

**BEFORE THE JUDICIAL PANEL ON
MULTIDISTRICT LITIGATION**

**IN RE: POWER MORCELLATOR
PRODUCTS LIABILITY LITIGATION**

MDL No. 2652

**BRIEF OF DEFENDANTS JOHNSON & JOHNSON; JOHNSON & JOHNSON
SERVICES; ETHICON, INC.; AND ETHICON ENDO-SURGERY, INC. IN
OPPOSITION TO PLAINTIFFS' MOTION FOR TRANSFER**

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PRELIMINARY STATEMENT

Defendants Johnson & Johnson; Johnson & Johnson Services; Ethicon, Inc.; and Ethicon Endo-Surgery, Inc. (collectively, “Ethicon”) hereby oppose the motion to consolidate pretrial proceedings in federal product-liability cases involving power morcellators. Consolidation—on an industry-wide basis, or on a per-manufacturer basis—would neither serve the convenience of the parties and witnesses, nor promote the just and efficient litigation of the actions.

This Panel is “typically hesitant to centralize litigation against multiple, competing defendants which marketed, manufactured and sold [allegedly] similar products,” *In re Watson Fentanyl Patch Prods. Liab. Litig.*, 883 F. Supp. 2d 1350, 1351 (J.P.M.L. 2012), and there is no reason to depart from that practice here. An industry-wide MDL may sweep in at least nine unrelated manufacturers. The morcellators these manufacturers have sold differ in crucial ways, including the mechanism by which they work and the warnings provided. There is no industry-wide conspiracy alleged. The manufacturers are direct competitors in the medical-device industry. And the number of cases (20 at this writing) is far smaller than necessary to justify such an unwieldy undertaking.

An Ethicon-only MDL—which Plaintiffs have not requested—makes no more sense. Plaintiff-specific discovery is a major part of every product-liability case, but these cases, which allege that a doctor’s use of a power morcellator during surgery worsened the prognosis of a patient’s *already existing* cancer, are individualized to an entirely different degree. Moreover, contrary to Plaintiffs’ speculation, the number of Ethicon morcellator cases is likely to stay very low. Ethicon voluntarily withdrew its power morcellators from the market over a year ago, so the number of possible injuries is fixed. The relevant statistics suggest that the number of potential unfiled cases is small and manageable. And, due to statute-of-limitations considerations, most of the unfiled cases that *might* exist can never be brought.

Under these circumstances, centralization would harm more than it would help, and Plaintiffs' motion should be denied outright. In any event, the District of Kansas (suggested by the movants) and the Southern District of Illinois (suggested by a responding plaintiff) lack any connection to this litigation and are inappropriate transferee districts.

FACTUAL BACKGROUND

A. Uterine Fibroids Versus Uterine Sarcoma

The Plaintiffs here all allegedly underwent surgery to remove uterine fibroids. Fibroids (also known as uterine leiomyomas or myomas) are *benign* muscle tumors that occur on or around the uterus, and 20-80 percent of women have them by the time they reach the age of 50. They are usually asymptomatic, and treatment is typically not needed. However, they may cause symptoms such as irregular bleeding, abdominal pain, or increased/decreased urinary frequency.¹

Some—but not all—Plaintiffs allege that they actually had uterine sarcomas. Sarcomas are a form of *malignant* tumor. They represent less than 5% of all uterine cancers. They are relatively aggressive and have relatively poor prognoses. One form of uterine sarcoma alleged by several Plaintiffs is leiomyosarcoma (LMS). LMS is an especially rare and deadly form of uterine sarcoma, occurring in approximately 1–1.5 in 100,000 U.S. women.² “Overall survival for women diagnosed with LMS is universally poor, with only 40% alive at 5 years.”³

B. Traditional Surgery Versus Laparoscopic Surgery With Morcellation

If a woman's physician determines that fibroids should be surgically removed, the first decision is whether to remove the entire uterus (*i.e.*, hysterectomy), or whether to remove only

¹ FDA, *Executive Summary: Laparoscopic Power Morcellation* (July 2014) at 5-6, <http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/ObstetricsandGynecologyDevices/UCM404148.pdf>.

² *Id.* at 6-7.

³ AAGL, *Morcellation During Uterine Tissue Extraction* at 4, http://www.aagl.org/wp-content/uploads/2014/05/Tissue_Extraction_TFR.pdf.

the fibroids themselves (*i.e.*, myomectomy). Once that decision is made, the doctor must decide whether to use traditional surgical procedures, or minimally-invasive laparoscopic procedures.

In the traditional or “open” procedure, a large incision is made in the wall of the lower abdomen; the woman’s abdominal cavity is opened; and the uterus is exposed. The uterus or the fibroids are surgically detached and removed, typically in a single piece, through the incision in the abdominal wall. The incision is then sutured closed. On average, it takes six weeks to recover from this type of surgery.⁴

In the laparoscopic procedure, by contrast, tiny incisions of about 1 millimeter in width are made in the abdominal wall, and an endoscope (a small, flexible camera) is inserted into the abdominal cavity. Surgical instruments are then introduced into the cavity using small, hollow tubes that are inserted into the tiny incisions. The doctor controls the instruments remotely while observing the interior of the patient’s body on a screen. The uterus or the fibroids are then removed using a tool called a *power morcellator*, which cores the targeted tissue into long strips so that it can be removed through the tiny incisions.

The laparoscopic method has advantages over the “open” method, such as reduced pain, bleeding, and scarring; shorter hospital stays and recovery times; and less exposure to external contaminants, thereby reducing the risk of infection and death.⁵ The Society of Gynecological Oncology recently noted that “[m]ultiple studies ... have shown that compared to traditional [‘open’] surgery,” the laparoscopic method “results in a substantial reduction in morbidity” and a

⁴ Mayo Clinic Staff, *Abdominal Hysterectomy: What You Can Expect*, <http://www.mayoclinic.org/tests-procedures/abdominal-hysterectomy/basics/what-you-can-expect/prc-20020767>.

⁵ Hurst et al., *Laparoscopic myomectomy for symptomatic uterine myomas*, *Fertil Steril*. 2005 Jan;83(1):1-23; Siedhoff et al., *Laparoscopic hysterectomy with morcellation vs. abdominal hysterectomy for presumed fibroid tumors in premenopausal women: a decision analysis*. *Am J Obstet Gynecol*. 2015 May;212(5):591.e1-8.

“significant improve[ment]” in “quality of life, body image and return to base line function.”⁶

C. Risks Allegedly Associated With Morcellation

Plaintiffs allege that fragments of the morcellated tissue can be dispersed within the abdominal cavity during surgery, and that in rare cases, this may lead to complications.

One alleged risk concerns malignant cancer. There is no way to determine with certainty prior to surgery that what looks like a fibroid is not, in fact, a malignant sarcoma.⁷ This is because “sarcomas ... may mimic the radiographic appearance of benign [fibroids], and other preoperative diagnostic testing may not always discriminate between benign and malignant conditions.”⁸ If the physician misdiagnoses a sarcoma as a fibroid and performs morcellation, this allegedly may disperse cancer cells within the abdominal cavity, leading to “upstaging” (*i.e.*, worsening the prognosis) of the existing cancer. Many of the complaints filed in this litigation allege this sort of “upstaging”—although, as noted below, a number of Plaintiffs do not allege the sort of uterine cancer (sarcoma) that is capable of confusion with a benign fibroid, and one complaint (*Sanders*) does not allege uterine cancer *at all*, but rather, *ovarian* cancer.

“The [available] data on the risk of upstaging ... after power morcellation are limited.”⁹ Moreover, uterine sarcoma is aggressive and often fatal “whether morcellation is used or not.”¹⁰ Out of four cohort studies that compared the overall survival rate in morcellation and non-morcellation patients, the morcellation group fared worse to a statistically significant degree in only one study. Because outcomes for uterine sarcoma are already poor, “determining the degree

⁶ Statement of the Society of Gynecologic Oncology (July 10-11, 2014), <https://www.sgo.org/wp-content/uploads/2014/04/SGO-Testimony-to-FDA-on-Power-Morcellation-FINAL.pdf>.

⁷ FDA, *Executive Summary*, *supra* note 1, at 7; Stacy Simon, *FDA Warns of Cancer Risk in a Type of Uterine Fibroid Surgery*, *Am. Cancer Soc’y* (Apr. 22, 2014), <http://www.cancer.org/cancer/news/fda-warns-of-cancer-risk-in-a-type-of-uterine-fibroid-surgery>.

⁸ AAGL, *Morcellation During Uterine Tissue Extraction*, *supra* note 3, at 3-4.

⁹ AAGL Statement to the FDA on Power Morcellation (July 11, 2014), <http://www.aagl.org/aaglnews/aagl-statement-to-the-fda-on-power-morcellation/>.

¹⁰ *Id.*

to which power morcellation contributes to worsened outcomes for patients ... is difficult.”¹¹

Plaintiffs claim, without any supporting citation, that “[e]vidence linking [power morcellators] and upstaging of occult cancer ... [was] not disclosed to or shared with the public.” (Movants’ Br. at 4.) To the contrary, since the introduction of power morcellators, the alleged risk that tissue dissemination might “upstage” preexisting cancer was well known.¹² It also has long been known that tumors that appear to be fibroids may, in fact, be malignant sarcomas.¹³ For that reason, manufacturers (including Ethicon) have long warned against use of morcellators when malignancy is present or suspected, and have advised taking precautionary measures against disseminating malignant tissue.¹⁴

The second alleged risk does not involve cancer at all. Rather, it concerns the possibility that all morcellated fibroid tissue may not be removed from the body following surgery, and that fibroid remnants may “parasitize” (*i.e.*, begin taking blood supply from) adjacent organs in the abdominal cavity and grow into new fibroids.¹⁵ Like ordinary fibroids, these “parasitic” fibroids are benign and ordinarily asymptomatic, but occasionally cause symptoms and require removal. The surgeon can effectively prevent parasitic fibroids by paying careful attention to remove all residual fragments and performing “intraperitoneal lavage,” or irrigating the body cavity following surgery.¹⁶ Parasitic fibroids are alleged in only one case in this litigation (*Whitehead*).

