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THIS IS A MAJOR JURY CASE
JURY TRIAL DEMANDED

Attorneys for Plaintiff

DEBBIE NEWTON **9936 North East 126th Street, D2** **Kirkland, WA 98034** **Plaintiff,** **vs.** **OLYMPUS AMERICA, Inc.** **3500 Corporate Parkway** **Center Valley, Pennsylvania 18034** **and** **OLYMPUS CORPORATION OF THE AMERICAS** **3500 Corporate Parkway** **Center Valley, Pennsylvania 18034** **Defendants.**	**COURT OF COMMON PLEAS** **PHILADELPHIA COUNTY** **TERM, 2015** **NO.**

PLAINTIFF'S CIVIL ACTION COMPLAINT

Plaintiff, Debbie Newton, by and through her attorneys McEldrew Young, hereby brings a civil claim against Olympus America, Inc. and Olympus Corporation of the Americas and in support thereof avers as follows:

PARTIES

1) Plaintiff, Debbie Newton, is an adult individual living in the State of Washington residing at 9936 North East 126th Street, D2, Kirkland, WA, 98034.

2) Defendant, Olympus America, Inc. (hereinafter "Olympus America") is a corporation organized and existing under the laws of the State of New York. Olympus America's principal place of business is 3500 Corporate Parkway, Center Valley, Pennsylvania 18034.

3) Defendant, Olympus Corporation of the Americas (hereinafter "Olympus Corp.") is a corporation organized and existing under the laws of the State of New York. Olympus Corp's principal place of business is 3500 Corporate Parkway, Center Valley, Pennsylvania 18034.

4) Defendants, Olympus America, and Olympus Corp., (hereinafter, collectively, "Olympus") designed, developed, manufactured, advertised, promoted, marketed, sold and/or distributed the defective Olympus endoscopes throughout the United States.

VENUE & JURISDICTION

5) Among its global business activities, Olympus sells, markets, and services Olympus medical products in the city and county of Philadelphia, Pennsylvania, including but not limited to an entire endoscopy team that is, inter alia, responsible for marketing and selling the specific Q180V Scope involved in the subject incident.

6) Olympus American coordinates, maintains and engages in the sales and marketing of its endoscopes specifically focusing on the city and county of Philadelphia, Pennsylvania through its Endoscopy Sales Group – referred to as "Greater Philadelphia Area" sales team.

7) At all times relevant to this action, Olympus America has made a concerted and strategic effort to conduct substantial business in the Commonwealth of Pennsylvania and regularly caused its products – including the unapproved Q180V Scope at present issue - to be sold in in the city and county of Philadelphia, Pennsylvania.

FACTUAL ALLEGATIONS

8) Olympus is in the business of manufacturing and selling medical devices, *inter alia*, duodenoscopes, which are specialized endoscopic medical devices used in invasive medical procedures within the human body.

9) The duodenoscope amounts to a flexible tube that is fed through the patients mouth, down the throat and stomach in order to perform diagnostic and other procedures to the patients, *inter alia*, intestine, pancreas, gall bladder, bile duct and liver.

10) The duodenoscope was designed and intended for repeated and recurrent use in multiple medical procedures on different patients, including but not limited to, Endoscopic Retrograde Cholangiopancreatography procedure (ERCP).

11) After each and every procedure duodenoscopes, like all types of flexible endoscopes, require thorough cleaning and high-level disinfecting – known as "reprocessing" – before the scope can be reused on a new patient.

12) In or about 2010, Olympus redesigned and replaced its TJF-Q160V Duodenoscope with the TJF-Q180V Duodenoscope ("Q180V Scope").

13) Upon information and belief the design change was intended to increase functionality by, among likely other features, broadening the range of scope positions in which the device's guide wire can be securely locked.

14) At least one of the defective design changes between the Q160V and the Q180V was the "sealed" elevator channel in the Q180V – as opposed to the "open" elevator channel in the Q160V, which required time-consuming manual reprocessing after each exam.

