IN THE CIRCUIT COURT IN AND FOR
THE FIFTEENTH JUDICIAL CIRCUIT
PALM BEACH COUNTY, FLORIDA

CASE NO.:

CARMINE CONVERTINO, as Personal Representative of the Estate of MARTINO CONVERTINO,
Plaintiff,

vs.

CORDIS CORPORATION, a Florida corporation and CARDINAL HEALTH, INC., an Ohio corporation,

Defendants.

_____/

COMPLAINT

COMES NOW, Plaintiff CARMINE CONVERTINO, as Personal Representative of the Estate of MARTINO CONVERTINO, (hereinafter, "Plaintiff"), by and through the undersigned attorneys, and sues Defendants, CORDIS CORPORATION, a Florida corporation and CARDINAL HEALTH, INC., an Ohio corporation (hereinafter, collectively, "Defendants"), and alleges:

PARTIES

1. Plaintiff MARTINO CONVERTINO was an individual who was at all times mentioned in this complaint a resident of Passaic County, New Jersey.

2. As a result of the Device's defects and Defendants' tortious acts/omissions, Plaintiff MARTINO CONVERTINO, and many other patients who received these Devices, endured unnecessary pain and suffering; debilitating lack of mobility; and subsequent surgeries to replace the faulty Device and address complications arising from the Device, giving rise to

more pain and suffering, a prolonged recovery time, and an increased risk of complications and death.

3. The Plaintiff, CARMINE CONVERTINO, is the duly appointed Personal Representative of the Estate of MARTINO CONVERTINO, deceased, and brings this action on behalf of the Estate, as well as in the name of the decedent's statutory survivors, wife CARMINE CONVERTINO and sons STEFANO CONVERTINO and PETER CONVERTINO.

4. On March 24, 2016, MARTINO CONVERTINO died in Passaic County, New Jersey.

5. At all material times, Defendant CORDIS CORPORATION was a corporation organized and existing under the laws of Florida, with its principal place of business located at 14201 N.W. 60 Ave., Miami, Dade County, FL 33014.

6. At all material times, Defendant CARDINAL HEALTH, INC. was a corporation organized and existing under the laws of Ohio, with its principal place of business located at 7000 Cardinal Pl., Dublin, OH 43017. In or around October 2015, Defendant CARDINAL HEALTH, INC. publicly announced that it acquired Defendant CORDIS CORPORATION.

JURISDICTION

7. This is an action for damages that exceed $15,000.00.

8. Defendants were, at all times material hereto, authorized to do business in the State of Florida and were doing business in Florida. Furthermore, Defendants developed, designed, set specifications for, licensed, manufactured, prepared, packaged, maintained, labeled, compounded, assembled, processed, sold, distributed and/or marketed the OptEase™™ Retrievable Vena Cava Filter and/or the TrapEase™™ Permanent Vena Cava Filter and Introduction Kit throughout the State of Florida, including Palm Beach County. Defendants

operated, conducted, and engaged in or carried out a business venture in Florida, or had an office or agency in Florida, and engaged in the solicitation or service activities in Florida, including Palm Beach County. These actions fall within the meaning of Fla. Stat. § 48.193.

NO FEDERAL CLAIMS PLEADED

9. Plaintiff's claims in this action are brought solely under state law. Plaintiff does not herein bring, assert, or allege, either expressly or impliedly, any causes of action arising under any federal law, statute, regulation, or provision. Thus, there is no federal jurisdiction in this action on the basis of a federal question under 28 U.S.C. § 1331.

10. Furthermore, although the parties are of diverse citizenship, this action may not be removed because Defendant CORDIS CORPORATION is a citizen of the State of Florida within the meaning of 28 U.S.C. § 1332(c)(1). *See* 28 U.S.C. § 1441(b)(2).

BACKGROUND
INFERIOR VENA CAVA FILTERS GENERALLY

11. Inferior vena cava ("IVC") filters first came on to the medical market in the 1960's. Over the years, medical device manufacturers have introduced several different designs of IVC filters.

12. An IVC filter is a device that is designed to filter or "catch" blood clots that travel from the lower portions of the body to the heart and lungs. IVC filters are designed to be implanted, either permanently or temporarily, in the inferior vena cava.

13. The inferior vena cava is a vein that returns deoxygenated blood to the heart from the lower portions of the body. In certain people, for various reasons, blood clots travel from the vessels in the legs and pelvis, through the vena cava and into the lungs. Oftentimes, these blood clots develop in the deep leg veins, a condition called "deep vein thrombosis" or "DVT." Once

blood clots reach the lungs, they are considered "pulmonary emboli" or "PE." Pulmonary emboli present risks to human health.

14. People at risk for DVT/PE can undergo medical treatment to manage the risk. For example, a doctor may prescribe medications like Heparin, Warfarin, or Lovenox to regulate the clotting factor of the blood. In some people who are at high risk for DVT/PE, or who cannot manage their conditions with medications, physicians may recommend surgically implanting an IVC filter to prevent thromboembolitic events.

15. As stated above, IVC filters have been on the market for decades. All IVC filters are only cleared for use by the FDA for prevention of recurrent pulmonary embolism in patients at risk for pulmonary embolism and where anticoagulation has failed or is contraindicated. In 2003, however, an explosion in off-label use began with the introduction of IVC filters that were cleared for both permanent placement and optional removal. Most of this market expansion came from uses such as prophylactic prevention of pulmonary embolism without a prior history of pulmonary embolism.

16. Indeed, from 2000 through 2003 there was a race between manufactures to bring the first IVC filter to market with the added indication of optional retrieval. In 2003, the FDA cleared the first three (3) IVC filters for a retrieval indication. These were the OptEase™ filter (Cordis & J&J), the Recovery Filter (C.R. Bard, Inc.) and the Gunther Tulip Filter (Cook Medical).

17. Upon information and belief, Plaintiff alleges that this market expansion and off-label use was driven by baseless marketing campaigns made by Defendants targeting bariatric, trauma, orthopedic and cancer patient populations.

18. The medical community has just recently begun to awaken to the fact that despite marketing claims by Defendants, there is no reliable evidence that any IVC filter offers a benefit and that these products expose patients to substantial safety hazards. For example, an October 2015 article published in the Annals of Surgery concerning trauma patients inserted with IVC filters concluded that IVC filters were not effective in preventing pulmonary emboli, and instead actually caused thrombi to occur

19. Comparing the results of over 30,000 trauma patients who had not received IVC filters with those who had received them, the Annals of Surgery study published its alarming results:

a. Almost twice the percentage of patients with IVC filters in the study died compared to those that had not received them.

b. Over five times the relative number of patients with IVC filters developed DVTs.

c. Over four times the relative percentage of patients with filters developed thromboemboli.

20. Over twice the percentage of patients developed a pulmonary embolus -the very condition Defendants represented to the FDA, physicians, and the public that its IVC filters would prevent.

