IN THE UNITED STATES DISTRICT COURT
THE DISTRICT OF SOUTH CAROLINA
FLORENCE DIVISION

JOHN EICHIN, Plaintiff, v. COVIDIEN LP, COVIDIEN SALES LLC, COVIDIEN HOLDING, INC., and MEDTRONIC, INC. Defendants.	)	C/A No.:2021

PLAINTIFF'S COMPLAINT AT LAW

NOW COMES the Plaintiff, JOHN EICHIN, by and through his attorneys, HAWK LAW, P.A., and HART, DAVID, CARSON, LLP, and files this Complaint against Defendants, COVIDIEN LP, COVIDIEN SALES LLC, COVIDIEN HOLDINGS, INC., and MEDTRONIC, INC. Plaintiff states the following:

JURISDICTION AND VENUE

1. This is a civil action of which this Court has original jurisdiction under 28 U.S.C. § 1332 because it is a civil action between citizens of different states and citizens of a state and citizens of a foreign state, and the amount in controversy exceeds the sum or value of seventy-five thousand dollars, exclusive of costs and interest.

2. This Court has personal jurisdiction over Defendants because said Defendants have regularly and purposefully transacted business and engaged in commercial activities within the State of South Carolina.

3. Venue is proper in this Court pursuant to 28 U.S.C. § 1391(a) and Local Civ. Rule 3.01(A)(1). A substantial portion of the events and omissions giving rise to this lawsuit occurred in the Florence Division, and the Court has personal jurisdiction over each of the parties as alleged through this complaint.

INTRODUCTION AND SUMMARY OF ACTION

4. Plaintiff contends that Defendants designed, manufactured and marketed a defective class of surgical staplers that includes the Endo GIA, EEA, and other similar products. 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.

5. Instead, the majority of the reports were submitted to the ASR Program, which had the effect of hiding the information and severity of the problems with the devices from surgeons and the public.

6. While the ASR Program enabled manufacturers of certain device types to submit quarterly summary reports of specific well-known and well-characterized events in lieu of individual reports of each 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.

7. Plaintiff's injuries occurred shortly after this time period. Since the discovery of this conduct by Defendants, the staplers used on Plaintiff have been the subject of a recall and are

being considered for reclassification from Class 1 devices (similar to an adhesive bandaid) to Class 2 devices.

8. Surgical staplers at issue in this action were designed, manufactured, and marketed by Defendants, and malfunctioned during Plaintiff's surgery. That malfunction caused Plaintiff to undergo subsequent surgeries and extensive medical treatment.

PARTIES

9. Plaintiff, JOHN EICHIN, is a citizen of the State of South Carolina and resides in Anderson County, South Carolina.

10. Defendant, MEDTRONIC, INC., is a Minnesota Corporation that has its principal place of business at 710 Medtronic Parkway, Minneapolis, Minnesota. Medtronic is a 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 South Carolina and regularly caused its products to be sold in South Carolina, including to Grand Strand Regional Medical Center in the city of Myrtle Beach, County of Horry, and State of South Carolina. Therefore, personal jurisdiction is proper under the Due Process Clauses of the Fifth and Fourteenth Amendments to the Constitution of the United States of America.

11. 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. Among its business activities, Covidien LLC is involved in the manufacture, distribution, sales, marketing, regulatory management, and services related to Covidien LLC medical products in the United States, and in South Carolina where it maintains a

large sales operation selling Covidien LLC products all over the State of South Carolina, including the specific surgical stapler involved in the subject incident. At all times relevant to this action, Covidien LLC has conducted substantial business in South Carolina. Therefore, personal jurisdiction is proper under the Due Process Clauses of the Fifth and Fourteenth Amendments to the Constitution of the United States of America.

12. Covidien LLC is registered to do business in the state of South Carolina 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 South Carolina operating as a subsidiary under the complete control of Medtronic, Inc. At all times relevant, Defendant Covidien LLC sold, marketed and distributed its products, including surgical staplers, throughout the United States, including the state of South Carolina.

13. 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 South Carolina 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 South Carolina operating as a subsidiary under the complete control of Medtronic, Inc.