15) The Q180V "sealed elevator wire channel" design change is dangerously defective due, *inter alia*, to the "wicking effect" of the elevator wire, which occurs when the elevator wire is

extended through, manipulated and withdrawn back through the "sealed elevator channel" via an "o-ring." The wicking effect is the process whereby biological material, including but not limited to the CRE bacteria, is wicked or dragged through the o-ring by the movement of the elevator wire. Through the "wicking effect" the bacteria are effectively suctioned into and behind the unreachable portion of the "sealed elevator wire". The "wicking effect" is but one of a number of other effects of similar potential consequence that, too, may result in the infectious contamination of areas of the Q180V Scope not accessible to cleaning and high-level disinfection, posing an increased and unacceptable risk of disease transmission, with associated morbidity and mortality.

16) Olympus' decision to "seal the elevator channel" of the Q180V, among other apparent design changes featured in the Q180V Scope, was **never approved or cleared for marketing and/or sale, by the Food and Drug Administration (hereinafter "FDA") as required by the Food, Drug and Cosmetic Act (hereinafter "FD&C Act) prior to the introduction of a medical device into inter-state commerce.**.

17) Olympus never sought 510(k) clearance for the "sealed elevator wire channel" from the FDA.

18) The "sealed elevator wire channel" design change is clearly one that was significant and could significantly affect the safety and effectiveness of the Q180V Scope, thereby requiring FDA clearance before marketing the device.

19) Upon information and belief, Olympus did not sufficiently test the Q180V Scope in order to identify the "wicking effect" or additional to be identified design defects.

20) Upon information and belief Olympus also failed to perform the necessary risk management activities to identify and manage each and every potential adverse consequence and

unacceptable risk that the "sealed elevator wire channel" design change featured in the Q180V Scope, as compared to the Q160V Scope, could cause.

21) Olympus made an internal – and arguably self-serving - decision that the "sealed elevator wire channel" design change to the Q180V Scope did not require a pre-market submission to the FDA for 510(k) clearance.

22) The sealed elevator wire channel significantly and negatively affected the safety of the Q180V Scope and required the submission of either a 510(k) or a premarket approval application.

23) A modified device marketed without a necessary 510(k) or premarket approval is misbranded and adulterated – and therefore not able to be sold on the open market.

24) Despite Olympus' failure to obtain the FDA's clearance for, inter alia, the Q180V Scope "sealed elevator wire channel", Olympus actually did submit numerous pre-market design changes to the FDA related to the overall Evis Exera II 180 Endoscopic Video Imaging system (which is the entire system that the Q180V Scope is a part of) on two separate occasions.

i. On or about February 26, 2010 Olympus submitted a 510(k) summary, requesting clearance based upon previous clearance of an underlying design, to the FDA related to the Evis Exera II 180 System that identified no less than thirteen (13) separate design changes. Not one of the thirteen design changes related to the sealed elevator wire channel.

ii. Thereafter, on or about January 18, 2012 Olympus submitted a 510(k) summary, requesting clearance based upon previous clearance of an underlying design, to the FDA related to the Evis Exera II 180 System that identified twelve (12) additional design changes. Not one of the additional twelve design changes related to the sealed elevator wire channel.

25) Olympus' decision to "seal the elevator channel" of the Q180V was intended, at least in part, to eliminate the need to manually reprocess the scope, increasing the user's convenience and experience at the expense of patient safety.

26) Upon information and belief, Olympus decided to "seal" the elevator wire channel of the Q180V to allow for additional sales of Olympus Automatic Endoscope Reprocessor (hereinafter "AER") – which allegedly required a sealed design to be effective - in concert with the new Q180V duodenoscope design.

27) Olympus, as a manufacturer of a reusable medical device, such as a duodenoscope which requires reprocessing in order to be used in multiple patients, has an obligation to develop, test and validate sufficiently safe reprocessing protocols, and to incorporate these protocols into the device's labeling, to ensure infectious agents are not transmitted from patient to patient.

28) The product labeling must provide sufficient instructions on how to reprocess the duodenoscope for the next patient use, and these instructions or protocol must have been validated by the manufacturer prior to the Q180V Scope's introduction into interstate commerce.

29) The manufacturer – Olympus - must ensure that the validated reprocessing protocol is disseminated to medical facilities and professionals.

30) Furthermore, the manufacturer must maintain a Device Master Record (hereinafter "DMR") and/or design history file which documents that appropriate validation tests along with the confirming data were performed and collected to demonstrate that the instructions are complete and understandable, can reasonable be executed by the user, and prevent disease transmission.

i. The DMR must comply, *inter alia*, with the requirements of 21 CFR 820.181.

