UNITED STATES DISTRICT COURT OF MARYLAND
SOUTHERN DISTRICT

Monica Jeffries, pro se
Estate Next of Kin

Plaintiff

Civil Action No.: RWT 15CV3480

COMPLAINT FOR DAMAGES
DEMAND FOR A JURY TRIAL

Boston Scientific et.al.
Contact: Charles Rudnick (508)650-8660
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Boston Scientific Corporate Headquarters
300 Boston Scientific Way
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&
Boston Scientific/ Ray Elliott CEO
480 Pleasant Street, Watertown, MA 02172
Resident Agent: CSC-Lawyers Incorparating Service Company
7 St. Paul Street, #820, Baltimore Maryland, 21202

Defendants

COMPLAINT

Comes now the plaintiff Monica Jeffries pro SE and in proper person, hereby sue defendant Boston Scientific ET AL., a subsidiary corporation and or division of Boston Scientific et. al. (collectively, the Defendants) and allege as follows:

1. This is an action for damages relating to Defendants development, testing, assembling, manufacturing, packaging, labeling, preparing, distribution, marketing, supplying and or selling the defective product sold under the name 'inferior vena cava filter' (hereinafter 'IVC filter').

PARTIES TO THIS MATTER

2. Plaintiff Monica Jeffries and next of kin at all times relevant to this action resided in, continued to reside in, and are citizens of Oxon Hill Maryland which is located in Prince Georges County.

3. Defendants Boston Scientific ET AL is a corporation duly organized and existing under the laws of the state of Maryland and his its principle place of business at the address hereto included. Boston Scientific at all times relevant to this action, designed, set specifications, manufactured, prepared, compounded, assembled, processed, marketed, distributed, and sold the 'Greenfield vena cava filter' system to be implanted in patients throughout the United States, including Maryland. At all times relevant hereto, Defendants Boston Scientific was or has been engaged in business in Maryland, and has conduct substantial business activity in Maryland. Defendants has also carried on solicitations or service activities in the State of Maryland. Service of Process can be had

on Defendants Boston Scientific, Inc. by serving it's registered agent,CSC.

4. Defendants Boston Scientific, Inc. (Boston Scientific) is a wholly owned subsidiary corporation of defendants Boston Scientific, with its principal place of business at all times: 480 Pleasant Street, Watertown, MA 02172 relevant to this action, designed, set specifications, manufacturing, prepared, compounded, assembling, processed, marketed, distributed, and sold the Greenfield IVC filter to be implanted in patients throughout the United States, including Maryland. At all relevant times relevant hereto, Defendants Boston Scientific has also carried on solicitations or service activities in the State of Maryland. Service of process can be had on defendants Boston Scientific ET AL by serving its registered agent,CSC-Lawyers Incorporating Service Company.

JURISDICTION AND VENUE

5. Jurisdiction is proper in this Court under 28 U.S.C. § 1332(a)(1) because the plaintiff and the defendants are citizens of different states, and the amount in controversy exceeds $750,000 excluding interest and costs.

6. On December 2, 2005, defendants Boston Scientific Corporation announced this it is recalling all Stainless Steel Greenfield Vena Cava Filter with 12Fr femoral Introducer Systems manufacture before March 10, 2004.

GENERAL FACTUAL ALLEGATIONS

7. Plaintiff brings this case for serious injuries suffered as a result of a surgically implanted medical device, know as a "Greenfield IVC Filter", causing serious an ongoing physical, emotional, and economic damages, heart issues, migration and perforations.

8. The Greenfield IVC filter was designed, manufactured, prepared, compounded, assembling, processed, labeled, marketed, distributed, and sold by defendants from inception of plaintiffs Greenfield IVC to the present for prevention of blood clots (thrombi) from traveling from the lower portions of the body to the heart and lungs.

9. Prior to Plaintiff Monica Jeffries being implanted with the Greenfield IVC on or before March, 2004, Defendants knew and should have known that the device was defective and unreasonably dangerous or, *inter alias,* the following reasons:

a. Defendants failed to conduct any 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 Greenfield IVC filter had a high rate of fracture, migration, and excessive tilting and perforation of the vena cava wall once implanted in the human body. Defendants clearly knew and should have known that ch failures exposed patients to serious injuries, including: death, hemorrhage, cardiac/pericardium tampering, 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. Upon information and belief, defendants also know 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.

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c. Further, defendants knew and or should have known that the Greenfield IVC filter contained conditions, which defendants did not intend, which resulted in the device not performing as safely as the ordinary customer would expect.

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

e. Even when defendants designed an began marketing what they allege to be a device that specifically reduced these risks, they still failed to issue a recall or notify consumers that a safer device was available.

INFERIOR VENA CAVA FILTER GENERALLY

10. The IVC filter at issue in this matter bears the trademark name "Greenfield" IVC filter. The 'Greenfield' IVC filter was manufactured, marketed, and sold by defendants, Boston Scientific from sometime prior to March 2004 until approximately 2007. Defendants have now ceased manufacturing and selling the Greenfield filter throughout the United States and abroad.

11. 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.

12. 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 be implanted, either permanently or temporarily, in the human body, more specifically, within the inferior vena cava.

13. The inferior vena cava is a vein that returns blood to the heart from 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 embolism' or 'PE'. Pulmonary emboli present grave risks to human health. They can, and often do result in death.

14. Certain people are at increased risk or the development of DVT or PE. For instance someone who undergoes knee or hip and joint replacement is at risk for development DVT/PE. Obese patients are also at increased risk fo9r 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.

15. 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.

16. As stated in this Complaint, IVC filters have been on the market for decades. The first IVC filter was introduced in the later 1960's. Since then, the market has been supplemented with all types an designs of filters offered by many different manufacturers.

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17. Over the years, a concern developed within the medical community, which was shared with IVC filter manufacturers, that an IVC filter should be designed and manufactured so that it is able to be retrieved from the human body. Ultimately, retrievable IVC filter designs were offered in the market. However, these IVC filter designs were not intended to remain with 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 Greenfield filter was introduced to the market in the late 1960's (and subsequently removed from the market in late 2004 as an IVC filter that was able to be retrieved after an indeterminate time of placement within the human body.

THE GREENFIELD IVC FILTER

18. The 2004 recall of the Greenfield IVC filters, include the Stainless Steel Greenfield® Vena at the Cava Filter with 12Fr Femoral Introducer Systems manufactured prior to March 10, 2004. All unused devices with a 'use before date' prior to March 2007 are to be returned to Boston Scientific. The product code for these devices under recall is M001505010. The total number of devices involved in this recall is estimated at 18,000.

19. The company is initiating this recall because of reports of detachment, perforation of the vena cava, detachment at the bond between the carrier capsule and the outer sheath of the filters delivery system during the implant procedures. If the carrier capsule should detach during an implantation procedures, there is a risk of cardiac and pulmonary embolization. Potential adverse events include serious patient injury even death.

20. As stated *supra*, the Greenfield IVC filter was indeed the predecessor/predicate device for many other IVC filters to follow. Soon after its introduction to the market, reports were made that portions of the device-were fracturing and migrating to the anatomy an vital organs of the patients in whom it was implanted. These reports continued to surface and were made to healthcare providers, the FDA, and to the defendants. In fact, as early a 1960's, the defendants were made aware that the Greenfield IVC was severely flawed an was causing injuries and even death to patients who had the filter implanted in their bodies.