21. Other studies have also revealed that these devices suffer common failure modes such as migration, perforation, thrombosis, fracture all of which can cause serious injury or death. For example, recent studies for Defendants IVC Filters have revealed fracture rates as high as 50% and recommend medical monitoring and/or removal.

22. These studies, including the Annals of Surgery study, have now shown that not only is there no reliable evidence establishing that IVC filters are efficacious but that they also pose substantial health hazards.

THE TRAPEASE™ AND OPTEASE™ IVC FILTERS

23. On January 10, 2001, Defendants bypassed the more onerous Food and Drug Administration's ("FDA' s") approval process for new devices and obtained "clearance" under Section 510(k) of the Medical Device Amendments to the Food, Drug, and Cosmetic Act to market the Trap Ease™ Permanent Vena Cava Filter and Introduction Kit ("TrapEase™ filter") as a permanent filter by claiming it was substantially equivalent in respect to safety, efficacy, design, and materials as the then already available IVC filters.

24. Section 510(k) permits the marketing of medical devices if the device is substantially equivalent to other legally marketed predicate devices without formal review for the safety or efficacy of the device. The FDA explained the difference between the 510(k) process and the more rigorous "premarket approval" ("PMA") process in its amicus brief filed with the Third Circuit in *Horn v. Thoratec Corp.*, from which the court quoted:

> A manufacturer can obtain an FDA finding of 'substantial equivalence' by submitting a premarket notification to the agency in accordance with section 510(k) of the [Food Drug and Cosmetic Act.] 21 U.S.C. § 360(k). A device found to be 'substantially equivalent' to a predicate device is said to be 'cleared' by the FDA (as opposed to "approved' by the agency under a PMA.

376. F.3d 163, 167 (3d. Cir. 2004). A pre-market notification submitted under 510(k) is thus entirely different from a PMA, which must include data sufficient to demonstrate that the produce involved is safe and effective.

25. In *Medtronic, Inc. v. Lohr*, the U.S. Supreme Court similarly described the 510(k) process, observing:

> If the FDA concludes on the basis of the [manufacturer's] § 510(k) notification that the device is 'substantially equivalent' to a pre-existing device, it can be

> marketed without further regulatory analysis.... The § 510(k) notification process is by no means comparable to the PMA process; in contrast to the 1,200 hours necessary to complete a PMA review, the § 510(k) review is completed in average of 20 hours .... As on commentator noted: "The attraction of substantial equivalence to manufacturers is clear. Section 510(k) notification required little information, rarely elicits a negative response form the FDA, and gets processed quickly.

518 U.S. 470, 478-79 (1996).

26. Pursuant to *Wyeth v. Levine*, 555 U.S. 555 (2009), once a product is cleared "the manufacturer remains under an obligation to investigate and report any adverse associated with the drug... and must periodically submit any new information that may affect the FDA's previous conclusions about the safety, effectiveness, or labeling ...." This obligation extends to post-market monitoring of adverse events/complaints.

27. On July 7, 2000, Defendants obtained clearance through this 510(k) process to begin marketing the Trap Ease filter as a permanent filter.

28. The TrapEase™ filter is made of NITINOL (a nickel titanium alloy whose full name is Nickel Titanium Naval Ordinance Laboratory) and has a symmetrical double-basket design with six straight struts connecting the proximal and distal baskets. The device has proximal and distal anchoring barbs located on each connecting strut for fixation of the filter to the vena cava wall to prevent movement after placement.

29. On September 18, 2002, Defendants sought clearance through the 510(k) process to market the Cordis OptEase™ Permanent Vena Cava Filter ("OptEase™ filter") for the same indicated uses as the TrapEase™ Filter. Defendants represented that the OptEase™ filter had the same basic fundamental technology and was substantially equivalent in respect to safety and efficacy as the predicate devices (TrapEase™ Filter, Gunther Tulip filter, and the Vena Tech LGM Vena Cava Filter).

30. Defendants have further represented that the OptEase™ filter has the same design as TrapEase™ filter except that unlike the TrapEase™ filter, which has proximal and distal anchoring barbs located on each connecting strut for fixation of the filter to the vena cava wall, the OptEase™ filter has anchoring barbs for fixation of the filter only on the superior end of each of the six straight struts and has a hook at the inferior end of the basket to allow retrieval with a snare.

31. Both designs suffer similar design flaws rendering them defective and unreasonably dangerous. Defendants filters are designed in such way that when exposed to expected and reasonably foreseeable in-vivo conditions the devices will fracture, migrate, tilt, perforate internal organs and vasculature, and lead to the formation of thromboembolism and pulmonary embolism.

32. For instance, Defendants chose not to electropolish their filters. The manufacturing process used to manufacture NITINOL medical devices leads to surface blemishes, draw marking, pitting, gouges and cracks, which can act as stress concentrators leading to fatigue failure. Electropolishing removes these conditions, which substantially increase fatigue and corrosion resistance. Electropolishing has been industry standard for implanted NITINOL medical devices since at least the 1990's.

33. The anchoring mechanism of Defendants' filters is also insufficient to prevent tilting and migration post-placement.

34. The configuration of Defendants' filters also renders them prothrombotic. This means that these filters actually lead to the formation of blood clots and pulmonary embolism - the exact condition that devices are meant to prevent.

35. That Defendants allowed these devices to proceed to market indicates that they

failed to establish and maintain an appropriate Quality System in respect to design and risk analysis.

36. At a minimum, a manufacturer must undertake sufficient research and testing to understand the anatomy of where a medical device will be implanted so as to understand what forces the device may be exposed to once implanted in the human body. This design input must then be used to determine the minimum safety requirements or attributes the device must have to meet user needs. In the case of an IVC filter, user needs include: a device that will capture DVTs of sufficient size to cause harmful consequences and that will not fracture, migrate, tilt, perforate the vena cava or be prothrombotic.

37. Prior to bringing a product to market, a manufacturer must also conduct sufficient testing under real world or simulated use conditions to ensure that the device will meet user needs even when exposed to reasonably foreseeable worst-case conditions.

38. Defendants failed to adequately establish and maintain such policies and procedures in respective to their IVC filter devices.

39. Once brought to market, Defendants' post-market surveillance system should have revealed that the TrapEase™ and OptEase™ filters were unreasonably dangerous and substantially more prone to failing and causing injury than other available treatment options.

40. For instance, soon after market release, Defendants began receiving large numbers of adverse event reports ("AERs") from health care providers reporting that the TrapEase™ and OptEase™ filters were fracturing post-implantation and that fractured pieces and/or the entire device was migrating throughout the human body, including the heart and lungs. Defendants also received large numbers of AERs reporting that the TrapEase™ and OptEase™ filters were found to have excessively tilted, perforated the inferior vena cava, or

caused thrombosis or stenosis of the vena cava post-implantation. These device malfunctions were often associated with reports of inability to retrieve the device and/or severe patient injuries such as:

a. Death;

b. Hemorrhage;

c. Cardiac/pericardial tamponade;

d. Cardiac arrhythmia and other symptoms similar to myocardial infarction;

e. Severe and persistent pain;

f. Perforation of tissue, vessels and organs;

g. compartment syndrome.

