RUSSELL WARNKE,	:	
	:	**UNITED STATES DISTRICT COURT**
Plaintiff	:	
	:	
v.	:	**EASTERN DISTRICT OF TEXAS – SHERMAN DIVISION**
ARGON MEDICAL DEVICES, INC.	:	
and	:	
REX MEDICAL L.P.	:	
	:	**JURY TRIAL DEMANDED**
Defendants	:	
	:	
	:	
	:	

COMPLAINT

NOW COMES the Plaintiff, RUSSELL WARNKE, by and through her undersigned attorneys, THE LAW OFFICES OF A. CRAIG EILAND, P.C. who herein file this Complaint and bring this civil action against the above-captioned Defendants based upon the predicate facts, causes of action, and demands for relief set forth in the Counts below. Plaintiff avers the following:

PARTIES

1. Plaintiff, RUSSELL WARNKE, at all times relevant hereto, was, and currently is, a resident and citizen of the State of Ohio.

2. Defendant, Rex Medical, L.P. ("Rex Medical" or “Rex”) is a limited partnership organized and existing under the laws of the State of Pennsylvania, with its principal place of business located at 1100 E. Hector Street, Suite 245, Conshohocken, PA 19428. At all times relevant to this action, Rex Medical designed, developed, manufactured, and marketed the Option^{tm} Elite Retrievable Inferior Vena Cava Filter (“the IVC Filter” and/or “Option Elite”), a device used in the prevention of Pulmonary Embolism (PE), implanted in patients throughout the United States.

3. Defendant, ARGON MEDICAL DEVICES, INC. ("ARGON") is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business located at 5151 Headquarters Dr #210, Plano, TX 75024. ARGON may be served with process by serving its registered agent, CT Corporation System, 350 N. St. Paul Street, Suite 2900, Dallas, Texas 75201-4234. At all times relevant to this action, ARGON has holds the exclusive global rights to market and distribute the Option and Option Elite Filters.

4. At all times relevant hereto, Argon conducted and continues to regularly conduct substantial business within the state of Texas within Collin County, which included and continues to include, the research, sale, distribution and marketing of Option Elite, which is distributed through the stream of interstate commerce into Texas and throughout America.

5. Defendants, Rex Medical and Argon, shall be referred to herein individually by name or jointly as "Defendants."

6. At all times alleged herein, "Defendants" shall include any and all named or unnamed parent companies, parent corporations, subsidiaries, affiliates, divisions, franchises, partners, joint venturers, and any organizational units of any kind, their predecessors, successors, successors in interest, assignees, and their officers, directors, employees, agents, representatives and any and all other persons acting on their behalf.

7. At all times herein mentioned, each of the Defendants was the agent, servant, partner, predecessor in interest, aider and abettor, co-conspirator, and joint venturer of each of the remaining Defendants herein.

8. At all times herein mentioned, each of the Defendants was the agent, servant, partner, predecessor in interest, aider and abettor, co-conspirator, and joint venturer of each of the

remaining Defendants thereby operating and acting with the purpose and scope of said agency, service, employment, partnership, conspiracy and joint venture.

9. At all times relevant and material hereto, Defendants were engaged in the business of researching, developing, designing, licensing, manufacturing, testing, distributing, selling, labeling, marketing, promoting, advertising, and/or introducing into interstate commerce throughout the United States, and in the Commonwealth of Pennsylvania, either directly or indirectly, through third-parties, subsidiaries and/or related entities, the Option Elite, a device used in the prevention of Pulmonary Embolism (PE), implanted in patients throughout the United States.

JURISDICTION AND VENUE

10. Federal subject matter jurisdiction in the constituent action is based upon 28 U.S.C. § 1332 (a), in that there is complete diversity among Plaintiff and all Defendants and the amount in controversy exceeds $75,000.00.

11. Defendant Argon Medical Devices, Inc. has significant contacts with the Eastern District of Texas, Sherman Division, in that Defendant Argon Medical Devices, Inc. maintains its principle place of business in Plano, Texas in Collin County, such that they are subject to the personal jurisdiction of this Court.

NATURE OF THE CASE – GENERAL ALLEGATIONS

12. Plaintiff brings this case for serious, life-threatening injuries she suffered as a result of the Defendants' surgically implanted medical device, the Option Elite Filter. On January 3, 2014 at University of Toledo Medical Center, Toledo, OH, Doctor Munier Nazzal, surgically implanted the Option Elite Filter within the Plaintiff's body.

13. The IVC Filter was designed, manufactured, assembled, processed, labeled, marketed, distributed, and sold by Defendants in the United States after receiving 510k approval on December 17, 2013.

14. As stated on the 510k application summary of September 30, 2013, The Option Elite Vena Cava Filter is intended for the prevention of recurrent pulmonary embolism (PE via placement in the vena cava.

