IN THE UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF TEXAS
HOUSTON DIVISION

YOLANDA O. CARVAJAL, Plaintiff, v. MEDTRONIC, INC., and COVIDIEN, L.P., Defendants.	NO. 4:20-cv-347 COMPLAINT AND DEMAND FOR JURY TRIAL

PLAINTIFF'S COMPLAINT

COMES NOW, Yolanda O. Carvajal, Plaintiff, (hereinafter referred to as "Plaintiff" or "Carvajal") complaining of Defendants, Medtronic, Inc., and Covidien, L.P., (hereinafter referred to as "Defendants"), and would respectfully show unto the Court as follows:

I. INTRODUCTION

1.1 Defendants, and each of them, designed, manufactured, and marketed without proper notice, defective Endo GIA surgical staplers. The FDA recently reported that during the time period from January 1, 2011 through December 31, 2018 it received close to 110,000 reports related to issues with surgical staplers. Of these, 412 were submitted as deaths, 11,181 were submitted as serious injuries, and 98,404 were submitted as malfunction.[a] The numbers reported by the FDA were largely hidden from public view because the majority of the reports were not submitted to the Manufacturer and User Facility Device Experience, or MAUDE, a publicly-accessible database run by the FDA, but instead, were submitted to the ASR Program. The ASR program enabled manufacturers of certain device types to submit quarterly summary

[a] FDA Executive Summary Prepared for the May 30, 2019 Meeting of the General and Plastic Surgery Devices Panel Reclassification of Surgical Staplers for Internal Use: https://www.fda.gov/media/126211/download

reports of specific well known and well characterized events in lieu of individual reports of each such event that tracks medical device failures. Defendants, and each of them, used the ASR program to keep the scope of injuries related to surgical staplers hidden from surgeons and their patients.

1.2 Plaintiff Yolanda O. Carvajal was injured when a surgical stapler, designed, manufactured, and marketed by Defendants, malfunctioned during her October 19, 2018 surgery, resulting in a leak in her bowel that had to be repaired through a series of subsequent surgeries.

II. PARTIES

2.1. At all times material, Plaintiff Yolanda O. Carvajal was and is an individual residing in the State of Texas.

2.2 Defendant Medtronic, Inc., is a Minnesota corporation authorized to do business in the state of Texas and may be served with process by serving its registered agent, Corporation Service Company d/b/a CSC-Lawyers Incorporating Service Company, 211 E. 7th Street, Suite 620, Austin, Texas, 78701-3136.

2.3 Defendant Covidien, L.P., is a foreign limited partnership authorized to do business in the state of Texas and may be served with process by serving its registered agent, Corporation Service Company d/b/a CSC-Lawyers Incorporating Service Company, 211 E. 7th Street, Suite 620, Austin, Texas, 78701-3136.

III. JURISDICTION AND VENUE

3.1 The Court has jurisdiction over this civil action pursuant to 28 U.S.C. § 1332(a) inasmuch as the amount in controversy exceeds $75,000, exclusive of interests and costs, and Plaintiff is a citizen of a different state than one or more of Defendants.

3.2 Venue in this district for pretrial proceedings in these civil actions is proper under 28 U.S.C. § 1391, inasmuch as a substantial part of the events or omissions giving rise to the claim occurred in this district.

3.3 At all times material, Medtronic, Inc., has been in the business of the researching, developing, selling, and marketing of surgical staplers and staples. At all times material, Medtronic, Inc., has been in the business of and did design, research, manufacture, test, advertise, promote, market, sell, and distribute the surgical stapler and staples that make the basis of this suit in the State of Texas. This Court has personal jurisdiction over Medtronic, Inc., because Defendant has submitted itself to the jurisdiction of this Court by engaging in conduct set forth in this Complaint in the State of Texas.

3.4 At all times material, Covidien, L.P., has been in the business of the researching, developing, selling, and marketing of surgical staplers and staples. At all times material, Covidien, L.P., has been in the business of and did design, research, manufacture, test, advertise, promote, market, sell, and distribute the surgical stapler and staples that make the basis of this suit in the State of Texas. This Court has personal jurisdiction over Covidien, L.P., because Defendant has submitted itself to the jurisdiction of this Court by engaging in conduct set forth in this Complaint in the State of Texas.

