IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

BRIAN CORRIGAN and SHERI BEMENT Plaintiffs, v. COVIDIEN LP, COVIDIEN SALES LLC, COVIDIEN HOLDING INC., and MEDTRONIC, INC., Defendants.	**CIVIL ACTION** Case No. COMPLAINT AND JURY DEMAND

COMPLAINT AND JURY DEMAND

COME NOW Plaintiffs BRIAN CORRIGAN and SHERI BEMENT, by and through their undersigned counsel, hereby file this Complaint and state as follows:

PARTIES, JURISDICTION & VENUE

1. Plaintiffs Brian Corrigan and Sheri Bement, husband and wife, are and were at all times relevant, residents and citizens of Ohio.

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 design, testing, manufacture, distribution, sales, marketing, regulatory management, and services related to Covidien surgical stapling systems, including the surgical staplers 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 testing, manufacture, distribution, sales, marketing, regulatory management, and services related to Covidien surgical stapling systems, including the surgical staplers 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 design, testing, 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 design, testing, manufacture, distribution, sales, marketing, regulatory management, and services related to Covidien surgical stapling systems, including the surgical staplers at issue in this case.

6. All acts and omissions of 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 Plaintiffs and Defendants and the amount in controversy exceeds $75,000.

8. Defendants have significant contacts with this federal judicial district and operates its surgical stapler systems' design, manufacturing, and marketing business in this federal district such that it is subject to the personal jurisdiction of the Court in this district.

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

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

GENERAL FACTUAL ALLEGATIONS

10. Plaintiffs contend that Defendants designed, manufactured, and marketed a defective class of surgical stapler systems that includes the Endo GIA, EEA, and other related products.

11. That on or about February 14, 2019, Plaintiff Brian Corrigan was injured when one of the defective surgical stapler device systems used during a surgical procedure that took place on or about February 14, 2019, malfunctioned, resulting in life threatening injuries, pro-longed hospitalizations and surgical intervention to repair.

12. That at all times relevant to this matter, Defendants were aware its device would malfunction in the manner suffered by Plaintiff Brian Corrigan and failed to inform the medical community or the public that its surgical stapler device system was defective and would harm patients when it failed to perform in the manner it for which it was designed.

13. The FDA recently reported that between 2011 and 2018, there were approximately 110,000 reports -- including 412 reported deaths, nearly 12,000 reported severe injuries, and roughly 98,500 malfunctions -- related to issues with surgical staplers systems, including those designed, manufactured, and marketed by Defendants.[1] These events, however, were largely hidden from public knowledge because the majority of the reports were not submitted to the Manufacturer and User Facility Device Experience (or "MAUDE"), which is a publicly-accessible database run by the FDA. Rather, a majority of the reports were submitted to the ASR Program,

[1] FDA Executive Summary Prepared for May 30, 2019, Meeting of the General and Plastic Surgery Devices Panel Reclassification of Surgical Staplers for Internal Use: https://www.fda.gov/media/126211/download

which hid information on adverse events and severity of problems with the surgical stapler systems from surgeons, patients, and the public. Until recently, the ASR data was not publicly available.

14. While the ASR Program enabled manufacturers of certain device types to submit quarterly summary reports of specific well-known and well-characterized events in lieu of individual reports of each event that tracks medical device failures, the Program did not discharge all duties imposed on manufacturers by Federal Regulations[2] to report device related events to the MAUDE data base. For instance, the FDA did not exempt ASR participating manufacturers from reporting *within 5 days* device associated events related to deaths and when action is necessary to prevent substantial harm to public health.[3] A device manufacturer was required to report all serious events to FDA's MAUDE data base which is available to the public, even when the manufacturer participated in the ASR program.

15. Due to its misuse, as of 2019, the ASR program is no longer available to device manufacturers.

16. Defendants (and each of them) breached their reporting duties by using the ASR program to keep the scope and seriousness of injuries related to surgical staplers hidden from surgeons and the public and kept important and relevant safety information from the Plaintiff and his caregivers.

17. Plaintiff's injuries occurred during this timeframe of "hidden harms." Since the discovery of this conduct by Defendants, the staplers used on Plaintiff have been the subject of a recall.