15. Prior to Plaintiff being implanted with the Filter on or about on or about January 3, 2014, the Defendants knew and should have known that the device was defective and unreasonably dangerous for, *inter alia*, the following reasons:

a. Defendants failed to conduct sufficient clinical testing, such as animal studies, to determine how the device would function once permanently implanted in the human body.

b. Defendants knew and/or should have known that the Filter had a high rate of embedment, fracture, migration, and excessive tilting and perforation of the vena cava wall once implanted in the human body. Defendants knew and/or should have known that such failures exposed patients to serious injuries, including: death; hemorrhage; cardiac/pericardial tamponade; cardiac arrhythmia and other symptoms similar to myocardial infarction; severe and persistent pain; perforations of tissue, vessels, and organs; and inability to remove the device.

c. Upon information and belief, Defendants also knew or should have known that certain conditions or post-implant procedures, such as morbid obesity or open abdominal procedures, could affect the safety and integrity of the device.

d. Defendants knew and should have known that these risks for the Option Elite Vena Cava Filter were and are substantially higher than other similar devices.

e. Further, Defendants knew and/or should have known that the Vena Cava Filter contained conditions, which Defendants did not intend, which resulted in the device not performing as safely as the ordinary customer would expect.

f. Despite being aware of these risks, Defendants misrepresented, omitted, and/or failed to provide adequate warnings of these risks or instructions for safe use.

g. Even as Defendants designed, marketed and sold what they alleged to be a device that specifically reduced these risks of the Filter, they nonetheless failed to issue a recall of the Filter or otherwise notify consumers that a safer device was available.

INFERIOR VENA CAVA FILTERS GENERALLY

16. IVC Filters first came on the medical market decades ago. Over the years, several different medical device manufacturers have introduced several different designs of IVC filters.

17. An IVC filter is a device that is designed to filter or "catch" blood clots (called "thrombi") that travel from the lower portions of the body to the heart and lungs. IVC filters may be designed to be implanted, either permanently or temporarily, in the human body, more specifically, within the inferior vena cava.

18. The inferior vena cava is a vein that returns blood to the heart from the lower portions of the body. In certain people, for various reasons, thrombi travel from the vessels in the legs and pelvis, through the vena cava and into the lungs. Oftentimes, these thrombi develop in the deep leg veins. These thrombi are called "deep vein thrombosis" or "DVT". Once thrombi reach the lungs, they are considered "pulmonary emboli" or "PE". Pulmonary emboli present grave risks to human health, and can, and often do, result in death.

19. Certain people are at increased risk for the development of DVT or PE. For instance someone who undergoes knee or hip joint replacement is at risk for developing DVT/PE. Obese patients are also at increased risk for DVT/PE. So too are people who have vascular diseases or whom have experienced previous strokes. A number of other conditions predispose people to develop DVT/PE.

20. Those 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 thromboembolic events.

21. The first IVC filter was introduced in the later 1960's. Since then, the market has been supplemented with all types and designs of filters offered by many different manufacturers.

22. Over the years, concern developed within the medical community (and was shared by IVC filter manufacturers) that an IVC filter should be designed and manufactured in a manner to enable retrieval of the device from the body.

23. Ultimately, retrievable IVC filter designs became available for use. However, these retrievable IVC filter designs were not intended to remain within the human body for indeterminate periods of time. In other words, the initial designs of retrievable IVC filters were intended to remain implanted for a finite period of time.

THE OPTION ELITE VENA CAVA FILTER

24. On September 30, 2013, the Rex Defendant submitted a Section 510(k) FDA premarket notification of intent to market the Option Elite [tm] Vena Cava Filter System for the prevention of recurrent pulmonary embolism via placement in the inferior vena cava. The Rex

25. Defendants cited the Option [tm] Recovery Filter as the predicate device for the Option Elite [tm] Vena Cava Filter System.

26. The Option [tm] Vena Cava Filter System, in its 510(k) FDA premarket notification of intent to market cites six products as substantially similar predicate devices, and represented

that any differences between the devices were dimensional and no material or additional components were added.

27. The six products Defendant Rex contends are substantially similar to the Option Vena Cava Filter are:

a. Boston Scientific's Greenfield Vena Cava Filter determined substantially equivalent on January 6, 1997 (also K964284; (K955396; K951508);

b. Cordis Trapease Vena Cava Filter (K000062) determined substantially equivalent on July 7, 2000;

c. Cordis Optease Vena Cava Filter (K023116) substantially equivalent on October 18, 2002;

d. Bard Recovery Vena Cava Filter (K022236) determined substantially equivalent on November 27, 2002;

e. Gunther-Tulip Vena Cava Filter Set (K032426) determined substantially equivalent on October 31, 2003

f. Recovery G2 Filter (K073090) determined substantially equivalent on January 15, 2008;

28. The Option Vena Cava Filter was cleared by the FDA on June 4, 2009. The Option Elite Vena Cava Filter System was cleared by the FDA on December 17, 2013.

29. Contrary to the Defendants' claims concerning the safety and efficacy of the Filter, the FDA's "MAUDE" (Manufacturer and User Facility Device Experience) database includes numerous reports of device failure, including filter fracture, migration, perforation, caval thrombosis, and pulmonary embolism associated with the device.

30. Upon information and belief, failure of the Filter leads to a number of different, and potentially fatal, complications; including but not limited to: death, hemorrhage, cardiac/pericardial tamponade (pressure caused by a collection of blood in the area around the heart), severe and persistent pain, and perforation of tissues, vessels and organs.

31. Upon information and belief, Defendants' Filter is adulterated pursuant to 21 U.S.C. § 351 because, among other things, it failed to meet established performance standards, and/or the methods, facilities, or controls used for its manufacture, packing, storage or installation are not in conformity with federal requirements. *See* 21 U.S.C. § 351.

32. Upon information and belief, Defendants' Filter is misbranded because, among other things, it is dangerous to health when used in the manner indicated, recommended or suggested in the labeling thereof. *See* 21 U.S.C. § 352.

33. Upon information and belief, Defendants' Filter is adulterated pursuant to 21 U.S.C. § 351 because Defendants failed to establish and maintain CGMP for their Filter System in accordance with 21 CFR § 820 *et seq.*, as set forth above.

