Richard H. Friedman (CA Bar No. 221622)
rfriedman@friedmanrubin.com
Peter J. Mullenix (admitted pro hac vice)
pmullenix@friedmanrubin.com
Friedman | Rubin
51 University Street, Suite 201
Seattle, WA 98101
Tel: 206-501-4446
Fax: 206-623-0794

John Graham Hill (admitted pro hac vice)
ghill2013@gmail.com
2323 S. Shepherd Drive, 14th Floor
Houston TX 77019
Tel: 713-979-4695

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
AT SAN FRANCISCO

RICHARD POHLY,

Plaintiff,

v.

INTUITIVE SURGICAL, INC., a Delaware corporation headquartered in California,

Defendant.

No. 3:15-cv-04113 MEJ

MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT OF PLAINTIFF'S MOTION FOR PARTIAL SUMMARY JUDGMENT

Hearing Date: January 19, 2017
Time: 10:00 a.m.

REDACTED

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Plaintiff Richard Pohly submits the following memorandum in support of his Motion for Partial Summary Judgment.

I. Relief Requested

Plaintiff Richard Pohly respectfully asks this Court to order, pursuant to Fed. R. Civ. P. 56, that (1) any electrified scissors made by defendant Intuitive Surgical, Inc. ("ISI") that were sold with "microcracks" in their main tube were defective under either California or Texas law, (2) ISI's Fifth ("misuse"), Seventh ("intervening or superseding conduct"), Ninth ("wrongful conduct of third parties"), and Fifteenth (failure to mitigate) affirmative defenses are stricken, as there is no evidence that anyone other than ISI is at fault for Mr. Pohly's injuries, and (3) ISI's Eleventh Defense (statutes of limitations) is stricken, as the parties entered into a tolling agreement that did not expire before Plaintiff filed this suit.

II. Succinct Statement of Relevant Facts

A. Overview of Issues in this Motion

From 2009 to 2013, Intuitive Surgical, Inc. admits it was missing a "critical design parameter"[1] in the manufacturing process for its most popular electrosurgical instrument: electrified scissors called "MCS" (Monopolar Curved Scissors) or "Hot Shears." The missing parameter – Redacted Redacted – led a subset of these instruments to have "microcracks" so small that they could not be seen by the doctors who used them. ISI admits that these microcracks create "a potential for insulation failure, resulting in a pathway for electrosurgical energy to leak to tissue and potentially cause unintended burns" during surgery.[2] Worse, "the micro-cracks may be outside the view of the surgeon during a procedure,"[3] meaning the burns "might not manifest in detectable symptoms until days after surgery."[4]

The plaintiff in this case, Richard Pohly, alleges he suffered a delayed thermal injury to his rectum during a prostatectomy surgery at the University of Texas Southwestern Medical

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[1] Exhibit 19 to Mullenix Declaration at 74036.
[2] Exhibit 19 to Mullenix Declaration at 74032.
[3] Exhibit 27 to Mullenix Declaration at 65684.

Center in July 2012. His surgeon used a model of MCS that was subject to the flawed manufacturing process and has opined that "microcracks" are the best explanation for Mr. Pohly's rectal injury. ISI disputes this and supports its dispute with expert testimony, and Plaintiff concedes the question of specific causation of Mr. Pohly's injury is one for a jury.

What is ripe for summary ruling, however, is the more general question of whether scissors with microcracks are defective within the meaning of either California or Texas product liability law. As explained below, there is no material difference in either state's law on this question; both make manufacturer's liable for products that differ from the manufacturer's specifications in a way that matters to patient safety.[5]

ISI admits that microcracked scissors failed its specifications. In its witness disclosures in a related case,[6] ISI designated one of its clinical engineer employees to "testify regarding the … product requirements, [and] specifications" for the relevant versions of the MCS.[7] In her deposition, that witness confirmed that scissors with microscopic insulation failures "would not meet specifications"[8] and that "one of the requirements and specifications" of the scissors "is not

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[4] Exhibit 27 to Mullenix Declaration at 65682.

[5] *Compare* CACI 1201, CACI 1202, with *Ford Motor Co. v. Ridgway*, 135 S.W.3d 598, 600 (Tex. 2004), as set out in the Argument and Authority section below.

