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State of Minnesota
12/17/2021 1:56 PM

DISTRICT COURT OF MINNESOTA
FOURTH JUDICIAL DISTRICT
HENNEPIN COUNTY DISTRICT COURT

WILLIAM BRUCE JONES and KATHLEEN GAIL JONES,

Plaintiffs,

v.

MEDTRONIC, INC., a Minnesota corporation; MEDTRONIC USA, INC., a Minnesota corporation; MEDTRONIC LOGISTICS LLC, a Minnesota limited liability company; COVIDIEN LP, a Delaware limited partnership; COVIDIEN HOLDING INC., a Delaware corporation; and COVIDIEN SALES LLC, a Delaware limited liability company,

Defendants.

INTRODUCTION

COME NOW William Bruce Jones and Kathleen Gail Jones, Plaintiffs herein, complaining of MEDTRONIC, INC., a Minnesota corporation; MEDTRONIC USA, INC., a Minnesota corporation; MEDTRONIC LOGISTICS LLC, a Minnesota limited liability company; COVIDIEN LP, a Delaware limited partnership; COVIDIEN HOLDING INC., a Delaware corporation; and COVIDIEN SALES LLC, a Delaware limited liability company, Defendants herein, and would show the Court the following:

PARTIES

1. Plaintiffs William Bruce Jones and Kathleen Gail Jones are, and at all times relevant, are residents of Montgomery County, Texas.

2. Defendant Medtronic, Inc. ("Medtronic") is a Minnesota Corporation that has its principal place of business at 710 Medtronic Parkway, Minneapolis, Minnesota. Medtronic is a

Filed in District Court
State of Minnesota
12/17/2021 1:56 PM

medical device company involved in the manufacturing, marketing, packaging, labeling and sale of medical devices. At all times relevant to this action, Medtronic has conducted substantial business in Minnesota, and may be served by its registered agent, Corporation Service Company at 2345 Rice Street Suite 230, Roseville, MN 55113–5603.

3. Defendant Medtronic USA, Inc. ("Medtronic USA") is, and at all times materially hereto was, a corporation organized under the laws of the State of Minnesota, with its principal place of business in Minnesota. At all times relevant to this action, Medtronic USA has conducted substantial business in Minnesota, and may be served by its registered agent, Corporation Service Company at 2345 Rice Street Suite 230, Roseville, MN 55113–5603.

4. Defendant Medtronic Logistics LLC ("Medtronic Logistics") is, and at all times materially hereto was, a limited liability company organized under the laws of the State of Minnesota. Upon information and belief, Plaintiffs allege that all of the principals of Medtronic Logistics LLC are citizens of Minnesota; and, therefore, that Medtronic Logistics LLC is a citizen of Minnesota. At all times relevant to this action, Medtronic Logistics has conducted substantial business in Minnesota, and may be served by its registered agent, Corporation Service Company at 2345 Rice Street Suite 230, Roseville, MN 55113–5603.

5. Defendant Medtronic, Inc., Defendant Medtronic USA, Inc. and Defendant Medtronic Logistics LLC shall hereinafter, jointly and severally, be referred to as "Medtronic."

6. Covidien LP ("Covidien") is a Delaware Limited Partnership with its principal place of business in Massachusetts. It is the single member of Covidien Sales LLC, a Delaware limited liability company with its principal place of business in Massachusetts. Covidien has one general partner: Covidien Holding Inc., a Delaware corporation with its principal place of business in Massachusetts. Among their business activities, Covidien Sales LLC and Covidien

Filed in District Court
State of Minnesota
12/17/2021 1:56 PM

are involved in the manufacture, distribution, sales, marketing, regulatory management, and services related to Covidien medical products in the United States, and in Minnesota. At all times relevant to this action, Covidien has conducted substantial business in Minnesota, and may be served by its registered agent, Corporation Service Company at 2345 Rice Street Suite 230, Roseville, MN 55113–5603.

7. Defendant Covidien LP is registered to do business in the State of Minnesota and, thus, has consented to jurisdiction in the State. Furthermore, Covidien LLC is a wholly owned subsidiary of Medtronic, Inc., a Minnesota Corporation, and has systematic and continuous connections with the State of Minnesota operating as a subsidiary under the complete control of Medtronic, Inc. Covidien LLC, is a Delaware Limited Liability Company with its principal place of business in Massachusetts. Covidien LLC, has a single member: Covidien LP, a Delaware Limited Partnership with its principal place of business in Massachusetts. Covidien LP, in turn, has one general partner: Covidien Holding, Inc., a Delaware Corporation with its principal place of business in Massachusetts. At all times relevant, Defendant Covidien LLC sold, marketed, and distributed its products, including surgical staplers, throughout the United States, including the State of Minnesota. Covidien LP may be served by its registered agent, Corporation Service Company at 2345 Rice Street Suite 230, Roseville, MN 55113–5603.

