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CAUSE NO. 296-02801-2016

AMY C. RUDY,	§	IN THE DISTRICT COURT FOR
	§	
Plaintiff,	§	
•	§	
vs.	§	
	§	COLLIN COUNTY, TEXAS
ARGON MEDICAL DEVICES, INC.	§	
and REX MEDICAL, INC., d/b/a	§	
REX MEDICAL, L.P. and REX	§	
MEDICAL, L.P.	§	
	§	
Defendants.	§	JUDICIAL DISTRICT

PLAINTIFF'S ORIGINAL PETITION

TO THE HONORABLE JUDGE OF SAID COURT:

COMES NOW Amy C. Rudy, Plaintiff, and files this Original Petition complaining of Argon Medical Devices, Inc., Rex Medical, Inc. d/b/a Rex Medical, L.P. and Rex Medical, L.P. and for cause of action would respectfully show this Honorable Court the following:

I. <u>Discovery Control Plan</u>

1.1 Discovery in this matter is intended to be conducted under Level 3 of the Texas Rules of Civil Procedure.

II. PARTIES

- 2.1 Plaintiff Amy C. Rudy is a natural person residing in Greenville, Darke County, Ohio.
- 2.2 Defendant Argon Medical Devices, Inc. is a Delaware corporation that maintains its corporate headquarters and principal place of business in Collin County, Texas at 5151 Headquarters Drive, Suite 201, Plano, Texas. Argon Medical Devices, Inc., may be served with process by delivering a Citation with a copy of this Petition attached thereto, to its registered agent, National

Corporate Research, Ltd., 1601 Elm Street, Suite 4360, Dallas, Texas 75201. Argon Medical Devices, Inc., has conducted business in and derived substantial revenue from sales of its products, including the Defendants' IVC filters, in Texas.

- 2.3 Defendant Rex Medical, Inc. d/b/a Rex Medical, L.P. is a Pennsylvania corporation is the general partner of Defendant Rex Medical, L.P. Defendant Rex Medical, Inc.'s principal place of business is located at 1100 E. Hector Street, Suite 245, Conshohoken, Montgomery County, Pennsylvania 19428. Rex Medical, Inc. may be served with process by delivering a Citation with a copy of this Petition attached thereto, via certified mail, return receipt requested, to its president, William W. Gardner at 1100 E. Hector Street, Suite 245, Conshohocken, Pennsylvania 19428-2397. Rex Medical, Inc. has conducted business in and derived substantial revenue from sales of its products, including the Defendants' IVC filters, in Texas.
- 2.4 Defendant Rex Medical, L.P. is a partnership organized under the laws of the State of Pennsylvania with its principal place of business located at 1100 E. Hector Street, Suite 245, Conshohocken, Montgomery County, Pennsylvania 19428. Rex Medical, L.P. may be served with process by delivering a Citation with a copy of this Petition attached thereto, via certified mail, return receipt requested, to its general partner Rex Medical, Inc., by serving William W. Gardner, President of Rex Medical, Inc. at 1100 E. Hector Street, Suite 245, Conshohocken, Pennsylvania 19428-2397.
 - 2.5 Defendant Argon Medical Devices, Inc. shall be referred to herein as "Argon".
- 2.6 Defendants Rex Medical, Inc. d/b/a Rex Medical, L.P. and Rex Medical, L.P. shall be referred to herein individually by name or jointly as the "Rex Defendants."
- 2.7 At all times alleged herein, the Rex Defendants include and included any and all parent companies, subsidiaries, affiliates, divisions, franchises, partners, joint venturers, and

organizational units of any kind, their predecessors, successors and assigns and their officers, directors, employees, agents, representatives and any and all other persons acting on their behalf.

