2011 WL 470613
United States District Court,
D. Rhode Island.

Christopher THORPE and Laure Thorpe, Plaintiffs
v.
DAVOL, INC. and C.R. Bard, Inc., Defendants.
In re Kugel Mesh Hernia Repair Patch Litigation.

C.A. No. 008–463ML.
|
MDL No. 07–1842ML.
|
Feb. 4, 2011.

Synopsis
Background: Patient who had received hernia patch brought product liability action against patch manufacturer. Jury found in favor of patient. Manufacturer moved for judgment as a matter of law.

Holdings: The District Court, Mary M. Lisi, C.J., held that:

[1] expert testimony of surgeon specializing in abdominal hernias regarding cause of break in hernia patch implanted in patient, was admissible;

[2] evidence was sufficient to lead a reasonable jury to find that manufacturer acted unreasonably in designing the patch and failed to adopt a safer alternative design;

[3] evidence was sufficient that a reasonable jury could conclude that a negligently designed patch was the cause of patient's injury;

[4] evidence was insufficient to establish claim of inadequate warning or instruction; and

[5] hernia patch manufacturer was not entitled to new trial.

Motion granted in part and denied in part.

MEMORANDUM AND ORDER

MARY M. LISI, Chief Judge.

***1** This case is one of a multitude of cases transferred to this Court by the United States Judicial Panel on Multidistrict Litigation as *In re Kugel Mesh Hernia Patch Products Liability Litigation,* MDL No. 1842, No. 07–MD–1842–ML (D.R.I.). The multidistrict litigation ("MDL") involves claims surrounding allegedly defective hernia repair patches designed and manufactured by Defendants Davol, Inc. and C.R. Bard, Inc., (together, "Davol"). Following a 13 day jury trial, the matter is now before the Court on the defendants' motion for judgment as a matter of law pursuant to Rule 50 of the Federal Rules of Civil Procedure, or, in the alternative, for a new trial pursuant to Rule 59 of the Federal Rules of Civil Procedure.

Primarily, the defendants submit that the plaintiffs' experts' opinions on medical causation were "speculative, unreliable, and unfounded" and that, therefore, they should be stricken, post-trial, under *Daubert.*[1] Defs.' Mot. 1. The defendants also assert that plaintiffs failed to support their claims for inadequate design and inadequate warnings with sufficient evidence. *Id.* at 2. With respect to the motion for a new trial, the defendants argue that (1) the evidence weighed heavily in the defendants' favor; Defs.' Mem. 30, (2) the jury's verdict was based on prejudicial introduction of plaintiffs' "scar contracture" causation theory, *id.* at 32; and (3) the implanting surgeon used the hernia patch contrary to instructions. *Id.* at 34.

1 *Daubert v. Merrell Dow Pharm., Inc.,* 509 U.S. 579, 113 S.Ct. 2786, 125 L.Ed.2d 469 (1993).

In response, the plaintiffs state that their experts' opinions satisfied the *Daubert* standard and that the plaintiffs provided evidence of both inadequate design and defendants' failure to warn. Pltfs.' Mem. 4. The plaintiffs also assert that the jury verdict was "overwhelmingly" supported by the evidence presented at trial and that the defendants are not entitled to a new trial. *Id.* at 48. In

addition, the plaintiffs submit that the Court erred in dismissing plaintiffs' claims for breach of implied warranty and for punitive damages and state that they incorporate their previously submitted arguments by reference.[2] *Id.* at 47.

2 There is no motion pending before the Court on these issues, however, and they will not be addressed herein.

After considering the parties' arguments and the entire trial record, the Court denies, in part, and grants, in part, the defendants' motion for judgment as a matter of law. The Court denies the defendants' motion for a new trial pursuant to Fed.R.Civ.P. 59 and conditionally denies the motion for a new trial pursuant to Fed.R.Civ.P. 50(c).

I. Factual Background

A. The Hernia Patch

A hernia, in its simplest terms, is a hole in the abdominal wall or fascia that allows abdominal contents to protrude outside the abdominal cavity. The most common type of hernias are located in the groin; these defects are known as inguinal hernias. The second most common hernias are located on the abdomen; they are referred to as ventral or incisional hernias. Ventral or incisional hernias are commonly the result of prior surgery in the abdominal area. In order to repair the hole in a patient's abdominal wall, a surgeon may perform a primary tissue repair or a reinforced repair. A primary repair involves the use of sutures to close up the defect; however, such primary repair is subject to a high recurrence rate for further hernias. The reinforced repair offers a more permanent solution, particularly for larger hernias, and involves the use of a repair patch to cover the hole and to reinforce the surrounding tissue. One frequently used technique, known as the underlay approach, involves repairing the hernia by placing the hernia repair patch underneath the defect inside the abdomen and fixating it against the undersurface of the abdominal wall. The repair can be performed through a conventional incision or laparoscopically, using a small incision and performing the surgery through a trocar.

***2** The Composix Kugel Patch in the extra large size (the "XL CK Patch"), which is at issue in this case, is described as a single use, self-expanding polypropylene and ePTFE patch used for soft tissue reconstruction. The XL CK Patch contains two memory recoil rings made of polyethylene terathylate ("PET") which are intended to assist the patch to open and lay flat upon placement and to faciliate fixation of the patch against the abdominal wall. Pltfs.' Ex. 341, Trial Tr. IX 55:106, Aug. 16, 2010. The composite aspect of the CK Patch refers to the two different surfaces of the patch. One side of the XL CK Patch consists of a two-layer polypropylene mesh, the purpose of which is to encourage tissue ingrowth where the patch is affixed to the abdominal wall. Polypropylene mesh should never be placed in contact with the bowel itself, because it would cause adhesions and other complications in the patient. The other side of the XL CK Patch is made of polytetrafluoroethylene or ePTFE, which is a smooth, glossy, Teflon-type material, designed to avoid adherence between the patch and the bowel, the intestines, and the colon. Between the two polypropylene layers of the XL CK Patch are the two memory recoil rings made of PET. The rings are relatively rigid and serve to keep the patch flat and open.

Davol, Inc. is a Delaware company with its principal place of business in Rhode Island. C.R. Bard, Inc. is the New Jersey parent corporation of Davol, Inc. In 1997, Davol released the Composix hernia patch, a forerunner to the CK Patch. The Composix patch is composed of two layers of polypropylene mesh for tissue ingrowth on the abdominal side, and a layer of ePTFE on the other side to prevent bowel adhesion to the mesh. The Composix patch does not contain a ring. Prior to placing the Composix patch on the market, Davol conducted animal testing by implanting the patch into the abdominal cavity of pigs. Davol submitted the testing results in a so-called 510(k) application to the Food and Drug Administration ("FDA") in order to get clearance to market the Composix patch.

In 2000, Davol acquired the Kugel[3] hernia patch from Surgical Sense Inc., which had marketed the Kugel patch for several years. At that time, the Kugel patch was available only in five sizes; it did not contain a Teflon or ePTFE side; and it was primarily used for inguinal repair. The Kugel patch had previously been cleared as a medical device by the FDA in 1996. Following its acquisition of the

Kugel patch, Davol considered various potential upgrades for the device, including a resorbable ring, a change in the mesh and additional sizes, and the addition of an ePTFE layer making the patch suitable for ventral hernia repair.

3 Named after its inventor, surgeon Dr. Robert Kugel.

Eventually, the CK Patch was designed with two layers of polypropylene mesh, a layer of ePTFE, and a PET memory recoil ring welded between the layers of polypropylene mesh. The XL CK Patch featured larger sizes, two PET rings, and placement pockets for easier deployment of the patch. As explained by Roger Darois, Davol's Vice President of Research and Advanced Technologies, the memory recoil rings allow mesh that has been folded for deployment through a small incision into the limited space of an abdominal cavity to "spring open and assure that the mesh stays flat and ... in the correct shape." Tr. IX 54:20–55:4. It also facilitates fixation of the mesh and proper anchoring against the abdominal wall. *Id.* 55: 4–6. Because Davol considered the XL CK Patch products a modification to an existing product (the one-ringed CK Patch in small and medium sizes), it made an internal determination that a 510(k) submission to the FDA was not warranted. Defs.' Ex. 1015.

***3** The XL CK Patch was first sold in 2002. Davol first learned of a ring break in its CK Patch product line in 2003. Davol's field assurance department conducted an investigation into the claims, which included assessing Davol's manufacturing record and contacting the customers involved to request additional information and, if possible, return of the product. In October 2003, Davol decided to enhance the weld strength of the memory recoil rings in all its CK patch products. [4]

4 To enhance the strength of the welds, Davol increased the pull strength testing of the ring from two to four pounds; the design specification of the weld strength remained the same, however. Tr. IX 134:5–19; Tr. XI 114:25–115:16. Existing inventory prior to the implementation of the enhancement was sold. Tr. XI 7:25–8:18.

By mid to late 2005, Davol became aware of an increase in reported ring breaks in the XL CK Patch. Davol initiated a Corrective and Preventive Action ("CAPA") investigation into the complaints. Davol also communicated the complaints to the FDA, informing it that the exact cause of the ring breaks was undetermined and that a recall did not appear warranted at that time. Defs.' 1020–0006. On August 31, 2005, production of XL CK Patches was halted while Davol investigated ring break complaints. Distribution of the XL CK Patches was discontinued on December 8, 2005. In a December 21, 2005 letter from Karen Kane ("Kane"), Manager of Davol's marketing department, the sales force was advised that XL sizes of the CK Patch were being recalled because "the strength of the memory recoil ring may not withstand aggressive manipulation that may sometimes be applied during the placement of these extra-large sizes." Pltfs.' Ex. 322–001. Kane further stated that customers asking for XL sizes of the CK Patch should be advised that the XL CK Patches were "currently not available and that Customer Service is offering the equivalent sizes of the Composix EX [5] as an alternative." *Id.*

5 The Composix EX features an ePTFE side and a polypropylene mesh, but no memory recoil ring.

On December 28, 2005, Davol issued an "Urgent Product Recall" for the XL CK Patch to "Distributor: (Hospital Administrator, Materials Manager, O.R. Manager, Surgeon)." Pltfs.' Ex. 676. Davol informed its customers that it was voluntarily recalling three product codes of the XL CK Patch because it had "received complaint reports of the PET recoil ring breaking which could potentially lead to bowel perforation and/or chronic enteric fistulas. We have identified a rate increase of recoil ring breaks since the introduction of these product codes in 2002. We estimate the frequency of these reported events to be in the range of 0.08%. [6] "

6 According to a January 2006 Remedial Action Plan by Davol, it received 24 complaints for 31,750 units sold. Pltfs.' Ex. 341–004. A September 2006 Problem Investigation Report refers to 31 ring break complaints for 28,547 distributed XL CK Patches, for a .109% complaint rate. Pltfs.' Ex. 594–003.

Davol conducted a supplemental failure investigation in 2006, in which it considered manufacturing data, customer complaints, and the instructions for use (the "IFU") packaged with the product. The project team tasked with investigating the possible reason for the

reported problems with the XL CK Patch looked at the device with respect to potential mechanical failure, as well as the overall systems that were in place to ensure that the product was designed and tested correctly. The team determined that, prior to the recall, ring breakage was not identified as a potential failure mode as part of the design failure mode and effects analysis ("DFMEA") of the device. Pltfs. Ex. 334–002. The team also determined that there "was no challenge to the [memory recoil ring] weld strength specification and whether it was still sufficient for the larger size products." *Id.* No clinically relevant testing had been done to validate or quantify the two-pound weld specification of the ring in the XL CK Patch, Pltfs. Ex. 592, and the project team concluded that the two-pound weld specification in place before the recall was insufficient and that "it had the potential to fail once implanted in the body and exposed to loads or forces that were other than the axial load or the tensile load that it was tested to." Tr. I 108:19–109:10, Aug. 3, 2010.

***4** With respect to the methodologies used to train surgeons on the use of CK Patches, the project team noted that, although the pre-recall surgical technique guide provided an "illustration suggesting that the [CK Patch] be folded on its long axis, the lack of folding technique specificity could result in a surgeon not realizing that the long axis was the recommended method and the potential negative consequences of not following this illustrated method." Pltfs.' Ex. 375–003. The project team noted that technique guides, however, are not intended to comprehensively communicate key instructions and warnings about products. Likewise, surgeon training cannot exclusively be relied upon for that purpose, because Davol did not provide the actual training materials used by surgeons to educate their peers. *Id.*

Unlike technique guides and surgeon training, the IFU is intended to communicate key instructions and warnings about products. *Id.* As the project team discovered, the pre-recall IFU for the XL CK Patch "did not contain appropriate folding technique instructions and warnings and was not effective in comprehensively communicating this information." Pltfs.' Ex. 375–003. The team concluded that deficiencies in the IFU "could have been a contributory root cause of reported broken ring failures, in some cases due to ring welds unable to withstand the stresses induced by folding the product across the weld." *Id.*

In its final assessment, Davol concluded that the most probable root cause of the ring breaks was failure to take into consideration "potential stresses incurred during the folding and insertion techniques required to implant the X–Large Composix codes which may cause the recoil ring weld to break." Pltfs.' Ex. 341–007.

B. The Hernia Repair

Christopher Thorpe ("Thorpe") and his wife Laure ("Laure") are North Carolina residents. Thorpe, who has a history of diverticulitis, was first hospitalized for the condition in 1989. Initially, Thorpe was successfully treated with antibiotics and was able to control occasional bouts of inflammation. However, after increasingly frequent occurrences, Thorpe was hospitalized again in March 2002. At that time, surgeon Dr. Kenneth L. Parish, M.D. ("Dr .Parish"), recommended that Thorpe have the affected portion of his colon removed. Dr. Parish performed the surgery by making an incision in Thorpe's abdomen, removing an 18 inch long affected piece of colon and suturing the ends back together. Thorpe began to recover but had to return to the hospital within a few days because he was in severe pain and was diagnosed with an intestinal blockage caused by scar adhesions. After Dr. Parish performed a second surgery to remove the blockage, together with 4 inches of small bowel, Thorpe recovered, returned to work, and resumed his normal life activities.