34. Upon information and belief, Defendants failed to establish and maintain CGMP with respect to the quality audits, quality testing and process validation for their Filter.

35. As a result of Defendants' failure to establish and maintain CGMP as set forth above, Defendants' Filter was defective and failed, resulting in injuries to the Plaintiff.

36. If Defendants had complied with the federal requirements regarding CGMP, Defendants' Filter would have been manufactured properly such that it would not have resulted in injuries to the Plaintiff.

FACTUAL ALLEGATIONS SPECIFIC TO PLAINTIFF

37. Upon information and belief, Plaintiff, was implanted with an Option Elite Retrievable Inferior Vena Cava Filter manufactured by Rex Medical and marketed and distributed by Argon on January 3, 2014. Subsequently, on June 12, 2015, Doctor Munier Nazzal unsuccessfully attempted surgical retrieval of the filter implanted within Plaintiff's body. Dr.

Nazzal found the filter to be completely tilted and embedded in the Plaintiff's inferior vena cava wall.

38. As a direct result, Plaintiff suffered significant injuries, including but not limited to, the embedment of the retrieval hook of the Option Elite Retrievable Inferior Vena Cava which has made the filter un-retrievable. The embedded filter places the Plaintiff at an increased and continual risk of complications such as the potential for the filter to become occluded with blood clots thereby disrupting the normal flow of blood to the heart and lungs. The embedded filter also poses an increased and continual risk of perforation, including perforation of the Plaintiff's vena cava, perforation of surrounding vital organs, and perforation of the spinal column, all of which can result in severe pain and life-threatening complications. The embedded filter also poses an increased and continual risk of fracturing, including the risk that fractured portions will travel to the Plaintiff's lungs or heart with the possibility of causing immediate death or serious injury. Plaintiff is forced to live with the possibility that the filter could cause any of the above-listed complications at any moment, this reality has led to severe fear, stress, and anxiety.

39. As a proximate result of Defendants' acts and omissions, Plaintiff suffered the injuries described hereinabove due to the implantation of the Option Elite Retrievable Inferior Vena Cava Filter. Plaintiff accordingly seeks damages associated with these injuries.

40. Plaintiff would not have used Option Elite Retrievable Inferior Vena Cava Filter had Defendants properly disclosed the risks associated with its use, as safer alternatives were available.

DISCOVERY RULE AND FRAUDULENT CONCEALMENT

41. Plaintiff incorporates by reference the factual portion of this petition as if fully set forth herein and additionally, or in the alternative, if same be necessary, alleges as follows.

42. Plaintiff pleads that the discovery rule should be applied to toll the running of the statute of limitations until Plaintiff knew, or through the exercise of reasonable care and diligence should have known, of facts indicating that Plaintiff had been injured, the cause of the injury, and the tortuous nature of the wrongdoing that caused the injury.

43. Despite diligent investigation by Plaintiff into the cause of her injuries, including consultations with Plaintiff's medical providers, the nature of Plaintiff's injuries and damages and their relationship to the Filter and Defendants' wrongful conduct was not discovered, and through reasonable care and due diligence could not have been discovered, until a date within the applicable statute of limitations for filing Plaintiff's claims. Therefore, under appropriate application of the discovery rule, Plaintiff's suit was filed well within the applicable statutory limitations period.

44. Any applicable statutes of limitation have been tolled by the knowing and active concealment and denial of material facts known by the Defendants when they had a duty to disclose those facts. The Defendants' purposeful and fraudulent acts of concealment have kept Plaintiff ignorant of vital information essential to the pursuit of her claims, without any fault or lack of diligence on Plaintiff's part, for the purpose of obtaining delay on Plaintiff's part in filing on their causes of action. The Defendants' fraudulent concealment did result in such delay.

45. The Defendants are estopped from relying on the statute of limitations defense because Defendants failed to timely disclose, among other things, facts evidencing the defective and unreasonably dangerous nature of the Filter.

46. The Defendants were, and remain under a continuing duty to disclose the true character, quality and nature of the device that was implanted in Plaintiff, but instead they concealed them. The Defendants' conduct, as described in this complaint, amounts to conduct

purposely committed, which they must have realized was dangerous, heedless and reckless, without regard to the consequences or the rights and safety of Plaintiff.

CORPORATE/VICARIOUS LIABILITY

47. At all times herein mentioned, the Defendants were agents, servants, partners, aiders and abettors, co-conspirators and/or joint venturers, and were at all times operating and acting within the purpose and scope of said agency, service, employment, partnership, conspiracy and/or joint venture and rendered substantial assistance and encouragement to each other, knowing that their collective conduct constituted a breach of duty owed to the Plaintiff.

48. There exists and, at all times herein mentioned, there existed a unity of interest in ownership between the Defendants such that any individuality and separateness between them has ceased and these Defendants are alter egos. Adherence to the fiction of the separate existence of these Defendants as entities distinct from each other will permit an abuse of the corporate privilege and would sanction a fraud and/or would promote injustice.

49. At all times herein mentioned, the Defendants, and each of them, were engaged in the business of, or were successors in interest to, entities engaged in the business of researching, designing, formulating, compounding, testing, manufacturing, producing, processing, assembling, inspecting, distributing, marketing, labeling, promoting, packaging, prescribing and/or advertising for sale, and selling products for use by the Plaintiff. As such, each Defendant is individually, as well as jointly and severally, liable to the Plaintiff for Plaintiff's damages.