- 2.8 At all times herein mentioned, each of the Rex Defendants was the agent, servant, partner, predecessors in interest, and joint venturer of each other and were at all times operating and acting with the purpose and scope of said agency, service, employment, partnership, joint enterprise and/or joint venture.
- 2.9 At all times herein mentioned, Argon was the agent, servant, partner, predecessors in interest, and joint venturer of the Rex Defendants and was at all times operating and acting within the purpose and scope of said agency, service, employment, partnership, joint enterprise and/or joint venture.
- 2.10 At all times relevant to this cause of action, Argon and the Rex Defendants were conducting, and continue to conduct, business throughout the United States, including the State of Texas. At all times relevant to this cause of action, Argon and the Argon and the Rex Defendants maintained, and continue to maintain, significant, systematic and continuous contacts with the State of Texas. Argon and the Rex Defendants develop, manufacture, sell and distribute medical devices for use in various applications including vascular surgical products throughout the State of Texas, the United States, and around the world, including Collin County. Argon's and the Rex Defendants' products include the Option Vena Cava Filter, which is used for the prevention of recurrent pulmonary embolism via placement in the vena cava.
- 2.11 Upon information and belief, Argon and the Rex Defendants, each and all, expected or should have expected its acts to have consequence within the United States of America and the State of Texas, and derived substantial revenue from interstate commerce within the United States and the State of Texas.

III. JURISDICTION & VENUE

- 3.1 Defendant Argon maintains its headquarters, principal office and/or principal place of business in Collin County, Texas, meaning Collin County, Texas is a place where Argon's officers, direct, control and coordinate the corporation's activities and the decision makers for Argon conduct the daily affairs of the organization. Thus, jurisdiction and venue are proper in Collin County, Texas. *See*, 28 U.S.C. 1332(c)(1); Tex. Civ. Prac. & Rem.§§ 15.001(a) & 15.002(a)(3). The damages sought are within the jurisdictional limits of this Court.
- 3.2 Venue is proper as to Argon, therefore this court also has venue over the Rex Defendants as all claims or actions arise out of the same transaction, occurrence, or series of transactions or occurrences. Tex. Civ. Prac. & Rem. §§ 15.005.

IV. FACTS

- 4.1 Argon and the Rex Defendants design, research, develop, manufacture, test, market, advertise, promote, distribute, and/or sell products such as IVC filters that are marketd and sold as a temporary/retrievable device to prevent, among other things, recurrent pulmonary embolism via placement in the vena cava. One such product is the Option Vena Cava Filter.
- 4.2 The Option Vena Cava Filter is referred to herein as the Option filter.
- 4.3 The Defendants sought Food and Drug Administration ("FDA") clearance to market the Option filter and/or its components under Section 510(k) of the Medical Device Amendment.
- 4.4 On or about June 4, 2009, the Defendants obtained FDA clearance to market the Option filter device and/or its components under Section 510(k) of the Medical Device Amendment.
- 4.5 Section 510(k) allows marketing of medical devices if the device is deemed substantially equivalent to other legally marketed predicate devices without formal review for the

safety or efficacy of said device.

- 4.6 An IVC filter, like the Option Filter, is a device designed to filter blood clots (called "thrombi") that would otherwise travel from the lower portions of the body to the heart and lungs. IVC filters may be designed to be implanted, either temporarily or permanently, within the vena cava.
- 4.7 The inferior vena cava is a vein that returns blood to the heart from the lower portion of the body. In certain people, and for various reasons, thrombi travel from vessels in the legs and pelvis, through the vena cava into the lungs. Often these thrombi develop in the deep leg veins. The thrombi are called "deep vein thrombosis" or DVT. Once the thrombi reach the lungs, they are considered "pulmonary emboli" or PE.
- 4.8 An IVC filter, like the Option filter, is ostensibly designed to prevent thromboembolic events by filtering or preventing blood clots/thrombi from traveling to the heart and/or lungs.
- 4.9 The Option filter was designed, manufactured marketed and sold a retrievable filter. The Defendants represented that the Option filter was be based on the Bard Recovery filter, Bard Recovery G2 filter, the Gunther Tulip filter, the Cordis Trapease Vena Cava filter and the Cordis Optease Vena Cava filter.
- 4.10 The Option filter consists of shape memory nitinol struts emanating from a central location which is represented to be designed for clot capture.
- 4.11 On or about December 7, 2013, Plaintiff was implanted with an Argon Option filter in response to the presence of deep vein thrombosis.
- 4.12 On June 30, 2014, Ms. Rudy presented to the Dayton Interventional Radiology Clinic for removal of her Option filter. During the attempted retrieval procedure, the physicians