[6] Plaintiff's counsel also represents two women who allege they were injured by the same defect (microcracked MCS scissors) as Mr. Pohly. Those women, Larice Roop and Sarah Bosshart, suffered injuries to their ureters as a result of the insulation failures during "da Vinci" hysterectomies in July 2012 and October 2012 in Washington state. The *Roop/Bosshart* case is currently pending in state court in King County, Washington. In that case, the hospital that purchased the scissors used in the hysterectomies has brought cross-claims against Intuitive for breaching the Washington Consumer Protection Act by selling the hospital defective scissors. All three injured plaintiffs, the Washington hospital, and Intuitive Surgical have agreed that the two cases (*Roop/Bosshart* and *Pohly*) are related. All parties are coordinating discovery on liability issues between the two cases. *See* e.g., Exhibit 50 to Mullenix Declaration (email confirming Roop-Bosshart litigation is "collateral" for purposes of sharing documents under the protective order in this case).

[7] Exhibit 36 to Mullenix Declaration.

[8] Exhibit 54 to Mullenix Declaration (Nixon Deposition) at 121:14-19 ("Q. … [Y]ou agree your electrosurgical instruments should not have microscopic insulation failures? In other words, that's not acceptable to Intuitive? A. That would not meet the specifications as I understand them.").

to have micro-cracks[.]"[9] Thus, when scissors with microcracks left ISI's control, they deviated from ISI's specifications.

There can be no doubt this deviation was one that mattered to safety. The engineer who discovered the source of the cracks says resolving the microcrack problem was an "all hands on deck" situation for ISI.[10] It even hired new security so it could have its engineers working on the problem 24 hours a day.[11] ISI did this because of the potential severity of the injuries:

> Q. Why was it important to resolve the microcrack issue?
> A. Well, we recognize that cautery energy has the potential of, you know, getting out through that crack. It doesn't always happen. As I mentioned before, some of the cracks aren't all the way through. It also depends on clinical setting, if there is tissue in the area of the crack, etc., but we recognize the potential severity of the issue and wanted to resolve it quickly.

ISI even decided to stop shipping *all* of its MCS once it learned of the microcracks in *some* of its MCS.[12] It undertook a Class II[13] recall of all MCS in May 2013.[14] No reasonable trier of fact could find the microcracks immaterial under these circumstances, and the Court should rule on that issue as a matter of law.

Certain other issues are also now amenable to a dispositive ruling. First, as described in more detail below, there is no evidence that any non-party is at fault for the injuries suffered by Mr. Pohly. Likewise, there is no evidence he failed to mitigate his damages. Those issues should be removed from this case. Finally, there is no evidence the statute of limitations bars this claim. The parties entered into a tolling agreement that did not expire before the filing of this suit.

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[9] Exhibit 54 to Mullenix Declaration (Nixon Deposition) at 95:14-17.
[10] Exhibit 55 to Mullenix Declaration (Orban Deposition) at 56:7-19.
[11] Exhibit 55 to Mullenix Declaration (Orban Deposition) at 57:9-21.
[12] Exhibit 13 to Mullenix Declaration.
[13] *See* http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm049070.htm#RecallClassifications (accessed 12/7/16) (Class II recalls concern products "that might cause a temporary health problem, or pose only a slight threat of a serious nature.").
[14] Exhibit 38 to Mullenix Declaration.

B. Overview of MCS Instrument and Microcrack Recall.[15]

Defendant ISI makes reusable surgical instruments used during robotic surgery, and it also makes the "da Vinci" robot that wields those instruments. This case concerns the instruments, not the robot. The instruments are attachable to the robot, which is then remotely operated by a surgeon at a console from across the room. The instruments, after being attached to the robot, are inserted through small incisions in the body so that the surgeries can be performed laparoscopically. The surgeon can see the instruments inside the body because an endoscope is also attached to the robot and inserted through an incision.

Some of the instruments that ISI makes for attachment to its robot are electrified. One of those instruments is ISI's "monopolar curved scissors," or "Hot Shears," which is a pair of miniature scissors that can both cut and cauterize tissue inside the body. The Hot Shears relevant to this case were made by ISI in 2009 and 2010 and look like this:[16]

When using this instrument, the surgeon can press a foot pedal and make electrical current come from the scissor tips. Because the Hot Shears are electrified, they have various forms of insulation. One form, the "Tip Cover Accessory," covers the metal "wrist" of the instrument. The other form covers the "shaft" or "main tube" of the instrument. This case concerns the shaft.

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[15] Plaintiff believes that, except where noted, none of the assertions in this overview section are in dispute. For that reason, Plaintiff does not generally provide specific exhibits to support statements in this section.

Mr. Pohly had a prostatectomy surgery in July 2012. No complication was recognized at the time of surgery, but his bowel was found to be perforated by the second postoperative day. This led to horrible infections and other complications, and he spent over 200 days in the hospital. His surgeon could not explain why the perforation happened at the time.