1. 21 CFR 820.181 (d) – **Packaging and labeling specifications**, including methods and processes used; and
2. 21 CFR 820.181 (e) Installation, **maintenance, and servicing procedures and methods**.

ii. The design history file must be comply with requirements of 21 CFR 820.30(j) which requires that "[e]ach manufacturer shall establish and maintain a DHF [design history file] for each type of device. The DHF shall contain or reference the records necessary to demonstrate that the design was developed in accordance with the approved design plan and the requirements of this part."

31) The original instructions for the unapproved "sealed elevator wire channel" design change of the Q180V duodenoscope clearly states that "**NOTE**: The elevator wire channel of the TJF-Q180 is sealed and does not require reprocessing."

32) Olympus failed, *inter alia*, to take the above detailed critical steps with the respect to the unapproved portion of the redesigned Q180V Scope as well as to the development of sufficient reprocessing protocol for the Q180V Scope.

33) Olympus failed to provide an effective and validated reprocessing protocol for the redesigned Q180V Scope as well as the management of risk pursuant to the CFR's 820 design control regulations.

34) Instead, Olympus provided its customers – medical facilities, physicians and ultimately patients – with a safety cleaning protocol that was patently incorrect, inadequate and dangerously defective and not supported by any validation data that it may have filed.

35) As a result, end-users were not able to consistently and safely reprocess the unapproved redesign of the Q180V Scope, resulting in instances of disease transmissions with associated morbidity and mortality.

36) Even before the redesign, marketing and sale of the Q180V Scope, Olympus was put on notice that Defendants' endoscope devices were difficult to clean and, as such, that they posed health risks to patients exposed to the devices.

i. In 1987, an outbreak of carbapenem resistant pseudomonas bacteria attributed to a contaminated duodenoscope occurred in Minnesota and killed at least ten (10) patients.

ii. In 2011, French scientists published an article which attributed sixteen (16) CRE infections - involving Klebsiella pneumoniae bacteria - occurring between 2008 and 2009 to a contaminated duodenoscope and isolated "abnormalities in procedures for duodenoscope disinfection" as the root cause of the outbreak.

iii. A 2012 publication by the American Society of Microbiology, studied the transmission of infections during flexible gastrointestinal endoscopic procedures and determined that "[c]ontaminated endoscopes are the medical device frequently associated with outbreaks of health care-associated infections."

iv. Thereafter, a group of researchers from the Netherlands published an article that reviewed a CRE outbreak occurring January 2012 through April 2012 in which twenty-four- (24) patients were infected with a CRE - Pseudomonas aeruginosa – related to a contaminated Olympus TJF-Q180V duodenoscope used during an ERCP. The research posited that "[t]he new design of the TJF-180V duodenoscopes might have contributed to the risk for infection as its complexity hampers cleaning and disinfection. The TJF-Q180V has a fixed distal cap, as reprocessing of the elevator wire channel was not needed any more as the forceps elevator wire channel was sealed with the so called o-ring. Sampling of the interior of the fixed distal cap, which is unreachable for cleaning brushes, revealed VIM-2 p. aeruginosa strain identical to the outbreak strain and determined the presumed source of the outbreak. Monitoring the unintended consequences that may occur due to design modifications can improve safety."

v. Again in 2012, Olympus was notified by the University of Pittsburgh Medical Center that the facility was experiencing an increase in CRE infections that were

believed to be related to Olympus duodenoscope used in ERCP procedures and insufficient reprocessing of the scope.

vi. In 2013, Olympus was informed of infections to patients in the State of Washington involving multiple duodenoscopes from its 160 and 180 series. At least four patients who were infected as a result of exposure to contaminated duodenoscopes died.

37) All of the above scientific information was publically available to Olympus.

38) Olympus knew, or should have known, that the "sealed elevator wire channel" and the associated moving parts and the design of the forceps elevator mechanism of the Q180V Scope are collectively defective.

39) Olympus knew, or should have known, that the above detailed design defect resulted in a "wicking effect", or a comparable effect, whereby residual fluids containing microbial contamination would penetrate the unapproved defective "sealed elevator wire channel" design, thereby effectively avoiding the reprocessing protocol provided by Olympus and thereby exposing patients to serious risk of harm, including potentially lethal infection.

40) Olympus knew, or should have known, that the unapproved and complex design of the Q180V "sealed elevator wire channel" rendered it extremely difficult – if not impossible - to consistently and safely reprocess the Scope.

