UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

DENISE HOPKINS,	
Plaintiff,	**Case No. 1:26-cv-8098**
v.	
OLYMPUS AMERICA INC., OLYMPUS CORPORATION, OLYMPUS MEDICAL SYSTEMS CORP., OLYMPUS CORPORATION OF THE AMERICAS, OLYMPUS SURGICAL TECHNOLOGIES AMERICA, AIZU OLYMPUS CO. LTD, AOMORI OLYMPUS CO. LTD., SHIRAKAWA OLYMPUS CO. LTD.,	**Judge**
Defendants.	

COMPLAINT

I. PRELIMINARY STATEMENT

1. This is a medical device tort action arising out of the failure of Defendants' endoscope, the Olympus CF-HQ190L colonoscope ("Endoscope Device"). As a direct and proximate result, Plaintiff has suffered permanent injuries and significant pain and suffering, emotional distress, loss wages and earnings capacity, and diminished quality of life. Plaintiff respectfully seeks damages in excess of $75,000 for all damages to which Plaintiff may be legally entitled.

II. PARTIES

2. At all material times, Plaintiff was a citizen and resident of Chicago, Illinois.

3. Defendant Olympus America Inc. is and, at all times relevant to this action, has been a United States corporation that is incorporated under the laws of the State of New York.

Olympus America Inc. has its principal place of business at 3500 Corporate Parkway, Center Valley, PA 18034.

4. Olympus Corporation of the Americas is and, at all times relevant to this action, has been a United States corporation that is incorporated under the laws of the State of New York. Olympus Corporation of the Americas has its principal place of business at 3500 Corporate Parkway, Center Valley, PA 18034.

5. Olympus Surgical Technologies America is and, at all times relevant to this action, has been a subsidiary of Olympus Corporation of the Americas. Olympus Surgical Technologies America has its headquarters at 800 West Park Drive, Westborough, Massachusetts, 01581.

6. Defendant Olympus Medical Systems Corp. is and, at all times relevant to this action, has been a Japanese Corporation with its principal place of business at 2951 Ishikawa-maschi, Hachioji-shi, Tokyo 192-8507, Japan.

7. Aizu Olympus Co. is and, at all times relevant to this action, has been a Japanese Corporation having its principal place of business at 3-1 Nishi-Shinjuku 2-Chome Shinjuku-Ku Tokyo 163-0914 Japan.

8. Aomori Olympus Co. Ltd is and, at all times relevant to this action, has been a Japanese Corporation having its principal place of business at 2-248-1 Okkonoki, Kuroishi-shi, Aomori 036-0357, Japan.

9. Shirakawa Olympus Co. Ltd is and, at all times relevant to this action, has been a Japanese Corporation having its principal place of business at 3-1 Oaza-Odakura-Aza-Okamiyama, Nishigo-mura, Nishishirakawa-gun, Fukushima 961-8061, Japan.

10. Defendant Olympus Corporation is and, at all times relevant to this action, has been a Japanese corporation having a principal place of business at 2951 Ishikawa-maschi, Hachioji-shi, Tokyo 192-8507, Japan.

11. Defendant Olympus Corporation is and, at all times relevant to this action, has been the parent company of Olympus America Inc., Olympus Medical Systems Corp., Olympus Corporation of the Americas, Olympus Surgical Technologies America, Aizu Olympus Co. Ltd, Aomori Olympus Co. Ltd., and Shirakawa Olympus Co. Ltd.

12. Defendant Olympus Corporation is and, at all times relevant to this action, has exercised and exercises dominion and control over Olympus America Inc., Olympus Medical Systems Corp., Olympus Corporation of the Americas, Olympus Surgical Technologies America, Aizu Olympus Co. Ltd, Aomori Olympus Co. Ltd., and Shirakawa Olympus Co. Ltd.

13. Defendant Olympus Corporation was at all material times responsible for the actions of Olympus America Inc., Olympus Medical Systems Corp., Olympus Corporation of the Americas, Olympus Surgical Technologies America, Aizu Olympus Co. Ltd, Aomori Olympus Co. Ltd., and Shirakawa Olympus Co. Ltd. It exercised control over these entities specific to the oversight and compliance with applicable safety standards regarding Endoscope Devices sold throughout the states and territories of the United States.[1] In such capacity, Defendant Olympus Corporation committed or allowed to be committed tortious and wrongful acts, including the violation of numerous safety standards relating to manufacturing, quality assurance/control, and conformance with design and manufacturing specifications.

[1] *See* Olympus Corporation; First Quarter Financial Results FY2026, Presentation Materials at 5-10, *available at* https://www.olympus-global.com/ir/data/brief/2026.html?page=ir (emphasizing its leadership in responding to FDA compliance and regulatory issues and guiding new innovations and product launches).

14. Each of the Olympus Defendants was the agent and employee of the other Olympus Defendants and, in doing the things alleged, was acting with the court and scope of such agency and employment with the other Olympus Defendants' actual and implied permission, consent, authorization, and approval.

15. The Olympus Defendants, in collaboration amongst themselves, designed, tested, researched, and developed the Endoscope Device at issue in this litigation.

16. As part of their business and at all relevant times, the Olympus Defendants have been involved in the design, research, manufacture, testing, advertisement, promotion, marketing, sale, and distribution of the Endoscope Devices.

17. The Olympus Defendants, in collaboration amongst themselves, designed and developed the Endoscope Devices.

18. The Olympus Defendants, in collaboration amongst themselves, manufacture and market the Endoscope Devices in the United States.

19. The Olympus Defendants have transacted and conducted business related to the Endoscope Devices in each of the states and territories of the United States.

20. The Olympus Defendants have expected or should have expected their acts to have consequence within each of the states and territories of the United States, and derived substantial revenue from interstate commerce in each of the states and territories of the United States related to the Endoscope Devices.

21. The Olympus Defendants, in collaboration amongst themselves, have, at all relevant times, been involved throughout all states and territories in the United States in the research, development, testing, manufacture, production, marketing, promotion and/or sale of medical devices, including the Endoscope Device in this litigation. The Olympus Defendants have

derived substantial revenue related to Endoscope Devices from their business throughout each of the states and territories of the United States. All acts and omissions of the Olympus Defendants as described herein, including but not limited to, those resulting in the design, manufacture, marketing, labeling, distribution, sale and placement of its Endoscope Device at issue in the instant suit, were done by their agents, servants, employees and/or owners, acting in the course and scope of their representative agencies, services, employments and/or ownership. At all times material hereto, the Olympus Defendants did business in the United States, and specifically, engaged with regulatory authorities and the medical community within the United States and Illinois.

22. The Olympus Defendants control the largest U.S. market share of Endoscope Devices and participate in the manufacture and distribution of the Endoscope Devices throughout all states and territories of the United States.

23. The Olympus Defendants are individually and jointly and severally liable to Plaintiff for damages Plaintiff suffered arising from the design, manufacture, marketing, labeling, improper/inadequate warnings, distribution, sale, and placement of Defendants' Endoscope Devices, effectuated directly and indirectly through Defendants' agents, servants, employees and/or owners, all acting within the course and scope of their representative agencies, services, employments and/or ownership.

24. The Olympus Defendants are also vicariously liable for the acts and omissions of their employees and/or agents who were at all material times acting on Defendants' behalf and within the scope of their employment or agency.

III. JURISDICTION AND VENUE

25. At all relevant times, Plaintiff has been a citizen and resident of Chicago, Illinois.

26. This Court has subject-matter jurisdiction over this action pursuant to 28 U.S.C. § 1332(a) based on complete diversity of citizenship between Plaintiff and all Defendants. The amount in controversy exceeds $75,000.00.

27. This Court has personal jurisdiction over Defendants because at all times relevant to this lawsuit, Defendants transacted business within the State of Illinois and contracted to sell and supply their Endoscope Devices in this State. Defendants employ sales representatives in this state to sell their products throughout the State, including the Endoscope Device used in Plaintiff in Chicago, Illinois. Defendants' tortious acts and omissions in the State of Illinois caused injury to Plaintiff.

28. Defendants have purposefully engaged in Illinois in the business of developing, manufacturing, publishing information, marketing, distributing, promoting and/or selling, either directly or indirectly, through third parties or other related entities, medical devices including the Endoscope Device at issue, for which they derived significant and regular income. Defendants intended and reasonably expected that their defective Endoscope Devices, including the CF-HQ190L colonoscope, would be sold and used in Illinois and could cause injury in Illinois.

29. Further, Defendants have purposely availed themselves of the privilege of conducting business within this State and have the requisite minimum contacts with this State such that the maintenance of this suit does not offend traditional notions of fair play and substantial justice and that Defendants should reasonably anticipate being hailed into Court here.

30. Consistent with the Due Process Clause of the Fifth and Fourteenth Amendments, Defendants are subject to personal jurisdiction in this District.

31. A substantial part of the events and omissions giving rise to Plaintiff's causes of action occurred in this District.

32. Venue is proper in this Court pursuant to 28 U.S.C. §1391(a).

IV. FACTS COMMON TO ALL COUNTS

33. On or about August 8, 2024, Plaintiff underwent an endoscopic procedure, specifically a colonoscopy using Olympus colonoscope CF-HQ190L (2637933) performed by Dr. Sanra Naffouj at Northwestern Memorial Gastroenterology in Chicago, Illinois.