Then, in May 2013, after it was too late for Mr. Pohly, ISI disclosed a defect in its Hot Shears in an "Urgent" notification:[17]

Urgent Medical Device Notification – 2955842-05-07-2013-005
Intuitive Surgical *EndoWrist*® Instrument Hot Shears™ Monopolar Curved Scissors

This Notification, later changed to a "Recall,"[18] made clear that the version of the Hot Shears that had been used in the Pohly surgery had "a potential issue" in that those instruments "may develop micro-cracks near the distal (scissor) end of the shaft following reprocessing." The location of the instrument where the cracks would occur was an area that would likely be *outside* the view of surgeons during the surgery, which ISI marked with the following red box:

According to the notice: "**These micro-cracks may <u>not</u> be visible to the [surgeon].**" And according to the notice, the issue is significant because: "This may create a pathway for electrosurgical energy to leak to tissue during use and potentially cause thermal injury."

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[16] *See* Exhibit 47 to Mullenix Declaration (ISI-R&B 00000749).
[17] Exhibit 2 to Mullenix Declaration (ISI-R&B 00000933-936).
[18] *See* Exhibit 25 to Mullenix Declaration.

ISI's internal documents make clear that ISI considers cracked scissors to be defective. In its root cause analysis, it described the cracks as a "[Redacted.]"[19] ISI's ultimate explanation for how the defect happened was that "[Redacted] [20] According to ISI: '[Redacted]]"[21]

C. ISI's history of insulation problems with MCS instruments.

ISI long had insulation problems with its scissors. For instance, a study published in 2011 by the *American Journal of Obstetrics and Gynecology* found that ISI's instruments failed at a rate higher than other manufacturers' laparoscopic instruments.[22] That paper specifically identified insulation failures in a 54 percent of a prior version of the MCS, and even identified the area where the later microcracks were later found as "the most common location" of failure.[23]

The insulation problems were so significant that, after arcing had been reported by eight doctors from the shaft of that earlier version of the scissors,[24] ISI's Senior Vice President of Product Operations considered "100% testing of all cautery instruments … before shipping."[25] ISI believed such testing had "shown to be an effective and non-destructive method to detect if any maintubes have been damaged."[26] But for reasons not yet explained: the testing "never happened."[27] Thus, at all relevant times, ISI's only method of inspecting main tube insulation for defects was '[Redacted].]"[28]

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[19] Exhibit 19 to Mullenix Declaration at 74036.
[20] Exhibit 19 to Mullenix Declaration at 74036.
[21] Exhibit 19 to Mullenix Declaration at 74036.
[22] Exhibit 29 to Mullenix Declaration at 68637-68641.
[23] Exhibit 29 to Mullenix Declaration at 68641 (Insulation failures "were detected in 54% of monopolar scissors, the most common location being on the metal ring near the tip of the instrument.")
[24] Exhibit 31 to Mullenix Declaration at 82151 ("eight MCS RMA instrument (400179 and 420179) returns have involved arcing through the main tube").
[25] Exhibit 29 to Mullenix Declaration at 68634.
[26] Exhibit 31 to Mullenix Declaration at 82154.
[27] Exhibit 29 to Mullenix Declaration at 68634.
[28] Exhibit 19 to Mullenix Declaration at 74037.

Rather than increasing testing and inspection, ISI proposed to address its insulation problems by, in 2009, changing the *material* that formed the main tube. Specifically, ISI changed from a "Redacted" to Redacted[29] To make this change, ISI contracted with an outside firm, Redacted Redacted

ISI now concedes that neither it, Redacted Redacted Redacted[32] An expert ISI has retained for this litigation admits that this information was easily discoverable: "there is awareness within the composites industry that machining composites can initiate local damage such as micro-cracking due to the hard fibers wearing on the tools[.]"[33] It is for this reason that Plaintiffs' retained materials expert opines that "ISI acted recklessly in not controlling the manufacturing process or having a materials scientist involved with the project who understood how to use Redacted composites."[34] He explains that a simple Google search, or retention of a materials expert by ISI, would have disclosed these issues.[35] No such efforts were taken.

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[29] Exhibit 32 to Mullenix Declaration at 4. Exhibit 48 to Mullenix Declaration at 1 ("the incoming quality control inspection (IQC) reports from Easton for the epoxy tube revealed that the composition of the tube was S2 glass fibers with an epoxy resin"). *See also* Exhibit 1 to Mullenix Declaration at 43892 (Change History Summary for 420179).

[30] Exhibit 32 to Mullenix Declaration at 11.

[31] Exhibit 32 to Mullenix Declaration at 4.

[32] Exhibit 19 to Mullenix Declaration at 74036.