50. At all times herein mentioned, the officers and/or directors of the Defendants named herein participated in, authorized and/or directed the production and promotion of the aforementioned products when they knew, or with the exercise of reasonable care and diligence

should have known, of the hazards and dangerous propensities of said products, and thereby actively participated in the tortious conduct that resulted in the injuries suffered by the Plaintiff.

COUNT I
NEGLIGENCE

51. Plaintiff re-alleges and incorporates by reference each and every allegation contained in the foregoing paragraphs as though fully set forth herein.

52. At all times relevant to this cause of action, Defendants were in the business of designing, developing, setting specifications, manufacturing, marketing, selling, and/or distributing the Option Elite Filter.

53. Defendants designed, manufactured, marketed, inspected, labeled, promoted, and/or distributed and sold Option Elite Filter that was implanted in Plaintiff.

54. 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 Option Elite Filter so as to avoid exposing others to foreseeable and unreasonable risks of harm.

55. Defendants knew or reasonably should have known that the Option Elite Filter was dangerous or was likely to be dangerous when used in its intended or reasonably foreseeable manner.

56. Defendant knew or should have known that the predicate device, Option Filter, was dangerous due to its poor performance and failures. Therefore, Defendant never should have introduced the Option Elite Filter.

57. At the time of manufacture and sale of the Option Elite Filter (December 2013 until Present), Defendants knew or should have known that the Option Elite Filter:

a. Was designed and manufactured in such a manner so as to present an unreasonable risk of fracture of portions of the device;

b. Was designed and manufactured so as to present a unreasonable risk of migration of the device and/or portions of the device; and/or

c. Was designed and manufactured so as to present a unreasonable risk of the device tilting, and/or embedding into or perforating the vena cava wall;

d. Was designed and manufactured to have unreasonable and insufficient strength or structural integrity to withstand normal placement within the human body.

58. At the time of manufacture and sale of the Option Elite Filter (June 2009 until Present), Defendants knew or should have known that using the Option Elite Filter in its intended use or in a reasonably foreseeable manner created a significant risk of a patient suffering severe health side effects, including, but not limited to: hemorrhage; cardiac/pericardial tamponade; cardiac arrhythmia and other symptoms similar to myocardial infarction; perforations of tissue, vessels and organs; 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.

59. Defendants knew or reasonably should have known that consumers of the Option Elite Filter would not realize the danger associated with using the device in its intended use and/or in a reasonably foreseeable manner.

60. Defendants breached their duty to exercise reasonable and prudent care in the development, testing, design, manufacture, inspection, marketing, labeling, promotion, distribution and sale of the Option Elite Filter in, among others, the following ways:

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 device 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 physicians, or the general health care community about the Option Elite Retrievable Inferior Vena Cava Filter's substantially dangerous condition or about facts making the product likely to be dangerous;

e. Failing to perform reasonable pre and post-market testing of the Option Elite Retrievable Inferior Vena Cava Filter to determine whether or not the product was safe for its intended use;

f. Failing to provide adequate instructions, guidelines, and safety precautions, including pre and post-sale, to those persons to whom it was reasonably foreseeable would recommend, use, and implant the Option Elite Retrievable Inferior Vena Cava Filter;

g. Advertising, marketing and recommending the use of the Option Elite Retrievable Inferior Vena Cava Filter, while concealing and failing to disclose or warn of the dangers known by Defendants to be connected with and inherent in the use of the Option Elite Retrievable Inferior Vena Cava Filter;

h. Representing that the Option Elite Retrievable Inferior Vena Cava Filter was safe for its intended use when in fact, Defendants knew and should have known the product was not safe for its intended purpose;

i. Continuing manufacture and sale of the Option Elite Retrievable Inferior Vena Cava Filter with the knowledge that said product was dangerous and not reasonably safe, and failing to comply with FDA good manufacturing regulations;

j. Failing to use reasonable and prudent care in the design, research, manufacture, and development of the Option Elite Retrievable Inferior

Vena Cava Filter so as to avoid the risk of serious harm associated with the use of the Option Elite Retrievable Inferior Vena Cava Filter;

k. Advertising, marketing, promoting and selling Option Elite Retrievable Inferior Vena Cava Filter for uses other than as approved and indicated in the product's label;

l. Failing to establish an adequate quality assurance program used in the manufacturing of the Option Elite Retrievable Inferior Vena Cava Filter; and

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

61. A reasonable manufacturer, distributor, or seller under the same or similar circumstances would not have engaged in the aforementioned acts and omissions.

62. As a direct and proximate result of the foregoing negligent acts and omissions by the Defendants, Plaintiff has suffered and will continue to suffer serious physical injuries, economic loss, loss of enjoyment of life, disability, and other losses, in an amount to be determined at trial.

COUNT II
STRICT PRODUCTS LIABILITY - FAILURE TO WARN

63. Plaintiff re-alleges and incorporates by reference each and every allegation contained in the foregoing paragraphs as though fully set forth herein.

64. Defendants designed, set specifications, manufactured, prepared, compounded, assembled, processed, marketed, labeled, distributed, and sold the Option Elite Retrievable Inferior Vena Cava Filter, including the one implanted into Plaintiff, into the stream of commerce and in the course of same, directly advertised and marketed the device to consumers or persons responsible for consumers.