41) Despite the knowledge of the defective design of the Q180V Scope and the associated defective reprocessing protocol, Olympus negligently, recklessly, and with conscious disregard of the extreme risks to public health and both marketed and sold the unapproved and/or cleared Q180V Scope that lacked adequate design testing and controls to the medical service end-users across the United States, including both Washington State and the Commonwealth of

Pennsylvania, claiming that the Q180V was both safe and effective for recurrent and invasive use in multiple patients for ERCP procedures.

42) Olympus knew that medical service end-users of the Q180V Scope relied on the manufacturer to provide effective and validated reprocessing protocols necessary for the safe operation of the Q180V Scope.

43) Olympus intended and expected that the Q180V Scope would be used invasively and recurrently by medical service providers, in multiple patients across the United States, including both the State of Washington and the Commonwealth of Pennsylvania.

44) Upon information and belief, the Harborview Medical Center purchased and used Q180V Scopes and thereafter complied with the reprocessing protocols provided by Olympus in its operation and use of the Q180V Scopes.

45) The Olympus Q180V scope was defectively designed and sold with patently inadequate reprocessing protocol. Despite using the Q180V Scope as directed and intended, as well as complying with the reprocessing protocols provided by Olympus, Debbie Newton – and unknown numbers of other patients – was infected with highly drug-resistant CRE Super bacteria.

46) Upon information and belief, Debbie Newton, was exposed to a contaminated Q180V Scope when she underwent an ERCP with an Olympus TJF - Q180V duodenoscope at Harborview Medical Center on or about February 7, 2013 and as a direct result thereof was subjected to a CRE infection that she is still affected by today.

i. Upon information and belief, Debbie Newton was diagnosed with gall stones in January 2013 by the physicians at Harborview Medical Center.

ii. Upon information and belief, on or about February 7, 2013 Debbie Newton presented to Harborview Medical Center for a routine – same day – ERCP procedure to address the above referenced gallstones.

iii. Upon information and belief, after the ERCP procedure was completed, the medical staff informed Debbie Newton and her family that they wanted to admit her overnight for observation.

iv. Upon information and belief, at approximately midnight on February 7, 2013 Debbie Newton's mother received a phone call informing her that Debbie needed to be placed on life support.

v. Upon information and belief, Debbie Newton was transferred to life support on February 7, 2013 due to heart failure, respiratory failure, renal failure, pancreatitis, septic shock and bacteremia.

vi. Upon information and belief, on February 8, 2013 Debbie Newton was cultured positive for klebsiella, e-coli and enterococcus bacterial infections.

vii. Upon information and belief, Debbie Newton required a PIC line for, inter alia, the extensive antibiotic treatment she required.

viii. Upon information and belief, Debbie Newton was discharged from Harborview Medical Center on or about February 21, 2013 with a diagnosis of pancreatitis, acute shock, septic shock, bacteremia, ARDS, heart failure, AKI – acute kidney injury and choledocholithiasis.

ix. Upon information and belief, Debbie Newton was discharged with a PIC line and was prescribed an intravenous regiment of Imipenem-cilastatin (a carbapenem antibiotic).

x. Upon information and belief, thereafter on March 3, 2013 Debbie Newton was forced to be re-admitted to Harborview Medical Center due to a bacterial infection of her pancreas.

xi. Upon information and belief, Debbie Newton underwent a laparascopic procedure to drain her pancreas whereby she was implanted with a drainage port.

xii. Upon information and belief, Debbie Newton was discharged from Harborview Medical Center on or about March 6, 2013.

xiii. Upon information and belief, as recently as January of 2015 Debbie Newton was forced to seek emergent medical care due to a kidney infection.

xiv. Upon information and belief, as recently as March 17, 2015 Debbie Newton was forced to seek emergent medical care due to a colon infection.

47) Debbie Newton was reasonably unaware, and had no reasonable way of knowing, that the above detailed infection and subsequent injuries were related to her exposure to a contaminated Q180V Scope at Harborview Medical Center on or about March 7, 2013 until the media began to report the CRE Superbug outbreaks at UCLA Medical Center and elsewhere in March 2015.