3.5 At all times material, Defendant Medtronic, Inc., has been the parent company of Covidien, Ltd., and, as part of its business, Medtronic, Inc., and its "family of companies" has been involved in the research, development, sales, and marketing of surgical staplers and staples. At all times material, Defendant Medtronic, Inc., has been in the business of and did design, research, manufacture, test, advertise, promote, market, sell, and distribute the surgical stapler and staples that make the basis of this suit in the State of Texas. This Court has personal jurisdiction over Defendant Medtronic, Inc., because Defendant has submitted itself to the jurisdiction of this Court by engaging in conduct set forth in this Complaint in the State of Texas.

3.6 In January 2015, Medtronic acquired Covidien. From that point forward, Medtronic has been responsible for the actions of Covidien, and exercised control over

Covidien's functions specific to the oversight of compliance with applicable safety standards relating to and including the Covidien Product sold in the United States. In such capacity, Medtronic committed or allowed to be committed tortious and wrongful acts, including the violation of numerous safety standards relating to device manufacturing, quality assurance/control, and conformance with design and manufacturing specifications. Medtronic's misfeasance and malfeasance caused Plaintiff to suffer injury and damages.

3.7 Covidien and Medtronic (collectively referred to as "Defendants") are individually, jointly, and severally liable to Plaintiff for damages suffered by Plaintiff arising from their design, manufacturing, marketing, labeling, distribution, sale, and placement of the defective Covidien Product at issue in this suit. All acts were effectuated directly and indirectly through Defendants' respective agents, servants, employees, and/or owners, acting within the course and scope of their representative agencies, services, employments, and/or ownership.

3.8 Defendants are vicariously liable for the acts and/or omissions of their employees and/or agents, who were at all times relevant acting on Defendants' behalf and within the scope of their employment or agency with Defendants.

IV. FACTS

4.1 On October 19, 2018, Dr. Nestor F. Esnaola began to perform laparoscopic right hemicolectomy surgery to remove possible malignant tissue from Plaintiff's ascending colon. During the surgery, Dr. Esnaola encountered some difficulties accessing the possible malignant tissue in Plaintiff's colon which resulted in Dr. Esnaola electing to convert to an open procedure because he did not feel that he could safely mobilize the hepatic flexure, right colon, cecum or terminal ileum from the retroperitoneum. In the Operative Report, Dr. Esnaola noted, "A functional end-to-end, side-to-side ileocolonic anastomosis was then performed using a single fire of the Endo 60 mm blue load stapler." The intraoperative and postoperative course was

otherwise unremarkable, and Plaintiff was discharged to a skilled nursing facility on October 28, 2018 for further rehabilitation.

4.2 On October 31, 2018, Plaintiff presented to the Houston Methodist Emergency Care Center in The Woodlands with complaints of progressive fatigue and anorexia. A CT scan of Plaintiff's abdomen was performed and revealed 3 large intra-abdominal fluid collections in the right anterior abdomen, right retroperitoneum, and pelvis. As a result, Plaintiff was emergently transported via ambulance to Houston Methodist Hospital where she was resuscitated, placed on broad-spectrum IV antibiotics, and underwent 3 CT-guided percutaneous drain placements.

4.3 After undergoing the drain placements, Plaintiff's condition improved, but a follow up CT scan performed on November 3, 2018 revealed persistent intra-abdominal fluid collections in her right anterior abdomen near the staple line indicating an anastomotic leak.

4.4 Since Plaintiff failed non-surgical management, her medical providers elected to perform an exploratory laparotomy for an abdominal washout and source control. The exploratory laparotomy was performed on November 5, 2018 and during the surgery it was determined that she needed to undergo placement of an ileocostomy tube and intraabdominal drains as a result of the large amount of fluid present in her abdomen. It was also discovered during the surgery that the source of the leak was a 0.5-1 cm opening in the lateral aspect of the anastomosis where the staples that were placed during her hemicolectomy surgery appeared to be disrupted. The operative report stated in part, "1 cm disruption of the stapled common enterotomy anastomosis (due to an apparent staple malfunction)."