65. At the time Defendants designed, manufactured, prepared, compounded, assembled, processed, marketed, labeled, distributed, and sold the device into the stream of

commerce, Defendants knew or should have known the device presented an unreasonable danger to users of the product when put to its intended and reasonably anticipated use. Specifically, Defendants knew or should have known at the time they manufactured, labeled, distributed and sold the Option Elite Inferior Vena Cava Filter, which was implanted in Plaintiff, that the Option Elite Inferior Vena Cava Filter, *inter alia*, posed a significant and higher risk than other similar devices of device failure (fracture, migration, tilting, and perforation of the vena cava wall) and resulting serious injuries.

66. Upon information and belief, Defendants also knew or should have known that certain conditions or post-implant procedures, such as morbid obesity or open abdominal procedures, could affect the safety and integrity of the device.

67. Consequently, Defendants had a duty to warn of the risk of harm associated with the use of the device and to provide adequate instructions on the safe and proper use of the device.

68. Defendants further had a duty to warn of dangers and proper safety instructions that it became aware of even after the device was distributed and implanted in Plaintiff.

69. Despite their duties, Defendants failed to adequately warn of material facts regarding the safety and efficacy of the Option Elite Inferior Vena Cava Filter, and further failed to adequately provide instructions on the safe and proper use of the device.

70. No health care provider, including Plaintiff's, or patient would have used the device in the manner directed, had those facts been made known to the healthcare providers and/or ultimate users of the device.

71. The health risks associated with the device as described herein are of such a nature that ordinary consumers would not have readily recognized the potential harm.

72. Plaintiff and Plaintiff's health care providers used the device in a normal, customary, intended, and foreseeable manner, namely as a surgically implanted device used to prevent pulmonary embolisms.

73. Therefore, the Option Elite Inferior Vena Cava Filter implanted in Plaintiff was defective and unreasonably dangerous at the time of release into the stream of commerce due to inadequate warnings, labeling and/or instructions accompanying the product.

74. The Option Elite Inferior Vena Cava Filter implanted in Plaintiff was in the same condition as when it was manufactured, inspected, marketed, labeled, promoted, distributed and sold by Defendants.

75. As a direct and proximate result of Defendants' lack of sufficient warning and/or instructions, Plaintiff has suffered and will continue to suffer serious physical injuries, economic loss, loss of enjoyment of life, disability, and other losses, in an amount to be determined at trial.

COUNT III
STRICT PRODUCTS LIABILITY – DESIGN DEFECT

76. Plaintiff re-alleges and incorporates by reference each and every allegation contained in the foregoing paragraphs as though fully set forth herein.

77. At all times relevant to this action, Defendants developed, tested, designed, manufactured, inspected, labeled, promoted, distributed and sold into the stream of commerce the Option Elite Inferior Vena Cava Filter, including the one implanted in Plaintiff.

78. The Option Elite Inferior Vena Cava Filter was expected to, and did, reach its intended consumers without substantial change in the condition in which it was in when it left Defendants' possession. In the alternative, any changes that were made to Option Elite Inferior Vena Cava Filter implanted in Plaintiff were reasonably foreseeable to Defendants.

79. The Option Elite Inferior Vena Cava Filter implanted in Plaintiff was defective in design because it failed to perform as safely as persons who ordinarily use the product would have expected at the time of use.

80. The Option Elite Inferior Vena Cava Filter implanted in Plaintiff was defective in design, in that its risks of harm exceeded its claimed benefits.

81. Plaintiff and Plaintiff's health care providers used the Option Elite Inferior Vena Cava Filter in a manner that was reasonably foreseeable to Defendants.

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

83. As a direct and proximate result of the Option Elite Inferior Vena Cava Filter's defective design, Plaintiff has suffered and will continue to suffer serious physical injuries, economic loss, loss of enjoyment of life, disability, and other losses, in an amount to be determined at trial.

COUNT IV
STRICT PRODUCTS LIABILITY – MANUFACTURING DEFECT

84. Plaintiff re-alleges and incorporate by reference each and every allegation contained in the foregoing paragraphs as though fully set forth herein.

85. Defendants designed, set specifications, manufactured, prepared, compounded, assembled, processed, marketed, labeled, distributed, and sold the Option Elite Inferior Vena Cava Filter that was implanted into Plaintiff.

86. The Option Elite Inferior Vena Cava Filter implanted in Plaintiff contained a condition or conditions, which Defendants did not intend, at the time it left Defendants' control and possession.

87. Plaintiff and Plaintiff's health care providers used the device in a manner that was reasonably foreseeable to Defendants.

88. As a result of this condition or these conditions, the product injured Plaintiff and failed to perform as safely as the ordinary consumer would expect when used in a reasonably foreseeable manner.

89. As a direct and proximate result of the Option Elite Inferior Vena Cava Filter's manufacturing defects, Plaintiff has suffered and will continue to suffer serious physical injuries, economic loss, loss of enjoyment of life, disability, and other losses, in an amount to be determined at trial.

COUNT V
BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY

90. Plaintiff re-alleges and incorporates by reference each and every allegation contained in the foregoing paragraphs as though fully set forth herein.

91. At all times relevant to this action, Defendants designed, researched, developed, manufactured, tested, labeled, inspected, advertised, promoted, marketed, sold, and distributed into the stream of commerce the Option Elite Inferior Vena Cava Filter for use as a surgically implanted device used to prevent pulmonary embolisms and for uses other than as approved and indicated in the product's instructions, warnings, and labels.

