IN THE UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA

DALE LEWIS, Plaintiff, v. ETHICON ENDO-SURGERY, INC., ETHICON ENDO-SURGERY, LLC, JOHNSON & JOHNSON HEALTH CARE SYSTEMS, INC., and JOHNSON & JOHNSON CONSUMER, INC. Defendants.	Civil Action No. _____ JURY TRIAL DEMANDED

PLAINTIFF'S COMPLAINT

COMES NOW, Dale Lewis, Plaintiff, (hereinafter referred to as "Plaintiff" or "Lewis") complaining of Defendants, Ethicon Endo-Surgery, Inc., Ethicon Endo-Surgery, LLC, Johnson & Johnson Health Care Systems, Inc. and Johnson & Johnson Consumer, Inc., (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 Ethicon Endo-Surgery 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.[1]

[1] 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

1.2 Plaintiff Dale Lewis was injured when a surgical stapler, designed, manufactured, and marketed by Defendants, malfunctioned during his April 18, 2019 surgery, resulting in a leak in his abdomen that had to be repaired through a series of subsequent surgeries.

II. PARTIES

2.1. At all times material, Plaintiff Dale Lewis was and is an individual residing in the State of Florida.

2.2 At all times material, Defendant Ethicon Endo-Surgery, Inc., was and is an Ohio corporation with its principal place of business at 4545 Creek Road, Mail Location 11, Cincinnati, Ohio 45242. At all times material, Defendant Ethicon Endo-Surgery, Inc., has been conducting business throughout the State of Florida and maintains significant, systematic and continuous contacts throughout the State of Florida, but does not appear to have a designated agent within the state upon whom service of process may be had for causes of action arising out of such business.

2.3 At all times material, Defendant Ethicon Endo-Surgery, LLC, was and is a foreign corporation with its principal place of business at 475 Calle C, Guaynabo, Puerto Rico 00969. At all times material, Defendant Ethicon Endo-Surgery, LLC, has been conducting business throughout the State of Florida and maintains significant, systematic and continuous contacts throughout the State of Florida, but does not appear to have a designated agent within the state upon whom service of process may be had for causes of action arising out of such business.

2.4 At all times material, Defendant Johnson & Johnson Health Care Systems, Inc., ("Johnson & Johnson") was and is a New Jersey corporation with its principal place of business at One Johnson & Johnson Plaza, New Brunswick, New Jersey 08933. Defendant Johnson & Johnson can be served with process through its Chief Executive Officer, Alex Gorsky, One

Johnson & Johnson Plaza, New Brunswick, New Jersey 08933. At all times material, Johnson & Johnson has been conducting business throughout the State of Florida and maintains significant, systematic and continuous contacts throughout the State of Florida, but does not appear to have a designated agent within the state upon whom service of process may be had for causes of action arising out of such business.

2.5 At all times material Defendant Johnson & Johnson Consumer, Inc., ("Johnson & Johnson Consumer") was and is a New Jersey corporation with its principal place of business at One Johnson & Johnson Plaza, New Brunswick, New Jersey 08933. Defendant Johnson & Johnson Consumer can be served with process through its Chief Executive Officer, Alex Gorsky, One Johnson & Johnson Plaza, New Brunswick, New Jersey 08933. At all times material, Defendant Johnson & Johnson Consumer, Inc. has been conducting business throughout the State of Florida and maintains significant, systematic and continuous contacts throughout the State of Florida, but does not appear to have a designated agent within the state upon whom service of process may be had for causes of action arising out of such business.

2.6 Defendants Ethicon Endo-Surgery, Inc., Ethicon Endo-Surgery, LLC, Johnson & Johnson Health Care Systems, Inc., and Johnson & Johnson Consumer, Inc., shall be referred to herein individually by name or jointly as the "Ethicon Defendants."

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, Ethicon Endo-Surgery, Inc., has been in the business of the researching, developing, selling, and marketing of surgical staplers and staples. At all times material, Ethicon Endo-Surgery, 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 Florida. This Court has personal jurisdiction over Ethicon Endo-Surgery, 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 Florida.