found the Option filter had tilted and become embedded in her vena cava. The filter could not be removed. During the procedure she developed chest pain and was instructed to report directly to the Emergency Department at Kettering Hospital. At the Kettering Hospital she was found to have chest pain/pressure and an elevated troponin level. She was admitted to the hospital for further evaluation and discharged on July 1, 2014.

- 4.13 In November of 2014, Ms. Rudy suffered from recurrent thrombosis in her lower extremity. These recurrent clots have resulted in further pain, physical disability and a need for additional medical care.
- 4.14 Plaintiff's injury was inherently undiscoverable or objectively verifiable such that, despite Plaintiff's reasonable diligence, she was unable to discover her injury until on or about June 30, 2014, when she presented for retrieval of her Option filter.
- 4.15 As long as the Option filter remains embedded in her vena cava, Plaintiff is at risk for further thrombosis and future filter fractures, migrations and perforations and tilting. She faces numerous health risks, including the risk of death. Plaintiff will require ongoing medical monitoring for the rest of her life.
- 4.16 At all times relevant hereto, the Option filter was widely advertised and promoted by Argon and the Rex Defendants as a safe and effective treatment for prevention of recurrent pulmonary embolism via placement in the vena cava.
- 4.17 At all times relevant hereto, Argon and the Rex Defendants knew the Option filter was defective and knew that the defect was attributable to the design's failure to withstand the normal anatomical and physiological loading cycles exerted in vivo.
- 4.18 Argon and the Rex Defendants failed to disclose to physicians, patients, or Plaintiff that its Option filter was subject to tilting, embedment, breakage and migration or the appropriate

degree of risk of perforation and damage to the vena cava wall.

- 4.19 At all times relevant hereto, Argon and the Rex Defendants continued to promote the Option filter as safe and effective even though the clinical trials that had been performed were not adequate to support long or short term efficacy.
- 4.20 Argon and the Rex Defendants concealed the known risks and failed to warn of known or scientifically knowable dangers and risks associated with the Option filter, as aforesaid.
- 4.21 The failure of the Option filter is attributable in part to the fact that the Option filter suffers from a design defect causing it to be unable to withstand the normal anatomical and physiological loading cycles exerted in vivo.
- 4.22 At all times relevant hereto, Argon and the Rex Defendants failed to provide sufficient warnings and instructions that would have put Plaintiff and the general public on notice of the dangers and adverse effects caused by implantation of the Option filter, including, but not limited to, the design's failure to withstand the normal anatomical and physiological loading cycles exerted in vivo.
- 4.23 The Option filter was designed, manufactured, distributed, sold, and/or supplied by Argon and the Rex Defendants, and was marketed while defective due to the inadequate warnings, instructions, labeling, and/or inadequate testing in light of Argon's and the Rex Defendants' knowledge of the product's failure and serious adverse events.
- 4.24 At all times relevant hereto, the officers and/or directors of Argon and the Rex Defendants named herein participated in, authorized, and/or directed the production and promotion of the aforementioned products when they knew or should have known of the hazardous and dangerous propensities of said products, and thereby actively participated in the tortious conduct that resulted in the injuries suffered by Plaintiff.

Causes of Action Argon Medical Devices, Inc., Rex Medical, Inc. d/b/a Rex Medical L.P. and Rex Medical L.P.