34. Defendants manufactured, sold, and/or distributed the CF-HQ190L to be used in endoscopic procedures like the procedure performed on Plaintiff.

35. On or about August 31, 2024, Plaintiff reported to the emergency room and was referred to her primary care provider. On or about September 3, 2024, approximately 26 days after the colonoscopy, Plaintiff reported to the emergency room at Northwestern Memorial Hospital after having been sent there by her primary care physician.

36. Plaintiff has been having loose stool since the procedure. Around August 29, 2024, Plaintiff had developed liquid diarrhea, severe lower abdominal cramping, and bright red blood in the stool. Plaintiff.

37. On September 3, 2024, she was admitted to the hospital for 10 days. During this time, she was diagnosed with a C. difficile infection for the first time.

38. Plaintiff was given vancomycin then switched to fidaxomicin before her discharge.

39. On October 19, 2024, Plaintiff was again diagnosed with C. difficile and given a different medication.

40. Plaintiff continues to experience complications related to the Endoscope Device including recurring infections, likelihood of recurrence, chronic fatigue, and fear of future endoscopic procedures.

41. Defendants were responsible for the research, design, development, testing, manufacture, production, marketing, promotion, distribution and sale of the Endoscope Device, including providing warnings and instructions concerning their product.

42. Among the intended purposes for which Defendants designed, manufactured and sold the Endoscope Device was its use by doctors for endoscopic procedures. That was the purpose for which the Endoscope Device was used on Plaintiff.

43. Defendants represented to Plaintiff and Plaintiff's physician that the Endoscope Device was safe and effective for endoscopic procedures.

FDA 510(k) CLEARANCE PROCESS

44. The "510(k) clearance process" of the U.S. Food & Drug Administration (FDA) refers to Section 510(k) of the 1976 Medical Device Amendments to the Federal Food, Drug and Cosmetic Act (MDA). Under this process, medical device manufacturers are only required to notify the FDA at least 90 days before they market a device claimed to be "substantially equivalent" to a device the FDA had approved for sale before 1976 (when the MDA was enacted).

45. No clinical testing or clinical study is required to gain FDA approval under this process. Instead, a given device was supposed to demonstrate substantial equivalence to a predicate medical device.

46. Subsequent amendments to the MDA allowed for 510(k) clearance of products deemed "substantially equivalent" to post-MDA, 510(k)-cleared devices.

47. Through this domino effect, devices deemed "substantially equivalent" to devices previously deemed "substantially equivalent" to devices the FDA had approved for sale pre-1976 could be sold to patients in a matter of 90 days—without any clinical testing.

48. Therefore, clearance for sale under the 510(k) process does not equate to FDA approval of the cleared medical device.

49. At the request of the FDA in 2012, the National Institute of Health (NIH) conducted a thorough review of the 510(k) process, reaching the following major conclusion:

> **The 510(k)-clearance process is not intended to evaluate the safety and effectiveness of medical devices with some exceptions. The 510(k) process cannot be transformed into a pre-market evaluation of safety and effectiveness so long as the standard for clearance is substantial equivalence to any previously cleared device.**

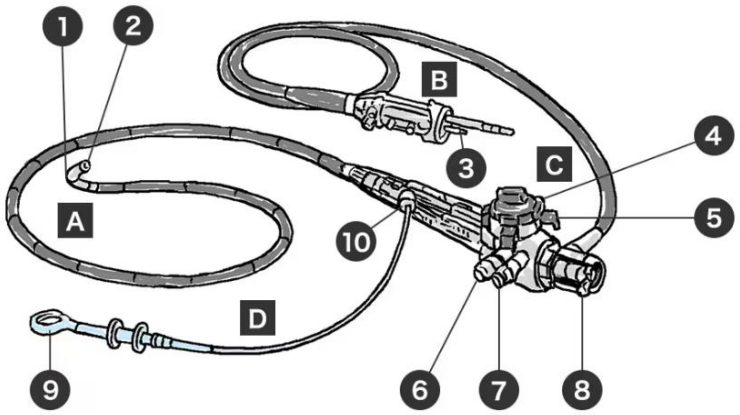
50. The NIH explained: "The assessment of substantial equivalence does not require an independent demonstration that the new device provides a 'reasonable assurance of safety and effectiveness.'" Further, the NIH even pointed out that the classification of predicate devices approved for sale prior to 1976 "did not include any evaluation of the safety and effectiveness of individual medical devices . . .Thus it is common for devices to be cleared through the 510(k) program by being found substantially equivalent to devices that were never individually evaluated for safety and effectiveness, either through the original device classification program or through the 510(k) process."

51. Defendants sought and obtained FDA clearance to market their Endoscopic Devices under Section 510(k) of the Medical Device Amendment to the Food, Drug and Cosmetics Act. Section 510(k) provides for marketing of a medical device if the device is deemed "substantially equivalent" to other predicate devices marketed prior to May 28, 1976. The 510(k) process is not a formal review for safety or efficacy. No clinical testing or clinical study is required to gain FDA clearance under this process. Upon information and belief, no formal review for safety or efficacy was ever conducted for the Endoscopic Devices.

DEFENDANTS' ENDOSCOPE DEVICE: DEFECTS & RISKS

45. In 2017, there were more than 20 million endoscope procedures in the U.S.[2] By 2019, that number had grown to 22 million.[3]

46. Defendants' Endoscope Device is a thin, tube-like instrument used to look at tissues inside the body. It has a light and lens for viewing, a channel for inserting tools to remove tissue, an auxiliary water channel, and an air/water nozzle. The insertion tube contains long, narrow working channels (a diagram of an Olympus endoscope is shown below)[4]:



A: Distal end / B: Connecting section / C: Control section / D: Flexible section of the main body / 1: Bending section / 2: Objective lens / 3: Air pipe / 4: Right and left angulations controlknob / 5: Up and down angulations controlknob / 6: Air and water valve button / 7: Suction valve button / 8: Eyepiece lens / 9: Forceps / 10: Forceps port

47. Defendants' Endoscope Devices are designed and intended for repeated and recurrent use in multiple medical procedures involving different patients. After each use, Defendants' Endoscope Devices necessarily require cleaning and disinfecting (known as "reprocessing"), before they can be safely used on a new patient.

[2] Wang P., Xu T., Ngamruengphong S., Makary M.A., Kalloo A., Hutfless S. Rates of infection after colonoscopy and osophagogastroduodenoscopy in ambulatory surgery centres in the USA. Gut. 2018;67:1626–1636. doi: 10.1136/gutjnl-2017-315308.
[3] Peery A., Crockett S., Murphy C., Jensen E., Kim H., Egberg, M. Lund J., Moon A., Pate V., Barnes E., Schlusser C., Baron T., Shaheen N., Sandler R. Burden and Costs of Gastrointestinal, Liver, and Pancreatic Diseases in the United States: Update 2021. Gastroenterology. 2021 Oct.
[4] https://www.olympus-global.com/technology/museum/fiber.html?page=technology (last visited May 16, 2026).

48. Defendants knew or should have known that their Endoscope Devices would be used in multiple procedures involving many different patients and have an obligation to develop and validate a safe and effective reprocessing protocol to be included in the Devices' packaging and labeling instructions such as the Instructions for Use (IFU), and/or Reprocessing Manual, and/or Operation Manual ("Product Labeling").

49. The Product Labeling must provide sufficient instructions on how to prepare the Endoscopic Devices for the safe use on the next patient. Pursuant to federal law, the manufacturer of a medical device is required to maintain a Device Master Record and/or design history file as appropriate, which must include documentation of tests that were performed to demonstrate that the processing instructions are complete, understandable, and can reasonably be executed by the user in a safe and effective manner. The Device master Record must comply with the 21 C.F.R. § 820.181 and the design history file must comply with 21 C.F.R. § 820.30(j). The manufacturer must ensure that the validated reprocessing protocol is disseminated to medical providers.

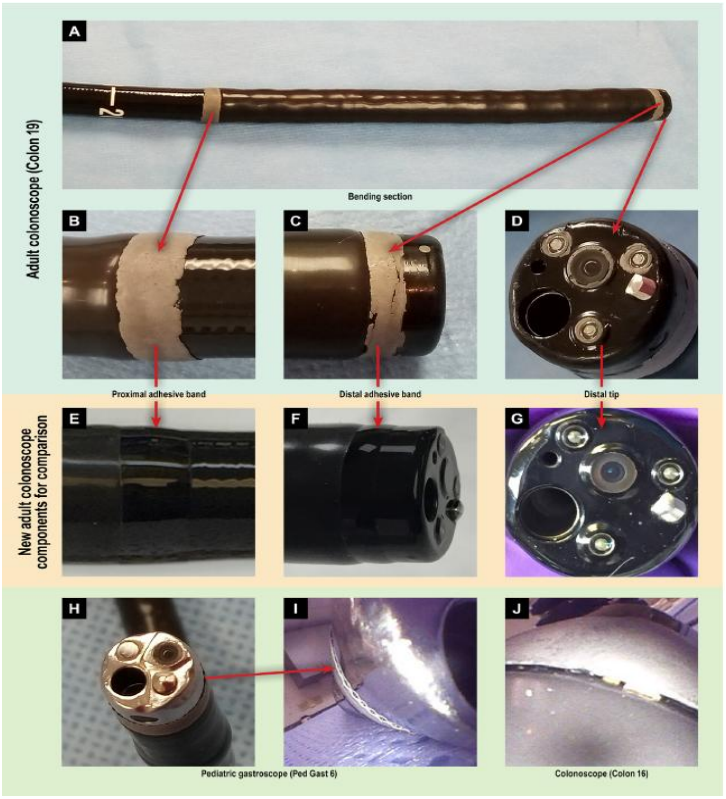
50. Defendants' Endoscope Device is defective because, among other defects, medical providers were not able to safely and effectively sanitize and clean the Endoscope Device even if the providers strictly complied with Defendants' reprocessing instructions contained in the Product Labeling.