92. At the time and place of the sale, distribution, and supply of the Defendants' Option Elite Inferior Vena Cava Filter System to Plaintiff by way of Plaintiff's health care providers and medical facilities, Defendants expressly represented and warranted, by labeling materials

submitted with the product, that the Option Elite Inferior Vena Cava Filter System was safe and effective for its intended and reasonably foreseeable use.

93. Defendants knew of the intended and reasonably foreseeable use of the Option Elite Inferior Vena Cava Filter, at the time they marketed, sold, and distributed the product for use by Plaintiff, and impliedly warranted the product to be of merchantable quality, and safe and fit for its intended use.

94. Defendants impliedly represented and warranted to the healthcare community, Plaintiff and Plaintiff's health care providers, that the Option Elite Inferior Vena Cava Filter was safe and of merchantable quality and fit for the ordinary purpose for which the product was intended and marketed to be used.

95. The representations and implied warranties made by Defendants were false, misleading, and inaccurate because the Option Elite Inferior Vena Cava Filter was defective, unsafe, unreasonably dangerous, and not of merchantable quality, when used in its intended and/or reasonably foreseeable manner. Specifically, at the time of Plaintiff's purchase of the Option Elite Inferior Vena Cava Filter from the Defendants, through Plaintiff's physicians and medical facilities, it was not in a merchantable condition in that:

a. It was designed in such a manner so as to be prone to an unreasonably high rate of failure, including fracture, migration, excessive tilting, and perforation of bodily organs;

b. It was designed in such a manner so as to result in an unreasonably high rate of injury to the organs and anatomy; and

c. It was manufactured in such a manner so that the exterior surface of the Option Elite Inferior Vena Cava Filter System was inadequately, improperly and inappropriately prepared and/or finished, so as to be prone to an unreasonably high rate of failure and/or causing the device to fail.

96. Plaintiff and Plaintiff's health care providers reasonably relied on the superior skill and judgment of Defendants as the designers, researchers and manufacturers of the product, as to whether the Option Elite Inferior Vena Cava Filter was of merchantable quality and safe and fit for its intended use, and also relied on the implied warranty of merchantability and fitness for the particular use and purpose for which the Option Elite Inferior Vena Cava Filter was manufactured and sold.

97. Defendants placed the Option Elite Inferior Vena Cava Filter into the stream of commerce in a defective, unsafe, and unreasonably dangerous condition, and the product was expected to and did reach Plaintiff without substantial change in the condition in which the Option Elite Inferior Vena Cava Filter was manufactured and sold.

98. Defendants breached their implied warranty because their Option Elite Inferior Vena Cava Filter was not fit for its intended use and purpose.

99. As a proximate result of Defendants breaching their implied warranties, Plaintiff has suffered and will continue to suffer serious physical injuries, economic loss, loss of enjoyment of life, disability, and other losses, in an amount to be determined at trial.

COUNT VI
NEGLIGENT MISREPRESENTATION

100. Plaintiff re-alleges and incorporates by reference each and every allegation contained in the foregoing paragraphs as though fully set forth herein.

101. At all times relevant to this cause, and as detailed herein, Defendants negligently provided Plaintiff, Plaintiff's health care providers, and the general medical community with false or incorrect information, or omitted or failed to disclose material information concerning the Option Elite Inferior Vena Cava Filter; including, but not limited to, misrepresentations relating to the safety, efficacy, failure rate and approved uses of the Option Elite Inferior Vena Cava Filter.

102. The information distributed by Defendants to the public, the medical community and Plaintiff's health care providers, including reports, press releases, advertising campaigns, labeling materials, print advertisements, commercial media containing material representations, was false and misleading, and contained omissions and concealment of truth about the dangers of the use of the Option Elite Inferior Vena Cava Filter. Defendants made the foregoing misrepresentations knowing that they were false and/or without reasonable basis in fact. These materials included instructions for use and warning document that was included in the package of the Option Elite Inferior Vena Cava Filter that was implanted in Plaintiff.

103. Defendants' intent and purpose in making these misrepresentations was to deceive and defraud the public and the medical community, including Plaintiff's health care providers; to gain the confidence of the public and the medical community, including Plaintiff's health care providers; to falsely assure them of the quality of the Option Elite Inferior Vena Cava Filter and its fitness for use; and to induce the public and the medical community, including Plaintiff's healthcare providers to request, recommend, prescribe, implant, purchase, and continue to use the Option Elite Inferior Vena Cava Filter.

104. The foregoing representations and omissions by Defendants were in fact false. The Option Elite Inferior Vena Cava Filter is not safe, fit, and effective for human use in its intended and reasonably foreseeable manner. The use of the Option Elite Inferior Vena Cava Filter is hazardous to the user's health, and said device has a serious propensity to cause users to suffer serious injuries, including without limitation, the injuries Plaintiff suffered. Further, the device has a significantly higher rate of failure and injury than do other comparable devices.

105. In reliance upon the false and negligent misrepresentations and omissions made by Defendants, Plaintiff and Plaintiff's health care providers were induced to, and did use the Option

Elite Inferior Vena Cava Filter, thereby causing Plaintiff to sustain severe and permanent personal injuries.

106. Defendants knew and had reason to know that Plaintiff, Plaintiff's health care providers, and the general medical community did not have the ability to determine the true facts intentionally and/or negligently concealed and misrepresented by Defendants, and would not have prescribed, recommended and implanted same, if the true facts regarding the device had not been concealed and misrepresented by Defendants.

107. Defendants had sole access to material facts concerning the defective nature of the product and its propensity to cause serious and dangerous side effects in the form of dangerous injuries and damages to persons who are implanted with the Option Elite Inferior Vena Cava Filter.

