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

PRESENT: HON. JOAN B. LOBIS PART 6
Justice

KAREN HENDERSON,

Plaintiff,

- v -

STRYKER CORPORATION, et al,

Defendants.

INDEX NO. 110566/05
MOTION DATE 05/20/08
MOTION SEQ. NO. 006
MOTION CAL. NO.

The following papers, numbered 1 to 76 were read on this motion for summary judgment

		PAPERS NUMBERED
Order to Show Cause	Affidavit, Exhibits	1-21
X-Motion	Affidavit, Exhibits	22-37
Affidavit in Opposition	Exhibits	38-41
X-Motion	Affidavit, Exhibits	42-57
X-Motion	Affidavit, Exhibits	58-62
Affidavit in Opposition	Exhibits	63-65
Reply	Exhibits	66-67B
Affidavit in Opposition & Reply	Exhibits	68-72
Reply	Exhibits	73-76

Cross-Motion: [X] Yes [ ] No

Upon the foregoing papers, it is ordered that this motion is decided in accordance with the accompanying decision and order.

Dated: 9/25/08

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

Check one: [ ] FINAL DISPOSITION [X] NON-FINAL DISPOSITION

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

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KAREN HENDERSON, as Administratrix of the Estate of JAMES HENDERSON, and KAREN HENDERSON, individually,

Plaintiff,

Index No. 110566/05

-against-

Decision and Order

STRYKER CORPORATION, EDWIN M. CHANG, SAMANTHA TUTTAMORE, SAINT VINCENT'S CATHOLIC MEDICAL CENTERS OF NEW YORK a/k/a SISTERS OF CHARITY MEDICAL CENTER, FRANK MICHAEL ROSELL, JEFFREY MICHAEL-NICASTRO, DANIEL ROESLER, DENNIS NG, HELEN HYOSUN KIM, ZHENQUING WU, STATEN ISLAND UNIVERSITY HOSPITAL, KENNETH J. WOOH, M.D., P.C., and HEALTHCARE ASSOCIATES IN MEDICINE, P.C.

Defendants.

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

Motion Sequence Numbers 006, 008, 009, and 010 are consolidated for disposition.[1] In Motion Sequence Number 006, Stryker Corporation ("Stryker") moves, by order to show cause, for summary judgment pursuant to C.P.L.R. Rule 3212 dismissing all claims against it; plaintiff cross-moves for summary judgment against Edwin M. Chang, M.D. ("Dr. Chang") and Dr. Chang's practice, Healthcare Associates in Medicine, P.C. ("Healthcare"); and, Dr. Chang and Healthcare each cross-move for summary judgment dismissing all claims against them.[2] In Motion Sequence Number 008, Samantha Tuttamore, P.A., and Saint Vincent's Hospital - Staten Island, a Hospital of

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[1] Motion Sequence Number 007 was resolved by decision and order of this court dated May 2, 2008.

[2] Plaintiff's claims against Healthcare sound in Healthcare's vicarious liability for Dr. Chang.

St. Vincent's Catholic Medical Centers of New York s/h/a Saint Vincent's Catholic Medical Centers of New York a/k/a Sisters of Charity Medical Center ("St. Vincent's") move for summary judgment dismissing all claims against them. On May 9, 2008, a stipulation of discontinuance as to Samantha Tuttamore was filed in the county clerk's office; thus, Motion Sequence Number 008 is now solely on behalf of St. Vincent's. In Motion Sequence Number 009, Helen Hyosun Kim, M.D. ("Dr. Kim") and Kenneth J. Wooh, M.D., P.C. ("Wooh P.C.") move for partial summary judgment dismissing the claims for lack of informed consent. In Motion Sequence Number 010, Dennis Ng, M.D. ("Dr. Ng"), Frank Michael Rosell, M.D. ("Dr. Rosell"), Jeffrey Michael Nicastro, M.D. ("Dr. Nicastro"), and Staten Island University Hospital ("SIUH")[3] move for partial summary judgment dismissing the claims against them for lack of informed consent.

This is an action for medical malpractice which arose from the treatment of plaintiff's decedent, James Henderson. Plaintiff also alleges that the anterior cervical plating system manufactured by Stryker that was implanted in Mr. Henderson's cervical spine was defective. Karen Henderson, who brings this cause of action as the Administratrix of Mr. Henderson's estate, was Mr. Henderson's wife. Mr. Henderson first saw Dr. Chang in December 2002, with complaints of

[3] Dr. Kim was also named as a moving defendant in Motion Sequence Number 010, although this appears to have been inadvertent, as by the time this motion was made, Dr. Kim was represented by different counsel from Dr. Rosell, Dr. Nicastro, and SIUH, as is indicated by Dr. Kim's own motion for summary judgment under Motion Sequence Number 009 by separate counsel. Additionally, although Dr. Ng is not named as a moving defendant in paragraph one of defense counsel's moving affirmation on Motion Sequence Number 010, Dr. Ng is named as a defendant in the notice of motion by counsel for the moving defendants. Furthermore, counsel makes affirmative arguments in Dr. Ng's favor in the moving papers, and plaintiff's opposition papers oppose summary judgment as to Dr. Ng. While there is some confusion as to which defendants moved for summary judgment under Motion Sequence Number 010, this court will treat the motion as if Dr. Ng is included as one of the moving defendants.

progressive, severe neck pain radiating to the left shoulder and arm and accompanied by paresthesia. An MRI revealed a herniated disc with impinged nerves at the C4-5 and C5-6 levels. Mr. Henderson had been treated with steroid injections without success, so Dr. Chang recommended cervical decompression and fusion. Dr. Chang explained the risks associated with the procedure, including paralysis, loss of function of the limbs, wound infection, loss of voice, difficulty swallowing, and even death, and specifically explained that a screw could back out of the surgical hardware. On April 22, 2003, Mr. Henderson decided to go ahead with the surgery; by this point his pain had progressed and he was experiencing weakness in his left arm and shoulder muscles.

On May 21, 2003, Dr. Chang met with Mr. Henderson before the scheduled surgery surgery and re-explained the risks; Mr. Henderson also executed a consent form for the procedure. Dr. Chang performed a discectomy and spinal fusion on Mr. Henderson at St. Vincent's hospital. During that procedure, Dr. Chang installed an anterior cervical plating system (the "Reflex System") manufactured by Stryker. Mr. Henderson was discharged the next day.

Five days after his initial surgery, Mr. Henderson was experiencing severe pain, swelling in his neck, and difficulty breathing. At Dr. Chang's direction, Mr. Henderson sought emergency treatment at SIUH, since Dr. Chang was on duty there at the time. An x-ray revealed that one of the screws that had been inserted during the spinal fusion procedure had "backed out," causing a cervical hematoma and potential damage to Mr. Henderson's esophagus. On May 27, 2003, Dr. Rosell and Dr. Chang performed exploratory surgery to determine what damage had been caused by the backed-out screw and whether Mr. Henderson's esophagus had been perforated.

During that surgery, Dr. Rosell evacuated a cervical hematoma that had formed and inserted a Jackson-Pratt drain so that the wound could drain. Dr. Chang inspected the screws of the plating system and found that one screw had loosened from the fourth cervical spinal vertebral body (the "C4"), which was then removed by him. The other screws appeared intact and were not removed.

Over the next few days, there were some signs of infection at the wound site. Dr. Chang recommended consulting the infectious diseases unit. On May 31, it was noted by the medical staff that the Jackson-Pratt drain was not holding suction, and Dr. Chang noticed that the fluid draining from the drain was thinner than before and not purulent.

Dr. Wooh made a single bedside visit to Mr. Henderson on May 31, 2003. According to his note and deposition testimony, Dr. Wooh reviewed Mr. Henderson's chart, examined him, and noted his condition and appearance of the wound. The Jackson-Pratt drain was in place at this time. Dr. Wooh recommended continued wound care and antibiotics; he further recommended that the nasogastric tube be replaced with a PEG (percutaneous endoscopic gastrostomy tube, which is inserted through the abdomen as opposed to the esophagus). This was Dr. Wooh's only encounter with Mr. Henderson.