[33] Exhibit 32 to Mullenix Declaration at 10.

[34] Exhibit 48 to Mullenix Declaration at 2.

[35] Exhibit 48 to Mullenix Declaration at 2. *See also id.* at 4 ("A material science expert would have first done a literature search and found numerous publications, mostly from the aerospace industry, on drilling holes into Redacted composites and the relationship to the fracture toughness (G1c) of the various types of resins (Redacted etc.). They also would have learned about the influence of the fibers (glass, carbon or graphite) on the Redacted and the subsequent composite cracking and failure. Finally, they would have learned about the environmental stresses and fatigue that contribute to the growth of micro cracking to cracks that would cause catastrophic failure.").

Because ISI did not do the research necessary to become aware of the danger of microcracking in the material it selected, and because it did not hire a supplier experienced in making electrosurgical insulation, ISI had no specifications in place for Redacted Redacted [36] The only time the supplier would be required to change the drilling tools was if the tubes being made were so far off that they did not meet the Redacted specifications.[37] Thus, beginning September 2009, ISI started selling scissors with the potential for microcracking[38] even though microcracking was a known danger in the composites industry.

This violated ISI's own policies. Those policies required ISI to "maintain a Quality Management System" in "compliance with … FDA 21 CFR 820[.]"[39] That regulation, which ISI admits it had to follow as an industry standard,[40] sets out requirements for manufacturers who purchase their products from other firms. Relevant here, a manufacturer must "[e]valuate and select potential suppliers, contractors, and consultants on the basis of their ability to meet specified requirements."[41] The manufacturer must also "monitor production processes to ensure that a device conforms to its specifications."[42] This includes a requirement that each manufacturer "shall ensure that all equipment used in the manufacturing process meets specified requirements"[43] and "shall establish and maintain **schedules for the adjustment, cleaning, and other maintenance of equipment** to ensure that manufacturing specifications are met."[44]

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[36] Exhibit 33 to Mullenix Declaration at "pFMEA" tab (noting that "Line item 69 added on 5/13/13). *See also* Exhibit 4 to Mullenix Declartion ("We have defined the Redacted Redacted and Redacted in the drawing. Should these be in the pFMEA? Currently, we do not have hard data that these are from a validated process. Is validation required?). *See also* Exhibit 41 to Mullenix Declaration (setting out specific Supplier Corrective Action Requests).

[37] *See* Exhibit 33 to Mullenix Declaration at "pFMEA" tab (MA-2, MA-3).

[38] Exhibit 19 to Mullenix Declaration at 74033.

[39] Exhibit 34 to Mullenix Declaration.

[40] Exhibit 56 to Mullenix Declaration (Second Reed Deposition) at 84:1-11.

[41] Exhibit 35 to Mullenix Declaration at 8 (§ 820.50(a)(1)).

[42] Exhibit 35 to Mullenix Declaration at 8 (§ 820.70(a)).

[43] Exhibit 35 to Mullenix Declaration at 8 (§ 820.70(g)).

[44] Exhibit 35 to Mullenix Declaration at 8 (§ 820.70(g)(1)) (emphasis added).

ISI has produced no document showing that it established Redacted Redacted Rather, as ISI concedes: 'Redacted Redacted]"[45]

Scissors with microcracks did not meet ISI's specifications.[46] Moreover, based on ISI's design specifications, MCS instruments were required to be able to withstand Redacted Redacted[47] Of the instruments ISI tested in 2013 (after finally identifying the microcrack issue), 25 out of 30 had microcracks after two autoclave cycles.[48]

D. ISI receives complaints of arcing from MCS shafts.

As noted, ISI began selling scissors subject to microcracking in September 2009. Under its policies, even one adverse event could be sufficient to trigger the "PPIR" investigation process related to potential manufacturing defects. ISI's internal documents show that it knew of at least 6 such events before the Pohly surgery in July 2012, but took no corrective or preventative action until April 2013:

- By February 25, 2010, ISI had a report from a doctor of an MCS instrument "arcing near the the metal ring" and causing "superficial burns to the patient bowel."[49]
- By September 2, 2011, ISI had a report of another instrument arcing during surgery and causing a superficial burn to a patient's uterus.[50] The hospital told