51. As a direct result of Defendants' failure to develop and validate effective reprocessing protocol for their Endoscope Devices, multiple patients, like Plaintiff can be exposed to contaminated Endoscope Devices.

52. The medical providers who are the end-users of Defendants' Endoscope Devices rely on the manufacturer Defendants to provide an effective and validated reprocessing protocol. Providers are not aware that Defendants' protocols are not effective in removing all residual bodily

fluids and organic debris from the Endoscope Device after use, which can become trapped in tiny crevices near the tip of the device and within the long narrow channels of the device, which contain microbial contamination thereby exposing patients who undergo a procedure with a contaminated device to health risks, including severe infection, sepsis, organ failure, and death, among other injuries.

53. Not only does the design of the Endoscope Device's complex tip and long, narrow channels pose a risk of microbial contamination, but the repetitive use—with reprocessing in between uses—of Defendants' Endoscope Devices results in cracked lenses, degraded channel linings, and degraded adhesives (see image below). This damage and degradation allows bacteria to hide from chemical disinfectants, thereby exposing patients who undergo a procedure with Defendants' Endoscope Device to health risks, including severe infection, sepsis, organ failure, and death, among other injuries.



54. Defendants knew or should have known that available research has demonstrated that, using magnification and borescopes inspection, 100% of endoscopes with narrow channels, like Defendants' Endoscope, showed visible damage, residue, and/or debris, requiring repair 76% of the time.

55. In endoscopes, like Defendants' Endoscope, channel shredding, scratches, and/or defects appear within a few uses, requiring repair. These grooves and defects allow buildup of biofilm and the proliferation of bacteria.

56. Medical providers are not aware that Defendants' Endoscope Devices can become so easily cracked and degraded, making them even more susceptible to bacterial contamination. Upon information and belief, Defendants (through their employees and/or agents) actively discouraged the use of borescope monitoring (which could detect such cracks in the Endoscope Device,) while responding in writing to any inquiries about borescope monitoring that "Olympus does not currently have an official stance on the use of borescopes as a tool for visualization of flexible endoscope channels after manual cleaning."[5]

57. In addition to harboring dangerous microbes, the aforementioned channel adhesive degradation has been shown to fragment inside patients during endoscopic procedures. Such shredding and degradation, due to Defendants' defective endoscope devices and accompanying protocol, result in the fragmented pieces perforating patients' bowels, and/or gastrointestinal tracts, and/or organs, all of which cause catastrophic injuries in patients, like Plaintiff, including sepsis, organ failure, and death.

[5] https://medical.olympusamerica.com/sites/default/files/us/files/pdf/Borescope-Use-with-Olympus-Flexible-Endoscopes.pdf (last visited May 16, 2026).

58. As recently as July 2025, Defendants' position on implementing additional monitoring tools, such as adenosine triphosphate (ATP) testing, microbial culturing, or borescope monitoring was to refer medical providers to their IFU. To date, Defendants' Product Labeling is silent on the use of such monitoring tools.

59. Defendants knew or should have known that the Product Labeling accompanying their Endoscope Devices are inadequate and that human factors were not appropriately considered in the creation of the Product Labeling and product design.

60. Between October of 2017 and October of 2018 FDA ordered Defendants to conduct a 522 study on one of Defendants' endoscopes—the specific device studied was a duodenoscope, which, other than the forceps elevator, shares the same characteristics (insertion tube containing multiple narrow, working channels, and a distal end), as Defendants' Endoscope.

61. The 522 study design discretion was "to demonstrate that representative reprocessing personnel can follow the recommended reprocessing instructions in the Duodenoscope labeling and user materials without causing reprocessing errors or failures that could result in harm to patients."[6] This human factors study consisted of 30 test participants (including 15 GI nurses and 15 GI techs) to reprocess an Olympus endoscope in accordance with the manufacturer's reprocessing manual. Of the 73 critical manual cleaning tasks, 45 were not successfully performed by 27% or more of participants. In another endoscope model (with the substantially similar narrow channels as Defendants' Endoscope Device), 75 of 111 manual cleaning tasks were not successful performed.

[6] FDA. Olympus 522 Post Market Surveillance Studies-Human factors study. Accessed Mar. 15, 2026. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pss.cfm?t_id=354&c_id=3692 (last visited May 16, 2026).

62. The final effectiveness findings of the 522 study were that the user materials (i.e., Product Labeling) for the Olympus endoscopes were "not sufficient to consistently ensure user adherence in the core reprocessing areas: precleaning, manual cleaning, manual high-level disinfection, rinsing, and storage and disposal."[7]

63. As a direct result of Defendants' Endoscope Device's inadequate Product Labeling, medical professionals are not able to properly clean the Endoscope Device even when strictly adhering to Defendants' reprocessing protocol contained in the Product Labeling.

64. As a direct result of Defendants' Endoscope Device's inadequate Product Labeling, soil retained inside the nonvisible channels of Defendants' Endoscope prevents disinfectants from making full contact and can shield microbes. If the soil is organic, it doubles as a food source, allowing bacterial contaminants to multiply exponentially. When a sterile tool or water is pushed across this food source and inserted into the organs of the next patient, the microbes transfer as well. Defendants knew or should have known that allowing moisture to remain inside the unseen interior channels of Defendants' Endoscope Device can harbor enough bacteria or viral load to become catastrophic for patients, like Plaintiff. If even small amounts of moisture remain in Defendants' Endoscope Device, bacteria can proliferate at alarming rates.

65. Defendants knew or should have known that moisture trapped inside the channels of Defendants' Endoscope Device cannot be observed by reprocessors and/or medical providers, yet Defendants fail to mandate (or even recommend) drying indicators to test for residual fluid before storage.

66. In a 2022 post-market surveillance study ordered by FDA, Defendants could only demonstrate 34.8% of Defendants' sampled endoscopes contained no contamination.

[7] Id.

67. Defendants knew or should have known that their failure to instruct medical providers to conduct borescope inspections, dryness indicator tests, adenosine triphosphate (ATP) testing, and/or microbial culturing would expose multiple patients, like Plaintiff, to contaminated Endoscope Devices.

68. The level of processing Defendants' instruct medical providers to perform as part of the reprocessing protocol contained in their Product Labeling is also inadequate. The Spaulding Classification System categorizes three levels of processing: low-level disinfection, high-level disinfection ("HLD"), and sterilization. Scientific literature reports that real-world testing has detected microbes on 6%–72% of reprocessed (and clinically used) endoscopes after HLD. Although the scientific literature advocates for sterilization of endoscopes instead of HLD, Defendants' Product Labeling for the Endoscope Device calls for HLD and implicitly advises against sterilization. Defendants knew or should have known that (1) sterilization kills all microbes, including spores, whereas HLD at best kills vegetative microbes and may allow spores to survive; (2) sterilization shows roughly double the reduction in microbial bioburden than HLD; (3) sterilization would give proper consideration to the expected human factor deficiencies, which have been shown to exist as a direct result of Defendants' inadequate and defective Product Labeling. Upon information and belief, in accordance with Defendants' Product Labeling, the majority of facilities in the United States utilize HLD instead of sterilization on Defendants' endoscope devices, including the Endoscope Device at issue.

DEFENDANTS' ACTS & OMISSIONS REGARDING THEIR DEFECTIVE DEVICE

69. At all material times, Defendants were responsible for designing, manufacturing, producing, testing, studying, inspecting, labeling, marketing, advertising, selling, promoting, and

distributing their Endoscope Devices, and providing warnings/information about the Endoscope Devices.

70. Defendants' Endoscope Devices were defectively designed and manufactured; and were also defective as marketed due to inadequate warnings, instructions, labeling and/or inadequate testing, despite Defendants' knowledge of the Endoscopes Devices' lack of safety and inadequate reprocessing protocol.

71. Defendants had independent obligations to know and timely and adequately disclose scientific and medical information about their Endoscope Devices and inadequate reprocessing protocol; and to warn of their risks and side effects as soon as each Defendant was aware of them. Defendants did not do so.

72. Defendants also knew or should have known that their Endoscope Devices and accompanying inadequate reprocessing protocol unreasonably exposed patients, like Plaintiff, to the risk of serious harm, while conferring no benefit over available feasible and safer alternatives that did not present the same risks and adverse effects.