8. Defendant Covidien Holding, Inc. is a Delaware Corporation with its principal place of business in Massachusetts. Defendant Covidien Holding, Inc., is registered to do business in the State of Minnesota and has consented to jurisdiction in the State. Furthermore, Covidien LLC is a wholly owned subsidiary of Medtronic, Inc., a Minnesota Corporation, and has systematic and continuous connections with the state of Minnesota operating as a subsidiary under the complete control of Medtronic, Inc. As well, Covidien Holding, Inc. operates out of the same

Filed in District Court
State of Minnesota
12/17/2021 1:56 PM

headquarters as Medtronic, Inc. at 710 Medtronic Parkway, Minneapolis, Minnesota and its listed CEO, Bob White, works out of the Medtronic Parkway office. Covidien Holding may be served by its registered agent, Corporation Service Company at 2345 Rice Street Suite 230, Roseville, MN 55113–5603.

9. At all times relevant, Defendant Covidien Holding, Inc. sold, marketed, and distributed its products, including surgical staplers, throughout the United States, including the State of Minnesota.

10. Covidien Sales LLC ("Covidien Sales"), is a Delaware limited liability company with its principal place of business in Massachusetts. Covidien Sales is a wholly owned subsidiary of Medtronic. Covidien Sales has a single member: Covidien, a Delaware Limited Partnership with its principal place of business in Massachusetts. Covidien, in turn, has one general partner: Covidien Holding Inc., a Delaware corporation with its principal place of business in Massachusetts. Among its business activities, Covidien Sales is involved in the manufacture, distribution, sales, marketing, regulatory management, and services related to Covidien Sales medical products in the United States, and in Minnesota. At all times relevant to this action, Covidien Sales has conducted substantial business in Minnesota, and may be served by its registered agent Corporation Service Company at 2345 Rice Street Suite 230, Roseville, MN 55113–5603.

11. Defendants Covidien LP, Covidien Holding, Inc., Covidien Sales LLC will hereinafter be collectively called "Covidien."

12. In January 2015, Medtronic wholly 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

Filed in District Court
State of Minnesota
12/17/2021 1:56 PM

including the Covidien Products sold in the United States. In that capacity, Medtronic committed tortious and wrongful acts or allowed those acts to occur, 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 Plaintiffs to suffer injury and damages.

13. Medtronic and Covidien will collectively be called Defendants. Defendants are individually, jointly, and severally liable to Plaintiffs for damages suffered by Plaintiffs arising from Defendants' design, manufacturing, marketing, labeling, distribution, sale, and placement of the defective Covidien Products at issue in this suit. All acts were effectuated directly or 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.

JURISDICTION & VENUE

14. This Court has jurisdiction because Defendant Medtronic is a Minnesota business corporation with its principal place of business in Minnesota. Defendant Covidien, at all times relevant to this action, conducted substantial business in Minnesota.

15. Venue is proper in Hennepin County, Minnesota, because the principal place of business of Defendant Medtronic, Inc. is located at 710 Medtronic Parkway, Minneapolis, Minnesota, and Defendants do business in Hennepin County, Minnesota. This Court has subject matter jurisdiction and this matter exceeds jurisdictional minimums.

FACTUAL BACKGROUND

A. The Dangers of Surgical Staplers

16. Surgical staplers, until very recently, were classified as Class I medical devices by the Food & Drug Administration ("FDA").

Filed in District Court
State of Minnesota
12/17/2021 1:56 PM

17. Surgical Staplers were popularized in medical procedures since at least the early 1990s. Typically, a stapler is comprised of a stapler body, a stapler cartridge, an anvil and a firing mechanism. The surgeon loads a staple cartridge into the stapler, places the stapler in the human body, and activates the firing mechanism to shoot a staple into place.

18. Innovations in the manufacturing of surgical staplers have led to the creation of staplers for specific procedures. One of these is the circular stapler, which is used in colorectal, gastric and thoracic surgeries.

19. Over the years, surgical staplers have been used to remove a part of an organ (otherwise known as a "resection"), to cut through tissue and organs ("transection"), and to create connections between structures in the body ("anastomoses").

20. The risk of serious adverse effect and malfunction of surgical staplers is well documented in medical literature. For example, by 2004, studies had shown that 112 deaths, 2,180 injuries, and 22,804 adverse events ("AEs") were reported to the FDA connected to surgical stapler use. S. Lori Brown, *Ethicon Stapler-associated fatalities and adverse events reported to the Food and Drug Administration*, 199 J. AM. COLL. SURG. 3, 374-81 (May 2004).

21. Since 2004, other studies have reported that between 8,000 and 9,000 AEs related to surgical staplers occur each year, with 90% of these AEs resulting from a malfunction with the device. Sophie Childs, *Surgical Staples: Everything Healthcare Professional Need to Know* (Apr. 18, 2017), *available at* https://www.ciamedical.com/insights/everything-healthcare-professionals-need-to-know-about-surgical-staples/.

22. The FDA recently reported that between 2011 and 2018, there were approximately 110,000 reports -- including 412 reported deaths, nearly 12,000 reported severe injuries, and roughly 98,500 malfunctions -- related to issues with surgical staplers, including those designed,

manufactured, and marketed by Defendants. These events, however, were largely hidden from public knowledge; the majority of the reports were not submitted to the Manufacturer and User Facility Device Experience (or "MAUDE"), which is a publicly-accessible database run by the FDA. Instead, the majority of the reports were submitted to an Alternative Summary Reporting "ASR" Program, which had the effect of hiding the information and severity of the problems with the devices from surgeons and the public.

