

UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF LOUISIANA

DERICK PAUL SMITH

Civ. A. No.

Plaintiffs,

v.

Judge:

**COVIDIEN LP; and
MEDTRONIC, INC.;**

Magistrate:

Defendants.

Jury Trial Demanded

COMPLAINT FOR DAMAGES

NOW INTO COURT, through undersigned counsel, comes Plaintiff, DERICK PAUL SMITH, and for his Complaint, alleges as follows:

THE PARTIES

1. Plaintiff, DERICK PAUL SMITH, is, and was at all material times hereto, an individual of the full age of majority domiciled and residing in Slidell, Louisiana.

2. Defendant, Covidien LP, is, and was at all material times hereto, a limited partnership organized under the laws of the State of Delaware. Upon information and belief, all of the principals of Covidien LP are citizens of state(s) other than the State of Louisiana. Covidien LP is a subsidiary of Defendant Medtronic, Inc. Covidien LP maintains its principal place of business in Mansfield, Massachusetts, and at all times material hereto, conducted business in Louisiana and maintained a principal business establishment in Louisiana at 501 Louisiana Avenue, Baton Rouge, LA 70802.

3. Defendant, Medtronic, Inc., is, and was at all times material hereto, a corporation organized under the laws of the State of Minnesota, having its principal place of business in

Minneapolis, Minnesota. At all times material hereto, Medtronic, Inc. conducted business in Louisiana and maintained a principal business establishment in Louisiana at 501 Louisiana Avenue, Baton Rouge, LA 70802.

4. At all times material hereto, Defendants, Covidien LP and/or Medtronic, Inc., was/were responsible for the sale, marketing, promotion, and distribution of Covidien medical instruments, including the Covidien Tri-Staple ENDO GIA Surgical Stapling Device apparatus at issue (hereinafter “Covidien device” or “ENDO GIA Surgical Stapling device”), in the United States.

5. At all times material hereto, defendants, Covidien LP and/or Medtronic, Inc., transacted and conducted substantial business in the State of Louisiana and in this District, distributed ENDO GIA Surgical Stapling devices in this District, derived substantial revenue from sales within this District and from interstate commerce, and made material omissions and misrepresentations and breaches of warranties in this District so as to subject them to *in personam* jurisdiction in this District. At all times material hereto, Covidien LP and Medtronic, Inc. expected or should have expected that its/their acts would have consequences within the State of Louisiana.

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

Program. 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 such event that tracks medical device failures. Defendants, and each of them, used the ASR program to keep the scope of injuries related to surgical staplers hidden from surgeons and their patients.

7. At all times material hereto, Covidien LP and/or Medtronic, Inc. (hereinafter, collectively, “Defendants”) was/were in the business of designing, researching, manufacturing, testing, advertising, promoting, marketing, selling and distributing the ENDO GIA surgical stapling device at issue into interstate commerce throughout the United States, either directly or indirectly through third parties, subsidiaries or related entities, as a minimally invasive surgical device or system.

8. All of the described conduct, acts, and failures to act are attributed to agents and employees under the direction and control, and with the permission, consent and authorization of Defendants. Said acts, conduct and failures to act were within the scope of such agency and/or employment, and each Defendant ratified the acts and omissions of each of the other Defendants. Each of these acts and failures to act is alleged against each Defendant whether acting individually, jointly, or severally. At all times relevant herein, each Defendant was acting within the course and scope of his or her employment.

9. There exists a sufficient nexus between Defendants’ forum contacts and Plaintiffs’ claims to justify assertion of jurisdiction in Louisiana.

VENUE AND JURISDICTION

10. This is an action for products liability upon Plaintiff, which is brought against the above-referenced Defendants.

11. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. § 1332 because the amount in controversy exceeds \$75,000, exclusive of interest and costs, and Plaintiffs and Defendants are citizens of different states, as per the factual allegations contained in Paragraphs 1-9 above.