14. 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 South Carolina.

15. 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 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 Plaintiff to suffer injury and damages.

16. Covidien and Medtronic (collectively referred to as "Defendants") are individually, jointly, and severally liable to Plaintiff for damages suffered by Plaintiff 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.

GENERAL ALLEGATIONS

17. Defendants design, manufacture and sell End to End Anastomosis Stapler, a surgical stapler to be used by medical service providers in surgical procedures. The stapler comes in various models, which are generally denominated as "EEA" followed by a number. EEA staplers enable surgeons to create a secure anastomosis (connection between two internal bodily structures) within the body and form a seal.

18. Defendants designed, manufactured and sold defective EEA staplers, surgical staplers that were available in the market to be used in surgical procedures before, during and after 2017. These staplers frequently malfunctioned and were defective, compromising staple integrity and surgical procedures, with the potential to lead to patients' death or serious injuries when used by a surgeon, even as instructed by Defendants in the device user manual.

19. Defendant Covidien initiated a recall of EEA staplers on August 17, 2018. Specifically, Covidien "identified the potential for a device to have an incorrect tissue gap. Use of a device with an incorrect tissue gap may result 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." The FDA determined the cause was "process design." Id.

20. Plaintiff, JOHN EICHIN, was admitted to Grand Strand Regional Medical Center on October 15, 2019, to undergo surgery for diverticulitis and the removal of a large mass in his colon, including a Sigmoid resection on October 16, 2019.

21. After the surgery on October 16, 2019, Plaintiff, JOHN EICHIN, began to suffer tremendously. He became tachycardiac, had a fever, and began feeling so poor that he "would rather die."

22. On October 21, 2019, Plaintiff, JOHN EICHIN, was diagnosed with sepsis and rushed to the operating room for emergency surgery. Dr. Clatterbuck, together with Dr. Baughman, performed surgery to repair a colorectal anastomic leak. In his operative report, Dr. Clatterbuck writes that the anastomic leak was caused by an area of non-functional staples.

23. As a result of the above surgery, Plaintiff, JOHN EICHIN, had to undergo numerous other surgeries, including the placement of a very large area of mesh throughout his entire abdomen.

24. Plaintiff alleges, upon information and belief, that the specific stapler that failed during his initial October surgery was a model that was known by Defendants to frequently malfunction. In fact, that model was later subject to recall.

25. Plaintiff alleges that the stapler that was used during his surgery was among a class of staplers known by Defendants to malfunction or contain defects, whether it was included specifically in a recall or not.

26. 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. An alternative reporting system (ASR) was established, though, for reporting well-known and well-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 re classification.

27. 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 Plaintiff's surgery, and that the devices would have been appropriately recalled before being used on Plaintiff by her unsuspecting surgeons.

28. 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.

29. 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.[2]

30. 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.[3] 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.[4] 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 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.

31. 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).[5] Among other things, this required manufacturers, including Defendants, to publicly report all malfunctions or injuries related to the Covidien staple; 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 more than 11,000 reports in 2018.

32. 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.

33. Defendants intentionally failed to: (1) provide warnings regarding the potential for their staplers to malfunction in the very manner that occurred during Plaintiff's surgery; (2) warn and inform surgeons of the potential for its staplers to malfunction in that manner; and (3) recall their defective products when Defendants knew their surgical staplers were prone to injurious malfunction. Through that conduct -- as well as the affirmative concealment of the known risks of the products 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. That conduct was motivated by consideration of profit, financial advantage, monetary gain, economic aggrandizement, and cost avoidance, to the virtual exclusion of all other considerations.

FIRST CLAIM FOR RELIEF
STRICT PRODUCTS LIABILITY MANUFACTURING DEFECT

(AGAINST ALL DEFENDANTS)

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

35. A manufacturer of a medical device or instrument, such as a surgical stapler, who sells or otherwise distributes a defective device is subject to liability for harm to persons caused by the defect. A medical device is defective if at the time of sale, the device departs from its intended design, even though all possible care was exercised in the preparation and marketing of the product. Thus, a medical device is defective if at the time of sale, the device is manufactured in such a way that it poses harm and risk of injury when used by the intended consumer as the manufacturer intended.