At some point on May 31, 2003, the Jackson-Pratt drain was removed, either at Dr. Chang's or another doctor's direction. Over the next twenty-four hours, Mr. Henderson developed a syndrome of sepsis, requiring intubation to protect his airway and mechanical ventilation. On June 2, 2003, Dr. Kim, an employee of Wooh P.C., saw Mr. Henderson at his bedside when she was

covering for Dr. Wooh. Dr. Kim performed wound care and inserted a Penrose drain, because the Jackson-Pratt drain had been removed. Later, doctors determined that the Penrose drain was either not draining properly or had become dislodged. On June 3, 2003, Dr. Rosell performed a second exploratory surgery, debrided the wound, drained esophageal fluid that had collected at the wound site, and reinserted a Jackson-Pratt drain; also during that surgery, Dr. Nicastro inserted a gastrostomy and jejunostomy tube.

Between June 3, 2003 and June 10, 2003, there was a sharp decline in Mr. Henderson's neurological responses. He was heavily sedated and intubated during this time period. On June 10, 2003, Dr. Nicastro reported that Mr. Henderson was showing signs of quadriplegia. On June 11, 2003, Dr. Chang noted that Mr. Henderson had no spontaneous movement of the extremities, even though sensory function was intact to touch and an MRI of the spine on June 12, 2003 revealed no demonstrable spinal cord compression. On June 16, 2003, Dr. Chang performed a decompressive cervical laminectomy from C4-C6 to explore, inspect, and hopefully treat the cause of Mr. Henderson's paralysis; however, the procedure revealed that no epidural material was causing spinal cord compression. Mr. Henderson remained at SIUH for approximately two more months, during which time, *inter alia*, he needed to be put on a ventilator; he also developed bedsores. Dr. Chang last saw Mr. Henderson on August 6, 2003. On August 12, 2003, Mr. Henderson was transferred to the Kessler Institute for Rehabilitation. On December 2, 2003, Mr. Henderson was transferred to the Bronx Veterans Affairs Medical Center, where he died on January 7, 2004.

Plaintiff's verified complaint sets forth nine causes of action:[4] (1) negligent design, manufacture, and distribution of the Reflex System, as against Stryker; (2) strict products liability, as against Stryker; (3) breach of warranty, as against Stryker; (4) negligence, as against Dr. Chang; (5) negligence, as against Samantha Tuttamore; (6) negligence, as against St. Vincent's; (7) negligence, as against Dr. Rosell, Dr. Nicastro, Dr. Roesler, Dr. Ng, Dr. Kim, Wooh P.C., and SIUH; (8) conscious pain and suffering, and funeral and burial costs, as against all defendants; and, (9) lack of informed consent, as against all defendants. Plaintiff's amended verified complaint, dated May 9, 2007, adds Healthcare as a defendant to the fourth cause of action.

Stryker seeks dismissal of the products liability claims against it. In addressing products liability claims, the Court of Appeals has set forth that

> 'the manufacturer of a defective product is liable to any person injured or damaged if the defect was a substantial factor in bringing about his injury or damages; provided: (1) that at the time of the occurrence the product is being used * * * for the purpose and in the manner normally intended, (2) that if the person injured or damaged is himself the user of the product he would not by the exercise of reasonable care have both discovered the defect and perceived its danger, and (3) that by the exercise of reasonable care the person injured or damaged would not otherwise have averted his injury or damages.' As the law of strict products liability has developed in New York, a plaintiff may assert that the product is defective because of a mistake in the manufacturing process or because of an improper design or because the manufacturer failed to provide adequate warnings regarding the use of the product.

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[4] Plaintiff misnumbered the eighth and ninth causes of action in her verified complaint and her amended verified complaint. What is really the eighth cause of action (paragraphs 87-92) is referred to as a second fifth cause of action, and what is really the ninth cause of action (paragraphs 93-99) is misnumbered as a second sixth cause of action. For the purposes of this motion, these causes of action shall be referred to as the eighth and ninth causes of action, respectively.

Voss v. Black & Decker Mfg. Co., 59 N.Y.2d 102, 106-07 (1983) (internal citations omitted). Of the three distinct types of strict products liability claims, the pleadings and plaintiff's expert report indicate that plaintiff has not pled a cause of action for strict products liability based on a mistake in the manufacturing process; nothing in plaintiff's pleadings or papers alleges that "there was any impropriety in the manufacture" of the Reflex System. Perazone v. Sears, Roebuck and Co., 128 A.D.2d 15, 19 (3d Dep't 1987); see also Sita v. Danek Med., 43 F. Supp. 2d 245, 252 (E.D.N.Y. 1999). Plaintiff's claim is for design defect and failure to provide adequate warnings.

In support of its contention that plaintiff's claim under the theory of strict liability based on design defect should be dismissed, Stryker submits an affidavit from Albert H. Burstein, Ph.D.,[5] a biomechanical engineer with experience in spinal devices such as the Reflex System. Dr. Burstein submits his affidavit to describe the screw locking mechanism of the Reflex System. He explains that there are three components to the Reflex System: cervical plates, bone screws, and blocking rings. The plate is affixed to the bone by screws inserted into holes in the plate; the holes contain blocking rings that close over the top of the screw once the screw is fully inserted. If the screw is properly inserted into the holes and the head of the screw is under the blocking ring, the blocking ring is prevented from reopening or collapsing by the presence of the screw itself, and the screw is thus prevented from backing out. Dr. Burstein opines that it is not possible for the screw head to overcome the strength of the blocking ring. He states that the maximum force exerted by the body is not sufficient to break the blocking ring. Thus, a properly locked screw is prevented from backing out of the vertebral body.

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[5] Counsel for Dr. Chang objected to the initial report submitted by Dr. Burstein as insufficient, as it lacked the essential elements of an affidavit. In Stryker's reply papers, Dr. Burstein's report is resubmitted in the form of an affidavit.

Dr. Burstein also explains that fixation plates in general, including the Reflex System, are designed to "minimize the possibility of a screw backing out" and he describes three classifications of mechanisms by which to do so: blocking rings, double threaded screws, and cover caps. Each requires an additional manufacturing detail, and all require the surgeon to fully insert the screw into the screw hole to engage the locking mechanism or attach a separate component after the screw is inserted. Dr. Burstein states that the unthreaded blocking ring—the system used in the Reflex System—is the simplest of all designs to engage, as it only requires the surgeon to tighten the screw fully into the bone to automatically engage the locking mechanism. This simplicity, Dr. Burstein states, provides for quicker learning for the surgeon and less likelihood for surgical error. He states that the Reflex System has proven to be reliable, with a reported screw back-out rate of only two back-outs out of 158,606 applications. He also notes that an additional consideration is the "complexity and difficulty of intentionally removing the screw should the need arise . . . ." Of the possible systems, Dr. Burstein opines that the Reflex System is the simplest to intentionally remove, "in that it only requires attaching the removal screw driver to the screw head and then unscrewing the bone screw."

Stryker also submits the affidavit of Marta L. Villarraga, Ph.D., a biomechanical engineer who specializes in spine biomechanics and failure analysis of medical devices. Dr. Villarraga reviewed the pleadings; Mr. Henderson's medical records, x-rays, and autopsy report; the 510(k) submissions[6] for the Reflex System submitted in January 2001, and the 510(k) submissions

[6] A 510(k) submission is a premarket notification sent by medical device manufacturers to the United States Food and Drug Administration to demonstrate that the device to be marketed is at least as safe and effective as a legally marketed device that is not subject to premarket approval. See 21 C.F.R. part 807, subpart E (2008).

for the subsequent modification of the screws submitted in February and March 2002; deposition transcripts; and, exemplar implant components, including bone screws and a cervical plate. She also examined the actual screw that backed out of Mr. Henderson and was surgically removed, referred to as the "subject screw."