In 2003, Thorpe was told by his family physician ("Dr.Glenn") that he had developed a hernia in the midline above his navel. According to Thorpe, he was not initially bothered by the hernia, although he had been advised by Dr. Glenn that the hernia could be expected to increase in size. In November 2005, after the hernia had become bigger and painful, Dr. Glenn referred Thorpe to Dr. Parish. At that time, Dr. Parish diagnosed Thorpe with an incisional hernia, located in the area of Thorpe's previous surgeries. Dr. Parish recommended that Thorpe have the hernia surgically repaired. When Thorpe decided to proceed with the surgery, Dr. Parish advised him that he might be able to do a primary repair because the hernia appeared relatively small, but that Thorpe might

ultimately require a mesh repair, if the surgery revealed the hernia to be more significant. Dr. Parish also discussed the risks of surgery with Thorpe, including infection, bleeding, lung, or cardiac problems, and obstruction of, or injury to, the intestines.

***5** On November 17, 2005, in the course of the hernia repair surgery, Dr. Parish discovered that Thorpe's hernia was far larger than anticipated, which required him to make a larger incision and repair the hernia with a mesh. Dr. Parish used a sublay or underlay technique that involved placing the mesh below the muscle layer against the inside of the defect. Tr. II 21:22–22:11, Aug. 4, 2010. According to Dr. Parish, he chose the extra large size 8 by 10 inch CK Patch to cover the significant defect of Thorpe's hernia. In his opinion, the CK Patch was "the best mesh available for him, as it had both layers, the one that would provide ingrowth as well as one that would protect the intestine underneath." Tr. II 30:15–24. Dr. Parish was aware that the CK Patch contained two rings and understood their purpose to help the mesh lie flat.

Prior to repairing Thorpe's hernia, Dr. Parish had to clear some adhesions around the small bowel where a portion of the small intestine was stuck against the abdominal wall because of Thorpe's prior surgery. After clearing the adhesions, Dr. Parish made a large pocket under the muscle, inserted the XL CK Patch into that pocket, and attached the patch by tacking its outer portion against the abdominal wall with a tacking device.

Thorpe stayed at Frye Regional Medical Center for about ten days, in part, because he developed an ileus, a disruption of normal bowel functions, post surgery. Thorpe recovered within days and resumed regular physical activities, including running 15 miles a week.

In 2006, Thorpe repeatedly consulted Dr. Glenn and other physicians because he was suffering from abdominal pain. Although he underwent various tests, x-rays, and CT-scans, he did not receive a definitive diagnosis. He was, however, treated with medication. Dr. Parish also saw Thorpe in February 2006 for abdominal pain. According to Dr. Parish, a CT scan taken at that time revealed no problems with the patch and the pain resolved without treatment.

In October 2007, Thorpe began suffering from constant sharp pain on the left side of his abdomen. After he also developed a fever, Thorpe consulted Dr. Glenn, Dr. Delagarza from the same office, and, eventually, Dr. Parish. Dr. Parish sent Thorpe for an immediate CT scan. After detecting a pocket or pouch on the scan, Dr. Parish concluded that Thorpe's pain and fever was caused by an infection. On his recommendation, Thorpe underwent a CT guided drain at Catawba Memorial Hospital ("Cawtaba") and he was treated with intravenous antibiotics. After four or five days at Catawba, Thorpe returned home and, by his own accounts, felt great.

However, the pain and fever returned within days, and on October 31, 2007, Dr. Parish had Thorpe re-admitted to Cawtaba. On that occasion, Thorpe underwent surgery under general anesthesia during which Dr. Parish drained the abscess and debrided the XL CK Patch. During that procedure, Dr. Parish detected that a very small portion of the XL CK Patch mesh had not become incorporated into the tissue. According to Dr. Parish, he then removed two layers of mesh and a portion of the ePTFE from that area with a very small pair of scissors.

***6** Following this surgery, Thorpe's wound was left open with a wound vacuum assisted closure device ("wound vac") attached to his abdomen. Thorpe was required to wear the wound vac on a harness over his shoulder while the device was connected to his abdomen in order to provide suction to the wound. Apart from an hour on Mondays, Wednesdays, and Fridays, when the wound dressing was changed by a home health care worker, Thorpe was continuously attached to the device for about a month. Thorpe was unable to shower while wearing the vac and the changing process was painful.

After removal of the wound vac, Thorpe's wound required wet-to-dry gauze changes for about two weeks. By the end of November 2007, the wound had started to close, although it was not completely healed. Shortly before Thorpe was scheduled to return to work, the wound began to drain profusely, necessitating dressing changes every two hours. Based on the greenish, brownish color of the liquid draining from Thorpe's wound, Dr. Parish diagnosed Thorpe with an enterocutaneous fistula[7].

Thorpe was fitted with a 6 inch ostomy bag. There was some difficulty fitting the ostomy bag, resulting in leakage and, although the process was not particularly painful, the device emitted a bad odor. According to Dr. Parish, he considered removing the XL CK Patch at that time because it was a potential source of the infection. However, because most of the mesh was incorporated well into Thorpe's tissue and only a small area was involved, Dr. Parish believed that debriding that area was sufficient to let the infection heal.

7 A fistula is a "tract or tunnel between one structure to another structure." Tr. II 92:5–6. Thorpe's enterocutaneous fistula reached from the intestine inside the abdomen out to the outside skin. *Id.* 92:10–15.

In mid-December 2007, Thorpe decided to get a second opinion. He consulted with surgeon Dr. Sandhya A. Lagoo–Deenadayalan, M.D., Ph.D. ("Dr.Lagoo")[8] at Duke University Medical Center ("Duke") in Durham, North Carolina. Dr. Lagoo had Thorpe fitted with a new ostomy bag and she ordered an x-ray, or fistulagram. Dr. Lagoo advised Thorpe that he would need additional surgery if the fistula did not close, which was not expected for several months. Thorpe also consulted Dr. Williams, an infectious disease specialist, and he continued to see Dr. Parish as well.

8 Because Dr. Lagoo's testimony was presented to the jury by means of a video taped deposition, no transcript was prepared during the trial and no citations are given herein.

In the first week of February 2008, Thorpe was again examined by Dr. Lagoo, who told him that they were "just going to hold and wait and maybe, maybe do something in May, but nothing definitive, again." Tr. V 8:4–8, Aug. 10, 2010. Thorpe returned home after the examination but, a few days later, suffered severe stomach pains in the middle of a Friday night. As the pain intensified, Thorpe noticed solid material coming out the fistula. Laure drove Thorpe to the Duke Emergency Room. Thorpe was admitted and stayed at Duke for six days. He was diagnosed with a blockage that cleared while he was at the hospital. Before he left, Dr. Lagoo decided to move the surgery, tentatively planned for May 2008, to a fixed date of March 28th, 2008. Thorpe traveled back to Durham on March 27, 2008 and began the process of preparing for surgery at his hotel. Thorpe tried to drink the preparation fluid but realized that the fluid just exited into the fistula bag instead of working its way through his bowels. Thorpe informed Dr. Lagoo the following morning about the difficulty he experienced with the preparation and Dr. Lagoo cancelled the surgery. Thorpe's surgery was rescheduled for April 11, 2008 and it was arranged that he be admitted to Duke the day before surgery to allow hospital staff to administer the preparation fluid.

***7** Dr. Lagoo performed surgery on Thorpe on April 11, 2008, assisted by Dr. David Sindram ("Dr.Sindram"). Dr. Lagoo made an incision over the long axis of the mesh, then excised the left side from Thorpe's tissue. Part of one ring, which was found sticking out into subcutaneous tissue, was grasped and pulled from the mesh. The ring end was bile stained and in touch with an open portion of the bowel. Dr. Lagoo then separated the mesh from Thorpe's bowel, noticing that the mesh had lost its normal alignment and folded upon itself, exposing the rough side to the bowel. According to Dr. Lagoo, neither she nor Dr. Sindram cut the ring during surgery, and she made no determination of what caused the fold in the XL CK Patch. She concluded, however, that the contact of the polypropylene mesh with the bowel and the formation of a dense adhesion with the bowel was the likely cause of the fistula. Following removal of the XL CK Patch and debridement of adhesions, Dr. Lagoo then used a primary closure instead of a mesh because the infection that was present could result in infection of the new mesh.

The morning after the surgery, Thorpe first talked to Dr. Sindram, who also showed him pictures of the explanted mesh he had taken with his cell phone following Thorpe's surgery. Dr. Lagoo then advised Thorpe that he was likely to develop another hernia in the future and that it would have to be addressed at that time.

Thorpe remained at Duke until April 25, 2008. Thorpe was left with a very large open wound and he was placed on a wound vac again. On his return home, Thorpe received a visit from a home health nurse who changed his dressing and then instructed Laure in performing the task. Laure changed Thorpe's dressing from then on, taking care not to hurt him during the process.

Around June 23, 2008, Thorpe returned to work, while his wound was still open and packed with gauze, covered with a pad, and contained in a laced-up binder. By September 2008, Thorpe's wound was continuing to heal, although some abdominal wall bulging revealed that he had developed a ventral hernia, as expected. Thorpe had additional surgery in December 2008, in which the surgeon used a biomesh material made from porcine tissue to perform additional repair on the hernia. According to Thorpe, he continues to experience some pain and, although he has resumed many of his regular activities, Thorpe refrains from running and heavy lifting.

II. Procedural Background

On November 25, 2008, the Thorpes filed a diversity based complaint (the "Complaint") against Davol in this Court, asserting claims of (Count I) Negligence, (Count II) Strict Product Liability, (Count III) Negligent Infliction of Emotional Distress, (Count IV) Intentional Infliction of Emotional Distress, (Count V) Breach of Implied Warranty, (Count VI) Failure to Warn, (Count VII) Fraud, (Count VIII) Misrepresentation by Omission, and, with respect solely to Laure Thorpe, (Count IX) Loss of Consortium. Generally, the Complaint alleges that Thorpe was injured because the CK Patch used to repair his hernia was "inherently dangerous" for its intended use; that it was sold in a defective condition; that, as designed and manufactured by Davol, the CK Patch was unsafe; and that Davol failed to implement a safe and effective memory recoil ring that would interact with the CK Patch mesh in such a way as to withstand foreseeable stresses in the intraabdominal space. Complaint ¶ 55 (C.A. No. 008–463ML, Docket No. 1).

***8** The Complaint states that, immediately after placing the CK Patch on the market, Davol was informed of memory ring failures and CK Patch defects and that Davol concealed such information from patients such as Thorpe, his physician, and the general public. Complaint ¶ 10. The Complaint also alleges that, although Davol conducted physician screenings and reviews after the CK Patch was placed on the market, Davol "failed to properly conduct and monitor [its] own post market design validation physician surveys, including those which demonstrated unfavorable or 'dissatisfied' results." Complaint ¶ 11. The Complaint details the complications Thorpe experienced after undergoing hernia repair involving the CK Patch in November 2005. Complaint ¶¶ 12, 24–30. According to the Complaint, the CK Patch was "authorized" by the FDA as a Class II medical device in early 2001 and, after an increasing number of complaints regarding the CK Patch were received, Davol recalled varying sizes of the CK Patch under a Class I recall notice in December 2005. Complaint ¶¶ 9–17. Subsequently, the recall was expanded to other sizes and production lots of the CK Patch. Complaint ¶¶ 20, 21.

Thorpe states that he has suffered and will continue to suffer physical pain and mental anguish as a result of Davol's conduct. –18–Complaint ¶ 30. He also asserts substantial medical bills and lost wages. Complaint ¶ 31. Thorpe seeks monetary damages from Davol in compensation for his injuries and loss, as well as costs of this litigation; Laure requests compensation for the loss of consortium and society of her husband. Complaint ¶ 99.

On December 4, 2008, the case was consolidated with MDL Case No. 07–1842ML and was subsequently selected to be tried as the second of four agreed upon bellwether cases. A discovery and trial schedule was set. On September 4, 2009, Davol filed a master answer to the Complaint, followed by a Complaint specific answer on September 10, 2009. In its response, Davol admitted manufacturing the CK Patch, Answer ¶ 3; receiving reports of "ring migration, internal fistulae, bowel perforation, and death," *id.* ¶ 18; and voluntarily recalling CK Patches in 2005, 2006, and 2007, *id.* ¶ 17. Davol generally denied Thorpe's allegations that it concealed notice of defects in the Composix Kugel Patches or that it failed to conduct proper post market design validation physician surveys. Answer ¶¶ 10, 11. Davol also asserted 45 affirmative defenses. Answer 13–21.

On June 25, 2010, about six weeks prior to trial, the parties filed a number of motions *in limine* regarding anticipated trial testimony and evidence. Significant with respect to the instant motions, the defendants sought to exclude any testimony by plaintiffs' medical expert witness, Dr. Stephen Ferzoco ("Dr.Ferzoco"), that was not referenced in his report and first deposition, and, in particular, any opinion to the effect that scar contracture can cause memory recoil rings to break, Defs.' Mot. No.

6, Docket No. 2867. Specifically, Davol objected to Dr. Ferzoco's opinion that scar contracture can make rings break "[b]ecause there was no credible evidence in the medical literature that scar contracture, in the face of adequate fixation, can cause a CK Patch to 'buckle.' " Defs. Mot. No. 6 at 1. Davol explained that (1) when he was first deposed, Dr. Ferzoco did not have an opinion on whether contracture forces could break a ring or what caused Thorpe's injuries; and (2) Dr. Ferzoco is not an engineer and his theory that scar contracture forces caused Thorpe's CK Patch to break is without scientific support. Defs.' Mot. No. 6 at 2.

***9** The defendants also sought to exclude any opinion by plaintiffs' biomaterials engineering expert witness, Dr. Paul Ducheyne ("Dr.Ducheyne"), that scar contracture can pull a ring apart. Defs .' Mot. Docket No. 2869.

The plaintiffs opposed Davol's motions on July 2, 2010, *see* Docket No. 2911 and Docket No. 2913. The Thorpes asserted, *inter alia,* that Dr. Ferzoco's expert report, issued October 18, 2009, concluded that the broken ring, together with contracture of the composite materials, caused the mesh to warp and expose the polypropylene to Thorpe's bowel, which led to Thorpe's injuries. Pltfs.' Opp. No. 6, Docket No. 2911. The Thorpes also pointed out that, following issuance of Dr. Ferzoco's report and after his first deposition, Davol produced voluminous additional documentation related to the CK Patch. *Id.* at 2. Moreover, the Thorpes stated that Dr. Ferzoco would not offer testimony in the field of biomedical engineering, but that, as a surgical clinician, he would opine on the use of hernia mesh prostheses and the alleged defects in the CK Patch implanted in Thorpe. *Id.* at 8. As such, his testimony would be supported by peer-reviewed scientific studies and articles and based on reliable methods and data. *Id.*

With respect to Dr. Ducheyne's testimony, Davol's motion was essentially predicated on *Daubert,* asserting that Dr. Ducheyne's theory that scar contracture can pull apart a memory ring (1) has not been tested; (2) has not been subjected to independent peer review nor has it been published; (3) has no standard or controls; and (4) has not been generally accepted in the relevant scientific community. Defs. Mot. No. 8 at 1–2, Docket No. 2869. Davol also pointed out that Dr. Ducheyne concluded that the ring welds in Thorpe's CK Patch were not sufficient in strength simply by observing that the welds apparently broke. *Id.* at 5–6. Davol pointed out that Dr. Ducheyne had conceded that he did not know the exact weld strength of the rings, nor how much force had been exerted on them. In addition, Davol noted that Dr. Ducheyne is an engineer, not a doctor; that he has never treated any patients with hernias or performed hernia surgery; and that he should be precluded from providing a medical opinion, *i.e.,* that the broken memory recoil rings caused Thorpe's bowel fistula. *Id.* at 6–7.