4.5 Ms. Carvajal underwent a prolonged postoperative course which required long term antibiotic treatment and placement of intraabdominal drains to obtain adequate source

control. This included Ms. Carvajal undergoing a placement of an enteral tube on December 31, 2018 after the ileocostomy tube became dislodged. On January 2, 2019, Plaintiff underwent a failed colonscopic attempt to clip the anastomotic leak site.

4.6 Plaintiff underwent five more days of antibiotic treatment and a final CT scan which showed the source control of the leak and she was discharged from Houston Methodist Hospital on January 9, 2019 with two percutaneous drains for continued fluid drainage and a gastronomy-jejunostomy tube.

4.7 Plaintiff was admitted to Houston Methodist Hospital again on January 14, 2019 with a fever and change in her drain output, from purulent to fecaloid. A CT scan was performed which showed the gastronomy-jejunostomy tube that had been placed into her anastomic leak had become dislodged and as a result she underwent exchange of jejunostomy tube into the ileocolic anastomotic leak and a replacement of the percutaneous drain in the anterior aspect of the anastomosis. Plaintiff completed inpatient antibiotic treatment and her fever subsided and she was discharged on January 23, 2019 after receiving instructions on how to flush and care for her drains. Home health care was also arranged to assist her in her recovery prior to discharge.

4.8 Plaintiff returned to Houston Methodist Hospital on February 4, 2019 and underwent an ileocostomy tube study which showed no radiologic evidence of an ongoing leak in her abdomen.

4.9 Plaintiff returned to Houston Methodist Hospital on March 27, 2019 and her ileocostomy balloon was deflated.

4.10 Plaintiff once again returned to Houston Methodist Hospital on April 24, 2019 and underwent removal of her ileocostomy tube and placement of colostomy bag. She was discharged on April 26, 2019 and told to follow up with the ostomy clinic on May 1, 2019.

4.11 The failure of the surgical stapler and staples to properly close Plaintiff's colon resulted in a number of complications, including:

a. the need to convert from a less invasive laparoscopic procedure to an open surgical procedure;

b. development of tertiary abdominal sepsis which necessitated her to be emergently transported via ambulance to Houston Methodist Hospital where she was resuscitated, placed on broad-spectrum IV antibiotics, and underwent 3 CT-guided percutaneous drain placements, and was hospitalized from October 31, 2018 until January 9, 2019;

c. placement of an ileocostomy tube and additional intraabdominal drains as a result of the large amount of fluid present in her abdomen;

d. two additional procedures to reposition her ileocostomy tube and replacements of the percutaneous drains at the site of the anastomic leak; and

e. removal of her ileocostomy tube and placement of colostomy bag.

4.12 Plaintiff alleges on information and belief that the specific stapler used in her October 19, 2018 surgery was a model, known by Defendants, to frequently malfunction. In May 2018, Defendant Medtronic issued a recall on endo GIA staplers. Additionally, as recently as June 3, 2019, Defendant Medtronic issued a second recall on its endo Gia surgical staplers, including staplers that were distributed between April 2014 and April 2019. Plaintiff alleges on information and belief that the stapler used in her surgery was included in one or both of the recalls.

4.13 Plaintiff has since learned that the stapler in question was likely recalled and that the FDA recently reported that surgical staplers, including those manufactured by Defendants,

have been responsible for tens of thousands of adverse outcomes attributed to malfunctioning staplers.

4.14 Defendants, and each of them, have taken advantage of FDA exemptions and have refused and failed to report non-fatal stapler related injuries to the MAUDE. Instead, Defendants, and each of them, have utilized an alternative summary reporting program, which is not publicly accessible. By not reporting all stapler-related injuries on MAUDE, Defendants have hidden the true risks of the using the devices from surgeons and their patients. For example, in 2016, while reports of 84 stapler injuries or malfunctions were openly submitted, nearly 10,000 malfunctions reports were included in the hidden database, according to the FDA.[b]

4.15 Though Defendants, and each of them, attempted to keep the number of stapler related injuries hidden from medical professionals, in surveys of surgeons conducting surgeries with surgical staplers, up to 73% reported personal experience of, and 86% reported knowing of someone experiencing stapler misfire or malfunction during surgery.