Dr. Villarraga conducted an evaluation of an exemplar plate and screw in order to examine the head of a properly locked screw, after it was removed using the Stryker tool provided for screw removal. She used a foam block with a density similar to human cancellous bone, the type of bone fixed with the Reflex System. She inserted the exemplar screws into the exemplar plate following the instructions in Stryker's Reflex Surgical Technique brochure, having previously been instructed in the procedure by a Stryker representative. She ensured that the screws were properly locked, and then removed the screws using the Revision Screwdriver provided by Stryker.

Upon examination of the removed exemplar screw, Dr. Villarraga noticed "multiple circumferential markings on the spherical underside of the screw heads [sic] up to the rim of the shoulder of the screw head, which allowed [her] to conclude that this exemplar screw was properly locked in the plate." The circumferential markings occur where the blocking ring scraped off the turquoise anodized coating on the surface of the underside of the screw head up to the rim of the shoulder as the screw passed through the blocking ring upon insertion. Dr. Villarraga's inspection of the subject screw "did not show evidence of multiple sequential circumferential markings on the spherical underside of the screw head up to the rim of the shoulder." Having examined the appearance of the underside of a properly locked screw, and having compared the appearance of the

subject screw, Dr. Villarraga opines that the subject screw was not properly locked under the blocking ring in the plate hole when the surgeon inserted it into Mr. Henderson.

Stryker further submits a portion of the deposition transcript of Charles Bush, Jr. Mr. Bush is the senior engineering manager for the cervical division of Stryker. He testified that it is not possible for a screw to back out once the locking mechanism is engaged because "[o]nce the ring closes over the screw, there's no way for the screw to generate enough force to back out through the open mechanism of the ring." Another Stryker engineer, Marcel Metellus, testified at his deposition that it would take "350 Newtons" of force to cause a screw to push out of a locking mechanism, and that there is no internal action that could cause the kind of force that would cause a screw would back out.

Stryker's argument against liability for design defect, distilled, is that a properly locked Reflex System bone screw cannot back out of the plate, and that the subject screw was not properly locked. Thus, Stryker asserts that if Mr. Henderson was indeed injured by the bone screw backing out of the plate, it was not any defect in the design that caused injury to the plaintiff; rather, the injury occurred because the screw was not properly locked below the blocking ring, which Stryker contends is an error made by the surgeon, Dr. Chang.

To meet its burden on summary judgment, Stryker is "required to present evidence in admissible form demonstrating that plaintiff's injuries were not caused by a defect in the product." Wojcik v. Empire Forklift, Inc., 14 A.D.3d 63, 65 (3d Dep't 2004). Stryker did so by submitting Dr.

Burstein's affidavit describing how a properly locked screw cannot back out, and Dr. Villarraga's affidavit describing the tests that she performed on the Reflex System and her findings that the subject screw was not properly locked. See id. Stryker has demonstrated that the Reflex System is a safely designed product, "that is, one whose utility outweighs its risks when the product has been designed so that the risks are reduced to the greatest extent possible while retaining the product's inherent usefulness at an acceptable cost." Voss, supra, 59 N.Y.2d at 108.

To survive a motion for summary judgment on the design defect issue, plaintiff must demonstrate that "the product, as designed, was not reasonably safe because there was a substantial likelihood of harm and it was feasible to design the product in a safer manner." Voss, supra, 59 N.Y.2d at 108; see also Sita v. Danek Med. Ctr., supra, 43 F.Supp. at 255. In opposition to Stryker's motion, plaintiff submits the affidavit of James Pugh, P.E., a licensed professional engineer in New York, with a Ph.D. in biomedical engineering. Dr. Pugh reviewed Mr. Henderson's medical records and x-rays; Stryker's instant order to show cause and exhibits; deposition testimony; and, documents produced in discovery by Stryker, including the surgical technique guide operating instructions and pre-market documents.

Dr. Pugh first contends that the Reflex System has a "less-than-two" safety factor "because, by design, only the blocking ring, and nothing else, prevents the screw from backing out . . . ." Dr. Pugh asserts that the maximum force exerted by the screw is 200 newtons, and the force required to break the blocking ring is 350 newtons. Dr. Pugh opines that for a minimal safety factor of two, the strength of the blocking ring should be 400 newtons. It is Dr. Pugh's "considered

opinion that this less-than-two safety factor is unacceptable and defective by design." Without citing any authority, he asserts that in this, and all, engineering applications, the minimum safety factor is two, and for dynamic applications such as the Reflex System, the recommended safety factor is either four or eight. Dr. Pugh contends that a safety factor of less-than-two is inadequate, because there are *in situ* (internal) forces that can cause the screw to back out past the blocking ring.

Dr. Pugh also asserts that certain "aspects of the surgical technique . . . can affect the proper engagement of the blocking ring therefore allowing a screw to back out." He claims that direct visualization of the screw locked into place (the surgical technique recommended by Stryker) is very difficult to ascertain intraoperatively, due to factors such as the limited nature of the surgical exposure; the presence of blood, fat, and biological debris; and, the "need to limit the duration of the operative procedure." Dr. Pugh also opines that Stryker's recommended technique that the surgeon evaluate resistence by "feel" is impractical and virtually impossible to perceive, because bone of varying quality will result in the sensation of uneven resistence as the screw is tightened. Thus, Dr. Pugh concludes that the "design is not ergonomically conducive to production of the desired result, and therefore is defective."

Further, Dr. Pugh sets forth that biological debris can prevent the blocking ring from properly locking the screw into place, and that the blocking ring will not engage properly if the screw is driven in at an angle to the plate. Stryker claims that the Reflex System employs the use of a drill guide to keep the screwdriver within the range of angulation for the proper insertion of the screws, thereby preventing a screw from being overangulated and thus unable to be fully locked. But, Dr.

Pugh argues that Stryker's claims are untrue and unsupported by Stryker's witness, Mr. Bush, who testified that overangulation of a screw is still possible if the surgeon maintains the drill guide in an overangulated position and drills the hole. Dr. Pugh also asserts that the design of the Reflex System is defective because the screws are held in place by the secure fixation of the plate by other screws; if all the screws are rotating and the plate becomes elevated from the spine, all of the screws can back out.

Dr. Chang also opposes summary judgment in favor of Stryker. Dr. Chang's opposition papers contend that there is an issue of fact as to whether a properly locked screw can back out, because Stryker's package insert indicates that "[e]arly loosening may result from inadequate initial fixation, latent infection, premature loading of the device or trauma. Late loosening may result from trauma, infection, biological complications or mechanical problems . . . ." However, Dr. Chang's expert, William J. Sonstein, M.D., a board certified neurosurgeon, never addresses whether the use of the word "loosening" in Stryker's materials has anything to do with a screw not being properly locked into the blocking ring in the first instance or "backing out." Dr. Chang's papers also discount Dr. Villarraga's test results and report as conclusory and speculative. However, Dr. Chang's expert, who is not a biomechanical engineer, did not perform any tests on the system to refute Dr. Villarraga's report. Dr. Sonstein merely reviewed the intraoperative film taken after the Reflex System was implanted in Mr. Henderson. Dr. Sonstein observes from the film that the "head of the screw [is] appropriately flush with the face of the plate," indicating that Dr. Chang "obtained adequate placement of the screw into the plate." Dr. Sonstein therefore concludes, to a reasonable degree of medical certainty, that "Dr. Chang's placement of the screw was within good

and acceptable medical practice, and Dr. Chang's surgical technique was not a proximate cause or substantial factor in the screw backing out."