The plaintiffs submitted 21 exhibits in support of their opposition to Davol's motion *in limine* regarding Dr. Ducheyne's opinion that buckling of the CK Patch (possibly as a result of scar contracture) is a phenomenon recognized by Davol and mentioned in scientific publications. The plaintiffs asserted that Dr. Ducheyne, a Professor of Bioengineering and Orthopaedic Research with 30 years of experience in biomedical engineering and materials science, is "more than qualified to testify that the materials and designs of the CK patch could cause certain injuries within the body." Pltfs.' Opp. No. 8 at 15, Docket No. 2913. The plaintiffs also maintained that Dr. Ducheyne would not be offering a medical causation opinion. *Id.*

***10** The jury heard from many witnesses over twelve days of testimony. On August 16, 2010, at the close of the plaintiffs' presentation of evidence, Davol made an oral motion for judgment as a matter of law on the plaintiffs' claims for breach of implied warranty and for punitive damages. [9] Tr. IX 25:20–32:8. The Court took the motion under consideration and requested additional briefing and case law in support. *Id.* at 27:2–3, 29:23–25.

9 Although Davol's counsel primarily argued with respect to the breach of implied warranty and punitive damages claims, he also asserted that no evidence had been offered by the plaintiffs to support the claims of failure to warn or design defect. Tr. IX 28:17–29:9.

At a charge conference on August 19, 2010, the Court informed counsel that Davol's motion was granted in part and that the jury would not be instructed on the claim for breach of implied warranty. *See* Jury Instructions, Docket No. 3036.

On August 20, 2010, Davol filed a written motion for judgment as a matter of law under Rule 50(a) with respect to all claims in the Complaint. Docket No. 3030. Davol submitted that the Thorpes had failed to support their punitive damages claim pursuant to North Carolina law, because they did not show, by clear and convincing evidence, that the defendants committed "egregiously wrongful acts." *Id.* at 1. With respect to the inadequate warnings claim, Davol stated that the submitted evidence failed to establish that the IFU for Thorpe's CK Patch was inadequate or that Thorpe's surgeon would have altered his treatment of Thorpe, had the IFU contained different or additional information. *Id.* at 1–2. Davol also asserted that Thorpe's claim for inadequate design was not supported by sufficient evidence and that Davol acted reasonably at all relevant times. *Id.* at 2. Finally, Davol sought dismissal of Laure Thorpe's derivative loss of consortium claim.

On August 23, 2010, the jury found in favor of the plaintiffs and awarded $1.3 million to Christopher Thorpe for personal injury and $200,000 to Laure Thorpe for loss of consortium. [10] Following the verdict, the Court formally granted Davol's motion for dismissal of Thorpe's punitive damages claim. Vol. XIV 5:1–6:3, Aug. 23, 2010. At that time, the Court explained that, notwithstanding the jury's verdict in favor of the plaintiff, submission of the punitive damages claim to the jury was not automatic under North Carolina law. *Id.* 5:15–20. Instead, North Carolina law requires a "deliberate, malicious, wanton approach to doing business." The Court found that plaintiffs' proof of negligence was insufficient to submit the question of punitive damages to the jury. *Id.* 5:21–6:3.

10 The jury found that (1) Davol failed to provide an adequate warning or instruction with the CK Patch, proximately causing Thorpe's injury; (2) Davol acted unreasonably in designing the CK patch, proximately causing Thorpe's injury; (3) Thorpe's injury was not caused by Dr. Parish using the CK patch in a manner contrary to any express and adequate instructions or warnings which Dr. Parish knew or should have known were delivered with the CK Patch; and (4) Davol's negligence proximately caused Laure Thorpe to lose the consortium of her husband. *See* Docket No. 3038.

On September 2, 2010, the plaintiffs filed a written objection to Davol's motion for judgment as a matter of law pursuant to Rule 50(a). Docket No. 3067. The plaintiffs asserted that (1) the evidence at trial demonstrated that the defendants knew the CK Patch posed a substantial risk of harm to foreseeable users but failed to take reasonable steps to warn or instruct; (2) plaintiffs submitted sufficient evidence at trial to show that (a) the defendants acted unreasonably during the design process for the CK Patch, Docket No. 3067 6–7; and (b) the broken recoil ring was the cause of Thorpe's injury, *id.* 7–8; and (3) because Thorpe's claims are supported, the derivative claim by his wife was not subject to dismissal, *id.* 9. [11]

11 In addition, the plaintiffs argued that dismissal of the plaintiffs' punitive damages claim was improper, *id.* 9–19; and (5) dismissal of the plaintiffs' breach of implied warranty claim was improper as well, *id.* 19–22. The plaintiffs also suggested that the defendants' motion failed to state specific grounds, *id.* 22.

***11** Davol's instant motion for judgment as a matter of law under Rule 50(b) was filed on September 17, 2010. Thorpe filed an opposition on October 15, 2010. Finally, Davol filed a reply to Thorpe's opposition on November 5, 2010.

III. Standard of Review

A. Motion for Judgment as a Matter of Law

Rule 50 of the Federal Rules of Civil Procedure authorizes a trial court to grant judgment as a matter of law "[i]f a party has been fully heard on an issue during a jury trial and the court finds that a reasonable jury would not have a legally sufficient evidentiary basis to find for the party on that issue." Fed.R.Civ.P. 50(a)(1). The movant is required to raise the motion "at any time before the case is submitted to the jury" and "specify the judgment sought and the law and facts that entitle the movant to the judgment." Fed.R.Civ.P. 50(a)(2). "If the court does not grant the motion for judgment as a matter of law under Rule 50(a)," it is "considered to have submitted the action to the jury subject to the court's later deciding the legal questions raised by the motion." Fed.R.Civ.P.50 (b). The movant may then file a renewed motion for judgment as a matter of law and "may include an alternative or

joint request for a new trial under Rule 59." *Id.* "A renewed motion for judgment as a matter of law under Fed.R.Civ.P. 50(b) is bounded by the movant's earlier Rule 50(a) motion." *Parker v. Gerrish,* 547 F.3d 1, 12 (1st Cir.2008)(movant under Rule 50(b)is precluded from introducing "a legal theory not distinctly articulated in its close-of-reference motion for a directed verdict.").

[1] **[2]** In deciding a motion for judgment as a matter of law, the Court is required to "scrutinize the evidence and the inferences reasonably extractable therefrom in the light most hospitable to the nonmonvant." *Martinez–Serrano v. Quality Health Serv. of Puerto Rico,* 568 F.3d 278, 284 (1st Cir.2009); *Tobin v. Liberty Mut. Ins. Co.,* 553 F.3d 121, 135 (1st Cir.2009) (Motion for judgment as a matter of law to be granted only if, when viewed under the established Rule 50 standard, "the evidence could lead a reasonable person to only one conclusion, 'favorable to the movant.' " (citations omitted); *Zimmerman v. Direct Fed. Credit Union,* 262 F.3d 70, 75 (1st Cir.2001)(court may grant motion for judgment as a matter of law only "when, after examining the evidence of record and drawing all reasonable inferences in favor of the nonmoving party, the record reveals no sufficient evidentiary basis for the verdict"). The Court "may not consider the credibility of witnesses, resolve conflicts in testimony, or evaluate the weight of the evidence." *Wagenmann v. Adams,* 829 F.2d 196, 200 (1st Cir.1987).

B. Motion for New Trial

[3] **[4]** **[5]** **[6]** It is well established that "a district court's power to grant a motion for a new trial is much broader than its power to grant a motion for [judgment as a matter of law.]" *Jennings v. Jones,* 587 F.3d 430, 436 (1st Cir.2009). Pursuant to Rule 59 of the Federal Rules of Civil Procedure, "[t]he court may, on motion, grant a new trial on all or some of the issues ... after a jury trial, for any reasons for which a new trial has heretofore been granted in an action at law in federal court." Fed.R.Civ.P. 59(a)(1)(A). The court may consider the credibility of the witnesses who testified at trial and may "independently weigh the evidence." *Jennings v. Jones,* 587 F.3d at 436. Based on the court's determination, a new trial may be granted if "the verdict is against the weight of the evidence." *Id.* Moreover, the court " 'has the power and duty to order a new trial whenever, in its judgment, the action is required in order to prevent injustice.' " *Kearns v. Keystone Shipping Co.,* 863 F.2d 177, 181 (1st Cir.1988)(quoting 11 C. Wright & A. Miller, *Federal Practice and Procedure* § 2805).

***12** **[7]** However, the First Circuit has cautioned that "a 'district court cannot displace a jury's verdict merely because [she] disagrees with it' or because 'a contrary verdict may have been equally ... supportable.' " *Ahern v. Scholz,* 85 F.3d 774, 780 (1st Cir.1996) (citation omitted). Therefore, the court "may set aside a jury's verdict and order a new trial only if the verdict is so clearly against the weight of the evidence as to amount to a manifest miscarriage of justice." *Rivera Castillo v. Autokirey, Inc.,* 379 F.3d 4, 13 (1st Cir.2004)(court may exercise its discretion to grant a new trial if it determines that "the verdict is against the weight of the evidence, that the damages are excessive, or that, for other reasons, the trial was not fair to the party moving.").

IV. Analysis

A. The Motion for Judgment as a Matter of Law

1. Admissibility of Testimony by Plaintiffs' Experts

The principal thrust of Davol's argument with respect to liability is directed against the alleged "unreliability and inadmissibility of Plaintiffs' 'scar contracture' causation theory." Davol's Mem. 1. Davol suggests that the testimony by Dr. Ferzoco and Dr. Ducheyne to establish that scar contracture could cause ring breaks should be stricken because it was not "the product of good science" or "supported by scientifically accepted corroboration" and because it failed to meet Rule 702 and *Daubert* standards. Davol's Mem. 1. Specifically, Davol submits that "there was no valid scientific corroboration showing that scar contracture is capable of breaking a single PET memory recoil ring in a CK Patch, let alone two." *Id.* at 4.

[8] A court's decision to admit or exclude relevant expert testimony is discretionary. *United States v. Shay,* 57 F.3d 126, 132 (1st Cir.1995); *Pages–Ramirez v. Ramirez–Gonzalez,* 605 F.3d 109, 115 (1st Cir.2010)(trial court "enjoys substantial discretion whether to admit or exclude relevant expert testimony"). Before accepting the

testimony of an expert witness, the Court must determine that the expert is "qualified as an expert by knowledge, skill, experience, training, or education." Fed.R.Evid. 702. [12] Further, the proffered testimony is admissible only if it is "based upon sufficient facts or data, ... the product of reliable principles and methods, and.. the witness has applied the principles and methods reliably to the facts of the case." *Id.*

12 The Court notes that the defendants did not request *Daubert* hearings prior to trial, nor did they raise objections to Dr. Ferzoco's or Dr. Ducheyne's general qualifications as expert witnesses. Tr. V 154:25–155:3.

[9] [10] [11] As established by the Supreme Court in *Daubert,* a trial court performs a "gatekeeping" role in determining the admissibility of expert testimony. *United States v. Diaz,* 300 F.3d 66, 73 (1st Cir.2002). In performing that role, the court is required to conduct a preliminary evaluation of the proffered expert testimony with respect to both reliability and relevance. *Id.* With respect to reliability, the assessment of the testimony includes a determination as to " 'whether the reasoning or methodology underlying the testimony is scientifically valid and ... whether that reasoning or methodology properly can be applied to the facts in issue.' " *Id.* (quoting *Daubert,* 509 U.S. at 592–93). Regarding relevancy, " 'expert testimony must be relevant not only in the sense that all evidence must be relevant, but also in the incremental sense that the expert's proposed opinion, if admitted, likely would assist the trier of fact to understand or determine a fact in issue.' " *Id.* (quoting *Ruiz–Troche v. Pepsi Cola of Puerto Rico Bottling Co.,* 161 F.3d 77, 81 (1st Cir.1998).

***13** To aid the trial court in determining the admissibility of an expert's testimony, the *Daubert* Court identified four factors significant to the inquiry: "(1) whether the theory or technique can be and has been tested; (2) whether the technique has been subject to peer review and publication; (3) the technique's known or potential rate of error; and (4) the level of the theory or technique's acceptance within the relevant discipline." *United States v. Mooney,* 315 F.3d 54, 62 (1st Cir.2002). "[D]ue investigation of such matters will ensure that proposed expert testimony imparts 'scientific knowledge' rather than guesswork." *Ruiz–Troche v. Pepsi Cola of Puerto Rico Bottling Co.,* 161 F.3d 77, 81 (1st Cir.1998) (quoting *Daubert* 509 U.S. at 592, 113 S.Ct. 2786, 125 L.Ed.2d 469).

However, the factors "are not definitive or exhaustive, and the trial judge enjoys broad latitude to use other factors to evaluate reliability." *United States v. Mooney,* 315 F.3d at 62 (citing *Kumho Tire Co., Ltd. v. Carmichael,* 526 U.S. 137, 119 S.Ct. 1167, 143 L.Ed.2d 238 (1999)); *Ruiz–Troche v. Pepsi Cola of Puerto Rico Bottling Co.,* 161 F.3d at 85 (enumerated factors "do not function as a 'definitive checklist or test,' but form the basis for a flexible inquiry into the overall reliability of a proffered expert's methodology."). *United States v. Diaz,* 300 F.3d at 73–74 (" 'The trial court must have the same kind of latitude in deciding *how* to test an expert's reliability ... as it enjoys when it decides *whether* that expert's relevant testimony is reliable.' ")(quoting *Kumho* Tire, 526 U.S. at 152).