23. Additionally, studies identified issues with the "fixed-style surgical staplers," like the staplers used in this case. Fixed-style staplers are devices that present a bar indicator window showing when proper compression of tissue is achieved. The indicator window for viewing the compression scale is narrow, and the stapler is designed to allow stapling when only part of the green bar is viewable. Therefore, scientists found that surgeons could over-compress the tissue, leading to injury. Gyung Mo Son, et al., *Compression injury of the circular stapler for gastrointestinal end-to-end anastomosis: preliminary in-vitro study*, 99 Ann. Surg. Treat. Res. 2, 72-81 (2020).

24. The consequences of malfunction are serious, and sometimes deadly. "In a retrospective study of 349 colorectal resections using a circular stapler, surgeries with surgical stapler malfunctions were found to have higher incidences of unplanned proximal diversions, ileus, gastrointestinal bleeding, and blood transfusions." Likewise, "[a]nastomotic leaks from surgical stapler malfunctions have also been associated with an increased risk of cancer recurrence." *FDA Executive Summary, Reclassification of Staplers for Internal Use*, at 10, Food & Drug Admin. (May 30, 2019), *available at* https://www.fda.gov/media/126211/download (hereinafter "FDA Executive Summary").

Filed in District Court
State of Minnesota
12/17/2021 1:56 PM

25. Even if the malfunction does not cause a fatal injury for the patient, "complications frequently require additional diagnostic studies, invasive procedures and the need for reoperation resulting in prolonged hospitalization and additional skilled nursing care." *Id*. at 9.

B. **Defendants' EEA Circular Stapler, Regulatory Requirements, & Recalls**

26. Defendants design, manufacture and sell surgical staplers to be used by medical service providers in surgical procedures.

27. The surgical stapler(s) manufactured by Defendants at issue in this matter are the EEA Circular Stapler with DST Series Technology 28 mm- 4.8 mm and the EEA Circular Stapler with DST Series Technology 31 mm- 4.8 mm. Collectively, they will be referred to hereinafter as the "Covidien Stapler(s)."

28. The Covidien Stapler(s) at issue in this case are a circular stapler used for end-to-end, end-to-side, and side-to-side anastomoses.

29. Between 2017 and 2019, Defendants, under the identifiers "Covidien LLC" and "Covidien Medtronic" issued various recalls to Endo GIA staplers and EEA staplers including a recall in June 2019 that covered Endo GIA staplers distributed between April 2014 and April 2019. The recalls were conducted because of "the potential for a device to be missing one of two pin components that maintain alignment of the device jaws," and "the potential for a device to have an incorrect tissue gap . . . result[ing] in incomplete staple formation and/or the inability to remove the device from tissue following application potentially leading to bleeding, anastomotic leak or tissue trauma."

30. Manufacturers of medical devices such as Defendants must provide reports to MAUDE when they learn that any of their devices contributed to death or serious injury. The alternative reporting system (ASR) was established, though, for reporting well-known and well-

Filed in District Court
State of Minnesota
12/17/2021 1:56 PM

characterized events on a summary basis. Here, Defendants misused that system. They did so to dilute reports, so that the injuries did not seem as prevalent; this included the non-reporting of events involving new and novel malfunctions that caused severe injury and would have subjected their staplers to recall or reclassification. In fact, these recalls occurred as soon as the issue was discovered and published in 2019. The staplers are being considered for reclassification.

31. The ASR system further requires accurate reporting of deaths, injuries, and malfunctions. Upon information and belief, Defendants reported various injuries merely as "malfunctions" to avoid FDA scrutiny and attention and to forestall the chance that any of these reports would require public disclosure. Had these incidents been accurately reported, it is highly likely that public notice, FDA scrutiny, and product recalls would have preceded Plaintiffs surgery, and that the devices would have been appropriately recalled before being used on Plaintiff by his unsuspecting surgeons.

32. Defendants, and each of them, have manipulated the reporting systems in a way that ensured healthcare providers could not review the dangers posed by the products. Defendants also often listed injuries as "malfunctions" to avoid attention that would have resulted in product recalls or serious questions about whether the devices were properly classified in the very low risk category. Instead, Defendants, and each of them, have utilized an alternative summary reporting program that is not publicly accessible.

33. By not reporting all stapler-related injuries on the publicly-available MAUDE database, Defendants have hidden the true risks of the using the devices from surgeons and their patients. Strikingly, in 2016, reports of only 84 stapler injuries or malfunctions were openly submitted, while nearly 10,000 "malfunctions" reports were included in the hidden database, according to the FDA.

Filed in District Court
State of Minnesota
12/17/2021 1:56 PM

34. Despite the ASR system, a manufacturer was still required to report deaths related to its product's use in the public MAUDE data base. This public Database shows that Medtronic has reported more than 250 deaths related to staplers or staples since 2001. Despite this manifest knowledge of the dangers associated with its products, Medtronic nevertheless still used reporting exemptions to hide stapler-related reports from public view by reporting them to an inaccessible database through July 2017. By doing so, Defendants intentionally concealed the many injuries caused by the use of its defective classes of surgical staplers. This concealment denied critical information concerning the safety of those products from not only the public, but from treating medical providers and surgeons, including the surgeons who performed Plaintiff's surgery (and patients like Plaintiff). Ultimately, Defendants continued to sell staplers to healthcare providers during this time period without disclosing serious risks of injury from use.