41. Recent medical studies have confirmed what Defendants have known or should have known since shortly after the release of each of these filters - not only do TrapEase™ and OptEase™ filters fail at alarming rates, but they also fail at rates substantially higher than other available IVC Filters. For instance, a recent large medical study found that OptEase™ and TrapEase™ filters suffer fracture rates of 37.5% and 23.1%, respectively, when left implanted a minimum of 46 months. Another recent study found that the TrapEase™ filter had a 64% fracture rate when left in more than four (4) years. Another study found a statistically significant increased rate of caval thrombosis with the OptEase™ filter compared to Gunther Tulip and Recovery Filters.

42. As a minimum safety requirement, manufacturers must establish and maintain post-market procedures to timely identify the cause of device failures and other quality problems and to take adequate corrective action to prevent the recurrence of these problems.

43. Defendants, however, failed to take timely and adequate action to correct known

design and manufacturing defects with the OptEase™ and TrapEase™ filters.

44. Defendants also misrepresented and concealed the risks and benefits of the TrapEase™ and OptEase™ filters in labeling and marketing distributed to the FDA, physicians and the public.

45. For instance, Defendants represented that these devices were safe and effective. As discussed above, however, there is no reliable evidence establishing that these devices actually improve patient outcomes.

46. Defendants also represented that the design of these devices would eliminate the risk that pieces of the devices could perforate the vena cava, that the devices could tilt, or that fractures could occur and migrate throughout the body. The medical literature and AERs have proven these claims to be false.

47. Defendants also represented that these devices were more effective and safer than other available IVC filters. As discussed above, there is no reliable basis for such claims and the evidence indicates otherwise.

48. Defendants also marketed the OptEase™ filter as being "easy" to remove. However, the OptEase™ filter is one of the most difficult filters to remove after implantation and quite often cannot be removed at all. As Dr. William T. Kuo, one of the leading authors on IVC filters, recently explained in the *Journal of Vascular Interventional Radiology*:

> ". . . we thought the OPTEASE™ and TRAPEASE™ filter types were subjectively among the most difficult to remove in our study, often requiring aggressive blunt dissection force in addition to laser tissue ablation to achieve removal. A possible explanation is the relatively large amount of contact these filters make with the underlying vena cava and the possible induction of greater reactive tissue formation."

49. This is particularly concerning because having an IVC filter for a prolonged period of time increases the risk of developing chronic deep venous thrombosis, PE, IVC

occlusion, post-thrombotic syndrome, filter fracture, and caval perforation with pain and organ injury. Many patients with IVC filters are now routinely managed with lifelong anticoagulation solely to reduce the risk of having the filter in place, subjecting patients to the risks and inconvenience of anticoagulation.

50. Defendants also failed to adequately disclose the risks of these filters, such as migration, fracture, perforation, tilt, thrombosis, the prothrombotic nature of the devices, that the devices may not be retrievable, or that these failures were known to be causing severe injuries and death or the rate at which these events were occurring.

51. Defendants labeling was additionally defective in that it directed physicians to implant the OptEase™ filter upside down. When the OptEase™ was placed as directed by the labeling, the hooks designed to ensure stability were facing in the wrong direction, rendering an already inadequate anchoring system even further defective. As Defendants' now explain in their labeling, implanting the device in this fashion "can result in life threatening or serious injury including, but not limited to dissection, vessel perforation, migration of the filter with secondary damage to cardiac structures, ineffective pulmonary embolism prevention or death."

52. Defendants began a series of recalls on March 29, 2013 relating to its labeling, which instructed physicians to implant the devices upside down. These recalls were not timely, nor did they fully correct the defects in Defendants' labeling. Further, Defendants downplayed the danger patients were exposed to and failed to take adequate steps to ensure patients actually received notice of the recall.

53. The FDA classified the initial recall as a Class I recall, which are the most serious type of recall and involve situations in which the FDA has determined there is a reasonable probability that use of these products will cause serious adverse health consequences or death.

54. Defendants have admitted that any patients implanted with one of these recalled units should receive medical monitoring. Specifically, these patients should undergo imaging to ascertain whether or not the device was properly deployed and, if not, be assessed for removal.

55. Given the unreasonably high failure and injury rates associated with Defendants filters when left implanted long-term, Defendants should be required to pay for medical monitoring to assess the condition of these devices and whether or not retrieval should be undertaken.

ESTOPPEL FROM PLEADING STATUTES OF LIMITATIONS OR REPOSE

56. Plaintiff incorporates by reference all prior allegations.

57. Plaintiff is within the applicable statute of limitations for Plaintiff's claims because Plaintiff (and Plaintiff's healthcare professionals) did not discover, and could not reasonably discover, the defects and unreasonably dangerous condition of Defendants' IVC filters.

58. Plaintiff's ignorance of the defective and unreasonably dangers nature of Defendants' IVC filters, and the causal connection between these defects and Plaintiff's injuries and damages, is due in large part to Defendants' acts and omissions in fraudulently concealing information from the public and misrepresenting and/or downplaying the serious threat to public safety its products present.

59. In addition, Defendants are estopped from relying on any statutes of limitation or repose by virtue of its unclean hands, acts of fraudulent concealment, affirmative misrepresentations and omissions.

60. Such conduct includes intentional concealment from Plaintiff, Plaintiff's prescribing health care professionals, the general consuming public and the FDA of material

information that Defendants' filters had not been demonstrated to be safe or effective, and carried with them the risks and dangerous defects described above.

61. Defendants had a duty to disclose the fact that Defendants' filters are not safe or effective, not as safe as other filters on the market, defective, and unreasonably dangerous, and that their implantation and use carried the above described risks.

FACTUAL ALLEGATIONS: IMPLANTATION OF THE IVC FILTER IN THE PLAINTIFF AND RESULTING INJURIES

62. On or about October 29, 2012, Plaintiff, at the age of 68, was implanted with the TrapEase™ REF: 466P396AU, Lot: 15622584, at St. Joseph's Regional Medical Center in Paterson, New Jersey.

63. The TrapEase™ filter that is the subject of this action reached Plaintiff and Plaintiff's physicians without substantial change in the condition from the time it left Defendants' possession.

64. Plaintiff and Plaintiff's physicians used the TrapEase™ filter in the manner in which it was intended.

65. On March 23, 2016, Plaintiff presented to St. Joseph's Wayne Hospital Emergency Department for generalized weakness and lightheadedness that improved with sitting. Additionally, Plaintiff was experiencing severe low back pain and bilateral leg pain which was worse on the right side. Plaintiff was hypotensive, borderline tachycardic. Plaintiff was diagnosed with orthostatic hypotension and dehydration and discharged to follow up with his physician.