[12] [13] Moreover, "[t]he factors identified in *Daubert* may or may not be pertinent in assessing reliability, depending on the nature of the issue, the expert's particular expertise, and the subject of his testimony." *Kumho Tire,* 526 U.S. at 150. Instead, *Daubert* demands that "the proponent of the evidence show that the expert's conclusion has been arrived at in a scientifically sound and methodologically reliable fashion." *Ruiz–Troche v. Pepsi Cola of Puerto Rico Bottling Co.,* 161 F.3d at 85. "*Daubert* does not require that a party who proffers expert testimony carry the burden of proving to the judge that the expert's assessment of the situation is correct. As long as an expert's scientific testimony rests upon 'good grounds, based on what is known,' *Daubert,* 509 U.S. at 590, 113 S.Ct. 2786, 125 L.Ed.2d 469 (internal quotation marks omitted), it should be tested by the adversary process—competing expert testimony and active cross-examination—rather than excluded from jurors' scrutiny for fear that they will not grasp its complexities or satisfactorily weigh its inadequacies." *Ruiz–Troche v. Pepsi Cola of Puerto Rico Bottling Co.,* 161 F.3d at 85; *Daubert,* 509 U.S. at 596, 113 S.Ct. 2786, 125 L.Ed.2d 469 ("Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence.")

***14** In sum, "[t]he inquiry envisioned by Rule 702 is ... a flexible one. Its overarching subject is the scientific validity and thus the evidentiary relevance and reliability of the principles that underlie a proposed submission. *The focus, of course, must be solely on principles and methodology, not on the conclusions they generate.*" *Daubert,* 509 U.S. at 594–95 (emphasis added).

(a) Testimony by Dr. Ferzoco

Dr. Ferzoco is a board-certified general surgeon with a specialty in abdominal hernias. In addition, Dr. Ferzoco is an assistant professor of surgery at Harvard Medical School, a clinical instructor in surgery at Tufts School of Medicine, and the Director of the Comprehensive Hernia Center at the Brigham & Womens' Hospital in Boston. Dr. Ferzoco's work has been published in peer-reviewed literature and he has contributed to book chapters and other publications on various topics related to surgery, including hernia repair. At his own estimation, Dr. Ferzoco performs between 200 and 300 hernia surgeries per year, including many very complex cases. Prior to the recall of the CK Patch, Dr. Ferzoco implanted approximately ten CK Patches. He has also explanted between six to ten CK Patches. In his experience with CK Patches, Dr. Ferzoco has encountered abscesses or fistulization which required removal of the implant. Tr. VI 112:7–10, 112:22–113:10, Aug. 11, 2010.

Based on his review of Thorpe's medical records, Dr. Ferzoco testified in detail on Thorpe's health issues and the treatment he received for them. Dr. Ferzoco also provided general descriptions of diverticulitis, colonoscopy, colectomy, bowel obstruction, and resection of the bowel. Tr. VI 117–123. Dr. Ferzoco explained that the two rings of the XL CK Patch provide the advantage of ensuring the patch will lie flat for the surgeon. After explaining the mechanics of a tacker, a device he uses in his own practice, Dr. Ferzoco demonstrated how Dr. Parish fired two rows of spiral tacks around the circumference of the mesh to affix it to Thorpe's anterior abdominal wall. Tr. VI 134:14–135:1. Dr. Ferzoco concluded that, based on his review of Thorpe's medical records, the radiologist's report, the surgical note and testimony by Dr. Parish [13], Dr. Parish implanted the patch correctly, *i.e.* the patch was fully expanded and placed flat and planar in Thorpe's abdomen. Tr. VIII 8:14–9:18. Dr. Ferzoco also opined that there was nothing in the medical records that suggested, subsequent to the surgery, that the patch had not been fully expanded upon implantation. Tr. VIII 64:6–65:5. Further, Dr. Ferzoco stated that the implanted XL CK Patch was the appropriate size; that it had been sufficiently fixated; that there was appropriate tissue ingrowth; and that the patch was placed flat, not folded, into Thorpe's abdomen. Tr. VIII 65:6–66:23.

13 Dr. Ferzoco also referred to radiologic films. Upon defense counsel's objection, the Court conducted a conference with counsel for both parties out of hearing of the jury and permitted Davol's counsel to voir dire Dr. Ferzoco about the timing of his review of certain CT scans. Because Dr. Ferzoco's review of CT scans during the time between his first and second deposition had not been properly disclosed to Davol, the jury was instructed to disregard Dr. Ferzoco's reference to radiological films. Tr. VIII 9:18—63:20.

With respect to Thorpe's condition after he received the hernia patch implant, Dr. Ferzoco stated that there was no evidence in 2005 and 2006 that Thorpe developed an infection, abscess, or fistula around the patch. Tr. VIII 66:24–67:23. Likewise, there was no clinical evidence that Thorpe was developing adhesions to the patch in 2005 or 2006 or that the hernia had recurred. Tr. VIII 68:5–69:9.

***15** Dr. Ferzoco noted that Thorpe did develop complications in late 2007. Based on a microbiology report analyzing fluid sampled from Thorpe's abdominal wall above the implanted patch, it was determined that Thorpe had developed an abscess. Tr. VIII 78:14–79:15. Bacteria cultures revealed, *inter alia,* a bacteria related to succus or bile fluid, which is normally found within the bowel. Tr. VIII 80:14–25. Dr. Ferzoco concluded that the bacteria came from leakage of bowel fluid above the patch. When specifically asked whether he had an opinion, to a reasonable degree of medical certainty, how material from inside the bowel ended up above the CK Patch, Dr. Ferzoco opined that

> "there was a communication between the bowel, which is below the patch, and the area above the patch due to a break of the CK ring at the weld, which led to puncture of the bowel and leakage of the fluid, which channeled above the mesh into the subcutaneous space

and the beginning of the organization of the abscess." [14] Tr. VIII 81:17–82:4.

14 Defense counsel's objection on grounds of nonresponsiveness and lack of foundation was overruled. Tr. VIII 82:5–7.

Dr. Ferzoco then explained to the jury how a break at the ring weld would create two points which could puncture the bowel below the mesh, resulting in leakage of fluid. Tr. VIII 82:20–83:11. He further opined that the cause of Thorpe's enterocutaneous fistula was caused by "a break in the ring at the weld that led to injury and puncture of the bowel leading to a fistula formation and abscess formation." Tr. VIII 83:21–84:4.

In Dr. Ferzoco's opinion, Dr. Parish successfully debrided Thorpe's abscess and appropriately managed the fistula by collecting the leaking fluid and preserving the integrity of the surrounding skin with the application of a stoma bag. Tr. VIII 85:2–18, 87:3–21.

Based on his review of the cell phone pictures taken by Dr. Sindram after the explantation of Thorpe's patch, Dr. Ferzoco again concluded that a PET ring broke at the weld and caused Thorpe's fistula. Tr. VIII 93:20–24. Specifically, Dr. Ferzoco pointed out that the explanted patch showed intense bile staining around the area of the break in the PET ring and that the fistula was located "where the break in the ring is at the weld with bile staining of the mesh." Tr. VIII 93:6–9. He concluded that the PET ring broke "due to an insufficient weld at the weld site of the ring." Tr. VIII 108:21–109:6.

Dr. Ferzoco then explained the explantation procedure performed by Dr. Lagoo and Dr. Sindram and concluded that the care Thorpe received during and after the explant surgery was very reasonable. Tr. VIII 94:10–96:8, 99:10–17. With respect to the fold in the patch observed by Dr. Lagoo during the explantation, Dr. Ferzoco stated that the fold was "driven by the break in the ring. So, again, with a break in the ring, it is providing forces of contracture and warping of the graft, of the mesh itself, so that it can fold itself in the space that it was placed in." [15] Tr. VIII 99:24–100:9. According to Dr. Ferzoco, none of the medical records he reviewed or any clinical information provided in testimony revealed a description of a folded patch prior to October 2007. Tr. VIII 100:22–101:8.

15 Defense counsel's objection and motion to strike based on lack of foundation was overruled. Tr. VIII 100:10–12.

***16** Defendants then conducted a thorough cross examination of Dr. Ferzoco. Tr. VIII 114:19–215:19. In the course of cross examination, Dr. Ferzoco acknowledged that he did not conduct a medical literature review in preparing his report on this case, Tr. VIII 140:23–141:7, and that he was not aware of any study that described a higher rate of fistulas in patients implanted with the CK patch. Tr. VIII 151:19–25. Dr. Ferzoco also acknowledged that he had never conducted a test to establish how a memory recoil ring might break; he had never explanted a CK Patch with a broken ring; and he had never published an article describing the way he believed CK Patches might break in the body. Tr. VIII 154:6–155:18.

Dr. Ferzoco conceded that his theory on how memory recoil rings can break was not generally accepted in the scientific community. Tr. VIII 155:19–157:10. Further, Dr. Ferzoco agreed that neither his original report nor the two supplements thereto stated that a memory recoil ring had punctured Thorpe's bowel; that there had been a break at the ring weld; or that there was a fistula in the location of the ring. Tr. VIII 167:3–25. Upon questioning by defense counsel, Dr. Ferzoco agreed that he offered an opinion in his expert report that "the Composix Kugel patch warped," although he did not confirm whether "this concept of the patch warping led to the ring breaking." Tr. VIII 158:17–159:14. Dr. Ferzoco also agreed that his report stated that, "with the ring broken and contracture of the two materials occurring at different rates, the mesh became warped leading to exposed polypropylene" and that "if the ring did not break and the mesh did not warp, the ePTFE would have remained in contact with the abdominal contents to prevent adhesion formation." Tr. VIII 168:1–17. Further, Dr. Ferzoco agreed that, in his report, he stated that "since the surgeon encountered adhesions of bowel to mesh as well as fistula formation, it is clear that the polypropylene component had come in contact with the bowel," Tr. VIII 168:22–25, and "the only way this can happen is if the mesh became warped

after the two materials contracted at different rates ... [t]he ring, which had broken, allowed the material to fold in an undesirable fashion allowing the polypropylene to come into contact with the small bowel." Tr. VIII 169:4–15. [16]

16 The specific conclusions contained in this entire paragraph were not part of Dr. Ferzoco's testimony on direct examination. Instead, it was presented to the jury, for the first time, during cross examination, inter alia, by reference to prior deposition testimony and statements in his expert reports. The expert reports from which defense counsel repeatedly quoted were not introduced as full exhibits and were not made available to the jury for review and consideration. Defs.' Ex. 1335, 1336, 1340.

Dr. Ferzoco agreed that Thorpe appeared to have a strong adhesion response to the XL CK Patch, but, based on the information available to him, Dr. Ferzoco could not state when Thorpe started to develop those adhesions. Tr. VIII 174:11–176:10–14. He confirmed that, in his opinion, Dr. Parish's choice of the XL CK Patch was a reasonable decision, Tr. VIII 177:25–178:3, and that, although he, himself, preferred suturing as a fixation technique, "tacks, if they have good purchase in the abdominal wall, should pretty much stay where they are." Tr. VIII 178:15–25.

Dr. Ferzoco conceded that, at the time of his first deposition, he could not say whether the CK Patch was implanted in such a way that the polypropylene came in contact with the bowel and that he could "not comment on whether Dr. Parish tacked the patch folded over at the time of surgery." Tr. VIII 183:9–19. Dr. Ferzoco also acknowledged that, based on the cell phone pictures taken by Dr. Sindram, the tacks did not reach "all the way to the edge of the Composix Kugel explanted patch." Tr. VIII 185:18–23. During his first deposition, Dr. Ferzoco also stated that he did not know whether the patch was tacked while it was folded under, thus exposing the polypropylene to the bowel. Tr. VIII 188:18–25, 189:10–14. At that time, Dr. Ferzoco believed that the inner ring was found broken at the time of explant, but he had no opinion why, when or how the inner ring broke. Tr. VIII 196:9–20. Dr. Ferzoco agreed that neither Dr. Lagoo nor Dr. Sindram stated that they saw a ring in Thorpe's bowel. Tr. VIII 203:9–204:7. Instead, in their explant report, the two surgeons described the ring as being in the subcutaneous tissue on Thorpe's right side, closer to the skin than the bowel, whereas his fistula was on the left side. Tr. VIII 191:22–193:21. Dr. Ferzoco, however, maintained that, although he did not state this in prior depositions, he was now of the opinion that there was a ring in the bowel. Tr. VIII 205:15–206:22. Dr. Ferzoco acknowledged that, in his first deposition, he stated that "the absolute cause of the fistula was the patch folding over and the Marlex [mesh] coming into contact with [the] bowel, forming a dense adhesion at the place where the foldover occurred and leading to injury of the bowel", but that he was not in a position to say when that adhesion started. Tr. VIII 212:15–213:17.

***17** On re-direct, Dr. Ferzoco explained that he had been provided with more information about the case between his first and second deposition, including the six cell phone photographs Dr. Sindram had taken of Thorpe's explanted patch, as well as some deposition transcripts. Tr. VIII 217:14–23. Based on those photographs which, according to Dr. Ferzoco, "demonstrat[ed] a ring break, photos of the explanted material with the ring demonstrating bile staining surrounding the area of the fistula," Tr. VIII 222:5–16, and based on Dr. Lagoo's testimony regarding the ring she extracted from Thorpe, Tr. VIII 223:8–23, Dr. Ferzoco concluded that the ring was involved in the fistula formation and that "the bowel adhesion allowed that ring to puncture that bowel and form the fistula." Tr. VIII 225:2–9. Dr. Ferzoco explained that "the ring itself allowed the adhesion to form because of the contracture forces provided and the rigidity of the ring, allowing the material to warp." Tr. VIII 225:18–226:3. He conceded on re-cross that Dr. Lagoo did not observe a ring in Thorpe's bowel. Tr. VIII 231:24–232:6.

(b) Testimony by Dr. Ducheyne

Dr. Ducheyne has been a professor of bioengineering and orthopedic surgery research on biomaterials and dentistry at the University of Pennsylvania in Philadelphia for 27 years. At the beginning of his testimony, he explained that the Ph.D. he earned in materials science corresponds to today's degree in bioengineering/biomaterials and that his career has been focused on medicine, engineering-applied medicine, and the materials used within the context of medicine. Tr. V 137:19–138:1, 139:10–12. By his own estimate, Dr. Ducheyne has published more than 300 articles in peer-reviewed journals and books; he has edited

or contributed to a number of books on biomaterial engineering and medical devices; and his work has been honored by the American Society for Biomaterials. Tr. V 138:2–7, 139:4–12, 140:5–8. In addition to his teaching responsibilities, Dr. Ducheyne has also consulted with a number of medical device manufacturers; he has founded such a company himself; and he holds a number of patents for medical devices he has designed or co-designed. Tr. V 143:16–145–24, 147:7–19.