Negligence

- 5.1 At all times relevant hereto, Argon and the Rex Defendants were under a duty to act reasonably to design, develop, manufacture, market and sell a product that did not present a risk of harm or injury to the Plaintiff and to those people receiving the Option filter.
- 5.2 At the time of manufacture and sale of the Option filter, Argon and the Rex Defendants knew or reasonably should have known that the Argon and the Rex Filter:
 - a. Was designed and manufactured in a way so as to present an unreasonable risk of tilt and or embedment;
 - b. Was designed and manufactured so as to present an unreasonable risk perforation and/or damage to the vena cava wall;
 - c. Was designed and manufactured in such a manner so as to present an unreasonable risk of fracture of portions of the device;
 - d. Was designed and manufactured so as to present an unreasonable risk of migration of the device and/or portions of the device;
 - e. Was designed and manufactured to have unreasonable and insufficient strength or structural integrity to withstand normal placement within the human body; and/or
 - f. Was designed and manufactured in a way that increased the potential for recurrent thrombosis and clot formation.
- 5.3 Argon and the Rex Defendants breached their duty of reasonable care and were negligent in:
 - a. Unreasonably and carelessly failing to properly warn of the dangers and risks of harm associated with the Option Filter, specifically its incidents of tilt, embedment, fracture, migration, perforation, recurrent thrombosis and other failures;
 - b Unreasonably and carelessly designed, manufactured, marketed and sold a product that was insufficient in strength or structural integrity to withstand the foreseeable use of normal placement within the human body; and

- c. Unreasonably and carelessly designed, manufactured, marketed and sold a product that presented a risk of harm to Plaintiff and others similarly situated in that it was prone to fail.
- 5.4 As a direct and proximate result of Argon's and the Rex Defendants' negligence, as described herein, Plaintiff has suffered and will continue to suffer serious physical injuries, pain and suffering, mental anguish, medical expenses, economic loss, disability, and other losses, in an amount to be determined at trial.

Strict Product Liability – Failure to Warn

- 5.5 Argon and the Rex Defendants designed, set specifications, manufactured, prepared, compounded, assembled, processed, marketed, labeled, distributed, and sold the Option 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.
- 5.6 At the time Argon and the Rex Defendants designed, manufactured, prepared, compounded, assembled, processed, marketed, labeled, distributed, and sold the device into the stream of commerce, Argon and the Rex 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.
- 5.7 Argon and the Rex Defendants knew or should have known at the time they manufactured, labeled, distributed and sold the Option filter, which was implanted in Plaintiff, that the filter posed a significant risk of device failure (tilt, embedment, perforation of the vena cava wall, fracture, migration and recurrent thrombosis) and resulting serious injuries.
- 5.8 Argon and the Rex 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. Argon and the Rex 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.

- 5.9 Argon and the Rex Defendants failed to adequately warn of material facts regarding the safety and efficacy of the Option filter, and further failed to adequately provide instructions on the safe and proper use of the device. These failures rendered the Cook Filter unreasonably dangerous to Plaintiff.
- 5.10 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 prescribing healthcare providers and/or ultimate users of the device.
- 5.11 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.
- 5.12 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.
- 5.13 The Option 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.
- 5.14 The Option filter implanted in Plaintiff was in the same condition as when it was manufactured, inspected, marketed, labeled, promoted, distributed and sold by Argon and the Rex Defendants.
- 5.15 As a direct and proximate result of Argon's and the Rex Defendants' lack of sufficient warning and/or instructions, Plaintiff has suffered and will continue to suffer serious

physical injuries, pain and suffering, mental anguish, medical expenses, economic loss, disability, and other losses, in an amount to be determined at trial.

