IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

TRACY HUNT Plaintiff, v. COVIDIEN LP, COVIDIEN SALES LLC, COVIDIEN HOLDING INC., and MEDTRONIC, INC., Defendants.	**CIVIL ACTION** Case No. COMPLAINT AND JURY DEMAND

PLAINTIFF'S ORIGINAL COMPLAINT AND JURY DEMAND

COMES NOW Plaintiff TRACY HUNT, by and through her undersigned counsel, and hereby files this Complaint and states as follows:

PARTIES, JURISDICTION & VENUE

1. Plaintiff, Tracy Hunt, is and was at all times relevant, a resident and citizen of North Carolina.

2. Defendant Covidien LP 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 LP has one general partner: Covidien Holding Inc., a Delaware corporation with its principal place of business in Massachusetts. Among its business activities, Covidien LP is involved in the manufacture, distribution, sales, marketing, regulatory management, and services related to Covidien surgical stapling systems, including the surgical stapler reloads at issue in this case.

3. Defendant Covidien Holding Inc. is a Delaware corporation with its principal place of business in Massachusetts. Among its business activities, Covidien Holding Inc. is involved in the manufacture, distribution, sales, marketing, regulatory management, and services related to Covidien surgical stapling systems, including the surgical stapler reloads at issue in this case.

4. Defendant Covidien Sales LLC is a Delaware corporation with its principal place of business in Massachusetts. Among its business activities, Covidien Sales LLC is involved in the manufacture, distribution, sales, marketing, regulatory management, and services related to Covidien surgical stapling systems, including the surgical stapler reloads at issue in this case.

5. Defendant Medtronic, Inc. is a Minnesota corporation with its principal place of business in Minnesota. Among its business activities, Medtronic, Inc. is involved in the manufacture, distribution, sales, marketing, regulatory management, and services related to Covidien surgical stapling systems, including the surgical stapler reloads at issue in this case.

6. All acts and omissions of Covidien LP, Covidien Sales LLC, Covidien Holding Inc., and Medtronic, Inc. (collectively referred to as "Defendants") as described herein were done by their agents, servants, employees and/or owners, acting in the course and scope of their respective agencies, services, employments and/or ownership.

7. Federal subject matter jurisdiction in this action is based upon 28 U.S.C. § 1332(a), in that there is complete diversity between Tracy Hunt and Defendants, and the amount in controversy exceeds $75,000.

8. Defendants have significant contacts with this federal judicial district and operate their surgical stapler design, manufacturing, and marketing business in this federal district such that they are subject to the personal jurisdiction of the Court in this district.

9. A substantial part of the events and omissions giving rise to Plaintiff's causes of

action occurred in this federal judicial district. Pursuant to 28 U.S.C. § 1391(a), venue is proper in this district.

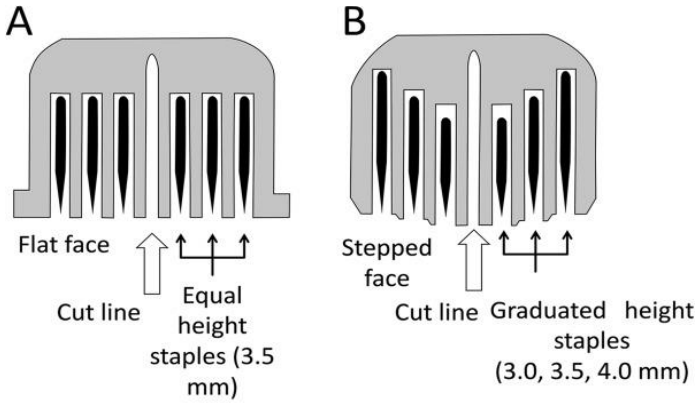
FACTS COMMON TO ALL COUNTS

Surgical Staplers

10. Surgical staplers for internal use have the primary function of delivering staples to tissues inside the body during both minimally invasive (laparoscopic) and open surgery when removing part of an organ (resection), cutting through and sealing organs and tissues (transection), or creating connections between structures (anastomoses).[1]

11. Many laparoscopic staplers consist of handles, fashioned much like a pistol in shape and firing mechanism, and compatible "reloads," which can be attached to these handles and contain a knife blade to cut tissue and staple cartridges with rows of titanium staples to form a staple line. Defendants have developed a particular type of reload technology, called Tri-Staple Technology, which provides varied-height staples that are deployed in two triple-staggered, height-progressive rows (*see Model B in Figure 1*).

Figure 1



12. During the procedure in question, the following products manufactured by

[1] *Surgical Staplers and Staples*, FDA.GOV, https://www.fda.gov/medical-devices/general-hospital-devices-and-supplies/surgical-staplers-and-staples (last updated October 7, 2021).

defendants were used: Endo GIA Ultra Universal XL Stapler Handle (EGIAUXL), Endo GIA Reload with Tri-Staple Technology - Reinforced Reload Purple (SIGTRSB60AMT), and Endo GIA Reload with Tri-Staple Technology - Reinforced Reload Black (SIGTRSB60AXT). These attachable reloads are available in a variety of dimensions and are color-coded based on the height of the staples within the cartridges, which are selected depending on the thickness of the tissue to be transected and/or anastomosed.

13. Tracy Hunt's medical records show that the particular reloads that injured her were each 60 mm in length, with the purple reload containing staples that were 3 mm, 3.5 mm, and 4 mm in height, intended for medium/thick tissue, and the black reload measuring 4 mm, 4.5 mm, and 5 mm tall, containing staples meant for extra-thick tissue.

Surgical Stapler Failure and Malfunction

14. The risk of failure and malfunction of surgical staplers has been well-known to the Defendants since the start of the device's widespread use in the early 1990s, and the figures pulled from these studies are startling. For example, by 2001, Defendants knew, or should have known, that 112 deaths, 2,180 injuries, and 22,804 adverse events (AEs) associated with device malfunction had been reported to the FDA's Manufacturer and User Facility Device Experience (MAUDE) database.[2] The sheer bulk of AEs should have signaled to the Defendants that there was a defect in their product.

15. The pattern continued. From January 2006 to January 2016, there was a total of 13,312 reports, with 106 events resulting in death, 3,234 resulting in injury, and 9,972 involving a device malfunction.[3] To put these numbers into perspective, over this 10-year period, 75% of all

[2] S. Lori Brown, *Surgical Stapler-Associated Fatalities and Adverse Events Reported to the Food and Drug Administration*, 199 J. AM. COLL. SURG. 3, 374 (Sept. 2004)
[3] MK Riggs, *Examining Relationships Between Device Complexity and Failure Modes of Minimally Invasive Surgical Staplers*, 3 Biomedical and Biotechnology Engineering (Feb. 2017)

reported stapler-related events involved device malfunction, and more than 25% resulted in injury or death.