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[2] 21 CFR 803.50 Subpart E reads in part: Manufacturer Reporting Requirements: a) if you are a manufacturer, you must report to us [FDA] . . .no later than 30 calendar days after the day that you receive or otherwise become award of information, from any source, that reasonably suggests that a device that you market:

1) May have caused or contributed to a death or serious injury or, 2) Has malfunctioned and this device or a similar device that you market would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur.

[3] Types of Events not covered by [ASR] exemption: a) Events that require the submission of a 5-day report, b) Events where the device, . . ., may have caused or contributed to death. (Guidance for Industry Medical Device Reporting-Alternative Summary Reporting (ASR) Program.) 2000, October 19.

18. In October 2021, the FDA reclassified Surgical Stapler devices from Class 1 devices (as used for Band-Aids and cotton balls) to Class 2 devices, which will now make devices, such as Plaintiff's, subject to premarket review.

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

20. Had the Plaintiff been truthfully informed of the risks associated with the Surgical Stapler system used during his surgical procedure, the system would not have been used during his surgery.

HISTORY OF SURGICAL STAPLERS AND MALFUNCTIONS

21. Since the early 1900s, surgical staplers have been used in the medical community to assist in a number of medical operations and procedures.[4]

22. Typically, a stapler is comprised "of the stapler body, a staple cartridge/reload with lines of staplers, an anvil, and a firing mechanism. The surgeon loads a staple cartridge into the stapler (unless they are using a preloaded device) before placing the tissue to be connected between the stapler jaws (comprising of the cartridge and anvil). They then activate a firing mechanism to shoot staples into place."[5]

23. Innovations in the manufacturing of surgical staplers have led to the creation of different categories of staplers to assist with specific procedures. Some of the categories are the Linear Stapler and the circular Stapler. These staplers are used in general surgery as well as thoracic surgery, bariatric surgery, and colo-rectal surgery.

[4] *See* Sophie Childs, *Everything Healthcare Professionals Need to Know about Surgical Staples*, CIA (Apr. 18, 2017) https://www.ciamedical.com/insights/everything-healthcare-professionals-need-to-know-about-surgical-staplers/.
[5] *Id.*

24. Surgical staplers, have been used for decades for a variety of procedures,including to remove a part of an organ (otherwise known as a "resection"), to cut through tissue and organs ("transection"), and to create connections between structures in the body ("anastomoses").[6]

25. The most significant benefit of Surgical Stapler use is that it permits a surgical procedure whether requiring removal and resection, transection, or anastomoses of tissue, to be performed laparoscopically. In other words, large incisions are not necessary to perform these surgical procedures, because a Surgical Stapler device can fit into a small external tissue opening, requiring only minimal incisions at site entry.

26. The FDA has acknowledged that the advantages of using surgical staples and staplers include: "Quick placement; Minimal tissue reaction; Low risk of infection; [and] Strong wound closure."[7]

27. Despite their many uses in a variety of surgical operations and history of development in the medical community, surgical staplers also have a long history of malfunctions. For example, by 2004 studies had shown that 112 deaths, 2,180 injuries, and 22,804 adverse events ("AEs") had been reported to the FDA that were connected to surgicalstaplers.[8]

28. In fact, one survey found that the incidence rate of surgical stapler malfunction is so high that "86% of laparoscopic surgeons either had personal experience with or knew of surgeons whoexperienced stapler malfunction."[9]

29. Other studies have found that, on average, 8,000-9,000 AEs related to surgical staplers occur per year, with 90% of these AEs resulting from a malfunction with the device.[10]

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[6] *Surgical Staplers and Staples*, FDA (June 25, 2019), https://fda.gov/medical-devices/general-hospital-devices-and-supplies/surgical-staplers-and-staples.
[7] *Id.*
[8] *See* S. Lori Brown, *Surgical stapler-associated fatalities and adverse events reported to the Food and Drug Administration*, JACS (May 2004), available at https://www.journalacs.org/article/S1072-7515(04)00754-9/abstract.
[9] Samwel Okoth Makanyengo and Dhan Thiruchelvam, *Literature Review on the Incidence of Primary Stapler Malfunction*, 27 SURG. INNOV., 229-34 (Apr. 2020)
[10] *Everything Healthcare Professionals Need to Know*, *supra* note 15.