73. Defendants made claims regarding the benefits of using the Endoscope Devices but minimized or omitted their risks and adverse effects. Although Defendants knew or should have known that their claims were false and misleading, they failed to adequately disclose the true health consequences and the true risks and adverse effects of the Endoscope Devices.

74. At all material times, Defendants failed to provide sufficient warnings and instructions that would have put Plaintiff, Plaintiff's health care providers, and the general public on notice of the dangers and adverse effects caused by the use of the Endoscope Devices.

75. Defendants have marketed and continue to market their Endoscope Devices to Plaintiff and Plaintiff's health care providers as safe, effective and reliable. Further, Defendants

continue to market their Devices as safer and more effective than available feasible alternatives, and other competing products. Those alternatives have existed at all material times and have always presented less frequent and less severe risks and adverse effects than the Endoscope Devices.

76. The risks of the Endoscope Devices' design outweigh any potential benefits associated with the design. As a result of their defective design and/or manufacture, an unreasonable risk of severe adverse reactions can occur, including but not limited to: infection, pneumonia, tuberculosis, HIV, sepsis, organ failure, organ perforation, and death.

77. Defendants omitted mention of the Devices' risks, dangers, defects, and disadvantages when they advertised, promoted, marketed, sold and distributed them as safe to regulatory agencies, health care providers, Plaintiff, and other consumers. But Defendants knew or should have known that the Endoscope Devices were not safe for their intended purposes, and that they would and did cause serious medical problems, including severe and permanent injuries and damages—and in some cases, catastrophic injuries and death.

78. Defendants have underreported complications and injuries resulting after the use of Endoscope Devices; and have made unfounded representations regarding the efficacy and safety of the Devices through various means and media.

79. Defendant Olympus Medical Systems Corporation pleaded guilty to failing to file required adverse event reports ("AERs") involving infection and continuing to sell Defendants' endoscope devices despite that failure. A former senior executive pleaded guilty to distributing misbranded medical devices.

80. In addition to the criminal prosecution, a July 2022 inspection by the FDA of one of Defendants' Japanese factories (Defendant Aizu Olympus Co. Ltd.) found that Defendants'

endoscope devices were "adulterated" and resulted in a Form 483 Warning Letter. The letter stated that the FDA inspection revealed that the entire device design for endoscopes was not validated to ensure that devices conform to defined user needs under actual or simulated conditions. It also found that there were no medical device report ("MDR") procedures.

81. In 2022, FDA also cited Defendants Aizu Olympus Co. Ltd. and Aomori Olympus Co. Ltd. for not having procedures in place for dealing with MDRs—one of the most important post-market surveillance tools available to FDA for monitoring the safety and efficacy of devices on the market.

82. Also in 2022, FDA cited Defendant Olympus Corporation of the Americas for having an insufficient/nonexistent MDR system. FDA found Defendant Olympus Corporation of the Americas' MDR internal systems were inadequate, staff was not trained, and there were no procedures for evaluating complaints.

83. Further compounding these issues, the FDA inspector for Defendant Aomori discovered that all of its MDRs were submitted to FDA to inaccurately reflect Olympus Medical Systems Corporation or the Olympus Corporation of the Americas as the manufacturing site. This practice affects the ability of FDA to detect and remove unsafe devices, such as Defendants' Endoscope Device.

84. Despite the mislabeling of MDRs, the failure of Defendants' facilities to have a process for MDRs, and the general underreporting of adverse events, there are thousands of complaints involving Olympus endoscopes on the Manufacturer and User Facility Device Experience ("MAUDE") database maintained by FDA, many of which report the contraction of multi-drug resistant organisms (or "super bugs"), sepsis, organ failure, device fragmentation, and death related to Defendants' endoscope device.

85. In addition to the MDRs (both reported and not reported) that should have put Defendants on notice of their defective Endoscope Devices and inadequate reprocessing protocol, outbreaks related to endoscopes have been widely reported in scientific literature. For example, in July 2022 an outbreak was detected in Northern Germany. The outbreak strain was eventually isolated from a reprocessed, ready-to-use colonoscope. By the end of the outbreak, 32 people had been infected and 6 died.

86. In November 2014, 25 cases of multidrug-resistant bacteria were identified in Pittsburg. 76% of the cases had been exposed to the same bronchoscope. Researchers noted no breaches in technique, precleaning or HDL. The researchers noted that even following the manufacturer's reprocessing procedures there was accumulation of proteinaceous debris and biofilm allowing subsequent contamination.

87. Defendants knew or should have known that at all material times their communications about the benefits, risks and adverse effects of the Endoscope Devices, including communications in labels, advertisements and promotional materials, were materially false and misleading.

88. Defendants' nondisclosures, misleading disclosures, and misrepresentations were material and were substantial factors contributing directly to the serious injuries and damages Plaintiff has suffered.

89. Plaintiff would not have agreed to the Endoscope Devices had Defendants disclosed the true health consequences, risks and adverse effects caused by their Endoscope Devices.

90. Upon information and belief, Defendants failed to conduct adequate pre-market clinical testing and research and failed to conduct adequate post-marketing surveillance to

determine the safety of the Endoscope Devices and the safety and effectiveness of the associated reprocessing protocol.

91. Upon information and belief, Defendants failed to disclose on their warning labels or elsewhere that adequate pre-market clinical testing and research, and adequate post-marketing surveillance had not been done on the Endoscope Devices, thereby giving the false impression that the Endoscopic Devices and associated reprocessing protocol had been sufficiently tested.

92. The Endoscope Devices are defective due to Defendants' failure to adequately warn or instruct Plaintiff and Plaintiff's medical providers concerning at least the following subjects:

a) The Endoscope Devices' propensities for cracking, degradation, and fragmentation.

b) The risk of harboring microorganisms, including multi-drug-resistant organisms, HIV, and tuberculosis, even after following the protocols outlined in the IFU. resulting from the Devices.

c) The severity of complications that could arise as a result of the use of the Endoscope Devices.

d) The hazards associated with the Endoscope Devices.

e) The Endoscope Devices' defects described in this Complaint.

f) Use of the Endoscope Devices is no more effective than with feasible available alternatives; and exposes patients to greater risk than with feasible available alternatives.

g) Use of the Endoscope Devices puts patients at greater risk of developing HIV, tuberculosis, and being infected with multi-drug-resistant organisms requiring extensive hospital stays and IV antibiotics, and resulting in sepsis, organ failure, and other catastrophic injuries, including death than use of feasible available alternatives.

h) Clearing of the infections acquired after the use of the Endoscope Devices may be difficult and, in some cases impossible, resulting in organ failure, septic shock, and death.

i) Due to the inability to clean Defendants' Endoscope Device, medical providers should discard and/or not utilize a reusable Endoscope Device if used in a patient with a communicable disease and/or multi-drug-resistant organisms.

93. The Endoscope Device used in Plaintiff was at all times used and reprocessed in a manner foreseeable to Defendants: Defendants generated Product Labeling, Including the Instructions for Use for the Endoscope Device, created procedures for the use, re-use, and reprocessing of the Endoscope Device, and allegedly trained medical providers. But Defendants provided incomplete and insufficient training and information to medical providers regarding the use and reprocessing of the Endoscope Device, as well as instructions and/or warnings about the need to monitor, inspect, and/or visualize the Endoscope Devices to ensure that they are not damaged, cracked, degraded, and/or contaminated with bacterial microbes or other infectious organisms prior to using in the next patient, like Plaintiff.

94. The Endoscope Device used in Plaintiff was in the same or substantially similar condition as when they left Defendants' possession, and in the condition directed by and expected by Defendants.

95. As a result of having the Endoscope Device used, Plaintiff has experienced significant physical and mental pain and suffering, sustained permanent injury, undergone medical treatment and will likely undergo further medical treatment, and suffered financial or economic loss, including obligations for medical services and expenses, lost income, and other damages.

DISCOVERY RULE; STATUTORY OR EQUITABLE TOLLING; ESTOPPEL

96. Plaintiff asserts all applicable state statutory and common law rights and theories related to the tolling or extension of any applicable statute of limitations, including statutory and equitable tolling, delayed discovery, discovery rule, and/or fraudulent concealment.

97. The discovery rule applies to toll limitations until Plaintiff knew, or through the exercise of reasonable care and diligence should have known, of facts indicating Plaintiff's injuries; the cause of the injuries; or the tortious nature of the wrongdoing that caused the injuries.

98. The nature of Plaintiff's injuries, damages, or their resulting relationship to Defendants' conduct was not discovered, and through reasonable care and due diligence could not have been discovered, until a date within the applicable statute of limitations for filing Plaintiff's claims.

99. Limitations are tolled due to equitable or statutory tolling. Defendants are therefore estopped from asserting a statute of limitations defense due to their fraudulent concealment, through affirmative misrepresentations and omissions, from Plaintiff and Plaintiff's health care providers of the risks and defects associated with Defendants' Endoscope Device and associated reprocessing protocol contained in the Product Labeling, including the severity, duration and frequency of risks and complications. Defendants affirmatively withheld and/or intentionally misrepresented facts concerning the safety of their Devices, including adverse data and information from studies and testing conducted with respect to the Endoscope Devices, showing that the risks and dangers associated with the Endoscope Devices were unreasonable.