12. Venue is proper in this District pursuant to 28 U.S.C. § 1391(b) because the underlying acts and/or omissions, as well as the injuries complained of, occurred in this District. Specifically, Plaintiffs allege the surgery in suit during which the ENDO GIA surgical stapling device at issue failed and caused injury occurred in this District and that the defective product was, upon information and belief, marketed, sold and delivered within this District.

BACKGROUND

13. The claims in this Complaint arise from the use of an ENDO GIA Surgical Stapling device on Plaintiff by Dr. Asahel L. Gridley on March 16, 2020 at Slidell Memorial Hospital located in Slidell, Louisiana. During the laparoscopic surgery, the Covidien ENDO GIA purple load Stapling device was used to assist in the resection of a Meckel's Diverticulum and obstructed small bowel within Plaintiff's body, including the stapling of a side-by-side small bowel anastomosis. A distal transection was performed, with healthy tissue connected using a Covidien ENDO GIA purple load stapler. A laparoscopic surgery is a minimally-invasive surgical approach that allows for smaller incisions to be made and for a faster recovery after surgery.

14. Defendants, and each of them, were responsible for the research, design, development, testing, manufacture, production, marketing, promotion, distribution, and sale of the ENDO GIA surgical stapler at issue in this lawsuit. Defendants knew or reasonably should have known the device should not have been widely and unconditionally promoted for use in all laparoscopic bowel resections.

15. In particular, Defendants knew or reasonably should have known the 60mm version of the device, which was the version used during Plaintiff's surgery, had a higher propensity for failure such that it was unreasonably dangerous in design and/or required further and adequate warnings to surgeons (1) to use either built-in or additional means of reinforcement such as buttressing, oversuturing, or other available options and/or (2) to at least very closely and carefully inspect the area of anastomosis for staple malfunctions, misfirings, non-firings or inadequate staple formation, which were very well-known issues to Defendants, but ones Defendants hid from surgeons, including Plaintiff's surgeon, the healthcare community and the general public, and actively lied about, falsely representing their devices to be virtually failure proof for nearly a decade. The device failures at issue have also been shown to (and Defendants knew or reasonably should have known they would) be more common the longer the staple line option used (such as 60mm, the widest option Defendants offer) and/or the thicker the tissue being resected.

16. Upon information and belief, Plaintiff's injury was caused by the above defects in design and/or inadequate warnings as the medical evidence from Plaintiff's repair surgery points to, more probably than not, a failed anastomosis caused by inadequate staple line formation.

17. But for the defect(s) in design described above, Plaintiff's injury would not have occurred; while discovery may reveal other issues with the device that was used (at this time known only to Defendants), it is clear at this time that a reasonable alternative design was available and feasible and would have prevented Plaintiff's injury—specifically, one Defendants already offered: shorter staple line attachments, such as the 30mm or 45mm options. Given the high propensity of the technology for staple line failure, the 60mm option was unreasonably dangerous insofar as the longer the staple line, the higher the probability of a staple malfunction, misfiring, non-firing or inadequate staple formation. While making the anastomosis in smaller segments may

add to surgical time and minimally to surgical costs, cost-cutting and profits cannot be put before safety in the way Defendants did by overpromoting the safety and efficacy of their device and actively misleading the public as to its propensity for failure.

18. Further and/or in the alternative, but for the inadequate warnings and active misrepresentations described above regarding the safety and efficacy of the device, upon information and belief, Plaintiff's surgeon would not have used it during Plaintiff's surgery and/or would have altered use of the device (as described in paragraph 15 above) such that Plaintiff's injury and damages would not have occurred. To protect the patient, it is reasonable to believe Plaintiff's surgeon would have opted to simply use the 30mm or 45mm version more times to create the anastomosis, would have more carefully inspected for staple malfunctions of the type described above and/or would have used intra-operative means of reinforcement of the staple line at the time of creation to prevent leak and/or failure, as occurred in this case.