D. New Developments Precipitating This Litigation

For many years, the risk that a woman with presumed fibroids actually had sarcoma was

¹¹ FDA, *Executive Summary*, *supra* note 1, at 22-23.

¹² John Kamp & Jennifer Levitz, *Johnson & Johnson Pulls Hysterectomy Device From Hospitals*, Wall Street Journal (July 30, 2014), <http://www.wsj.com/articles/johnson-johnson-to-call-for-voluntary-return-of-morcellators-1406754350>.

¹³ *Id.*

¹⁴ *Infra* at 10; *see also* Appendix.

¹⁵ FDA, *Executive Summary*, *supra* note 1, at 17; Sinha, et al., *Parasitic myoma after morcellation*, *J Gynecol Endosc Surg.* 2009 Jul-Dec; 1(2): 113–115.

¹⁶ *Id.*

widely believed to be small (1 in 10,000). In fact, not a single case of uterine cancer allegedly exacerbated by power morcellation had been reported to the FDA as of December 2013.¹⁷

In late 2013 and early 2014, “the medical field began re-evaluating [this] risk” after a Boston anesthesiologist diagnosed with cancer following fibroid surgery began a public campaign.¹⁸ In April 2014, the FDA issued a “safety communication” announcing that, in its view, the risk of a malignant sarcoma being mistaken for a benign fibroid was greater than previously believed—potentially as high as 1 in 350.¹⁹ However, FDA recognized “limitations to [its] analysis,” including the “relatively small number” of studies and the “small number of patients” in those studies; the non-randomized nature of those studies; and “potential publication, selection, and referral bias” in those studies.²⁰ Following that announcement, Ethicon suspended sales of its power morcellator devices and directed surgeons to stop using them. Then, in July 2014, Ethicon issued a voluntary worldwide recall of the devices.²¹

In November 2014, FDA recommended that manufacturers of power morcellators include a “boxed warning” in their labeling.²² At that time, the FDA also determined that power morcellators’ labeling should contain “contraindications” (*i.e.*, directions against use) for fibroid removal in menopausal or post-menopausal women, and in women who are good candidates for other removal methods. FDA continues to recognize that “laparoscopic power morcellation may be an appropriate therapeutic option” for some categories of women, *e.g.*, “younger women who

¹⁷ FDA, *Executive Summary*, *supra* note 1, at 26; Jon Kamp, *Women’s Cancer Risk Raises Doubts About FDA Oversight*, Wall Street Journal (July 8, 2014), <http://www.wsj.com/articles/womens-cancer-risk-raises-doubts-about-fda-oversight-1404842368>.

¹⁸ Kamp & Levitz, *Johnson & Johnson Pulls Hysterectomy Device*, *supra* note 12.

¹⁹ FDA Safety Communication (April 17, 2014), <http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm393576.htm>; Simon, *FDA Warns of Cancer Risk*, *supra* note 7.

²⁰ FDA, *Executive Summary*, *supra* note 1, at 23-24.

²¹ Linda Johnson, *FDA strengthens warning on device linked to cancer*, AP, Nov. 24, 2014, <http://finance.yahoo.com/news/fda-strengthens-warning-device-linked-163440402.html>.

²² FDA News Release (Nov. 24, 2014), <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm424435.htm>.

are interested in maintaining their ability to have children or wish to keep their uterus intact.”²³

To date, no manufacturer of power morcellators other than Ethicon has recalled its devices or directed doctors to stop using them. A number of hospitals have voluntarily stopped using all morcellators. Others continue to “offer[] power morcellation” using non-Ethicon morcellators, “with detailed informed consent” in line with FDA’s new guidelines.²⁴

Prominent voices in the medical community have disagreed with FDA’s actions. In July 2014, the Society of Gynecologic Oncology told the FDA that it “is not supportive of any overt restriction on power morcellation” in light of its proven “clinical benefit for American women.”²⁵ The Society determined that FDA’s analysis of the relevant data “is questionable.”²⁶ It also noted that “even when uterine sarcomas are removed intact [*i.e.*, without morcellation], there is still a very poor prognosis with these aggressive malignancies.”²⁷ It concluded:

The question comes down to this: Is it better to expose about 1,000 women to increased morbidity and potential mortality by doing an [open] abdominal hysterectomy to avoid morcellation of one unsuspected sarcoma? Or: How do we weigh the proven benefit of [laparoscopy with morcellation] ... against the potential and very low risk of disseminating a sarcoma through morcellation? ... [M]orcellation has benefited hundreds of thousands of women. ... It would be a disservice to deny [them] this surgical option.²⁸

Similarly, the AAGL (formerly, American Association of Gynecologic Laparoscopists) took issue with the FDA’s conclusions, noting that the data “show a lower prevalence rate” for undetected uterine sarcoma than the 1-in-350 rate calculated by the FDA,²⁹ and preliminarily

²³ *Id.*

²⁴ Kamp & Levitz, *Johnson & Johnson Pulls Hysterectomy Device*, *supra* note 12.

²⁵ Statement of the Society of Gynecologic Oncology, *supra* note 6.

²⁶ *Id.*

²⁷ *Id.*

²⁸ *Id.*

²⁹ AAGL, *Member Update #5: AAGL Reponse to FDA Guidance on Use of Power Morcellation during Tissue Extraction*, <http://www.aagl.org/aaglnews/member-update-5-aagl-response-to-fda-guidance-on-use-of-power-morcellation-during-tissue-extraction-for-uterine-fibroids/>.

finding that laparoscopic surgery with morcellation “may be safer and result in fewer deaths compared with the open approach, even when using prevalence estimates that are [as] high” as the FDA’s. In other words, even using FDA’s prevalence statistics, “the combined mortality from leiomyosarcoma and the potential dissemination through power morcellation would be less than the mortality from open hysterectomy.”³⁰

E. The Different Power Morcellators At Issue

The power morcellator was first described in the medical literature in 1993. “[D]evelopment, manufacturing, and use of [power morcellators] expanded through the 1990s and 2000s.”³¹ As of April 2014, at least nine companies were cleared by FDA to sell power morcellators for gynecological surgery. These companies included Ethicon, headquartered in New Jersey;³² Blue Endo, headquartered in Kansas; Cook Medical, headquartered in Indiana; Karl Storz, Richard Wolf, and Trokamed, headquartered in Germany; LiNA, headquartered in Denmark; Olympus, headquartered in Japan; Lumenis, headquartered in Israel; and Smith & Nephew, headquartered in the U.K.

Not all power morcellators are created equal. They differ, *inter alia*, in these ways:

Reusability. Ethicon’s now-recalled morcellators were all disposable, single-use instruments. Other morcellators were intended to be sterilized and reused on multiple patients.

Fragmenting mechanism. Power morcellators “generally rely on spinning blades (100-1200 rpm) to fragment tissue.”³³ “Early” morcellators “used the ‘coring principle’ to core out cylindrical pieces of tissue for removal with morcellation rates of < 15 g/min [*i.e.*, less than 15

³⁰ AAGL Statement to the FDA, *supra* note 9.

³¹ FDA, *Executive Summary*, *supra* note 1, at 14.

³² Ethicon Inc., which designed and marketed the Ethicon devices, is based in Somerville, New Jersey. The other related corporate entities sued by Plaintiffs (Johnson & Johnson, Johnson & Johnson Services, Inc., and Ethicon Endo-Surgery, Inc.) did not design, supply, promote, distribute, or sell the Ethicon power morcellators.

³³ FDA, *Executive Summary*, *supra* note 1, at 14.

grams of tissue per minute].”³⁴ “Second generation devices are based on the ‘peeling principle’ where the device incorporates an overhanging edge at the distal end allowing the blade to provide more continuous tissue removal. These devices have morcellation rates of ≥ 30 grams/minute.”³⁵ One company, Olympus, sells morcellators that rely on “radiofrequency energy,” rather than mechanical blades, to fragment tissue.

The FDA has raised the possibility that “the mode of morcellation, *i.e.*, [mechanical blades] versus radiofrequency, or other design factors, *e.g.*, speed of rotation,” may correspond with increased or decreased “dissemination [of morcellated tissue] into the [abdominal] cavity.”³⁶ For this reason, some morcellator models may pose considerably less risk of “parasitic” fibroids or “upstaged” cancer than others.

Specimen Bags. Many power morcellators, including those formerly sold by Ethicon, are compatible with laparoscopic specimen bags. These are nylon or polyurethane bags that are optionally used to surround the target tissue in order to assist in retrieval. The FDA recognizes that a “specimen bag” is “a potential mitigation strategy to limit/prevent dissemination of tissue.”³⁷ At least one manufacturer’s morcellators (Olympus) currently are incompatible with specimen bags, and the manufacturer warns against their use.

Moreover, like morcellators, not all specimen bags are the same.³⁸ FDA has observed that “the thickness of the material, its sewing/seams, the introduction and deployment mechanisms, [and other features of the bag] vary from product to product.”³⁹ These variations

³⁴ *Id.*

³⁵ *Id.*

³⁶ *Id.* at 15.

³⁷ *Id.* at 24, 27.

³⁸ *See id.* at 28 (listing brands and manufacturers).

³⁹ *Id.* at 27.

may impact “the risk of ... tissue dissemination during morcellation” to differing extents.⁴⁰

Warnings. FDA has observed that, prior to April 2014, morcellators “varie[d] across manufacturers in terms of statements regarding use on malignant tissue and on the use with a specimen bag.”⁴¹ The chart in the Appendix lists some of the leading morcellators cleared by FDA for use in gynecologic surgeries that were available as of FDA’s April 2014 announcement, along with the relevant pre-April 2014 language contained in their warning labels.