16. 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.[4] To make matters worse, over half of these adverse event reports were not submitted into MAUDE, but to a secret FDA database. This abuse of FDA policy to the extreme detriment of thousands of patients like Tracy Hunt will be discussed at length in another section. All of this information – from 2001 to 2019 – was known to Defendants.

Manufacturer-Created Knowledge Gap

17. In many operations, surgical staplers are used to ligate and divide major blood vessels and other structures. The device cuts the tissue, and then it staples the open tissue closed. This frequently occurs in laparoscopic procedures, which are greatly facilitated by using surgical staplers and are associated with lower risk of surgical site infection. This less invasive form of surgery does not require large incisions, and surgical staplers allow surgeons to perform procedures within laparoscopic operations that carry a high risk of infection, such as anastomoses, more rapidly.[5] However, there is no pause and no indicator of stapler success before the cutting blade activates.[6] Additionally, adequate grip strength is necessary to fire the stapler, yet too much force too quickly can put pressure on delicate tissue and damage it.[7]

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[4] *FDA Executive Summary Prepared for the May 30, 2019, Meeting of the General and Plastic Surgery Devices Panel: Reclassification of Surgical Staplers for Internal Use*, FDA.GOV, https://www.fda.gov/media/126211/download (last updated July 2, 2019).
[5] Y. Kagawa, *The association between the increased performance of laparoscopic colon surgery and a reduced risk of surgical site infection*. 49 Surg Today 474 (Jan. 2019).
[6] Helen J. A. Fuller, *Surgical Stapler Adverse Events in the Veterans Health Administration: Root Causes and Lessons Learned*, 3 Proceedings of the International Symposium on Human Factors and Ergonomics in Health Care 1, 153 (June 2014)
[7] *Id.*

18. The device's complexity is perhaps best illustrated by the complicated process of choosing the right stapler and corresponding staple cartridge for the specific type of tissue involved in a procedure. The selection of a stapler based on shaft length, diameter, and staple height can have a great effect on the clinical outcome. Staple height in particular is a key decision, as choosing a staple height that is incompatible with a specific tissue's thickness and biomechanical properties can lead to anastomotic leaks, tissue damage, and other complications. A variety of model types and functionality provide customized tool selection, but the same choices make consistent safe use difficult.[8] Despite the importance of this selection, very little guidance is provided by Defendants, and staple selection and stapler operation are therefore largely based on anecdotal evidence and the practices of attending surgeons passed down from teacher to student at each institution.[9]

19. Doctors and surgeons appropriately depend on the manufacturers to educate them on their products, which Covidien fails to do adequately. Surgical staplers are constantly evolving and being created for an ever-increasing list of procedures, without sufficient training, instruction, and education for providers. As a result, Defendants have created a 'knowledge gap' in the medical community concerning safe use of the product.

20. For example, in a cohort study of 210 laparoscopic general surgery cases over a two-year period, medical device-related interruptions during procedures occurred frequently and were classified into five distinct categories, of which device failure was the most common. Laparoscopic staplers contributed to over 50% of these device failures and 25% of all interruptions of any category.[10] The authors attribute the pervasiveness of surgical stapler failure in their research

[8] Fuller, *supra*.
[9] Edward Chekan, *Surgical stapling device-tissue interactions: what surgeons need to know to improve patient outcomes*, 7 Med Devices Auckl. 305 (Sept. 2014).
[10] James J. Jung, *Characterization of device-related interruptions in minimally invasive surgery: need for intraoperative data and effective mitigation strategies*, 33 Surg Endosc. 3, 717 (March 2019)

to the "accelerated innovation and development [of surgical staplers] and lack of systematic data collection after the implementation of surgical devices."[11]

21. The Defendants knew, or should have known, about this knowledge gap discussed at length in a 2014 medical literature review published by doctors with industry ties. The review cites a previous study which identified a wide educational gap in surgical stapling and posits that in order to bridge the educational gap, the surgical stapler manufacturing industry must work together with the medical community:

> McColl et al created a multiple-choice test to assess general surgery residents' knowledge on the purpose and function of linear, circular, and laparoscopic staplers. The test was administered both before and after a 40-minute didactic teaching lecture delivered through a collaborative effort between an attending general surgeon and industry representative with comprehensive knowledge of stapling devices. Mean test scores significantly increased from 53% (pretest) to 77% (posttest), ($P<0.05$). In this small group ($n=26$), this study again identifies a significant gap in existing stapling knowledge and showed the feasibility and value of industry–surgeon collaboration to develop an effective educational program for clinicians.[12]

The authors later double down on their conclusions regarding education needed to avoid patient injury and ensure surgeons are adequately informed on the safe use of the device, stating that:

> Bringing the surgical community together with other professionals in the device industry, such as stapler manufacturers, engineers, and scientists, to collaborate on the development of educational programs to keep surgeons apprised of the optimal use of medical devices should be a national priority. To facilitate this process, *currently available data* need to be *collected in a principal location* and critically assessed and summarized. Further, prospective databases into which surgeons can *enter specific case information* regarding their stapling practices (*type of stapler*, staple size, tissue thickness, etc.) and short term clinical results (leak, bleeding, stricture, and diversion rates) need to be developed. Purposefully and carefully studying current stapling methods will, hopefully, lead to the development of more specific and scientifically based recommendations regarding the choice of staple height and best stapling methods for the diverse range of clinical situations encountered by surgeons. (Emphasis added)[13]

[11] *Id.*
[12] Chekan, *supra*.
[13] *Id.*

22. The FDA recognized this need to gather data on specific surgical devices and the negative clinical cases associated with them. Since the 1990s, the FDA has given manufacturers, the medical community, and the public at large access to the MAUDE Database (the Manufacturer and User Facility Device Experience Database) for all surgical and medical devices. A 2017 journal article describes MAUDE in the following manner:

> MAUDE contains over four million medical device adverse event and product problem reports dating back to 1991. With nearly two thousand new adverse event and product problem reports submitted every day the MAUDE database is an important tool for monitoring and investigating safety issues involving medical devices. MAUDE has facilitated the identification and investigation of medical product problems ranging from cardiovascular and gynecological devices to stretchers and tanning beds.[14]

23. In regard to its utility to the medical community and ability to search for specific products, the authors state:

> The FDA uses MAUDE reports to monitor device performance, detect potential device-related safety issues, and inform the risk-benefit assessments of these products. Health care professionals use MAUDE to review events associated with specific products, body systems or procedures. More than 120 articles referencing MAUDE have been published to date, the majority of these summarizing adverse events specific to a particular outcome, product or body system.[15]