19. Plaintiff alleges on information and belief that the specific stapler used in his March 16, 2020 surgery was a model known by Defendants to frequently malfunction. In May 2018, Defendant Medtronic issued a recall on ENDO GIA staplers. Additionally, as recently as June 3, 2019, Defendant Medtronic issued a second recall on its ENDO GIA surgical staplers, including staplers that were distributed between April 2014 - April 2019. And yet again, in August 2020, just months after Plaintiff's surgery, Defendants initiated another recall of the device at issue—the 60mm unit in particular—for the stated reason: “The device staples may not properly form upon application preventing adequate hemostasis. **Use of a product with this assembly error may result in incomplete staple formation.**” Plaintiff alleges on information and belief the stapler used in his surgery was essentially the same model version and/or was or should have been subject to the latest recall of August 2020, for the very failure that occurred,

upon information and belief, during Plaintiff's surgery: incomplete or inadequate staple formation leading to anastomotic leak and further injuries, surgeries and damages, as described below.

20. Following surgery, Plaintiff did well for a few weeks and then started having some abdominal pains and some nausea. This progressed to include vomiting. Plaintiff re-presented to Slidell Memorial Hospital, was evaluated and nothing abnormal was noted. He worsened and re-presented to the Hospital ER again the following morning on May 17, 2020 and was noted on repeat studies to have "extraluminal free-air with suspicious anastomotic breakdown". General Surgery was consulted, and Plaintiff was taken back to the operating room by Dr. Heather Bronaugh.

21. This time Plaintiff had an open major laparotomy incision performed (not laparoscopic) with a finding of an anastomotic leak. The prior anastomotic leak was resected using a GIA stapler proximal and distal to the anastomosis. A side-to-side functional end-to-end anastomosis was then performed in the usual fashion with a GIA stapler and TA stapling device. The surgeon also noted that the appendix was secondarily inflamed from the anastomotic leak and it was removed.

22. Pathology revealed an anastomosis site transmural defect with associated fecal particles, severe acute suppurative inflammation, acute suppurative mesenteritis and acute peritonitis.

23. Plaintiff's hospital course following the corrective surgery was complicated by ileus as well as fever thought to be related to a levofloxacin resistant E. coli bacterium. Plaintiff was discharged home on May 26th some nine days after his re-admission to the Emergency Room.

24. Plaintiff then developed a post-operative wound dehiscence requiring a return to the operating room on June 4, 2020 to attempt to repair the fascial dehiscence. Plaintiff underwent

wound exploration and secondary wound closure with drain. Plaintiff was discharged home on June 5th, 2020. What should have been a fairly straight-forward and uncomplicated minimally invasive Meckel's Diverticulum – a rather simple procedure in terms of degree of skill and difficulty, especially on a patient as young and otherwise healthy as Plaintiff – turned into a major invasive abdominal surgery with months of healing required because of a faulty ENDO GIA Stapling device which caused a leak at the anastomosis site. In the FDA Executive Summary Prepared for the May 30, 2019 Meeting of the General and Plastic Surgery Devices Panel, the FDA included the following example of a common result of a defective surgical stapler: “early postoperative anastomotic leak resulting from stapler malfunction may lead to sepsis due to peritonitis, requiring immediate surgery”. All of the hallmarks of this problem, which again was well known to Defendants but well hidden by Defendants from the public, occurred in this case such that it is clear Plaintiff's injury was caused by the very defect(s) alleged herein for which Defendants are liable.

25. Defendants, and each of them, prior to and at the time of Plaintiff's surgery, took advantage of FDA exemptions and refused and failed to report non-fatal stapler related injuries to the MAUDE Database. Instead, Defendants, and each of them, utilized an alternative summary reporting program, which is not publicly accessible, as a means of circumventing their duty under the law to reasonably warn patients, surgeons and the medical community about known injuries resulting from actual or potential device failures, defects or use. By not reporting all stapler-related injuries on MAUDE, Defendants have hidden the true risks of using the devices from surgeons, their patients and the healthcare community. For example, in 2016, while reports of 84 stapler injuries or malfunctions were openly submitted, nearly 10,000 malfunction reports were included in the hidden database, according to the FDA.