21. The company initiated this recall after a review of complaint records and analysis of returned devices revealed the potential problems. A total of eight complaints were received, exclusive of this current complaint, o which two were reported as involving serious patient injury requiring intervention and one was reported as a death.

22. A vena cava filter is a small cone shaped device that is implanted in the inferior Vena cava, the large vein that carries blood from the lower part of the body to the heart. The filter prevents pulmonary embolization by capturing blood clots before they can be carried to the lungs. The blood clots are trapped in the filter which blood flows both through and around the entrapped clot, allowing the clot to dissolve naturally.

23. The products affected by this recall were distributed to hospitals worldwide. Boston Scientific the defendants should have notified affected hospitals through detailed recall notification letters, including instruction on how to return recalled products.

24. Patients in whom the diameter of the inferior vena cava exceeds 28 mm (for example some patients wit congestive heart failure) are contraindicated for Greenfield Titanium vena Filter

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placement. Proper fixation of the Greenfield Titanium Vena Cava Filter in the IVC may be compromised when Cava diameter exceeds 28 mm.

25. Presence of thrombosis the femoral juncture site, in the iliac vein or in the inferior vena cava risks the dis-lodgement and embolism of thromboembolic during catheter manipulation. These conditions are absolute contraindications to implantation via femoral vein approach.

'GREENFIELD VENA CAVA FILTERS'

26. Current indications for Greenfield Titanium Vena Cava Filter placement are as follows: When adequate anti coagulation fails to prevent recurrent embolism.

27. Patients with venous thrombosis or pulmonary embolism who have a contraindication to anti coagulation, or are difficult to manage on anticoagulant.

28. The Greenfield IVC filter should not be activated prior to proper positioning in the Vena cava, a the Greenfield Titanium Vena Cava filter cannot be safely reloaded into the carrier capsule, and should not be modified in any way prior to release.

29. There should never be an attempt to remove or reposition a filter when the hooks are engaged in vessel or heart walls. As in the plaintiffs case the removal of the IVC filter makes it very dangerous and may not be retrievable at all.

30. Any attempt per cutaneous or repositioning of a filter with hooks engaged in a vessel is close to grave risks.

31. A misplaced filter which nevertheless provides adequate protection against pulmonary embolism should be left in place. If the filter is not positioned to give adequate protection against pulmonary embolism, a second filter should be placed.

32. Operative removal has been recommended for a misplace filter which may interfere with the function of the cuspid valve and or produce cardiac rhythm disturbance.

33. A relative contraindication exists for this device for younger patients whose life expectancy is substantially greater than the clinical experience is substantially greater than the clinical experiences of the Greenfield Vena Cava Filter.

WHAT HAPPENS WHEN THE GREENFIELD FILTER FAILS

34. Failure (fracture and or migration,or perforation) of the Greenfield filter leads to a number of different, and potentially fatal, complications. These complications include, but are not limited to:

    1. Death
    2. Hemorrhage
    3. Cardiac pericardium tamponade
    4. Severe and persistent pain
    5. Perforation and migration to other organs

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6. Incorrect release or placement of the filter
7. Formation of clots on the Filter which could result in complete blockage
8. Hematoma (severe bruising)
9. Infection
10. Failure of the Filter to attach itself securely and potential migration of the filter to the heart or lungs
11. Perforation of the vena cava, adjacent blood vessels or organ by one or more hooks
12. Air embolism during filter insertion
13. Insertion site thrombosis
14. Death due to movement of clots to the heart or lungs.

35. The person who experiences failure of the filter typically experience an acute onset of chest pain and shortness of breath. This typically results in the person presenting to an emergency room, hospital, and or physician for evaluation.

36. The IVC filter prevents the blood clot from migrating to the lungs an event that usually proves disastrous.

37. The inferior vena cava filter in 40 percent of study participants was found to have tilted away from its original optimum position for capturing wayward blood clots from the leg.

THE CASE/CAUSES FOR MEDICAL MONITORING

38. In certain cases, medical monitoring is required to evaluate whether a Greenfield filter has fractured, tilted and or migrated. (collectively referred to herein as 'device failure'). In order to determine whether failure of the IVC has occurred, imaging studies must be performed. Typically, these imaging studies will include unenhanced computed tomography scat (CT Scan) so that the filter may be visualized, CT scan imaging produces an image of the filter and is able to reveal whether the filter has fractured or migrated.

39. Patients requiring medical monitoring are recommended to undergo regular and frequent imaging studies of the device or portion of the device at least once or twice annually. As long as the device or portions of the device remains within the body of the patient, the potential for future device failure exists. Consequently, these patients require regular and frequent medical monitoring for the duration of time the device or portions of the device remain within their bodies.

40. Patients eligible for medical monitoring for the Greenfield filter pr portions of the device need not have experienced past failure of the filter. For example patients who have undergone implant f the filter learn that the filter cannot be removed due to the fact that it has 'grown into' tissue, but the fracture, tilt or migration of the device may not yet have occurred. Such is not the case in plaintiffs case. The filter has migrated, perforated, and continue to cause the plaintiff great harm and constant pain. In fact the filter 'may not' be retrievable at all in her case. As a result of the inability to remove the filter, the device must remain permanently implanted in the patient, for the patients lifetime. Although these patients may not yet have experienced device failure, they are at risk for future device failure and require regular and frequent monitoring to evaluate the integrity of the filter. In addition to the aforementioned imaging studies, endovascular intervention(typically characterization) may also be used by medical professionals to diagnose or discover whether

fractured portions of the filter have migrated to the heart or lungs. Furthermore, endovascular surgery may assess the nature and extent of the damage resulting from failure of the filter.

41. In those instances where device fracture has occurred, and depending on the circumstances particular to the patient, a person may be required to undergo one or all of the following medical procedures:

a. CT scanning or other imaging studies
b. Cardiac catherization
c. Open heart surgery
d. Removal of the IVC filter from the vena cava

THE NECESSITY FOR MEDICAL MONITORING

42. The Greenfield IVC filter was placed in plaintiff Monica Jeffries body and person sometime prior to 2004. Plaintiff had been having medical problems with: shortness of breath, severe and lasting pain daily, pain in back, severe weight loss, confusion, asthma conditions, and underwent numerous tests and scans to find out the cause of all her illnesses. In February of 2015 it was discovered that the Greenfield IVC filter had migrated and perforated the vena cava. Plaintiff has and continues to undergo a series of tests to see if the filter is retrievable. Plaintiff had no idea nor could have discovered her injury, the cause of her injury, nor the defendants part in the cause of her injury until Sept, 2015 at the earliest. Plaintiff has incurred significant medical expenses and has endure extreme pain and suffering, loss of enjoyment of life, and other losses, some of which are permanent in nature. Plaintiff is currently afraid to have any medical procedures unto the filter at this time. Plaintiff is tormented as of today and frequently reminded as she remains in pain of the defective filter. Plaintiff in lieu of the filing of this complaint for damages that she be compensated in a timely manner for all the continued and ongoing medical nuances in this matter. Plaintiff is mentally and emotionally, as well as physically worried about the next step to get some relief from this very tormenting situation as it stands today.

43. Plaintiff has incurred significant medical expenses and has endure extreme pain and suffering, loss o enjoyment with her grand kids and family, and other losses, some of which are permanent in nature. As a result of the failure of the filter, plaintiff has become impair an her ability to earn wages has been diminished, and will remain so in the future.