24. For surgeons who use a variety of surgical devices daily, MAUDE allows them to familiarize themselves with new technologies and identify and analyze trends in malfunctions. Over the 20-year period in which MAUDE was the only reporting system known to the public and the clandestine reporting system remained an industry secret, "[d]ata from MAUDE also established what was assumed to be the baseline incidence and prevalence of surgical device malfunctions and related patient harm or death. Other studies used this data to assess the safety

[14] Lisa Garnsey Ensign, *A Primer to the Structure, Content and Linkage of the FDA's Manufacturer and User Facility Device Experience (MAUDE) Files*, 5 EGEMS Wash DC 1, 12 (June 2017).
[15] *Id.*

and efficacy of staplers for procedures in the specialties of colorectal, pancreatic, bariatric, and robotic surgery."[16]

25. As one of the largest surgical stapler manufacturers in the world, Defendants have been in possession of massive amounts of data on surgical stapler-related injuries, fatalities, and malfunctions. But rather than contributing this knowledge to the powerful MAUDE database, Defendants purposely kept this information from the attention and scrutiny of the public. As will be discussed in depth below, in the years preceding Tracy Hunt's bariatric procedure and subsequent injury, the medical providers who performed her surgery were deprived of over half of Defendants' data on adverse events associated with its staplers, totaling over 56,000 reports that were never publicly submitted.

Alternative Summary Reporting

26. It was in this era of clandestine reporting that Tracy Hunt's initial surgery (May 9, 2019) and subsequent injury and repair surgery occurred—a context which is critical to understanding how a defective surgical stapler ended up in the hands of Plaintiff's surgeon. Per the FDA's Executive Summary issued in May 2019:

> Prior to February 2019, surgical staplers for internal use were also eligible for the ASR Program. This 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. FDA carefully reviewed and considered all such reports, but reports prior to 2017 were not made publicly available because the format was not compatible with the public database. [17]

27. The existence and subsequent corrupted use of the Alternative Summary Reporting (ASR) Program was publicly revealed in a March 2019 article by Christina Jewett of Kaiser Health News (KHN). The investigative piece featured insights from various ex-FDA officials who worked

[16] Samwel Okoth Makanyengo, *Literature Review on the Incidence of Primary Stapler Malfunction*, 27 Surgical Innovation 2, 229 (Dec. 2019).
[17] *FDA Executive Summary*, *supra*.

for the agency at the inception and throughout the lifespan of the ASR program, including Larry Kessler. The origins of the ASR program, which was in place from 1997 until it was formally ended in June 2019, are described in the following manner:

> The alternative summary reporting program started two decades ago with a simple goal: to cut down on redundant paperwork, according to officials who were at the FDA at the time.
>
> Kessler, the former FDA official, said the program took shape after scandals over under-reporting of device problems spurred changes allowing criminal penalties against device companies.
>
> Soon, thousands of injury and malfunction reports poured into the agency each month, with about 15 staff members dedicated to reviewing them, Kessler said. Many reports were so similar that reviewing them individually was "mind-numbing." Kessler went to the FDA's legal department and to device manufacturers to propose a solution.
>
> Device makers would be able to seek a special "exemption" to avoid reporting certain complications to the public database. The manufacturers would instead send the FDA a spreadsheet of injury or malfunctions each quarter, half-year or year.
>
> That way, Kessler said, reviewers could quickly look for new problems or spikes in known issues. When the program launched in 2000, the list of exempted devices was made public and only a few devices were involved, Kessler said.

28. In 2019, for reasons as yet unknown, the list of exempted products was no longer public. "I don't know why it's not [made public] now," Kessler said. "I'm surprised about that."[18]

29. The series of articles by KHN, in combination with its many FOIA requests, eventually spurred the FDA to release all of its previously undisclosed ASR data.[19] Comparing this secret data with the data that had been publicly available revealed some shocking statistics from the years preceding Tracy Hunt's surgery. While Defendants released the two reloads used in Plaintiff's injury-causing procedure too late to be included in the ASR system, malfunctions associated with the EGIAUXL handle to which the reloads were affixed during the surgery were

[18] Christina Jewett, *Hidden FDA Reports Detail Harm Caused by Scores of Medical Devices*, KAISER HEALTH NEWS, https://khn.org/news/hidden-fda-database-medical-device-injuries-malfunctions/, (March 7, 2019).
[19] *MDR Data Files*, FDA.GOV, https://www.fda.gov/medical-devices/medical-device-reporting-mdr-how-report-medical-device-problems/mdr-data-files, (last updated June 21, 2019).

in fact entered into the secret system. The data on Defendants' total usage of the ASR system is summarized by the bullet points below:

- In 2012, Covidien submitted over **6,800** adverse event reports related to surgical staplers to the ASR program. Of those reports, **149** were specifically related to the EGIAUXL surgical stapler handle.
- In 2013, Covidien submitted over **6,400** adverse event reports related to surgical staplers to the ASR program. Of those reports, **235** were specifically related to the EGIAUXL surgical stapler handle.
- In 2014, Covidien submitted over **14,000** adverse event reports related to surgical staplers to the ASR program. Of those reports, **835** were specifically related to the EGIAUXL surgical stapler handle.
- In 2015, Covidien submitted over **8,900** adverse event reports related to surgical staplers to the ASR program. Of those reports, **596** were specifically related to the EGIAUXL surgical stapler handle.
- In 2016, Covidien submitted over **9,900** adverse event reports related to surgical staplers to the ASR program. Of those reports, **659** were specifically related to the EGIAUXL surgical stapler handle.
- In 2017, Covidien submitted over **4,700** adverse event reports related to surgical staplers to the ASR program. Of those reports, **355** were specifically related to the EGIAUXL surgical stapler handle.

30. Comparing the ASR-reported figures to the MAUDE numbers shows the scope of potential life-saving knowledge that was hidden from medical providers. This is illustrated by the table and bullet points below (*see Table 1*).

Table 1

Year	Covidien Surgical Stapling Entries in ASR Program*	Covidien Surgical Stapling Entries in MAUDE	Covidien EGIAUXL Entries in ASR Program	Covidien EGIAUXL Entries in MAUDE
2012	6,800	747	149	3
2013	6,400	894	235	0
2014	14,000	1,316	835	7
2015	8,900	1,111	596	10
2016	9,900	1,693	659	64
2017	4,700	5,037	355	444
2018	-	~11,000	-	636

*Numbers have been rounded for ease of comparison

- From January 1, 2011, through December 31, 2018, the FDA received almost 110,000 reports related to issues with surgical staplers.
- Over half of these reports–56,277 in total–were submitted secretly through the ASR program.
- Going back further to 2001, this number increases to more than 66,000.

