that the parties shall appear for their previously scheduled pretrial conference on September 25, 2012, at 9:30 a.m.

Dated: September 5, 2012

ENTER:

JOAN B. LOBIS, J.S.C.