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[45] Exhibit 19 to Mullenix Declaration at 74036.
[46] Exhibit 54 to Mullenix Declaration (Nixon Deposition at 121:14-19) ("Q. … [Y]ou agree your electrosurgical instruments should not have microscopic insulation failures? In other words, that's not acceptable to Intuitive? A. That would not meet the specifications as I understand them.").
[47] Exhibit 10 to Mullenix Declaration ("The Instrument … shall be able to withstand a minimum of 5 autoclave cycles more than the released resposable life of the instrument or 20 cycles, whichever is greater."); Exhibit 57 to Mullenix Declaration (Hazebrouck Confidential Deposition) at 86:21-25 ("Q. All right. So an MCS that … was not able to withstand 20 autoclave cycles would fail Intuitive's design specifications? A. During the testing of our product before we put it into market.").
[48] Exhibit 27 to Mullenix Declaration at 65700 (total of cases 1, 3, and 5 is 25/30).
[49] Exhibit 56 to Mullenix Declaration (Reed Second Deposition) at 127:11-14.
[50] Exhibit 56 to Mullenix Declaration (Reed Second Deposition) at 131:25-132:4.

ISI "the issue was related to the MCS instrument."[51] This instrument had microcracks in it, but ISI did not discover that fact until 2013.[52]

- By November 4, 2011, ISI had a report of an MCS arcing during surgery "with burnt shaft … confirmed."[53] The instrument had microcracks, but ISI did not discover that fact until 2013.[54]
- By January 19, 2012, ISI had another report of arcing from the MCS during surgery.[55] ISI's failure analysis at that time "did not find any evidence of arcing,"[56] but the instrument was later found in 2013 to have microcracks.[57]
- By April 19, 2012, ISI had received a report of arcing from an MCS instrument that had caused "a cautery injury on the iliac vein" of the patient.[58] ISI's analysis found no microcracks at that time, but the instrument was confirmed to have microcracks in 2013.[59]
- By June 19, 2012, ISI had received a report that an MCS instrument was "smoking" from the shaft during use, that "the shaft had been hot and defective."[60] ISI confirmed "arcing damage" on the instrument[61] and a "hairline crack" led up to the damaged area.[62] No determination of the root cause of the crack was noted on ISI's investigation report.[63]

During this same time period, the *Journal of Endourology* published an independent study that tested various 9 MCS in January through October 2010. The study found "stray currents detected in all instruments" that had reached the end of their lifecycle.[64] On visual inspection, none of these instruments "demonstrated evidence of cracks or loss of insulator integrity."[65]

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[51] Exhibit 56 to Mullenix Declaration (Reed Second Deposition) at 133:1-4.
[52] Exhibit 56 to Mullenix Declaration (Reed Second Deposition) at 134:4-16 (ending at "Correct.").
[53] Exhibit 56 to Mullenix Declaration (Reed Second Deposition) at 140:13-25.
[54] Exhibit 56 to Mullenix Declaration (Reed Second Deposition) at 140:23-141:3.
[55] Exhibit 56 to Mullenix Declaration (Reed Second Deposition) at 144:9-14.
[56] Exhibit 56 to Mullenix Declaration (Reed Second Deposition) at 147:19-148:3.
[57] Exhibit 56 to Mullenix Declaration (Reed Second Deposition) at 145:1-4.
[58] Exhibit 56 to Mullenix Declaration (Reed Second Deposition) at 148:14-149:7.
[59] Exhibit 56 to Mullenix Declaration (Reed Second Deposition) at 150:22-24, 153:11-17.
[60] Exhibit 56 to Mullenix Declaration (Reed Second Deposition) at 156:5-25.
[61] Exhibit 56 to Mullenix Declaration (Reed Second Deposition) at 156:5-25.
[62] Exhibit 56 to Mullenix Declaration (Reed Second Deposition) at 157:5-7.
[63] Exhibit 56 to Mullenix Declaration (Reed Second Deposition) at 162:9-12.
[64] Exhibit 51 to Mullenix Declaration.
[65] Exhibit 51 to Mullenix Declaration. *See also* Exhibit 24 to Mullenix Declaration at 106635, 106644, 106647, 106650, which shows how difficult the cracks can be to see even at 50 times magnification.

E. ISI finally discovers the microcrack problem.

Although ISI did not credit the incidents or studies above as indicative of a recurring problem with the main tube (shaft) of its MCS, it did eventually discover that problem. That process began in January 2013, when ISI was investigating another change to the MCS configuration.[66] During engineering tests of *that* change, one of the instruments "had saline leaking from what appeared to be cracks in the distal area of the main tube."[67]

ISI engineer Scott Manzo remarked that he was "Not comfortable with the anomaly"[68] and sought to do more testing on similar instruments. He found no cracks in those instruments, but in the *next* round of testing in March 2013 he again noted "cracks on the main tube, on the distal end."[69] At that point, Manzo told his supervisor about the issue and ran further tests, finding more cracks. This was the end of March 2013.[70] Manzo felt at that time "like there might be cracks in production tubes[.]"[71] ISI did not notify FDA or any hospital at that time.