30. The consequences of a malfunction are profoundly serious, as the FDA explained, "[i]n a retrospective study of 349 colorectal resections using a circular stapler, surgeries with surgical stapler malfunctions were found to have higher incidences of unplanned proximal diversions, ileus, gastrointestinal bleeding, and blood transfusions." Likewise, "[a]nastomotic leaks from surgical stapler malfunctions have also been associated with an increased risk of cancer recurrence."[11]

31. Injuries caused by malfunctioning internal surgical staplers can be permanent and fatal.

32. Even if the malfunction does not cause a potentially fatal injury for the patient, such "complications frequently require additional diagnostic studies, invasive procedures and in the need for reoperation resulting in prolonged hospitalization and additional skilled nursing care."[12]

33. As a result of these complications and the ubiquitous malfunctions that have plagued surgical staplers for years, the FDA conducted a review of the studies that have been conducted to investigate these issues.[13]

34. By examining these studies, the FDA concluded that the most commonly reported malfunctions associated with surgical stapler systems include malformed staples, missing staples, *staplerjamming, and misfires*. [*Emp. Added*][14]

35. By 2013, Defendants and the medical device industry were aware that malfunctioning surgical staplers presented serious risks of injuries during surgery and that the true risk of injury was unknown and unexamined. Despite this obvious problem, these Defendants took no steps to measure the true risks of these devices.

[11] *FDA Executive Summary, FDA (May 30, 2019), 11, https://www.fda.gov/medical/126211/download.*
[12] *Id.* at 9.
[13] *Id.* at 10.
[14] *Id.* at 10-11.

36. One medical article concluded "[m]ost minimally invasive surgeons have experienced laparoscopic linear stapler malfunction and 25% have had to significantly alter the planned operative procedure due to the malfunction."

> Our surgeons recently experienced several independent adverse events involving the laparoscopic linear stapler. Although the Food and Drug Administration maintains a Manufacturer and User Facility Device Experience (MAUDE) database to track such voluntary reports, many events are not reported, and the true incidence of adverse events is unknown.[15]

37. Part of the problem was the method by which these Defendants and other manufacturers chose to track and report AEs relating to their products. The FDA allowed some makers of surgical staplers to make *summary* reports of AEs into an FDA database which allowed manufacturers to knowingly conceal injuries related to these devices from public scrutiny.[16]

38. Overall, Defendants at all relevant times were, or should have been, aware of the dangers a defective surgical stapler system posed for the general public and should have, and were expected to, maintain effective procedures to properly manufacture the surgical stapler system and appropriately respond when the stapler was found to be defective. Unfortunately, this is not the case.

DEVICE REGULATIONS AND RECALL

39. As previously explained, Defendants have long known of the risks of serious injury and death associated with its surgical staplers like the one used on Plaintiff. Between January 2011-March 2018, over 41,000 adverse events were reported with these devices—including over 360 deaths.[17]

40. Once knowing the risks, medical device manufacturers, like Defendants, must

[15] D. R. Kwazneski, et al., *The Unacknowledged Incidence of Laparoscopic Stapler Malfunction,* 27 SURG.ENDOSC., 86-9 Jan. 2013).
[16] Christina Jewett, Hidden FDA Reports Detail harm Caused by Scores of Medical Devices, KHN (Mar. 7, 2019), https://khn.org/news/hidden-fda-database-medical-device-injuries-malfunctions/.
[17] *Safe use, supra* note 7.

establish and follow Quality Systems ("QS") to help ensure that their products are manufactured as intended for use and can safely be used in patient surgical procedures. QS for FDA-regulated products, including medical devices, are known as Current Good Manufacturing Practices ("CGMP's").[18]

41. However, as opposed to other medical devices, surgical staplers were considered a Class I medical device, so Defendants were not required to gain FDA's premarket approval ("PMA") before selling a surgical stapler.[19]

42. Thus, utility and safety profiles for surgical staplers were never reviewed nor approved by the FDA.

43. Further, the FDA never reviewed nor approved manufacturing processes for any lines of the internal Surgical Stapler.

44. Finally, as a Class I medical device which does not require premarket approval from the FDA also means Defendants' surgical stapler lines did not require device design controls as Class II devices do.[20]

45. As a consequence, Defendants were given unfettered freedom to design, manufacture and market surgical staplers.

46. Despite this and the potential for serious injury, Defendants failed to maintain QS and CGMP's to ensure that its surgical staplers such as the stapler used in Plaintiff's procedure, would not feature any manufacturing defects and expose patients to risks of serious injury or death when the device is used as intended by the surgeon.