Defendants' Defense of the Knowledge Gap and ASR System Abuse

31. During a May 30, 2019 meeting of the General and Plastic Surgery Devices Panel, two representatives from the Minimally Invasive Therapies Group of Medtronic attempted to justify the company's abuse of the ASR System and the gap in publically available information that it created:

> In 1997 the FDA introduced an alternative summary reporting, or ASR, pathway for certain medical device complaints. Between 2001 and 2017, Medtronic submitted reportable complaints involving malfunctions to the FDA on a quarterly basis through the ASR pathway. Throughout this time, Medtronic submitted reportable complaints involving death or serious injury as individual MDRs rather than through the ASR pathway.[20]

32. Defendants seem to make a bright line distinction between malfunctions and "serious injury," as if a malfunctioning surgical stapler—a medical device capable of slicing through and deploying titanium staples into human organs—does not present a danger to medical patients, cannot lead to a disastrous clinical outcome, and is reasonable to be kept secret from medical professionals who depend on the reliable performance of said staplers during surgeries. To underscore the extreme difficulty of recovering from an intraoperative device malfunction, an FDA medical officer and general surgeon of 35 years, who was also in attendance at the panel, provided a description of what the idea of surgical stapler malfunctions that lead to "no major consequences" brought to mind:

> …the malfunctions "had no major consequences," where the intraoperative problems were managed by surgical techniques such as restapling [sic] or suturing. And when I read that, what came to mind was the point in the low anterior resection under the drapes where I'm ready to fire the stapler after a really long case, the OR team is tired and I'm hoping for a

[20] *General and Plastic Surgery Devices Panel May 30, 2019 Transcript*, FDA.GOV, https://www.fda.gov/media/128552/download (last updated June 2, 2019).

> good crunch and two complete donuts and a negative bubble test, and then I find a leak and realize that the operation is going to be even longer. I need to find the exact point of the leak. Laparoscopically, that can be difficult down deep in the pelvis where you don't have a lot of mobility of the anastomosis. Do I suture the leak? How confident am I about that being the point of the leak? Do I suture and divert? Do I redo the anastomosis, increasing the risk of a foreshortened bowel and tension at the staple line, having to then mobilize the bowel and hoping I don't cause ischemia? All those things came through my head as I read that, and somehow, no major consequences, it didn't pay justice to the actual challenge of these intraoperative problems resulting from failed staple lines.[21]

33. Besides Defendants' attempt to ignore, circumvent and/or downplay the connection between malfunctions and their imminent potential to cause injuries, a position which the above excerpt from a seasoned surgeon strongly rebukes, upon information and belief, Defendants also knowingly reported injuries as malfunctions in the ASR system.

The Effects of ASR Program Abuse

34. While the FDA's reason for using this program may have been a pragmatic one, manufacturers like Defendants chose to under-report via MAUDE for one clear motive: profit. The secrecy of the ASR program was advantageous to sales representatives and company executives alike, shielding them from public scrutiny and allowing them to provide potential buyers with only the publicly reported adverse event reports associated with their products. The ability to hide malfunctions and injuries associated with Covidien products undoubtedly increased their sales. To put it in perspective, a Covidien sales representative promoting an EGIAUXL surgical stapler handle in 2017, just two years before Tracy Hunt's surgery, could omit almost 45% of the total number of adverse events reported for that year when making a sales pitch. If looking to promote the safety and reliability of Covidien's surgical stapling system as whole, that same salesperson could hide roughly 50% of the total number of adverse events, only being obligated to disclose just about 5,000 out of the roughly 10,000 reported malfunctions and injuries in 2017. The stark

[21] *Id.*

contrast in reporting only becomes more apparent heading back toward 2012, with 2014 being a particular egregious year (to be discussed below). These earlier numbers are highly relevant and concerning nonetheless, especially given that surgical stapling products have a long shelf-life and can often take five years to be considered 'expired' once purchased by a medical facility.[22]

35. The sheer magnitude of surgical stapling system-related reports that were submitted via ASR clearly suggests a level of risk that was unknown to researchers, physicians, and the public alike. Despite this, data analysis suggests that the longer this secretive reporting system went undetected, the more emboldened Covidien became. From 1999 to 2018, Covidien surgical stapler reports to ASR increased yearly versus MAUDE, with a positive correlation between number of reports to ASR and calendar year. In contrast, the MAUDE database showed negative trends over the calendar years for surgical staplers, with the rate of reporting on surgical staplers decreasing annually by 24%. In total, 84.4% of all surgical stapler malfunctions were reported via ASR, with a peak of 97.9% of all surgical stapler malfunctions being secretly reported in 2014.[23] Covidien reaped great benefits from that year of excessive secret reporting, as it was acquired by Medtronic in 2015. According to Medtronic's fourth quarter and fiscal year 2015 financial results, the company's Surgical Solutions branch, which includes surgical staplers, posted a revenue of $1.293 billion and cited staplers as major drivers of revenue performance.[24]

36. While Covidien enjoyed increasing economic benefits from the ASR program as time went on, the medical community was denied critical information necessary to inform

[22]For example, a 510(k) premarket notification of intent to market the EEA Circular Stapler with Tri-Staple Technology (K172361) shows that the stapler has a shelf-life of five years. https://www.accessdata.fda.gov/cdrh_docs/pdf17/K172361.pdf

[23] Derek A. Benham, *Revealing the scope of surgical device malfunctions: Analysis of the "hidden" Food and Drug Administration device database*, 221 AM. J. SURG. 6, 1121 (June 2021).

[24] *Medtronic Reports Fourth Quarter and Fiscal Year 2015 Financial Results*, GLOBE NEWS WIRE, https://www.globenewswire.com/news-release/2015/06/02/1891811/0/en/Medtronic-Reports-Fourth-Quarter-and-Fiscal-Year-2015-Financial-Results.html, (June 2, 2015).

providers' decisions to select one Covidien stapler over another or to purchase any Covidien stapling products at all. By keeping the scope of injuries related to surgical staplers hidden, surgeons only had access to the diluted public reports, which meant that injuries, malfunctions, and trends did not seem as prevalent. Some of this essentially non-reporting also involved new and novel malfunctions that caused severe injury and would have subjected their staplers to recall or reclassification.

37. Perhaps most importantly, the lack of public information and post-market reporting from Covidien adversely affected the knowledge and decision making of experts like the surgeon who performed Tracy Hunt's procedure, creating a dangerous landscape in which to be operating and preventing doctors from making informed decisions. Covidien's conduct directly led to Plaintiff's physician electing to use a surgical stapler without full knowledge of all foreseeable risks.