On April 10, 2013, ISI contacted the supplier of the tubes (Easton), about the cracks: "It appears small cracks can appear in the tube's distal end after some cycles of cleaning/sterilization."[72] ISI told Easton: "This is a very urgent matter for us."[73]

Even so, ISI decided to continue shipping the MCS until April 29, 2013.[74] ISI, which was being audited by the FDA at the time,[75] first informed FDA of the issue the next day.[76]

By May 1, 2013, ISI had isolated Redacted as the source of the microcracks.[77] By May 2, ISI had determined that only some of the Redacted tubes

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[66] Exhibit 21 to Mullenix Declaration at 68065.
[67] Exhibit 21 to Mullenix Declaration at 68065.
[68] Exhibit 21 to Mullenix Declaration at 68065.
[69] Exhibit 58 to Mullenix Declaration (Manzo Deposition) at 41:17-19.
[70] Exhibit 58 to Mullenix Declaration (Manzo Deposition) at 42:2-43:3.
[71] Exhibit 58 to Mullenix Declaration (Manzo Deposition) at 42:24-43:3.
[72] Exhibit 12 to Mullenix Declaration.
[73] Exhibit 12 to Mullenix Declaration.
[74] Exhibit 13 to Mullenix Declaration.
[75] Exhibit 20 to Mullenix Declaration at 63703 (Entry re 4/30/2013 and asterisk on next page).
[76] Exhibit 20 to Mullenix Declaration at 63703.
[77] Exhibit 14 to Mullenix Declaration.

showed cracks.[78] By May 4, ISI determined that, after just one autoclave cycle, "6 out of 6 instruments machined with a dull drill" showed "at least one crack," and "1 out of 6 instruments machined with sharp tooling" showed at least one crack.[79] In an email dated May 8, 2013, ISI's engineers admitted: "I'm not at all sure we have a tube/extension level test that will catch machining defects."[80] At this time, ISI made several changes to its manufacturing process, including the 'Redacted' it had considered in 2007.[81]

On May 8, 2013, ISI sent a presentation to FDA about the microcracks, followed by a conference call.[82] ISI proposed to send an "Urgent Medical Device Notification" to hospitals about the cracks, rather than sending a recall.[83] Despite the six events described above, ISI told FDA there had never been a confirmed injury due to the microcracks. Even so, five days later, FDA directed ISI to change its "Notification" to a "Recall."[84] FDA also directed ISI that users "should be instructed to stop using the product and quarantine product."[85] ISI formally recalled the scissors on May 16, 2013.[86]

F. This Lawsuit

Richard Pohly ultimately learned of the recall and brought this suit in September 2015. In addition to the manufacturing defects described above, the suit alleges claims for defective warnings (for failing to instruct hospitals to test the insulation on the instruments before using them) and defective design (for failing to incorporate a feasible failsafe technology known as active electrode monitoring). In its answer, ISI denied responsibility and raised, among others, the affirmative defenses described above. To date, no evidence of nonparty fault, unforeseen causes, or unreasonable failure to mitigate by Mr. Pohly has been produced or identified by ISI.

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[78] Exhibit 5 to Mullenix Declaration.
[79] Exhibit 16 to Mullenix Declaration at 73037.
[80] Exhibit 23 to Mullenix Declaration.
[81] Exhibit 9 to Mullenix Declaration.
[82] Exhibit 20 to Mullenix Declaration.
[83] Exhibit 20 to Mullenix Declaration at 63075-63078.
[84] Exhibit 25 to Mullenix Declaration.
[85] Exhibit 25 to Mullenix Declaration at ISI_Pohly 2525.

Specifically, even ISI's surgeon expert has denied any implication of wrongdoing by any health care provider.[87]

III. Statement of Issues

1) Is a medical instrument considered defective under California or Texas product liability law when it does not meet its manufacturer's specifications and the failure to meet specifications raises the possibility of an unrecognized thermal injury to internal organs during surgery?

2) Has ISI produced sufficient admissible evidence to sustain any of the blame-shifting affirmative defenses it has raised, such that some party other than ISI could be placed on the verdict form at trial?

3) Should the Court strike ISI's statute of limitations defense when the parties entered a tolling agreement and there is no evidence plaintiff failed to comply with that agreement?

IV. Argument and Authority

Summary judgment may be granted when, drawing all inferences and resolving all doubts in favor of the nonmoving party, there are no genuine issues of material fact and the moving party is entitled to judgment as a matter of law. Fed.R.Civ.P. 56(c); *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986). A fact is material when, under governing substantive law, it could affect the outcome of the case. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). A dispute about a material fact is genuine if "the evidence is such that a reasonable jury could return a verdict for the nonmoving party." *Id.* Bald assertions that genuine issues of material fact exist are insufficient. *Galen v. Cnty. of L.A.*, 477 F.3d 652, 658 (9th Cir.2007).