48) The above detailed exposure and subsequent infection, as well as all damages and injuries stemming therefrom, resulted solely from the recklessness, negligence and carelessness the Defendants, acting individually and/or collectively, by and through their agents, servants, workmen, and/or employees, and was due in no manner whatsoever due to any act or failure to act on the part of Debbie Newton.

49) As a direct result of the aforesaid exposure and subsequent infection, Debbie Newton has suffered grave, serious and ongoing injuries which are serious and permanent in nature, including but not limited to, CRE infection, septic infection, multiple organ failure, diverticulitis, colon infection, depression and other various ills and injuries which Debbie Newton still suffers and will continue to suffer for an indefinite period of time into the future.

50) As a direct result of the aforesaid exposure and subsequent infection, Debbie Newton has required extensive medical treatment and physical therapy all of which may continue indefinitely into the future all to her personal and financial detriment.

51) As a direct result of the aforesaid exposure and subsequent infection, Debbie Newton has or may suffer a severe loss of her earnings and impairment of her earning capacity and ability, all of which may continue indefinitely into the future.

52) As a direct result of the aforesaid exposure and subsequent infection, Debbie Newton has suffered severe physical pain and trauma, mental upset and anguish and humiliation and may continue to suffer the same for an indefinite time into the future.

53) As a direct result of the aforesaid exposure and subsequent infection, Debbie Newton has suffered a diminution in her ability to enjoy life and life's pleasures, all of which may continue indefinitely into the future.

COUNT I: PRODUCT LIABILITY – NEGLIGENCE

Plaintiff, Debbie Newton v. All Defendants

54) Plaintiff hereby incorporates by reference all preceding paragraphs of this Complaint as if fully set forth here.

55) Defendants designed, manufactured, promoted, distributed, marketed and sold the Q180V Scope.

56) At all times material hereto, the Q180V Scope, that was designed, manufactured, promoted, distributed, marketed, and sold by the Defendants, was expected to reach, and did reach, physicians, consumers and patients, including Plaintiff, without substantial change to the medical device and/or the reprocessing instructions with which it was sold.

57) At all times material hereto, the Q180V Scope that was designed, manufactured, promoted, distributed, marketed and sold by the Defendants, was in a defective and unreasonably

dangerous condition at the time it was placed in the stream of commerce. Such condition included, but is not limited to, one or more of the following particulars:

i. When placed in the stream of commerce, the Q180V Scope was not approved by the FDA for marketing and/or sale.

ii. When placed in the stream of commerce, the unapproved "sealed elevator wire channel" design specific to the Q180V Scope was defective in that it created a "wicking effect", due to the extension, manipulation and withdrawal of the elevator wire, that allowed CRE resistant bacteria to enter and remain behind the sealed channel via the o-ring.

iii. When placed in the stream of commerce, the required reprocessing protocol specific to the Q180V Scope was both inadequate and patently wrong – in that the reprocessing protocol instructed end users not to manually reprocess the "sealed elevator wire channel."

iv. When placed in the stream of commerce, the Q180V Scope was marketed and sold with reprocessing protocol that was not properly validated by Defendant, thus rendering the Q180V Scope unsafe and defective for its intended use.

v. When placed in the stream of commerce, the reprocessing protocol associated with the Q180V Scope was insufficiently tested, rendering that reprocessing protocol unsafe, and, thus, rendering the Q180V Scope dangerously defective.

vi. At the time the Q180V scope was placed into the stream of commerce, Defendant failed to develop safe, effective, tested and validated reprocessing protocol for the unapproved redesigned Q180V Scope, thus rendering the device dangerously defective.

vii. When placed in the stream of commerce, the unapproved Q180V Scope was defective in both design and inadequate reprocessing protocol that rendered the scope susceptible to microbial contamination thereby rendering the Q180V Scope dangerously defectively.

58) Defendants knew or should have known of the dangers associated with the Q180V Scope, as well as, the fact that the existing reprocessing protocol was insufficient and patently wrong in order to reprocess the newly redesigned and unapproved Q180V Scope.

59) Notwithstanding this knowledge, Defendants continued to manufacture, market, promote, sell, distribute and supply the Q180V Scope so as to maximize sales and profits at the expense of the health and safety of the public.

60) Defendants actually marketed the benefits of the very same unapproved design changes that are ultimately responsible for the deadly CRE Superbug infections.

61) Defendants took these actions in conscious disregard of the foreseeable harm and of the rights and safety of consumers caused by the unapproved and defective Q180V Scope.