Strict Product Liability - Defective Design

- 5.16 At all times relevant to this action, Argon and the Rex Defendants developed, tested, designed, manufactured, inspected, labeled, promoted, distributed and sold into the stream of commerce the Option filter, including the one implanted in Plaintiff.
- 5.17 The Option filter was expected to, and did, reach its intended consumers without substantial change in the condition in which it was in when it left Argon's and the Rex Defendants' possession. In the alternative, any changes that were made to Option filter implanted in Plaintiff were reasonably foreseeable to Argon and the Rex Defendants.
- 5.18 The Option filter implanted in Plaintiff was defective in design in the following ways:
 - a. It failed to perform as safely as persons who ordinarily use the product would have expected at the time of use; and
 - b. Its risks of harm exceeded its claimed benefits.
- 5.19 Argon and the Rex Defendants knew that safer alternative designs were available, which would have prevented or significantly reduced the risk of the injury presented by Option filter. Further, it was economically and technologically feasible at the time the filter left the control of the Defendants to prevent or reduce the risk of such a dangerous event by application of existing, or reasonably achievable, scientific knowledge.
- 5.20 Plaintiff and Plaintiff's health care providers used the Option filter in a manner that was reasonably foreseeable to Argon and the Rex Defendants.
- 5.21 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.

- 5.22 The defective design of the Option filter was a producing cause of Plaintiff's injuries.
- 5.23 As a result of the Option filter's defective design, Plaintiff has suffered and will continue to suffer serious physical injuries, pain and suffering, mental anguish, medical expenses, economic loss, disability, and other losses, in an amount to be determined at trial.

Strict Liability - Manufacturing Defect

- 5.24 Argon and the Rex Defendants designed, set specifications, manufactured, prepared, compounded, assembled, processed, marketed, labeled, distributed, and sold the Option filter that was implanted into Plaintiff.
- 5.25 At the time it left Argon and the Rex Defendants' control and possession, the Option filter implanted in Plaintiff contained a deviation from design that rendered it unreasonably dangerous.
- 5.26 Plaintiff and Plaintiff's health care providers used the device in a manner that was reasonably foreseeable to Argon and the Rex Defendants.
- 5.27 The manufacturing defect of the Option filter was a producing cause of Plaintiff's injuries.
- 5.28 As a result of the Option filter's manufacturing defect, Plaintiff has suffered and will continue to suffer serious physical injuries, pain and suffering, mental anguish, medical expenses, economic loss, disability, and other losses, in an amount to be determined at trial.

Breach of Express Warranty

5.29 Argon and the Rex Defendants breached express warranties under the Texas Business and Commerce Code §2.313.

- 5.30 Plaintiff, through her medical providers, purchased the Option filter from Argon and the Rex Defendants.
- 5.31 At the time and place of sale, distribution, and supply of the Option filter to Plaintiff, Argon and the Rex Defendants expressly represented and warranted that the Option filter was safe.
- 5.32 Plaintiff, through her attending physicians, relied on these representations in determining which IVC filter to use for implantation in Plaintiff.
- 5.33 At the time of Plaintiff's purchase from Argon and the Rex Defendants, the Option filter was not safe, in that:
 - a. It was designed in such a manner so as to be prone to an unreasonably high incident of tilt, embedment, fracture, perforation of vessels and organs, and/or migration;
 - b. It was designed in such a manner so as to result in an unreasonably high incident of injury to the organs including the vena cava of its purchaser; and
 - c. It was manufactured in such a manner that the Option filter would weaken and fail.
- 5.34 Argon's and the Rex Defendants' filter was unfit and unsafe for use by users as it posed an unreasonable and extreme risk of injury to persons using said products, and accordingly, Argon and the Rex Defendants breached their expressed warranties associated with the product.
- 5.35 As a direct and proximate result of the Option filter's defects, as described herein, Plaintiff has suffered and will continue to suffer serious physical injuries, pain and suffering, mental anguish, medical expenses, economic loss, disability, and other losses, in an amount to be determined at trial.