3.4 At all times material, Ethicon Endo-Surgery, LLC, has been in the business of the researching, developing, selling, and marketing of surgical staplers and staples. At all times material, Ethicon Endo-Surgery, LLC, 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 Florida. This Court has personal jurisdiction over Ethicon Endo-Surgery, LLC, because Defendant has submitted itself to the jurisdiction of this Court by engaging in conduct set forth in this Complaint in the State of Florida.

3.5 At all times material, Johnson & Johnson Health Care Systems, Inc., has been in the business of the researching, developing, selling, and marketing of surgical staplers and staples. At all times material, Johnson & Johnson Health Care Systems, 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 Florida. This Court has personal jurisdiction over Johnson & Johnson Health Care Systems, 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 Florida.

3.6 At all times material, Johnson & Johnson Consumer, Inc., has been in the business of the researching, developing, selling, and marketing of surgical staplers and staples. At all times material, Johnson & Johnson Consumer, 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 Florida. This Court has personal jurisdiction over Johnson & Johnson Consumer, 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 Florida.

3.7 The Ethicon 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 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 April 18, 2019, Plaintiff Dale Lewis underwent a sigmoid colectomy procedure performed by Dr. Marcos Szomstein at Baptist Hospital of Miami. Dr. Szomstein noted in part in the operative report, "Then we proceeded to place the anvil of the 28 circular

stapler in the descending colon. The pursestring was tied around it…Under direct vision the assistant placed the CEA 28 stapler into the anus all the way up to the rectal stump. The stapler was opened and the spike went through. The stapler and anvil were connected. The stapler was closed. We confirmed that the mesentery of the descending colon was straight. The stapler was fired by the assistant. The stapler was opened and removed. The 2 donuts were complete. They were sent to pathology together. Hemostasis was satisfactory. There was no tension in the anastomosis." The intraoperative course was otherwise unremarkable, and Plaintiff was sent to the recovery room in stable condition.

4.2 Following his surgery, Plaintiff developed severe abdominal pain and was not resuming normal bowel movements. On April 21, 2019, x-rays of Plaintiff's abdomen were taken which revealed a suspected ileus and a moderate amount of free air under his diaphragm which the radiologist noted was abnormal and recommended further monitoring and imaging be performed to determine the source of the fluid. On April 22, 2019, a CT Scan of Plaintiff' abdomen was performed which revealed fluid and contrast adjacent to the anastomotic site as well as air tracking to the mid upper pelvic collection with apparent fecal matter and extensive pneumoperitoneum. The radiologist also noted that the CT Scan findings were most concerning for an anastomotic leak. Following these findings, Plaintiff underwent an emergent laparoscopic Hartman's procedure by Dr. Szomstein. Upon entering Plaintiff's abdomen, Dr. Szomstein encountered feculent peritonitis and fluid between Plaintiff's small bowel loops. Dr. Szomstein noted in part in his operative report, "Then we placed our attention in the colorectal anastomosis. We found that there was liquid stool coming out of the anterior area on the left side of the anastomosis…Under direct vision we could see exactly where the hole was in the anastomosis. It was an 8 mm hole on the left anterior wall of the anastomosis." While repairing the

anastomosis leak, Dr. Szomstein was concerned that the tissue would not hold and would create a fistula, so he proceeded with a takedown of the anastomosis and a Hartman's procedure. The intraoperative course was otherwise unremarkable, and Plaintiff was sent to the recovery room in stable condition.

4.3 Following his April 22, 2019 surgery, Plaintiff was advised by Dr. Szomstein that the "staples did not take" in his April 18, 2019 surgery.

4.4 Plaintiff remained hospitalized and underwent a rigorous regimen of antibiotics to treat the sepsis he developed as a result of the anastomotic leak that occurred following his first surgery. On May 3, 2019, Plaintiff had a PICC line placed and was discharged from Baptist Hospital of Miami.

4.5 On August 1, 2019, Plaintiff underwent a laparoscopic colostomy reversal surgery by Dr. Szomstein, which had to be converted to an open procedure due to small bowel loops located near his left pelvis. His postoperative course was unremarkable, and Plaintiff was discharged on August 3, 2019.