Ethicon devices, for example, expressly warned that morcellation “may lead to dissemination of malignant tissue” and advised use of a specimen bag when extracting “malignant tissue or tissue suspected of being malignant” or “tissue that the physician considers to be potentially harmful when disseminated in a body cavity.” Other manufacturers’ labels warned against use on “malignant tumors” or in “patients who have been diagnosed with a malignant condition,” and/or recommended use of tissue extraction bags where malignancy was suspected, but did not expressly warn about potential tissue *dissemination*. And one manufacturer (Olympus) advised against use where the physician determined it “would be contrary to the best interests of the patient,” and advised *against* use of specimen bags.

F. Litigation Concerning Power Morcellators

In March 2014—as the FDA was preparing to issue its first announcement, and as the publicity campaign surrounding morcellators continued—the first action in this litigation, *Burkhardt v. Lina Medical U.S.* (E.D. Pa. Mar. 14, 2014), was filed. That case was resolved in June 2015 and has recently been dismissed. Ten other federal cases were also filed in 2014. So far in 2015, 12 federal cases were filed, one of which has recently been dismissed. The 21 active cases are pending in district courts in South Carolina (4); California (3); Pennsylvania (2), New

⁴⁰ *Id.*

⁴¹ *Id.*

Jersey (2), New York (2), Colorado (1), Florida (1), Georgia (1), Kansas (1), Louisiana (1), Maryland (1), Tennessee (1), and Wisconsin (1).⁴²

The cases placed at issue by this Motion display a wide range of variation. Sixteen are brought against Ethicon and related defendants; five against Karl Storz; and one each against Richard Wolf and Gyrus (a subsidiary of Olympus).⁴³ Plaintiffs allege negligence, design defect, failure to warn, breach of express and/or implied warranties, fraudulent misrepresentation, and/or loss of consortium. Eight complaints contain state-specific statutory claims (*e.g.*, for violation of state consumer protection acts). The patients in nine cases are deceased, and their estates bring claims for wrongful death.

Most, but not all, of the complaints involve some type of uterine cancer: a number involve LMS; one, myeloid sarcoma; one, endometrial stromal sarcoma; one, endometrial adenocarcinoma; and one, adenosarcoma with sarcomatous overgrowth. One complaint (*Sanders*) alleges a form of *ovarian* cancer (low grade serous carcinoma), not uterine cancer. Another complaint (*Nielsen*) alleges unspecified “cancer.” One complaint (*Whitehead*) alleges “recurrent parasitic fibroids,” but *not* cancer. And one complaint (*A. Phillips*) alleges “tumors ... of *uncertain* malignant potential.” In some complaints, Plaintiffs allege that their doctor performed pre-surgery testing for cancer; in some, not. At least one Plaintiff’s surgery (*Johnson*) used a specimen bag; others did not. Most Plaintiffs’ surgeries took place in 2011 and 2012, but one (*N. Phillips*) was as recent as 2014, and one (*Whitehead*) was as long ago as 2006.

The Plaintiffs with cancer allege that morcellation affected their preexisting cancer in

⁴² The Motion does not include *Montalvo-Ariri v. Johnson & Johnson Inc.*, No. 5:14-cv-01421 (C.D. Cal. July 11, 2014), although that case involves an Ethicon power morcellator.

⁴³ These add up to more than 21 because a handful of lawsuits name multiple manufacturers—likely because the plaintiff was unable to identify which device was used in her surgery. Based on the dismissal of *Burkhardt*, two manufacturers, LiNA and Blue Endo, are no longer defendants in any pending case.

varying ways. Some (*e.g.*, *Ostrander*) allege that their cancer would not have metastasized absent morcellation and would have remained “encapsulated.” Others (*e.g.*, *Watkins*) allege that morcellation “amplified the speed [at which] the cancer metastasized and ... depreciated the long-term prognosis.” Others (*e.g.*, *Galambos*) were told they were cancer-free but suffered a recurrence which they attribute to earlier morcellation.

ARGUMENT

Section 1407 permits consolidation when (1) the actions “involv[e] one or more common questions of fact,” (2) consolidation would serve “the convenience of [the] parties and witnesses,” and (3) consolidation would “promote the just and efficient conduct of [the] actions.” However, “*centralization under Section 1407 ‘should be the last solution after considered review of all other options,’*” including voluntary coordination. *In re Nutek Baby Wipes Prods. Liab. Litig.*, 2015 U.S. Dist. LEXIS 44048, at *3 n.3 (J.P.M.L. Apr. 2, 2015) (emphasis added). The moving party bears the burden of demonstrating that transfer is appropriate. *In re G.D. Searle & Co. “Copper 7” IUD Prods. Liab. Litig.*, 483 F. Supp. 1343, 1345 (J.P.M.L. 1980). Even when common questions of fact exist, the movant must still show that “the inherent disadvantages of Section 1407 transfer” do not “outweigh the benefits.” *Id.*

I. AN INDUSTRY-WIDE MDL WILL NOT SERVE THE CONVENIENCE OF THE PARTIES OR THE INTERESTS OF JUSTICE

Plaintiffs seek to create an unwieldy MDL against potentially nine unrelated manufacturers that have manufactured and sold power morcellators. This goes against the Panel’s general practice. *See Fentanyl Patch*, 883 F. Supp. 2d at 1351 (“*[W]e are typically hesitant to centralize litigation against multiple, competing defendants which marketed, manufactured and sold [allegedly] similar products.*” (emphasis added)); *In re Androgel Prods. Liab. Litig.*, 24 F. Supp. 3d 1378, 1379 (J.P.M.L. 2014) (“*We are typically hesitant to centralize litigation on an industry-wide basis.*” (emphasis added)).

There is especially good reason for hesitation here. Plaintiffs “have not alleged any conspiracy, collaboration, or other industry-wide conduct by the defendants that would justify centralizing actions naming different [manufacturers and distributors] as defendants.” *In re Honey Prod. Mktg. & Sales Practices Litig.*, 883 F. Supp. 2d 1333, 1333 (J.P.M.L. 2012). And industry-wide centralization would “complicate these matters, as defendants may need to erect complicated confidentiality barriers, since they are business competitors.” *Fentanyl Patch*, 883 F. Supp. 2d at 1351.

Moreover, power morcellators are not all alike. As discussed above, they vary with regard to mechanism of action; disposability; compatibility with protective specimen bags; and the warnings their labeling provided with regard to tissue dissemination, cancer risk, and use of a specimen bag. These differences bear on each device’s likelihood of potentially disseminating malignant cells in the body cavity; on the likelihood that a different warning may have convinced the treating physician not to use the device (or to use the device with a protective specimen bag); and on other core elements of the plaintiffs’ product-liability claims.

Given these facts, lumping all morcellators together is more likely to confuse the issues and prejudice the Defendants than to serve the convenience of the parties and the interest of justice. *Cf. In re OxyElite Pro & Jack3d Prods. Liab. Litig.*, 11 F. Supp. 3d 1340, 1341 (J.P.M.L. 2014)); *In re Ambulatory Pain Pump-Chondrolysis Prods. Liab. Litig.*, 709 F. Supp. 2d 1375, 1377 (J.P.M.L. 2010).

Notably, in instances when this Panel placed different products or manufacturers in the same MDL, the facts were very different from those at issue here:

- **Number of actions.** The Panel has created multi-product or multi-manufacturer MDLs when the number of cases was much higher than the 21 cases at issue here. *See In re Diet Drugs Prods. Liab. Litig.*, 990 F. Supp. 834 (J.P.M.L. 1997) (209 actions, including tag-alongs); *Bextra & Celebrex Prods. Liab. Litig.*, 391 F. Supp. 2d 1377 (J.P.M.L. 2005) (more than 131); *Androgel*, 24 F. Supp. 3d 1378 (126); *Incretin Mimetics Prods. Liab. Litig.*, 968 F. Supp. 2d 1345 (J.P.M.L. 2013).
- **Identical product or single manufacturer.** The Panel has created multi-manufacturer MDLs when all manufacturers involved sold identical or near-identical products. *See Androgel*, 24 F. Supp. 3d 1378 (all manufacturers sold testosterone). And it has sometimes created multi-product MDLs when all products involved were sold by a single manufacturer. *See Bextra & Celebrex*, 391 F. Supp. 2d 1377 (both products sold by Pfizer). Here, by contrast, at least nine unrelated manufacturers manufacture over a dozen different power morcellators that differ in key ways.
- **Defendants' consent.** The Panel has created multi-product or multi-manufacturer MDLs when there was significant support for centralization on the defense side. *See Androgel*, 24 F. Supp. 3d 1378; *Incretin*, 968 F. Supp. 2d 1345; *Bextra & Celebrex*, 391 F. Supp. 2d 1377. Here, to Ethicon's knowledge, no defendant supports centralization. *Accord In re Discover Card Payment Protection Plan Mktg. & Sales Practices Litig.*, 764 F. Supp. 2d 1341, 1342 (J.P.M.L. 2011).
- **Class actions.** The Panel has created multi-manufacturer MDLs when many constituent actions were "brought on behalf of alleged nationwide or statewide classes," finding centralization necessary to avoid "inconsistent ... rulings ... with respect to class certification." *Diet Drugs*, 990 F. Supp. 834. None of the actions in this litigation is a class action. *See In re Narconon Drug Rehab. Mktg., Sales Practices, & Prod. Liab. Litig.*, 2015 U.S. Dist. LEXIS 14292, at *3 (J.P.M.L. Feb. 5, 2015).