4.16 The public Database shows that Medtronic has reported more than 250 deaths related to staplers or staples since 2001.[c] Despite this knowledge of the dangers associated with using its products, Medtronic used reporting exemptions to file stapler-related reports in a database hidden from doctors and from public view through July 2017.[d] By doing so, Defendants intentionally concealed from public view the many injuries caused by the use of its endo Gia staplers. This concealment denied surgeons, including the surgeon who performed Plaintiff's surgery, and patients like Plaintiff, critical information on the safety of its products.

[b] *Hidden FDA Reports Detail Harm Caused By Scores Of Medical Devices,* https://khn.org/news/hidden-fda-database-medical-device-injuries-malfunctions/
[c] *Id.*
[d] *Id.*

4.17 Based on the number of stapler-related injuries, in May 2019, the FDA proposed reclassifying surgical staplers for internal use from Class I to Class II (Special Controls).[e] Further, device manufacturers are no longer able to use the reporting exemptions for injuries related to surgical staplers. As a result, reports by Defendant Medtronic, related to malfunctions or injuries related to the Covidien staple, skyrocketed from 1,000 reports in 2015 to 11,000 reports in 2018.

4.18 Despite knowing that its endo GIA staplers caused injuries due to malfunction, Defendants, and each of them, represented and marketed the endo GIA staplers as safe and effective. Defendants, and each of them, failed to include warnings regarding potential malfunctions that were known to them, including the risks described in the FDA publication.[f]

4.19 Defendants intentionally engaged in the following conduct: 1) failing to provide warnings regarding the potential for its endo GIA surgical staplers to malfunction in a manner exactly like what occurred during Plaintiff's surgery; 2) failing to warn and inform surgeons of the potential for its endo GIA surgical staplers to malfunction in a manner exactly like what occurred during Plaintiff's surgery; 3) failing to recall its defective products until 2018 and 2019 when it knew earlier that endo GIA surgical staplers were prone to malfunction; 4) failing to publicly report each endo GIA surgical stapler malfunction or injury in the publicly accessible database and thereby conceal know incidents from public view. By engaging in the conduct described above, Defendants engaged in willful, wanton, reckless, malicious behavior and/or exhibited a gross indifference to, and a callous disregard for human life, the safety and the rights of others, and more particularly, the rights, life and safety of the Plaintiff; and Defendants were motivated by consideration of profit,

[e] FDA Executive Summary Prepared for the May 30, 2019 Meeting of the General and Plastic Surgery Devices Panel Reclassification of Surgical Staplers for Internal Use: https://www.fda.gov/media/126211/download

[f] *Id.* at Pg. 9.

financial advantage, monetary gain, economic aggrandizement and cost avoidance, to the virtual exclusion of all other considerations.

V. PLAINTIFF'S CAUSES OF ACTION

A. (STRICT LIABILITY MANUFACTURING DEFECT) Against all DEFENDANTS

5.1 Plaintiff hereby incorporates the allegations contained in the preceding paragraphs, as though fully set forth herein.

5.2 Plaintiff was harmed by Defendants' defective endo GIA surgical stapler, which was distributed, manufactured, and sold by Defendants. Defendants' endo GIA surgical stapler contained a manufacturing and design defect that made it unsafe to perform the function it was intended to perform. Specifically, there was a design or manufacturing defect that would result in an anastomotic leak despite proper utilization by a surgeon.

5.3 As a direct and proximate result of Defendants' negligence, manufacturing and design defects, Plaintiff has incurred losses and damages for personal injury, loss of use and enjoyment of life, the need for periodic medical examination and treatment, and economic losses, including additional medical expenses, and the expenditure of time and money, and will continue to incur losses and damages in the future.

5.4 Due to Defendants' negligence, manufacturing and design defects, Plaintiff is entitled to compensatory damages in a sum to be determined by a jury, plus punitive damages in a sum equal to a multiplier of damages determined to be adequate by a jury.

WHEREFORE, Plaintiff requests relief as hereinafter provided.

PLAINTIFF'S SECOND CAUSE OF ACTION

B. (STRICT LIABILITY DESIGN DEFECT) Against all DEFENDANTS

5.5 Plaintiff hereby incorporates the allegations contained in the preceding paragraphs, as though fully set forth herein.