In connection with this case, Dr. Ducheyne stated that he had reviewed company documents, scientific literature, a sample patch, the explanted patch, Thorpe's medical and surgical records, and the images made of the patch in order to form an opinion as to what led to the failure of the patch in Thorpe. Tr. V 154:3–24. Dr. Ducheyne also reviewed internal Davol documents related to *in vitro* testing on the weld strength [17] of the XL CK Patch rings. Tr. V 175:17–20.

17 As established during the course of the trial, the initial ring weld specification of the XL CK Patch called for a two-pound tensile break strength. As explained by David Paolo, former manager of advanced manufacturing engineering for Davol, "[a] tensile load is something that's applied axially. So the product is welded here in a joint. The product would be pulled in this manner to see if it broke greater than or equal to two pounds, which was specified." Tr. I 108:6–14.

Dr. Ducheyne defined design validation and summarized the critical components of a good design process for a medical materials product or device, including considerations and laboratory tests of how the material will be tolerated in the body, Tr. V 151:8–15, tests for functioning, first in the laboratory, i.e. *in vitro* testing, followed by *in vivo, i.e.* animal testing. Tr. V 151:18–152:10. After those steps, a clinical evaluation with human subjects is indicated. Tr. V 152:22–153:12.

***18** Dr. Ducheyne then explained the components of the XL CK Patch and their intended functions, Tr. V 155:5–157:13. Dr. Ducheyne described the appearance of the explanted XL CK Patch based on his examination of the patch, the pathology report, and the cell phone photographs taken by Dr. Sindram following explantation. Tr. V 163:17–19, 164:24–165:11, 166:14–167:10. Based on his review of the explant, Dr. Ducheyne concluded that there was a weld break on one of the two pieces of the PET rings in the XL CK Patch. Tr. V 164:24–165:11, 169:16–23. According to Dr. Ducheyne, the photographs taken by Dr. Sindram also showed that the explanted patch still contained a portion of the outer ring that was broken at the weld joint and stained with bile. Tr. V 169:16–23, 170:5–9, 171:1–6.

With respect to the process of design validation, Dr. Ducheyne testified that he reviewed internal Davol documents and concluded that "too little analysis was done in terms of first identifying what the requirements were for the welds and how to test them in the best possible way in order to assure proper functioning later on *in vivo,* in patients." Tr. V 175:17–20, 176:7–14. Particularly, an August 31, 2006 summary report of the clinical relevance of PET ring stock and ring weld specifications stated:

> "There was no testing conducted and documented to justify that the 2 lb tensile break strength for the PET recoil ring for Kugel products was clinically relevant. This specification was in effect from March of 2000 to March of 2006. In May of 2006 the specification was revised to 8 lbs and is considered clinically relevant." Pltfs.' Ex. 592–001. [18]

18 Although Davol decided to enhance the weld strength of the memory recoil rings in October 2003, this enhancement was limited to increasing the pull test for the rings from two to four pounds. The design specification was not changed from two to eight pounds until after the recall of the XL CK and other size CK Patches. Tr. XI 7:25–8:18.

Dr. Ducheyne suggested that Davol should have performed tests to "determine [ ] a proper level of strength" and "whereby the force on the welds is not just pulling along the axis of that wire but really where you bend because that's the likely event in vivo, and so thereby clinically relevant means a bent type of mechanical solicitation." Tr. V 177:23–178:10.

Dr. Ducheyne stated that, in his opinion, animal testing should have been performed to study the effect of tissue response on the overall performance of a product designed to stay in the body. Tr. V 180:7–20. He explained that

"when a product stays in vivo, there is tissue formation, which one can study in vivo, in animals, that then would reveal what failure modes would occur, and that one then can relate back to the two-pound weld strength." Tr. V 179:13–17. With respect to tissue responses, Dr. Ducheyne further explained that "[i]f you just make a cut in your hand, there is a tissue response, there is a healing. When you implant a patch, there is a healing-in period." Tr. V 179:20–25.

Dr. Ducheyne stated that animal testing would have allowed Davol to study the patch "over a certain duration in the body, in the body ... of animals, and that then would show the tissue response and what the effect may be on the overall performance of the patch." Tr. V 180:7–20. He noted that no animal testing was conducted on the XL CK Patch before implantation into Thorpe. Tr. V 180:2–6. Moreover, clinical studies of the XL CK Patch were limited to clinical evaluations performed by three surgeons for three patients, which, in Dr. Ducheyne's opinion, was insufficient. Tr. V 181:3–9, 192:11–17.

***19** Dr. Ducheyne also reviewed an internal Davol Problem Investigation Report from September 2006 which stated that "improper deployment technique," and "deficiencies in the Design Control system" were the likely root causes of ring break failures and that "inadequate weld strength specification" was a likely root cause for weld break failures. Pltfs.' Ex. 594–009. Based on his review of the document, Dr. Ducheyne concluded that there was "insufficient input in the overall design process of [the XL CK Patch], not sufficient input in order to arrive at a well-designed and functioning product." Tr. V 183:22–184:3. Although "there was analysis of performance regarding one aspect of the device ... but not nearly enough regarding some other critical aspects and so, therefore, was not satisfactory." Tr. V 186:3–7.

Dr. Ducheyne explained the function of a design failure mode and effects analysis ("DFMEA"). Tr. V 186:23–187:19. He concluded that a failure mode of ring weld breaks should have been included in the DFMEA at the time the XL CK Patch was released "because a weld is a potentially weak part in any structure, and it is normal for anyone who has an understanding of materials to look at welds and their properties and whether those properties are sufficient or not." Tr. V 189:3–15. Davol's internal review of the original DFMEA for the XL CK Patch showed that "ring breakage was not identified as a failure mode ... until Dec[ember]2005 even though there were customer complaints of ring breaks." Pltfs.' Ex. 334–002. In addition, Dr. Ducheyne stated that "design validation of the product did not include aspects of weld strength" and that the 2 lb. weld strength of the rings appeared to have been "plucked from thin air." Tr. VI 15:24–16:16. Prior to Thorpe's hernia repair with the XL CK Patch, the DFMEA did not include ring weld failures. Tr. V 190:4–8.

Dr. Ducheyne then proceeded to describe, in detail, the phenomenon of scar contracture as a form of tissue response to a medical device implanted in the body. Tr. V 193:10–194:3. He explained that

> "Tissue response to when a material or device is implanted is very typical to that wound—it's very comparable to that wound healing, and so you get [a] scar. If it's a rough wound, you'll get a big scar. Now, you can have all sorts of different reactions to implanted materials. You can have a very, very well-tolerated material, almost no disease process and you get little scar tissue. But as is typical here with these devices, you get an extensive response, and during that reaction of the body with tissue formation, you get a pulling together, there is contraction, and so that's what it means." Tr. V 193:10–194:3.

He further explained that there was a tissue response to every medical device implanted in the body. Tr. V 194:4–6. The mesh side of the XL CK Patch was designed to "elicit tissue ingrowth and thereby fixation of the patch." By contrast, the ePTFE side would not cause ingrowth or adhesion. Tr. V 194:15–195:1, 201:7–14. [19] The two PET rings in the XL CK Patch were intended to "facilitate in the placement, the flat placement of the rings [sic] in—under the fascia; that is, within the body." Tr. V 197:2–12.

19 Davol's objections to questions of when tissue ingrowth turned into contracture, what type of contracture Davol hoped to elicit from the patch, and what contracture could be expected from the CK Patch, were sustained. Tr. V 195:4–23.

***20** According to Dr. Ducheyne, he has published extensively on tissue reactions and forces and stresses in

tissues. Tr. V 199:24–200:3. He explained that, of the three materials in the XL CK Patch, the polypropylene mesh could lead to scar contracture, while the ePTFE "will fold and the PET rings will bend." Tr. V 201:19–202:10. Ultimately, Dr. Ducheyne concluded that scar contracture can lead to ring breaks in the XL CK Patch, Tr. V 202:14–203:8 and that, in Thorpe's case, "the ring breaks were the result of the contraction and the other forces that act upon the abdomen." Tr. V 204:9–14, 205:19–24.

On cross examination, Dr. Ducheyne conceded that, when he first expressed his opinions regarding the XL CK Patch in a written report in December 2009, he had not seen or examined a patch sample or the actual explanted patch, nor had he ever designed a hernia patch. Tr. VI 19:7–16, 21:3–12. Dr. Ducheyne did not measure any aspect of Thorpe's patch. Tr. VI 23:18–21.

He agreed that the design of the CK Patch held useful benefits, such as the use of ePTFE on one side of the CK Patch and polypropylene on the other. Tr. VI 28:12–18, 29:2–17. He also agreed that the memory recoil rings designed to flatten out the hernia patch, when placed, were beneficial. Tr. VI 29:18–30:1. Dr. Ducheyne further agreed that the Kugel Patch, which has a PET ring like the CK Patch, was cleared by the FDA for use in humans in 1996 and that the Kugel Patch, together with the Composix and the Composix E/X, was a predicate device for the CK Patch. Tr. VI 30:12–33:5.

With respect to factors that can impact the safety and effectiveness of a medical device, such as a hernia patch, Dr. Ducheyne concurred that, besides design and manufacturing, the patient's medical history and activities and the implanting physician's technique could have an impact on the success of the device. Tr. VI 41:21–42:15. He did not determine, however, whether Dr. Parish's technique in implanting the patch may have contributed to the condition of the memory recoil rings. Tr. VI 51:5–16.

Dr. Ducheyne believed that, based on an observation of an indentation and a bend in one of the rings removed from Thorpe, the rings were probably grasped with forceps during the explant procedure in April 2008. Tr. VI 43:3–12. The rings may have been damaged during the debridement and were "certainly cut in certain places" when Thorpe's patch was removed. Tr. VI 43:13–44:22. Dr. Ducheyne also believed, however, that any cuts made to the rings during the explant procedure were unrelated to weld break failures. Tr. VI 86:19–87:10. Dr. Ducheyne acknowledged that he did not count the surgical tacks used to affix the patch in Thorpe's abdomen or note their location. Tr. VI 45:22–50:9. He explained that he, instead, focused on the failure of the weld, Tr. VI 46:2–6, and that he considered the method by which the patch was inserted to be a surgical issue. *Id.* 51:5–8.

Dr. Ducheyne conceded that he was not aware of any peer-review article in the medical, scientific, or engineering literature or any clinical study of a hernia patch with a PET ring where the weld was broken by naturally occurring scar contracture. Tr. VI 52:4–53:6, 54:24–55:4. He further agreed that the weld strength of the ring inside Thorpe's patch could not be measured and that it could not be determined, after the fact, what level of stress the welds could withstand. Tr. VI 65:8–25, 66:1–5. Although he conceded that he never measured the force of scar contracture in this case, he stated that he reviewed literature whereby he developed his scientific insight. Tr. VI 55:19–23. He also agreed that, at the time of trial, the theory that naturally occurring scar contracture can cause ring welds to break was not generally accepted in the scientific community. [20]

20 At this point, Davol's counsel stated that he renewed his *Daubert* motion and moved to strike Dr. Ducheyne's opinion. The motion was denied. Tr. VI 56:23–57:13.

***21** As Davol's counsel pointed out, internal Davol reports from 2005, 2006 indicated that "Davol specifically looked at the issue of whether scar contracture could break the rings" and "concluded that scar contracture was likely not the root cause of the ring breaks they were seeing." Tr. VI 57:15–58:6. An August 31, 2006 memorandum by Davol's failure investigation team regarding literature review on scar contracture forces, which Dr. Ducheyne considered, stated that "[a] review of the literature and returned Composix Kugel complaint product [21] suggests that forces generated by contracting tissue during healing could cause deformation of the Composix Kugel patch and PET ring if the patch is not well-fixated." The memorandum concluded that "scar contracture is not a likely root cause of ring

break failures since several returned complaint explants indicated the rings were folded at the weld." Pltfs.' Ex. 403–001. The memorandum also stated that "[f]orces generated by healing tissue during the contraction phase of healing are measurable and have been shown to lead to contraction of implanted meshes." *Id.* at 004. In support, the memorandum cited to four articles related to cellular contractility, handling properties of polypropylene meshes, and shrinkage of polypropylene mesh in ventral hernia repair. *Id.* at 002–003, n. 1–4.

21 Davol requested the return of CK patches that were the subject of a complaint.

Dr. Ducheyne acknowledged that the exact strength of the ring welds in Thorpe's patch were unknown. Tr. VI 65:8–16. Previously, when questioned at his deposition what evidence he had that scar tissue in Thorpe was strong enough to cause two welds in his patch to break, Dr. Ducheyne testified that

> "There is a failure. There is based on photographic observations, there is a weak weld. There is folding. These are the facts in the case. Then, generally, what is well known in the field is that contraction takes place and is associated with scar tissue formation and that here, given the very open network that polypropylene has and, therefore, limited resistance that can be that is present against contraction, it is very easily possible that overall here there was a bending that is occurring in this—bending and folding occurring in this particular device that then exceeds the actual properties, strength properties of the weld." [22] Tr. VI 66:23–67:18.

22 Although the jury did not receive deposition transcripts to review, the quoted testimony was read by Davol's counsel at trial and Dr. Ducheyne confirmed his prior answer.

Dr. Ducheyne acknowledged that he was familiar with an article by Davol's medical expert and consultant, Dr. David Iannitti ("Dr.Iannitti"), based on data collected on 455 patients who underwent open ventral hernia repair surgery, but he had not considered it when he prepared his report. Tr. VI 69:9–70:6, 73:22–74:3.

(d) Discussion

At the outset, it is clear that Dr. Ferzoco and Dr. Ducheyne have the requisite qualifications in their respective fields to render expert opinions in this case. Davol now argues that the Court improperly admitted testimony by these expert witnesses on the contested issue of causation. Specifically, Davol asserts that "Plaintiffs' experts never identified any scientific evidence to substantiate that scar contracture can break a PET memory recoil ring" and that "there is no corroboration for it in any published study or peer-reviewed literature, it has not been tested, it is not generally accepted in the relevant scientific community, and it fails to account for the facts or empirical data in the record that refute it." Davol's Supporting Mem. at 1.