108. At the time Defendants failed to disclose and misrepresented the foregoing facts, and at the time Plaintiff used the Option Elite Inferior Vena Cava Filter, Plaintiff and Plaintiff's health care providers were unaware of said Defendants' negligent misrepresentations and omissions.

109. Plaintiff, Plaintiff's health care providers and general medical community reasonably relied upon misrepresentations and omissions made by Defendants where the concealed and misrepresented facts were critical to understanding the true dangers inherent in the use of the Option Elite Inferior Vena Cava Filter.

110. Plaintiff and Plaintiff's health care provider's reliance on the foregoing misrepresentations and omissions by Defendants' were the direct and proximate cause of Plaintiff's injuries as described herein.

PUNITIVE DAMAGES ALLEGATIONS

111. Plaintiff re-alleges each and every allegation in this Complaint and incorporates each allegation into this Count, as if set forth at length, in its entirety.

112. Plaintiff is entitled to an award of punitive and exemplary damages based upon Defendants' intentional, willful, knowing, fraudulent, malicious acts, omissions, and conduct, and their complete and total reckless disregard for the public safety and welfare.

113. Defendants had knowledge of, and were in possession of evidence demonstrating that, the Option Elite Inferior Vena Cava Filter was defective and unreasonably dangerous and had a substantially higher failure rate than did other similar devices on the market. Despite their knowledge, Defendants failed to, among other purposeful acts, inform or warn Plaintiff or her health care providers of the dangers, establish and maintain an adequate quality and post-market surveillance system, and recall the Option Elite Inferior Vena Cava Filter from the market.

114. As a direct, proximate, and legal result of Defendants' acts and omissions a described herein, Plaintiff has suffered and will continue to suffer serious physical injuries, economic loss, loss of enjoyment of life, disability, and other losses, in an amount to be determined at trial.

PRAYER FOR DAMAGES

WHEREFORE, Plaintiff, Russell Warnke, prays for relief on the entire complaint, as follows:

a. Judgment to be entered against all Defendants on all causes of action of this Complaint, including but not limited to:

   1. Physical pain and suffering in the past and which, in reasonable probability, she will continue to suffer in the future;

   2. Physical impairment and incapacity in the past and which, in reasonable probability, she will continue to suffer in the future;

3. Mental anguish in the past and which, in reasonable probability, she will sustain in the future;

4. Reasonable and necessary medical expenses for treatment received in the past and, based upon reasonable medical probability, the reasonable medical expenses she will need in the future;

5. Disfigurement in the past and which, in reasonable probability, she will continue to suffer in the future;

6. Loss of earning capacity and wages in the past and future; and

7. Punitive damages.

b. Plaintiff be awarded full, fair, and complete recovery for all claims and causes of action relevant to this action;

c. Plaintiff be awarded all appropriate costs, fees, expenses, and pre-judgment and post judgment interest pursuant to the laws of the State of Pennsylvania as authorized by law on the judgments entered in Plaintiff's behalf; and

d. Such other relief the court deems just and proper.

DEMAND FOR JURY TRIAL

Plaintiff hereby demands trial by jury on all issues.

Respectfully Submitted,

Dated: June 12, 2017

By: s/ A. Craig Eiland

THE LAW OFFICES OF A. CRAIG EILAND, P.C.
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JS 44 (Rev. 06/17)

CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. *(SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)*

I. (a) PLAINTIFFS
Russell Warnke

(b) County of Residence of First Listed Plaintiff _____
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorneys *(Firm Name, Address, and Telephone Number)*
A. Craig Eiland and Bret Stanley - 2211 Strand, Ste. 201, Galveston TX 409-763-3260
The Law Offices of A. Craig Eiland, P.C.

DEFENDANTS
Argon Medical Devices, Inc. and
Rex Medical L.P.

County of Residence of First Listed Defendant Collin County
(IN U.S. PLAINTIFF CASES ONLY)
NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.

Attorneys *(If Known)*

II. BASIS OF JURISDICTION *(Place an "X" in One Box Only)*

- ☐ 1 U.S. Government Plaintiff
- ☐ 3 Federal Question *(U.S. Government Not a Party)*
- ☐ 2 U.S. Government Defendant
- ☒ 4 Diversity *(Indicate Citizenship of Parties in Item III)*

III. CITIZENSHIP OF PRINCIPAL PARTIES *(Place an "X" in One Box for Plaintiff and One Box for Defendant)*
(For Diversity Cases Only)

	PTF	DEF		PTF	DEF
Citizen of This State	☐ 1	☒ 1	Incorporated *or* Principal Place of Business In This State	☐ 4	☒ 4
Citizen of Another State	☒ 2	☐ 2	Incorporated *and* Principal Place of Business In Another State	☐ 5	☒ 5
Citizen or Subject of a Foreign Country	☐ 3	☐ 3	Foreign Nation	☐ 6	☐ 6

IV. NATURE OF SUIT *(Place an "X" in One Box Only)*
Click here for: Nature of Suit Code Descriptions.

CONTRACT
- ☐ 110 Insurance
- ☐ 120 Marine
- ☐ 130 Miller Act
- ☐ 140 Negotiable Instrument
- ☐ 150 Recovery of Overpayment & Enforcement of Judgment
- ☐ 151 Medicare Act
- ☐ 152 Recovery of Defaulted Student Loans (Excludes Veterans)
- ☐ 153 Recovery of Overpayment of Veteran's Benefits
- ☐ 160 Stockholders' Suits
- ☐ 190 Other Contract
- ☐ 195 Contract Product Liability
- ☐ 196 Franchise