35. 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). Among other things, this required manufacturers, including Defendants, to publicly report all malfunctions or injuries related to the Covidien stapler; device manufacturers, such as Covidien, are no longer able to use the reporting exemptions for injuries related to surgical staplers. Consequently, the number of public reports of deaths, injuries, and malfunctions skyrocketed from approximately 1,000 reports in 2015 to 11,000 in 2018.

36. Also in May 2019, the FDA also prepared an "Executive Summary on the Reclassification of Staplers for Internal Use." The FDA's analysis revealed that it received more than 41,000 reports, which included 366 deaths, over 9,000 serious injuries, and over 32,000 malfunctions. FDA Executive Summary, at 10. One of the most commonly reported problems with these devices is staple malformation. *Id.* at 11.

Filed in District Court
State of Minnesota
12/17/2021 1:56 PM

37. The FDA Guidance for staplers issued in October 2021 was created "because malfunctions and misuse associated with these devices have resulted in serious adverse events, including death." *Ethicon Staplers and Staples for Internal Use – Labeling Recommendations, Guidance for Industry*, at 3, Food & Drug Admin. (Oct. 8, 2021), *available at* https://www.fda.gov/media/123572/download. The FDA Guidance noted that "[s]tapler and/or staple malfunctions may result in prolonged surgical procedures or unplanned, additional surgical interventions, and other complications such as bleeding, sepsis, fistula formation, tearing of internal tissues and organs, and death." *Id.* at 4.

38. The FDA Guidance recommended inclusion of several contraindications and warnings, including:

a. "A statement noting that the device should not be used to staple tissues that are necrotic, friable, or have altered integrity, e.g. ischemic or edematous tissues."

b. "A statement noting that the device should not be used to staple tissue outside of the labeled limits for maximum and minimum tissue thickness."

c. "A statement to visually inspect prior to firing for inclusion of unintended anatomic structures within the staple line."

d. "A statement to ensure that no obstructions, such as clips, are incorporated into the instrument jaws when positioning the stapler on the application site, and that firing over an obstruction may result in incomplete cutting action and/or improperly formed staples."

e. "A statement that there is a risk of increased leak rates when staple lines are crossed, even if there may be clinical circumstances when a surgeon may deem it necessary or appropriate to do so."

39. Also in October 2021, the FDA issued a Letter to Health Care Providers "to help protect patient safety and reduce the risk of adverse events associated with surgical staplers and staples for internal use." *UPDATE: Safe Use of Ethicon Staplers and Staplers – Letter to Health*

Filed in District Court
State of Minnesota
12/17/2021 1:56 PM

Care Providers, Food & Drug Admin. (Oct. 7, 2021), *available at* https://www.fda.gov/medical-devices/letters-health-care-providers/update-safe-use-surgical-staplers-and-staples-letter-health-care-providers.

40. While the reclassification brought transparency to the number of incidents involving the Defendants' products, it also revealed their concealment of the dangers posed by the products and demonstrated rank misrepresentations in the marketing of those products. Indeed, despite knowing that their staplers caused injuries due to malfunction, Defendants, and each of them, had undertaken to affirmatively represent and marketed their staplers were safe and effective. Defendants, and each of them, failed to include warnings regarding potential malfunctions that were known to them by virtue of, among other things, the reports that had theretofore been concealed in the ASR system. Defendants also failed to warn about the very risks described in the FDA publication.

41. Defendants failed to establish quality systems and good manufacturing practices to ensure that its staplers would not be sold with manufacturing defects, exposing patients to serious risks of injury or death when the device is used as intended by surgeons.

42. As a medical device manufacturer, Defendants are required by 21 CFR §820.198 to establish and maintain a tracking system to evaluate and review complaints received from end users for the purpose of timely identifying problems with its devices and either filing a medical device report, publishing a safety letter, or taking other corrective action to ensure patients' safety. Defendants failed to establish and maintain a complaint file and tracking system that would timely identify defective staplers and remove defective staplers from the market before causing serious risk of injury or death.

Filed in District Court
State of Minnesota
12/17/2021 1:56 PM

C. **William Bruce Jones' December 2019 Medical Procedures**

43. On December 19, 2019, Plaintiff William Jones underwent a sigmoidectomy, colorectal anastomosis, repair of colotomy and intraoperative colonoscopy at St. David's South Austin Medical Center to treat his recurrent diverticulitis.

44. During the surgery, Plaintiff's surgeons used Covidien Staplers for the anastomosis. While Plaintiff's surgeon was attempting to place the first Covidien Stapler, the pin popped out of place when the anvil was pulled through the colonic wall. The surgeon was unable to mobilize the anvil to the previously created colotomy. The surgeon had to instead enter the peritoneum through another port and milk the anvil to the open end of the colon, and from there was able to remove it. After removing the broken Covidien Stapler, the surgeon had to utilize a second Covidien Stapler to complete the anastomosis. Plaintiff's surgeons noted that the anastomosis "did not have any tension or kinking or torsing" and noted no issues during the surgery. The leak test revealed no leaks related to the anastomosis, and the donuts appeared intact. However, Plaintiff's surgeon did note a small leak proximal to the anastomosis that appeared due to a small colotomy caused by the removal of the first Covidien Stapler. That leak was repaired with sutures, and a second leak test showed no further leakage.