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

27. The public Database shows that Medtronic has reported more than 250 deaths related to staplers or staples since 2001. Despite this knowledge of the dangers associated with using its products, Medtronic used reporting exemptions to file stapler-related reports in a database hidden from doctors and from public view through July 2017. By doing so, Defendants intentionally hid from public view the many injuries caused by the use of its ENGO GIA staplers. This concealment denied surgeons, including the surgeon who performed Plaintiff's surgery, and patients like Plaintiff, critical information on the safety of Defendants' products. Plaintiff specifically and affirmatively pleads, upon information and belief, that had the true nature of Defendants' device been revealed to Plaintiff's surgeon prior to his March 2020 surgery, said surgeon would not have used the device or would have altered his use of the device as described above such that injury either would not have occurred or would have been detected intra-operatively and fixed with minimal additional surgical time.

28. 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). Further, device manufacturers are no longer able to use the reporting exemptions for injuries related to surgical staplers. As a result, reports by Defendants, related to malfunctions or injuries related to the type of Covidien devices in question, skyrocketed from 1,000 reports in 2015 to 11,000 reports in 2018.

29. Despite knowing that its ENDO GIA staplers caused injuries due to malfunction, Defendants, and each of them, represented and marketed the ENDO GIA staplers as safe and effective. Defendants, and each of them, failed to include warnings regarding potential malfunctions that were known to them, including the risks described in the FDA publication and described in the above paragraphs of this Complaint.

30. Defendants intentionally engaged in the following conduct: 1) failing to provide warnings regarding the potential for their ENDO GIA surgical staplers to malfunction in a manner exactly like what occurred during Plaintiff's surgery; 2) failing to warn and inform surgeons of the potential for their ENDO GIA surgical staplers to malfunction in a manner exactly like what occurred during Plaintiff's surgery; 3) failing to recall their defective products until 2018, 2019 and 2020 when they knew earlier ENDO GIA surgical staplers were prone to malfunction; and 4) failing to publicly report each ENDO GIA surgical stapler malfunction or injury in the publicly accessible database and thereby concealing know incidents from public view. By engaging in the conduct described above, Defendants engaged in willful, wanton, reckless, malicious behavior and/or exhibited a gross indifference to and/or a callous disregard for human life, the safety and the rights of others, and more particularly, the rights, life and safety of the Plaintiff. Defendants were motivated by consideration of profit, financial advantage, monetary gain, economic aggrandizement and cost avoidance, to the virtual exclusion of all other considerations.

LOUISIANA PRODUCTS LIABILITY ACT – CAUSES OF ACTION

COUNT I

STRICT LIABILITY – FAILURE TO WARN

31. The allegations above are incorporated by reference to support this Count.

32. Defendants, and each of them, failed to provide accurate information to the public including surgeons, on the risks associated with using their ENDO GIA staplers. Specifically,

Defendants, and each of them, promoted the staplers as being safe while they used FDA reporting exemptions to avoid publicly disclosing known incidents where ENDO GIA staplers injured patients due to malfunctions. As a result, neither Plaintiff nor her surgeon knew of the risks of injury like the one Plaintiff suffered, prior to her surgery.

33. The ENDO GIA Surgical Stapler device was not reasonably safe for its intended use and was defective as a matter of law due to lack of appropriate and necessary warnings, as detailed above, including but not limited to the lack of warning/instruction that the staple line may not adequately hold and that the risk of an anastomosis related leak is higher than with a more traditional suturing technique and/or lack of warnings including but not limited to those described above in Paragraphs 15-19.