TORTS

PERSONAL INJURY
- ☐ 310 Airplane
- ☐ 315 Airplane Product Liability
- ☐ 320 Assault, Libel & Slander
- ☐ 330 Federal Employers' Liability
- ☐ 340 Marine
- ☐ 345 Marine Product Liability
- ☐ 350 Motor Vehicle
- ☐ 355 Motor Vehicle Product Liability
- ☐ 360 Other Personal Injury
- ☐ 362 Personal Injury - Medical Malpractice

PERSONAL INJURY
- ☒ 365 Personal Injury - Product Liability
- ☐ 367 Health Care/ Pharmaceutical Personal Injury Product Liability
- ☐ 368 Asbestos Personal Injury Product Liability

PERSONAL PROPERTY
- ☐ 370 Other Fraud
- ☐ 371 Truth in Lending
- ☐ 380 Other Personal Property Damage
- ☐ 385 Property Damage Product Liability

FORFEITURE/PENALTY
- ☐ 625 Drug Related Seizure of Property 21 USC 881
- ☐ 690 Other

BANKRUPTCY
- ☐ 422 Appeal 28 USC 158
- ☐ 423 Withdrawal 28 USC 157

PROPERTY RIGHTS
- ☐ 820 Copyrights
- ☐ 830 Patent
- ☐ 835 Patent - Abbreviated New Drug Application
- ☐ 840 Trademark

OTHER STATUTES
- ☐ 375 False Claims Act
- ☐ 376 Qui Tam (31 USC 3729(a))
- ☐ 400 State Reapportionment
- ☐ 410 Antitrust
- ☐ 430 Banks and Banking
- ☐ 450 Commerce
- ☐ 460 Deportation
- ☐ 470 Racketeer Influenced and Corrupt Organizations
- ☐ 480 Consumer Credit
- ☐ 490 Cable/Sat TV
- ☐ 850 Securities/Commodities/ Exchange
- ☐ 890 Other Statutory Actions
- ☐ 891 Agricultural Acts
- ☐ 893 Environmental Matters
- ☐ 895 Freedom of Information Act
- ☐ 896 Arbitration
- ☐ 899 Administrative Procedure Act/Review or Appeal of Agency Decision
- ☐ 950 Constitutionality of State Statutes

REAL PROPERTY
- ☐ 210 Land Condemnation
- ☐ 220 Foreclosure
- ☐ 230 Rent Lease & Ejectment
- ☐ 240 Torts to Land
- ☐ 245 Tort Product Liability
- ☐ 290 All Other Real Property

CIVIL RIGHTS
- ☐ 440 Other Civil Rights
- ☐ 441 Voting
- ☐ 442 Employment
- ☐ 443 Housing/ Accommodations
- ☐ 445 Amer. w/Disabilities - Employment
- ☐ 446 Amer. w/Disabilities - Other
- ☐ 448 Education

PRISONER PETITIONS

Habeas Corpus:
- ☐ 463 Alien Detainee
- ☐ 510 Motions to Vacate Sentence
- ☐ 530 General
- ☐ 535 Death Penalty

Other:
- ☐ 540 Mandamus & Other
- ☐ 550 Civil Rights
- ☐ 555 Prison Condition
- ☐ 560 Civil Detainee - Conditions of Confinement

LABOR
- ☐ 710 Fair Labor Standards Act
- ☐ 720 Labor/Management Relations
- ☐ 740 Railway Labor Act
- ☐ 751 Family and Medical Leave Act
- ☐ 790 Other Labor Litigation
- ☐ 791 Employee Retirement Income Security Act

IMMIGRATION
- ☐ 462 Naturalization Application
- ☐ 465 Other Immigration Actions

SOCIAL SECURITY
- ☐ 861 HIA (1395ff)
- ☐ 862 Black Lung (923)
- ☐ 863 DIWC/DIWW (405(g))
- ☐ 864 SSID Title XVI
- ☐ 865 RSI (405(g))

FEDERAL TAX SUITS
- ☐ 870 Taxes (U.S. Plaintiff or Defendant)
- ☐ 871 IRS—Third Party 26 USC 7609

V. ORIGIN *(Place an "X" in One Box Only)*

☒ 1 Original Proceeding | ☐ 2 Removed from State Court | ☐ 3 Remanded from Appellate Court | ☐ 4 Reinstated or Reopened | ☐ 5 Transferred from Another District *(specify)* | ☐ 6 Multidistrict Litigation - Transfer | ☐ 8 Multidistrict Litigation - Direct File

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing ***(Do not cite jurisdictional statutes unless diversity)***:

Brief description of cause:
Product Liabililty Case - Inferior Vena Cava Filter Implant

VII. REQUESTED IN COMPLAINT:

☐ CHECK IF THIS IS A **CLASS ACTION** UNDER RULE 23, F.R.Cv.P.

DEMAND $ 5,000,000.00

CHECK YES only if demanded in complaint:
JURY DEMAND: ☒ Yes ☐ No

VIII. RELATED CASE(S) IF ANY

(See instructions): JUDGE _____ DOCKET NUMBER _____

DATE 06/12/2017

SIGNATURE OF ATTORNEY OF RECORD /s/ A. Craig Eiland

FOR OFFICE USE ONLY

RECEIPT # _____ AMOUNT _____ APPLYING IFP _____ JUDGE _____ MAG. JUDGE _____

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