100. As a result of Defendants' misrepresentations and concealment, Plaintiff and Plaintiff's health care providers were unaware, and could not have known or have learned through reasonable diligence, that Plaintiff had been exposed to the risks alleged in this Complaint; and that those risks were the direct and proximate result of Defendants' wrongful acts and or omissions. Defendants are estopped from asserting any limitations defense based on their intentional acts of withholding material information about the safety of the Endoscope Devices from Plaintiff and Plaintiff's health care providers.

COUNT I: STRICT PRODUCT LIABILITY: DEFECTIVE DESIGN

101. Plaintiff realleges and incorporates by reference all paragraphs in this Complaint.

102. Defendants' Endoscope Device is defectively designed and unreasonably dangerous.

103. At the time the Endoscope Device was used in Plaintiff, the Device was defectively designed. As described in this Complaint, there was an unreasonable risk that a Device would not perform safely and effectively for the purposes for which it was intended. Defendants failed to design against such dangers and failed to provide adequate warnings and instructions concerning the risks.

104. Defendants' Endoscope Device was defectively designed when supplied, sold, distributed and/or otherwise placed into the stream of commerce and when it was used in Plaintiff.

105. Defendants expected and intended the Endoscope Device to reach users like Plaintiff in the condition in which the Devices were sold.

106. The usage of Endoscope Device into Plaintiff was medically reasonable and was the type of use Defendants intended and foresaw when they designed, manufactured and sold the Devices.

107. The risks of the Endoscope Device's designs significantly outweigh any benefits allegedly associated with the designs.

108. When the Endoscope Device was used in Plaintiff, there existed safer alternative designs for such devices, which were economically and technologically feasible at the time the Devices left Defendants' control. In all reasonable probability, those alternative designs would have reduced the likelihood, severity, frequency, and duration of the injuries Plaintiff suffered, without substantially impairing the utility of the endoscope devices.

109. The Endoscope Device used in Plaintiff failed to reasonably perform as intended and resulted in complications. In many cases, these complications necessitated further surgery to

repair the injuries caused by the defective Devices, and to repair the very issue the Devices were intended to repair. Thus, the Devices provided no benefit to Plaintiff.

110. Defendants' Endoscope Device failed to meet consumer safety expectations, as they did not perform as safely when used in an intended or reasonably foreseeable manner, as an ordinary consumer would have expected.

111. Defendants' Endoscope Device injured Plaintiff.

112. Defendants are strictly liable to Plaintiff for designing a defective product. Defendants' actions give rise to a claim for damages under the product liability statutes and common law jurisprudence in all states and territories of the U.S.

113. As a direct and proximate result of Defendants' defectively designed Endoscope Device, Plaintiff has been injured and undergone medical treatment, and/or will likely undergo future medical treatment. Plaintiff also sustained severe and permanent physical and mental pain, suffering, disability, impairment, loss of enjoyment of life, economic loss, and damages, including medical expenses, lost income, other damages.

114. Plaintiff is entitled to recover compensatory, non-compensatory, punitive, and all other damages available under law for injuries sustained as a result of Defendants' defectively designed Endoscope Device. Plaintiff realleges and incorporates by reference all paragraphs in this Complaint.

COUNT II
STRICT PRODUCT LIABILITY: FAILURE TO WARN

115. Defendants were manufacturers, distributors, and/or retailers of the Endoscope Device.

116. Defendants' Endoscope Devices are inherently dangerous.

117. The use of any of Defendants' Endoscope Device in a reasonably foreseeable manner involves a substantial danger that a user would not readily recognize.

118. Defendants knew or should have known of these dangers, given the generally recognized and prevailing scientific knowledge available at the time of the manufacture and distribution of their Endoscope Device.

119. Defendants failed to provide adequate warning of the dangers created by the reasonably foreseeable use of their Device.

120. At the time the Devices were used in Plaintiff, Defendants' warnings and instructions for it were inadequate and defective. As described in this Complaint, there was an unreasonable risk that the Endoscope Device would not perform safely and effectively for the purposes for which it was intended. Defendants failed to design and/or manufacture against such dangers and failed to provide adequate warnings and instructions concerning these risks.

121. Defendants failed to properly and adequately warn and instruct Plaintiff and Plaintiff's health care providers concerning the risks of Endoscope Device, given Plaintiff's conditions and need for that information.

122. Defendants also failed to properly and adequately warn and instruct Plaintiff and Plaintiff's health care providers concerning the inadequate research and testing of Endoscope Device, and the complete lack of a safe, effective procedure for removal of the Device.

123. Defendants expected and intended the Endoscope Device to reach Plaintiff, Plaintiff's health care providers, and other consumers in the condition in which their products were sold.

124. Plaintiff and Plaintiff's health care providers were unaware of the defects and dangers of Defendants' Endoscope Device; and were further unaware of the frequency, severity, and duration of the defects and risks associated with the Devices.

125. Defendants' Instructions for Use for the Device expressly understated, misstated, or concealed the risks Defendants knew or should have known were associated specifically with it, as described in this Complaint.

126. Defendants' Instructions for Use for the Endoscope Device failed to adequately warn Plaintiff or Plaintiff's health care providers of numerous risks Defendants knew or should have known were associated with the Device.

127. Defendants failed to adequately train or warn Plaintiff or Plaintiff's health care providers about the necessity for surgical intervention in the event of complications, or how to properly treat such complications associated with the Endoscope Device when they occurred.

128. With respect to Defendants' warnings about complications associated with the Device, they provided inadequate or no information regarding the complications, frequency, severity, and duration, even though the complications were more frequent and more severe and lasted longer than those associated with safer feasible alternative treatments.

129. If Plaintiff or Plaintiff's health care providers had been properly warned of the defects and dangers of Endoscope Device, and of the frequency, severity and duration of the risks associated with the Device, Plaintiff would not have consented to allow the Device to be used, nor would Plaintiff's health care providers have used them.

130. Defendants are strictly liable in tort to Plaintiff for their wrongful conduct, including their failure to warn or provide adequate instructions regarding Endoscope Device.

Defendants' actions give rise to a claim for damages under the product liability statutes and common law jurisprudence of all states.

131. As a direct and proximate result of Defendants' inadequate and defective warnings and instructions, Plaintiff has been injured and undergone medical treatment and will likely undergo future medical treatment. Plaintiff has also sustained severe and permanent physical and mental pain, suffering, disability, impairment, economic loss, and damages, including medical expenses, lost income, and other damages.

132. Plaintiff's injuries were a reasonably foreseeable result of Defendants' failure to provide adequate warnings and instructions.

133. Plaintiff is entitled to recover compensatory, non-compensatory, punitive, and all other damages available under law for injuries sustained as a result of Defendants' failure to provide adequate warnings and instructions on the risks and dangers associated with their Endoscope Device.

134. As a result of Defendants' failure to warn or to provide adequate warnings, Plaintiff and Plaintiff's health care providers were unaware, and could not have known or learned through reasonable diligence, that Plaintiff had been exposed to the risks alleged in this Complaint; and that those risks were the direct and proximate result of Defendants' wrongful acts and/or omissions.

COUNT III: STRICT PRODUCT LIABILITY MANUFACTURING DEFECT

135. Plaintiff realleges and incorporates by reference all paragraphs in this Complaint.

136. Defendants' Endoscope Device was not reasonably safe for their intended use and were defective with respect to their manufacture, in that they deviated materially from Defendants'

manufacturing and/or design specifications and thus posed unreasonable risks of serious bodily harm to Plaintiff.

137. Defendants' Endoscope Device was unreasonably dangerous as a result of a malfunction, failure to properly manufacture to specifications as intended, improper assembly, or improperly broken or damaged packaging.

138. At the time the Endoscope Device was used, the Devices were defective with respect to their manufacture, in that Defendants deviated materially from their manufacturing and/or design specifications and thus posed an unreasonable risk of harm to Plaintiff in whom the Endoscope Device was used.

139. The manufacturing defects associated with the Endoscope Device were not known, knowable or readily visible to Plaintiff's health care providers or to Plaintiff, nor were they discoverable upon reasonable examination. The Endoscope Device was used and used in the very manner in which they were intended to be used and used, in accordance with Defendants' Instructions for Use and marketing materials.

140. The Endoscope Device used in Plaintiff was different from their intended design and failed to perform as safely as a device manufactured in accordance with the intended design would have performed.

141. As a direct and proximate result of the aforementioned defects, Plaintiff has been injured and undergone medical treatment and will likely undergo future medical treatment and procedures. Plaintiff has also sustained severe and permanent physical and mental pain, suffering, disability, impairment, loss of enjoyment of life, economic loss, and damages, including medical expenses, lost income, other damages.

142. Defendants' defective manufacture of the Endoscope Device was a proximate cause of the damages and injuries Plaintiff suffered.

143. Defendants are strictly liable to Plaintiff for designing, manufacturing, marketing, labeling, packaging and selling defective Endoscope Device.

144. Defendants' actions give rise to a claim for damages under the product liability statutes and common law jurisprudence of all states.