A. Electrified scissors with microcracks in the insulation are defective.

The first question on the issue of whether the microcracks are a defect is that of which state's law applies: California or Texas. "In a diversity case, the district court must apply the choice-of-law rules of the state in which it sits." *Abogados v. AT & T*, Inc., 223 F.3d 932, 934

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[86] Exhibit 49 to Mullenix Declaration.
[87] Mullenix Declaration ¶2.

(9th Cir.2000). Under California's choice-of-law rules, "the forum will apply its own rule of decision unless a party litigant timely invokes the law of a foreign state." *Washington Mut. Bank, FA v. Superior Court*, 24 Cal. 4th 906, 919, 15 P.3d 1071, 103 Cal. Rptr. 2d 320 (2001) (citations omitted). The foreign law proponent "must identify the applicable rule of law in each potentially concerned state and must show it materially differs from the law of California[.]" *Id.*

Here, no party has yet invoked the law of any foreign state. Moreover, for the purposes of the manufacturing defect question in this motion, there is no material difference between California and Texas law. California law imposes liability for a manufacturer if a product's defect was a substantial factor in causing harm and the defect is that the product "differs from the manufacturer's design or specifications or from other typical units of the same product line." *See* CACI 1201, CACI 1202 ("A product contains a manufacturing defect if the product differs from the manufacturer's design or specifications or from other typical units of the same product line.") (citing *Barker v. Lull Engineering Co.* (1978) 20 Cal.3d 413, 429 [143 Cal.Rptr. 225, 573 P.2d 443], and *Jiminez v. Sears, Roebuck & Co.* (1971) 4 Cal.3d 379, 383 [93 Cal.Rptr. 769, 482 P.2d 681]). In Texas, the same is true. *See Ford Motor Co. v. Ridgway*, 135 S.W.3d 598, 600 (Tex. 2004). The *Ford* case states that a manufacturer is liable when "a product deviates, in its construction or quality, from the specifications or planned output in a manner that renders it unreasonably dangerous." *Id.*

Here, there is no question that a product with microcracks deviates from ISI's specifications. As set out above, ISI's own witnesses and internal documents show that the microcracks deviated from ISI's internal specifications for intact insulation and for the ability to withstand the autoclaving process. And if the microcracks were a substantial factor in causing Mr. Pohly's injuries – a question not raised by this motion – then the microcracks were unreasonably dangerous. If the danger of burns from invisible insulation failures was not unreasonable, ISI would not have stopped shipping its scissors and issued its recall after discovering and investigating the problem.

As such, this Court should rule that California law applies. This Court should also rule that, to the extent the scissors used in Mr. Pohly's surgery had "microcracks," they were defective within the meaning of California law.

B. No entity other than ISI should be available for apportionment of fault at trial, as ISI has produced no evidence that any other person caused Mr. Pohly's harm.

Although ISI has raised several blame-shifting defenses, it has failed to prove them. For instance, ISI's Fifth and Ninth defenses are misuse of the product and nonparty fault. But no witness has yet accused the surgeon who used the ISI scissors of misusing them, and he has denied wrongdoing:

> Q. I don't know if you were ever asked this question directly. Were you negligent in the performance of Richard Pohly's surgery?
>
> A. I was not negligent in the performance of the surgery or in the after care of Mr. Pohly. Inasmuch as I responded to the circumstances as they unfolded on the postoperative day one, and I believe that every step that was taken in postoperative day one was taken as expeditiously and as efficiently as was humanly possible in a large healthcare system. And I was fortunate to have him in the operating room in a relatively short period of time. I'm fairly convinced if he would have been discharged that afternoon by some happenstance, he would not have survived.[88]

No other witness – including the urologic surgery expert ISI retained – has contradicted this opinion.[89] Thus, there is no evidence that any health care provider tortiously harmed Mr. Pohly or misused any ISI product. The Court should strike the fifth and ninth defenses.

Nor is there any evidence that any provider did anything so far out of the ordinary that it could be considered an intervening or superseding cause, as claimed in ISI's seventh defense. Under California law, the intervening cause analysis requires the defendant to prove both that the injury was unforeseeable and that the act causing it was unforeseeable:

> [W]here [an] injury was brought about by a later cause of independent origin ... [the question of proximate cause] revolves around a determination of whether the later cause of independent origin, commonly referred to as an intervening cause, was foreseeable by the defendant or, if not foreseeable, whether it caused injury of a type which was foreseeable. **If either of these questions is answered in the**

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[88] Exhibit 59 to Mullenix Declaration (Roehrborn Deposition) at 236:20-237:9.
[89] Mullenix Declaration ¶2.