4.6 Plaintiff is still receiving care for the injuries he suffered in his April 18, 2019 surgery.

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

a. undergoing emergent surgery to repair the anastomotic leak which included a laparoscopic Hartman's procedure;

b. development of sepsis which required Plaintiff to be hospitalized from April 18, 2019 until May 3, 2019;

c. placement of a PICC line upon his discharge which had to remain in place for weeks;

d. a laparoscopic colostomy reversal surgery on August 1, 2019; and

f. ongoing care for the injuries he suffered in his April 18, 2019 surgery.

4.8 Plaintiff alleges on information and belief that one of the specific staplers used in his April 18, 2019 surgery was a model, known by Defendants, to frequently malfunction. In April of 2019, the Ethicon Defendants issued a recall on Ethicon Endo-Surgery Intraluminal Staplers, because uncut washers in the stapler and malformed staples occur with their intraluminal circular staplers due to insufficient firing, which can compromise staple line integrity. The recall further states that the failure to cut the washer suggests complete 360-degree staple line failure, which could lead to potential risks to patients including death, sepsis, bleeding, the need for permanent ostomy "bag," life-long nutritional and digestive issues, leak in the closure (anastomotic leak), additional surgeries, need for additional closures (anastomoses), need for antibiotics, and the need for additional imaging studies.

4.9 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.

4.10 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).[2]

4.11 Despite knowing that its Ethicon Endo-Surgery Intraluminal Staplers caused injuries due to malfunction, Defendants, and each of them, represented and marketed the Ethicon

[2] 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

Endo-Surgery Intraluminal 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.[3]

4.12 Defendants intentionally engaged in the following conduct: 1) failing to provide warnings regarding the potential for its Ethicon Endo-Surgery Intraluminal 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 Ethicon Endo-Surgery Intraluminal Staplers to malfunction in a manner exactly like what occurred during Plaintiff's surgery; 3) failing to recall its defective products until 2019 when it knew earlier that Ethicon Endo-Surgery Intraluminal Staplers were prone to malfunction. 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, 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-Surgery Intraluminal Staplers, which was distributed, manufactured, and sold by Defendants. Defendants' Endo-Surgery Intraluminal Staplers contained a manufacturing and design defect that made it unsafe to

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

perform the function it was intended to perform. Specifically, there was a design or manufacturing defect that would result in staple line failure and anastomotic leak despite proper utilization by a surgeon.

5.3 In April of 2019, the Ethicon Defendants issued a recall for its Endo-Surgery Intraluminal Staplers, because uncut washers in the stapler and malformed staples occur with their intraluminal circular staplers due to insufficient firing, which can compromise staple line integrity. The recall further states that the failure to cut the washer suggests complete 360-degree staple line failure, which could lead to potential risks to patients including death, sepsis, bleeding, the need for permanent ostomy "bag," life-long nutritional and digestive issues, leak in the closure (anastomotic leak), additional surgeries, need for additional closures (anastomoses), need for antibiotics, and the need for additional imaging studies. The recall also stated that an investigation conducted by Ethicon of the manufacturing process of the Ethicon Endo-Surgery Intraluminal Staplers detected a shift in a process, which occurred in March of 2018 through March 8, 2019, at which time the line was shut down.

5.4 On May 15, 2019, the FDA issued a Class One Device Recall for Defendants' Endo-Surgery Intraluminal Staplers which were designed and manufactured for use in gastrointestinal surgeries including in patients undergoing surgery for a sigmoid colectomy. The recall was issued because the stapler may have an insufficient firing stroke to break the washer and completely form staples. The recall also stated that an investigation conducted by Ethicon of the manufacturing process of the Ethicon Endo-Surgery Intraluminal Staplers detected a shift in a process, which occurred in March of 2018 through March 8, 2019, at which time the line was shut down. This recall notice is still active.

5.5 Following his April 22, 2019 surgery, Plaintiff was advised by Dr. Szomstein that the "staples did not take" in his April 18, 2019 surgery. The April 2019 recall issued by the Ethicon Defendants and the May 2019 recall issued by the FDA both stated that as a "***result of manufacturing defects"***[4] in the recalled devices the stapler may have an insufficient firing stroke to break the washer and completely form staples which may result in compromised staple line integrity and anastomotic leak. This is exactly what the Plaintiff has alleged occurred and has been confirmed by his medical providers and medical records.