In sum, this is not one of the rare instances where it would be appropriate to sweep all manufacturers and devices into an enormous industry-wide MDL. Plaintiffs have provided no good reason why the Panel should deviate from its usual rule, and there are many reasons not to.

II. AN ETHICON-ONLY MDL ALSO IS INAPPROPRIATE

An Ethicon-only morcellator MDL would no more serve the ends of Section 1407 than an industry-wide one. Centralization would not create efficiencies, because discovery in these actions will be intensely plaintiff-specific. Moreover, the number of pending cases is low, the pace of new filings has been slow, and the number of new cases is self-limited. Finally, discovery in some cases is at a relatively advanced posture.

A. Discovery Will Be Intensely Plaintiff-Specific

This Panel has long declined to centralize when it appeared that plaintiff-specific issues would constitute the bulk of discovery. *See, e.g., In re Wireless Lifestyle Inc.*, 842 F. Supp. 2d 1382, 1383 (J.P.M.L. 2012). This has especially been true in product-liability cases. *See, e.g., Pain Pump*, 709 F. Supp. 2d at 1377; *In re Blair Corp. Chenille Robe Prods. Liab. Litig.*, 703 F. Supp. 2d 1379, 1380 (J.P.M.L. 2010).⁴⁴

The lopsidedness as between common and individual issues is even more pronounced here than in other product-liability cases. The common issues, such as what warnings Ethicon gave to the medical community and the public, are relatively straightforward. On the other hand, issues requiring plaintiff-specific discovery will include:

- ***Whether an Ethicon morcellator was used.*** The threshold issue of whether each Plaintiff was exposed to an Ethicon product *at all* is a significant one. Unlike many drug and device cases, where plaintiffs received a prescription and had it filled themselves, or received a device which they used on an ongoing basis, this case involves a device used by a surgeon, on one isolated occasion, likely while the plaintiff was under sedation. Plaintiffs will not know, and will not have records, of what morcellator (if any) was used on them. Discovery will need to be taken from doctors or hospitals.
- ***What warnings the treating physician received from Ethicon or other sources.*** Plaintiffs' failure-to-warn claims depend on what information each Plaintiff's surgeon had in his or her possession at the relevant time, whether from Ethicon's warnings or through independent channels. Although the warnings issued by Ethicon may represent common discovery, what each treating physician actually *saw*—especially from non-Ethicon sources—will require individualized discovery from each physician.
- ***Whether the treating physician would have chosen to use morcellation anyway.*** Even if a Plaintiff's physician was not sufficiently warned, there can be no recovery if that physician would have followed the same course of action despite a stronger warning. This will be a major issue in these cases: even now, prominent societies of physicians oppose restrictions on power morcellators, and believe any risk is outweighed by the safety benefits of minimally-invasive laparoscopic surgery over traditional open hysterectomies. Indeed, many surgeons continue to utilize power morcellators today. This suggests that many of Plaintiffs' physicians would have opted to use a morcellator,

⁴⁴ Many of the product-liability litigations for which the Panel denied centralization are far larger than this one. *See, e.g., Pain Pump*, 709 F. Supp. 2d at 1377 (102 actions and “more than 70 additional related actions”); *In re Asbestos and Asbestos Insulation Material Prods. Liab. Litig.*, 431 F. Supp. 906, 909-10 (J.P.M.L. 1977) (103 actions).

even if the warnings currently mandated by the FDA had been provided at the time of Plaintiffs' surgeries. Making this determination will require discovery from the physician(s) involved in each Plaintiff's surgery.

- ***Whether the risk was communicated to the plaintiff prior to surgery.*** The possibility that morcellation may spread or “upstage” undetected cancer has long been known in the medical community. Although some physicians may have made the judgment not to communicate this to their patients prior to 2014, others did communicate the possibility. Individual discovery will be required as to what each surgeon communicated to each Plaintiff about the risks. Similarly, for the plaintiffs who bring express warranty claims, discovery will be required into what (if anything) Ethicon communicated to each Plaintiff about its products and the attendant risks.
- ***Whether the patient's doctor performed a proper pre-operative examination to screen for uterine cancer.*** While not all cancers can reliably be detected prior to morcellation, many can—including most non-sarcoma uterine cancers. That many Plaintiffs in these cases have non-sarcoma cancers (*e.g.*, “low grade serious carcinoma”) raises doubts that their doctors performed a proper screening. This will require extensive discovery from each Plaintiff's surgeon(s) about events that may have transpired years ago.
- ***Whether the doctor used proper care during surgery itself.*** Other things equal, the risk of spreading malignant cells may be increased or decreased by actions taken by the physician during surgery, such as using proper morcellation technique; choosing to use a specimen bag; lavage (washing out) of the body cavity following surgery; etc. For this reason, too, each case will require extensive plaintiff-specific discovery.
- ***Whether the patient's cancer would have followed a similar or identical progression even without use of a morcellator.*** Whether morcellation of a malignant tumor potentially disseminates cancer cells depends on whose statistics one accepts. Meanwhile, uterine sarcoma is an aggressive form cancer that often progresses and causes death, “whether morcellation is used or not.”⁴⁵ Thus, “determining the degree to which power morcellation [actually] contributes to worsened outcomes ... is difficult.”⁴⁶ If the question is difficult on a population-wide basis, it will be next to impossible to determine whether *a specific patient* would have survived longer, or experienced less pain and suffering, absent morcellation. If it can be determined at all, it will require hypothetical modeling of how each specific Plaintiff's cancer would have unfolded absent morcellation. Since cancer is so variable, an accurate model (if such a thing is possible) will require discovery of each plaintiff's genetics, family history, course of treatment, and much more.
- ***When the plaintiff discovered, or should have discovered, her injury.*** In all but three states, the statute of limitations for personal injury claims is four years or shorter; in many states, it is three years, and in some states, it is only one or two years. The statute of limitations for wrongful death claims is usually even shorter—between one and three

⁴⁵ AAGL Statement to the FDA, *supra* note 9.

⁴⁶ *Id.*

years.⁴⁷ Here, Plaintiffs' surgeries took place as long ago as 2006. Thus, many of their claims are facially time-barred. If Plaintiffs live in states that employ a discovery rule, then the timeliness of their claims will ultimately turn on when the Plaintiff discovered her injury or could have discovered it employing reasonable diligence—another intensely plaintiff-specific issue. Moreover, accrual and tolling rules vary from state to state, and will necessitate state-specific legal analyses that do not lend themselves to centralization. *See Narconon*, 2015 U.S. Dist. LEXIS 14292, at *3.

Under these circumstances, “informal cooperation” as to the few and manageable overlapping issues “is both practicable and preferable.” *In re Ne. Contaminated Beef Prods. Liab. Litig.*, 856 F. Supp. 2d 1354, 1354-55 (J.P.M.L. 2012). Notably, Ethicon is represented by the undersigned counsel in all morcellator cases; the undersigned counsel is already coordinating discovery in all cases and will continue doing so. Moreover, a small handful of plaintiffs'-side firms have filed over half of the cases. (The movants' counsel, Weitz & Luxenberg, has filed six cases, and Motley Rice, Medley & Spivy, and Alonso Krangle have each filed two). *Cf. In re Boehringer Ingelheim Pharms., Inc.*, 763 F. Supp. 2d 1377, 1378-79 (J.P.M.L. 2011).

B. The Number Of Ethicon Actions Is Small, And Will Remain Small

As noted above, there are 21 power morcellator cases in the federal courts, and only 16 that name an Ethicon entity as a Defendant. Since the first lawsuit in March 2014, the rate of filing of new cases has been gradual and stable, with no noticeable acceleration. Two cases, moreover, have been resolved or dismissed. Plaintiffs assert that “additional actions are expected to be filed ... in the future.” (Movants' Br. at 2, 6.) However, the mere “allu[sion] to the prospect of additional actions ... not now before the Panel” is not a “persuasive reason for transfer.” *In re Zimmer, Inc. Centralign Hip Prosthesis Prods. Liab. Litig. (No. II)*, 366 F. Supp. 2d 1384, 1385 (J.P.M.L. 2005). Indeed, for reasons ignored by plaintiffs, the number of claims against Ethicon will remain low.

First, the number of women who might possibly have been injured in the manner alleged

⁴⁷*See* Matthiesen, Wickert & Lehrer, S.C., *Statutes of Limitations for All 50 States*, at <http://www.mwl-law.com/wp-content/uploads/2013/03/statute-of-limitations-for-all-50-states.pdf>.

here is necessarily small. Plaintiffs estimate that “650,000 women a year” undergo surgical myomectomy or hysterectomy. (Movants’ Br. at 3.) But that statistic is irrelevant. The relevant question is (1) how many women underwent the *laparoscopic* variety of those surgeries; (2) how many of *those* women were operated upon using Ethicon’s morcellators; (3) how many of *those* women had undetectable uterine sarcomas at the time of surgery; and (4) how many of *those* women had their prognosis measurably worsened as a result. Plaintiffs fail to provide any estimate of *that* number, even though they bear the burden on this motion. Indeed, over the past 18 months, Plaintiffs’ lawyers have invested millions of dollars advertising for morcellator cases, and this investment has yielded just 16 lawsuits against Ethicon.

Second, Ethicon directed physicians to stop using its products in April 2014, and voluntarily withdrew them from the market in July 2014. Thus, all (or virtually all) surgeries using the challenged Ethicon products—and, *a fortiori*, all (or virtually) all injuries allegedly caused by those products—occurred a year or more in the past. No new injuries have transpired since mid-2014 that might add to the number of cases against Ethicon.

Third, as noted above, the statute of limitations for personal injury claims is four years or less in all but three states, and is as short as one or two years in some states. The statutes of limitations for wrongful death are generally even shorter. Thus, most of the claims against Ethicon that might potentially be outstanding are time-barred, and will never be filed.