34. Defendants negligently and/or intentionally failed to withdraw the device from the market, restrict its use and/or warn of its potential dangers, given their knowledge or constructive knowledge of the potential for its failure under the circumstances presented here and the resultant harm it could and did cause in this and many other surgical cases.

35. Defendants failed to exercise reasonable care in informing physicians and/or hospitals using the device about their own knowledge regarding said device's potential to cause harm; in fact, Defendants' actions signify a conscious decision to mislead the public in order to continue the flow of profits to the detriment of patients.

36. Defendants negligently and/or intentionally promoted and marketed the ENDO GIA stapler device, particularly the 60mm option, as safe and/or safer than other comparative methods and/or products on the market. Defendants negligently and/or intentionally promoted and marketed the device as more fully described above, including in Paragraphs 15-19, and despite knowledge of a vastly greater propensity for failure than it promoted to the public.

37. Upon prayer and belief, and as more fully described in Paragraphs 15-19 above, had Plaintiff's surgeon been made aware of the true nature and potential for harm of the subject device, said surgeon either would not have used it during Plaintiff's surgery or would have altered use of the device such that Plaintiff's injury either would not have occurred or would have been detected and repaired intra-operatively without the need for further emergency and invasive surgery.

38. As a direct and proximate result of Defendants' negligence and/or 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, and will continue to incur losses and damages in the future.

39. Defendants are strictly liable to Plaintiff for designing, manufacturing, marketing, labeling, packaging and selling a defective product.

COUNT II
STRICT LIABILITY – DESIGN DEFECT

40. The allegations above are incorporated by reference to support this Count.

41. Defendants, and each of them, failed to provide accurate information to the public including surgeons, on the risks associated with using their ENDO GIA staplers. Specifically, Defendants, and each of them, promoted the staplers as being safe while they used FDA reporting exemptions to avoid publicly disclosing known incidents where ENDO GIA staplers injured patients due to malfunctions. As a result, neither Plaintiff nor her surgeon knew of the risks of injury like the one Plaintiff suffered, prior to her surgery.

42. Upon information and belief, the ENDO GIA Surgical Stapler device was not reasonably safe for its intended use and was defective as a matter of law in terms of its "design."

Specifically, information in this regard and factual support for the foregoing includes but is not limited to the FDA's determination and/or Defendants' determination that "assembly error" was the cause of the issue, for which Defendant Covidien initiated a recall in August 2020, and that caused, in whole or in part, Plaintiff's failed anastomosis.

43. The nature of this design defect, as well as at least one potential reasonable, feasible and available alternative design that would have prevented Plaintiff's injury, is all more fully described in Paragraphs 15-19 above and in the background/facts section of this Complaint more generally.

44. Defendants failed to withdraw the device from the market, restrict its use and/or warn of its potential dangers, given their knowledge or constructive knowledge of the potential for its failure under the circumstances presented here and the resultant harm this could cause. Defendants, and each of them, knew that the ENDO GIA stapler posed a risk to patients when used as intended because certain units were manufactured without a component that resulted in a failure to form a staple line further resulting in leakage and/or because Defendants knew or should have known of the above-described "assembly error" that results in "incomplete staple formation" as occurred in this case. *See* Paragraphs 15-19, *supra*.

45. Despite knowing about this/these defect(s), Defendants, and each of them, failed to warn potential surgeons or patients until an initial recall in 2018, a second recall in 2019 and yet a third recall in 2020. Defendants failed to exercise reasonable care in informing physicians and/or hospitals using the ENDO GIA Surgical Stapling device about their own knowledge regarding said device's potential to cause harm and defective condition.

46. 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.

47. Defendants are strictly liable to Plaintiffs for designing, manufacturing, marketing, labeling, packaging and selling a defective product.