Recalls and Defective Product Lines: EGIAUXL Handle

38. In addition to operating while uninformed, Tracy Hunt's providers were saddled with equipment that was both actively under recall and part of a problematic product line. As previously stated, the surgical stapling products used in this case were a combination of the EGIAUXL handle and two different reloads with Tri-Staple Technology. On February 18, 2016, the FDA announced a Class II recall of the EGIAUXL Endo GIA Ultra Universal XL, affecting over 325,000 units world and nationwide. Defendants stated the reason for the recall was that "staplers fail to fire or partially fire" and that there were "reports of the instrument articulating level disengaging during use."[25] The recall was not terminated until July 18, 2019, meaning that

[25] https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=142119#1

at the time of Plaintiff's surgery, the stapler handle was still under active recall. The FDA states the following in regards to its recall termination procedures:

> A recall will be terminated when the Food and Drug Administration determines that all reasonable efforts have been made to remove or correct the product in accordance with the recall strategy, and when it is reasonable to assume that the product subject to the recall has been removed and proper disposition or correction has been made commensurate with the degree of hazard of the recalled product. [26]

39. Given the May 2019 date of Plaintiff's ill-fated procedure, her surgical team still faced the full-fledged hazard of a stapler handle known to malfunction by failing to fire or partially firing staples, a defect which could certainly cause an anastomotic leak at the staple line like the injury suffered by Plaintiff.

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[26] *Regulatory Procedures Manual Ch.7 – Recall Procedures*, FDA.GOV, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/compliance-manuals/regulatory-procedures-manual (last updated February 18, 2022).

Recalls and Defective Product Lines: SIGTRSB60AMT and SIGTRSB60AXT Reloads

40. The two reloads which the surgeon attached to the defective handle belonged to Defendants' trademark line of Endo GIA Reloads with Tri-Staple Technology (*see Figure 2*).

Figure 2

Endo GIA™ Reloads with Tri-Staple™ Technology

MEDTRONIC

Standard Reload Length	Device	Reorder Code	Color Code	Staple Heights	Tissue Type
30 mm		SIG30AV†	Gray	2 mm, 2 mm, 2 mm	Vascular
		SIG30AVM	Tan	2 mm, 2.5 mm, 3 mm	Vascular/Medium
		SIG30AMT	Purple	3 mm, 3.5 mm, 4 mm	Medium/Thick
45 mm		EGIA45AV†	Gray	2 mm, 2 mm, 2 mm	Vascular
		EGIA45AVM	Tan	2 mm, 2.5 mm, 3 mm	Vascular/Medium
		EGIA45AMT	Purple	3 mm, 3.5 mm, 4 mm	Medium/Thick
		EGIA45AMT	Purple	4 mm, 4.5 mm, 5.0 mm	Medium/Thick
		EGIA45AMT	Purple	3 mm, 3.5 mm, 4 mm	Medium/Thick
		SIG45AXT	Black	4 mm, 4.5 mm, 5 mm	Extra-Thick
60 mm		—	—	—	—
		EGIA60AVM	Tan	2 mm, 2.5 mm, 3 mm	Vascular/Medium
		EGIA60AMT	Purple	3 mm, 3.5 mm, 4 mm	Medium/Thick
		EGIA60AMT	Purple	3 mm, 3.5 mm, 4 mm	Medium/Thick
		EGIA60AMT	Purple	3 mm, 3.5 mm, 4 mm	Medium/Thick
		SIG60AXT	Black	4 mm, 4.5 mm, 5 mm	Extra-Thick
Reinforced Reload Length	**Device**	**Reorder Code**	**Color Code**	**Staple Heights**	**Tissue Type**
45 mm		SIGTRSB45AMT	Purple	3 mm, 3.5 mm, 4 mm	Medium/Thick
		SIGTRSB45AXT	Black	4 mm, 4.5 mm, 5 mm	Extra-Thick
60 mm		SIGTRSB60AMT	Purple	3 mm, 3.5 mm, 4 mm	Medium/Thick
		SIGTRSB60AXT	Black	4 mm, 4.5 mm, 5 mm	Extra-Thick
Signia™ Small Diameter Reload	**Device**	**Reorder Code**	**Color Code**	**Staple Heights**	**Tissue Type**
30 mm		SIGSDS30CTV	Gray	2 mm, 2 mm	Vascular
		SIGSDS30CTVT	White	2.5 mm, 2.5 mm	Vascular/Medium
45 mm		SIGSDL45CTVT	White	2.5 mm, 2.5 mm	Vascular/Medium
Curved Tip Reload Length	**Device**	**Reorder Code**	**Color Code**	**Staple Heights**	**Tissue Type**
30 mm		SIG30CTAV†	Gray	2 mm, 2 mm, 2 mm	Vascular
		SIG30CTAVM	Tan	2mm, 2.5mm, 3 mm	Vascular/Medium
45 mm		SIG45CTAV†	Gray	2 mm, 2 mm, 2 mm	Vascular
		SIG45CTAVM	Tan	2 mm, 2.5 mm, 3 mm	Vascular/Medium
		SIG45CTAMT	Purple	3 mm, 3.5 mm, 4 mm	Medium/Thick
60 mm		SIG60CTAVM	Tan	2 mm, 2.5 mm, 3 mm	Vascular/Medium
		SIG60CTAMT	Purple	3 mm, 3.5 mm, 4 mm	Medium/Thick
Radial Reload	**Device**	**Reorder Code**	**Color Code**	**Staple Heights**	**Tissue Type**
		SIGRADMT	Purple	3 mm, 3.5 mm, 4 mm	Medium/Thick
		SIGRADXT	Black	4 mm, 4.5 mm, 5 mm	Extra Thick

41. This Tri-Staple product line of roughly 30 reloads consists of Standard, Reinforced, Small Diameter, Curved Tip, and Radial reloads, with Plaintiff's reloads falling into the Reinforced category. All of these categories of reloads are essentially variations of the same design, and are manufactured to be compatible with the EGIAUXL handle. They are substantially similar in size, material, composition, design, and intended use. The mechanisms for attaching, detaching, and firing are also the same.

42. It should come as no surprise then that when a manufacturing problem plagues one Tri-Staple reload, it plagues them all. From 2018 up until most recently in 2021, more than 20 products within the Tri-Staple reload product line have been recalled, which can be broken down by Defendants' reasons for the recalls in the following manner:

- Device **missing sled component** (May 2018 – **3** Tri-Staple reload varieties recalled)
- Device **missing sled component** (July 2018 – **14** Tri-Staple reloads recalled)
- Device may be **missing a pin component** (June 2019 – **5** Tri-Staple reload varieties recalled)
- May contain an **extra laminate layer** (April 2021 – **1** Tri-Staple reload variety recalled)

43. By the time Plaintiff's surgery involving two different varieties of Tri-Staple reloads had taken place in May 2019, there had already been 17 instances of Tri-Staple reloads being recalled for defects, almost all of which were explicitly said by the FDA to potentially cause anastomotic leaks. Given the substantial technical similarity between all the iterations of the Tri-Staple reload product line, it is more likely than not that the design processes, manufacturing processes, and quality control measures associated with these staplers are also shared. The surgery that caused Tracy Hunt's injuries took place in the context of a veritable whirlwind of Tri-Staple

reload recalls, and her particular injury, anastomotic leak, was a known consequence of these defects.