36. A reasonably prudent manufacturer of those products would also know that a stapler failing to fire staples could cause serious injury because the procedure may need to be converted to an open procedure, and that even where it might cause only serious injury, the injured patient would require multiple hospitalizations, surgeries, and significant medical care to treat.

37. A reasonably prudent manufacturer of surgical staplers would know that if it failed to exercise care in the manufacture of its product, that its product could malfunction and/or fail to properly and permanently close a surgical repaired site, causing anastomotic leak and other serious, related harm.

38. Defendants' stapler(s) were manufactured in such a way that deviated from their intended design and made those staplers unreasonably dangerous to the patient. Specifically, certain units among the stapler(s) manufactured by Defendants - including the stapler used in Plaintiff's surgery - were manufactured without a component that resulted in a failure to "fire" the staples;

the failure to "fire" staples, in turn, caused injury to the Plaintiff. The Defendants knew the specific staplers used on Plaintiff's surgical site contained a defect that caused it to fail to perform the function it was intended to perform. Specifically, the failure to manufacture these staplers in compliance with their intended design resulted in a product that malfunctioned, causing an anastomotic leak, even after proper utilization by a surgeon. These manufacturing defects existed when the products left the manufacturers' control.

39. The manufacturing defect to the EEA stapler used in Plaintiff's October 15, 2019 surgical procedure was a substantial factor in producing Plaintiff's severe injuries when the stapler misfired and failed to provide an effective anastomosis.

40. The Plaintiff's physician used the EEA stapler as directed for its intended purpose.

41. The EEA stapler used in Plaintiff's procedure had not been materially altered or modified prior to its use in Plaintiff.

42. As a direct and proximate result of the exposure to the defective EEA stapler, Plaintiff suffered injuries and damages as described herein.

SECOND CLAIM FOR RELIEF
NEGLIGENCE
(AGAINST ALL DEFENDANTS)

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

44. A Defendant who designs a medical device or instrument, such as surgical staplers, who sells or otherwise distributes a defective device is subject to liability for harm to persons caused by the design defect. A reasonably prudent manufacturer must design its products so as to avoid any unreasonable risk of harm to anyone who is likely to be exposed to the harm when the product is put to its intended use or to any use that is unintended but is reasonably foreseeable. A medical device is defective if at the time of sale, the device is designed in such a way that it

poses harm and risk of injury when used by the intended consumer in the manner the manufacturer has directed and designed.

45. A reasonably prudent manufacturer of those products would also know that a stapler failing to fire staples could cause serious injury because the procedure may need to be converted to an open procedure, and that even where it might cause only serious injury, the injured patient would require multiple hospitalizations, surgeries, and significant medical care to treat.

46. Plaintiff, JOHN EICHIN, was harmed by Defendants' defective surgical staplers, which were distributed, manufactured, and sold by Defendants. Defendants' surgical staplers contained a design defect that made the products unreasonably dangerous to patients. Specifically, there was a design or manufacturing defect that would result in a stapler failing to fire staples, despite proper utilization by a surgeon. That design defect in the staplers existed when those products left the manufacturer's control. Defendants' conduct in failing to correct aforesaid design defect before allowing consumers to use their dangerous staple guns was reckless, willful and wanton.

47. As a direct and proximate result of Defendants' 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. He will continue to incur losses and damages in the future.

48. Plaintiff alleges there were safer alternative designs of EEA staplers available to Defendants at the time the EEA stapler at issue in this case was sold. Those designs were reasonable, and economically and technologically feasible at the time the stapler at issue in this case was sold. Moreover, Plaintiff alleges that sutures are a safer alternative to surgical staplers in procedures such as that performed on him on October 15, 2019. Further evidence of the safer

alternative designs will be presented by Plaintiff's expert witnesses.

49. As a direct and proximate result of Defendants' negligence, Plaintiff has suffered significant damages, including but not limited to physical injury, economic loss, pain and suffering, and will continue to suffer such damages in the future.