145. Plaintiff is entitled to recover compensatory, non-compensatory, punitive, and all other damages available under law for injuries sustained as a result of Defendants' defectively manufactured Endoscope Device.

COUNT IV: NEGLIGENCE

146. Plaintiff realleges and incorporates by reference all paragraphs in this Complaint.

147. Defendants owed a duty to Plaintiff to exercise reasonable care when designing, manufacturing, producing, marketing, labeling, packaging and selling Defendants' Endoscope Device, and when creating instructions and warnings for them.

148. Defendants did not exercise reasonable care when designing, manufacturing, producing, labeling, packaging, marketing, selling, creating, and explaining the instructions or warnings for the Device.

149. In addition to the acts and omissions described in this Complaint, Defendants, by and through their authorized divisions, subsidiaries, agents, servants and/or employees, acted with carelessness, recklessness, negligence, gross negligence and/or willful, wanton, outrageous and reckless disregard for human life and safety in manufacturing, designing, labeling, creating instructions and warnings, marketing, distributing, supplying, selling and/or placing into the stream of commerce their Endoscope Device, including but not limited to the following:

a) failing to use due care in design and/or manufacture of the Endoscope Devices so as to avoid the aforementioned risks to patients, such as Plaintiff;

b) failing to conduct adequate testing, including pre-clinical and clinical testing and post-marketing surveillance to determine the safety of their Endoscope Devices;

c) failing to recognize the significance of their own and other testing, and information regarding their Endoscope Devices, which testing and information evidenced such products are dangerous and potentially harmful when used in humans;

d) failing to respond promptly and appropriately to their own and other testing, and information regarding the Endoscope Devices; and failing to promptly and adequately warn of the injuries as described in this Complaint;

e) failing to promptly, adequately and appropriately recommend monitoring of patients used with the Endoscope Devices, in light of the Devices' dangers and potential harm to humans;

f) failing to properly, appropriately and adequately monitor the post-market performance of their Endoscope Devices;

g) aggressively promoting, marketing, advertising and/or selling their Endoscope Devices despite their knowledge and experience of the Devices' dangers and risks;

h) failing to use reasonable and prudent care in their statements of the efficacy, safety and risks of using the Endoscope Devices, which were knowingly false and misleading, in order to influence patients' health care providers to use the Devices;

i) failing to accompany their Endoscope Devices with proper and adequate warnings regarding all possible adverse effects and risks associated with the usage of the Devices;

j) failing to disclose to Plaintiff and Plaintiff's health care providers their full knowledge and experience regarding the potential risks and harm associated with the usage of the Endoscope Devices;

k) failing to disclose to Plaintiff and Plaintiff's health care providers in an appropriate and timely manner, facts relative to the potential risks and harm associated with the usage of the Endoscope Devices;

l) failing to warn Plaintiff and Plaintiff's health care providers of the severity and duration of such adverse effects;

m) failing to warn Plaintiff and Plaintiff's health care providers directly or indirectly, whether orally or in writing, before actively encouraging the sale of their Endoscope Devices, about the increased risk associated with the Devices;

n) placing and/or permitting the placement of the Endoscope Devices into the stream of commerce without adequate warnings that their usage is harmful to humans and/or without proper warnings of the Devices' risks;

o) failing to respond or react promptly and appropriately to reports that the Endoscope Devices caused harm to patients;

p) disregarding government and/or industry studies, information, documentation and recommendations, consumer complaints and reports or other information regarding the hazards of usage of the Endoscope Devices and their potential harm to humans;

q) under-reporting, underestimating or downplaying the serious dangers and risks of their Endoscope Devices;

r) failing to exercise reasonable care in informing health care providers using the Endoscope Devices about Defendants' own knowledge regarding the potential risks and harm associated with the usage of the Devices;

s) failing to adequately warn Plaintiff and Plaintiff's health care providers of the known or reasonably foreseeable danger that Plaintiff would suffer serious injuries or death after being used with their Endoscope Devices;

t) promoting the Endoscope Devices in advertisements, websites and other modes of communication aimed at creating or increasing the rate and frequency of usage of the Devices, without regard to the dangers and risks associated with their usage;

u) failing to conduct or respond to post-marketing surveillance of complications and injuries associated with the use of the Endoscope Devices;

v) failing to use due care under the circumstances; and

w) other acts or omissions constituting negligence and carelessness, as may appear during the course of discovery or at the trial of this matter.

150. Defendants knew or should have known that their failure to exercise ordinary care in the manufacture, design, packaging, labeling, the creation of warnings and instructions, sale, marketing and distribution of the Devices, and their training of health care providers to use the

Devices or to treat Device complications, would cause foreseeable harm, injuries, and damages to individuals used with Endoscope Devices, including Plaintiff.

151. Defendants knew, or in the exercise of reasonable care should have known, that the Endoscope Device was defectively and unreasonably manufactured and/or designed, and were unreasonably dangerous and likely to injure patients in whom Endoscope Device was used. Defendants knew or should have known that Plaintiff and Plaintiff's health care providers were unaware of the dangers and defects inherent in the Devices.

152. Defendants' Endoscope Device caused Plaintiff to suffer injuries.

153. Plaintiff suffered injuries as a result of Defendants' failure to exercise reasonable care in designing, manufacturing, producing, marketing, labeling, packaging and selling, and creating instructions or warnings for Endoscope Device.

154. Defendants' actions constitute negligence under the common law of all states.

155. Defendants' negligence proximately caused the damages and injuries to Plaintiff.

156. As a direct and proximate result of Defendants' negligence in designing, testing, inspecting, manufacturing, packaging, labeling, marketing, distributing and training, and preparing inadequate and improper written instructions and warnings for the Endoscope Device, Plaintiff has been injured and undergone medical treatment, and will likely undergo future medical treatment and procedures, sustained severe and permanent physical and mental pain, suffering, disability, impairment, economic loss, and damages, including, but not limited to, medical expenses, lost income, other damages.

157. Plaintiff is entitled to recover compensatory, non-compensatory, punitive, and all other damages available under law for injuries resulting from Defendants' negligence.

COUNT V: NEGLIGENCE PER SE

158. Plaintiff realleges and incorporates by reference all paragraphs in this Complaint.

159. Defendants' actions also constitute negligence per se under the applicable health and safety statutes and regulations of all state, as well as federal law.

160. The applicable statutes and regulations are aimed at preserving the health and safety of Plaintiff and the general public.

161. Plaintiff is among the class of individuals that the statutes and regulations were meant to protect.

162. Plaintiff's injuries are among the type that the statutes and regulations were intended to prevent.

163. As a result of the acts and omissions described in this Complaint, Plaintiff was caused to suffer serious injuries as described in this Complaint, which are permanent and lasting in nature, physical pain and mental anguish, diminished enjoyment of life and financial expenses for hospitalization and medical care.

164. Defendants' negligence per se proximately caused the damages and injuries to Plaintiff.

165. Plaintiff is entitled to recover compensatory, non-compensatory, punitive, and all other damages available under law for injuries resulting from Defendants' negligence per se.

COUNT VI: GROSS NEGLIGENCE

166. Plaintiff realleges and incorporates by reference all paragraphs in this Complaint.

167. Defendants' conduct, as described in this Complaint, was extreme and outrageous. Defendants risked the life of Plaintiff, and other consumers and users of their products, with

knowledge of the safety and efficacy problems with their drugs; and they withheld their knowledge from Plaintiff, Plaintiff's health care providers, and others. Further, Defendants made conscious decisions not to redesign, re-label, warn or inform unsuspecting consumers.

168. Defendants' wrongs were aggravated by the kind of malice, fraud, and grossly negligent disregard for the rights of others, the public, and Plaintiff, for which the law would allow—and for which Plaintiff will seek at the appropriate time under governing law—the imposition of exemplary damages. Defendants' conduct was specifically intended to cause substantial injury to Plaintiff, or when viewed objectively from Defendants' standpoint at the time of the conduct, involved an extreme degree of risk, considering the probability and magnitude of the potential harm to others. Further, Defendants were actually subjectively aware of the risk involved, but nevertheless proceeded with conscious indifference to the rights, safety, or welfare of others, including Plaintiff. Defendants' outrageous conduct warrants an award of punitive damages.

169. As a direct and proximate result of Defendants' gross negligence, Plaintiff has been injured and undergone medical treatment and will likely undergo future medical treatment. Plaintiff has also sustained severe and permanent physical and mental pain, suffering, disability, impairment, economic loss, and damages, including medical expenses, lost income, other damages.

170. Defendants' actions constitute gross negligence under the common law of all states.

171. Plaintiff alleges that the acts and omissions of Defendants, whether taken alone or in combination with others, constitute gross negligence that proximately caused the injuries to Plaintiff. In that regard, Plaintiff will seek exemplary damages in an amount to punish Defendants for their conduct, and to deter other manufacturers from engaging in such misconduct in the future.

COUNT VII: BREACH OF IMPLIED WARRANTY

172. Plaintiff realleges and incorporates by reference all paragraphs in this Complaint.

173. Defendants sold the Endoscope Device used in Plaintiff.

174. Defendants knew or reasonably should have known at the time of sale, that each Endoscope Device was intended to be used for the purpose of introduction into the human body and reprocessing before additional usage on another patient.