44. The under-recall EGIAUXL stapler handle and the entire product family of compatible Tri-Staple reloads, and more specifically the SIGTRSB60AMT and SIGTRSB60AXT variations that are at issue in this action, were designed, manufactured, and marketed by Defendants, and malfunctioned during Tracy Hunt's surgery. That malfunction caused her to undergo further surgical procedures and prolonged medical treatment. As a direct and proximate result of the actions and/or omissions by the Defendants, Tracy Hunt suffered serious and permanent injuries and damages, including but not limited to:

(a) Sepsis;

(b) Multiple surgical procedures;

(c) Abscess debridement;

(d) Abscess drain placement;

(e) Pain, suffering, mental anguish, fear, loss of enjoyment of life and emotional distress; and

(f) Medical expenses.

PLAINTIFF'S SPECIFIC FACTUAL ALLEGATIONS

45. Defendants design, manufacture, and sell surgical stapler handles and compatible reloads to be used by medical service providers in surgical procedures. These components are attached together to form staplers which come in various models to assist surgeons in creating a secure anastomosis within the body and form a seal.

46. Defendants designed, manufactured, and sold a defective stapler handle and a defective product family of Tri-Staple reloads which were available in the market to be used in

surgical procedures before, during, and after the time of Tracy Hunt's surgery. These stapler components 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.

47. On or about February 2016, Defendants initiated a recall of the exact stapler handle used on Tracy Hunt which was still in effect at the time of her procedure. Starting in May 2018 and continuing until April 2021, Defendants also initiated a barrage of Tri-Staple reload recalls for defects known to cause anastomotic leaks. The reloads used on Plaintiff belonged to this defective reload family and caused exactly the type of injury that would be expected from reloads that fail to form secure staple lines.

48. On May 9, 2019, Tracy Hunt presented to Carteret General Hospital in Morehead City, North Carolina for a laparoscopic hiatal hernia repair with posterior crural closure and laparoscopic vertical sleeve gastrectomy. A Covidien EGIAUXL stapler handle combined with six total firings of the black and purple varieties of the 60mm Tri-Staple reinforced reloads (SIGTRSB60AMT and SIGTRSB60AXT) were used during the surgery to create the gastric sleeve by cutting away a portion of the stomach intended for removal and forming a staple line to seal off the section remaining. Per the operative report, the newly formed staple line was tested under water in a "Jacuzzi test" which was negative for a leak.

49. Tracy Hunt was never informed that the stapler handle was actively under recall, nor was she told that the reloads attached to it belonged to a defectively designed and manufactured product group of Tri-Staple staplers.

50. Within two weeks of surgery, Plaintiff developed a fever and began to suffer from severe abdominal pain. She reported to the emergency room on May 22, 2019 and was found to

be tachycardic with an elevated white blood cell count and signs of sepsis. Tracy Hunt was readmitted to the hospital.

51. A CT scan with contrast revealed findings most consistent with an abscess at the staple line site near the distal esophagus and GE junction. On May 23, 2019, an esophagogastroduodenoscopy under anesthesia was performed to evaluate the abscess and potential anastomotic leak. The endoscopy showed purulent discharge at the GE junction. Due to the large amount of abdominal distension, surgeons elected to wait 24 hours until the next procedure.

52. On May 24, 2019 Plaintiff was re-anesthetized for a second procedure. Upon further visualizing the gastric sleeve, an abscess caused by a staple line leak on the lateral left side of the distal esophageal GE junction was detected. Surgeons performed an abscess debridement and drain placement.

53. Post-surgery, Plaintiff was treated with IV antibiotics and TPN therapy. Doctors continued to monitor the staple line perforation and abscess drainage via imaging studies until her discharge on June 3, 2019.

54. As a result of the defective nature of the EGIAUXL stapler handle and Tri-Staple reinforced reloads, Tracy Hunt suffered intense abdominal pain, had two additional procedures under anesthesia, and underwent a prolonged hospitalization.

55. Plaintiff alleges, upon information and belief, that the specific stapler components that failed to form a lasting staple line during her initial May 9, 2019 surgery were stapler components known by Defendants to frequently malfunction. In fact, the stapler handle was under recall at the time of surgery, and from 2012 to 2017, Defendants had submitted more than 2,800 secret reports regarding ‘malfunctions’ related to it (*refer to Table 1*). In addition to the defective

nature of the handle, the reloads attached to it were part of the Tri-Staple reload product line, which is associated with almost 25 instances of recalls occurring both before and after Plaintiff's surgery.

56. Plaintiff alleges that the Tri-Staple reloads in particular were among a class of attachable reloads known by Defendants to malfunction or to contain defects, whether they were included specifically in a recall or not.

57. 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 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, and as of October 2021, surgical staplers have been reclassified to class II devices requiring special controls and premarket notification.

58. 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 surgeon.

59. 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. 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.

60. 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 Defendants have reported more than 250 deaths related to staplers or staples since 2001. Despite this manifest knowledge of the dangers associated with their products, Defendants 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 their 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 Tracy Hunt's surgery. Ultimately, Defendants continued to sell staplers and stapler components to healthcare providers during this time period without disclosing serious risks of injury from use.

61. 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 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. This reclassification was finalized in October 2021.

62. 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.

63. Defendants failed to: (1) provide warnings regarding the potential for their stapler components to malfunction in the very manner that occurred during Plaintiff's surgery; (2) warn and inform surgeons of the potential for their stapler components to malfunction in that manner, including all foreseeable use and misuse of the product; (3) train, instruct, and educate surgeons regarding safe use and foreseeable misuse of their product; and (4) recall their defective products when Defendants knew their surgical stapler components were prone to injurious malfunction, and to timely and properly effectuate the recall. 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 and safety of Tracy Hunt. 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.

COUNT I: BREACH OF WARRANTY – DEFECTIVE MANUFACTURE AND DESIGN

64. All previous paragraphs are hereby incorporated by reference as if fully set forth herein. Defendants impliedly warranted that the EGIAUXL handle, SIGTRSB60AMT reload, and SIGTRSB60AXT reload (the components which together formed the stapler used) were merchantable and were fit for the ordinary purposes for which they were intended.