5.6 On information and belief, Plaintiff alleges the device subject to the recalls is the same device used in his April 18, 2019 surgery and has also been identified as the device that was used in his surgery by his medical providers and medical records.

5.7 The surgical stapler used in Plaintiff's April 18, 2019 surgery was: (1). manufactured by the Defendants; (2) malfunctioned as a result of manufacturing defect which rendered the surgical stapler unreasonably dangerous (3) the defect existed at the time the stapler was distributed by the Defendant as evidenced by the company's own recall notice and the FDA recall notice; and (4) the defect was a producing cause of Plaintiff's injuries.

5.8 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.

[4] https://www.fda.gov/medical-devices/medical-device-recalls/ethicon-recalls-circular-staplers-insufficient-firing-and-failure-completely-form-staples#:~:text=On%20April%2011%2C%202019%2C%20Ethicon,distributors%2C%20and%20other%20customers%20should%3A&text=To%20receive%20replacement%20product%2C%20customers,recall%20by%20June%2030%2C%202019.

5.9 Due to Defendants' negligence, failure to warn, 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

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

5.11 Plaintiff was harmed by Defendants' Endo-Surgery Intraluminal Stapler, which was distributed, manufactured, and sold by Defendants. Defendants' Endo-Surgery Intraluminal Staplers contained a design defect that made it unsafe to perform the function it was intended to perform. Specifically, there was a design defect that would result in a compromised staple line integrity and anastomotic leak despite proper utilization by a surgeon.

5.12 As previously alleged, the Defendants' own recall notice and the FDA recall notice identified that the product used in Plaintiff's April 18, 2019 surgery was defectively designed. Specifically, the October of 2019 recall instituted by the Defendants stated the recall was instituted because, "***uncut washers in the stapler and malformed staples occur with their intraluminal circular staplers due to insufficient firing, which can compromise staple line integrity***." This recall notice is still active. Plaintiff alleges on information and belief that the defective design of the device used in Plaintiff's surgery was a cause of the device to malfunction and lead to insufficient firing.

5.13 Additionally, on May 15, 2019 the FDA issued a Class One Device Recall for Defendants' Endo-Surgery Intraluminal Staplers because, "***the staplers may have an insufficient***

firing stroke to break the washer and completely form staples." This recall notice is still active. Plaintiff alleges on information and belief that the defective design of the device used in Plaintiff's surgery was a cause of the device to malfunction and fail to completely form staples.

5.14 These recall notices have not been terminated and the Defendants have resumed manufacturing, marketing and selling the device that is the subject of Plaintiff's claims. Presumably the design defect issues have been fixed, otherwise the Defendants would not have resumed the manufacturing, marketing and selling of the device. This clearly indicates that a safer alternative design of the surgical stapler in question existed at the time of Plaintiff's surgery. The design defect of the surgical stapler in question was a producing cause of Plaintiff's injuries as incorporated in the preceding allegations. Had the Defendants implemented the safer alternative design prior to Plaintiff's surgery it would have prevented or significantly reduced the risk of Plaintiff's injuries and implementing the safer alternative design would not have substantially impaired the Defendants' product's utility. Likewise, Plaintiff asserts it was economically and technologically feasible for the Defendants to implement the safer alternative design prior to the time the device left the Defendants' control.

5.15 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.

5.16 Due to Defendants' negligence, failure to warn, 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

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

5.18 Defendants, and each of them, failed to provide accurate information to the public including surgeons, on the risks associated with using their Endo-Surgery Intraluminal Staplers. Specifically, Defendants, and each of them, promoted the staplers as being safe while they knew at least as early as March of 2018 about the risk of the staplers to malfunction and fail to completely form which could compromise staple line integrity. As a result, neither Plaintiff nor his surgeon knew of the risks of injury like the one Plaintiff suffered, prior to his surgery.

5.19 Defendants, and each of them, knew that the Endo-Surgery Intraluminal Stapler posed a risk to patients when used as intended because, as stated in the recalls issued by the Defendants and the FDA both stated , "***a breakdown in the manufacturing process causing certain units to be manufactured with an insufficient firing stroke to break the washer and completely form staples and the failure to form a staple line that resulted in leakage***."[5] Defendants have hidden the true risks of the using the devices from surgeons and their patients.