44. As a direct and proximate result of the conduct and defective product of the defendants, as alleged in this complaint, the plaintiff has incurred substantial medical expenses, and will continue to incur substantial medical experiences into the future.

45. As a direct and proximate result of the conduct and defective product of the defendants, as alleged in this complaint, medical monitoring is necessary for Plaintiff Monica Jeffries inclusive of and not limited to the following:

a. Regularly scheduled CT scans or other appropriate imaging studies; and or
b. Potential cardiac catherization or other endovascular procedure to detect the presence of migrated pieces and any future migration of the filter; and or physicians visits and examination.

THE DEFENDANTS KNOWLEDGE OF THE FAILURE OF THE GREENFIELD IVC FILTER AND THE DANGERS ASSOCIATED WITH THE DEVICE

46. Upon information and belief, plaintiff allege that as early as 2004, the defendants Boston Scientific, Inc., were aware and had knowledge of the fact that the Greenfield IVC Filter was defective and unreasonably dangerous and was causing injury and death to patients who had received the Greenfield filter.

47. Data established that the failure rate of the Greenfield Filter was is exceedingly higher than the rates the defendants have published in the past, and currently continue to published in the past, and currently continue t publish to the medical community, members of the public, and the F.D.A.

48. Over 921 adverse events ere identified by the FDA through a warning issued in August of 2010 regarding risks associated with IVC filters complications.

49. Upon information and belief, from the time the Greenfield filters became available on the market, the defendants, embarked on an aggressive campaign of 'off label marketing' concerning the Greenfield filters. This included representation made to physicians, healthcare professionals, and other members of the medical community.

50. The conduct of the defendants Boston Scientific, Inc. as alleged in this complaint, constituted, willful,wanton, gross, and outrageous corporate conduct that demonstrates and consciously disregarded for the safety of plaintiff Monica Jeffries, failed to act reasonably. The defendants had actual knowledge of dangers to the life and limb of the plaintiff presented by the Greenfield filter, yet consciously failed to act reasonably to:

a. Inform or warn the plaintiff her physicians,or the public at large of the dangers; and

b. Recall the Greenfield IVC filters from the market in a timely and safe fashion.

51. Despite having knowledge as early as 2004 of the unreasonably dangerous and defective nature of the product, the defendants consciously disregarded the known risks and continued to actively market and offer for sale the Greenfield filters.

52. Plaintiff further allege that the defendants acted in willful, wanton, gross manner, and in total
disregard for the health and safety of the users or consumers of its filter including plaintiff Monica Jeffries, and acted to serve their own interests and having reason to know and consciously pursued a course of conduct knowing that such conduct created a substantial risk of significant harm to other persons. Therefore defendants Boston Scientific should be require to respond to the plaintiffs in the form of a punitive or exemplary damage award.

THE FEDERAL REQUIREMENTS

53. Federal regulation states that ;recall means a firms removal or correction of a marketed product that the Food and Drug Administration considers to be in violation of the laws it administers and against which the agency would initiate legal action, erg. seizure. (See 21 CFR § 7.3(g).

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54. Federal regulation states that recall classification means the numerical designation, 1, 2, 3, assigned b the Food and Drug Administration to a particular product recall to indicate the relative degree of health hazard presented by the product being recalled to indicate the relative degree of health hazard presented by the product being recalled. See 21 CFR § 7.3(m).

55. Federal regulation states that 'class II is a situation in which use of, or exposure to, a violation product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote. See 21 CFR § 7.3(m).

56. The classification of the product withdrawals and corrections of the defendants devices (described above) as Class II Recalls by the F.D.A. Confirms by definition that the devices were in violation of federal law and that initiation of legal action or seizure would be indicated for these devices.

57. Pursuant to federal law, a device is deemed to be adulterated if, among other things, it fails to meet established performance standards, or if the methods, facilities or controls used for it manufacture, packing, storage or installation are not in conformity with the federal requirements. See 21 U.S.C. § 351.

58. Pursuant to federal law a device is deemed to be unbranded if, among other things, its labeling is false or misleading in any particular manner, or it it is dangerous to health when used in the manner prescribed, recommended or suggested in the labeling thereof. See 21 U.S.C. § 352.

59. Pursuant to federal manufacturer are required to comply with F.D.A. Regulation of medical devices including FDA requirements for records and reports, in order to prohibit introduction of medical devices that are adulterated or unbranded, and to assure the safety and effectiveness of medical devices. In particular, manufactures must keep records and make reports if any medical device that may have caused or contributed to death or serious injury, or if the device has malfunction in a manner likely to cause or contribute to death or serious injury. Federal law also mandates that the FDA establish regulations requiring a manufacturer of a medical device to report promptly to FDA any correction or removal of a device undertaken to reduce a risk to health posed by the device, or to remedy a violation of federal law by which a device may present a risk to health. See 21 U.S.C. § 360(i).

60. Pursuant to federal law, the Secretary of Health and Human Services may prescribe regulations requiring that the methods used in, and that facilities and controls used for, the manufacture, pre production design validation (including a process to assess the performance of a device but not including an evaluation of the safety or effectiveness of a device), packing, storage, and installation of a device conform to current good manufacturing proactive, as prescribed in such regulation, to assure that the device will be safe and effective and other wise in compliance with federal law. See 21 U.S.C § 360j(f).

61. Pursuant to FDA regulation, adverse events associated with a medical deice must be reported FDA within 30 days after the manufacturer becomes aware that a device may have caused or contributed to death or serious injury, or that a device has malfunctioned an would be likely to cause or contribute to death or serious injury if the malfunction was to recur. Such reports must contain all information reasonably known to the manufacturer, including any information that can be obtained by analysis, testing, or other evaluation of the device, and any information in the manufacturers possession. In addition, manufactures are responsible for conducting an

investigation of each adverse event, and must evaluated the cause of the adverse event. See 21 CFR §803.52.

62. Pursuant to federal regulation, manufacturers of medical devices must also describe in every individual averse event report whether remedial action was taken in regard to the adverse event report whether the remedial action was reported to FDA as a removal or correction of the device. See 21 CFR § 803.52.

63. Pursuant to federal regulation, manufacturers must report to FDA within five (5) business days after becoming aware of any reportable MDR event or events, including a trend analysis that necessitates remedial action to prevent an unreasonable risk of substantial harm to the public health. See 21 CFR § 803.53.

64. Pursuant to federal regulation device manufacturers must report promptly to FDA any device corrections and removals. FDA regulations require submission of a written report within ten (10) working days of any correction or removal of a device initiate by the manufacturer to reduce a risk to health posed by the device, or remedy a violation of the Act caused by the device, which may present a risk to health. The written submission must contain , among other things, a description of the event giving rise to the information reported and the corrective or removal actions taken, and any illness or injuries that have occurred with use of the device, including reference to any device report numbers. Manufacturers must also indicate the total number of devices manufactured or distributed which are subject to the correction or removal, and provide a copy of all communication regarding the correction or removal. See 21 CFR §806.

65. Pursuant to federal regulation, manufacturers must comply with specific quality system requirements promulgated by FDA. These regulations require manufacturers to meet design control requirements, including but not limited to, conducting design validation to ensure that devices conform to defined user needs and intended uses. Manufacturers must also meet quality standards in manufactures and production. Manufacturers must establish and maintain procedures for implementing corrective actions and preventive actions. An investigate the cause of nonconforming products and take corrective action to prevent recurrence. Manufacturers are also required to review and evaluate all complaints and determine whether an investigation is necessary. Manufacturers are also required to sue statistical techniques where necessary to evaluate product performance. See 21 CFR §820.