62) Plaintiff's medical provider and/or physician unwittingly used the unapproved and defective Q180V Scope as directed for its intended purpose and relied upon the assurances of the Defendant as to both the safety and efficacy of both the Q180V Scope as well as the associated reprocessing protocol.

63) At all times relevant hereto, the Q180V Scope was defective, the Defendants knew or should have known that it was defective and that the Scope was to be used without inspection, by the medical service provider end user, for defects in the scope and/or the reprocessing protocol.

64) Neither the Plaintiff nor Plaintiff's medical provider and/or physician knew, or had reason to know, at the time of the use of the subject Q180V Scope, of the existence of the aforementioned defects, nor could they have discovered the defects in the Q180V Scope or reprocessing protocol through the exercise of reasonable care.

65) The Q180V Scope that was invasively introduced to the Plaintiff's body had not been materially altered or modified, since its manufacturing, labeling and packaging by the Defendant, prior to its use in the Plaintiff.

66) As a direct and proximate result of Defendants' negligence, Plaintiffs have suffered significant damages and will continue to suffer such damages in the future as described in detail above.

WHEREFORE, Plaintiff demands judgment in his favor and against Defendants, Olympus America, Inc., and Olympus Corporation of the Americas in an amount in excess of Fifty Thousand Dollars ($50,000), plus interest, costs, and any other amount that this Honorable Court deems fit to award.

COUNT II: NEGLIGENCE

Plaintiff, Debbie Newton v. All Defendants

67) Plaintiff hereby incorporates by reference all preceding paragraphs of this Complaint as if fully set forth herein.

68) Defendants had a duty to exercise reasonable care in the design, manufacture, testing, validating, labeling (reprocessing protocol), marketing and distribution into the stream of commerce of the Q180V Scope, including a duty to ensure that the Q180V Scope did not pose a significantly increased risk of adverse events.

69) Defendants failed to exercise reasonable care and were therefore negligent, *inter alia*, in the design, manufacture, testing, validating, labeling (reprocessing protocol), marketing and distribution into the stream of commerce of the Q180V Scope. Defendants negligence included, but is not limited to, the following:

i. Defendants failed to obtain FDA approval for the "sealed elevator wire channel" design change;

ii. Defendants failed to the design, manufacture, test, validate, label (reprocessing protocol), market and/or distribute a safe and effective design for the unapproved Q180V Scope in that the "sealed elevator wire channel" created a "wicking effect" whereby CRE Superbug bacteria were allowed through the o-ring and within and/or behind the "sealed elevator wire channel";

iii. Defendants failed to properly test and/or investigate the "sealed elevator wire channel" of the Q180V Scope prior to marketing and sale of same;

iv. Defendants failed to provide a sufficient reprocessing protocol for the Q180V Scope to the end user;

v. Defendants failed to adequately validate the reprocessing protocol for the Q180V Scope that was provided to and relied upon by the end user;

vi. Defendants failed to adequately test the reprocessing protocol for the Q180V Scope that was provided to and relied upon by the end user;

vii. Defendants failed to protect the Plaintiff from known and/or knowable risks associated with the Q180V Scope design and/or reprocessing protocol;

viii. Any other instances of negligence to be determined through the discovery process; and

ix. Any other instances of negligence under the common law and/or applicable statutes, codes and/or regulations.

70) Despite the fact that Defendants knew or should have known that the Q180V Scope was unapproved by the FDA, was dangerous and defective by the nature of the "sealed elevator wire channel" design, and lacked an adequate, effective and validated reprocessing protocol posing a significant risk of contamination and associated risks to Plaintiff, Defendants continued to market and sell the Q180V Scope as a safe and effective device.

71) In so doing, the Defendants failed to act as a reasonable manufacturer and distributer of the Q180V Scope.

72) As a direct and proximate result of Defendants' negligence, Plaintiffs have suffered significant damages and will continue to suffer such damages in the future as described in detail above.

WHEREFORE, Plaintiff demands judgment in his favor and against Defendants, Olympus America, Inc., and Olympus Corporation of the Americas in an amount in excess of Fifty Thousand Dollars ($50,000), plus interest, costs, and any other amount that this Honorable Court deems fit to award.