66. On March 24, 2016, at the age of 72, Plaintiff entered hypovolemic shock secondary to massive retroperitoneal hematoma (40 x 30 x 15 cm) centered around the infra-

renal inferior vena cava and extending to the peripancreatic fat, mesenteric root and pelvic outlet. As a result of these injuries, Plaintiff expired on March 24, 2016.

67. A full autopsy was performed on March 28, 2016 at Robert Wood Johnson University Hospital which identified:

a. Acute inferior vena cava dissection and rupture with evidence of pre-existing microscopic chronic dissection adjacent to IVC filter struts.

b. The lumen contains a Cordis TrapEase™ style IVC filter. The superior aspect of the IVC filter is located 2 cm inferior to the renal vein. There is complete occlusion of the IVC filter by an 11 x 2 x 2 cm thromboembolus. . . . radiographs taken prior to further dissection of the tissue demonstrate an IVC filter located within the venous lumen which appears intact and without obvious strut fracture. On removal of the thromboembolus, there is extensive endothelialization of the vertical struts. The filter barbs protrude 0.1 to 0.2 cm through the adventitial surface of the IVC. On sectioning through the venous wall adjacent to the vertical filter struts the luminal thromboembolus is adhered to a hematoma, which dissects through a small defect in the IVC lumen, extends 2 cm inferiorly and communicates with the previously described retroperitoneal hematoma. The dissection also extends inferiorly to the bifurcation of the common iliac veins.

c. In addition to the acute organizing hematoma, the media also contains a focal area of granulation tissue with recanalization, which suggests the acute dissection expanded in an area of a prior small (microscopic) chronic dissection. There was no other identifiable source of the retroperitoneal hematoma.

d. Plaintiff suffered an acute and complete IVC thrombosis which may have elevated the pressure within the IVC enough to allow significant expansion of the previously microscopic dissection with eventual rupture into the retroperitoneal space.

68. Plaintiff's autopsy results were reportedly discussed with Maria Sanchez, RN, Senior Manager – Complaint Handling and Product Safety Surveillance, Cordis Corporation on April 25, 2016. A copy of the autopsy report, photographs and radiographs of the IVC filter were forwarded to Defendants on May 20, 2016.

COUNT I:
STRICT PRODUCTS LIABILITY- DESIGN DEFECT

69. Plaintiff re-alleges and incorporates by reference each and every allegation contained in the foregoing paragraphs 1 through 68 as though fully set forth herein pursuant to Rule 1.130(b), Florida Rules of Civil Procedure.

70. At all times relevant to this action, Defendants developed, tested, designed, manufactured, inspected, labeled, promoted, distributed and sold into the stream of commerce the TrapEase™ and OptEase™ filters, including the devices implanted in the Plaintiff.

71. At the time the Device left the Defendants' possession and the time the Device entered the stream of commerce in the State of New Jersey, it was in an unreasonably dangerous or defective condition. These defects include, but are not limited to, the following:

a. the TrapEase™ was not reasonably safe as intended to be used;

b. the TrapEase™ had an inadequate design for the purpose of implantation in the inferior vena cava to block blood clots;

c. the TrapEase™ device contained unreasonably dangerous design defects, including device composition of Nitinol – a nickel titanium alloy; a double basket or double filter for the capture of blood clots and/or emboli and the design of the TrapEase™ filter was defective in that it was designed to remain in placed once implanted in the inferior vena cava in order to

prevent thrombosis, in practice its design was not such that it would remain in place. Instead, it would actually dislodge and create thrombotic conditions.

d. The TrapEase™ device design created an unreasonable risk of fracture of portions of the filter(s);

e. The TrapEase™ device design created an unreasonable risk of migration of the filter(s) and/or portion of the filter(s);

f. The TrapEase™ device design created an unreasonable risk of filter(s) tilt and/or perforation of the vena cava wall;

g. The TrapEase™ device design created an unreasonable risk insufficient strength or structural integrity to withstand normal and intended placement within the human body, including Plaintiff;

h. The TrapEase™ device design created an unreasonable risk of inadequate structural integrity (fatigue resistance) and stability (tilt/migration) when used in an intended and reasonably foreseeable manner;

i. The TrapEase™ device design created an unreasonable risk of the device becoming irretrievable;

j. the Device's unstable and defective design resulted in a device which had risks which exceeded the benefits of the medical device;

k. the Device was not appropriately or adequately tested before its distribution; and,

l. the Device has an unreasonably high propensity for fatigue, fracture, perforation, migration and/or tilting; under normal and expected use of the Device.

72. The device implanted in Plaintiff was expected to, and did, reach the intended consumers without substantial change in the condition in which they were in when they left Defendants' possession. In the alternative, any changes that were made to the device implanted in Plaintiff was reasonably foreseeable to Defendants.

73. The TrapEase™ and OptEase™ filters, including the device implanted in Plaintiff, was defective in design and unreasonably dangerous at the time the device left Defendants' possession because they failed to perform as safely as an ordinary consumer would

expect when used as intended or in a manner reasonably foreseeable by the Defendants, and because the foreseeable risks of these devices exceeded the alleged benefits associated with their use.

74. At the time Defendants placed their TrapEase™ and OptEase™ filters, including the TrapEase™ device implanted in Plaintiff, into the stream of commerce, safer alternative designs were commercially, technologically, and scientifically attainable and feasible.

75. Plaintiff and Plaintiff's health care provider(s) used the device in a manner that was reasonably foreseeable to Defendants.

76. Neither Plaintiff, nor Plaintiff's health care providers, could have by the exercise of reasonable care discovered the defective condition or perceived the unreasonable dangers with these devices prior to Plaintiff's implantation with the device.

77. As a direct and proximate result of the defective and unreasonably dangerous condition of the device, Plaintiff suffered injuries and damages.

78. Defendants' dangerous design and failure to adequately test the safety of the Device was a substantial factor in causing MARTINO CONVERTINO's death.

79. As a direct and proximate result of the result of Defendants' defective product and tortious conduct as set forth herein, the decedent's statutory survivors have been damaged in the following regards:

a. They have lost the value of their husband/father's support and services from the date of his injury to his death, with interest, and future loss of support and services from the date of his death to be reduced to present value at the time of trial;

b. They have lost MARTINO CONVERTINO's parental companionship, instruction and guidance from the date of his injury and death and will continue to suffer such losses in the future.

c. They have and will continue to suffer for the remainder of their lives, mental pain and suffering as a result of their husband/father's injury and death.

80. As a direct or proximate result of the aforesaid, the Estate of MARTINO CONVERTINO has been damaged in the following regards:

a. The Estate has incurred medical and funeral expenses due to the decedent's injury and death which have become a charge against his Estate.

WHEREFORE, the Plaintiff, CARMINE CONVERTINO as Personal Representative of the Estate of MARTINO CONVERTINO, demands judgment against the Defendants, in an amount in excess of the minimum jurisdictional limits of this Court, costs and further demands trial by jury.