65. When the stapler implanted a staple line inside Tracy Hunt, it was being used for the ordinary purposes for which it was intended, Plaintiff, individually and/or by and through her physician, relied upon Defendants' implied warranties of merchantability in consenting to have a surgical procedure involving a Covidien surgical stapler.

66. Defendants breached these implied warranties of merchantability because the stapler that deployed a staple line in Tracy Hunt was neither merchantable nor suited for its intended uses as warranted.

67. Defendants' breach of their implied warranties resulted in the use of stapler made up of unreasonably dangerous and defective components, placing Plaintiff's health and safety in jeopardy. The stapler handle and two reloads used in the sleeve gastrectomy resulted from improper or incorrect manufacturing processes, such that the stapler as manufactured and assembled deviated from its intended design.

68. The defects caused by improper or incorrect manufacturing rendered the stapler components unreasonably dangerous, deficient, and defective to Tracy Hunt. The defects in the handle and reloads which were used to implant a staple line in Plaintiff existed from their manufacture. Therefore, the defects were present when they left the possession and control of Defendants.

69. The handle and reloads were defective, unfit, unsafe, inherently dangerous and unreasonably dangerous for their intended and reasonably foreseeable uses. The components were in said condition when they entered the stream of commerce and were used on Tracy Hunt. When assembled together as a stapler, these components do not meet or perform to the expectations of patients and their health care providers. These surgical stapler parts were dangerous to an extent beyond that which would be contemplated by the ordinary consumer.

70. The Covidien stapler components created a risk to the health and safety of patients that is far more significant and devastating than the risks posed by other products and procedures available to form a gastric sleeve with a secure staple line, and which far outweigh their utility.

71. Defendants intentionally and recklessly designed, manufactured, marketed, labeled, sold and distributed the EGIAUXL handle and corresponding SIGTRSB60AMT and SIGTRSB60AXT reloads with wanton and willful disregard for the health of Plaintiff and with malice, placing their economic interest above her health and safety.

72. As used by Tracy Hunt's physicians, the stapler components were not substantially changed, modified, or altered at any time in any manner whatsoever prior to use. The components were assembled and used to plant a staple line in such a condition that was unreasonably dangerous to her. The components were used in the manner for which they were intended. This use resulted in injuries and harm to Plaintiff.

73. At no time did Tracy Hunt have reason to believe that the Covidien stapling products were in a condition not suitable for their proper and intended use among patients.

74. Plaintiff was not able to discover, nor could she have discovered through the exercise of reasonable care, the defect of the internal surgical stapler. Furthermore, in no way could Plaintiff have known that Defendants had manufactured the stapler components in such a way as

to increase the risk of harm or injury to the patient receiving the implanted staple line fired from said components.

75. As a direct and proximate result of Defendants' wrongful conduct, including the design, manufacture, labeling, marketing, sale and distribution of the EGIAUXL, SIGTRSB60AMT reload, and SIGTRSB60AXT reload, Plaintiff has sustained and will continue to sustain severe and debilitating injuries, serious bodily injury, mental and physical pain and suffering, and has incurred economic loss.

COUNT II: BREACH OF WARRANTY – FAILURE TO WARN

76. All previous paragraphs are hereby incorporated by reference as if fully set forth herein. Defendants impliedly warranted that their stapling products were merchantable and fit for the ordinary purposes for which they was intended.

77. When the stapler components were assembled and used to implant a staple line in Tracy Hunt, they were being used for the ordinary purposes for which they were intended. Plaintiff, individually and/or by and through her physician, relied upon Defendants' implied warranties of merchantability in consenting to have a bariatric procedure involving surgical staplers. Defendants breached these implied warranties of merchantability because the stapler components used were neither merchantable nor suited for their intended uses as warranted.

78. The stapler handle and corresponding reloads used on Plaintiff were not reasonably safe for their intended uses and were defective as described herein as a matter of law due to their lack of appropriate and necessary warnings. Specifically, Defendants did not provide sufficient or adequate warnings regarding, among other subjects:

a) The EGIAUXL's propensity to fail to fire staples;

b) The EGIAUXL's propensity to partially fire staples;

c) The propensity of the EGIAXUL's instrument articulating lever to disengage during use;

d) The nature, magnitude, severity and frequency of complications that can arise as a result of using the EGIAUXL;

e) The use of the ASR system for the reporting of adverse events associated with the EGIAUXL;

f) The more than 2,800 secret reports regarding 'malfunctions' involving the EGIAUXL which had been withheld from the public prior to Plaintiff's surgery, between 2012 and 2017;

g) The risk of anastomotic leak specifically associated with the EGIAUXL;

h) The hazards associated with the EGIAUXL;

i) The EGIAUXL's defects described herein;

j) The propensity of the Tri-Staple reload products, of which SIGTRSB60AMT and SIGTRSB60AXT reloads are part, to have missing sled components, which can lead to a failed staple line and anastomotic leak;

k) The propensity of the Tri-Staple reload products, of which SIGTRSB60AMT and SIGTRSB60AXT reloads are part, to have missing pin components, which can lead to a failed staple line and anastomotic leak;

l) The propensity of the Tri-Staple reload products, of which SIGTRSB60AMT and SIGTRSB60AXT reloads are part, to have an extra laminate layer that increases risk of infection;

m) The risk of anastomotic leak specifically associated with the Tri-Staple reload products, of which SIGTRSB60AMT and SIGTRSB60AXT reloads are part;

n) The hazards associated with the Tri-Staple reload products, of which SIGTRSB60AMT and SIGTRSB60AXT reloads are part; and

o) The Tri-Staple reloads, of which SIGTRSB60AMT and SIGTRSB60AXT reloads are part, product defects described herein.

79. Defendants are liable to Tracy Hunt for designing, manufacturing, marketing, labeling, packaging and selling defective surgical stapling products.

80. As a direct and proximate result of the aforementioned defects as described herein, Plaintiff has experienced significant mental and physical pain and suffering, has undergone medical treatment, has endured prolonged hospitalization, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, and/or lost income, and other damages.