45. Three days later, when Plaintiff was still recovering from his surgery, he became tachycardic, began vomiting a greenish-black liquid, and his stomach became tight and distended. He was rushed back into surgery, where his surgeons found that his anastomosis had partially dehisced. The surgeons found an approximately 5-mm defect and significant contamination around the area. Due to the size of the defect, Plaintiff's surgeons were forced to fit Plaintiff with a colostomy.

Filed in District Court
State of Minnesota
12/17/2021 1:56 PM

46. Plaintiff remained hospitalized for several more weeks as his body fought the sequelae related to the contamination from the dehisced anastomosis. Plaintiff was intubated at various points, and a drain was also placed to remove pockets of infection. The incision line from the second surgery, which went from the bottom of his ribcage to his pelvic, became infected and so Plaintiff's physicians removed staples holding the incision closed and a wound vac was placed. Plaintiff left the hospital with the wound vac still attached to his body. He also left the hospital physically weakened and approximately 40 pounds lighter.

47. Plaintiff's complications continued once he was discharged in January 2020. Within a week, Plaintiff spiked a fever and was readmitted with pneumonia. Plaintiff spent several days in the hospital before again being discharged.

48. Beyond this date, Plaintiff has continued to suffer injuries and incur medical expenses related to the failure of the Covidien stapler.

CAUSES OF ACTION

FIRST CAUSE OF ACTION:
STRICT PRODUCT LIABILITY – DEFECTIVE DESIGN

49. Plaintiffs incorporate by reference as if fully set forth herein all of the allegations contained in the paragraphs above.

50. Defendants engaged in the business of researching, developing, designing, licensing, manufacturing, distributing, supplying, selling, marketing, and/or introducing into interstate commerce, including the state of Minnesota, either directly or indirectly, through third parties or related entities, its products, including the Covidien Stapler used to perform the anastomosis during the Plaintiff's surgery on December 19, 2019.

51. Defendants designed, manufactured, inspected, tested, and sold the Covidien Stapler used during Plaintiff's surgery in a defective and unreasonably dangerous condition.

Filed in District Court
State of Minnesota
12/17/2021 1:56 PM

52. The Covidien Stapler was defective and unreasonably dangerous when it left Defendants' control.

53. The Covidien Stapler was defectively designed because balancing the likelihood and gravity of the harm, against the burden of the precaution which would be effective to avoid the harm, there is an unreasonable risk of harm when the stapler is used in the manner for which it was intended, as well as an unintended yet reasonably foreseeable use including but not limited to the following ways:

a. Failing to ensure all component parts of the Covidien Stapler remain in the device during use, including pins;

b. Failing to "fire" staples; and

c. Other defects that caused an increased risk of issues that may compromise staple line integrity.

54. At the time the Covidien Stapler was designed, manufactured, and sold by Defendants, there were reasonable alternatives and safer designs available, including mechanisms to ensure the quality and integrity of staple lines and help ensure atraumatic stapler/tissue interaction, ensure that the staple size utilized was appropriate for the procedure and tissue, and proper firing of staples that would prevent or minimize the risk of issues that may compromise staple line integrity.

55. This alternative design would have avoided the foreseeable risk of serious injury and death posed by the Covidien Stapler.

56. Defendants' failure to include these alternative design mechanisms rendered the Covidien Stapler defective and unreasonably dangerous for foreseeable operators such as physicians.

Filed in District Court
State of Minnesota
12/17/2021 1:56 PM

57. The unreasonably dangerous design defects alleged above were foreseeable, and the failure to provide reasonable instruction or otherwise omit these design defects rendered the Covidien Stapler unreasonably dangerous.

58. Defendants expected the Covidien Stapler to reach Plaintiff and be used by his surgeon without substantial change in its condition, and the stapler did in fact reach Plaintiff and was used by his surgeon without substantial change in its condition from the time the stapler was designed, manufactured, and sold by the Defendants to when it was used.

59. The Covidien Stapler's defective design was a substantial contributing factor in bringing about the injuries and damages sustained by Plaintiff. 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. He will continue to incur losses and damages in the future.

WHEREFORE, the Plaintiffs demand judgment against the defendants jointly and severally for compensatory damages and punitive/exemplary damages in sums to be deemed fair and reasonable by the trier of fact, along with all actual and statutory costs, disbursements, and attorneys' fees of this action.

SECOND CAUSE OF ACTION:
STRICT PRODUCTS LIABILITY – MANUFACTURING DEFECT

60. Plaintiffs incorporate by reference as if fully set forth herein all of the allegations contained in the paragraphs above.

61. Defendants engaged in the business of researching, developing, designing, licensing, manufacturing, distributing, supplying, selling, marketing, and/or introducing into interstate commerce, including the state of Minnesota, either directly or indirectly, through third

Filed in District Court
State of Minnesota
12/17/2021 1:56 PM

parties or related entities, its products, including the Covidien Stapler used to perform the anastomosis during the Plaintiff's surgery on December 19, 2019.