***22** To arrive at his opinion that Thorpe's development of an enterocutaneous fistula and related abscess was the result of a PET ring breaking at the weld, leading to a puncture of the bowel and leakage of bowel fluid into subcutaneous space, Tr. VIII 78:14–84:4, Dr. Ferzoco relied, *inter alia,* on the results contained in a microbiology report on material collected from Thorpe's abdominal wall on October 19, 2007. Tr. VIII 75:7–77:9. As Dr. Ferzoco explained, the material consisted of fluid diagnosed as an abscess located above the XL CK Patch inside Thorpe's abdomen. Tr. VIII 78:14–23. A finding of bacteria normally found in succus or bile fluid, which in turn is only found in the lumen of the bowel, suggested to Dr. Ferzoco the existence of spillage or leakage of bowel fluid into subcutaneous tissue. Tr. VIII 79:19–81:16. Dr. Ferzoco deduced that the abnormal location of the fluid indicated a "communication" between the bowel and the area above the XL CK Patch, which was caused by a puncture of the bowel by a broken PET ring. Tr. VIII 81:17–82:4. Dr. Ferzoco's specific conclusion that the broken ring caused the fistula was based, in part, on the photographs taken by Dr. Sindram after explantation of Thorpe's hernia patch, which, in Dr. Ferzoco's opinion, showed bile staining around a portion of the PET ring that was broken at the weld. Tr. VIII 90:14–91:5.

In sum, Dr. Ferzoco's direct testimony was entirely based on the record submitted at trial and his own professional experience. Although his conclusions clearly differed from those later proffered by Davol's expert witnesses, they were based on his considerable expertise and experience as a specialist in hernia treatment and repair. As such,

none of his medical opinions required additional scientific corroboration pursuant to the four factors suggested by *Daubert.* Dr. Ferzoco is clearly qualified as an expert "by knowledge, skill, experience, training, or education" to explain to the jury the nature of Thorpe's complications and the surgical procedures Thorpe underwent to address these. Likewise, Dr. Ferzoco is well qualified to offer an interpretation of the significance of laboratory findings and photographic evidence in Thorpe's case and to offer an opinion on the cause of the complications suffered by Thorpe after undergoing the hernia repair.

Moreover, a thorough review of the voluminous trial record reveals that, with respect to Dr. Ferzoco, the plaintiffs did not succeed in offering the testimony Davol now seeks to exclude, i.e. that naturally occurring scar contracture causes ring breaks. On direct examination, Dr. Ferzoco opined that the fold in the hernia patch observed by Dr. Lagoo upon explantation "was driven by the break in the ring. So, again, with a break in the ring, it is providing forces of contracture and warping of the graft, of the mesh itself, so that it can fold on itself in the space that it was placed in." Tr. VIII 99:24–100:9. Dr. Ferzoco concluded that the breakage of the ring led the hernia patch to contract or warp and to expose the polypropylene side to Thorpe's bowel. In response to the specific question by plaintiffs' counsel regarding "what caused the PET ring, from a clinical standpoint, a surgical/clinical standpoint, what caused the PET ring to break in Mr. Thorpe," Tr. VIII 108:7–11, Dr. Ferzoco stated that "based on forces of the ring, the PET ring, that caused it to sort of bend and then ultimately break due to an insufficient weld at the weld site of the ring." Tr. VIII 109: 3–6. When further asked about "what type of forces in Mr. Thorpe, based on your review of the evidence in this case, acted upon the PET ring to cause it to break at the weld," Tr. VIII 109:14–17, Ferzoco responded: "The fact that Mr. Thorpe was an active individual after his hernia repair, was able to go running, was able to be an active individual, play with his children, coach his sporting teams, suggests to me activities of daily living were likely to be contributing forces to the breaking of the ring." Tr. VIII 110:18–23.

***23** In other words, nowhere in his testimony on direct examination did Dr. Ferzoco offer an opinion that naturally occurring scar contracture causes ring breaks. He did not define, explain, or even mention scar contracture, nor did he relate such occurrence to the break of PET rings generally, or in Thorpe's case, specifically. While Dr. Ferzoco may have offered such an opinion at prior depositions or in compliance with discovery requirements pursuant to Fed.R.Civ.P. 26(2)(B), he did not express this opinion on direct examination. His deposition transcripts and his expert reports (Pltfs.' Exhibits 1335, 1336, 1340) were not admitted as full exhibits and were, therefore, not available to the jury for review and consideration.

On cross examination, after discussing, at some length, the concept of evidence-based medicine and the varying quality levels of data, Dr. Ferzoco was questioned about the expert report he provided in December 2009, followed by a supplemental report in March 2010. Neither report cited to medical articles, and Dr. Ferzoco acknowledged that he conducted no medical literature review in preparation of the reports. Tr. VIII 140:23–143:25. He also agreed that he was unaware of any article or study that described a higher rate of fistula formation in patients implanted with a CK Patch, compared to other products. Tr. VIII 150:25–151:25.

Dr. Ferzoco agreed that he had "described to the jury an opinion that relates to ring breaks in Composix Kugel patients." Tr. VIII 152:1–4. He also agreed that he had not done any kind of test to try to establish how a ring might break, had not published any article that described the way he believed "Composix Kugels might break in the body," and had not seen an article that described his "theory or opinion as to how Composix Kugels might break in the body." Tr. VIII 154:6–155:18. He also conceded that his theory was not generally supported by peer-reviewed papers. Tr. VIII 157:7–10.

Dr. Ferzoco was then referred by Davol's counsel to his expert report in which he offered the opinion that "the Composix Kugel warped." The question of whether "this concept of the patch warping led to the ring breaking" remained unanswered, however. Tr. VIII 158:17–22. Detailed questioning about his expert reports also revealed that neither report reflected Dr. Ferzoco's subsequent testimony on direct examination: that the ring punctured the bowel, that there had been a break at the ring weld, and that the fistula was located near the

ring. Tr. VIII 167:3–25. When questioned, Dr. Ferzoco acknowledged that, in his report, with respect to the cause of Thorpe's fistula, he stated that "with the ring broken and contracture of the two materials occurring at different rates, the mesh became warped leading to exposed polypropylene." He also stated, in his report, that "it is clear that if the ring did not break and the mesh did not warp, the ePTFE would have remained in contact with the abdominal contents to prevent adhesion formation." Tr. VIII 168:1–15. His report further stated that "since the surgeon encountered adhesions of bowel to mesh as well as fistula formation, it is clear that the polypropylene component had come in contact with the bowel;" that "the only way this can happen is if the mesh became warped after the two materials contracted at different rates;" and that "the ring, which had broken, allowed the material to fold in an undesired fashion allowing the polypropylene to come into contact with the small bowel." Tr. VIII 168:22–169:12.

***24** Dr. Ferzoco agreed that Thorpe showed a strong pro-adhesion response and that adhesions had been formed even to the ePTFE side of the XL CK Patch. Tr. VIII 175:16–176:9. Dr. Ferzoco was presented with his deposition testimony in which he stated that, in his opinion, Thorpe's patch "folded over and formed an adhesion sometime in the 23 months between his implantation and abscess ... as well as a break in the ring." Tr. VIII 187:17–23. He also stated at the time of his deposition that he could not comment on whether the foldover of the patch occurred at the time of surgery. On cross examination he agreed that he could not comment on the issue because he had not looked at the explanted patch or at related CT scans prior to his deposition. Tr. VIII 189:1–14. Dr. Ferzoco agreed that, in his first deposition, he stated that the "absolute cause of the fistula was the patch folding over and the Marlex coming in contact with the bowel, forming a dense adhesion at the place where the foldover occurred and leading to injury to the bowel" but that he could not say when the adhesion started. Tr. VIII 212:22–213:24.

On redirect, Dr. Ferzoco explained that, following his first deposition, he received the photographs taken by Dr. Sindram and some deposition transcripts, including testimony by Dr. Lagoo, which informed his opinions expressed on direct examination. Tr. VIII 222:2–223:23. He then stated that, in his opinion, "the ring was involved in the fistula formation that was observed in Mr. Thorpe;" "the bowel adhesion allowed that ring to puncture that bowel and form the fistula;" and "the ring itself allowed the adhesion to form because of the contracture forces provided and the rigidity of the ring, allowing the material to warp." Tr. VIII 224:25–226:3.

From a close review of Dr. Ferzoco's testimony on direct examination, cross examination, and redirect, it appears that the theory that "naturally occurring scar contracture causes ring breaks," which Davol seeks to preclude on the grounds that it is unsupported by scientific evidence, was not presented to the jury by Dr. Ferzoco. On direct examination, the jury was only offered an opinion that a break at the ring weld had punctured Thorpe's bowel, which led to the fistula and related abscess. Dr. Ferzoco also opined that the ring break may have caused the fold in the patch later observed by Dr. Lagoo upon explantation. With respect to the exact cause of the ring break, Dr. Ferzoco only stated that "activities of daily living were likely to be contributing forces to the breaking of the ring." The concept of naturally occurring scar contracture, its impact on the CK Patch, and its role in an eventual ring break were not addressed.

[14] In sum, Dr. Ferzoco's testimony consisted primarily of a review of Thorpe's medical record, supplemented by detailed descriptions and explanations of human anatomy and surgical and/or clinical procedures. His proffered opinions were based on analysis of the provided materials in light of his considerable expertise, experience, and education, and were undoubtedly helpful in assisting the jury to understand or determine the facts at issue. Dr. Ferzoco's interpretation of the materials he reviewed and his ultimate opinion of what caused the injury to Thorpe were competently challenged in cross-examination and by competing expert testimony. Contrary to Davol's assertion, Dr. Ferzoco did not offer a "novel and unique biomechanical engineering opinion," *see* Defs.' Reply 15 n. 7, requiring the support of scientifically accepted corroboration as suggested by *Daubert.* Therefore, the Court is of the opinion that Dr. Ferzoco's expert testimony was both relevant and reliable and, therefore, admissible under Rule 702.

***25** Dr. Ducheyne, on the other hand, did express an opinion that scar contracture can cause ring breaks. Primarily, however, Dr. Ducheyne's testimony related to (1) the design process for biomedical devices, including testing methods for design validation and design failure modes; (2) the components and function of the XL CK Patch, including its beneficial aspects; (3) tissue responses to medical devices implanted in the body; and (4) his observation of Thorpe's explanted patch and the pictures thereof. Based on his education and expertise in biomaterial engineering and medical devices and his extensive experience in designing and developing such devices, Dr. Ducheyne clearly holds the requisite qualifications to testify regarding these topics. Dr. Ducheyne's descriptions of medical device development and tissue response to biomaterials were well within his area of expertise. As such, his testimony was both relevant and helpful to the jury.

With respect to Dr. Ducheyne's specific conclusion, that scar contracture may have caused the memory recoil rings to break in Thorpe's case, this conclusion was derived from, inter alia, (1) his personal observation, based on a visual inspection of the explanted patch itself and examining several photographs of the explant, that the ring broke at the weld; (2) the generally known and accepted phenomenon of contraction due to scar tissue formation, which was acknowledged in Davol's own investigation; and (3) the known properties of polypropylene.

Dr. Ducheyne explained in detail how he had arrived at the conclusion that the ring in Thorpe's patch had broken at the weld by pointing out that the piece of one ring still in the patch showed a break in the molded material by which the two parts of the ring were originally connected, and that one of the pieces removed from Thorpe showed a corresponding break in the weld. Tr. V 164:24–165:11, 169:16–170:9. With respect to his testimony on scar contracture and tissue responses to medical devices implanted in the body, Dr. Ducheyne explained that he had published extensively on tissue reactions and forces and stresses in tissues. Tr. V 199:24–200:3. His observations regarding the properties of polypropylene, including its intended function to become part of the surrounding tissue were supported by other testimony and not generally disputed. Moreover, the phenomenon of naturally occurring scar contracture generally, and in connection with medical devices, such as hernia patches, specifically, is well known; it was explained in detail by Davol's own witness, Vice President of Research and Development, Roger Darois, Tr. IX 123:17–126:2; and Davol itself conducted various animal studies to investigate the contracture of ringed and ringless mesh inside the body. Tr. IX 126:7–17.

[15] **[16]** While *Daubert* sets forth various factors to assist the Court in evaluating the principles and methodology relied upon by an expert witness to arrive at his ultimate conclusion, the factors are neither definitive nor exhaustive and may not be applicable in a particular case. Here, plaintiffs' expert acknowledged that there was no general acceptance of a general "scar contracture causes ring breaks" hypothesis, nor had such a theory been subjected to peer review or scientific investigation. However, *Daubert* does not require that every ultimate conclusion by an expert witness meet such standards; rather, the focus of a *Daubert* inquiry is on "principles and methodology, not on the conclusions that they generate." *Daubert,* 509 U.S. at 595. Nor does *Daubert* require that an expert witness have conducted his own research regarding his specific conclusion or that such conclusion is supported by peer-reviewed literature. Further, the expert is "permitted wide latitude to offer opinions, including those that are not based on firsthand knowledge or observation." *Daubert,* 509 U.S. at 592.

***26** **[17]** It is clear that Dr. Ducheyne's ultimate conclusion would have carried more weight, had it been supported by general acceptance or peer reviewed literature. However, the reasoning and methodology by which he arrived at his ultimate conclusion were sufficiently grounded in scientific knowledge and supported by factual evidence, thus making his testimony admissible. Moreover, like Dr. Ferzoco, Dr. Ducheyne was subjected to rigorous and competent cross examination that challenged both his conclusions and the sources from which he derived his conclusions, leaving it up to the jury to "decide among the conflicting views of different experts." *Daubert,* 509 U.S. at 153. For these reasons, the Court is of the opinion that Dr. Ducheyne's testimony was properly admitted and that Davol's motion to strike such testimony must be denied.

2. Inadequate Design

[18] Pursuant to North Carolina general products liability statute N.C. Gen.Stat. § 99B–6, a plaintiff alleging an inadequate design claim must prove[23] that (1) at the time of manufacture, the manufacturer acted unreasonably in designing the product; (2) the product was the proximate cause of the harm for which damages are sought; and (3)(a) at the time the product left the control of the manufacturer, the manufacturer unreasonably failed to adopt a safer, practical, feasible, and otherwise reasonable alternative design that could then have been reasonably adopted and that would have prevented or substantially reduced the risk of harm without substantially impairing the usefulness, practicality, or desirability of the product; or (b) at the time the product left the control of the manufacturer, the design of the product was so unreasonable that a reasonable person, aware of the relevant facts, would not use or consume a product of this design. N.C. Gen.Stat. § 99B–6 (a). Although Section 99B–6(b) provides a list of factors to be considered to determine whether a manufacturer acted "unreasonably" in designing the product, "[a] plaintiff is not required to present evidence on all of these factors in order to meet his burden of proving a defective design claim, as some of these factors may not be relevant to a particular plaintiff's claim." *DeWitt v. Eveready Battery Co., Inc.,* 144 N.C.App. 143, 154–55, 550 S.E.2d 511, 519 (2001).