Breach of Implied Warranties of Merchantability and Fitness for a Particular Purpose

- 5.36 Argon and the Rex Defendants breached the implied warranties of merchantability and fitness for a particular purpose under the Texas Business and Commerce Code §§2.314 and 2.315.
- 5.37 Plaintiff, through her medical providers, purchased the Option filter from Argon and the Rex Defendants.
- 5.38 At all times material to this cause of action, Argon and the Rex Defendants were merchants of goods of the kind including medical devices and vena cava filters (like the Option filter).
- 5.39 At the time and place of sale, distribution, and supply of the Option filter to Plaintiff, Argon and the Rex Defendants impliedly warranted that the product was reasonably fit for its intended purpose and was of marketable quality.
- 5.40 At the time the Option filter left Argon and the Rex Defendants' possession, and at the time of Plaintiff's purchase from Defendants, the Option filter 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 incident of tilt, embedment, fracture, perforation of vessels and organs, and/or migration;
 - b. It was designed in such a manner so as to result in an unreasonably high incident of injury to the organs including the vena cava of its purchaser; and
 - c. It was manufactured in such a manner so that the Option filter would weaken and fail.
 - 5.41 Additionally, implied warranties were breached as follows:
 - a. Argon and the Rex Defendants failed to provide the warnings or instructions and/or adequate warnings or instructions which a manufacturer exercising reasonable care would have provided concerning the risks, in light of the likelihood that the Option filter would cause harm;
 - b. Argon and the Defendants manufactured and/or sold the Option filter and that

- filter did not conform to representations made by the Defendants when it left Argon's and the Rex Defendants' control;
- c. Argon and the Rex Defendants manufactured and/or sold the Option filter, device that was more dangerous than an ordinary consumer would expect when used in an intended or reasonably foreseeable manner, and the foreseeable risks associated with the Option filter design or formulation exceeded the benefits associated with that design. These defects existed at the time the product left Argon's and the Rex Defendants' control; and
- d. Argon and the Rex Defendants manufactured and/or sold the Option filter when it deviated in a material way from the design specifications, formulas or performance standards or form otherwise identical units manufactured to the same design specifications, formulas, or performance standards, and these defects existed at the time the product left Argon's and the Rex Defendants' control.
- 5.42 Further, Argon's and the Rex Defendants' marketing of the Option filter was false and/or misleading.
- 5.43 Plaintiff, through her attending physicians, relied on these representations in determining which IVC filter to use for implantation in the Plaintiff.
- 5.44 Argon's and the Rex Defendants' filter was unfit and unsafe for use by users as it posed an unreasonable and extreme risk of injury to persons using said products, and accordingly Defendants breached the implied warranties associated with the product.
- 5.45 As a direct and proximate result of the Option filter's defects, as described herein, Plaintiff has suffered and will continue to suffer serious physical injuries, pain and suffering, mental anguish, medical expenses, economic loss, disability, and other losses, in an amount to be determined at trial.

Negligent Misrepresentation

5.46 At all times relevant to this cause, and as detailed above, Argon and the Rex

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 filter, including, but not limited to, misrepresentations relating to the following subject areas:

- 1. The safety of the Option filter;
- 2. The efficacy of the Option filter;
- 3. The rate of failure of the Option filter; and
- 4. The approved uses of the Option filter.
- 5.47 The information distributed by Argon and the Rex Defendants to the public, the medical community and Plaintiff's health care providers was in the form of reports, press releases, advertising campaigns, labeling materials, print advertisements, commercial media containing material representations, which were false and misleading, and contained omissions and concealment of the truth about the dangers of the use of the Option filter. These materials included instructions for use and warning document that was included in the package of the Option filter that was implanted in Plaintiff.
- 5.48 Argon and the Rex Defendants did not exercise reasonable care or competence in communicating the information. Argon and the Rex Defendants made the foregoing misrepresentations knowing that they were false or without reasonable basis.
- 5.49 Argon's and the Rex Defendants' intent and purpose in making these representations 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 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 filter.