COUNT II:
STRICT PRODUCTS LIABILITY - FAILURE TO WARN

81. Plaintiff re-alleges and incorporates by reference each and every allegation contained in the foregoing paragraphs 1 through 68 as though fully set forth herein pursuant to Rule 1.130(b), Florida Rules of Civil Procedure.

82. Prior to, on, and after the dates during which the TrapEase™ was implanted in Plaintiff, and at all relevant times, Defendants manufactured, designed, marketed, distributed, and sold the TrapEase™ and OptEase™ filters.

83. The TrapEase™ and OptEase™ filters had potential risks and side effects that were known or knowable to Defendants by the use of scientific knowledge available before, at, and after the manufacture, distribution, and sale of the TrapEase™ implanted in Plaintiff.

84. Defendants knew or it was knowable at the time they distributed the TrapEase™ device implanted in Plaintiff that the TrapEase™ and OptEase™ filters posed a significant and

higher risk of failure than other similar IVC filters, including for fracture, migration, tilting, thrombosis, migration, tilt, inability to retrieve and pulmonary embolism and that these failures were resulting in serious patient injuries and death. Defendants also knew or it was knowable that these devices were actually prothrombotic, that use of these filters did not improve patient outcomes, and the longer these filters were left implanted increased the likelihood of a device failure.

85. Adequate efforts to communicate a warning to the ultimate uses were not made by Defendants and, to the extent a warning was communicated by Defendants, the warning was inadequate.

86. The warnings (pre-surgery and/or post-surgery) to Plaintiff and his implanting physicians about the dangers the Device posed to consumers were inadequate. Examples of the lack and/or inadequacy of Defendants' warnings include, but are not limited to, one or more of the following particulars:

a. the Device contained warnings insufficient to alert Plaintiff and Plaintiff s physicians as to the reduced fatigue strength of the TrapEase™, as well as to the risk of adverse events, i.e., perforation; tilt; fractures, associated with the Device, subjecting Plaintiff to risks which exceeded the benefits of the Device;

b. the Device contained warnings insufficient to alert Plaintiff and his physicians as to the potential for premature failure of the Device, including fracture; tilt; perforation; and/or migration leading to injury and/or death;

c. the Device contained warnings insufficient to alert Plaintiff and plaintiff's physicians as to the excessively high rate of premature failure of the TrapEase™;

d. the Device contained warnings insufficient to alert Plaintiff and plaintiff's physicians that the TrapEase™ could not be consistently implanted with satisfactory alignment by skilled physicians;

e. the Device contained misleading warnings emphasizing the efficacy of the Device while downplaying the risks associated with it, thereby making use of the Device more dangerous than the ordinary consumer would expect;

f. the Device contained insufficient and/or incorrect warnings to alert consumers, including Plaintiff, through plaintiff's prescribing physicians regarding the risk, scope, propensity, frequency, duration and severity of the adverse events associated with the Device;

g. the Device's warnings did not disclose that it was inadequately tested;

h. the Device's warnings and instructions failed to convey adequate post-marketing warnings regarding the risk, severity, propensity, frequency, scope and/or duration of the dangers posed by the Device;

i. the Device failed to contain instructions sufficient to alert consumers to the dangers it posed and to give them the information necessary to avoid or mitigate those dangers;

j. the Defendants failed to communicate or failed to adequately communicate the events and conditions set forth above, incorporated herein by reference.

87. Plaintiff used the Device for its intended purpose.

88. Plaintiff could not have discovered any defect in the Device through the exercise of due care.

89. Defendants, as designers, manufacturers, distributors, promoters, marketers and/or sellers of medical devices are held to the level of knowledge of experts in their field.

90. Neither Plaintiff nor plaintiff's implanting physician had substantially the same knowledge about the Device as Defendants.

91. Defendants' TrapEase™ and OptEase™ filters were in a defective condition that was unreasonably and substantially dangerous to any user or consumer implanted with the filters, such as Plaintiff, when used in an intended and reasonably foreseeable way. Such ordinary consumers, including Plaintiff and their prescribing physician(s), would not and could not have recognized or discovered the potential risks and side effects of the device, as set forth herein.

92. The warnings and directions Defendants provided with its TrapEase™ and OptEase™ filters, including the devices implanted in Plaintiff, failed to adequately warn of the above- described risks and side-effects, whether as to existence of the risk, its likelihood, severity, or the comparative risk to other products.

93. The labeling also failed to provide adequate directions on how to appropriately use the product. The device was expected to and did reach Plaintiff without substantial change in its condition, labeling, or warnings as manufactured, distributed, and sold by Defendants.

94. Additionally, Plaintiff and Plaintiff's prescribing physician(s) used the devices in the manner in which they were intended to be used, making such use reasonably foreseeable to Defendants.

95. Defendants' lack of sufficient instructions or warnings prior to, on, and after the date Plaintiff used the TrapEase™ device was a substantial factor in causing Plaintiff's injuries and damages, as described herein.

96. As a direct result of Defendants' failure to warn and/or inadequate warning and their other tortious conduct, MARTINO CONVERTINO died. The decedent's statutory survivors have been damaged in the following regards:

a. They have lost the value of their husband/father's support and services from the date of his injury to his death, with interest, and future loss of support and services from the date of his death to be reduced to present value at the time of trial;

b. They have lost MARTINO CONVERTINO's parental companionship, instruction and guidance from the date of his injury and death and will continue to suffer such losses in the future.

c. They have and will continue to suffer for the remainder of their lives, mental pain and suffering as a result of their husband/father's injury and death.

97. As a direct or proximate result of the aforesaid, the Estate of MARTINO CONVERTINO has been damaged in the following regards:

a. The Estate has incurred medical and funeral expenses due to the decedent's injury and death which have become a charge against his Estate.

WHEREFORE, the Plaintiff, CARMINE CONVERTINO as Personal Representative of the Estate of MARTINO CONVERTINO, demands judgment against the Defendants, in an amount in excess of the minimum jurisdictional limits of this Court, costs and further demands trial by jury.

COUNT III:
STRICT PRODUCTS LIABILITY -MANUFACTURING DEFECT

98. Plaintiff re-alleges and incorporate by reference each and every allegation contained in the foregoing paragraphs 1 through 68 as though fully set forth herein pursuant to Rule 1.130(b), Florida Rules of Civil Procedure.

99. Prior to, on, and after the date the device was implanted in Plaintiff, and at all relevant times, Defendants designed, distributed, manufactured, sold, and marketed the TrapEase™ and OptEase™ filters for use in the United States.

100. At all times herein mentioned, Defendants designed, distributed, manufactured, marketed, and sold the devices such that they were dangerous, unsafe, and defective in manufacture, and contained a manufacturing defect when it left defendants' possession.

101. Plaintiff is informed and believes, and on that basis, alleges, that the TrapEase™ and OptEase™ filters, including the TrapEase™ device implanted in Plaintiff, contained manufacturing defects, in that they differed from Defendants' design or specifications, or from other typical units of the same product line.