5.6 Plaintiff was harmed by Defendants' defective endo GIA surgical stapler, which was distributed, manufactured, and sold by Defendants. Defendants' endo GIA surgical stapler contained a manufacturing and design defect that made it unsafe to perform the function it was intended to perform. Specifically, there was a design or manufacturing defect that would result in an anastomotic leak despite proper utilization by a surgeon.

5.7 As a direct and proximate result of Defendants' negligence, manufacturing and design defects, Plaintiff has incurred losses and damages for personal injury, loss of use and enjoyment of life, the need for periodic medical examination and treatment, and economic losses, including additional medical expenses, and the expenditure of time and money, and will continue to incur losses and damages in the future.

5.8 Due to Defendant's negligence, manufacturing and design defects, Plaintiff is entitled to compensatory damages in a sum to be determined by a jury, plus punitive damages in a sum equal to a multiplier of damages determined to be adequate by a jury.

WHEREFORE, Plaintiff requests relief as hereinafter provided.

PLAINTIFF'S THIRD CAUSE OF ACTION

C. (STRICT LIABILITY-FAILURE TO WARN) Against all DEFENDANTS

5.9 Plaintiff hereby incorporates the allegations contained in the preceding paragraphs, as though fully set forth herein.

5.10 Defendants, and each of them, failed to provide accurate information to the public including surgeons, on the risks associated with using their endo GIA staplers. Specifically, Defendants, and each of them, promoted the staplers as being safe while they used FDA reporting exemptions to avoid publicly disclosing known incidents where endo GIA staplers

injured patients due to malfunctions. As a result, neither Plaintiff nor her surgeon knew of the risks of injury like the one Plaintiff suffered, prior to her surgery.

5.11 Defendants, and each of them, knew that the endo GIA stapler posed a risk to patients when used as intended because certain units were manufactured without a component that resulted in a failure to form a staple line that resulted in leakage.

5.12 Despite knowing about this defect, Defendants, and each of them, failed to warn potential surgeons or patients until an initial recall in 2018 and a second recall in 2019. The 2019 recall included devices that were distributed between April 2014 and April 2019. Plaintiff's surgery was in 2018.

5.13 As a direct and proximate result of Defendants' negligence, manufacturing and design defects, Plaintiff has incurred losses and damages for personal injury, loss of use and enjoyment of life, the need for periodic medical examination and treatment, and economic losses, including additional medical expenses, and the expenditure of time and money, and will continue to incur losses and damages in the future.

5.14 Due to Defendants' negligence, manufacturing and design defects, Plaintiff is entitled to compensatory damages in a sum to be determined by a jury, plus punitive damages in a sum equal to a multiplier of damages determined to be adequate by a jury.

WHEREFORE, Plaintiff requests relief as hereinafter provided.

PLAINTIFF'S FOURTH CAUSE OF ACTION

D. (NEGLIGENCE) Against all DEFENDANTS

5.15. Plaintiff hereby incorporates the allegations contained in the preceding paragraphs, as though fully set forth herein.

5.16 Plaintiff's injuries associated with having a second and third surgery were all the result of Defendants' defective endo GIA surgical stapler.

5.17 At all times herein relevant, Defendants, and each of them, were in the business of designing, manufacturing, assembling, constructing, inspecting, and selling various types of medical devices, including the subject endo GIA stapler. Defendants were further in the business of inspecting, maintaining, installing and selling at retail to members of the public various types of medical devices designed and manufactured by Defendants, including the subject endo GIA stapler.

5.18 At all times herein relevant, Defendants so negligently and carelessly designed, manufactured, constructed, assembled, inspected, and/or sold the subject endo GIA surgical stapler that it was dangerous and unsafe to be used for its intended uses.

5.19 Furthermore, at all times relevant to this action, Defendants so negligently and carelessly inspected, maintained, installed, and sold the subject endo GIA surgical stapler that it was dangerous and unsafe for its intended uses.

5.20 Defendants had a duty to exercise reasonable care, and to comply with the existing standards of care, in their preparation, design, research, development, manufacture, inspection, labeling, marketing, promotion, and sale of the subject endo GIA surgical stapler device that was used on Plaintiff.