For these reasons—and contrary to plaintiffs’ speculation—the life span of this litigation and the number of claims is inherently bounded, and the substantial costs of centralization are not worthwhile. See *In re Power Balance, LLC, Mktg. & Sales Practices Litig.*, 777 F. Supp. 2d 1345, 1346 (J.P.M.L. 2011).

The only thing that might make the Plaintiffs’ prophecy of growth come true is if the Panel grants their motion. Creating an Ethicon morcellator MDL would accomplish little, other

than possibly multiplying an otherwise limited number of complaints. This is particularly true as it relates to alleged injuries other than cancer. The inclusion of non-cancer cases, such as the *Whitehead* lawsuit, in any consolidated proceeding would invite abuse and likely result in the filing of numerous, non-cancer cases collected as a result of a massive advertising campaign.

C. Some of the Long-Pending Cases Are Significantly Advanced in Discovery

Some of the lawsuits against Ethicon have been pending for more than a year. In some of the earlier-filed cases, discovery already has been exchanged, and some are about to enter scheduled mediations. Those cases stand in stark contrast to the new actions commenced by counsel for the movants on the eve of filing this petition. *See, e.g., Smith* (filed June 15, 2015); *Whitehead* (filed June 12, 2015). This disparity in case progress is another reason to deny consolidation. *See JP Morgan Chase & Co. Fair Labor Standards Act (FLSA) Litig.*, 729 F. Supp. 2d 1354, 1355 (J.P.M.L. 2010).

III. IN THE EVENT OF CENTRALIZATION, THE DISTRICT OF KANSAS AND THE SOUTHERN DISTRICT OF ILLINOIS ARE INAPPROPRIATE

Movants have requested centralization in the District of Kansas before the Hon. Kathryn H. Vratil. Plaintiff Timothy Schroeder has filed a response requesting centralization in the Southern District of Illinois before the Hon. David R. Herndon. In the event the Panel orders centralization over Ethicon's objections, neither of these fora is appropriate. This litigation has no meaningful connection to Kansas, and none whatsoever to the Southern District of Illinois.

First, only *one* manufacturer of power morcellators (Blue Endo) is based in Kansas, and that manufacturer is no longer named in any active case. (*Burkhardt*, which named Blue Endo as a defendant, was recently resolved.) Thus, no evidence is located in that District that relates to any Defendant in any pending case. Moreover, there is only a single action pending in Kansas (*Shafer*)—which, in any event, is not before Judge Vratil.

Second, it does not appear that any Defendant (and certainly no Ethicon party) is based in

the Southern District of Illinois, and there are no actions pending in the Southern District of Illinois. There is another substantial drawback to the Southern District of Illinois: that district is significantly overtaxed. It has the second-highest caseload per district judge of all districts nationwide: 2,026 per judgeship—more than three times the national average of 629.⁴⁸ Judge Herndon, moreover, is already overseeing two product liability MDLs.⁴⁹ As of May 15, 2015, Judge Herndon still was presiding over 3,378 cases between those two MDLs—the fifth-highest of any MDL judge in the country.⁵⁰ While the District of Kansas and Judge Vratil are less overburdened, Judge Vratil is also presiding over two active MDLs.⁵¹

CONCLUSION

For the reasons outlined above, the Panel should deny the motion to centralize.

Dated: July 10, 2015

Respectfully submitted,

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⁴⁸See United States Courts, *National Judicial Caseload Profile*, <http://www.uscourts.gov/file/14254/download?token=gJzW0jub>.

⁴⁹*In re Pradaxa Prods. Liab. Litig.* (MDL 2385); *In re Yasmin & Yaz Marketing, Sales Practices, and Prods. Liab. Litig.* (MDL 2100).

⁵⁰See MDL Statistics Report—Distribution of Pending MDL Dockets by District, http://www.jpml.uscourts.gov/sites/jpml/files/Pending_MDL_Dockets_By_District-October-15-2014.pdf.

⁵¹*In re Monsanto Co. Genetically-Engineered Wheat Litig.* (MDL 2473), *In re Motor Fuel Temperature Sales Practices Litig.* (MDL 1840).

APPENDIX

Manufacturer (Headquarters)	Device Name	Relevant Warnings in Labeling Pre-4/2014 (emphases added)
Ethicon (New Jersey)	Gynecare Morcellex Morcellex Sigma	The use of a tissue extraction bag is recommended for the morcellation of malignant tissue or tissue suspected of being malignant and for tissue that the physician considers to be potentially harmful when disseminated in a body cavity. As morcellation may affect endometrial pathologic examination, preoperative evaluation of the endometrium should be considered. Should malignancy be identified, use of the GYNECARE Morcellex Tissue Morcellator may lead to dissemination of malignant tissue.
Karl Storz (Germany)	Sawahle Rotocut G1	Direct use for electromechanical morcellation, resection, or tissue ablation is contraindicated in the case of malignant tumors and vascularized tissue. Note: A tissue extraction bag is advised for the morcellation of tumors or tissue suspected of being malignant and for tissue that the surgeon may consider to be harmful if disseminated in a body cavity.
Richard Wolf (Germany)	Morce Power Plus	Contraindicated for treatment of malignant tumors, treatment of vascularized tissue, and preparation of tissue. The use of a tissue extraction bag is recommended for the morcellation of tissue suspected of being malignant and for tissue the surgeon may consider to be potentially harmful when disseminated in the body cavity.
LiNA (Denmark)	LiNA Xcise	The LiNA Xcise should not be used in patients who have been diagnosed with a malignant condition.
Trokamed GmbH (Germany)	Trokamed Morcellator	Contraindicated for use in treatment of malignant tumors or for vascularized tissue.
Gyrus, subsidiary of Olympus (Japan)	ACMI PlasmaSord	Contraindicated when, in the best judgment of the physician, bipolar electrosurgical procedures would be contrary to the best interests of the patient. Do not use this device with tissue-removal bags.

PROOF OF SERVICE

I hereby certify that, on July 10, 2015, a copy of the foregoing BRIEF OF DEFENDANTS JOHNSON & JOHNSON, et al., IN OPPOSITION TO PLAINTIFFS' MOTION FOR TRANSFER was served by ECF and electronic mail on the following:

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District of Kansas (Kansas City), 2:14-cv-02633

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District of Maryland, 8:14-cv-03198

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Northern District of New York, 3:14-cv-01024

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Western District of New York (Rochester), 6:14-cv-06218

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District of Maryland, 8:14-cv-03198

District of New York, 3:14-cv-01024

District of South Carolina, 2:14-cv-04839

District of South Carolina, 3:15-cv-01585

Western District of Wisconsin, 3:15-cv-00242

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Eastern District of Pennsylvania (Philadelphia), 2:15-cv-00553
Eastern District of Pennsylvania (Philadelphia), 2:14-cv-07253
District of New Jersey (Trenton), 3:15-cv-03988

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Southern District of Florida, 0:15-cv-60566

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/s/ John D. Winter _____
John D. Winter

SCHEDULE OF ACTIONS

	CASE CAPTION	COURT	CASE NO.	JUDGE
1	<p>Robyn L. Barnett</p> <p>v.</p> <p>Karl Storz Endoscopy-America, Inc.; Karl Storz Endovision, Inc.; Karl Storz GMBH & Co. KG; Ethicon, Inc.; Ethicon Endo-Surgery, Inc.; Johnson & Johnson Services, Inc.; Johnson & Johnson; Vention Medical, Inc. (f/k/a The Medtech Group, Inc.); Vention Medical Acquisition Co.; Vention Medical Holdings, Inc.; ABC Corporations 1-10, the fictitious names for unknown companies and/or other business entities; John Does 1-10, the fictitious names for unknown companies and/or other business entities; and Jane Does 1-10, the fictitious names for unknown companies and/or other business entities</p>	Western District of Wisconsin (Madison)	3:15-cv-00242	Hon. Barbara B. Crabb
2	<p>Linda S. Bobletz</p> <p>v.</p> <p>Karl Storz Endoscopy-America, Inc.; Karl Storz Endovision, Inc.; Karl Storz GMBH & Co KG; and ABC Corporations 1-10 and John Does 1-10 and Jane Does 1-10.</p>	Northern District of New York (Syracuse)	3:14-cv-01024	Hon. Thomas J. McAvoy
3	<p>Bridget Caradori, Individually and as a Personal Representative of Patricia Daley, Deceased</p> <p>v.</p> <p>Ethicon Endo Surgery, Inc. d/b/a Ethicon Women's Health and Urology;</p>	District of Maryland (Greenbelt)	8:14-cv-03198	Hon. Theodore D. Chuang

	Karl Storz Endoscopy-America, Inc.; Karl Storz Endovision, Inc.; Karl Storz GMBH & Co. KG			
4	Eve C. Galambos and John T. Galambos, v. Ethicon, Inc.; Ethicon Endo-Surgery, Inc.; Johnson & Johnson Services; Johnson & Johnson; Vention Medical Group (f/k/a The Medtech Group, Inc.); Vention Medical Acquisition Co.; and Vention Medical Holdings, Inc.	Northern District of Georgia	1:15-cv- 01406	Hon. Orinda D. Evans
5	Romona Yvette Gourdine and Randolph Gourdine, Jr., v. Karl Storz Endoscopy-America, Inc.; Karl Storz Endovision, Inc.; and Karl Storz GMBH & Co. KG	District of South Carolina (Charleston)	2:14-cv- 04839	Hon. Richard M Gergel
6	Arthur T. Johnson, Individually and as Administrator for the Estate of Jonel Rollins Davis-Johnson, v. Ethicon, Inc.; Ethicon Women's Health & Urology Division of Ethicon, Inc.; Ethicon Endo-Surgery, Inc.; Johnson & Johnson Services; Johnson & Johnson; Vention Medical Acquisition Co.; Vention Medical Holdings, Inc.; HEI, Inc.; ABC Corporations, 1010, the fictitious names for unknown companies and/or other business entities; John Does, 1-10, the fictitious names for unknown corporations, association, or individuals; Jane Does, 1-10, the fictitious names for unknown corporations, associations, or individuals	Eastern District of Pennsylvania (Philadelphia)	2:15-cv- 00553	Hon. Joel H. Slomsky