COUNT III
STRICT LIABILITY – CONSTRUCTION/COMPOSITION DEFECT

48. The allegations above are incorporated by reference to support this Count.

49. The ENDO GIA surgical stapling device used was unreasonably dangerous in construction or composition as described more fully in Paragraphs 15-19 above. In particular, at this time Plaintiff pleads Defendants' exclusive knowledge as to whether the defect(s) in the device at issue were particular to certain devices within the product line, which "deviated" from Defendants' manufacturing specifications and/or performance standards (such that the defect was in the nature of a construction/composition defect) or, rather, the entire product line was defective in "design." All that Defendants' device recall reveals is that the issue was due to an "assembly error" which could fit into either category. As such, Plaintiff alternatively pleads a construction or compositive defect rendering the device used during Plaintiff's surgery unreasonably dangerous and causing Plaintiff's injuries and further pleads discovery is necessary before it can be determined which of the two applies here.

50. All of the foregoing having been said, concurrently and/or in the alternative, it is clear the device at issue failed to meet the "performance standard," as represented and marketed by defendants, that it would create a permanent anastomosis when used as directed or as reasonably foreseeable by Defendants, which the medical record reveals it was in this case.

51. 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.

52. Defendants are strictly liable to Plaintiff for designing, manufacturing, marketing, labeling, warranting, packaging and selling a defective product.

COUNT IV
BREACH OF IMPLIED WARRANTIES

53. The allegations above are incorporated by reference to support this Count.

54. As fully detailed hereinabove, the device at issue was not reasonably fit for its intended use and/or contained an inherent and unknown/unknowable defect or defects that reasonable investigation would not have revealed and that, if known, would have prevented the purchase/sale of the device that resulted in its use in Plaintiff's surgery. Plaintiff refers to the detailed facts above, particularly Paragraphs 15-19 above, as well as the remaining counts in this Complaint, which fully support the existence of redhibitory defect(s) in the product and/or defect(s) rendering the device in question unfit for its intended use—the very use to which it was put in Plaintiff's surgery (resecting the small intestine and creating a permanent anastomosis).

55. Under Louisiana law, “privity of contract” or a direct seller/purchaser relationship is not necessary to maintain breach of implied warranty claims of the type pled herein.

56. Further, under Louisiana law, because Defendants not only are presumed to have knowledge of such defects as manufacturer-sellers of the product but also are specifically alleged herein to have had such knowledge and hidden it for years from the public, Defendants must be

deemed “bad faith” sellers such that attorney’s fees, costs, expenses and/or other consequential damages are available to Plaintiff and demanded herein.

57. Defendants falsely represented that the ENDO GIA stapling device, and in particular the 60mm version, were safe and effective for use despite specific knowledge to the contrary. As a direct result of this false marketing and promotion of the device, it was purchased for and used in Plaintiff’s surgery. Plaintiff requests return of the purchase price for the device as reflected in the surgical billing (and passed on to Plaintiff) and further, since Defendants undoubtedly qualify as “bad faith sellers” under Louisiana law, Plaintiff prays for all such damages, penalties, costs and/or consequential damages, as this Court may determine, that are reasonably owed under the Louisiana Civil Code provisions concerning implied warranties of sale.

JURY DEMAND

58. Plaintiffs hereby demand a trial by jury on all Counts and as to all issues.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for relief as follows:

1. Compensatory damages in excess of the jurisdictional amount, including, but not limited to, damages for personal injuries, pain and suffering, severe emotional distress and mental anguish, financial or economic loss, including but not limited to obligations for past and future medical services and expenses, present and future lost wages and other damages in an amount to be determined by a jury at trial of this action;
2. Incidental and consequential damages as allowed by law;
3. Attorney’s fees and costs as allowed by law; and

4. Any other relief to which the law entitles Plaintiffs, with Plaintiffs reserving the right to amend and/or supplement this Complaint should the discovery process reveal further claims and/or damages to which Plaintiffs are entitled;

5. Such other and further relief as this Court deems just and proper.

Dated this 15th day of March, 2021.

JIM HALL AND ASSOCIATES, LLC

/s/ Jennifer L. Crose

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