66. The regulations requiring conformance to good manufacturing practices are set forth in 21 CFR §820 ET *seq.* As explained in the Federal Register, because the Current Good Manufacturing Practice (CGMP) regulations must apply to a variety of medical devices, the regulations do not prescribe the details for how a manufacturer must produce a device. Rather, the quality system regulations provide a framework of basic requirements for each manufacturer to use in establishing a quality system appropriate to the devices designed and manufactured, and the manufacturing processes employed. Manufacturers must adopt current and effective methods and procedures for each device they design and manufacture to comply with and implement the basic requirements set fort in the quality system regulations.

67. Pursuant to 21 CFR § 820.1(c), the failure to comply with any applicable provision in Part 820 renders a device adulterated under section 501(h) of the Federal Food and Drug & Cosmetic Act (the act) (21 USC § 351).

68. Pursuant to 21 CFR § 820.5, each manufacturer shall establish and maintain a quality system that is appropriate for the specific medical device designed or manufactured. 'Quality system" means the organizations structure, responsibilities, procedures processes, and resources for implementing quality management. Se 21 CFR § 820.3(v).

69. Pursuant to 21 CFR § 820.22, each manufacturer shall establish procedures for quality audits and conduct such audits to assure that the quality system is in compliance with the established quality system requirements and to determine the effectiveness of the quality system requirements and to determine the effectiveness of the quality system.

70. Pursuant to 21 CFR § 820.30(a), each manufacturer shall establish and maintain procedures to control the design of the device I order to ensure that specified design requirements are met.

71. Pursuant to 21 CFR §820.30(d), each manufacturer shall establish and maintain procedures for defining and documenting design output in terms that allow an adequate evaluation of conformance to design input requirements.

72. Pursuant to 21 CFR § 820.30(e), each manufacturer shall establish and maintain procedures to ensure that formal documented reviews of the design results are planned and conducted at appropriate stages of the devices design development.

73. Pursuant to 21 CFR § 820.30(f), each manufacture shall establish and maintain procedures for certifying the device design to confirm that the device design output meets the design input requirements.

74. Pursuant to 21 CFR § 820.30(g), each manufacturer shall establish and maintain procedures for validating the device design. Design validation shall be performed under defined operating conditions on initial production units, lots, or batches, or their equivalents. Design validations shall ensure that devices conform to defined user needs and intended uses and shall include testing of production units under actual or simulated use conditions.

75. Pursuant to 21 CFR §820,30(h), each manufacturer shall establish and maintain procedures to ensure that the device design is correctly translated into production specifications.

76. Pursuant to 21 CFR §820.30(i), each manufacture shall establish and maintain procedures for the identification, documentation, validation or where appropriate verification, review, and approval of design changes before their implementation.

77. Pursuant to 21 CFR § 820.70(a), each manufacturer shall develop, conduct control, and monitor production processes to ensure they a device conforms to its specifications. Where deviations from device conforms to its specifications. Where deviations from device specifications could occur as a result of the manufacturing processes, the manufacturer shall establish and maintain process control procedures that describe any process controls necessary to assure conformance to specifications. Such process controls shall include:

    a. Document instructions, standard operating procedures SOP's. And methods that define and control the manner of production:

    b. Monitoring and control of process parameters and component and device characteristics

during production

c. Compliance with specified reference standards or codes;

d. The approval of processes and process equipment; and

e. Criteria for workmanship which shall be expressed in document standards or by means of identified and approved representative samples.

78. Pursuant to 21 CFR §820.70(b), each manufacturer shall establish and maintain procedures to a specification, method, process, or procedure.

79. Pursuant to 21 CFR §820.70(c), each manufacturer shall establish and maintain procedures to adequately control environmental conditions that could reasonably be expected to have an adverse effect on product quality, including periodic inspection of environmental control systems, including necessary equipment, is adequate and functioning properly.

80. Pursuant to 21 CFR §820.70(e), each manufacturer shall establish and maintain procedures to prevent contamination of equipment or product by substances that could reasonably be expected to have an adverse effect on product quality.

81. Pursuant to 21 CFR §820.70(g), each manufacturer shall ensure that all equipment used in the manufacturing process meets specified requirement and is appropriately designed, constructed, placed, and installed to facilitate maintenance, adjustment, cleaning and use.

82. Pursuant to 21 CFR §820.70(h), each manufacturer shall establish and maintain procedures for the use and removal of manufacturing material which could reasonably be expected or limited to an amount that does not adversely affect the devices quality.

83. Pursuant to 21 CFR §820.70(i), when computers or automated data processing systems are used as part of production or the quality system, the manufacturer shall validate computer software for its intended use according to an established protocol.

84. Pursuant to 21 CFR §820.72, each manufacturer shall ensure that all inspection, measuring and test equipment, including mechanical, automated, or electronic inspection and test equipment, including mechanical, automated, or electronic inspection and test equipment, is suitable for its intended purposes and is capable of producing valid results. Each manufacturer shall establish and maintain procedures to ensure that equipment is routinely calibrate, inspect, checked, and maintained.

85. Pursuant to 21 CFR §820.75(a), where the results of a process cannot be fully verified b subsequent inspection and test, the process shall be validated with a high degree of assurance and approved according to established procedures. Process validation means establish by objective evidence that a process consistently produces a result o product meeting its predetermined specifications. See 21 CFR §820.3(z)(1).

86. Pursuant to 21 CFR §820.75(b), each manufacturer shall establish and maintain procedures for monitoring and control of process parameters for validated presses to ensure that the specified requirements continue to be met. Each manufacturer shall ensure that validated processes are

performed by qualified individuals.

87. Pursuant to 21 CFR §820.90, each manufacturer shall establish and maintain procedures to control product that does not conform to specified requirements.

88. Pursuant to 21 CFR §820.100, each manufacturer shall establish and maintain procedures for implementing corrective and preventive action. The procedures shall include requirements for:

a. Analyzing process, work operations, concessions, quality audit reports, quality records, service records, complaints, returned product, and other sources of quality data to identify existing and potential causes of nonconforming product, or other quality problem.

b. Investigating the cause of nonconformity relating to product, processes and the quality system;

c. Identifying the actions needed to correct and prevent recurrence of nonconforming product and other quality problems;

d. Verifying r validating the corrective an preventative action to ensure that such action is effective and does not adversely affect the finished device;

e. Ensuring that information related to quality problems;

f. Ensuring that information related to quality problems or nonconforming product is disseminated to those directly responsible for assuring the quality of such product or the prevention of such problems; and

g. Submitting relevant information on identified quality problems, as well as corrective and preventative actions, or management review.

DEFENDANTS 'GREENFIELD IVC FILTER'
WAS A 510(K) APPROVED MEDICAL DEVICE

89. Defendant submitted a §510(k) premarket notification and obtained marketing clearance for its Greenfield IVC Filter from the FDA under Section 510(k) of the act. *See 21 USC §360 et seq.*

90. Under the §510(k) approval process, the FDA determined that defendants Greenfield IVC filter was 'substantially equivalent' to devices that have been reclassified in accordance with the provisions of the Act and did not require FDA approval of a pre-market approval application (PMA)

91. Upon information and belief, defendants Greenfield filter IVC is adulterated pursuant to 21 U.S.C. §351 because, among other things, it failed to meet established performance standards,and or the method, facilities, or controls used for its manufacture, packing, storage or installation are not in conformity with federal requirements. See 21 USC §351.