7	<p>Evanthia Kotis and A.K., parent and minor daughter,</p> <p>v.</p> <p>Ethicon, Inc.; Ethicon Endo Surgery, Inc.; Ethicon Women's Health & Urology; Johnson & Johnson Services, Inc.; Johnson & Johnson</p>	Southern District of Florida (Ft. Lauderdale)	0:15-cv-60566	Hon. William P. Dimitrouleas
8	<p>George Leuzzi, as Administrator of the Estate of Brenda Leuzzi, deceased and George Leuzzi, individually,</p> <p>v.</p> <p>Ethicon, Inc.; Ethicon Endo Surgery, Inc.; Ethicon Women's Health & Urology; and ABC Corporations 1-10 and John Does 1-10 and Jane Does 1-10</p>	Western District of New York (Rochester)	6:14-cv-06218	Hon. Elizabeth A. Wolford
9	<p>Molly Patricia Minihan,</p> <p>v.</p> <p>Ethicon, Inc.; Ethicon Endo Surgery, Inc.; Ethicon Women's Health & Urology; FemRx, Inc.; Johnson & Johnson Services, Inc.; and Johnson & Johnson</p>	District of Colorado (Denver)	1:15-cv-00695	Hon. Wiley Y. Daniel
10	<p>Martha A. Montalvo-Ariri,</p> <p>v.</p> <p>Ethicon, Inc.</p>	Central District of California (Eastern Division – Riverside)	5:14-cv-01421	Hon. Virginia A. Phillips
11	<p>Lisa Nielsen and Kurt Nielsen</p> <p>v.</p> <p>Gyrus ACMI, LP; Gyrus ACMI, LLC; and Does 1-50</p>	Eastern District of California (Sacramento)	2:14-cv-02375	Hon. Dale A. Drozd
12	<p>John Ostrander, Individually and as the Representative of the Estate of Cynthia</p>	District of South	6:15-cv-	Hon. Mary G

	Ostrander, deceased, v. Ethicon, Inc.; Ethicon Women's Health and Urology; and Johnson & Johnson	Carolina (Greenville)	00516	Lewis
13	Andrea Phillips and Kevin Phillips, v. Ethicon, Inc.; Ethicon Endo Surgery, Inc.; Johnson & Johnson Services, Inc.; and Johnson & Johnson	District of South Carolina (Spartanburg)	7:15-cv-02114	Hon. Timothy M. Cain
14	Nidra L. Phillips, v. Ethicon Endo Surgery, Inc. d/b/a Ethicon Women's Health and Urology; Ethicon, Inc.; Ethicon, LLC; Ethicon, LTD; Johnson & Johnson; Johnson & Johnson Services, Inc.; and John Does 1-10 and Jane Does 1-10	Eastern District of Louisiana (New Orleans)	2:15-cv-01310	Hon. Carl Barbier
15	Sarah Salem-Robinson, and Alan A. Robinson, v. Richard Wolf GmbH; Richard Wolf Medical Instruments Corporation; and Does 1-50	Northern District of California (San Jose)	5:14-cv-02209	Hon. Edward J. Davila
16	Jennifer A. Sanders and Randall L. Sanders v. Ethicon, Inc.; Ethicon Endo Surgery, Inc.; Johnson & Johnson Services, Inc.; and Johnson & Johnson; Medtech Group, Inc.; and HEI, Inc.	Eastern District of Pennsylvania (Philadelphia)	2:14-cv-07253	Hon. Mark A. Kearney
17	Timothy Schroeder, individually and as husband of Cynthia Schroeder,	Middle District of Tennessee	3:14-cv-02389	Hon. Kevin H. Sharp

	<p>deceased,</p> <p>v.</p> <p>Ethicon Endo Surgery, Inc. d/b/a Ethicon Women's Health and Urology d/b/a Ethicon Johnson & Johnson</p>	(Nashville)		
18	<p>Terry L. Shafer, individually and as personal representative of the Estate of Carol Cecilla Merrill, deceased, and Doris Simpson, individually,</p> <p>v.</p> <p>Ethicon, Inc.; Ethicon Endo Surgery, Inc.; Ethicon Women's Health & Urology; and John Does 1-10 and Jane Does 1-10</p>	District of Kansas (Kansas City)	2:14-cv- 02633	Hon. John W. Lungstrum
19	<p>Ruthann Smith and Daryl Smith,</p> <p>v.</p> <p>Ethicon, Inc.; Ethicon Endo-Surgery, Inc.; Johnson & Johnson Services, Inc.; Johnson & Johnson; Vention Medical, Inc. (f/k/a The Medtech Group, Inc.); Vention Medical Acquisition Co.; Vention Medical Holdings, Inc.; ABC Corporations 1-10, the fictitious names for unknown companies and/or other business entities; John Does 1-10, the fictitious names for unknown companies and/or other business entities; and Jane Does 1-10, the fictitious names for unknown companies and/or other business entities</p>	District of New Jersey (Trenton)	3:15-cv- 03988	Hon. Michael A. Shipp
20	<p>Michael Watkins, individually and as personal representative for the Estate of Enid Watkins, deceased,</p> <p>v.</p> <p>Karl Storz Endoscopy-America, Inc.; Karl Storz Endovision, Inc.; Karl Storz</p>	District of South Carolina (Columbia)	3:15-cv- 01585	Hon. Richard M. Gergel

	GMBH & Co. KG			
21	<p>Carla Whitehead and Joe Whitehead,</p> <p>v.</p> <p>Ethicon, Inc.; Ethicon Endo-Surgery, Inc.; Johnson & Johnson Services, Inc.; Johnson & Johnson; Vention Medical, Inc. (f/k/a The Medtech Group, Inc.); Vention Medical Acquisition Co.; Vention Medical Holdings, Inc.; ABC Corporations 1-10, the fictitious names for unknown companies and/or other business entities; John Does 1-10, the fictitious names for unknown companies and/or other business entities; and Jane Does 1-10, the fictitious names for unknown companies and/or other business entities</p>	District of New Jersey (Trenton)	3:15-cv-03980	Hon. Michael A. Shipp

BEFORE THE JUDICIAL PANEL ON MULTIDISTRICT LITIGATION

**IN RE: POWER MORCELLATOR
PRODUCTS LIABILITY LITIGATION**

MDL No. 2652

NOTICE OF POTENTIAL TAG-ALONG ACTION

In accordance with Rule 6.2(d) of the Rules of Procedure for the Judicial Panel on Multidistrict Litigation Defendants Johnson & Johnson; Johnson & Johnson Services; Ethicon, Inc.; and Ethicon Endo-Surgery, Inc. write to notify the Panel of the potential tag along action listed on the attached Schedule of Action.

A docket sheet and complaint is attached.

July 10, 2015

/s/ John D. Winter

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BEFORE THE JUDICIAL PANEL ON MULTIDISTRICT LITIGATION

**IN RE: POWER MORCELLATOR
PRODUCTS LIABILITY LITIGATION**

MDL No. 2652

NOTICE OF POTENTIAL TAG-ALONG ACTION

	CASE CAPTION	COURT	CASE NO.	JUDGE
1	Martha A. Montalvo-Ariri, v. Ethicon, Inc.	Central District of California (Eastern Division – Riverside)	5:14-cv- 01421	Hon. Virginia A. Phillips

**UNITED STATES DISTRICT COURT for the CENTRAL DISTRICT OF
CALIFORNIA (Eastern Division - Riverside)
CIVIL DOCKET FOR CASE #: 5:14-cv-01421-VAP-SP**

Martha A Montalvo-Ariri v. Johnson & Johnson Inc
Assigned to: Judge Virginia A. Phillips
Referred to: Magistrate Judge Sheri Pym
Demand: \$75,000
Cause: 28:1332 Diversity-Personal Injury

Date Filed: 07/11/2014
Jury Demand: Both
Nature of Suit: 365 Personal Inj. Prod.
Liability
Jurisdiction: Federal Question

Plaintiff

Martha A Montalvo-Ariri

represented by **Derek S Raynes**

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V.