47. Further, abuse in the utilization of the ASR system resulted in Defendants'

[18] *See* 21 CFR 820.
[19] *See Safe use*, *supra* note7.
[20] *Id.*

marketing and selling a device which posed grave dangers to an unknowing medical and patient community.

48. However, corporate Defendants knew, and/or had reason to know, because of the thousands of adverse events that the company received or had reason to know, that surgical staplers, such as the device used during Plaintiff's surgical procedure, were defective, unreasonably dangerous, and not safe.

49. Defendants' failure to establish *effective* CGMP's, "AE" complaint reporting, and investigation units, allowed a serious manufacturing defect to go unreported after defective staplers were released to the U.S. public.

FDA RESPONSE TO COVIDIEN RECALL AND SURGICAL STAPLER MALFUNCTIONS

50. On March 8, 2019, the FDA issued a letter to healthcare providers highlighting the problems related to surgical staplers.[21]

51. By April of 2019, the FDA announced its intent to reclassify surgical staplers from a class I device (signifying low risk of harm to patients) to a Class II device, requiring a stricter approval process.[22]

52. The FDA explained that it intended to "to reclassify surgical staplers for internal use from Class I (general controls), exempt from premarket review, to Class II (special controls), subject to premarket review. The FDA believes that general controls by themselves are insufficient to provide reasonable assurance of safety and effectiveness for these devices, and that there is sufficient information to establish special controls to provide such assurance."[23]

[21] *Surgical Staplers and Staples for Internal Use – Labeling Recommendations,* FDA (April 2019) https://www.fda.gov/regulatory-information/search-fda-guidance-documents/surgical-staplers-and-staples-internal-use-labeling-recommendations.
[22] *General and Plastic Surgery Devices: Reclassification of Certain Surgical Staplers,* FED. REGISTER (Apr. 24, 2019). https://www.federalregister.gov/documents/2019/04/24/2019-8260/general-and-plastic-surgery-devices-reclassification-of-certain-surgical-staplers.
[23] *Id.*

53. The FDA reasoned that this reclassification was necessary, in part, due to complications that can result from surgical stapler malfunctions, which could result in "prolonged surgical procedures, unplanned surgical interventions, and other complications such as bleeding, sepsis, fistula formation, tearing of internal tissues and organs, increased risk of cancer recurrence, and death."[24]

54. The FDA also noted and illustrated the high rate of reported incidents, also known as MedicalDevice Reports ("MDRs"), associated with surgical staplers. The FDA summarized its findings by explaining that:

> From January 1, 2011, to March 31, 2018, FDA received over 41,000 individual MDRs for surgical staplers and staples for internal use, including 366 deaths, over 9,000 serious injuries, and over 32,000 malfunctions. Some of the most commonly reported problems in these adverse event reports include an opening of the staple line or malformation of staples, misfiring, difficulty in firing, failure of the stapler to fire the staple, and misapplied staples (e.g., user applying staples to the wrong tissue or applying staples of the wrong size to tissue).[25]

55. It was also noted that "[t]he most common device-related malfunctions included failure of the stapler to fire the staple, failure to form staples, difficulty of opening/closing the stapler, stapler misfiring, and stapler breakage. The most commonly reported patient consequences from malfunctions with surgical staplers for internal use included a delay in surgical procedure, hemorrhage, and tissue damage."[26]

56. Beyond these findings, however, the FDA also reported that "[f]rom November 1, 2002, to December 30, 2018, FDA received a total of 168 recalls for surgical staplers and staples for internal use under product codes GAG and GDW, including one class I recall and 167 class II recalls.[27]

[24] *Id.*
[25] *Id.*
[26] *Id.*
[27] *Id.*

57. As a result of the aforementioned data and findings, on or around April 24, 2019, the FDA issued a proposed order to allow for this reclassification. This proposed reclassification would include, among other requirements, adequate performance testing to mitigate the risk of device malfunction and would "include an evaluation of staple formation characteristics in the maximum and minimum tissue thicknesses for each staple type; measurement of the worst-case deployment pressures on stapler firing force; and a measurement of staple line strength."[28]