5.20 Despite knowing about this defect, Defendants, and each of them, failed to warn potential surgeons or patients until a recall in October of 2019. The 2019 recall included devices

[5] https://www.fda.gov/medical-devices/medical-device-recalls/ethicon-recalls-circular-staplers-insufficient-firing-and-failure-completely-form-staples#:~:text=On%20April%2011%2C%202019%2C%20Ethicon,distributors%2C%20and%20other%20customers%20should%3A&text=To%20receive%20replacement%20product%2C%20customers,recall%20by%20June%2030%2C%202019.

that were distributed between March 15, 2018 and March 8, 2019. Plaintiff's surgery was on April 18, 2019.

5.21 The Defendants continued to market, manufacturer and sell the devices with the knowledge of the defects and potential risk of harm to patients and failed to inform potential patients and their physicians of these known defects and risks at the time of the sale of the devices. The failure to notify or warn the patients and their physicians of the defects and risks renders the devices unreasonably dangerous to the patient and their physicians. The failure to warn patients and their physicians of the defects and risks of the devices in question was a producing cause of Plaintiff's injuries.

5.22 Plaintiff is unaware of any evidence that the Defendants warned Plaintiff's physicians of the defects and risks of the devices prior to Plaintiff's surgery. Plaintiff alleges on information and belief that had his physicians been warned or notified of the defects and risk of the devices prior to Plaintiff's surgery they would have not used the devices or subjected Plaintiff to the risks associated with using these devices. Plaintiff also alleges on information and belief that had his physicians been warned or notified of the defects and risk of the devices prior to Plaintiff's surgery they would have warned the Plaintiff prior to his surgery of the defects and risks associated with using the devices and Plaintiff would have been afforded the opportunity to make an informed decision on whether to proceed with the surgery given the risks.

5.23 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.

5.24 Due to Defendants' negligence, failure to warn, 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

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

5.26 Plaintiff's injuries associated with having a second and third surgery were all the result of Defendants' defective Endo-Surgery Intraluminal Stapler.

5.27 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-Surgery Intraluminal 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-Surgery Intraluminal Stapler.

5.28 At all times herein relevant, Defendants so negligently and carelessly designed, manufactured, constructed, assembled, inspected, and/or sold the subject Endo-Surgery Intraluminal Stapler that it was dangerous and unsafe to be used for its intended uses.

5.29 Furthermore, at all times relevant to this action, Defendants so negligently and carelessly inspected, maintained, installed, and sold the subject Endo-Surgery Intraluminal Stapler that it was dangerous and unsafe for its intended uses.

5.30 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-Surgery Intraluminal Stapler device that was used on Plaintiff.

5.31 At all times herein relevant, Defendants knew or reasonably should have known that the subject Endo-Surgery Intraluminal 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. Furthermore, Plaintiff was advised by Dr. Szomstein that the "staples did not take" following his April 18, 2019 surgery.

5.32 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-Surgery Intraluminal Stapler, which was unreasonably dangerous and defective when used as directed and designed, into the stream of commerce.

5.33 Further, Defendants were negligent for not providing sufficient notice or warnings of the risks associated with using the Endo-Surgery Intraluminal Stapler, including the risks associated with malfunction.

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

5.35 As a direct and proximate result of Defendants' negligence, failure to warn, 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 Dale Lewis 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 Florida 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.

JURY REQUEST

Plaintiff respectfully requests a jury trial.

RESPECTFULLY SUBMITTED,

BABBITT & JOHNSON, P.A.

/s/ Joseph R. Johnson
Joseph R. Johnson
Florida Bar No.:372250
1641 Worthington Road, Suite 100
West Palm Beach 33409
(561) 684-2500
jjohnson@babbitt-johnson.com

and

MARTIN BAUGHMAN, PLLC

/s/ Ben C. Martin
Ben C. Martin (*admission application forthcoming*)
Texas Bar No. 13052400
Kolter C. McKenzie (*admission application forthcoming*)
Texas Bar No. 24067762
3141 Hood Street, Suite 600
Dallas, Texas 75219
(214) 761-6614
Facsimile: (214) 744-7590
bmartin@martinbaughman.com
kmckenzie@martinbaughman.com

ATTORNEYS FOR PLAINTIFF