92. Upon information and belief, defendant Greenfield IVC filter is misbranded because, among other things, it is dangerous to health when used in the manner prescribed, recommended or suggested in the labeling thereof. See 21 U.S.C. §352.

93. Upon information and belief, Defendants IVC filter is adulterated pursuant to 21 U.S.C. §351 because defendants failed to establish and maintain CGMP for their IVC filter in accordance with 21 CR §820 et seq., as set forth above.

94. Upon information and belief, defendants failed to establish and maintain CGMP with respect to the quality audits, quality testing and prove validation for their IVC filter.

95. As a result of defendant failure to establish and maintain CGMP as set forth above defendants IVC filter was defective and failed, resulting in injuries to the plaintiff and ongoing as of today.

96. If defendants had complied with the Federal requirements regarding CGMP, defendant IVC Filters would have been manufactured properly such that it would not have resulted in injuries to the plaintiff in this matter.

FRAUDULENT CONCEALMENT

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

98. 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 Greenfield IVC filter.

99. The defendants are and were 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. Defendants conduct as described in this complaint, amounts to conduct purposely committed, which defendants must have realized was dangerous, heedless and reckless, without regard to the consequences or the rights and safety of plaintiff.

CORPORATE/VICARIOUS LIABILITY

100. At all times herein mentioned, each of the defendants was the agency, servant partner, aider and abettor, co-conspirator and or joint venture of each of the other defendants herein and was 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 the other defendants knowing that their collective conduct constituted a breech of duty owed to the plaintiff.

101. There exists and at all times herein mentioned, there existed a unity of interest in ownership between certain defendants and other certain defendants such that any individuality and separateness between the certain defendants as entities distinct from other certain defendants will permit an abuse of the corporate privilege and would sanction a fraud and or would promote injustice.

102. At all times herein mentioned, each defendant was 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 plaintiffs damages.

103. 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 propositions of said products and thereby actively participated in the tortuous conduct that resulted in the injuries suffered by the plaintiff.

FIRST CAUSE OF ACTION
NEGLIGENCE

104. Plaintiffs re-allege and incorporate by reference each and every allegation contained in the foregoing paragraphs as though fully set forth herein.

105. At all times relevant to this cause of action, the defendants were in the business of designing, developing, setting specifications, manufacturing, marketing selling, and distributing the Greenfield IVC filters.

106. Defendants designed, manufactured, marketed, inspected, labeled, promoted, distributed and sold the Greenfield IVC filters that was implanted in plaintiff Monica Jeffries.

107. 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 Filters so as to avoid exposing others to foreseeable and unreasonable risks of harm.

108. Defendant knew or reasonably should have known that the Greenfield filter was dangerous or was likely to be dangerous when used in its intended or reasonably foreseeable manner.

109. At the time of manufacture and sale of the Greenfield filter; defendants knew or should have know that the filters were:

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 resent an unreasonable risk of migration of the device and or portions of the device;

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

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

110. At the time of manufacture and sale of the Greenfield filter (1999- until it's discontinuance), defendant knew or should have known that using the Greenfield filter in its intended use or in a reasonable foreseeable manner created a significant risk of a patient suffering severe health side effects, including, but no limited to; hemorrhage; cardiac pericardium 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 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

111. Defendants knew or reasonably should have known that consumers of the Greenfield filter would not realize the danger associated with using the device in its intended use and or in a reasonably foreseeable manner.

112. Defendants breached their duty to exercise reasonable and prudent care in the development, testing design manufacture, inspection, marketing, labeling, promotions, distribution and sale of its filter 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 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 available for the same purpose;

c. Failing to use reasonable care in manufacturing the product and producing a product that differed from their designed 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 Monica Jeffries, Plaintiffs physicians or the general health care community about the Greenfield filter 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 Greenfield 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 reasonable foreseeable would prescribe, use, and implant the Greenfield filter;

g. Advertising, marketing and recommending the use of the Greenfield filter, while concealing and failing to disclose or warn of the dangers known by Defendants to be connected with the inherent in the use of the Greenfield filter;

h. Representing that the Greenfield 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 Greenfield filter and sale of the 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 Greenfield filter so as to avoid the risk of serious harm associated with the use of the filter.

k. Advertising, marketing promoting and selling the filter for uses other than as approved and indicated in the products label;

l. Failing to establish an adequate quality assurance program used n the manufacturing of the filter; and;

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

113. A reasonable manufacturer, distributor, or seller under the same or similar circumstance would not have engaged in the before mention acts and omissions.

114. As a direct and proximate result of the foregoing negligent acts and omissions by 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.

SECOND CAUSE OF ACTION
STRICT PRODUCTS LIABILITY- FAILURE TO WARN

115. Plaintiffs re-allege and incorporate by reference each and every allegation contained in the foregoing paragraphs as though fully set forth herein.

116. Defendants designed, set specifications, manufacture, prepared, compounded, assembled, processed, marketed, labeled, distributed, and sold the Greenfield filter, including the one implied into plaintiff Monica Jeffries, into the stream of commerce and in the course of same, directly advertise and marketed the device to consumers or persons responsible for consumers.

117. At the time Defendants designed, manufactured, prepared, compounded, assembled, processed, marketed, labeled, distributed, and sold the deice 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 reasonable anticipated use. Specifically, defendants knew or should have known, at the time the Greenfield filter was manufactured, labeled, distributed and sold the Greenfield filter, *inter ilia,* which was implanted in plaintiff Monica Jeffries 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. 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.

118. Therefore, defendants had a duty to warn of the risk of harm associated with the risk of harm associated with the use of the device and to provide adequate instruction on the safe and proper use of the device. 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 Monica Jeffries.

119. Despite this duty, defendants failed to adequately warn of material facts regarding the safety and efficacy of the Greenfield filter, and further failed to adequately provide instructions on the safe and proper use of the device.

120.No Health care provider, including Plaintiffs, or patient would have used the device in the manner directed, had those facts been made known to the prescribing health care providers and or ultimate users of the device.

121. 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.

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

123. Therefore, the Greenfield filter implanted in plaintiff Monica Jeffries 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.

124. The Greenfield filter in plaintiff Monica Jeffries was in the same condition as when it was manufactured, inspected, marketed, labeled, promoted, distributed and sold by defendants.

125. 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.

THIRD CAUSE OF ACTION
STRICT PRODUCTS LIABLITY-DESIGN DEFECTS

126. Plaintiffs re allege and incorporate by reference each and every allegation contained in the foregoing paragraphs as though fully set forth herein.

127. At all relevant times relevant to this action, defendants developed, tested, designed, manufactured, inspected, labeled, promoted, distributed and sold into the stream of commerce the Greenfield filter, including the one implanted in plaintiff Monica Jeffries hereto Pro Se in this matter.

128. The Greenfield 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 the Greenfield filter after market and implantation were not made aware to plaintiff Monica Jeffries at any time what so ever.

129. The Greenfield filter implanted in Plaintiff Monica Jeffries was defective in design because it failed to perform as safely as persons who ordinary use the product would have expected at the time of use.