62. Defendants designed, manufactured, inspected, tested, and sold the Covidien Stapler used during Plaintiff's surgery in a defective and unreasonably dangerous condition.

63. The Covidien Stapler was unreasonably dangerous because it left Defendants in a condition which was unreasonably dangerous to the ordinary consumer who uses it with the knowledge common to the community as to the stapler's characteristics and common usage.

64. The Covidien Stapler contained a manufacturing defect that departed from its intended design, including missing component parts, or parts that fall out of the device; presence of malformed staples due to insufficient firing, compromising staple line integrity; and other manufacturing defects leading to an increased risk of compromised staple line integrity.

65. The Covidien Stapler used during Plaintiff's December 2019 surgery did not conform to manufacturing specifications and deviated from the intended specification or design.

66. The Covidien Stapler's manufacturing defects were substantial contributing factors in bringing about the injuries and damages sustained by Plaintiff. 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. He will continue to incur losses and damages in the future.

WHEREFORE, the Plaintiffs demand judgment against the defendants jointly and severally for compensatory damages and punitive/exemplary damages in sums to be deemed fair and reasonable by the trier of fact, along with all actual and statutory costs, disbursements, and attorneys' fees of this action.

Filed in District Court
State of Minnesota
12/17/2021 1:56 PM

THIRD CAUSE OF ACTION:
PRODUCTS LIABILITY – FAILURE TO WARN

67. Plaintiffs incorporate by reference as if fully set forth herein all of the allegations contained in the paragraphs above.

68. Defendants introduced the Covidien Stapler into the stream of commerce and directly advertised or marketed its staplers to consumers or persons responsible for consumers, including medical service providers across the United States and in Texas, including St. David's South Austin Medical Center, claiming that the Covidien Stapler was a safe and effective device.

69. Defendants intended and expected the Covidien Stapler to be used invasively by medical service providers. Defendants sold the defective stapler used during Plaintiff's surgery to St. David's South Austin Medical Center with that intention and expectation.

70. Defendants knew or should have known that the Covidien Stapler was defective and unreasonably dangerous. Defendants had a duty to warn of foreseeable dangers inherent in the proper use of the Covidien Stapler. Defendants showed reckless indifference to or conscious disregard for the Plaintiff's safety by failing to provide proper warnings or instructions to the public and the medical community.

71. Defendants failed to give adequate warnings of the Covidien Stapler's dangers that were known or by the application of reasonably developed human skill and foresight should have been known and which failure rendered the product unreasonably dangerous as marketed.

72. Defendants failed to give adequate instructions to avoid the Covidien Stapler's dangers that were known or by the application of reasonably developed human skill and foresight should have been known and which failure rendered the product unreasonably dangerous as marketed.

Filed in District Court
State of Minnesota
12/17/2021 1:56 PM

73. Defendants failed to provide adequate warnings or instructions to consumers and users of its staplers concerning the significant dangers associated with the staplers and/or their component parts, or to instruct consumers and users regarding the operation of the staplers and warned or failed to warn and instructed or failed to instruct anticipated users of the staplers concerning defects.

74. Defendants failed to provide adequate warnings to consumers of the product, including Plaintiff's surgeons of the risk, limitations, and alternatives to the Covidien Stapler, and continued to aggressively market the product.

75. Defendants failed to properly and adequately warn and instruct the Plaintiff and his health care providers as to the safest and most effective methods of use of the Covidien Stapler used to perform Plaintiff's anastomosis on December 19, 2019.

76. Defendants failed to properly and adequately warn and instruct the Plaintiff and his health care providers, including St. David's South Austin Medical Center, as to the risks of the Covidien Stapler, given the Plaintiff's condition and need for information.

77. Had Plaintiff's surgeon been adequately warned of the potential risks, limitations, and alternatives, the surgeons would have discussed that risk with the Plaintiff and/or would not have recommended or used the stapler. Moreover, had Plaintiffs been adequately warned they would have declined to move forward with Plaintiff William Jones' surgery with the Covidien Stapler.

78. Defendants' failure to warn was a substantial contributing factor in bringing about the injuries and damages sustained by Plaintiff. Plaintiff has incurred losses and damages for personal injury, loss of use and enjoyment of life, the need for periodic medical examination and

Filed in District Court
State of Minnesota
12/17/2021 1:56 PM

treatment, and economic losses, including additional medical expenses, and the expenditure of time and money. He will continue to incur losses and damages in the future.

WHEREFORE, the Plaintiffs demand judgment against the defendants jointly and severally for compensatory damages and punitive/exemplary damages in sums to be deemed fair and reasonable by the trier of fact, along with all actual and statutory costs, disbursements, and attorneys' fees of this action.

FOURTH CAUSE OF ACTION: NEGLIGENCE

79. Plaintiffs incorporate by reference as if fully set forth herein all of the allegations contained in the paragraphs above.

80. Defendants had a duty to exercise ordinary care when they designed, manufactured, inspected, tested, assembled, promoted, distributed, marketed, and sold the Covidien Stapler including a duty to ensure that the stapler did not pose a significantly increased risk of adverse events.