- 5.50 The foregoing representations and omissions by Argon and the Rex Defendants were in fact false. The Option filter is not safe, fit and effective for human use in its intended and reasonably foreseeable manner. The use of the Option 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.
- 5.51 In reliance upon the false and negligent misrepresentations and omissions made by Argon and the Rex Defendants, Plaintiff and Plaintiff's health care providers were induced to, and did use the Option filter, thereby causing Plaintiff to sustain severe and permanent personal injuries.
- 5.52 Argon and the Rex 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 Argon and the Rex Defendants, and would not have prescribed and implanted same if the true facts regarding the device had not been concealed and misrepresented by Defendants.
- 5.53 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 filter.
- 5.54 At the time Defendants failed to disclose and misrepresented the foregoing facts, and at the time Plaintiff used the Option filter, Plaintiff and Plaintiff's health care providers were unaware of said Defendants' negligent misrepresentations and omissions.
- 5.55 Plaintiff, Plaintiff's health care providers, and general medical community reasonably relied upon the foregoing misrepresentations and omissions made by Argon and the Rex Defendants where the concealed and misrepresented facts were critical to understanding the

true dangers inherent in the use of the Option filter.

5.56 As a direct and proximate result of Plaintiff's and Plaintiff's health care provider's reliance on the foregoing misrepresentations and omissions by Argon and the Rex Defendants, Plaintiff has suffered and will continue to suffer serious physical injuries, pain and suffering, mental anguish, medical expenses, economic loss, loss of enjoyment of life, disability, and other losses, in an amount to be determined at trial.

VI. ACTUAL DAMAGES

- 6.1 Plaintiff re-alleges and incorporates by reference each and every allegation contained in the foregoing paragraphs as though fully set forth herein.
- 6.2 As a direct and proximate cause of Argon and the Rex Defendants' wrongful conduct, as set forth above, Plaintiff Amy C. Rudy seeks compensation for the following injuries and damages:
 - a. Past and future pain and suffering;
 - b. Past and future mental anguish;
 - c. Past and future physical impairment; and
 - d. Past and future medical expenses.

VII. EXEMPLARY DAMAGES

- 7.1 Plaintiff re-alleges and incorporates by reference each and every allegation contained in the foregoing paragraphs as though fully set forth herein.
- 7.2 The actions of Argon and the Rex Defendants, when viewed objectively, involved an extreme degree of risk, considering the probability and magnitude of potential harm to Plaintiff. Further, Argon and the Rex Defendants had actual, subjective awareness of the risk, but

nevertheless proceeded with conscious indifference to the rights, safety, or welfare of Plaintiff.

Such acts constitute gross negligence as the term is defined by Texas law and, therefore, Plaintiff is entitled to exemplary damages.

VIII. <u>Rule 47 Statement</u>

8.1 As required by Texas Rule of Civil Procedure 47(c), Plaintiff's counsel states that Plaintiff seeks monetary relief over \$1,000,000.00; however, Plaintiff recognizes and appreciates that the amount of monetary relief actually awarded will ultimately be determined by the jury. The damages sought are within the jurisdictional limits of the court.

IX. CLAIM FOR INTEREST

9.1 Plaintiff seeks all court costs and pre-judgment and post-judgment interest in accordance with the maximum legal interest rates allowable as interpreted under the laws of the State of Texas.

X. Conditions Precedent

10.1 All conditions precedent have been performed or have occurred.

XI. Intent to Use Defendants' Documents

11.1 Any document produced by each and every Defendant in response to written discovery will be used by Plaintiff at any pretrial proceeding, hearing, or trial.

XII. REQUEST FOR DISCLOSURE

12.1 Pursuant to Rule 194 of the Texas Rules of Civil Procedure, each Defendant is requested to disclose, within (50) days of service of this request, the information, or material described in Rule 194.2(a)-(1).

XIII. Jury Dem<u>and</u>

13.1 The Plaintiff requests that a jury be convened to try the factual issues in this cause.

WHEREFORE, PREMISES CONSIDERED, Plaintiff demands judgment against the Defendants, jointly and/or severally, in an amount well in excess of the minimum jurisdictional amount of this Court, plus prejudgment and post-judgment interest, costs of Court, and such further relief, general and special, both at law or in equity, to which Plaintiff may show herself justly entitled.

Respectfully submitted,
LAW OFFICES OF BEN C. MARTIN

/s/ Ben C. Martin

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