5.21 At all times herein relevant, Defendants knew or reasonably should have known that the subject endo GIA surgical stapler was unreasonably dangerous and defective when used as directed and designed, including but not limited to its failure to create staple lines leading to anastomotic leaks and other complications and injuries.

5.22 Based on what Defendants knew or should have known as described above, Defendants deviated from the standard of care and were negligent in introducing the endo GIA surgical stapler, which was unreasonably dangerous and defective when used as directed and designed, into the stream of commerce.

5.23 Further, Defendants were negligent for not providing sufficient notice or warnings of the risks associated with using the endo GIA surgical stapler, including the risks associated with malfunction.

5.24 The injuries and damages suffered by Plaintiff were the reasonably foreseeable results of Defendants' negligence.

5.25 As a direct and proximate result of Defendants' negligence, manufacturing and design defects, Plaintiff has incurred losses and damages for personal injury, loss of use and enjoyment of life, the need for periodic medical examination and treatment, and economic losses, including additional medical expenses, and the expenditure of time and money, and will continue to incur losses and damages in the future.

WHEREFORE, Plaintiff requests relief as hereinafter provided.

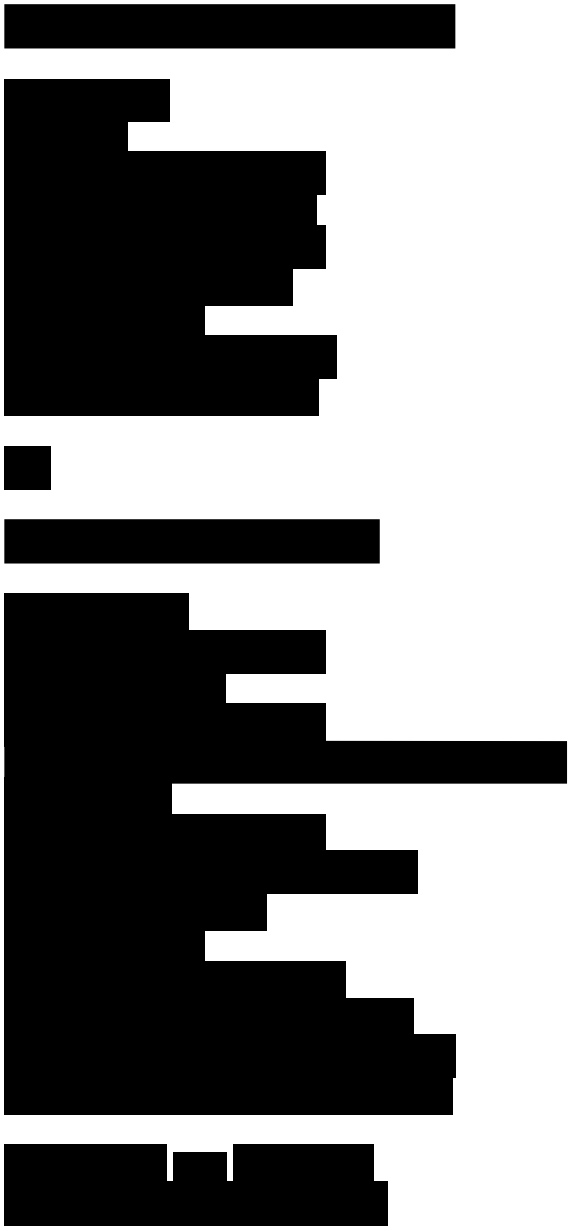
VI. DAMAGES

6.1 Plaintiff Yolanda O. Carvajal has been injured and damaged, including, but not limited to, repeated medical hospitalizations, medical procedures, past and future medical expenses, past and future lost wages, past and future diminished earning capacity, past and future pain and suffering, both physical and mental, past and future impairment of the ability and capacity to enjoy life and its pleasures, past and future disfigurement, and all other damages recoverable under Texas law.

VII. PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for judgment against Defendants, and each of them, by way of damages in such amounts as might be proven at the time of trial and determined by the trier-of-fact as reasonable and just under the evidence, as well as for costs and disbursements herein incurred and for such other and further relief as the court may deem just and proper.

Respectfully Submitted,



JURY REQUEST

Plaintiff respectfully requests a jury trial.