Assuming for the purposes of these motions that the backed-out screw led to a perforation of Mr. Henderson's esophagus, which was a substantial contributing cause of his death, there has been no evidence or claim that it was feasible to design the product in a safer manner. Voss, supra, 59 N.Y.2d at 108. Dr. Pugh does not explain how the Reflex System could have been alternatively designed with a safety factor of four or eight, the safety factors he suggests are necessary in dynamic applications. Nor does plaintiff's expert provide an alternative design to a plating system that would reduce or eliminate the problems caused by the surgical technique, which requires the surgeon to visualize and sense resistence to ensure that the device is fixed properly. Dr. Pugh does not offer a safer way to affix the device as opposed to the technique used by the Reflex System. Dr. Pugh also does not provide an alternative, safer design that reduces or eliminates the problems he claims are caused by biological debris during the implantation procedure, nor does he provide an alternative, safer choice to the drill guide that the Reflex System uses. In fact, the only expert who mentions alternative designs to the Reflex System is Stryker's own expert, Dr. Burstein, who touts the unthreaded blocking-ring mechanism as the simplest for the surgeon to engage. Neither plaintiff's nor Dr. Chang's opposition papers refute this assertion. In fact, a review of the record indicates that plaintiff, in opposition to Dr. Chang's cross motion for summary judgment, submits the expert opinion of Gene Bolles, M.D., who opines that the Reflex System "is designed to lock the screw in place *if the screw is correctly positioned and secured inside the plating system*." (Emphasis in original.) See infra, pp. 27-28. Dr. Bolles states that screw back-out is not a risk with

the Reflex System if the screws are correctly placed. Dr. Bolles' affidavit supports Stryker's contention that the Reflex System was reasonably safe for use in the manner in which it was used. Sita v. Danek Med., supra, 43 F. Supp. 2d at 255-56. Accordingly, this court grants that portion of defendant Stryker's motion for summary judgment on the second cause of action, the design defect claim. The opponents failed to introduce evidence of a feasible safer design alternative.

With respect to the claim of lack of informed consent as to Stryker, which is more properly termed a claim for "failure to warn," Stryker submits the Reflex System's Surgical Technique Guide, which sets forth that the

> REFLEX™ system has been designed not only to be clinically effective but also simple to use. The notes in this manual provide suggestions regarding surgical technique and instructions on implanting the REFLEX™ system during major spinal surgical procedures. This manual concentrates on operative technique and implant configurations of particular relevance to the REFLEX™ system.

The technique guide provides an overview of the appropriate use of the Reflex System, and overview of the surgical technique, and a description of the different components of the plating system. Stryker also submits the "insert packet" titled "Important Product Information" for the Reflex System, which includes, *inter alia*, considerations of use, anatomical limitations, contra-indications, recommendations, and side effects. Listed under "side effects" are the following relevant sentences:

> Early loosening may result from inadequate initial fixation, latent infection, premature loading of the device or trauma. Late loosening may result from trauma, infection, biological complications or mechanical problems, with the subsequent possibility of bone erosion, or pain.
>
> Serious complications may occur with any spinal surgery. These complications include, but are not limited to, genitourinary disorders;

> gastrointestinal disorders; vascular disorders, including thrombus; bronchopulmonary disorders, including emboli; bursitis, hemorrhage, myocardial infarction, infection, paralysis or death.

As to the surgical technique, the package insert specifically states that

> [b]efore clinical use, the surgeon should thoroughly understand all aspects of the surgical procedure and limitations of the spinal device. Knowledge of surgical techniques, proper reduction, selection and placement of implants, and pre- and post-operative patient management are considerations essential to a successful surgical outcome. Consult the medical literature for information regarding proper surgical techniques, precautions, and potential adverse effects associated with spinal fixation surgery.

Lorenzo Mastrandrea, a representative from Stryker, testified at his deposition that an "insert packet" was included with every implant. Further, Dr. Chang testified at his deposition that he was given and reviewed the following materials: a general brochure, a pamphlet, and Stryker general distribution material regarding the screws that are used in cervical plating. Dr. Chang testified that he informed Mr. Henderson of the risks of the procedure, including "paralysis, loss of function of the limbs, wound infection, loss of voice, swallowing difficulties, and [that] occasionally the screw can back out, and even [result in] death." Dr. Chang also testified that he was fully familiar with the Reflex System prior to May 21, 2003; that for his plating purposes, he had been using the Stryker Company as a supplier since the mid 1990s; and, that he continues (at least as of the date of his deposition) to use the Stryker Company for plating purposes. He further testified that he was instructed as to how to use the Reflex System from Neurosurgical Society meetings, journals, and from actual courses; Dr. Chang testified that he had "plenty of occasions to learn about this type of procedure and instruments."

Stryker is required to warn and reasonably bring to the medical community's attention all potential dangers which it knows or should know are associated with the Reflex System. Glucksman v. Halsey Drug Co., 160 A.D.2d 305, 307 (1st Dep't 1990). The manufacturer satisfies its duty to warn by providing the information to the physician, who acts as a "responsible intermediar[y]." Andre v. Mecta Corp., 186 A.D.2d 1, 2 (1st Dep't 1992); see also Glucksman, supra. "Where the warning given to the physician . . . through package inserts and/or other literature, gives specific detailed information on the risks of the drug [or device], the manufacturer may be absolved from liability." Glucksman, supra. Stryker demonstrated that Dr. Chang was furnished with materials providing the warnings, risks, and instructions for the Reflex System. The package insert included with the Reflex System "speaks for itself" and demonstrates that Stryker "adequately warned prescribing physicians of all the known risks" from using the Reflex System. Mulhall v. Hannafin, 45 A.D.3d 55, 59 (1st Dep't 2007). The burden then shifts to plaintiff to demonstrate a material issue of fact that the warnings were deficient. Id.

Plaintiff's expert, Dr. Pugh, opines that Stryker's representations regarding the ease and safety of its design as contained in surgical technique guide are misleading and likely to lead to surgical error. Additionally, he claims that the product is promotive of surgical error and that there are inadequate warnings issued by Stryker acknowledging or warning of the safety factors and deficiencies that must be taken into account by the surgeon. Finally, Dr. Pugh states that the warnings contained in the package insert are in an illegible type-written form because the font is so small that no average person would be able to read the insert, thereby discouraging it from being read. Dr. Pugh states that "[w]arnings are supposed to be designed to be read and should be made at a type-setting large enough to be easily readable, which was not done in this case."

Whether a warning is adequate is generally an issue for the trier of fact "'and is not ordinarily susceptible to the drastic remedy of summary judgment.'" Bukowski v. Coopervision, Inc., 185 A.D.2d 31, 33 (3d Dep't 1993). But, plaintiff must demonstrate more than just a general claim of failure to warn to defeat summary judgment. Except for broad statements about general deficiencies in the warnings, plaintiff does not point out which instructions or warnings Stryker failed to convey, so as a matter of law, the warnings are not inadequate. See Glucksman v. Halsey Drug Co., supra, 160 A.D.2d at 307-08; see also Martin v. Hacker, 83 N.Y.2d 1, 15 (1993). Additionally, to defeat summary judgment, plaintiff must demonstrate that any alleged failure on Stryker's part to warn Dr. Chang was the proximate cause of Mr. Henderson's injuries. Plaintiff argues that Dr. Chang either never received or never read the materials provided by Stryker, but Dr. Chang testified that he did receive and review certain materials, that he informed Mr. Henderson of the risks of the procedure, and that he was fully familiar with the Reflex System. See Glucksman, supra, 160 A.D.2d at 307 (finding that any alleged failure to warn by the manufacturer could not be the proximate cause of plaintiff's injuries because the physician testified that he was "independently aware of the dangers involved" in the procedure). Although plaintiff's expert claims the typeface on the product insert is illegible, even if that were true, Dr. Chang's personal knowledge of the Reflex System, the surgical procedure, and the specific potential adverse effects of the Stryker system was an intervening circumstance that severs the causal connection between the manufacturer's alleged failure to warn and plaintiff's injury. Banker v. Hoehn, 278 A.D.2d 720, 722 (3d Dep't 2000). Plaintiff has failed to demonstrate an issue of fact as to whether Stryker's alleged failure to warn of the dangers of implanting and using the Reflex System proximately caused Mr. Henderson's injuries. Plaintiff has provided only conclusory statements that the warnings to the

surgeon were inadequate and promotive of surgical error. Plaintiff provided no evidence concerning the insufficiency of the warning and how that insufficiency contributed to Mr. Henderson's injuries. As such, plaintiff cannot defeat Stryker's motion for summary judgment on the issue of failure to warn; the ninth cause of action is dismissed as to Stryker.