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TERMINATED: 04/03/2015

Date Filed	#	Docket Text
07/11/2014	1	COMPLAINT against defendant Johnson & Johnson Inc. Case assigned to Judge Virginia A. Phillips for all further proceedings. Discovery referred to Magistrate Judge Sheri Pym.(Filing fee \$ 400.00 paid) Jury Demanded., filed by plaintiff Martha A Montalvo-Ariri. (mrgo) (vp). (Entered: 07/15/2014)
07/11/2014	2	21 DAY Summons Issued re Complaint - (Discovery), 1 as to defendant Johnson & Johnson Inc. (mrgo) (Entered: 07/15/2014)
07/11/2014	3	NOTICE of Interested Parties filed by plaintiff Martha A Montalvo-Ariri, (mrgo) (vp). (Entered: 07/15/2014)
07/11/2014	4	NOTICE OF ASSIGNMENT to District Judge Virginia A. Phillips and Magistrate Judge Sheri Pym. (mrgo) (Entered: 07/15/2014)
07/11/2014	5	NOTICE TO PARTIES OF COURT-DIRECTED ADR PROGRAM filed. (mrgo) (Entered: 07/15/2014)
07/15/2014	6	STANDING ORDER by Judge Virginia A. Phillips. (See document for specifics) (mrgo) (Entered: 07/15/2014)
07/25/2014	7	CLERKS E-MAIL RE LOCAL RULE 3-2 TO COUNSEL on 7/25/2014 addressed to jraynes@rayneslaw.net. COURT REQUIRES YOUR IMMEDIATE RESPONSE. Pursuant to Local Rule 3-2, you are required to e-mail, within 24 hours of filing, a Filed stamped copy of your complaint and other civil case initiating documents, in PDF format to the Court. To date, we have not received the PDF images of your filing. Please do so within 24 hours or this matter will be referred to the Judge for further proceedings. (ad) (Entered: 07/25/2014)
09/10/2014	8	STIPULATION Extending Time to Answer the complaint as to Johnson & Johnson Inc answer now due 9/29/2014, re Summons Issued 2 , Complaint - (Discovery), 1 filed by defendant Johnson & Johnson Inc.(Attorney Rebecca Winder Gutierrez added to party Johnson & Johnson Inc(pty:df))(Gutierrez, Rebecca) (Entered: 09/10/2014)
09/18/2014	9	PROOF OF SERVICE Executed by Plaintiff Martha A Montalvo-Ariri, upon Defendant Johnson & Johnson Inc served on 8/25/2014, answer due 9/15/2014. Service of the Summons and Complaint were executed upon Jocelyn Hester, Paralegal in compliance with California Code of Civil Procedure by substituted service on a domestic corporation, unincorporated association, or public entity and by also mailing a copy. Original Summons NOT returned. (ad) (Entered: 09/19/2014)
09/29/2014	10	Second STIPULATION Extending Time to Answer the complaint as to Johnson & Johnson Inc answer now due 10/9/2014, re Complaint - (Discovery), 1 filed by defendant Johnson & Johnson Inc.(Gutierrez, Rebecca) (Entered: 09/29/2014)
10/01/2014	11	FIRST AMENDED COMPLAINT filed by plaintiff Martha A Montalvo-Ariri against Defendant Ethicon Inc; Party Johnson & Johnson Inc terminated amending Complaint - (Discovery) 1 . (iva) (iva). (Entered: 10/14/2014)

10/01/2014	12	21 DAY Summons Issued re Amended Complaint 11 as to Defendant Ethicon Inc. (iva) (Entered: 10/14/2014)
02/04/2015	13	MINUTE ORDER IN CHAMBERS ORDER TO SHOW CAUSE RE: FAILURE TO PROSECUTE by Judge Virginia A. Phillips.(Response to Order to Show Cause due by 2/16/2015.) (mrgo) (Entered: 02/05/2015)
02/12/2015	14	PROOF OF SERVICE filed by plaintiff Martha A Montalvo-Ariri, <i>ETHICON, INC.</i> served on 10-09-2014. (Attachments: # 1 Declaration re: OSC RE: Failure to Prosecute, # 2 Declaration re: OSC RE: Failure to Prosecute)(Raynes, Jeffrey) (Entered: 02/12/2015)
02/20/2015	15	MINUTE ORDER IN CHAMBERS by Judge Virginia A. Phillips DISCHARGING ORDER TO SHOW CAUSE 13 : On February 12, 2015, counsel for Plaintiff filed a Response to the OSC. (Doc. No. 14.) In the Response, counsel states that a proof of service was not filed because defense counsel had acknowledged receipt of the First Amended Complaint and it was his understanding a responsive pleading was forthcoming. For this reason, he believed it would be unnecessary to file a proof of service. Based on counsel's representations, the Court DISCHARGES the OSC. IT IS SO ORDERED. (ad) (Entered: 02/20/2015)
02/26/2015	16	ANSWER to Amended Complaint 11 with JURY DEMAND filed by defendant Ethicon Inc.(Attorney Rebecca Winder Gutierrez added to party Ethicon Inc(pty:df))(Gutierrez, Rebecca) (Entered: 02/26/2015)
02/26/2015	17	ANSWER to Amended Complaint 11 filed by defendant Ethicon Inc.(Gutierrez, Rebecca) (Entered: 02/26/2015)
02/26/2015	20	NOTICE TO FILER OF DEFICIENCIES in Electronically Filed Documents RE: Answer to Complaint (Discovery) 17 . The following error(s) was found: Local Rule 7.1-1 No Notice of Interested Parties and/or no copies. In response to this notice the court may order (1) an amended or correct document to be filed (2) the document stricken or (3) take other action as the court deems appropriate. You need not take any action in response to this notice unless and until the court directs you to do so. (la) (Entered: 03/02/2015)
03/02/2015	18	ORDER SETTING SCHEDULING CONFERENCE by Judge Virginia A. Phillips. Scheduling Conference set for 4/20/2015 at 01:30 PM before Judge Virginia A. Phillips. (wro) (Entered: 03/02/2015)
03/02/2015	19	RESPONSE BY THE COURT TO NOTICE TO FILER OF DEFICIENCIES IN ELECTRONICALLY FILED DOCUMENTS RE: Answer to Complaint (Discovery) 17 by Clerk of Court. Certification and Notice of Interested Parties to be filed no later than March 4, 2015. (iva) (Entered: 03/02/2015)
03/03/2015	21	<i>Defendant Ethicon, Inc.</i> 's NOTICE of Interested Parties filed by Defendant Ethicon Inc, identifying Johnson & Johnson. (Gutierrez, Rebecca) (Entered: 03/03/2015)
03/11/2015	22	Notice of Appearance or Withdrawal of Counsel: for attorney Jeffrey Stuart Raynes

		counsel for Plaintiff Martha A Montalvo-Ariri. Adding Douglas F. Welebir as attorney as counsel of record for Martha A. Montalvo-Ariri for the reason indicated in the G-123 Notice. Filed by Plaintiff Martha A. Montalvo-Ariri. (Raynes, Jeffrey) (Entered: 03/11/2015)
03/23/2015	23	(Welebir, Douglas) (Entered: 03/23/2015)
03/25/2015	24	NOTICE TO FILER OF DEFICIENCIES in Electronically Filed Documents RE: Miscellaneous Document 23 . The following error(s) were found: Incorrect event selected.Other error(s) with document(s) are specified below The correct event is: Association of Counsel. 1) The incorrect was used, please re-file using correct event referenced above 2) Docket entry is blank. In response to this notice the court may order (1) an amended or correct document to be filed (2) the document stricken or (3) take other action as the court deems appropriate. You need not take any action in response to this notice unless and until the court directs you to do so. (iva) (Entered: 03/25/2015)
03/25/2015	25	NOTICE of Association of Counsel associating attorney Douglas F. Welebir on behalf of Plaintiff Martha A Montalvo-Ariri. Filed by Plaintiff Martha A Montalvo-Ariri (Welebir, Douglas) (Entered: 03/25/2015)
04/02/2015	26	Notice of Appearance or Withdrawal of Counsel: for attorney Monee Takla Hanna counsel for Defendant Ethicon Inc. Adding Monee Takla Hanna as attorney as counsel of record for Ethicon, Inc. for the reason indicated in the G-123 Notice. Filed by Defendant Ethicon, Inc.. (Attorney Monee Takla Hanna added to party Ethicon Inc(pty:df))(Hanna, Monee) (Entered: 04/02/2015)
04/03/2015	27	Notice of Appearance or Withdrawal of Counsel: for attorney Monee Takla Hanna counsel for Defendant Ethicon Inc. Rebecca Winder Gutierrez is no longer attorney of record for the aforementioned party in this case for the reason indicated in the G-123 Notice. Filed by Defendant Ethicon, Inc.. (Hanna, Monee) (Entered: 04/03/2015)
04/06/2015	28	STIPULATION to Continue Scheduling Conference from April 20, 2015 to June 1, 2015, STIPULATION for Hearing filed by Plaintiff Martha A Montalvo-Ariri. (Attachments: # 1 Proposed Order)(Welebir, Douglas) (Entered: 04/06/2015)
04/08/2015	29	ORDER ON STIPULATION TO CONTINUE SCHEDULING CONFERENCE by Judge Virginia A. Phillips, re Stipulation for Hearing 28 .(Scheduling Conference continued to 6/1/2015 at 01:30 PM before Judge Virginia A. Phillips.) (mrgo) (Entered: 04/09/2015)
05/22/2015	30	JOINT REPORT Rule 26(f) Discovery Plan <i>with Exhibit A</i> ; estimated length of trial 12 days, filed by Defendant Ethicon Inc.. (Attachments: # 1 ADR Selection Form)(Benedict, Mollie) (Entered: 05/22/2015)
05/28/2015	31	APPLICATION for attorney James F. Murdica to Appear Pro Hac Vice(PHV Fee of \$325 receipt number 0973-15800942 paid.) filed by Defendant Ethicon Inc. (Attachments: # 1 Proposed Order)(Hanna, Monee) (Entered: 05/28/2015)
06/01/2015	32	MINUTES OF Scheduling Conference held before Judge Virginia A. Phillips. Last date to conduct settlement conference is 10/1/2015. Telephonic Conference set for 6/8/2015

		at 02:45 PM before Judge Virginia A. Phillips. Plaintiff's counsel shall initiate the telephonic conference, by calling Chambers at 951-328-4420, at the specified date and time. Court Reporter: Phyllis Preston. (mrgo) (Entered: 06/03/2015)
06/01/2015	33	CIVIL TRIAL SCHEDULING ORDER by Judge Virginia A. Phillips.(Discovery cut-off 2/29/2016. Motions due by 5/9/2016. Jury Trial set for 7/12/2016 at 08:30 AM before Judge Virginia A. Phillips. Pretrial Conference set for 6/27/2016 at 02:30 PM before Judge Virginia A. Phillips.) (mrgo) (Entered: 06/03/2015)
06/01/2015	34	ORDER by Judge Virginia A. Phillips: granting 31 Application to Appear Pro Hac Vice by Attorney James F Murdica on behalf of defendant Ethicon Inc, designating Monee T Hanna as local counsel. (mrgo) (Entered: 06/03/2015)
06/05/2015	35	SCHEDULING NOTICE: Telephonic Conference previously set for June 8, 2015 at 2:45 p.m., is advanced to 9:00 a.m., by Judge Virginia A. Phillips. THERE IS NO PDF DOCUMENT ASSOCIATED WITH THIS ENTRY. (wro) TEXT ONLY ENTRY (Entered: 06/05/2015)
06/08/2015	36	MINUTES OF Telephonic Status Conference held before Judge Virginia A. Phillips. Court Reporter: Phyllis Preston. (iva) (Entered: 06/12/2015)
07/02/2015	37	<i>Statement of Fact of Death of Plaintiff</i> (Welebir, Douglas) (Entered: 07/02/2015)