COUNT III: NEGLIGENCE

81. All previous paragraphs are hereby incorporated by reference as if fully set forth herein. Defendants had a duty to individuals, including Tracy Hunt, to use reasonable care in designing, manufacturing, marketing, labeling, packaging and selling the EGIAUXL and the SIGTRSB60AMT and SIGTRSB60AXT reloads. Defendants were negligent in failing to use reasonable care as described herein in designing, manufacturing, marketing, labeling, packaging and selling their surgical stapling components. Defendants breached their aforementioned duty by, among other things:

a) Failing to design the EGIAUXL handle and the SIGTRSB60AMT and SIGTRSB60AXT reloads so as to avoid an unreasonable risk of harm to patients whose surgeons used them to form anastomoses via staple lines, including Tracy Hunt;

b) Failing to manufacture the he EGIAUXL handle and the SIGTRSB60AMT and SIGTRSB60AXT reloads so as to avoid an unreasonable risk of harm to patients whose surgeons used them to form anastomoses via staple lines, including Tracy Hunt;

c) Failing to use reasonable care in the testing of the EGIAUXL handle and the SIGTRSB60AMT and SIGTRSB60AXT reloads so as to avoid an unreasonable risk of harm to patients whose surgeons used them to form anastomoses via staple lines, including Tracy Hunt;

d) Failing to use reasonable care in inspecting the EGIAUXL handle and the SIGTRSB60AMT and SIGTRSB60AXT reloads so as to avoid an unreasonable risk of harm to patients whose surgeons used them to form anastomoses via staple lines, including Tracy Hunt;

e) Failing to use reasonable care in the training and instruction to physicians for the safe use of the EGIAUXL handle and the SIGTRSB60AMT and SIGTRSB60AXT reloads so as to avoid an unreasonable risk of harm to patients whose surgeons used them to form anastomoses via staple lines, including Tracy Hunt;

f) Failing to use reasonable care in publically reporting adverse events associated with the EGIAUXL to evaluate its safety and to determine the nature, magnitude, and frequency of serious, life threatening complications that were known or knowable; and

g) Otherwise negligently or carelessly designing, manufacturing, marketing, labeling, packaging and/or selling the EGIAUXL handle and the SIGTRSB60AMT and SIGTRSB60AXT reloads so as to avoid an unreasonable risk of harm to patients whose surgeons used them to form anastomoses via staple lines, including Tracy Hunt.

82. The reasons that Defendants' negligence caused the surgical stapling components to be unreasonably dangerous and defective include, but are not limited to:

a) The use of manufacturing and design processes that caused the EGIAUXL handle to fail to fire staples, causing adverse reactions and injuries, including anastomotic leak;

b) The use of manufacturing and design processes that the EGIAUXL handle to partially fire staples, causing adverse reactions and injuries, including anastomotic leak;

c) The use of manufacturing and design processes that the EGIAUXL handle to have an articulating lever which disengages during use, causing adverse reactions and injuries, including anastomotic leak;

d) The use of manufacturing and design processes that caused Tri-Staple reloads to be missing sled components, causing adverse reactions and injuries, including anastomotic leak;

e) The use of manufacturing and design processes that caused Tri-Staple reloads to be missing pin components, causing adverse reactions and injuries, including anastomotic leak;

f) The use of manufacturing and design processes that caused Tri-Staple reloads to have an extra laminate later, causing adverse reactions and injuries, including post-operative infection.

83. Defendants also negligently failed to warn or instruct Tracy Hunt and/or her health care providers of subjects including, but not limited to, the following:

a) The EGIAUXL handle's propensity to fail to fire staples;

b) The EGIAUXL handle's propensity to partially fire staples;

c) The EGIAUXL handle's more than 2,800 malfunctions from 2012-2017 which were hidden from the public, including Tracy Hunt's health care providers, preventing full and adequate warnings;

d) The risk of anastomotic leak specifically associated with the EGIAUXL;

e) The hazards associated with the EGIAUXL;

f) The EGIAUXL's defects described herein;

g) The propensity of the Tri-Staple reload products to have missing sled components, which can lead to a failed staple line and anastomotic leak;

h) The propensity of the Tri-Staple reload products to have missing pin components, which can lead to a failed staple line and anastomotic leak;

i) The propensity of the Tri-Staple reload products to have an extra laminate layer that increases risk of infection;

j) The risk of anastomotic leak specifically associated with the Tri-Staple reload products;

k) The hazards associated with the Tri-Staple reload products; and

l) The Tri-Staple reload products' defects described herein.

84. As a direct and proximate result of Defendants' negligence, Tracy Hunt has experienced significant mental and physical pain and suffering, has undergone medical treatment, has endured prolonged hospitalization, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, lost income, and other damages.

COUNT IV: NEGLIGENT MISREPRESENTATION

85. All previous paragraphs are hereby incorporated by reference as if fully set forth herein. At all relevant times herein, Defendants represented to Tracy Hunt and her physicians that their surgical stapling products were safe to use to resect, transect, and anastomose within the body, knowing that their products had higher malfunction rates than were publically known and were defective and capable of causing the injuries described herein.

86. Defendants made the aforesaid representations with no reasonable ground for believing them to be true when their own data showed their surgical stapling components to be defective and dangerous when used in the intended manner.

87. The aforesaid representations were made to the physicians who used Covidien stapler components to form the failed staple line in Tracy Hunt prior to the date of said procedure with the intent that Plaintiff and these physicians would rely upon such misrepresentations about the safety and efficacy of the products. Plaintiff and her physicians did reasonably rely upon such representations that the EGIAUXL and Tri-Staple reloads were safe for use to form staple lines in procedures like the sleeve gastrectomy. The representations were false, and thereby caused Tracy Hunt's injuries as described.

88. As a direct and proximate result of Defendants' negligent misrepresentations, Plaintiff has experienced significant mental and physical pain and suffering, has undergone medical treatment, has endured prolonged hospitalization, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, and/or lost income, and other damages.

89. WHEREFORE, Tracy Hunt demands judgment against Defendants and requests compensatory damages, together with interest, cost of suit, attorneys' fees, and all such other relief as the Court deems just and proper.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff Tracy Hunt prays for judgment against Defendants, individually and collectively, jointly and severally, as follows:

(a) Trial by jury;

(b) Judgment against Defendants for all compensatory allowable to Plaintiff;

(c) Judgment against Defendants for all other relief sought by Plaintiff under this complaint;

(d) For reasonable attorneys' fees and costs;

(e) For pre-judgment and post-judgment interest; and

(f) For such further and other relief the Court deems just and equitable.

DEMAND FOR JURY TRIAL

Plaintiff demands a trial by jury on all counts and as to all issues.

Dated: May 7, 2022

Respectfully submitted,

/s/ Paula S. Bliss

Paula S. Bliss (BBO #652361)
Justice Law Collaborative, LLC
19 Belmont Street
South Easton, MA 02375
Tel: 508-230-2700
Email: paula@justicelc.com

And,

Ellen A. Presby, Esq.
FERRER, POIROT, WANSBROUGH
FELLER, DANIEL
2603 Oak Lawn Avenue, Suite 300
Dallas, TX 775219
Tel: 214-521-4412
Email: epresby@lawyerworks.com
Pro Hac Vice Admission Pending

COUNSEL FOR PLAINTIFF