Stryker also seeks summary judgment on plaintiff's claim of negligent design. For the reasons addressed above in the discussion of strict products liability for design defect, summary judgment in favor of defendant Stryker is granted on the first cause of action, the negligent design claim, as well. The opponent of the summary judgment motion is required to demonstrate the feasibility of a safer design to make out a prima facie case of negligent design (Rose v. Brown & Williamson Tobacco Corp., 53 A.D.3d 80, 82 [1st Dep't 2008], citing Voss, supra, at 108), which, as discussed supra, plaintiff did not do.

Defendants also seek summary judgment on plaintiff's third cause of action, the claim for breach of warranty. Plaintiff fails to differentiate between breach of express warranty and breach of implied warranty anywhere in her papers; however, Stryker's motion appears only to raise the issue of "fitness for ordinary purpose" and plaintiff's opposition papers, with respect to the breach of warranty claim, respond only as to "fitness for ordinary purpose." Since "fitness for ordinary purpose" is an element of breach of implied warranty, this court shall only address the merits of Stryker's motion as to breach of implied warranty.

Breach of implied warranty claims are different from strict liability design defect claims in that the concept of "defect" is different. Denny v. Ford Motor Co., 87 N.Y.2d 248, 258 (1995). "While the strict products concept of a product that is 'not reasonably safe' requires a weighing of the product's dangers against its over-all advantages," a breach of implied warranty claim "requires an inquiry only into whether the product in question was 'fit for the ordinary purposes for which such goods are used.'" Id.; see also U.C.C. § 2-314 (2004). An inquiry into fitness "focuses on the expectations for the performance of the product when used in the customary, usual and reasonably foreseeable manners." Denny v. Ford Motor Co., 87 N.Y.2d at 258-59. "[R]ecovery may be had upon a showing that the product was not minimally safe for its expected purpose--without regard to the feasibility of alternative designs or the manufacturer's 'reasonableness' in marketing it in that unsafe condition." Id. at 259.

Stryker argues that it is entitled to summary judgment on the issue of breach of implied warranty. Relying on its prior arguments as to why it is entitled to summary judgment on the design defect and negligent design claims, Stryker asserts, citing Denny v. Ford Motor Co., supra, that "it is beyond question that the Reflex plate, which uses the safest design available for preventing screw backout, provided far more than 'a minimal level of quality.'" Id. at 258, n.4. Plaintiff argues in response that any system which "allows for incorrect or difficult visualization of a blocking ring, or has expected failure whenever a screw is overangulated by a surgeon or is expected when there is biological debris in the area of the ring [sic], without a back-up safety device, is not fit for safe use." This argument, however, does not dispute that when used properly, the Reflex System performs the job for which it was intended. As noted before, in opposition to Dr.

Chang's motion for summary judgment, plaintiff's own expert opines that the Reflex System "is designed to lock the screw in place *if the screw is correctly positioned and secured inside the plating system*." (Emphasis in original.) See infra, pp. 27-28. Therefore, the Reflex System meets the standard of "minimal level of quality," as set forth in Denny. Stryker is entitled to summary judgment on the third cause of action, the claim for breach of implied warranty.

Plaintiff cross-moves against Dr. Chang for summary judgment. Plaintiff's claims against Dr. Chang are based primarily on his alleged failure to properly implant the Reflex System in Mr. Henderson's spine, although plaintiff also claims that Dr. Chang is responsible for a multitude of sequelae from which Mr. Henderson suffered. Plaintiff's claims against Healthcare are based on vicarious liability for the acts of Dr. Chang. Plaintiff asserts that Dr. Chang did not fully engage the blocking ring of the screw that backed out. Supposedly in support of this statement, plaintiff submits the affidavit of Marc R. Hamet, M.D., who is board certified in radiology, interventional radiology, and neuroradiolgy. Dr. Hamet reviewed films taken of Mr. Henderson, including the intraoperative x-ray from the May 21, 2003 fusion surgery, as well as x-rays and a CT-scan taken on May 27, 2003 at SIUH. He asserts that the studies from the May 21, 2003 surgery show a fusion plate over the C4-C6 region of the spine. He finds that the two uppermost screws were not affixed to any bone whatsoever; instead, they were inserted into the C4/5 disc space between the C4 and C5 bones. The middle two screws, although inserted into the C5 bone, were not centrally anchored. Similarly, the bottom two screws were affixed in the C6 bone but were not centrally anchored. Dr. Hamet asserts that the screw that eventually backed out — which was one of the uppermost screws inserted into disc space instead of bone—backed out because it had poor purchase (no fixation) at a location with

expected continued motion. He also asserts that the C4/5 joint was not immobilized because the two uppermost screws were not affixed in bone. Dr. Hamet concludes that "[g]iven the associated operative procedure, motion at this joint space rendered the neck unstable exposing the patient to severe neurological injury."

The party moving for summary judgment in a medical malpractice action must make a prima facie showing of entitlement to judgment as a matter of law by showing the absence of a triable issue of fact as to whether the defendant physician was negligent. Alvarez v. Prospect Hosp., 68 N.Y.2d 320, 324 (1986). Plaintiff has not met this burden. Dr. Hamet does not establish that Dr. Chang departed from any standard of care, and his assertion that the screw backed out due to "poor purchase" in the C4/5 disc space does not lend support to plaintiff's claim that the screw backed out due to Dr. Chang's failure to engage the blocking ring. Dr. Hamet does not state that the poor purchase led to the failure of the blocking ring to engage. He never addresses whether or not the intraoperative x-rays indicate that the blocking ring was engaged. Plaintiff has not demonstrated the absence of all material issues of fact; her motion for summary judgment against Dr. Chang and Healthcare is denied.

Turning to Dr. Chang's cross motion for summary judgment, Dr. Chang submits the affirmation of William J. Sonstein, M.D., a duly licensed physician admitted to practice in the State of New York and board certified in neurological surgery. Dr. Sonstein reviewed the pleadings, medical records, radiological films, and pertinent deposition transcripts to inform his opinion as to plaintiff's claims that Dr. Chang failed to properly perform the discectomy and cervical fusion using

the Reflex System, resulting in the screw backing out, and that Dr. Chang improperly removed or ordered the removal of a Jackson-Pratt drain, resulting in myriad complications.

Dr. Sonstein describes in detail Dr. Chang's treatment of Mr. Henderson. He sets forth that during the May 21, 2003 surgery, Dr. Chang felt for sufficient purchase (fixation), observed that the blocking ring indicated the screws were secured, and reviewed the intraoperative x-ray, which indicated that he had achieved proper and adequate insertion of the screws. Dr. Sonstein opines that Dr. Chang's surgical technique was proper. Dr. Sonstein observes that the intraoperative film reveals that the head of the screw was appropriately flush with the face of the plate, and was adequately placed and affixed. It is also his opinion that the screws were properly located and affixed to the vertebral body. According to Dr. Sonstein, the May 21 procedure was completed without complication and Mr. Henderson was discharged in stable condition. Dr. Sonstein further states that the May 27, 2003 x-ray revealed a properly placed plate and screws, except that the most proximal screw was displaced; otherwise, Dr. Sonstein states, the "anatomy was unremarkable." Thus, he opines that Dr. Chang's placement of the screw was within good and acceptable medical practice; that Dr. Chang did not deviate from the standard of care when he performed the decompression and cervical fusion on May 21, 2003; and, that his "surgical technique was not a proximate cause or substantial factor in the screw backing out."

Dr. Sonstein opines that the risk of a screw loosening and backing out is a known risk of cervical fusion surgery, and is not an indication of negligence on the part of the surgeon. Dr. Sonstein states that on three separate occasions, Dr. Chang explained all the risks, benefits, and

alternatives to cervical fusion surgery, including the risk that the screws could back out, and the risks of paralysis and death.