81. An ordinarily prudent manufacture exercising ordinary care would know that a stapler that fell apart during surgery or otherwise failed to operate correctly could cause serious injury.

82. Defendants failed to exercise ordinary care when they designed, manufactured, inspected, tested, assembled, promoted, distributed, marketed, and sold the Covidien Stapler used in Plaintiff's procedure, because they failed to act as a reasonable manufacturer of ordinary prudence would have done under the same or similar circumstances or doing what a reasonable manufacturer of ordinary prudence would not have done under the same or similar circumstances.

Filed in District Court
State of Minnesota
12/17/2021 1:56 PM

83. The Covidien Stapler used in Plaintiff's procedure featured a defect which prevented Plaintiff's surgeon from completing an anastomosis, causing injury during the procedure.

84. Defendants failed to exercise ordinary care in the following particulars:

a. Failing to use due care in the design and manufacturing of the Covidien Stapler so as to avoid defects from occurring and risks to patients including Plaintiff;

b. Failing to accompany the Covidien Stapler with proper warnings and/or instructions;

c. Failing to conduct adequate testing to determine the safety of the Covidien Stapler;

d. Failing to recall the Covidien Stapler when they knew or should have known the Covidien Stapler was unreasonably dangerous;

e. Failing to provide adequate training to medical care providers as to the appropriate use of the Covidien Stapler; and

f. Such other and further particulars as the evidence may show.

85. Defendants knew or should have known that patients such as the Plaintiff would suffer foreseeable injury as a result of Defendants failure, jointly and/or severally, to exercise ordinary care as described above.

86. The Covidien Stapler failure and damages resulting therefrom were caused by the negligence and carelessness of the Defendants in their design, manufacture, and sale.

87. Defendants' conduct was reckless, willful, wanton, malicious, and oppressive, and so outrageous as to warrant the assessment of punitive/exemplary damages in sums to be deemed fair and reasonable by the trier of fact in order to deter the Defendants and others from engaging in similar or wrongful conduct in the future, along with all actual and statutory costs, disbursements, and attorneys' fees of this action.

Filed in District Court
State of Minnesota
12/17/2021 1:56 PM

88. Defendants' negligence was a substantial contributing factor in bring about the injuries and damages sustained by Plaintiff. 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. He will continue to incur losses and damages in the future.

WHEREFORE, the Plaintiffs demand judgment against the defendants jointly and severally for compensatory damages and punitive/exemplary damages in sums to be deemed fair and reasonable by the trier of fact, along with all actual and statutory costs, disbursements, and attorneys' fees of this action.

FIFTH CAUSE OF ACTION:
FRAUDULENT MISREPRESENTATION

89. Plaintiffs incorporate by reference all other paragraphs of this complaint as if fully set forth here and further allege as follows:

90. At all times relevant, Defendants marketed, sold, and distributed the Covidien Stapler as a safe and effective device for treating end-to-end anastomosis.

91. At the time Defendants marketed, sold, and distributed the Covidien Stapler in or about December of 2019, Defendants knew or should have known that the stapler could fail to operate adequately and allow for dehiscence, causing injury. Defendants were aware, as far back as 2015, that the staplers they manufactured could fail, dehisce, and cause serious injury. Defendants were aware, through internal testing and quality controls that staplers, like the Covidien Stapler, were

92. Defendants intentionally and deliberately withheld relevant quality control that would have picked up defects in the product and withheld information from the consuming public and its sales representatives and agents regarding this modification. Defendants, as parties with

Filed in District Court
State of Minnesota
12/17/2021 1:56 PM

specialized knowledge or material facts related to the safety of the Covidien Staplers, had a duty to communicate these undisclosed facts.

93. Defendants intentional deliberate withholding of this information was a false and material misrepresentation of fact.

94. Defendants intentionally and deliberately made these misrepresentations with the express intent to induce physicians, including Plaintiff's physician(s), to purchase and use the Covidien Stapler.

95. Plaintiff's physician(s) relied on Defendants' material misrepresentations in choosing and recommending for use the Covidien Stapler for Plaintiff's procedure.

96. Defendants' fraudulent misrepresentations were substantial contributing factors bringing about the injuries and damages, including pecuniary damages, sustained by Plaintiff. 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. He will continue to incur losses and damages in the future.

WHEREFORE, the Plaintiffs demand judgment against the defendants jointly and severally for compensatory damages and punitive/exemplary damages in sums to be deemed fair and reasonable by the trier of fact, along with all actual and statutory costs, disbursements, and attorneys' fees of this action.

SIXTH CAUSE OF ACTION:
BREACH OF IMPLIED WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE

97. Plaintiffs incorporate by reference as if fully set forth herein all of the allegations contained in the paragraphs above.

Filed in District Court
State of Minnesota
12/17/2021 1:56 PM

98. Defendants, each of them, had reason to know of the buyers of their surgical staplers, medical providers' particular purpose to use their surgical staplers in association with surgery to the rectal area of humans for anastomosis.

99. Also, in connection with its distribution and sale of the Stapler and/or Staples, the Defendants impliedly warranted that the Covidien Stapler and/or staples were reasonably fit for their intended purpose, i.e., end-to-end anastomosis.