COUNT III: FRAUD – INTENTIONAL MISREPRESENTATION

Plaintiff, Debbie Newton v. All Defendants

73) Plaintiff hereby incorporates by reference all preceding paragraphs of this Complaint as if fully set forth herein.

74) Defendants owed legal duties to Plaintiff and Plaintiff's physician(s) to disclose important material facts concerning the safety of the Q180V Scope design and the adequacy of the reprocessing protocol for the Q180V Scope, to ensure it was designed properly for its intended use and that it was accompanied by sufficient reprocessing protocol to ensure the scope was safe for invasive reuse within the Plaintiff and countless other patients.

75) Defendants made false representations to Plaintiff and/or Plaintiff's physicians concerning the safety of the Q180V Scope and the risks associated with the reprocessing protocol for the Q180V Scope.

i. Defendants intentionally, knowingly, and/or recklessly without regard for the truth, misrepresented that the "sealed elevator wire channel" design change of the unapproved Q180V scope was safe and effective for its intended use.

ii. Defendants intentionally, knowingly, or recklessly without regard for the truth, misrepresented that the reprocessing protocol associated with the Q180V Scope was a safe and adequate means of reprocessing the Q180V Scope.

iii. Defendants falsely represented that the Q180V Scope would be disinfected and safe for subsequent use in a new patient after undergoing the reprocessing protocol.

iv. Defendants made the above detailed false representations in an effort to mislead consumers into purchasing the Q180V Scope and using it for medical procedures, so that Defendants could profit.

v. Through their agents, Defendants directly communicated - at least - the above detailed misrepresentations to Plaintiff and/or Plaintiff's physicians who were Plaintiff's fiduciaries.

76) Upon information and belief, Defendants sales representatives made the representations described above to physicians, medical provider and/or staff at Harborview Medical Center at some point between the Q180V design change effectuated in 2010 and the Plaintiff's contraction of a CRE infection on or about February 7, 2013.

77) At no time prior to the invasive use of Defendants Q180V Scope in Plaintiff's body did Defendants acknowledge that the "sealed elevator wire channel" design was defective and/or that the reprocessing protocol associated with the Q180V scope, provided to Harborview Medical Center, had not been validated, tested, was patently inaccurate and had been scientifically called into question.

78) Defendants' representation to Plaintiff and/or Plaintiff's physicians were false because in reality the "sealed elevator wire channel" design change was both unapproved and defective at

its core, and the reprocessing protocol was not only ineffective but patently wrong in order to adequately disinfect the Q180V Scope for re-use in patient. As such, the Q180V Scope was defectively dangerous and unsafe for use.

79) Defendants' reprocessing protocol did not eliminate all bodily fluids and organic debris from prior use, thereby rendering the Q180V Scope susceptible to microbial contamination – however, the Defendants actually explicitly instructed the end-user that no manual reprocessing of the "sealed elevator wire channel" was required. Defendants' design and/or reprocessing instructions did not prepare the Q180V Scope for safe re-use.

80) Defendants designed and intended for medical professionals, including Plaintiff's physicians and/or medical providers, and patients to rely on the Defendants' representations as to the safety of the Q180V Scope design and reprocessing protocol for safe re-use within patients such as the Plaintiff.

81) Plaintiff and Plaintiff's physicians reasonably relied on Defendants' misrepresentations to Plaintiffs' detriment. Plaintiff's physicians and/or medical providers used a previously used Q180V Scope on Plaintiff only after complying with the reprocessing protocol for the Q180V Scope provided by the Defendant. Following the reprocessing, Plaintiff and Plaintiff's physicians and/or medical providers reasonably believed that the Q180V Scope was safe for use within the Plaintiff when, in fact, the Scope was contaminated with CRE Super bacteria.

82) As a direct and proximate result of Plaintiff and Plaintiff's physicians' detrimental reliance on Defendants' false representations, Plaintiff was injured, thereby causing harm and damage to Plaintiffs as described in detail above.

WHEREFORE, Plaintiff demands judgment in his favor and against Defendants, Olympus America, Inc., and Olympus Corporation of the Americas in an amount in excess of Fifty

Thousand Dollars ($50,000), plus interest, costs, and any other amount that this Honorable Court deems fit to award.

COUNT IV: FRAUD – NEGLIGENT MISREPRESENTATION

Plaintiff, Debbie Newton v. All Defendants

83) Plaintiffs hereby incorporate by reference all preceding paragraphs of this Complaint as if fully set forth herein.