Dr. Sonstein further opines that the removal of the Jackson-Pratt drain on May 31 was not a departure. He notes that there was minimal nonpurulent drainage prior to the removal of the drain, and as such, the removal of said drain was within good and acceptable medical practice. Dr. Sonstein also opines that the removal of the drain was neither a proximate cause nor a substantial factor in the sequelae that Mr. Henderson experienced. He states that there is "no claim or evidence that a hematoma or collection restricted the spinal cord causing the decedent's paresis[;] thus the removal of the [Jackson-Pratt] drain cannot be the proximate cause of the decedent'[s] injuries."[7]

Healthcare also cross-moves for summary judgment as to all claims against it. Healthcare's request for summary judgment is premised on Dr. Chang's demonstration of entitlement to summary judgment in his own cross motion. See Karaduman v. Newsday, Inc., 51 N.Y.2d 531, 546 (1980).

In opposition to the cross motions of Dr. Chang and Healthcare, plaintiff argues that Dr. Sonstein relies on Dr. Chang's testimony that he properly engaged the locking mechanism of the Stryker System, but that Dr. Sonstein fails to provide any alternative explanation as to how the screw backed out. According to Dr. Chang's testimony, there was no noted malfunction or defect in the

[7] Dr. Chang's motion papers fail to set forth any affirmative arguments in favor of summary judgment on the issue of lack of informed consent.

mechanism; therefore, plaintiff asserts that if the screw were properly engaged, as Dr. Chang testified, the screw should not have backed out. Plaintiff claims that Dr. Sonstein's statement that screw back-out after implantation is a risk of the cervical fusion procedure is unsubstantiated and unsupported by the evidence and facts of this case. With respect to the issue of the removal of the Jackson-Pratt drain, plaintiff points out that Dr. Chang and either Dr. Wu or Dr. Wooh ordered the removal of the Jackson-Pratt drain on May 31, 2003, but that Dr. Rosell testified that the drain was not supposed to be removed, and that the removal of the drain caused plaintiff to become septic and require intubation and mechanical ventilation.

In her opposition papers, plaintiff relies on the expert affidavit from Dr. Hamet, which was previously submitted in support of her cross motion for summary judgment against Dr. Chang. See supra, pp. 21-22. Plaintiff also annexes an expert affidavit from Gene Bolles, M.D., a physician licensed to practice medicine in the State of Colorado who is board certified in neurosurgery. Dr. Bolles reviewed Mr. Henderson's medical and hospital charts, all of the deposition testimony, the diagnostic films taken of Mr. Henderson, other pertinent medical records, the autopsy results, and Stryker's surgical technique guide and instructions for use. Dr. Bolles concurs with Dr. Hamet's opinions as expressed in his affidavit. Dr. Bolles states that Dr. Chang's "incorrect and inadequate positioning of the screws caused one screw to back-out causing perforations in Mr. Henderson's esophagus." Additionally, he sets forth that because the screws were inadequately affixed and not centrally anchored, the purchase (fixation) was inadequate for the required immobilization of the spine and maintenance of screw position, rendering the neck unstable post-surgery and exposing Mr. Henderson to severe neurological injury. Dr. Bolles asserts that Dr. Chang's "incorrect and

inadequate placement of the screws and plating system was a breach of the standard of care in neurosurgery which was a substantial cause" of Mr. Henderson's injuries.

Dr. Bolles also opines that the standard of care is to order and perform additional diagnostic tests, such as an x-ray, prior to discharging a patient following cervical fusion surgery. Dr. Chang did not order post-operative x-rays, which Dr. Bolles opines is a departure from good and accepted practice. He opines that if a post-operative x-ray had been taken, Dr. Chang would have seen that the plating system was inadequately affixed, and corrective surgery would have been performed. Dr. Bolles opines that the inadequate fixation of the cervical plate and screws was a substantial cause of the screw backing out; the unstable neck, exposure to neurological injury, and resultant quadriplegia; and, the deteriorated, weak, and compromised condition which caused Mr. Henderson's death.

Dr. Bolles further opines that Dr. Chang breached the standard of care when he failed to diagnose and treat Mr. Henderson's deterioration and developing quadriplegia between May 30, 2003 and June 10, 2003. Although Mr. Henderson's reflexes went from "strong" to "absent" over the period of time between May 30, 2003 and June 2, 2003, Dr. Chang, who saw Mr. Henderson on June 4 and June 6, 2003, failed to notice that Mr. Henderson was a quadriplegic until Mr. Henderson was diagnosed by another physician on June 10, 2003. On June 10, Dr. Chang reported that there were no neurological issues that needed to be addressed. Dr. Bolles claims that Dr. Chang, and the other defendants who provided medical treatment from June 2, 2003 through June 10, 2003, failed to diagnose and treat the damage to Mr. Henderson's spinal cord, causing his spinal cord to be

"permanently and irreversibly damaged rendering Mr. Henderson a permanent quadriplegic." Dr. Bolles claims that certain treatment options, such as high dose steroids or surgery, could have stopped the damage from becoming permanent.

Dr. Bolles also points out that Mr. Henderson's chart indicates that Dr. Chang ordered the removal of the Jackson-Pratt drain because he observed the drainage to be nonpurulent.[8] However, the nursing notes indicate that the last output of fluid was 40 ccs. Dr. Bolles states that the Jackson-Pratt drain should not have been removed on May 31, 2003, as the "drain was in place to continue drainage from an esophagus that was perforated and had not healed." Under these conditions, Dr. Bolles opines that it was a departure from good and accepted medical practice to have ordered the removal of the drain, and that this removal was "the substantial cause" of Mr. Henderson's sepsis, further infection, and resultant injury to his spinal cord.

Dr. Bolles takes issue with Dr. Sonstein's statement that screw back-out is a known risk of fusion plate surgery. Dr. Bolles claims that this statement is inapplicable to the Stryker plating system, or any system that uses a locking mechanism, because this type of plating system "is designed to lock the screw in place *if the screw is correctly positioned and secured inside the plating system*." (Emphasis in original.) Dr. Bolles states that screw back-out is not a risk with the Stryker system if the screws are correctly placed. He points out that Dr. Sonstein provides no explanation as to how the screw backed out when the locking mechanism was allegedly properly engaged by Dr. Chang.

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[8] There is also a note in Mr. Henderson's chart from a physician's assistant named Robin Ludwig (whose deposition transcript is annexed to plaintiff's papers) that Dr. Wu also ordered the removal of the drain.

In reply, defendant argues that plaintiff's expert's statements are conclusory and unsupported by the available admissible evidence. Counsel for Dr. Chang reiterates his earlier arguments for summary judgment and takes issue with the claim that Dr. Chang ordered the removal of the Jackson-Pratt drain. Counsel for Dr. Chang insists that plaintiff's and her expert's assertion that Dr. Chang ordered the removal of the Jackson-Pratt drain results from a mistaken reading of one of Dr. Chang's notes on May 31, 2003. Counsel claims the note indicates that Dr. Chang intended to consult a gastroenterologist regarding the discontinuance of the Jackson Pratt drain, but not that Dr. Chang actually ordered the discontinuance of the Jackson Pratt drain. The note by Dr. Chang in Mr. Henderson's medical records reads: "will consult GI [gastroenterologist] for PEG & DC [discontinue] JP drain."

Dr. Chang's and Healthcare's motions for summary judgment are denied. There exist "material issues of fact which require a trial of the action." Alvarez v. Prospect Hosp., supra, 68 N.Y.2d at 324. The experts sharply dispute whether Dr. Chang departed from the standard of care during the cervical fusion surgery and fixation of the plating system. The issue of whether Dr. Chang improperly removed or ordered the removal of Mr. Henderson's Jackson-Pratt drain is also an issue of fact that must be determined by a jury. In view of the experts' conflicting opinions, summary judgment must be denied. See Cruz v. St. Barnabas Hosp., 50 A.D.3d 382 (1st Dep't 2008); Prigorac v. Park, 20 A.D.3d 363, 363-64 (1st Dep't 2005) (reversing summary judgment where questions of fact were presented by the experts' conflicting opinions as to whether defendant departed from the prevailing standard of care, and, if so, whether such departure resulted in plaintiff's injuries). It cannot be concluded as a matter of law that Dr. Chang did not depart from

the prevailing standards of care in the care and treatment he rendered to Mr. Henderson. The issues of the experts' opinions as to the standard of care, and Dr. Chang's departure from such, if any, are issues for the trier of fact.