> **affirmative, then the defendant is not relieved from liability towards the plaintiff;** if, however, it is determined that the intervening cause was not foreseeable and that the results which it caused were not foreseeable, then the intervening cause becomes a supervening cause and the defendant is relieved from liability for the plaintiff's injuries.

Pappert v. San Diego Gas & Elec. Co., 137 Cal. App. 3d 205, 210, 186 Cal. Rptr. 847, 850 (Cal. Ct. App. 1982) (emphasis added, citations omitted). Here, ISI has never produced evidence to show an unforeseeable intervening cause or an unforeseeable injury. To the contrary, the six adverse events involving arcing from MCS shafts and internal burns made both the cause and the injury Mr. Pohly suffered foreseeable. ISI simply did not investigate them. The Court should strike ISI's seventh defense.

Finally, ISI has yet to produce evidence of any unreasonable failure by Mr. Pohly to mitigate the damages he suffered. For context, Mr. Pohly was hospitalized for 200 days after his prostatectomy.[90] His complications included septic shock, and he was close to death.[91] He had severe respiratory distress and tachycardia.[92] His surgeon described his situation as a "completely life altering experience."[93] ISI has yet to show that Mr. Pohly acted unreasonably in recovering. The Court should strike ISI's Fifteenth Affirmative defense.

C. The Court should strike ISI's statute of limitations defense.

Whether Texas law or California law is applied, the statute of limitations for a product liability claim is two years. *See* TEX.CIV.PRAC. & REM.CODE § 16.003(b) *and* Cal. Code Civ. Proc., § 335.1. Thus, even assuming his claims accrued shortly after his July 2012 prostatectomy, Mr. Pohly had until July 2014 to bring a claim against the manufacturer of the instrument that harmed him. He entered a 120-day tolling agreement with ISI on May 29,

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[90] Exhibit 59 to Mullenix Declaration (Roehrborn Deposition) at 250:22-252:14.
[91] Exhibit 59 to Mullenix Declaration (Roehrborn Deposition) at 250:22-252:14.
[92] Exhibit 59 to Mullenix Declaration (Roehrborn Deposition) at 250:22-252:14.
[93] Exhibit 59 to Mullenix Declaration (Roehrborn Deposition) at 250:22-252:14.

2014.[94] That tolling period was then extended to September 14, 2015.[95] He brought this suit on September 9, 2015, and ISI waived service.[96] There is no statute of limitations issue in this case.

V. Conclusion

Plaintiff respectfully asks this Court to grant the relief described in § II, as set out in the accompanying proposed order.

Respectfully submitted this 15th day of December, 2016.

s/ Richard H. Friedman, No. 221622
rfriedman@friedmanrubin.com
s/ Peter J. Mullenix (admitted pro hac vice)
pmullenix@friedmanrubin.com
FRIEDMAN| RUBIN
51 University Street, Suite 201
Seattle, WA 98101
Tel: 206-501-4446 / Fax: 206-623-0794

s/ John Graham Hill (admitted pro hac vice)
ghill2013@gmail.com
2323 S. Shepherd Drive, 14th Floor
Houston TX 77019
Tel: 713-979-4695

Attorneys for Plaintiff Richard Pohly

[94] Exhibit 52 to Mullenix Declaration.
[95] Exhibit 53 to Mullenix Declaration.
[96] Dkt. #1, #7.

CERTIFICATE OF SERVICE

I hereby certify that on December 15, 2016, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system, which will send notification of such filing to the following:

Counsel for Defendant Intuitive Surgical, Inc.

Allen J. Ruby
S. Sheryl Leung
SKADDEN ARPS SLATE MEAGHER & FLOM LLP
525 University Avenue, Suite 1400
Palo Alto CA 94301
T: 650-470-4500
F: 650-470-4570
E: allen.ruby@skadden.com
E: Sheryl.leung@skadden.com

Lisa M. Gilford
SKADDEN ARPS SLATE MEAGHER & FLOM LLP
300 South Grand Avenue
Los Angeles CA 90071
T: (213) 687-5000
F: (213) 687-5600
E: lisa.gilford@skadden.com

Taylor F. Brinkman
LOCKE LORD
2200 Ross Avenue, Suite 2800
Dallas TX 75201
T: (214) 740-8442
E: tbrinkman@lockelord.com

/s/ Peter J. Mullenix