23 The Court notes that the defendants repeatedly refer to a "substantial evidence" standard in connection with the claims for inadequate design and inadequate warning. Defs.' Mot. at 15, 24. The North Carolina products liability statute, however, does not require such a heightened standard. The case cited by the defendants in support, *DeWitt v. Eveready Battery Co.,* 144 N.C.App. 143, 550 S.E.2d 511, 518 (2001), related to a motion for summary judgment, where such a standard was appropriate. The different posture of the case now before this Court requires a determination whether, when viewed in the light most favorable to the nonmoving party, "the record reveals no sufficient evidentiary basis for the verdict." *Zimmerman v. Direct Fed. Credit Union,* 262 F.3d at 75.

[19] **[20]** To support his case, a plaintiff is required to provide (1) expert opinion that the product was inadequately designed; and (2) "expert medical opinion that his medical problems were caused by the defective product." *Richardson v. General Motors Corp.,* 223 F.Supp.2d 753, 756 (M.D.N.C.2002). To establish a defective design claim on the grounds that the manufacturer 'unreasonably failed' to adopt an alternative design under section 99B–6(a)(1), a plaintiff must provide evidence that "the proposed alternative design or formulation was 'a safer, practical, feasible, and otherwise reasonable' design ...; that the alternative design ... 'could then have been reasonably adopted'; the alternative design ... 'would have prevented or substantially reduced the risk of harm' complained of; and the alternative design ... would not have 'substantially impaired the usefulness, practicality, or desirability of the product.' " *DeWitt v. Eveready Battery Co ., Inc.,* 144 N.C.App. at 164, 550 S.E.2d at 519.

***27** Davol asserts that there was no evidence that it acted unreasonably in designing the XL CK Patch; the plaintiffs failed to connect Davol's alleged negligence in designing the XL CK Patch to Thorpe's injury; and no evidence was presented of a reasonable alternative to the XL CK Patch. Davol Mem. at 16–22.

At trial, the jury was presented with a detailed explanation by Dr. Ducheyne on the process of designing a medical materials product, particularly the necessity for design validation, including DFMEA, as well as in vitro and in vivo testing, and clinical evaluation prior to placing a product in the market. Dr. Ducheyne concluded that Davol's design process included a number of inadequacies, including the failure of the DFMEA to include ring breaks, the lack of analysis for weld strength requirements, and the general lack of animal and/or clinical testing.

Testimony by David Paolo ("Paolo"), Davol's former manager of advanced manufacturing engineering, supported some of Dr. Ducheyne's conclusions. Paolo explained that, together with a team of quality engineers, he was tasked by Davol after the recall to "understand what went wrong with the product, how the product potentially failed, what could we do to ensure that it never happens again." Tr. I 93:20–25. Paolo stated that ring

breakage was not identified as a failure mode in the XL CK Patch until the product had been on the market for three to four years. Tr. I 104:9–20. Paolo also related that, based on a forensic study by his team, it was determined that no clinically relevant testing was done to validate or quantify the two-pound design specification for the PET ring weld that was in place from 2002 to the recall in 2005. Tr. I 107:14–25, 108:11–14. His team also concluded that the two-pound specification was "insufficient in a clinical setting", *i.e.,* that "it had the potential to fail once implanted in the body and exposed to loads or forces that were other than the axial load or the tensile load that it was tested to." Tr. I 109:2–13.

Paolo's team also investigated the effectiveness of the technique guide and the IFU developed for the XL CK Patch and concluded that the IFU "was not completely effective" and "did not adequately warn" physicians about the risks of the ring in the device. Tr. I 115:4–116:12. The team's summary report, issued in July 2006, [24] states that "deficiencies in the pre-recall Composix Kugel IFU related to limited warnings concerning user cutting of the ring (subject to other failure investigation analysis/ reports) and/or proper folding techniques could have been a contributory root cause of reported broken ring failures, in some cases due to the ring welds unable to withstand the stresses induced by folding the product across the weld." Pltfs.' Ex. 375–003. Similarly, in a remedial action plan ("RAP") regarding the XL CK Patch, which was submitted to the FDA, Davol reported that "[t]he IFU contained insufficient guidance to preclude inappropriate manipulation and surgical insertion of the XL Composix Kugel" and "[t]he product design specification of the welded recoil rings did not take into consideration the potential stresses incurred in the folding and insertion techniques required to implant the X–Large Composix codes which may cause the recoil ring to break." Pltfs.'s Ex. 341–007.

24 Davol points out that Paolo "had nothing to do with the CK Patch until after the first voluntary recall" and that plaintiffs relied on documents which, at times, "reflect[ ] the opinions of Davol's employees—formed years later—on steps they wanted to take to improve their product." To the extent that plaintiffs sought to establish the implementation of changes to the XL CK Patch after Thorpe's Patch was implanted, Davol's objections were sustained. *See,* e.g. Tr. I 109:18–110:20. However, to the extent Davol's own investigation looked back to the period prior to Thorpe's implantation to establish the steps taken in the design process and form conclusions regarding the adequacy of the design process, such evidence was admitted.

***28** Testimony by James Keegan, Marketing Director for Davol, established that Davol notified its sales force in December 2005 that XL CK Patches were recalled because it was determined that "the strength of the memory recoil ring may not withstand aggressive manipulation that may sometimes be applied during the placement of these extra-large sizes." Tr. III 53:14–21, Aug. 5, 2010, Pltfs.' Ex. 322–001. At the same time, Davol advised its sales force that, if customers called in to request XL CK patches, they were to be advised that the product was currently not available and that "Customer Service is offering the equivalent sizes of Composix EX as an alternative." Tr. III 54:12–20, Pltfs.' Ex. 322–001.

Similar testimony was offered by Daniel LaFever ("LaFever"), former president of Davol. According to LaFever, in what he described as the "ah-ha" moment on November 28, 2005, the Davol management team realized, for the first time, that "stresses to put the device in may cause ring breaks." Tr. IV 26:2–5, Aug. 6, 2010. LaFever explained that on that day, the Davol team received a returned product that, according to LaFever, had been folded across the short axis by the implanting surgeon and "upon that folding and creasing, the ring weld cracked." Tr. IV 27:14–24. LaFever acknowledged that, of the 25 reported ring breaks, this was the only report that was documented as an example of a ring breaking on the short axis. Tr. IV 28:24–29:8. LaFever also agreed that Davol advised its customers that the large Composix E/X was available as an alternative product while the XL CK Patches were off the market. Tr. VI 51:23–53:5. According to LaFever, Davol's product failure investigation team formed after the recall of the XL CK Patch found that Davol "had not uncovered all potential uses for the product and that part of [Davol's] design failure and effects analysis was in need of some fortification." Tr. IV 60:6–12. LaFever was not aware, however, that the team also discovered that "Davol did not include as a product failure mode in the DFMEA ring breaks until December of 2005." Tr. IV 62:8–18. As

a result of observations by the FDA following the recall, Davol hired Quintiles, an outside consulting company to perform an audit of Davol's quality control system. Tr. IV 66:2–67:18. Quintiles concluded that, before the recall, there were deficiencies in Davol's quality control system and that investigations into complaints were inadequate. Tr. IV 67:24–69:10.

Roger Darois ("Darois"), Davol's current Vice President of Research and Advanced Technologies, testified that animal testing was done on the Composix patch to measure the effectiveness of the ePTFE to prevent adhesion between the polypropylene mesh and bowel tissue. Tr. IX 47:13–48:2. With respect to the XL CK Patch, Darois explained that Davol determined that no 510k clearing process by the FDA was required, as set forth in Davol's "No 510k Rationale" from January 21, 2002. Defs.' Ex. 1015. The document described proposed modifications including adding a second PET ring, adding placement pockets, melting both layers of polypropylene mesh to the ePTFE layer, and decreasing the width of the material band extending beyond the finished edge of the device. Defs.' Ex. 1015–0002. Davol concluded that no 510k submission was necessary because "the proposed modifications to the Bard Composix Kugel products described in this document can be considered insignificant modifications to the regulatory baseline device that do not affect the safety or efficacy of the proposed product." Defs.' 1015–0004.

***29** Darois related that, at the time Davol acquired the Kugel line from Surgical Sense, no ring breaks had been reported in the three years the product had been on the market. Tr. IX 57:19–58:16. As Surgical Sense had no specification for ring weld strength, Davol established a two pound weld strength based on testing "how much force would be put on this ring during this deployment—this deployment process." Tr. IX 63:8–65:6. Once Davol developed the extra large size CK patch, the ring weld strength specification remained at two pounds because, according to Darois, "at the time we felt as though the insertion technique of pushing the patch through a defect with either fingers or instruments would be the same technique that was used in the past." Tr. IX 88:11–23.

Darois also recalled that a ring weld broke in 2000, prior to Davol's marketing of the smaller and extra large sizes of the CK Patch. Tr. IX 208:17–209:1. He acknowledged that Davol's failure investigation team, which he headed, found that the two pound weld strength design specification used for regular and smaller size CK Patches was not challenged for the development of the XL CK Patch. Tr. IX 217:18–22. The team's summary report stated that "[t]here was no testing conducted and documented to justify that the 2 lb tensile break strength for the PET recoil ring for Kugel products was clinically relevant." Pltfs.' Ex. 592–001, Tr. IX 238:12–24. According to e-mail communications between team members discussing possible responses to an FDA inquiry, "this low ring spec that was determined to be sufficient for the Kugel inguinal application was not sufficient as the sizes grew and more demands were placed on the product in ventral procedures with the release of the Composix products (bending and folding of the ring)." Pltfs. Ex. 671–001.

Darois also acknowledged the findings of the failure investigation team in review of Davol's design control system of the XL CK Patch, which included, inter alia, that "there was insufficient supporting evidence in the creation of the two-pound weld strength specification;" "there were no test results showing that the two-pound specification met user needs;" "and "there was no challenge to the weld strength specification and whether it was still sufficient in larger sizes." Tr. XI 34:11–37–25, Aug. 18, 2010. Pltfs.' Ex. 334.

[21] In sum, the evidence offered by the plaintiffs established that Davol designed the XL CK Patch with two PET recoil rings that were larger than those in patches previously marketed, without assessing whether the 2 pound weld specification was adequate for the new product or whether the specification used in the smaller sized CK Patches had a reasonable basis. It performed no in vitro or in vivo testing on the XL CK Patch, and its clinical testing was limited to three patients before the product was marketed. Davol's own failure response team concluded that the two pound weld strength was insufficient; that the IFU was not effective in providing guidance to preclude inappropriate manipulation of the patch; and that Davol's design validation process was inadequate. As such, when viewed against the background of what Dr. Ducheyne described as the critical components of a good design process, the

evidence offered by the plaintiffs was sufficient, under the established Rule 50 standard, to lead a reasonable jury to find that Davol acted unreasonably in designing the XL CK Patch and failed to adopt a safer alternative design that would have prevented or substantially reduced the risk of harm.

***30** With respect to expert medical opinion that Thorpe's injury was caused by the defective XL CK Patch, Dr. Ferzoco offered a detailed opinion that the ring was involved in the fistula formation and that the ring had broken and allowed the mesh to fold, leading to contact between the polypropylene side of the mesh and Thorpe's bowel. *See,* e.g., Tr. VIII 81:17–82:4, 83:21–84:4, 93:20–24. Dr. Ferzoco also opined that, based on the operative report and testimony by Dr. Parish and Thorpe's medical record, and in light of the two year period between implantation of the XL CK Patch and onset of pain, that the patch had been originally placed flat into Thorpe's abdominal area and implanted correctly. Tr. VIII 65:6–66:23.

The jury also heard testimony by Dr. Sindram as given at his deposition. Dr. Sindram, who explained that he wrote the operative note, which contained not opinions, but assessments of Thorpe's status and descriptions of the facts, stated, inter alia, that the patch was folded over and the bowel adhered to the rough portion of the mesh. Dr. Sindram's surgical note stated that Thorpe's fistula was on the patient's left side. [25] A ring that was keeping the border of the mesh extended was noted missing from the right lateral side of the mesh. The ring was found to be sticking out on the right side into the subcutaneous tissue. However, the surgical note did not describe where the rest of the ring was. Pictures Dr. Sindram took with his cell phone after the surgery showed a portion of the ring attached to the mesh. Dr. Sindram also recollected that he pulled one end of the ring out with a clamp and noticed that the other end was bile stained. He then remarked to Dr. Lagoo that the ring had to be close to the fistula in order to be bile stained. He further explained that a small bowel enterocutaneous fistula was expected to contain bile. He concluded that the portion of the ring he extracted was not a complete ring, since it was not large enough for the circumference of the mesh; however, it was not clear where the ring originated from, since the mesh and tissue around it had not yet been dissected out.

25 Dr. Sindram noted that he "had a hard time recalling which side of the patient [he] exactly was standing on," but explained that left and right referred to the left or right side of the patient.

Dr. Lagoo, who performed the explantation of Thorpe's patch, also concluded that the bile stained portion of the ring pulled from Thorpe's subcutaneous tissues had come into contact with the bowel. Dr. Lagoo stated that the accessible portion of the ring was sticking into Thorpe's subcutaneous tissue under the skin but above the fascia, but she could not determine where the other side of the ring was located. She explained that she just removed the entire patch without examining it. Dr. Lagoo did not cut the ring, but grasped and pulled a long portion of it from the mesh, noticing that the distal end of the ring was bile stained. According to Dr. Lagoo, the only ring portion she observed was located on the right side of the patient. The mesh itself had lost its normal alignment and folded upon itself exposing the rough Marlex side to the bowel and causing the enterocutaneous fistula. Dr. Lagoo also stated that, while it was possible for an abscess to develop two years after implantation, it was usually seen soon after surgery.

***31** **[22]** It is clear that the parties' experts in this case disagree on how Thorpe came to be injured after being implanted with the XL CK Patch. Plaintiffs' medical expert Dr. Ferzoco concluded that the PET recoil ring broke, caused a perforation of the bowel, and initiated the forming of a fistula. Defendants' expert Dr. Iannitti expressed his belief that Thorpe's patch was inserted into the abdomen in a folded position and fixed in place folded. This is a close case and both parties offered some evidentiary support for their respective positions at trial. However, the Court's role in ruling on a Rule 50 motion is limited to considering the evidence, together with all reasonable inferences therefrom, in the light most favorable to the nonmovant. The motion is to be granted only when the record has no sufficient evidentiary basis for the verdict and when it could have led a reasonable jury to only one conclusion, favorable to the movant. Based on Dr. Ferzoco's medical expert opinion and the facts presented by Dr. Lagoo and Dr. Sindram, the Court is of

the opinion that a reasonable jury could have concluded that a negligently designed XL CK Patch was the cause of Thorpe's injury. Therefore, the defendants' motion for judgment as a matter of law with respect to the inadequate design claim is denied.