102. As a direct and proximate result of Defendants' defective manufacture and sale of the TrapEase™ and OptEase™ filters prior to, on, and after the date Plaintiff used the device, Plaintiff suffered the injuries and damages herein described.

103. The decedent's statutory survivors have been damaged in the following regards:

a. They have lost the value of their husband/father's support and services from the date of his injury to his death, with interest, and future loss of support and services from the date of his death to be reduced to present value at the time of trial;

b. They have lost MARTINO CONVERTINO's parental companionship, instruction and guidance from the date of his injury and death and will continue to suffer such losses in the future.

c. They have and will continue to suffer for the remainder of their lives, mental pain and suffering as a result of their husband/father's injury and death.

104. As a direct or proximate result of the aforesaid, the Estate of MARTINO CONVERTINO has been damaged in the following regards:

a. The Estate has incurred medical and funeral expenses due to the decedent's injury and death which have become a charge against his Estate.

WHEREFORE, the Plaintiff, CARMINE CONVERTINO as Personal Representative of the Estate of MARTINO CONVERTINO, demands judgment against the Defendants, in an amount in excess of the minimum jurisdictional limits of this Court, costs and further demands trial by jury.

COUNT IV:
NEGLIGENCE

Plaintiff re-alleges and incorporates by reference each and every allegation contained in the foregoing paragraphs 1 through 68 as though fully set forth herein pursuant to Rule 1.130(b), Florida Rules of Civil Procedure.

105. Prior to, on, and after the date the device was implanted in Plaintiff, and at all relevant times, Defendants designed, distributed, manufactured, sold, and marketed the TrapEase™ and OptEase™ filters for use in the United States.

106. Defendants had a duty to exercise reasonable and prudent care in the development, testing, design, manufacture, inspection, marketing, labeling, promotion, distribution and sale of the TrapEase™ and OptEase™ filters so as to avoid exposing others to foreseeable and unreasonable risks of harm.

107. Defendants knew or reasonably should have known that the TrapEase™ and OptEase™ filters were dangerous or were likely to be dangerous when used in an intended or reasonably foreseeable manner.

108. At the time of manufacture and sale of the TrapEase™ and OptEase™ filters, Defendants knew or should have known that the TrapEase™ and OptEase™ filters:

a. Were designed and manufactured in such a manner as to lack sufficient structural integrity (fatigue resistance) and stability (tilt/migration) to meet user needs when used in an intended and reasonably foreseeable manner.

b. Were designed and manufactured so as to present an unreasonable risk of the devices perforating the vena cava wall and/or in the case of the OptEase™ filter becoming irretrievable;

c. Being designed and manufactured in such a manner as to be prothrombotic.

109. At the time of manufacture and sale of the TrapEase™ and OptEase™ filters, including the ones implanted in Plaintiff, Defendants knew or should have known that using the TrapEase™ and OptEase™ filters as intended or in a reasonably foreseeable manner created a significant risk of patients suffering severe health side effects including, but not limited to: hemorrhage; cardiac/pericardia tamponade; cardiac arrhythmia and other symptoms similar to myocardial infarction; perforations of tissue, vessels and organs; chronic deep vein thrombosis:

pulmonary embolism; thrombosis; compartment syndrome; and other severe personal injuries and diseases, which are permanent in nature, including, but not limited to, death, physical pain and mental anguish, scarring and disfigurement, diminished enjoyment of life, continued medical care and treatment due to chronic injuries/illness proximately caused by the device; and the continued risk of requiring additional medical and surgical procedures including general anesthesia, with attendant risk of life threatening complications.

110. Defendants knew or reasonably should have known that consumers of the TrapEase™ and OptEase™ filters, including Plaintiff's prescribing physicians, would not realize the danger associated with using the devices for their intended or reasonably foreseeable use.

111. Defendants breached their to duty to exercise reasonable and prudent care in the development, testing, design, manufacture, inspection, marketing, labeling, promotion, distribution and sale of the TrapEase™ and OptEase™ filters in, among other ways, the following acts and omissions:

a. Designing and distributing a product in which they knew or should have known that the likelihood and severity of potential harm from the product exceeded the burden of taking safety measures to reduce or avoid harm;

b. Designing and distributing a product in which they knew or should have known that the likelihood and severity of potential harm from the product exceeded the likelihood of potential harm from other devices and treatment options available for the same purpose;

c. Failing to use reasonable care in manufacturing the product and producing a product that differed from their design or specifications or from other typical units from the same production line;

d. Failing to use reasonable care to warn or instruct, including pre-and post-sale, Plaintiff, Plaintiff's prescribing physicians, or the general health care community about the TrapEase™ and OptEase™ filters' substantially dangerous condition or about facts making the products likely to be dangerous;

e. Failing to recall, retrofit, or provide adequate notice of such actions to Plaintiff or Plaintiff's health providers.

f. Failing to perform reasonable pre-and post-market testing of the TrapEase™ and OptEase™ filters to determine whether or not the products were safe for their intended use;

g. Failing to provide adequate instructions, guidelines, and safety precautions, including pre-and post-sale, to those persons to whom it was reasonably foreseeable would prescribe, use, and implant the TrapEase™ and OptEase™ filters;

h. Advertising, marketing and recommending the use of the TrapEase™ and OptEase™ filters, while concealing and failing to disclose or warn of the dangers known by Defendants to be connected with and inherent in the use of these filter systems;

i. Representing that the TrapEase™ and OptEase™ filters were safe for their intended use when, in fact, Defendants knew and should have known the products were not safe for their intended uses;

j. Continuing to manufacture and sell the TrapEase™ and OptEase™ filters with the knowledge that said products were dangerous and not reasonably safe, and failing to comply with good manufacturing regulations;

k. Failing to use reasonable and prudent care in the design, research, manufacture, and development of the TrapEase™ and OptEase™ filters so as to avoid the risk of serious harm associated with the use of these filter systems;

l. Advertising, marketing, promoting, and selling TrapEase™ and OptEase™ filters for uses other than as approved and indicated in the product's label;

m. Failing to establish an adequate quality assurance program used in the design and manufacture of the TrapEase™ and OptEase™ filters.

n. Failing to establish and maintain and adequate post-market surveillance program;

112. At the time of manufacture and sale of the TrapEase™ and OptEase™ filters, including the ones implanted in Plaintiff's decedent, Defendants knew or should have known that using the TrapEase™ filters as intended or in a reasonably foreseeable manner created a

significant risk of patients suffering severe health side effects including, but not limited to: hemorrhage; cardiac/pericardial tamponade; cardiac arrhythmia tamponade; cardiac arrhythmia and other symptoms similar to myocardial infarction; perforations of tissue, vessels and organs; chronic deep vein thrombosis; pulmonary embolism; thrombosis; compartment syndrome; and other severe personal injuries and diseases, which are permanent in nature, including, but not limited to, death, physical pain and mental anguish, scarring and disfigurement, diminished enjoyment of life, continued medical care and treatment due to chronic injuries/illness proximately caused by the device; and the continued risk of requiring additional medical and surgical procedures including general anesthesia, with attendant risk of life threatening complications.