THIRD CLAIM FOR RELIEF
STRICT PRODUCTS LIABILITY - FAILURE TO WARN

(AGAINST ALL DEFENDANTS)

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

51. Pleading in the further alternative, a manufacturer must provide adequate warning of dangers inherent in the improper use of the product, and adequate instructions for the safe use of the product. The warning must be in a form which could reasonably be expected to catch the attention of, and be understood by, the ordinary user. Thus, a medical device is defective if, at the time of sale, the warnings and instructions provided with the device fail to provide adequate warnings of the dangers inherent in the product's proper use.

52. A reasonably prudent manufacturer of those products would also know that a stapler failing to fire staples could cause serious injury because the procedure may need to be converted to an open procedure, and that even where it might cause only serious injury, the injured patient would require multiple hospitalizations, surgeries, and significant medical care to treat.

53. Defendants knew that their surgical staplers 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 the stapler cutting tissue, but the staples failing to "fire". Despite knowing about this defect, Defendants failed to adequately warn potential surgeons or patients at the time they discovered, or should have discovered, those defects. Defendants were

negligent for not providing sufficient notice or warnings of the risks associated with using the subject surgical staplers, including the risks associated with malfunction. Those inadequate warnings and instructions existed at the time the stapler(s) left the manufacturers' control. Defendants' conduct in failing to correct aforesaid design defect before allowing consumers to use their dangerous staple guns was reckless, willful and wanton

54. As a direct and proximate result of Defendants' failure to warn, 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.

FOURTH CLAIM FOR RELIEF
NEGLIGENCE-DESIGN DEFECT
(AGAINST ALL DEFENDANTS)

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

56. The surgical staplers designed, manufactured, and tested by defendants were defective in design, manufacture, and testing. As a result, the surgical stapler designed, manufactured, and tested by Defendants, misfired, causing great bodily injury and suffering to the Plaintiff.

57. The injuries incurred by the Plaintiff in this matter are the actual and proximate cause of the negligent design, manufacturing, and testing of the surgical staplers by the Defendants.

58. Defendants knew that their surgical staplers 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 the stapler cutting tissue, but the staples failing to "fire". Despite knowing about this design defect, Defendants failed to adequately design a reasonably

safe surgical stapler what would not misfire.. Defendants were negligent for designing a safer surgical stapler, including the risks associated with malfunction. That inadequate design, manufacturing, and testing existed at the time the stapler(s) left the manufacturers' control. Defendants' conduct in failing to correct aforesaid design defect before allowing consumers to use their dangerous staple guns was reckless, willful and wanton

FIFTH CLAIM FOR RELIEF
PUNITIVE DAMAGES
(AGAINST ALL DEFENDANTS)

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

60. The injuries sustained by Plaintiff were a direct and proximate result of the willful and wanton disregard of the dangers posed by Defendant's knowledge of the defective surgical stapler. Defendant's knew the stapler had a propensity to misfire, yet decided not to warn end users of its product about the dangers posed by misfiring staples. As a direct and proximate result of the Defendants' callous disregard for the safety of its product, Plaintiff, John Eichin, was caused to suffer extreme agony and pain including sepsis, hallucinations, multiple revisionary surgeries, lengthy hospital stays, and great loss of enjoyment of his life.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully requests this Honorable Court take jurisdiction in this matter and grant him the following relief:

1. Past and future medical and incidental expenses, according to proof;

2. Past and future loss of earning and/or earning capacity, according to proof;

3. Past and future general damages, according to proof;

4. Prejudgment and post-judgment interest;

5. Costs to bring this action; and

6. Such other and further relief as the court may deem just and proper.

7. Plaintiff demands trial by jury.

Respectfully submitted,

/s/ Logan Rollins
Logan Rollins
Attorney for Plaintiff
Hawk Law, P.A.
P: (864) 514-4383

/s/ J. Camden Hodge
J. Camden Hodge
Attorney for Plaintiff
Hawk Law, P.A.
P: (864) 514-4383

/s/ Brandon Carson Hall
Brandon C. Hall
Pro Hac Vice Admission Pending
Attorney for Plaintiff
Hart David Carson, LLP
P: (630) 395-9496
F: (630) 395-9451

Greenville, SC

October 6, 2021