58. That same day, the FDA also issued a draft guidance document to assist with the labeling of surgical staplers.[29] The FDA explained that "[b]oth device misuse and device malfunctions are root causes of these adverse events. FDA believes that these problems may be mitigated by providing specific information about the risks, limitations, and directions for use in the labeling for the surgical staplers and staples for internal use."[30]

59. Because of the risks associated with surgical staples, and to allow public comment, the FDA held a public meeting on or around May 30-31, 2019, to discuss whether surgical staplers should be reclassified as a Class II medical device, which would require manufacturers to give "premarket notification and allow the FDA to establish mandatory special controls to help mitigate known risks of the device."[31]

60. At the conclusion of the meeting, the FDA panel "unanimously recommended the reclassification of surgical staplers for internal use from Class I (general controls) to Class II (special controls).[32] A final order was issued on the reclassification and became effective October 8, 2021, wherein surgical staplers for internal use would be classified as a Class II (special controls)

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[28] *Id.*
[29] *Surgical Staplers and Staples for Internal Use-Labeling Recommendations: Draft Guidance for Industry and Food and Drug Administration Staff: Availability*, FED REGISTER (Apr. 24, 2019), http://www.federalregister.gov/documents/2019/04/24/2019-08259/surgical-staplers-and-staples-for-internal-use-labeling-recommendations-draft-guidance-for-industry.
[30] *Id.*
[31] *General and Plastic Surgery Devices Advisory Committee Meeting,* FDA (May 30, 2019), https://www.fda.gov/media/127627/download.
[32] *Id.*

device and subject to premarket review[33].

PLAINTIFF'S SPECIFIC FACTUAL ALLEGATIONS

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

62. Defendants tested, designed, manufactured, and sold defective Endo GIA and EEA surgical staplers that were available in the market to be used in surgical procedures before, during and after 2019.

63. These staplers frequently malfunctioned and were defective, compromising staple integrity and surgical procedures, with the potential to lead to patient death or serious injuries when used by a surgeon, even as instructed by Defendants in the device user manual.

64. Plaintiffs contend that a surgical stapler tested, designed, manufactured, and marketed by Defendants, malfunctioned during Plaintiff Corrigan's February 2019 surgery, resulting in an internal staple line failure that caused an anastomotic leak which required multiple additional corrective surgeries and prolonged hospital stays.

65. On February 14, 2019, Mr. Corrigan underwent a laparoscopic sigmoidectomy with end-to-end anastomosis, laparoscopic mobilization of splenic flexure, and percutaneous liver biopsy. During the procedure, a circular stapled anastomosis was created using a 31mm EEA stapler.

66. Mr. Corrigan's recovery seemed to be going well until approximately three days

[33] Federal Register :: General and Plastic Surgery Devices; Reclassification of Certain Surgical Staplers

later when he began complaining of abdominal pain, tachycardia, and tachypnea. Imaging studies showed what appeared to be a leak of the anastomosis.

67. On February 20, 2019, Mr. Corrigan was brought back to the operating room, status post laparoscopic sigmoidecotmy with anastomotic leak, for a diagnostic laparoscopy, and laparoscopic loop ileostomy creation with drainage of abscess. During this procedure, "manipulation of the small bowel demonstrated a pocket of inflammatory debris and enteric contents in the pelvis [lower abdomen]." This clinical presentation indicated that the surgical stapler used during the procedure failed to completely seal internal surgical tissue and as a result, bowel contents leaked into Plaintiff's lower abdomen, and contaminated his surrounding internal sterile spaces. To avoid catastrophe, "an everted loop ileostomy was created by exteriorizing and orienting the terminal ilium so that the efferent limb was superior, and the afferent limb was inferior. This was secured using interrupted sutures of 3-0 Vicryl. An ostomy pouch was placed over the ileostomy." Thus, it was necessary for Plaintiff's surgeon to create a temporary external receptacle (a heavy plastic bag) to hold Plaintiff's bowel contents while the area damaged by the failed stapler line was given time to heal.

68. The healing did not occur for approximately four months, during which time Plaintiff was required to manually process and empty the waste contents of the external receptacle.

69. A CT guided percutaneous drainage of abscess with insertion of abdominal catheter was performed on February 27, 2019.