113. A reasonable manufacturer, distributor, or seller under the same or similar circumstances would not have engaged in the before-mentioned acts and omissions Defendants' negligence prior to, on, and after the date of implantation of the device in Plaintiff was a substantial factor in causing Plaintiff's injuries and damages, as described herein.

114. Defendants' negligence prior to, on, and after the date of implantation of the devices in Plaintiffs was a substantial factor in causing Plaintiffs' injuries and damages, as described herein.

115. Prior to, on, and after the date of Plaintiff's decedent's implantation with a TrapEase™ filter, and at all relevant times, Defendants knew or reasonably should have known that TrapEase™ and OptEase™ filters and their warnings were defective and dangerous or were likely to be dangerous when used in a reasonably foreseeable manner.

116. Prior to, on, and after the date of Plaintiff's decedent's implantation with a TrapEase™ IVC filter and at all relevant times thereafter, Defendants became aware that the

defects of TrapEase™ and OptEase™ filters resulted in TrapEase™ and OptEase™ filters causing injuries similar to those Plaintiff's decedent suffered.

117. Reasonable manufacturers and distributors under the same or similar circumstances would have recalled or retrofitted TrapEase™ and OptEase™ filters, and would thereby have avoided and prevented harm to many patients, including Plaintiff's decedent.

118. At all relevant times, Defendants knew or should have known that TrapEase™ and OptEase™ filters were defective and dangerous or were likely to be dangerous when used in a reasonably foreseeable manner.

119. Such danger included the propensity of TrapEase™ and OptEase™ filters to cause injuries similar to those suffered by Plaintiff's decedent.

120. At all relevant times, Defendants also knew or reasonably should have known that the users of TrapEase™ and OptEase™ filters, including Plaintiff's decedent and his health care providers, would not realize or discover on their own the dangers presented by TrapEase™ and OptEase™ filters.

121. Reasonable manufacturers and reasonable distributors, under the same or similar circumstances as those of Defendants prior to, on, and after the date of Plaintiff's decedent's use of a TrapEase™ filter, would have warned of the dangers presented by TrapEase™ and OptEase™ filters, or instructed on the safe use of TrapEase™ and OptEase™ filters.

122. Prior to, on, and after the date of Plaintiff's decedent's use of the TrapEase™ filter, Defendants had a duty to adequately warn of the dangers presented by TrapEase™ and OptEase™ filters and/or instruct on the safe use of TrapEase™ and OptEase™ filters.

123. Defendants breached these duties by failing to provide adequate warnings to Plaintiff and Decedent communicating the information and dangers described above and/or providing instruction for safe use of TrapEase™ and OptEase™ filters.

124. As a direct and proximate result of Defendants' negligent conduct described herein, Plaintiff and Decedent suffered Injuries and Damages, and/or Death.

125. As a direct and proximate result of the aforesaid negligence, the decedent's statutory survivors have been damaged in the following regards:

a. They have lost the value of their husband/father's support and services from the date of his injury to his death, with interest, and future loss of support and services from the date of his death to be reduced to present value at the time of trial;

b. They have lost MARTINO CONVERTINO's parental companionship, instruction and guidance from the date of his injury and death and will continue to suffer such losses in the future.

c. They have and will continue to suffer for the remainder of their lives, mental pain and suffering as a result of their husband/father's injury and death.

126. As a direct or proximate result of the aforesaid negligence, the Estate of MARTINO CONVERTINO has been damaged in the following regards:

a. The Estate has incurred medical and funeral expenses due to the decedent's injury and death which have become a charge against his Estate.

WHEREFORE, the Plaintiff, CARMINE CONVERTINO as Personal Representative of the Estate of MARTINO CONVERTINO, demands judgment against the Defendants, in an amount in excess of the minimum jurisdictional limits of this Court, costs and further demands trial by jury.

COUNT V:
NEGLIGENT MISREPRESENTATION

127. Plaintiff re-alleges and incorporates by reference each and every allegation contained in the foregoing paragraphs 1 through 68 as though fully set forth herein pursuant to Rule 1.130(b), Florida Rules of Civil Procedure.

128. Prior to, on, and after the date the devices were implanted in Plaintiffs, and at all relevant times, Defendants negligently and carelessly represented to Plaintiffs, their health care providers, and the general public that certain material facts were true. The representations include, *inter alia*, the following:

a. That the TrapEase™ and OptEase™ filters were safe, fit, and effective for use to prevent pulmonary embolisms.

b. That the TrapEase™ and OptEase™ filters were not prothrombotic.

c. That the unique double-basket design of the TrapEase™ and OptEase™ filters was better than competitor designs and eliminated the risk that pieces of the device could perforate the vena cava, that the devices could tilt, or that fractures could occur and migrate throughout the body.

d. That the TrapEase™ and OptEase™ filters were as safe and as effective as the predicate devices set forth in their 510(k) applications to the FDA, which, by law, they were required to be.

e. That the TrapEase™ and OptEase™ filters were safer and more effective than other available IVC filters.

f. That the TrapEase™ and OptEase™ filters post-market were not found to have any increased risks of device failures or complications, such as tilt, perforation, fracture, migration, retrieval difficulties and/or death.

g. That the TrapEase filter was "easy" to remove.

129. Prior to, on, and after the dates during which Plaintiff and Plaintiff's physicians purchased and used the device, Defendants intended that Plaintiff, Plaintiff's physicians, and the general public would rely on said representations, which did in fact occur.

130. Prior to, on, and after the dates during which Plaintiffs and their physicians purchased and used the device, said representations were not true, and there was no reasonable ground for believing said representations to be true at the times said representations were made.

131. All of the aforementioned information and representations emanated from the same source, Defendants, and was vetted by its copy review department (or equivalent) to ensure uniformity and harmony of the marketing message. The manner by which such information and representations were distributed, made available, or otherwise provided by Defendants, to Plaintiff's decedent and his health care providers was the same and include, but are not limited to, the following: reports, press releases, advertising campaigns, product information, instructions for use and other labeling materials provided with the TrapEase™ and OptEase™ filters, print advertisements, commercial media containing material representations, as well as through their officers, directors, agents and representatives, including the Defendants' sales representatives that met with and detailed Plaintiff's decedent's prescribing and implanting physicians on the TrapEase™ and OptEase™ filters, the 510(k) applications Defendants' to the FDA for the TrapEase™ and OptEase™ filters, patient brochures, training seminars hosted by said Defendants, CME materials created and distributed by said Defendants, information supplied at professional conferences at booths hosted or manned by said Defendants or their Key Opinion Leaders, as well as the websites of said Defendants that provided information on the TrapEase™ and OptEase™ filters and/or the Nitinol material from which they are made, including product description, indications for use, instructions for use, and ordering information.