MOTION SEQUENCE NUMBER 008

In Motion Sequence Number 008, St. Vincent's moves for summary judgment pursuant to C.P.L.R. Rule 3212 as to all claims against it. St. Vincent's arguments in favor of summary judgment are based on the well-established rule in New York that a hospital, such as St. Vincent's, cannot be held liable for the acts of a patient's private physician, such as Dr. Chang. See Hill v. St. Clare's Hosp., 67 N.Y.2d 72, 79 (1986); Welsh v. Scheinfeld, 21 A.D.3d 802, 807 (1st Dep't 2005). Dr. Chang performed the initial fixation surgery on May 21, 2003 at St. Vincent's, and Mr. Henderson was discharged on May 22, 2003. St. Vincent's asserts that when Dr. Chang operated on Mr. Henderson, he was employed by Healthcare and not by St. Vincent's. Counsel for St. Vincent's references testimony from Karen Henderson's deposition in which she explains how Mr. Henderson came to be a patient of Dr. Chang's, and deposition testimony by Dr. Chang in which he does the same. St. Vincent's motion is accompanied by an expert affidavit from James E. O. Hughes, M.D., a physician duly licensed to practice medicine in the State of New York and a retired neurosurgeon. Dr. Hughes' affidavit supports St. Vincent's argument that Dr. Chang was operating as a privately retained physician and was dictating the care and treatment of his patient.

Similarly, with respect to the claim for lack of informed consent, St. Vincent's points out that a hospital is not required to obtain a patient's informed consent where the patient is treated by his own private physician. See Bailey v. Owens, 17 A.D.3d 222, 223 (1st Dep't 2006). In support of this argument, St. Vincent's annexes Mr. Henderson's signed consent as to the May 21, 2003 surgery performed at St. Vincent's by Mr. Henderson's private physician Dr. Chang. Finally, St. Vincent's argues that once the claims for negligence and lack of informed consent fall away, there can be no claim against St. Vincent's for pain and suffering or wrongful death.

In opposition, plaintiff fails to refute St. Vincent's argument that Dr. Chang was not an employee of St. Vincent's. Instead, plaintiff argues that St. Vincent's failed to annex a page of Mr. Henderson's chart, specifically, the report of Suresh T. Maximin, M.D., a radiologist at St. Vincent's, whose review of the intra-operative x-ray taken of Mr. Henderson on May 21, 2003, notes only: "Lateral portable C spine demonstrates fusion at C4-C6 with C spine below this level obscured on study." Plaintiff annexes this record with her papers, and it is tagged with an exhibit sticker with handwriting that reads: "Petitioner's 5 4/5/05". Plaintiff argues that this is a "critical record" and that it demonstrates that Dr. Maximin "made absolutely no findings when he analyzed the film, other than to note that a fusion was performed." Plaintiff's counsel claims that Dr. Maximin failed to correctly interpret the intra-operative x-ray and, therefore, failed to alert Dr. Chang about the incorrectly placed screws, which was a departure, leading to Mr. Henderson's injuries and death. Also annexed to plaintiff's papers is a supplemental bill of particulars as to St. Vincent's, dated January 14, 2008, which contains one sentence: "[t]his defendant departed from good and accepted medical care in failing to properly and adequately read the intra-operative x-ray and failing to warn

Dr. Chang that the x-ray showed that the screws were improperly placed and loose posing grave danger to plaintiff."

In support of plaintiff's claim of negligence by the St. Vincent's radiologist, plaintiff annexes a second affidavit from her expert radiologist, Dr. Hamet. He reiterates the findings from his first report (supra pp. 21-22) that the screws and plate were placed improperly. He goes on to say that Dr. Maximin failed to note these "critical findings" that he, Dr. Hamet, observed. Therefore, Dr. Hamet opines that Dr. Maximin, an employee of St. Vincent's, breached the standard of care in failing to correctly and adequately interpret the intra-operative film and in failing to warn Dr. Chang that the plate and screws were not placed properly. Dr. Hamet opines that this breach was a substantial contributing cause of the screw backing out.

St. Vincent's has made a prima facie showing of entitlement to judgment as a matter of law by showing the absence of a triable issue of fact as to whether St. Vincent's was negligent. Plaintiff's evidence in opposition is insufficient to raise a triable issue of fact. Dr. Hamet's opinions fail to explain how any alleged breach by Dr. Maximin proximately caused injury to Mr. Henderson; rather, Dr. Hamet simply concludes, without any analysis, that the breach *did* substantially contribute to the screw backing out. Dr. Hamet also does not address the fact that the report appears to have been dictated by Dr. Maximin on May 23, 2003, a day after Mr. Henderson was discharged from St. Vincent's. It appears that Dr. Maximin's only contact with this case was to read the intraoperative x-ray at some point after the surgery was complete, an x-ray which Dr. Chang had already reviewed during Mr. Henderson's procedure and found normal.

Furthermore, in claiming that St. Vincent's is vicariously liable for alleged departures of its radiologist, it appears that plaintiff's expert "improperly raised, for the first time in opposition to the summary judgment motion, a new theory of liability regarding the treatment of plaintiff's decedent that had not been set forth in the complaint or bills of particulars." Abalola v. Flower Hosp., 44 A.D.3d 522 (1st Dep't 2007). In its reply to plaintiff's opposition, St. Vincent's includes its demand for a bill of particulars, dated March 30, 2006, in which St. Vincent's demanded that plaintiff set forth "[e]ach date on which [St. Vincent's] rendered medical care to the Plaintiff(s)." Plaintiff responded with a verified bill of particulars, dated May 10, 2006, setting forth that the dates of treatment were "5/21-22/03." In opposing summary judgment, neither plaintiff's counsel nor her expert alleges any departure by St. Vincent's or Dr. Maximin that occurred on those two dates, nor does the expert assert that Dr. Maximin should have read the intraoperative report earlier than he did. Plaintiff's supplemental bill of particulars, which sets forth that St. Vincent's "departed from good and accepted medical care in failing to properly and adequately read the intra-operative x-ray and failing to warn Dr. Chang that the x-ray showed that the screws were improperly placed and loose posing grave danger to plaintiff," is insufficient to enlarge the time period of treatment beyond May 22, 2003, as alleged in plaintiff's original bill of particulars. A new theory of liability asserted for the first time in opposition to a summary judgment motion is insufficient to defeat summary judgment. See id.; see also Golobov v. Wolfson, 22 A.D.3d 635, 636 (2d Dep't 2005). As plaintiff has failed to raise a triable issue of fact sufficient to defeat St. Vincent's motion, St. Vincent's is entitled to summary judgment dismissing all claims against it. The sixth cause of action is dismissed in its entirety, and the eighth and ninth causes of action are dismissed as to St. Vincent's.

MOTION SEQUENCE NUMBERS 009 and 010

Defendants Dr. Kim, Wooh P.C., Dr. Ng, Dr. Rosell, Dr. Nicastro, and SIUH move for partial summary judgment as to plaintiff's claim for lack of informed consent. Plaintiff's claims against Wooh P.C. are based on vicarious liability for the acts of Dr. Kim,[9] and the claims against SIUH are premised on vicarious liability for the acts of Drs. Kim and Ng. A review of the pleadings and plaintiff's expert report indicates that plaintiff has not properly pled a cause of action of lack of informed consent as to Drs. Rosell and Nicastro, and plaintiff offers no opposition to these two defendants' assertion that no cause of action for informed consent has been shown as to them. The claims for lack of informed consent as against Drs. Rosell and Nicastro in the ninth cause of action are dismissed.