3. Inadequate Warning or Instruction

Pursuant to North Carolina general products liability statute N.C. Gen.Stat. § 99B–5, a plaintiff alleging inadequate warning or instruction must prove that (1) the manufacturer or seller acted unreasonably in failing to provide such warning or instruction; (2) the failure to provide adequate warning or instruction was a proximate cause of the harm for which damages are sought; and (3)(a) the product, without an adequate warning or instruction, created an unreasonably dangerous condition that the manufacturer or seller knew or should have known, posed a substantial risk of harm to a reasonably foreseeable claimant; or (b) the manufacturer or seller became aware of the risk and failed to take reasonable steps to give adequate warning or instruction or to take reasonable action under the circumstances. N.C. Gen.Stat. § 99B–5(a).

[23] **[24]** Pursuant to North Carolina law, a manufacturer must "provide warnings of any dangers associated with the product's use 'sufficiently intelligible and prominent to reach and protect all those who may reasonably be expected to come into contact with [the product].' " *Nicholson v. American Safety Utility Corp.,* 124 N.C.App. 59, 65, 476 S.E.2d 672, 676 (1996). A plaintiff's failure to provide evidence that lack of adequate warning or instruction was the proximate cause of his injury is fatal to his claim. *Evans v. Evans,* 153 N.C.App. 54, 59 569 S.E. 303, 306–307 (2002).

[25] Davol seeks judgment as a matter of law on the plaintiffs' claim for inadequate warning on the grounds that the plaintiffs failed to establish that the IFU packed with Thorpe's XL CK Patch was inadequate; no expert testimony was provided with respect to causation; and no evidence was submitted that Thorpe's surgeon Dr. Parish would have proceeded differently, had he been given additional or different information. In response, the plaintiffs rely primarily on statements by Davol's own employees that the IFU was deemed inadequate or insufficient to instruct surgeons how *not* to implant a XL CK Patch; that the IFU did not specifically warn of ring weld breaks; and that Davol failed to take reasonable steps to warn or instruct after it learned of ring break incidents.

***32** A thorough review of the trial testimony and admitted exhibits reveals that evidence regarding the IFU in question is limited to the following:

It is undisputed that the pre-recall IFU contained no warnings against folding the XL CK Patch across the short axis, nor did it state that folding or creasing the patch could result in a break in the ring weld. Joint Ex. 2. Nevertheless, Davol's own medical expert Dr. Iannitti stated that, in terms of describing the potential or possible complications of surgery, the IFU "seemed adequate." Tr. X 104:25–105:12, Aug. 17, 2010.

Dr. Parish testified that he saw the IFU before he implanted Thorpe's mesh. Tr. II 61:3–14. According to Dr. Parish, some of the warnings had no application to the surgery on Thorpe, but he complied with specific warnings to orient the patch properly, to ensure sufficient overlap, and not to suture or tack the sealed edge of the mesh. Tr. II 63:4–64:2, 64:16–19, 65:4–9. Dr. Parish also stated that he was aware of "essentially all the information" in the IFU and he agreed that "based on what [he] knew from [his] clinical experience and so forth, that [he] felt that [he was] provided enough information about how to use the Composix Kugel patch in Mr. Thorpe, including how to place it and how to fixate it." Tr. II 174:18–175:7.

James C. Keegan of Davol's Product Assessment Team acknowledged that the IFU was the primary source of information for doctors to use the product. Tr. III 40:18–24. The IFU for Thorpe's patch did not warn against folding on the short axis, nor did it state that certain folding and insertion techniques could cause ring welds to break. Tr. III 40:8–17, 58:11–59:4. According to LaFever, production of the XL CK Patch was halted in August of 2005 because Davol was contemplating a change in the IFU after receiving a number of ring break reports from Germany. However, Davol did not stop selling the XL CK Patch at that time because its failure investigation was still incomplete. Tr. IX 38:20–39:1, 92:17–24.

In December 2005, Davol received a returned patch that was creased and bent at the weld. According to Darois, at that time, he realized that the product had to be recalled and that the current instructions would have to be changed because they were not effective in preventing an implanting surgeon from creasing the weld. Tr. IX 161:1–165:4. In its 2006 post-recall investigation, Davol concluded that, although the pre-recall IFU warned against cutting or reshaping the patch, "as this could affect its effectiveness," the IFU did not warn of specific consequences of such action, nor did it provide warnings against folding the mesh, rendering it "not effective to minimize or prevent a ring weld break." Pltfs.' Ex. 375–002. Eventually, the IFU was revised to include a warning to follow the proper folding techniques for large-sized patches, together with an illustrative drawing. Tr. IX 184:13–185:1.

Based on this record, it appears that, even under the generous standard set by Rule 50, plaintiffs' claim of inadequate warning or instructions falls short with respect to proximate causation. It is true that, in its post-recall product failure investigation, Davol deemed the pre-recall IFU inadequate. Plaintiffs also established that Davol began to suspect as early as August 2005 that reported ring breaks in Germany could be attributed to forceful handling and that it contemplated a change in the IFU to prevent such incidents. However, even assuming that Davol knew or should have known that XL CK Patches were susceptible to ring breakage when the patches were first marketed, the plaintiffs fail to connect the inadequacy of the IFU to Thorpe's eventual injury. Likewise, even if Davol continued to market its product with an IFU that it knew, or reasonably should have known, was inadequate, the plaintiffs must still prove that such inadequacy was the proximate cause of Thorpe's injury. There is nothing to indicate, and plaintiffs offered no evidence, that an IFU specifically warning against folding the patch in a particular manner in order to prevent the risk of ring breaks would have prevented Thorpe's injury. Dr. Parish, who was aware of the potential risks of hernia surgery, followed those instructions in the IFU he deemed applicable in Thorpe's case. By his own account, Dr. Parish made an incision large enough to create a pocket into which he could fit his entire hand. He then inserted the patch, made sure it was lying flat, put his finger into the placement pockets and pushed it out to straighten the edges before tacking it against the abdominal wall. Nothing in his account indicates that he handled the patch in a manner that Davol failed to warn against. Any suggestion that Dr. Parish would not have chosen the XL CK Patch to repair Thorpe's hernia, had the IFU contained additional or different instructions on how to fold the patch to avoid ring breakage is entirely speculative. Because the evidence, even when viewed in the light most favorable to the plaintiffs, is insufficient to support a claim for inadequate warning, the defendants' motion for judgment as a matter of law on this claim is granted.

4. Claim for Loss of Consortium

***33** Because Davol's motion for judgment as a matter of law is denied with respect to at least one of Thorpe's substantive claims, Laure Thorpe's claim for loss of consortium, which is derivative of her husband's claims, stands. Therefore, Davol's motion for judgment as a matter of law is denied with respect to the loss of consortium claim.

B. Motion for New Trial

In support of their motion for a new trial, Davol asserts that (1) the plaintiffs failed to support their claims of inadequate design and inadequate warning; (2) the jury's verdict was the result of the prejudicial introduction of the "scar contracture" causation theory; and (3) Dr. Parish used the XL CK Patch contrary to instructions, which provided a complete defense to the plaintiffs' claims. In response, the plaintiffs assert, inter alia, that testimony offered by Davol's expert witnesses regarding improper implantation of the patch by Dr. Parish was not unrebutted; and that, under North Carolina law, contributory negligence by Dr. Parish, if proved, does not provide a complete defense against plaintiffs' claim.

Davol's arguments regarding the introduction of expert testimony by Dr. Ferzoco and Dr. Ducheyne, as well as its arguments regarding the plaintiffs' claims for inadequate design and inadequate warning have been thoroughly discussed in this memorandum and will not be repeated. What remains is Davol's argument that Dr. Parish, either by implanting Thorpe's patch incorrectly or by modifying the patch in a subsequent debridement procedure, in

contravention of the IFU, contributed to, or caused, Thorpe's injury. The jury was instructed to consider whether Davol had proved, by the greater weight of the evidence, that Dr. Parish used the patch contrary to adequate instructions, thus causing injury to Thorpe as a result.

In support of its defense theory, Davol offered, inter alia, testimony by Dr. Iannitti, a general surgeon with considerable experience in hernia surgeries. Dr. Iannitti expressed his opinion that the patch "was folded upon insertion into the abdomen" by Dr. Parish. Tr. X 137:9–138:2. Dr. Iannitti based this opinion on statements by Dr. Lagoo and Dr. Sindram that "they found the graft folded under like that" upon explantation, certain CT scans taken prior to explantation, the cell phone photographs by Dr. Sindram, and the placement of tacks on the explanted graft. Tr. X 139:17–144:3. Dr. Iannitti agreed, however, that there was nothing in Dr. Parish's surgery note to suggest that the patch was inserted incorrectly and that he could not state whether adhesions may have caused the graft to fold. Tr. X 224:11–229:4. He also agreed that Dr. Parish's technique in implanting the patch was "reasonable." Tr. XII 150:21–25, Aug. 19, 2010. Dr. Iannitti acknowledged that, when he examined the explanted patch, it had been stored in formalin for approximately a year and a half, that it had shrunken in size, and that he did not know whether any folds in the patch were caused by transportation. Tr. XII 118:6–18, 121:20–24.

***34** With respect to the debridement procedure which Dr. Parish performed after Thorpe developed an abdominal abscess, Dr. Iannitti agreed that the ring on the explanted patch was not "sharply transected" or cut by a scissor or scalpel, but suggested that it may have been "ripped and broken." Tr. XII 124:2–11.

In addition, Davol offered expert testimony by Dr. Maureen Reitman, Sc.D ("Dr.Reitman"), a scientific consultant specializing in polymeric materials. Dr. Reitman concluded that "the damage to the rings, the damage to the patch is the result of tight bending that occurred, so the position that the patch was held in while in the body [sic]. So the very tight bending is an extreme mechanical force, a mechanical deformation ... And it was as a result of being in that condition that there was damage to the filament in a number of locations and breaking of the weld." Tr. XI 132:2–12. When questioned about what caused the fold observed in Thorpe's patch after explantation, Dr. Reitman explained that "the physical signs of the evidence are that the folding, that it was tucked under while it was in the body, in the tissue." Tr. XI 147:14–24. With respect to the rings in Thorpe's patch, Dr. Reitman concluded that the outer ring was cut in three locations during explantation. Tr. XI 177:10–12. Dr. Reitman also stated that portions of the outer ring she examined after explantation showed "excessive mechanical damage" as result of twisting and bending in the body and that the break in the weld was also the result of those bending forces. Tr. XI 186:16–21, 188:11–23. According to Dr. Reitman, the cause of the damage was "tight bending and the forces that are the result of that bending associated with other mechanical forces externally applied, meaning associated with surgical processes and debridement." Tr. XI 192:4–12. She also agreed that "the inner ring had a separated weld as well as a fractured ring section." Tr. XII 55:24–56:1. With respect to the medical or surgical aspect of the folded patch, Dr. Reitman referred to Dr. Iannitti's opinion. Tr. XII 104:19–23.

Against the opinion of Dr. Iannitti, that the patch had been folded and incorrectly affixed by Dr. Parish, and the opinion of Dr. Reitman, that at least one ring had sustained a weld break because the patch had been in a folded position in the body, the plaintiffs offered testimony to the contrary. Dr. Parish described, in great detail, how he performed the implantation of the XL CK Patch. He understood that the patch was to be kept flat in order to repair the defect and to keep the polypropylene away from the bowel; during the surgery, he put his finger in the placement pocket and pushed out to straighten it. During the subsequent debridement procedure, Dr. Parish cut off a small portion of the patch that had not grown into Thorpe's tissue and had become infected. According to Dr. Parish, he was certain he did not cut the rings during the debridement because "the ring is very heavy and it would be very obvious if you cut it with a pair of scissors because it's not that easy to cut." Tr. II 89:6–10.

***35** Dr. Parish's testimony was supported by the expert opinion of Dr. Ferzoco who concluded, based on the operative report, Dr. Parish's testimony, and Thorpe's

medical record, that the XL CK Patch was placed flat inside Thorpe's abdomen at implantation. It is also undisputed that Thorpe's initial hernia repair surgery involved a large incision, which would have made folding of the patch unnecessary. Thorpe's medical record reveals that, following the November 2005 hernia repair, he did not develop an abdominal abscess in the location of the hernia mesh until October 2007. Regarding the timing aspect, Dr. Lagoo stated that, although it was possible, it was uncommon to see an abscess develop two years after implantation and that usually, it would be seen soon after surgery. Testimony by Dr. Lagoo and Dr. Sindram also established that the patch was cut during the explantation and that portions of the ring were cut and/or pulled out with surgical instruments.

[26] In sum, while some of the evidence supported a finding that the implanted XL CK Patch sustained a fold inside Thorpe's abdomen, neither of defendants' witnesses could establish, conclusively, when such folding may have occurred and why. Consequently, the jury concluded, and the Court, after its own thorough review and consideration of the evidence, agrees, that it was not established that Dr. Parish implanted the XL CK Patch incorrectly or that his actions during the debridement caused Thorpe's eventual injury.

Based on that determination, and after a consideration of the entire trial record, this Court is of the opinion that the jury's verdict was not "so clearly against the weight of the evidence as to amount to a manifest miscarriage of justice." *Rivera Castillo v. Autokirey, Inc.,* 379 F.3d at 13, and that Davol's alternative motion for a new trial must be denied.

Conclusion

For the reasons set forth above, Davol's motion for judgment as a matter of law is DENIED with respect to (1) Davol's request to strike testimony by Dr. Ferzoco and Dr. Ducheyne, (2) the plaintiffs' claim for inadequate design, and (3) Laure Thorpe's claim for loss of consortium. Davol's motion is GRANTED with respect to the plaintiffs' claim for inadequate warning. Davol's motion for a new trial pursuant to Federal Rule 59 of the Federal Rules of Civil Procedure is DENIED. In the event an appeal is taken from this decision and the granting of the motion for judgment as a matter of law with respect to the plaintiffs' inadequate warning claim is overturned, Davol's motion for a new trial is conditionally DENIED.

SO ORDERED.

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