84) Defendants owed legal duties to Plaintiff to disclose important material facts concerning the safety of the Q180V Scope design change and the adequacy of the reprocessing protocol for the Q180V Scope in reprocessing the scope to ensure it is safe for reuse.

85) Defendants made false representations to Plaintiff and Plaintiff's physicians concerning the safety of the unapproved Q180V Scope "sealed elevator wire channel" design and the inadequacy of the reprocessing protocol associated with the Q180V Scope.

86) Defendants unapproved design change relating to the Q180V Scope "sealed elevator wire channel" is dangerously defective as designed.

87) Additionally, Defendants failed to develop an effective and validated reprocessing protocol for the redesigned Q180V Scope and/or failed to test the reprocessing protocol on the Q180V Scope and/or failed to adequately investigate prior complaints by medical facilities of contamination of Defendants' scopes, despite the knowledge that both the device and the necessary protocol had been previously identified to cause CRE infections.

88) Nevertheless, Defendants falsely represented that the Q180V Scope was safe for use as designed and would be disinfected and safe for subsequent use in a new patient after administration of the reprocessing protocol.

89) Defendants made the above detailed false representations in an effort to encourage consumers to purchase and use the Q180V Scope for medical procedures, so Defendants could profit.

90) Through their agents, Defendants directly communicated these misrepresentations to decedent and/or decedent's physicians who were decedent's fiduciaries.

91) Upon information and belief, Olympus sales representatives made - at least - the representations described above to physicians and staff Harborview Medical Center at some point between the Q180V design change effectuated in 2010 and the Plaintiff's contraction of a CRE infection on or about February 7, 2013.

92) At no time prior to the use of Defendants Q180V Scope within Plaintiff, did Defendants acknowledge that the "sealed elevator wire channel" design change was defective and/or that the reprocessing protocol for the Q180V scope provided to Harborview Medical Center had not been tested, validated and proved effective and had actually been scientifically called into question.

93) Defendants' representation to Plaintiff and/or Plaintiff's physicians were false because in reality the "sealed elevator wire channel" design change was both unapproved and defective, and that the reprocessing protocol was not effective to adequately disinfect the Q180V Scope for re-use in a new patient pursuant to completion of the reprocessing protocol provided by Defendants. As such, the Q180V was defectively dangerous and unsafe for use.

94) Defendants' reprocessing protocol did not eliminate all bodily fluids and organic debris from prior use, thereby rendering the Q180V Scope susceptible to microbial contamination – however, the Defendants actually explicitly instructed the end-user that no manual reprocessing of the "sealed elevator wire channel" was required. Defendants' design and/or reprocessing instructions did not prepare the Q180V Scope for safe re-use.

95) Defendants designed and intended for medical professionals, including Plaintiff's physicians, and patients to rely on the Defendants' representations as to the safety of the Q180V Scope for safe re-use within patients such as the Plaintiff.

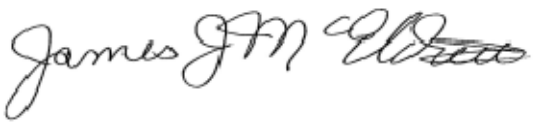
96) Plaintiff and Plaintiff's physicians reasonably relied on Defendants' misrepresentations to Plaintiffs' detriment. Plaintiff's physicians and/or medical providers used a previously used Q180V Scope on Plaintiff only after complying with the reprocessing protocol for the Q180V Scope provided by the Defendant. Following the reprocessing, Plaintiff and Plaintiff's physicians and/or medical providers reasonably believed that the Q180V Scope was safe for use within the Plaintiff when, in fact, the Scope was contaminated with CRE Super bacteria.

97) As a direct and proximate result of Plaintiff and Plaintiff's physicians' detrimental reliance on Defendants' false representations, Plaintiff was injured, thereby causing harm and damage to Plaintiffs as described in detail above.

WHEREFORE, Plaintiff demands judgment in his favor and against Defendants, Olympus America, Inc. and Olympus Corporation of the Americas in an amount in excess of Fifty Thousand Dollars ($50,000), plus interest, costs, and any other amount that this Honorable Court deems fit to award.

Respectfully Submitted,

McELDREW YOUNG



JAMES J. McELDREW, III, ESQUIRE
DANIEL PURTELL, ESQUIRE

Date: _____