130. The Greenfield filter manufactured by Boston Scientific and implanted in plaintiff Monica Jeffries was defective in design, in that its risks of harm exceeded its claimed benefits.

131. Plaintiff and plaintiffs health care providers used the filter in a manner that was reasonable foreseeable to defendants.

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

133. As a direct and proximate result of the Greenfield filter defective design, plaintiff has suffered and will continue to suffer serious physical injuries, economic loss, loss of enjoyment, disability, and other relevant losses, in an amount to be determined by a jury of her peers, to be determined at trial.

FOURTH CAUSE OF ACTION
STRICT PRODUCTS LIABLITY- MANUFACTURING DEFECT

134. Plaintiff Monica Jeffries re allege and incorporate by reference each and every allegation contained in the foregoing paragraphs as though fully set forth herein.

135. Defendants Boston Scientific designed, set specifications, manufactured, prepared, compounded, assembled, processed, marketed, labeled, distributed, and sold the Greenfield filter that was implanted into plaintiff Monica Jeffries.

136. The Greenfield filter implanted in plaintiff contained a condition which defendants did not intend at the time it left defendants control and possession.

137. Plaintiff and Plaintiff health care providers used the device in a manner that was reasonably foreseeable to defendants.

138. As a result of this condition, the product injured Plaintiff and failed to perform as safely as the ordinary consumer would expect when used in a reasonable foreseeable manner.

139. As a direct and proximate result of the Greenfield filters' manufacturing defect, 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 by a jury of her peers to be determined at trial.

FIFTH CAUSE OF ACTION
BREACH OF IMPLIED WARRANTY OF MERCHANTABLITY

140. Plaintiff Monica Jeffries re allege and incorporate by reference each and every allegation contained in the foregoing paragraphs as though fully set forth herein.

141. 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 Greenfield filter for use as a surgically implanted device used to prevent pulmonary embolisms and for used other than as approved and indicated in the products instructions, warnings, and labels.

142. Defendants knew of the intended and reasonably foreseeable use of the Greenfield filter, and impliedly warranted the product to be of merchantable quality, and safe and fit for its intended use.

143. Defendants knew of the intended and reasonably foreseeable use of the Greenfield 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.

144. Defendants impliedly represented and warranted to the healthcare community, plaintiff and plaintiffs healthcare providers, that the Greenfield filter was safe and of merchantable quality and fit for the ordinary purpose for which the product was intended and marketed to be used.

145. The representations and implied warranties made by defendants were false, misleading, and inaccurate because the Greenfield 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 Plaintiffs purchase of the Greenfield filter from the Defendants Boston Scientific. Through plaintiff 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 a statistically high incidence of failure, including fracture, migration, excessive tilting, and perforation of the inferior vena cava;

b. It was designed in such a manner so as to result in a statistically incidence of injury to the organs and anatomy; and,

c. It was manufactured in such a manner so that the exterior surface of the Greenfield filter was inadequately, improperly and inappropriately prepared and or finished causing the device to weaken and fail.

146. Plaintiff Monica Jeffries and plaintiffs 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 Greenfield 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 Greenfield filter was manufactured and sold.

147. Defendants placed the Greenfield 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 Greenfield filter was manufactured and sold.

148. Defendants breached their implied warranty because their Greenfield filter was not fit for its intended use and purpose.

149. As a proximate result of defendants breach-in their implied warranties, plaintiff Monica Jeffries 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 by a jury of her peers to be determined at trial.

SIXTH CAUSE OF ACTION
NEGLIENT MISREPRESENTATION

150. Plaintiff Jeffries re-allege and incorporate by reference each and every allegation contained in the foregoing paragraph herein.

151. At all times relevant to this cause, and as detailed *supra*, Defendants negligently provided plaintiff, plaintiffs health care providers, and the general medical community with false or incorrect information, or omitted or failed to disclose material information concerning the Greenfield filter,

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

a. The safety of the Greenfield filter
b. The efficacy of the Greenfield filter
c. The rate of failure of the device
d. The side effects of long term usage
e. The proposed approved uses of the Greenfield filter

152. The information distributed by defendants to the public, the medical community and plaintiffs health care providers was in the form of reprots, press releases, advertising campaigns, labeling materials, print advertisements, commercial media containing material representations, which were false and misleading, and contained ommissions and concealment of the truth about the dangers of the use of the filter. Defendants made the foregoing misrepresentations knowing that they were false or without reasonable basis. These materials included instructions for use and warning document that was included in the package of the Greenfield filter that was implanted in plaintiff.

153. Defendants intent and purpose in making these misrepresentations was to deceive and defraud the public and the medical community, including plaintiffs health care providers; to gain the confidence of the public and the medical community, including plaintiffs health care providers; to falsely assure them of the quality of the Greenfield filter and its fitness for use; and to induce the public and the medical community, including plaintiffs healthcare providers to request, recommend, prescriptive, implant, purchase and continue the use of the Greenfield filter.

154. The foregoing representations and ommissions by defendants were in fat false. The Greenfield filter is not safe, fit and effective for human use in its intended and reasonably foreseeable manner. The use of the Greenfield filter is hazardous to the users health and well being. The Defendants Boston Scientific clearly have known and should have known of the filters dangerous and frequently burdensome background, which clearly put Plaintiffs health and life in danger for years, in fact the implant is currently causing the plaintiff Monica Jeffries extreme grief, pain and other on going issues as of this day and will continue to do so until it can be removed. The use of the Greenfield filter is hazardous to the users health, and said device has a significantly higher rate of failure and injury than do other comparable devices. The device has a serious propensity to cause users to suffer serious injuries, including without limitation, the injuries plaintiff has suffered.

155. In reliance upon the false and negligent misrepresentations and ommissions made by defendants, plaintiff and plaintiffs health care providers were induced to, and did use the Greenfield filter, thereby causing plaintiff to sustain severe and permanent personal injuries.

156. Defendants knew and had reason to know that plaintiff, Plaintiffs 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 and implanted same, if true facts regarding the device had not been concealed and misrepresented by defendants.

157. 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 Greenfield filter.

158. At the time defendants failed to disclose and misrepresented the forgoing facts, and at the time plaintiff used the Greenfield filter, plaintiff and plaintiffs health care providers were unaware of said

defendants negligent misrepresentations and omissions.

159. Plaintiff, plaintiffs health care providers and general medical community reasonably relied upon misrepresentations and omission made by defendants where the concealed and misrepresented facts were critical to understanding the true dangers inherent in the use of the Greenfield filter.

160. Plaintiff and plaintiffs health care providers reliance on the foregoing misrepresentations and ommissions by defendants were the direct and proximate cause of plaintiffs injuries as described herein.

LOSS OF CONSORTIUM CLAIM

161. Plaintiffs re allege and incorporate each and every allegation in this complaint, as if fully set forth herein.

162. At all relevant times hereto, Monica Jeffries has been the primary care giver of her new born grand-daughter Dakota Monae' Cooper, Arianna, Madison Jhonae

163. As a direct and proximate result of defendants conduct, all three of plaintiffs grand-daughters have been deprived of and or suffered a loss of their grand-mothers love, companionship, society, solace, moral support and services and child care and has otherwise suffered losses, the extent of which will be more fully adduced at the trial of this matter.

PUNITIE DAMAGES ALLEGATIONS

164. Plaintiff re-allege and incorporate each and every allegation in this Complaint as if fully set forth herein.

165. 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.