175. Defendants warranted to Plaintiff, Plaintiff's health care providers, and other consumers, that the Devices were of merchantable quality, and safe for the use for which they were intended.

176. Plaintiff and Plaintiff's health care providers reasonably relied on Defendants' judgment, indications, and statements that Endoscope Device was fit for such use. Because of that reliance, Defendants' Endoscope Device was used in Plaintiff.

177. Defendants distributed into the stream of commerce and sold Endoscope Device that were unsafe for their intended use, and not of merchantable quality as warranted by Defendants, in that the Devices had dangerous propensities when used as intended and used.

178. As a result of Defendants' conduct, Plaintiff suffered injuries and damages, making Defendants liable for breaching their implied warranties.

179. As a direct and proximate result of Defendants' breach of the implied warranties associated with their Endoscope Device, Plaintiff has been injured and undergone medical treatment and will likely undergo future medical treatment. Plaintiff has also sustained severe and permanent physical and mental pain and suffering, disability, impairment, economic loss, and damages, including medical expenses, lost income, other damages.

COUNT VIII: BREACH OF EXPRESS WARRANTY

180. Plaintiff realleges and incorporates by reference all paragraphs in this Complaint.

181. Defendants warranted and represented to Plaintiff, Plaintiff's health care providers, and other consumers, that their Endoscope Device was safe and reasonably fit for their intended purposes.

182. Plaintiff and Plaintiff's health care providers chose Endoscope Device based upon Defendants' warranties and representations regarding the safety and fitness of their Endoscope Device, as described in this Complaint.

183. Plaintiff and Plaintiff's health care providers reasonably relied upon Defendants' express warranties and guarantees that the Devices were safe, merchantable, and reasonably fit for their intended purposes.

184. Defendants breached these express warranties because their Endoscope Device was unreasonably dangerous and defective, and not as Defendants had represented them to be. Defendants' breach of their express warranties resulted in the usage of unreasonably dangerous and defective Endoscope Device in Plaintiff, placing Plaintiff's health and safety in jeopardy.

185. As a direct and proximate result of Defendants' breach of the express warranties associated with Endoscope Device, Plaintiff has been injured and undergone medical treatment and will likely undergo future medical treatment. Plaintiff has also sustained severe and permanent physical and mental pain, suffering, disability, impairment, economic loss, and damages, including medical expenses, lost income, other damages.

COUNT IX: NEGLIGENT INFLICTION OF EMOTIONAL DISTRESS

186. Plaintiff realleges and incorporates by reference all paragraphs in this Complaint.

187. As described in this Complaint, Defendants engaged in negligent conduct by failing to use due care in adequately designing and constructing effective and safe Endoscope Device, by failing to warn of their dangerous propensities, and by negligently studying, designing, developing, testing, inspecting, manufacturing, advertising, marketing, promoting, labeling, distributing, and/or selling the Endoscope Device.

188. As a direct and proximate result of Defendants' negligence, Plaintiff has suffered severe emotional distress, as well as economic loss, and damages, including medical expenses, lost income, and other damages.

189. The emotional distress damages Plaintiff incurred were a reasonably foreseeable result of Defendants' actions.

190. Defendants' actions constitute negligent infliction of emotional distress under the common law of all states.

COUNT X: INTENTIONAL INFLICTION OF EMOTIONAL DISTRESS

191. Plaintiff realleges and incorporates by reference all paragraphs in this Complaint.

192. As described in this Complaint, Defendants engaged in intentional, willful, reckless, extreme, and outrageous conduct by failing to adequately design and construct effective and safe Endoscope Device, by failing to warn of their dangerous propensities, and by improperly studying, designing, developing, testing, inspecting, manufacturing, advertising, marketing, promoting, labeling, distributing, and/or selling the Devices.

193. The emotional distress damages Plaintiff incurred were a reasonably foreseeable result of Defendants' actions.

194. Defendants' actions constitute intentional infliction of emotional distress under the common law of all states.

COUNT XI: NEGLIGENT MISREPRESENTATION

195. Plaintiff realleges and incorporates by reference all paragraphs in this Complaint.

196. From the time Defendants' Endoscope Device was first tested, studied, researched, evaluated, endorsed, manufactured, marketed and distributed, through the present, Defendants made misrepresentations to Plaintiff, Plaintiff's health care providers, and the general public. Defendants' misrepresentations included but were not limited to representing that the reprocessed Endoscope Device was safe and effective for the introduction to the human body. At all relevant times, Defendants conducted sales and marketing campaigns to promote the sale and usage of the Endoscope Device and willfully deceived Plaintiff, Plaintiff's health care providers, and the general public as to the health risks and consequences of the usage of the Endoscope Device.

197. Defendants had a duty to ensure that the representations they made about their Endoscope Device were true and complete when made. Defendants made the foregoing representations without any reasonable ground for believing them to be true and complete.

198. At all relevant times, Defendants conducted sales and marketing campaigns to promote the sale and usage of their Endoscope Device and deceived Plaintiff and Plaintiff's health care providers, as well as other consumers, as to the health risks and consequences of the use of their Endoscope Device.

199. Defendants made these false and misleading representations concerning the safety and efficacy of Endoscope Device for the usage and/or reprocessed usage in the human body without any reasonable ground for believing them to be true.

200. These false and misleading representations were made directly by Defendants, their sales representatives and other authorized agents, to Plaintiff, Plaintiff's health care providers and the general public, in publications, the popular press, and other written materials directed to them;

and on Internet websites and applications also directed to them, with the intention of inducing and influencing the demand for, and the ultimate usage of, their Endoscope Device in Plaintiff and other patients.

201. The above representations were in fact false, in that Defendants' Endoscope Device was not safe, fit or effective for usage as labeled; using the reprocessed Endoscope Device was hazardous to consumers' health; and the Endoscope Device had a propensity to cause serious injuries to patients, as described in this Complaint.

202. Defendants' representations were made with the intention of inducing reliance and the ultimate usage of the Endoscope Device on Plaintiff and other patients.

203. In reliance on Defendants' false and misleading representations, Plaintiff's health care providers were induced to purchase and recommend usage of the Devices on Plaintiff; and Plaintiff was induced to consent to such usage. If Plaintiff or Plaintiff's health care providers had known the truth and the facts Defendants concealed, the health care providers would not have recommended, and Plaintiff would not have consented to, the usage of Defendants' Endoscope Device. The reliance of Plaintiff and/or Plaintiff's health care providers on Defendants' misrepresentations was justified because such misrepresentations were made and conducted by individuals and entities in a position to know all facts.

204. Defendants' acts and omissions caused Plaintiff to suffer serious injuries that are permanent and lasting in nature; physical pain and mental anguish; diminished enjoyment of life; and financial expenses for hospitalization and medical care.

205. Defendants' conduct, as described in this Complaint, was extreme and outrageous. Defendants risked the lives of the recipients of these Devices, including Plaintiff, with knowledge of the safety and efficacy problems with their Endoscope Device and suppressed this knowledge

from the general public, Plaintiff, and/or Plaintiff's health care providers. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consumer public. Defendants' outrageous conduct warrants an award of punitive damages.

COUNT XII: FRAUD AND FRAUDULENT MISREPRESENTATION

206. Plaintiff realleges and incorporates by reference all paragraphs in this Complaint.

207. Defendants designed, manufactured, marketed, and sold their Endoscope Device, and provided inadequate warnings and information about the Endoscope Device.

208. When Plaintiff or Plaintiff's healthcare providers received inadequate information and warnings, the Devices were defective and unreasonably dangerous for their intended and reasonably foreseeable use.

209. Further, Defendants fraudulently represented to Plaintiff, Plaintiff's health care providers, and the general public that their Endoscope Device was safe and effective. Additionally, even though Defendants were fully aware of the dangerous and defective nature of the Endoscope Device, which could and did cause injuries such as those Plaintiff suffered, Defendants intentionally concealed the defects in the Endoscope Device from Plaintiff.

210. Defendants fraudulently represented to Plaintiff, Plaintiff's health care providers, and the general public, that their Endoscope Device had been adequately tested, were safe for introduction into the human body, and were accompanied by adequate warnings.

211. Defendants widely advertised, marketed and promoted their Endoscope Device as safe and effective for usage in the human body after repeated use and reprocessing in accordance with the IFU and/or Product Labeling.

212. Defendants made these representations with the intent of deceiving Plaintiff, Plaintiff's health care providers, and other potential consumers; and with the intent of inducing the

usage of their Endoscope Device, under circumstances that Defendants knew were dangerous and unsafe, and created a high risk of harm.

213. Defendants also made material representations that were false. Further, Defendants knew they were false when made, or willfully, wantonly, and recklessly disregarded whether the representations were true or false. Defendants intended that Plaintiff, Plaintiff's health care providers, and other potential consumers would rely and act upon the false representations.

214. Plaintiff and/or Plaintiff's health care providers relied upon Defendants' fraudulent misrepresentations in allowing the defective Endoscope Device to be used. Plaintiff thus sustained severe and permanent personal injuries, and/or were at an increased risk of sustaining severe and permanent personal injuries in the future.

215. Defendants knew or should have known that their Endoscope Device had not been sufficiently tested, were defective in nature and/or lacked adequate warnings and information.