70. Mr. Corrigan was finally discharged on March 12, 2019.

71. Approximately four months after his initial surgery on June 6, 2019, Mr. Corrigan had a "takedown of ileostomy with small bowel anastomosis" That is, the injured bowel tissue was finally able to process bodily functions and the temporary waste bag was removed.

72. Further complications occurred when on or about September 21, 2020, Mr. Corrigan underwent laparoscopic surgery of an incisional hernia repair with extensive lysis of adhesions. This procedure resulted in a nine-day hospital stay.

73. Plaintiff alleges, upon information and belief, that the EEA stapler used in Plaintiff's surgery to create his staple line was defective, causing the staple line leak. This stapler was a model in a class of staplers known to fail and among a class of staplers with specific models subject to recall by Defendants in May 2018, because of the potential for the recalled EEA staplers to fail and cause a staple line leak.

A HISTORY OF RECALLS

74. Between 2017 and 2019, Defendants, under the identifiers "Covidien LLC" and "Covidien Medtronic" issued various recalls as to Endo GIA staplers including recalls in May 2018, August 2018, and June 2019, that covered Endo GIA staplers that had been distributed between April 2014, and April 2019.

FDA DISCOVERY OF MISUSE OF ADR PROGRAM

75. Manufacturers of medical devices, such as Defendants, must provide reports to MAUDE when they learn that any of their devices contributed to death or serious injury. An alternative reporting system (ASR) was established, though, for reporting well-known and well-characterized events on a summary basis. Here, Defendants misused that system. They did so to dilute reports, so that the injuries did not seem as prevalent; this included the non-reporting of events involving new and novel malfunctions that caused severe injury and would have subjected their staplers to recall or reclassification. In fact, these recalls occurred as soon as the issue was discovered and published in 2019. The staplers have been reclassified.

76. 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 his unsuspecting surgeons.

77. 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, each of the Defendants have utilized an alternative summary reporting program that is not publicly accessible.

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

79. Despite the ASR system, a manufacturer was still required to report deaths related to its product's use in the public MAUDE database. This public Database shows that Medtronic has reported more than 250 deaths related to staplers or staples since 2001. Despite this manifest knowledge of the dangers associated with its products, Medtronic nevertheless still used reporting exemptions to hide stapler-related reports from public view by reporting them to an inaccessible database through July 2017. By doing so, Defendants intentionally concealed the many injuries

caused by the use of its defective classes of surgical staplers. This concealment denied critical information concerning the safety of those products from surgeons, including the surgeons who performed Plaintiff's surgery, and patients like Plaintiff. Ultimately, Defendants continued to sell staplers to healthcare providers during this time without disclosing the serious risks of injury from use.

FDA RECLASSIFICATION AND CHANGED LABELING RECOMMENDATIONS

80. Based on the number of stapler-related injuries, in May 2019, the FDA proposed reclassifying surgical staplers for internal use from Class I to Class II (Special Controls). Among other things, this required manufacturers, including Defendants, to publicly report all malfunctions or injuries related to the Covidien stapler; device manufacturers, such as Covidien, are no longer able to use the reporting exemptions for injuries related to surgical staplers. Consequently, the number of public reports of deaths, injuries, and malfunctions skyrocketed from approximately 1,000 reports in 2015 to more than 11,000 reports in 2018.

81. 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, all Defendants had undertaken to affirmatively represent and marketed that their staplers were safe and effective. The Defendants 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.

82. Defendants intentionally failed to: (1) provide warnings regarding the potential for their staplers to malfunction in the very manner that occurred during Plaintiff's surgery; (2) warn

and inform surgeons of the potential for its staplers to malfunction in that manner; and (3) recall their defective products when Defendants knew their surgical staplers were prone to injurious malfunction. Through that conduct – as well as the affirmative concealment of the known risks of the products described above – Defendants engaged in willful, wanton, reckless, malicious behavior and/or exhibited a gross indifference to, and a callous disregard for human life, the safety and the rights of others, and more particularly, the rights, life, and safety of the Plaintiff. That conduct was motivated by consideration of profit, financial advantage, monetary gain, economic aggrandizement, and cost avoidance, to the virtual exclusion of all other considerations.