132. Prior to, on, and after the dates Plaintiff's decedent and his physicians purchased and used the device, said representations were untrue at the times they were made, and there was

no reasonable ground for Defendants to believe said representations were true when said Defendants made said representations.

133. Prior to, on, and after the dates Plaintiff's decedent his physicians purchased and used the device, Defendants intended that Plaintiff's decedent, his physicians, and the general public would rely on said representations and prescribe the TrapEase™ and OptEase™ filters, which did in fact occur.

134. Prior to, on, and after the dates during which Plaintiff's decedent and his physicians purchased and used the device, Defendants intended that Plaintiff's decedent, his physicians, and the general public would rely on said representations, which did in fact occur.

135. Defendants knew or should have known prior to introduction on the market and at the time of submitting the 510(k) applications that these representations were untrue, from their own internal testing, analysis and investigation throughout the design and manufacturing process. Moreover, post-market performance promptly revealed poor outcomes in patients who were suffering failures and adverse events at an increased rate compared to other IVC filters. This triggered the obligation for further investigation and analysis of the safety and efficacy of the TrapEase™ and OptEase™ filters which further confirmed that the TrapEase™ and OptEase™ filters were, in fact, inferior in safety and efficacy and posed greater risks of harm and death than other IVC filters on the market, including the predicate devices for the TrapEase™ filter and OptEase™ filter, respectively.[1]

[1] As set forth herein, the design of the TrapEase™ and OptEase™ are nearly identical, except for the OptEase™ does not have barbs on the inferior ends of each side strut and has a caudal hook, both designed to render this version of the Filter removable up to a certain point in time after implant. The designs and claims by Cordis related to the risk/safety profile of the TrapEase™ and OptEase™ filters are and have been, at all relevant times, otherwise identical. In fact, the Product Brochure notes state that the OptEase "inherits the proven strength of the TrapEase filter." Although the Brochure states "OptEase" it is the same substance provided by Defendants as to the TrapEase™ Brochure. For example, when you click the link online for the "TrapEase" brochure, it still takes the viewer to the "OptEase" brochure, which was the case, at all relevant times.

136. It was known or should have been known by Defendants, that the TrapEase™ filter was, in fact, not "easy" to remove prior to introduction on the market because of internal testing, analysis and investigation that showed these devices often required complex, off-label and aggressive surgical methods for retrieval. Based on information and belief, at all times since made commercially available, said Defendants knew from their own analysis of adverse events reported by health care providers related to their filters, and subsequent internal investigation, that the TrapEase™ and OptEase™ filters posed significant and greater level of difficulty to remove than other IVC filters.

137. It was known or should have been known by Defendants, at all relevant times, that the TrapEase™ and OptEase™ filters, by way of their unique double-basket design, created and caused these devices to be prothrombotic; blood clots, clotting and occlusion of the TrapEase™ and OptEase™ filters were found to occur at a significantly increased rate compared to other IVC filters. This information was revealed in said Defendants' pre-market testing and analysis, and has been reaffirmed throughout the post-market experience of these products, as reflected by the increased number of these adverse event reports by physicians and published opinions in medical literature.

138. Defendants owed a duty in all of their undertakings, including the dissemination of information concerning its IVC filters, to exercise reasonable care to ensure that they did not in those undertakings create unreasonable risks of personal injury to others.

139. As set forth, *supra*, these Defendants disseminated to health care professionals and consumers through published labels, labeling, marketing materials, and otherwise information concerning the properties and effects of TrapEase™ and OptEase™ filters with the

intention that health care professionals and consumers would rely upon that information in their decisions concerning whether to prescribe and use Defendants' IVC filters.

140. Defendants as medical device designers, manufacturers, sellers, promoters and/or distributors, knew or should reasonably have known that health care professionals and consumers, in weighing the potential benefits and potential risks of prescribing or using TrapEase™ and OptEase™ filters, would rely upon information disseminated and marketed by Defendants to them regarding the TrapEase™ and OptEase™ filters.

141. Defendants failed to exercise reasonable care to ensure that the information they disseminated to health care professionals and consumers concerning the properties and effects of TrapEase™ and OptEase™ filters was accurate, complete, and not misleading and, as a result, disseminated information to health care professionals, including Plaintiff's decedent's physician and consumers that was negligently and materially inaccurate, misleading, false, and unreasonably dangerous to consumers such as Plaintiff's decedent.

142. Defendants, as designers, manufacturers, sellers, promoters, and/or distributors, also knew or reasonably should have known that patients receiving TrapEase™ and OptEase™ filters as recommended by health care professionals in reliance upon information disseminated by Defendants as the manufacturer/distributor of Defendants' IVC filters would be placed in peril of developing the serious, life-threatening, and life-long injuries including, but not limited to, tilting, migration, perforation, fracture, lack of efficacy, and increased risk of the development of blood clots, if the information disseminated and relied upon was materially inaccurate, misleading, or otherwise false.

143. Defendants had a duty to promptly correct material misstatements Defendants' knew others were relying upon in making healthcare decisions. Said Defendants purposely chose

not to, however, in order to maintain their market share and level of competition with other IVC filter manufacturers.

144. Defendants' negligent misrepresentations prior to, on, and after the date when Plaintiff and Plaintiff's physicians purchased and used the devices were a substantial factor in causing Plaintiff s injuries and damages, as described herein.

145. As a direct and proximate result of the aforesaid negligence, the decedent's statutory survivors have been damaged in the following regards:

a. They have lost the value of their husband/father's support and services from the date of his injury to his death, with interest, and future loss of support and services from the date of his death to be reduced to present value at the time of trial;

b. They have lost MARTINO CONVERTINO's parental companionship, instruction and guidance from the date of his injury and death and will continue to suffer such losses in the future.

c. They have and will continue to suffer for the remainder of their lives, mental pain and suffering as a result of their husband/father's injury and death.

146. As a direct or proximate result of the aforesaid negligence, the Estate of MARTINO CONVERTINO has been damaged in the following regards:

a. The Estate has incurred medical and funeral expenses due to the decedent's injury and death which have become a charge against his Estate.

WHEREFORE, the Plaintiff, CARMINE CONVERTINO as Personal Representative of the Estate of MARTINO CONVERTINO, demands judgment against the Defendants, in an amount in excess of the minimum jurisdictional limits of this Court, costs and further demands trial by jury.

DEMAND FOR JURY TRIAL

Plaintiff demands a trial by jury to the full extent permitted by law.

PRAYER

WHEREFORE, Plaintiff demands judgment for damages against Defendants, together with interest and costs, and any other amounts allowed by law and to which Plaintiff may be justly entitled. In addition, and/or in the alternative, Plaintiff also requests such other and further relief, in whole or in part, at law or in equity, to which it is determined that he is justly entitled.

DATED this 29th day of November, 2017.

Respectfully submitted,

/s/ Joseph A. Osborne
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