166. Defendants had knowledge of, and were in possession of evidence demonstrating that, the Greenfield filter was defective and unreasonably dangerous and had a substantially higher failure rate than did other similar devices on the market. Yet, Defendants failed to:

a. Inform or warn Plaintiff or her health care providers of the dangers;

b. To establish and maintain an adequate quality and post market surveillance system; and
c. Recall the Greenfield from the market.

167. Defendants acted to serve their own interests and having reasons to know and consciously disregard the substantial risk that their product might kill or significantly harm patients, or significantly injure the rights of others, and consciously pursue a course of conduct knowing that such conduct created a substantial risk of significant harm to other persons.

168. As a direct, proximate, and legal result of Defendants acts and omissions 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, Plaintiffs pray 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, Plaintiff will continue to suffer in the future;
2. Physical impairment and incapacity in the past and which, in reasonable probability, plaintiff will continue ti suffer in the future;
3. Pain, suffering and mental anguish in the past and which, in reasonable probability, plaintiff 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 plaintiff will need in the future;
5. Loss of earning capacity in the past and future; and
6. Punitive damages, damages for stress and strain;
7. Actual medical and monetary damages attributed to the defendants product;

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

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

d. Such other relief this honorable court deems just and fair in the light most favorable unto the plaintiff Monica Jeffries.

DEMAND FOR EXPEDIATED JURY TRIAL OR AS SOON AS THIS COURTS CALENDAR WILL ALLOW

Plaintiff hereby demand trial by jury on all issues, as soon as this Honorable courts calendar will allow, since time is of the essence in regard to plaintiffs on going illness via of defendants failed actions.

Respectfully submitted,

Monica Jeffries

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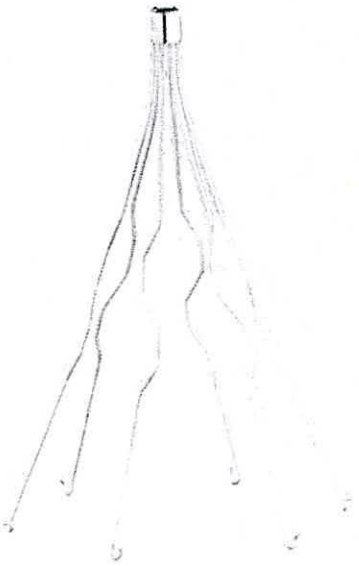
Greenfield™
Vena Cava Filters



Trusted Performance, Timeless Design

Key Resources

Indications, Safety, and Warnings ›

Entry Kit for Use with Greenfield Titanium Vena Cava Filter Directions for Use ›

REQUEST A SALES REP

Customer Support

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Product Details

Proven Stability

- 0.3% filter Fracture[1]

GREENFIELD™ VENA CAVA FILTER

- Indications, Safety, and Warnings

Greenfield Vena Cava Filters

Indications, Safety, and Warnings

Return to product page >

CAUTION: *Federal law (USA) restricts this device to sale by or on the order of a physician. Rx only. Prior to use, please see the complete "Directions for Use" for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator's Instructions.*

Greenfield Vena Cava Filter - Titanium

INTENDED USE/INDICATION FOR USE

Current indications for Greenfield Titanium Vena Cava Filter placement are as follows:

1. When adequate anticoagulation fails to prevent recurrent embolism.

2. Patients with venous thrombosis or pulmonary embolism who have a contraindication to anticoagulation, or are difficult to manage on anticoagulation.

3. Patients with chronic, recurrent pulmonary embolism with associated pulmonary hypertension and corpulmonale.

4. Following an episode of massive pulmonary embolism.

5. Patients with deep vein thrombosis on anticoagulants who develop a complication forcing the discontinuation of anticoagulation.

CONTRAINDICATIONS

Patients in whom the diameter of the inferior vena cava exceeds 28 mm (for example, some patients with congestive heart failure) are contraindicated for Greenfield Titanium Vena Cava Filter placement. Proper fixation of the Greenfield Titanium Vena Cava Filter in the IVC may be compromised when caval diameter exceeds 28 mm.

Presence of thrombus at the femoral puncture site, in the iliac vein, or in the inferior vena cava risks the dislodgement and embolism of thrombus during catheter manipulation. These conditions are absolute contraindications to implantation via femoral vein approach. Absence of thrombus at this level must be confirmed by venography or Doppler/duplex evaluation.

Percutaneous insertion in those patients with abnormal clotting times.

WARNINGS

Never advance the guidewire, sheath/dilator or introducer catheter without the use of fluoroscopic guidance. Always fully advance an 0.038 in (0.97 mm) guidewire to a point beyond the desired implant site The introducer catheter cannot be inserted through the sheath with the dilator or guidewire in place.

The introducer catheter must be advance through the sheath.

Do not activate the Greenfield Titanium Vena Cava Filter release mechanism prior to proper positioning in the vena cava, as the Greenfield Titanium Vena Cava Filter cannot be safely reloaded into the carrier capsule. Do not attempt to modify the Filter in any way prior to release.

Always use the jugular sheath/dilator set with the jugular introducer catheter. Likewise, always use the femoral sheath/dilator set with the femoral introducer catheter.

Never use the jugular introducer catheter for femoral vein insertion or vice versa.

Do not attempt to remove or reposition a Filter when the hooks are engaged in vessel or heart walls.

Do not attempt percutaneous removal and/or repositioning of a Filter with hooks engaged in a vessel or tissue.

A misplaced Filter which nevertheless provides adequate protection against pulmonary embolism should be left in place. If the Filter is not positioned to give adequate protection against pulmonary embolism, a second Filter should be placed. Operative removal has been recommended for a misplaced Filter which may interfere with the function of the tricuspid valve and/or produce cardiac rhythm disturbance

PRECAUTIONS

A relative contraindication exists for this device for younger patients whose life expectancy is substantially greater than the clinical experience of the Greenfield Vena Cava Filter.

Anatomical anomalies and other factors which can complicate insertion will alter the insertion technique. Careful attention to these instructions can shorten insertion time and reduce the likelihood of insertion difficulties.

POTENTIAL ADVERSE EVENTS

Potential adverse events associated with the use of vena cava Filters include the following:

- Incorrect release or placement of the Filter
- Movement or migration of the Filter
- Formation of clots on the Filter which could result in complete blockage of blood flow through the vena cava
- Hematoma (bruise) or bleeding at the insertion site
- Infection
- Failure of the Filter to attach itself securely and potential migration of the Filter to the heart or lungs
- Perforation of the vena cava, adjacent blood vessels or organ by one or more hooks
- Pulmonary embolism due to introducer catheter manipulation leading to dislodgement of clot during Filter placement
- Air embolism during Filter insertion
- Insertion site thrombosis
- Death due to movement of clots to the heart or lungs

Greenfield Vena Cava Filter SS

INTENDED USE/INDICATION FOR USE

The Greenfield Stainless Steel Vena Cava Filter with 12F (4.0 mm) Introducer System is indicated for the prevention of pulmonary embolism via placement in the vena cava in the following situations:

1. Venous thrombosis or pulmonary thromboembolism when anticoagulants are contraindicated or inadequate for management of venous thrombosis with significant risk of, or following, pulmonary thromboembolism.

2. Failure of anticoagulant therapy in thromboembolic

diseases.

3. Emergency treatment following massive pulmonary embolism where anticipated benefits of conventional therapy are reduced.