COUNT I:

BREACH OF WARRANTY – DEFECTIVE MANUFACTURE AND DESIGN

83. Plaintiffs hereby incorporate by reference the preceding paragraphs as if fully set forth herein.

84. Defendants impliedly warranted that the Covidien 31 mm EEA circular staplers were merchantable and were fit for the ordinary purposes for which they were intended.

85. When Plaintiff's surgeon performed a Laparoscopic sigmoidectomy with end-to-end anastomosis, the stapler device was being used for the ordinary purposes for which they were intended.

86. Plaintiff Brian Corrigan, individually and/or by and through his surgeon, relied upon the Defendants' implied warranties of merchantability in consenting to have the procedure with heavy usage of permanently implanted surgical staples.

87. Defendants breached these implied warranties of merchantability because the stapler used to form the staple line were neither merchantable nor suited for their intended uses as warranted.

88. Defendants' breach of its implied warranties resulted in the implantation of a faulty staple line which later burst, spewing biliary contents into Plaintiff's lower abdomen, requiring multiple surgeries and extended hospitalizations.

89. The defective EEA Surgical Stapler System used in Brian Corrigan resulted from an improper or incorrect manufacturing process, such that the devices as manufactured deviated from their intended design. The defects caused by improper or incorrect manufacturing rendered them unreasonably dangerous, deficient, and defective to Plaintiff. These defects existed since the devices were manufactured, meaning that the defects were present when the device system left the possession and control of Defendants.

90. The EEA stapler system used in Plaintiff's surgery was defective, unfit, unsafe, inherently dangerous, and unreasonably dangerous for their intended and reasonably foreseeable uses. The system was in said condition when it entered the stream of commerce and used in Brian Corrigan. As a result, the stapler system did not meet or perform to the expectations of patients and health care providers, but rather were dangerous to an extent beyond that which would be contemplated by the ordinary consumer.

91. The EEA stapler system used on Plaintiff was defective at the time of its sale or distribution, as the foreseeable risks of harm posed by the products at issue could have been reduced or avoided by the adoption of a reasonable alternative design. The omission of that reasonable alternative design renders the products at issue not reasonably safe. Reasonable alternative designs were available, technologically feasible, and practical, and would have reduced or prevented harm to patients like Plaintiff.

92. Defendants intentionally and recklessly designed, manufactured, marketed, labeled, sold, and distributed EEA stapler systems with wanton and willful disregard for the health

of Brian Corrigan, and with malice, placing their economic interest above the health and safety of Plaintiff.

93. As used by Plaintiff's surgeon, the EEA stapler system was not substantially changed, modified, or altered at any time in any manner whatsoever prior to use. While they were used in the manner for which they were intended, the system was in such a condition that was unreasonably dangerous to him, given its propensity to malfunction while forming staple lines, provoking anastomotic leaks, which is exactly the injury in which their use resulted.

94. At no time did Brian Corrigan have reason to believe that the surgical stapler system was in a condition not suitable for its proper and intended use among patients. He was not able to discover, nor could he have discovered through the exercise of reasonable care, the defect of the system. Furthermore, in no way could Plaintiff have known that Defendants had manufactured the devices in such a way as to increase the risk of harm or injury to the patient on which they were used.

95. As a direct and proximate result of Defendants' wrongful conduct, including the design, manufacture, marketing, and distribution of the EEA surgical stapler system, Plaintiffs have sustained serious injuries and damages, including but not limited to multiple surgeries, multiple life-threatening complications, pain, suffering, mental anguish, fear, loss of enjoyment of life, and emotional distress, and medical expenses.

COUNT II:

BREACH OF WARRANTY – FAILURE TO WARN

96. Plaintiffs hereby incorporate the allegations contained in the preceding paragraphs as though fully set forth herein.

97. The EEA Surgical Stapler system used on Plaintiff presented a danger to patients

like Plaintiff. Defendants were aware of the dangers the products at issue presented and knew that the danger would be present when the product was used in its intended manner, as it was here. Those dangers, however, were not known or reasonably knowable to patients like Plaintiff.

98. At no time did Brian Corrigan have reason to believe that the EEA surgical stapler system was dangerous or in a condition not suitable for its proper and intended use among patients. Plaintiff was not able to discover, nor could he have discovered through the exercise of reasonable care, the defect of the system. Furthermore, in no way could Plaintiff have known that Defendants had manufactured the device in such a way as to increase the risk of harm or injury to the patient on which they were used.