PACER Service Center			
Transaction Receipt			
07/10/2015 07:04:34			
PACER Login:	pb0373:2611633:0	Client Code:	J5410-2813-2180
Description:	Docket Report	Search Criteria:	5:14-cv-01421-VAP-SP End date: 7/10/2015
Billable Pages:	5	Cost:	0.50

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2014 OCT -1 PM 1:10

CLERK U.S. DISTRICT COURT
CENTRAL DIST. OF CALIF.
RIVERSIDE

BY: _____

8 Attorney for Plaintiff, MARTHA A. MONTALVO-ARIRI

9 UNITED STATES DISTRICT COURT
10 CENTRAL DISTRICT OF CALIFORNIA

11 MARTHA A. MONTALVO-ARIRI,

12 Plaintiff,

13 v.

14 ETHICON, INC.,

15 Defendants.
16
17

Case No.: EDCV14-01421 (VAP) (SPX)

Judge Assigned:
Complaint Filed: July 11, 2014

FIRST AMENDED COMPLAINT FOR DAMAGES

18
19 Plaintiff alleges:

20 **GENERAL ALLEGATIONS**

21 1. Plaintiff is informed and believes and upon such belief alleges that at all times
22 herein mentioned, Defendant ETHICON, INC., was and is a New Jersey Corporation with it
23 principal place of business in Bridgewater, New Jersey. Defendant ETHICON, INC. is, and
24 was at all times relevant herein, doing business in and/or having directed its activities in
25 California, and specifically within this judicial district.

26 2. At all times herein mentioned Plaintiff was and continues to be a resident of the
27 City of Riverside, County of Riverside, State of California.

28 ///

1 3. There is complete diversity of citizenship between the parties and the amount in
2 controversy exceeds the sum of \$75,000.00.

3 4. At all times herein mentioned Defendant was engaged in the business of
4 designing, manufacturing, testing, assembling, installing, distributing, merchandising,
5 recommending, advertising and promoting the Johnson & Johnson Power Morcellator surgical
6 instrument for the removal of masses of tissue during laparoscopic surgery.

7 5. On or about July 9, 2012, Defendant's Morcellation surgical device was used
8 upon Plaintiff, MARTHA A. MONTALVO-ARIRI at Kaiser Permanente located in Riverside,
9 California during a Morcellator-assisted laparoscopic hysterectomy.

10 6. The hysterectomy was performed secondary to the presence of intrauterine
11 fibroid tumors. The surgical pathology results of July 20, 2012 revealed leiomyosarcoma.

12 I

13 **FIRST CAUSE OF ACTION**

14 **(Strict Product Liability)**

15 7. Plaintiff hereby incorporates by reference each and every paragraph of the
16 General Allegations as though fully set forth herein.

17 8. Plaintiff is informed and believes and thereupon alleges that the Defendant
18 designed, manufactured, tested, assembled, installed, marketed, advertised, distributed and
19 sold the product and its component parts as set forth herein.

20 9. The Power Morcellation device is defective in design, manufacture and testing in
21 that the product is associated with the spreading of cellular material of the morcellated tissue.
22 It was well-known that this may result in the spread and dissemination of cancerous tissue
23 which is precisely what happened to Plaintiff, MARTHA A. MONTALVO-ARIRI.

24 10. With respect to the product and its component parts identified above, it was
25 foreseeable by Defendant that said users would use the product without inspection for defects.

26 11. At no time prior to the procedure was Plaintiff advised by her surgeon that a
27 Power Morcellator would be used. At no time prior to the surgery was it explained to Plaintiff

28 ///

1 the purpose and risk of a Power Morcellation device. As a result of using a Power Morcellator,
2 additional risks were unnecessarily incurred.

3 12. On April 17, 2014, the Federal Food & Drug Administration issued a safety
4 communication regarding the use of laparoscopic power morcellation for removal of the uterus
5 or uterine fibroids due to the risk of spreading cancerous tissue.

6 13. As a legal result of the aforesaid defects in the product, Plaintiff suffered serious
7 physical injuries, including but not limited to leiomyosarcoma, causing great pain and suffering.

8 **II**

9 **SECOND CAUSE OF ACTION**

10 **(Negligent Product Liability)**

11 14. Plaintiff hereby incorporates each and every paragraph of the General
12 Allegations and paragraphs 8 through 13 of the First Cause of Action as though fully set forth
13 herein.

14 15. Defendant owed a duty of care to Plaintiff to manufacture, assemble, design,
15 test, research, market, advertise and distribute the product free of defects. Defendant
16 breached its duty of care to Plaintiff in that they negligently designed, manufactured,
17 researched, tested, marketed, assembled, installed, advertised, distributed and sold the
18 product.

19 16. As a legal result of the aforesaid defects in the product, Plaintiff suffered serious
20 physical injuries, including but not limited to leiomyosarcoma, causing great pain and suffering.

21 17. As a further direct and proximate result of the aforesaid defects in the product,
22 Plaintiff has employed medical practitioners and has incurred and will continue to incur medical
23 expenses.

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III

**THIRD CAUSE OF ACTION
(Breach of Duty to Warn)**

18. Plaintiff hereby incorporates each and every paragraph of the General Allegations, paragraphs 8 through 13 of the First Cause of Action and paragraphs 15 through 17 of the Second Cause of Action as though fully set forth herein.

19. The product was defective in that Defendant failed to adequately warn, instruct, label, advise or inform users of the product of the inherent dangers embodied in said product, in that the product could spread cancerous tissue, fail, deform, shift, migrate, disintegrate, bend, weaken, break and/or fracture inside a person's body during the use for which it was intended.

20. The warning that accompanied the sale of the product, and the instructions issued thereto was defective, inappropriate and inadequate in that they did not warn of the known dangers in the use of the product, nor did they instruct users of the product as to the manner in which said product should be safely used.

21. As a legal result of the aforesaid defects in the product, Plaintiff suffered serious physical injuries, including but not limited to leiomyosarcoma, causing great pain and suffering.

22. As a further direct and proximate result of the aforesaid defects in the product, Plaintiff has employed medical practitioners and has incurred and will continue to incur medical expenses.

IV

**FOURTH CAUSE OF ACTION
(Breach of Warranty)**

23. Plaintiff hereby incorporates each and every paragraph of the General Allegations, paragraphs 8 through 13 of the First Cause of Action, paragraphs 15 through 17 of the Second Cause of Action and paragraphs 19 through 22 of the Third Cause of Action as though fully set forth herein.

///

1 24. At all times herein mentioned, the Defendant expressly and impliedly warranted
2 the product to be free from material defects, including, but not limited to, defects in design,
3 manufacture, testing, material selection, assembly and installation.

4 25. Defendant expressly and impliedly warranted to purchasers and users of the
5 product that the product was free from defects and was safe for its intended use.

6 26. Plaintiff relied to Plaintiff's detriment upon the warranties and representations of
7 the Defendant.

8 27. Defendant breached its expressed and implied warranty in that the product was
9 not safe for its intended use, was defective and was not merchantable.

10 28. As a legal result of said breach of the expressed and implied warranties of the
11 product, Plaintiff suffered serious physical injuries, including but not limited to leiomyosarcoma,
12 causing great pain and suffering.

13 29. As a further direct and proximate result of said breach of the expressed and
14 implied warranties of the product, Plaintiff has employed medical practitioners and has incurred
15 and will continue to incur medical expenses.

16 **V**

17 **FIFTH CAUSE OF ACTION**

18 **(General Negligence)**

19 30. Plaintiff hereby incorporates each and every paragraph of the General
20 Allegations, paragraphs 8 through 13 of the First Cause of Action, paragraphs 15 through 17 of
21 the Second Cause of Action, paragraphs 19 through 22 of the Third Cause of Action and
22 paragraphs 24 through 29 of the Fourth Cause of Action as though fully set forth herein.

23 31. At all times herein mentioned, Defendant was negligent in performing the acts, or
24 in omitting certain necessary acts, with respect to the product as set forth herein.

25 32. As a legal result of said negligence, Plaintiff suffered serious physical injuries,
26 including but not limited to leiomyosarcoma, causing great pain and suffering.

27 33. As a further direct and proximate result of said breach of the expressed and
28 implied warranties of the product, Plaintiff has employed medical practitioners and has incurred

1 and will continue to incur medical practitioners and has incurred and will continue to incur
2 medical practitioners and has incurred and will continue to incur medical expenses.

3
4 **WHEREFORE**, Plaintiff prays for judgment against Defendant as follows:


- 5 1. For general damages according to proof, in an amount exceeding this Court's
- 6 jurisdictional minimum;
- 7 2. For prejudgment interest to the extent allowed by law;
- 8 3. For special damages, including past and future medical expenses;
- 9 4. For loss of income and earning capacity according to proof;
- 10 5. For costs of suit incurred herein; and
- 11 6. For such other and further relief as the Court deems appropriate.

12 **JURY DEMAND**

13 Plaintiff demands a trial by jury.

14
15 Dated: September 29, 2014

RAYNES | ERICKSON

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18 By: 
19 _____
DEREK S. RAYNES
20 Attorney for Plaintiff
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