216. Defendants' actions constituted common law fraud and/or fraudulent misrepresentation in all states.

217. As a direct and proximate result of Defendants' fraud or fraudulent misrepresentation, Plaintiff has been injured and undergone medical treatment and will likely undergo future medical treatment and procedures. Plaintiff has also sustained severe and permanent physical and mental pain, suffering, disability, impairment, economic loss, and damages, including medical expenses, lost income, and other damages.

COUNT XIII: Fraudulent Concealment

218. Plaintiff realleges and incorporates by reference all paragraphs in this Complaint.

219. Before Defendants' Endoscope Device was used on Plaintiff, Defendants fraudulently concealed material information regarding the safety and efficacy of their Endoscope

Device, including information regarding adverse events, pre-marketing and post-marketing injuries, and literature indicating unreasonable risks associated with the usage of the Endoscope Device.

220. Although Defendants were aware of the dangerous and defective condition of the Endoscope Device, they intentionally concealed such information from Plaintiff, Plaintiff's health care providers, and the general public. The significant dangers Defendants concealed included sufficient warnings about the degradation and damage to the Endoscope Device, the difficulty of reprocessing, the usage of validating tests like dryness indicators and microbiology testing, and sterilization instead of HLD. Further, the dangers were not readily obvious to the ordinary user of the Devices, even after post-usage complications had arisen.

221. Defendants made these omissions with the intent of defrauding and deceiving Plaintiff and Plaintiff's health care providers specifically, and other consumers generally; and with the further intent of specifically inducing health care providers to recommend usage of the Endoscope Device. All such acts and omissions evinced Defendants' callous, reckless, willful, depraved indifference to the health, safety and welfare of Plaintiff.

222. When Defendants made the foregoing partial disclosures and fraudulent omissions, and at the time Plaintiff was exposed to the Endoscope Device, Plaintiff and/or Plaintiff's health care providers were unaware of their falsity and reasonably believed the misrepresentations and omissions to be true.

223. Defendants fraudulently concealed the safety issues associated with the usage of their Endoscope Device, to induce health care providers to recommend usage of the Endoscope Device in patients like Plaintiff, and to induce Plaintiff to consent to the usage of the Endoscope Device.

224. Plaintiff's health care providers reasonably relied on Defendants' omissions when they recommended usage of the Endoscope Device used on Plaintiff, thereby causing Plaintiff to sustain severe and permanent personal injuries. Defendants knew, or should have known, that their Endoscope Device had not been sufficiently tested and were defective in nature, and/or that their Endoscope Device lacked adequate warnings.

225. Defendants also knew or should have known that their Endoscope Device has a potential to, and would, cause severe injury to those exposed to their Device, and that the Endoscope Device was inherently dangerous in a manner exceeding any purported warnings.

226. Defendants had a duty to provide Plaintiff, Plaintiff's health care providers, and the general public, with full, complete, accurate and truthful information concerning their Endoscope Device.

227. By virtue of Defendants' omissions and partial disclosures about the Endoscope Device, in which Defendants touted their Devices as safe and effective for usage in patients, Defendants had a duty to disclose all facts about the risks associated with the Devices, including the risks described in this Complaint.

228. Plaintiff's health care providers reasonably relied on these material and fraudulent omissions when recommending usage of the Endoscope Device in Plaintiff, and Plaintiff reasonably relied on the material and fraudulent omissions when consenting to have the Devices used.

229. Defendants did not provide Plaintiff's health care providers with the information necessary to adequately warn Plaintiff.

230. The Endoscope Device was improperly marketed to Plaintiff and Plaintiff's health care providers because Defendants did not provide proper instructions on how to use the Devices and did not adequately warn about the risks associated with usage.

231. Plaintiff could not know in the exercise of reasonable diligence that Defendants' statements concerning their Endoscope Device were knowingly and intentionally false and misleading, or that Defendants had not disclosed material facts and information to Plaintiff or Plaintiff's health care providers that would have been material to the choice of treatment.

232. As a direct and proximate result of Defendants' malicious and intentional concealment of material information from Plaintiff and/or Plaintiff's health care providers, Defendants caused or contributed to Plaintiff's injuries.

233. Had Plaintiff's health care providers been aware of the hazards associated with the usage of Defendants' Endoscope Device, they would have used safer alternative devices for the Plaintiff's endoscopic procedure.

234. Defendants' conduct was reckless, willful, wanton, and outrageous, and manifested a reckless indifference for the safety and well-being of Plaintiff and other consumers.

235. As a direct and proximate result of Defendants' intentional and willful fraudulent concealment of material facts and information from Plaintiff and/or Plaintiff's health care providers, Defendants caused and increased the risk of harm of the injuries and damages Plaintiff suffered after having been used with Defendants' Endoscope Device.

236. Had Plaintiff been aware of the hazards associated with the usage of the Endoscope Device, they would not have consented to its use.

237. Defendants actively and fraudulently concealed information in their exclusive possession regarding the hazards associated with the usage of their Endoscope Device, for the

purpose of preventing Plaintiff and Plaintiff's health care providers from discovering these hazards.

238. Defendants' conduct was outrageous and shocked the conscience, and knowingly and intentionally placed considerations of financial gain, revenues and profits, market share and marketing advantage over patient safety and well-being.

239. As a result of the foregoing material and fraudulent omissions, Plaintiff was caused to suffer serious injuries as described in this Complaint, which are permanent and lasting in nature, physical pain and mental anguish, diminished enjoyment of life and financial expenses for hospitalization and medical care.

240. Defendants' conduct, as described in this Complaint, was extreme and outrageous. Defendants risked the lives of Plaintiff and other consumers and users of their products. Although Defendants had knowledge of the safety and efficacy problems with their Devices, they concealed this knowledge from Plaintiff, Plaintiff's health care providers, and the general public. Further, Defendants made conscious decisions not to redesign, re-label, or warn unsuspecting consumers. Defendants' outrageous conduct warrants an award of punitive damages.

COUNT XIV: PUNITIVE DAMAGES

241. Plaintiff realleges and incorporates by reference all paragraphs in this Complaint.

242. Defendants sold Endoscope Device to health care providers throughout the United States, without conducting adequate testing to ensure that the Devices were reasonably safe for usage.

243. Defendants knew their Devices posed unreasonable risks, including developing tuberculosis, HIV, being infected with multi-drug-resistant organisms or other infections requiring

extensive hospital stays and IV antibiotics and resulting in sepsis and sequalae of sepsis, organ failure, and other catastrophic injuries, including death, and other harm-causing defects.

244. Defendants sold their Endoscope Device to health care providers throughout the United States, despite knowing of these unreasonable risks.

245. At all material times, Defendants attempted to misrepresent and did misrepresent facts concerning the safety of their Endoscope Device, including adverse data and information from studies and testing conducted with respect to the Devices, which showed that the risks and dangers associated with the Devices were unreasonable.

246. Defendants' misrepresentations, omissions, and partial disclosures, included knowingly withholding material information from the medical community and the public, including Plaintiff, concerning the safety and efficacy of Defendants' Endoscope Device.

247. At all material times, Defendants knew and intentionally and/or recklessly disregarded the fact that their Endoscope Device caused severe and potentially permanent complications with greater frequency than safer and feasible alternative devices or treatments.

248. Notwithstanding that knowledge, Defendants continued to market their Endoscope Device to consumers without disclosing the true risk of side effects and complications, or the frequency, severity and duration of those risks.

249. Defendants knew of their Devices' defective and unreasonably dangerous nature. But they continued to manufacture, produce, assemble, market, distribute, and sell the Devices, and failed to include adequate warnings about them. Defendants' acts and omissions were taken with reckless disregard of the foreseeable harm caused by the Endoscope Device, so as to maximize sales and profits at the expense of the health and safety of the public, including Plaintiff.

250. Defendants' conduct described in this Complaint shows willful misconduct, malice, fraud, wantonness, oppression, or that entire want of care raising the presumption of conscious indifference to consequences. Therefore, an award of punitive damages is justified.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment against Defendants, jointly and severally, on each of the above claims or causes of action, as follows:

a) Compensatory damages in excess of $75,000, including, but not limited to damages for pain, suffering, discomfort, physical impairment, emotional distress, loss of enjoyment of life, and other noneconomic damages in an amount to be determined at trial;

b) economic damages in the form of medical expenses, out-of-pocket expenses, lost earnings and other economic damages, in an amount to be determined at trial;

c) punitive or exemplary damages for Defendants' wanton, willful, fraudulent, and reckless acts, established by their demonstration of complete disregard and reckless indifference for the safety and welfare of Plaintiff and the general public, in an amount sufficient to punish Defendants and deter future similar conduct;

d) prejudgment interest;

e) post-judgment interest;

f) an award of reasonable attorneys' fees;

g) costs of these proceedings; and

h) any further relief this Court deems just and proper.

JURY DEMAND

Plaintiff demands a trial by jury as to all issues triable by jury.

Dated: July 9, 2026

Respectfully submitted,

/s/ William F. Cash III
William F. Cash III (Ill. Bar No. 6330856)
James Caleb Cunningham (*pro hac vice* application forthcoming)
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