100. The buyer of Defendants' products -- medical providers including Plaintiff's medical providers -- relied on the skill and judgement of Defendants in designing, manufacturing, and selling surgical staplers that were without defect and appropriate for their intended use. Plaintiff was an intended beneficiary of those warranties.

101. The Defendants breached these implied warranties, in that the Covidien Stapler and/or staples were defective and failed during foreseeable use. Specifically, the Covidien Stapler and/or staples "malfunctioned" and failed to adequately form staple lines.

102. Defendants' breach of implied warranty were substantial contributing factors bringing about the injuries and damages sustained by Plaintiff. 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. He will continue to incur losses and damages in the future.

WHEREFORE, the Plaintiffs demand judgment against the defendants jointly and severally for compensatory damages and punitive/exemplary damages in sums to be deemed fair and reasonable by the trier of fact, along with all actual and statutory costs, disbursements, and attorneys' fees of this action.

Filed in District Court
State of Minnesota
12/17/2021 1:56 PM

SEVENTH CAUSE OF ACTION:
BREACH OF EXPRESS WARRANTY

103. Plaintiffs incorporate by reference as if fully set forth herein all of the allegations contained in the paragraphs above:

104. Through their use of marketing campaigns directed at health care providers, including brochures, websites and other media, the Defendants expressly warranted that the Covidien Stapler was safe, effective and reliable for its purpose as an instrument to be used IN anastomosis procedures.

105. Plaintiff's doctor(s) reasonably relied upon this express warranty in their decision to utilize the Covidien Stapler.

106. Defendants intended Plaintiff's doctor(s) to rely on this express warranty.

107. This express warranty was part of the basis of the bargain.

108. Defendants' breached this express warranty, in that the Covidien Stapler was not safe, effective or reliable but instead failed under foreseeable use. Specifically, the Stapler and/or Staples "malfunctioned" and failed, in violation of Minn. Stat. § 336.2-313.

109. Defendants' breach of express warranty was a substantial contributing factor bringing about the injuries and damages sustained by Plaintiff. 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. He will continue to incur losses and damages in the future.

WHEREFORE, the Plaintiffs demand judgment against the defendants jointly and severally for compensatory damages and punitive/exemplary damages in sums to be deemed fair and reasonable by the trier of fact, along with all actual and statutory costs, disbursements, and attorneys' fees of this action.

Filed in District Court
State of Minnesota
12/17/2021 1:56 PM

EIGHTH CAUSE OF ACTION:
LOSS OF CONSORTIUM

110. Plaintiffs incorporate by reference as if fully set forth herein all of the allegations contained in the paragraphs above:

111. As a direct and proximate result of Defendants' negligence and failure to warn, Plaintiff Kathleen Jones has suffered emotional, psychological and economic injuries, the loss of society and companionship, and loss of consortium as a result of the injuries inflicted on her husband, Bruce Jones.

WHEREFORE, the Plaintiffs demand judgment against the defendants jointly and severally for compensatory damages and punitive/exemplary damages in sums to be deemed fair and reasonable by the trier of fact, along with all actual and statutory costs, disbursements, and attorneys' fees of this action.

NINTH CAUSE OF ACTION:
VIOLATION OF MINNESOTA CONSUMER PROTECTION/FRAUD STATUTES

112. Plaintiffs incorporate by reference as if fully set forth herein all of the allegations contained in the paragraphs above:

113. At all pertinent times, Defendants engaged in deceptive trade practices, in violation of Minn. Stat. § 325D.13; § 325F.69, and § 325D.44, in the manufacturing, distributing, marketing, promoting, and sale of the Covidien Stapler the following ways:

a. representing that the Covidien Stapler is of a particular standard, quality or grade, or good for a particular use;
b. knowingly misrepresenting the safety and efficacy of the Covidien Stapler, by failing to inform consumers, including Plaint and Plaintiff's physicians, of the true risks associated with its use in end-to-end anastomosis; and
c. otherwise engaging in practices that are unfair and/or deceptive to consumers, including Plaintiff.

Filed in District Court
State of Minnesota
12/17/2021 1:56 PM

114. Defendants breach of Minnesota's consumer protection statutes were a substantial contributing factor bringing about the injuries and damages sustained by Plaintiff. 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. He will continue to incur losses and damages in the future.

WHEREFORE, the Plaintiffs demand judgment against the defendants jointly and severally for compensatory damages and punitive/exemplary damages in sums to be deemed fair and reasonable by the trier of fact, along with all actual and statutory costs, disbursements, and attorneys' fees of this action.

PRAYER FOR RELIEF

1. Defendants' actions have directly and proximately caused, and will cause, Plaintiff to sustain the following damages, including but not limited to:

a. Past and future medical and incidental expenses;

b. Past and future loss of earnings and/or earning capacity;

c. Past, present, and future physical and mental pain and suffering;

d. Past, present, and future disfigurement;

e. Past, present, and future disability;

g. Pre-judgment and post-judgment interest;

h. All other relief in law and equity as this Court may deem just and proper.

2. Due to Defendants' negligence, manufacturing and design defects, and fraudulent representations, Plaintiff is entitled to compensatory damages in a sum to be determined by a jury.

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State of Minnesota
12/17/2021 1:56 PM