99. As used by Plaintiff's surgeon, the EEA surgical stapler system was not substantially changed, modified, or altered at any time in any manner whatsoever prior to use. While it was used in the manner for which it was intended, the System was in such a condition that was unreasonably dangerous to him, given its propensity to malfunction while forming staple lines, provoking anastomotic leaks, which is exactly the injury in which its use resulted.

100. Defendants failed to provide proper warnings or instructions to the products end users and patients like Plaintiff so users and patients may reasonably avoid any hidden dangers associated with the products at issue and use them safely.

101. As a direct and proximate result of Defendants' wrongful conduct, including the design, manufacture, marketing, and distribution of the EEA Surgical Stapler System, Plaintiffs have sustained serious injuries and damages including, but not limited to, multiple surgeries, multiple life-threatening complications, pain, suffering, mental anguish, fear, loss of enjoyment of life, and emotional distress, and medical expenses.

COUNT III: NEGLIGENCE

102. Plaintiffs hereby incorporate the allegations contained in the preceding paragraphs as though fully set forth herein.

103. Defendants negligently designed, warned, and marketed the EEA surgical stapler system.

104. Defendants had a duty to individuals, including Brian Corrigan, to use reasonable care in designing, manufacturing, marketing, and distributing the EEA surgical stapler system. A Defendant who designs a medical device or instrument, such as a stapler system, who sells or otherwise distributes a defective device is subject to liability for harm to persons caused by a design defect. A reasonably prudent manufacturer must design its products so as to avoid any unreasonable risk of harm to anyone who is likely to be exposed to harm when the product is put to its intended use or to any use that is unintended but is reasonably foreseeable. A medical device is defective if at the time of sale, the device is designed in such a way that it poses harm and risk of injury when used by the intended consumer in the manner the manufacturer has directed and designed.

105. A reasonably prudent manufacturer of those products would also know that an internal stapler system that fails to form solid staple lines could cause serious injury because a burst staple line failure can cause an anastomotic leak, and the injured patient would require multiple hospitalizations, surgeries, and significant medical care to treat.

106. Plaintiff was harmed by a defective EEA surgical stapler system that was distributed, manufactured, and sold by Defendants. This system contained a design defect that made the product unreasonably dangerous to patients. Specifically, there was a design and/or manufacturing defect that would result in a stapler failing to form secure staple lines, despite proper

utilization by a surgeon. That design defect in the stapler system existed when the product left the manufacturer's control.

107. As a direct and proximate result of Defendants' negligence, Plaintiffs have sustained serious injuries and damages including, but not limited to, sepsis, Loop ileostomy, multiple surgeries, multiple life-threatening complications, pain, suffering, mental anguish, fear, loss of enjoyment of life, and emotional distress, and medical expenses.

COUNT IV: NEGLIGENT MISREPRESENTATION

108. Plaintiffs hereby incorporate the allegations contained in the preceding paragraphs as though fully set forth herein.

109. As a direct and proximate result of Defendants' negligent misrepresentation, Plaintiffs have sustained serious injuries and damages including, but not limited to, sepsis, Loop ileostomy, multiple surgeries, multiple life-threatening complications, pain, suffering, mental anguish, fear, loss of enjoyment of life, and emotional distress, and medical expenses.

COUNT V: LOSS OF CONSORTIUM

110. Plaintiffs hereby incorporate the allegations contained in the preceding paragraphs as though fully set forth herein.

111. At all times material Brian Corrigan was married to Sheri Bement. As a result of the injuries and damages sustained by Brian Corrigan, Ms. Bement has suffered loss of Brian Corrigan's care, comfort, society, and affection.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs Brian Corrigan and Sheri Bement pray for judgment against Defendants, individually and collectively, jointly and severally, as follows:

(a) Trial by jury;

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

(c) Judgment against Defendants for all other relief sought by Plaintiffs 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

Plaintiffs demand a trial by jury on all counts and as to all issues.

Dated: February 10, 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,

Gale D. Pearson
FEARS NACHAWATI, PLLC
5489 Blair Road
Dallas, TX 75231
Tel: (214) 890-0711
Email: gpearson@fnlawfirm.com
Pro Hac Vice Admission Pending

COUNSEL FOR PLAINTIFF