At her deposition, Dr. Kim testified that she had consent to perform the procedures she performed on June 2, 2003, because Mrs. Henderson had executed a consent form on June 1, 2003, consenting to Dr. Kim performing a "neck exploration / irrigation of wound / possible repair of esophagus." The consent form, which is annexed to the moving papers, states that Dr. Ng (a resident at SIUH) fully explained the purpose, benefits, complications, risks, and alternatives to procedure to Mrs. Henderson. The consent form was filled out by Dr. Ng and was signed by Mrs. Henderson on June 1, 2003. Dr. Chang signed the back of the consent form. Dr. Kim did not sign the form. Dr. Kim testified that when she saw Mr. Henderson on June 2, 2003, she saw that her

[9] In May-June 2003, Dr. Kim was the sole employee of Dr. Kenneth J. Wooh, whose practice was Wooh P.C. and who has since retired.

name was on a consent form dated June 1, 2003. When she saw Mr. Henderson on June 2, her decision was to drain his neck, and she testified that the consent form was "sufficient for [her] performing the procedure at bedside." At his deposition, Dr. Ng testified that although he had no recollection of obtaining the consent for any surgery on June 1, except for the signatures of Mrs. Henderson and Dr. Chang, it was clearly his handwriting on the consent form. Dr. Ng testified that the consent was obtained for Dr. Kim; he did now know why Dr. Chang would have signed the back of the consent form. Dr. Ng also testified that a consent form signed on one day was not necessarily for a procedure to be performed on that day, i.e., "just because the consent is obtained on the 1st of June, it doesn't necessarily mean it will be carried out on that particular day." The procedure could be carried out two or three days later.

Under Public Health Law § 2805-d, "[l]ack of informed consent means the failure of the person providing the professional treatment or diagnosis to disclose to the patient such alternatives thereto and the reasonably foreseeable risks and benefits involved." Recovery for lack of informed consent is limited to cases involving a "non-emergency treatment, procedure or surgery," or a "diagnostic procedure which involved invasion or disruption of the integrity of the body." Pub. Health Law § 2805-d(2). Further, plaintiff must demonstrate that, but for the lack of informed consent, a "reasonably prudent person in the patient's position would not have undergone the treatment or diagnosis," and that the lack of informed consent proximately caused the patient's injuries. Pub. Health Law § 2805-d(3).

Counsel for Dr. Ng argues that plaintiff does not claim that any invasive procedure performed by Dr. Ng caused Mr. Henderson's injuries. No one disputes that Dr. Ng procured the consent form at issue. However, he was not the "person providing the professional treatment or diagnosis." Pub. Health Law § 2805-d(1). Dr. Ng testified that it was his understanding that he was procuring the consent form for Dr. Kim to perform the procedure described on the consent form. Simply because Dr. Ng "undertook the ministerial task of recording the plaintiff's consent" did not relieve plaintiff's private physicians from their obligation to obtain informed consent nor did his act place the obligation on SIUH. Cirella v. Central Gen. Hosp., 217 A.D.2d 680, 681 (2d Dep't 1995) (citations omitted); see also Pub. Health Law § 2805-d(1). The facts of this case do not form a sufficient basis on which to make out a claim of lack of informed consent against Dr. Ng; as such, the claim against him for lack of informed consent in the ninth cause of action is dismissed, as is any claim against SIUH based on vicarious liability for Dr. Ng as to the claim against him for lack of informed consent.

Counsel for Dr. Kim argues that plaintiff has not properly pled a cause of action for lack of informed consent as against her. Dr. Kim claims that plaintiff cannot prove a causal relationship between the alleged non-disclosure and Mr. Henderson's injuries, nor that a reasonable person in the patient's position would have rejected to the treatment in the event that all the required risks, benefits and alternatives were disclosed. Dr. Kim also argues that plaintiff is not claiming that any "invasive procedure" performed by Dr. Kim caused Mr. Henderson's injuries, and that the facts behind plaintiff's claim do not fit within the elements necessary to demonstrate lack of informed consent.

This court declines to grant Dr. Kim partial summary judgment. The proponent of a summary judgment motion must demonstrate, through competent evidence, a prima facie showing of entitlement to judgment as a matter of law, i.e., the absence of any material issues of fact. Alvarez, supra, 68 N.Y.2d at 324. Dr. Kim asserts that plaintiff never claims that any invasive procedure performed by Dr. Kim caused Mr. Henderson's injuries, but is undisputed that Dr. Kim performed a bedside debridement on Mr. Henderson and inserted a Penrose drain, which is clearly an invasive procedure. The bill of particulars served on Dr. Kim alleges that Dr. Kim failed "to get informed consent from Karen Henderson to cancel the 6/1/03 - 6/2/03 surgery and change to bedside cleaning" and failed "to obtain consent from Karen Henderson for Dr. Kim to treat plaintiff." Dr. Kim did not submit the affidavit or affirmation of an expert on the issue of informed consent. Although she annexes the consent form to her papers, there is simply insufficient information to eliminate all material issues of fact as to the elements of plaintiff's claim for lack of informed consent against Dr. Kim. Regardless of the sufficiency of plaintiff's papers in opposition, the issues of whether the surgery performed on Mr. Henderson was different from the one Mrs. Henderson consented to and whether the consent form executed was indeed sufficient consent for the bedside procedure, demonstrate that material issues of fact remain.

Plaintiff also argues that Mr. Henderson entered SIUH through its emergency room, and therefore SIUH is vicariously liable for the alleged failure by Dr. Kim to obtain informed consent for the June 2, 2003 surgery. Plaintiff relies on Anderson v. Montefiore Med. Ctr., 41 A.D.3d 105 (1st Dep't 2007), to support her proposition that SIUH is vicariously liable for Dr. Kim, an attending physician. In Anderson, the First Department held that a hospital "'may be vicariously

liable for the acts of independent physicians where a patient enters the hospital through the emergency room and seeks treatment from the hospital, not from a particular physician.'" Id., at 107. Since it is undisputed that Mr. Henderson went to the emergency room at SIUH at the direction of Dr. Chang, his private physician who was there at the time, the holding in Anderson is inapposite to plaintiff's argument. As stated previously, in general, a hospital cannot be held liable for the acts of a patient's private physician, such as Dr. Kim, who was an attending at SIUH. See Hill v. St. Clare's Hosp., supra, 67 N.Y.2d at 79; Welsh v. Scheinfeld, supra, 21 A.D.3d at 807. Any claim plaintiff asserted against SIUH based on vicarious liability for the alleged acts or failures of Dr. Kim are dismissed.

Accordingly, it is hereby

ORDERED that Stryker's motion for summary judgment (Motion Sequence Number 006) as to the entire first, second, and third causes of action, and the eighth and ninth causes of action as against it, is granted, and the complaint is hereby severed and dismissed as against defendant Stryker Corporation, and the Clerk is directed to enter judgment accordingly; and it is further

ORDERED that plaintiff's cross motion for summary judgment (Motion Sequence Number 006) against Dr. Chang is denied; and it is further

ORDERED that Dr. Chang and Healthcare's cross motions for summary judgment (Motion Sequence Number 006) are denied; and it is further

ORDERED that St. Vincent's motion for summary judgment (Motion Sequence Number 008) as to the entire sixth cause of action, and the eighth and ninth causes of action against it, is granted, and the complaint is hereby severed and dismissed as against defendant Saint Vincent's Catholic Medical Center of New York a/k/a Sisters of Charity Medical Center, and the Clerk is directed to enter judgment accordingly; and it is further

ORDERED that Dr. Kim and Wooh P.C.'s motion for partial summary judgment (Motion Sequence Number 009) is denied; and it is further

ORDERED that Dr. Ng, Dr. Rosell, Dr. Nicastro, and SIUH's motion for partial summary judgment (Motion Sequence Number 010) is granted as to the ninth cause of action, the claim of lack of informed consent, and the complaint with respect to the claim of lack of informed consent is hereby severed and dismissed as against defendants Dennis Ng, Frank Michael Rosell, Jeffrey Michael-Nicastro, and Staten Island University Hospital; and it is further

ORDERED that the remaining parties are directed to appear for a pretrial conference on October 7, 2008, at 10:00 a.m.

This constitutes the decision and order of the court.

Date: September 25, 2008

JOAN B. LOBIS, J.S.C.