4. Chronic, recurrent pulmonary embolism where anticoagulant therapy has failed or is contraindicated.

CONTRAINDICATIONS

Patients in whom the diameter of the inferior vena cava exceeds 28 mm (for example, some patients with congestive heart failure) are contraindicated for Greenfield Stainless Steel Vena Cava Filter placement. Proper fixation of the Greenfield Stainless Steel Vena Cava Filter in the IVC may be compromised when caval diameter exceeds 28 mm.

Presence of thrombus at the femoral puncture site, in the iliac vein, or in the inferior vena cava risks the dislodgement and embolism of thrombus during catheter manipulation. These conditions are absolute contraindications to implantation via femoral vein approach. Absence of thrombus at this level must be confirmed by venography or Doppler/duplex evaluation.

Patients in whom pregnancy has been confirmed are contraindicated for Greenfield Stainless Steel Vena Cava Filter placement.

Caution: The safety and effectiveness of the 12F (4.0 mm) Greenfield Stainless Steel Vena Cava Filter used in association with septic thromboembolism has not been conclusively demonstrated in the clinical setting.

WARNINGS

Do not manipulate the FlexCarrier capsule prior to the procedure.

Never advance the guidewire, sheath/dilator or introducer catheter without the use of fluoroscopic guidance.

Always fully advance the included 0.035 in (0.89 mm) guidewire to a point beyond the desired implant site.

The introducer catheter must be advanced over the guidewire and through the sheath.

Do not activate the Filter release mechanism prior to proper positioning in the vena cava, as the Greenfield Stainless Steel Vena Cava Filter cannot be safely reloaded into the carrier capsule of the 12F (4.0 mm) introducer catheter. Do not attempt to modify the Filter in any way prior to release.

Always use the jugular sheath/dilator set with the jugular introducer catheter. Likewise, always use the femoral sheath/dilator set with the femoral introducer catheter.

Never use the 12F (4.0 mm) jugular introducer catheter for femoral vein insertion or vice versa, as this will result in improper Greenfield Stainless Steel Vena Cava Filter orientation in the inferior vena cava.

Do not attempt percutaneous removal and/or repositioning of a Filter with hooks engaged in a vessel or tissue.

A misplaced Filter which nevertheless provides adequate protection against pulmonary embolism should be left in place. If the Filter is not positioned to give adequate protection against pulmonary embolism, a second Filter should be placed. Operative removal has been recommended for a misplaced Filter which may interfere with the function of the tricuspid valve and/or produce cardiac rhythm disturbance.

MRI -Safe: No additional risk to the patients, but may affect the quality of the diagnostic information.

PRECAUTIONS

A relative contraindication exists for this device for younger patients whose life expectancy is substantially greater than the clinical experience of the Greenfield™ Stainless Steel Vena Cava Filter.

Anatomical anomalies and other factors which can complicate insertion will alter the insertion technique. Careful attention to these instructions can shorten insertion time and reduce the likelihood of insertion difficulties.

POTENTIAL ADVERSE EVENTS

Potential Adverse Events associated with the use of vena cava Filters include the following:

- Incorrect release or placement of the Filter
- Movement or migration of the Filter
- Formation of clots on the Filter which could result in complete blockage of blood flow through the vena cava
- Hematoma (bruise) or bleeding at the insertion site
- Infection
- Failure of the Filter to attach itself securely and potential migration of the Filter to the heart or lungs
- Perforation of the vena cava, adjacent blood vessels or organ by one or more hooks
- Pulmonary embolism due to introducer catheter manipulation leading to dislodgement of clot during Filter placement
- Air embolism during Filter insertion
- Insertion site thrombosis
- Death due to movement of clots to the heart or lungs

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Form Approved: OMB No. 0910-0291
Expiration Date: 6/30/2015
(See PRA Statement on preceding general information page)

MEDWATCH Consumer Voluntary Reporting (FORM FDA 3500B)

Section A – About the Problem

What kind of problem was it? *(Check all that apply)*

- [x] Were hurt or had a bad side effect *(including new or worsening symptoms)*
- [ ] Used a product incorrectly which could have or led to a problem
- [ ] Noticed a problem with the quality of the product
- [ ] Had problems after switching from one product maker to another maker

Did any of the following happen? *(Check all that apply)*

- [x] Hospitalization – admitted or stayed longer
- [ ] Required help to prevent permanent harm *(for medical devices only)*
- [x] Disability or health problem
- [ ] Birth defect
- [x] Life-threatening
- [ ] Death *(Include date)*: _____
- [ ] Other serious/important medical incident *(Please describe below)*

Date the problem occurred *(mm/dd/yyyy)*

2/1/2015

Tell us what happened and how it happened. *(Include as many details as possible)*

After experiencing stomach pains which became increasingly painful over 6 months, it was found that my IVC filter had migrated, perforated, and tilted outside the vena cava

Continuation Page

List any relevant tests or laboratory data if you know them. *(Include dates)*

MRI, Cat scan, X-rays, surgical + radiological intervention, endoscopy upper + lower, blood tests vascular tests

Continuation Page

For a problem with a product, including

- prescription or over-the-counter medicine
- biologics, such as human cells and tissues used for transplantation (for example, tendons, ligaments, and bone) and gene therapies
- nutrition products, such as vitamins and minerals, herbal remedies, infant formulas, and medical foods
- cosmetics or make-up products
- foods (including beverages and ingredients added to foods)

Go to Section B

For a problem with a medical device, including

- any health-related test, tool, or piece of equipment
- health-related kits, such as glucose monitoring kits or blood pressure cuffs
- implants, such as breast implants, pacemakers, or catheters
- other consumer health products, such as contact lenses, hearing aids, and breast pumps

Go to Section C (Skip Section B)

For more information, visit *http://www.fda.gov/MedWatch*

Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

Section B – About the Products

Name of the product as it appears on the box, bottle, or package *(Include as many names as you see)*

Name of the company that makes the product

Expiration date *(mm/dd/yyyy)*	Lot number	NDC number

Strength *(for example, 250 mg per 500 mL or 1 g)*	Quantity *(for example, 2 pills, 2 puffs, or 1 teaspoon, etc.)*	Frequency *(for example, twice daily or at bedtime)*	How was it taken or used *(for example, by mouth, by injection, or on the skin)*?

Date the person first started taking or using the product *(mm/dd/yyyy)*: _____

Date the person stopped taking or using the product *(mm/dd/yyyy)*: _____

Why was the person using the product *(such as, what condition was it supposed to treat?)*

Did the problem stop after the person reduced the dose or stopped taking or using the product? ☐ Yes ☐ No

Did the problem return if the person started taking or using the product again? ☐ Yes ☐ No ☐ Didn't restart

Do you still have the product in case we need to evaluate it? *(Do not send the product to FDA. We will contact you directly if we need it.)* ☐ Yes ☐ No

➡ ***Go to Section D (Skip Section C)***

Section C – About the Medical Device

Name of medical device
Greenfield dVC Filter

Name of the company that makes the medical device
Boston Scientific

Other identifying information *(The model, catalog, lot, serial, or UDI number, and the expiration date, if you can locate them)*
Greenfield dVC Filter implant

Was someone operating the medical device when the problem occurred?
☐ Yes
☑ No

If yes, who was using it?
☐ The person who had the problem
☐ A health professional *(such as a doctor, nurse, or aide)*
☐ Someone else *(Please explain who)*
N/A

For implanted medical devices ONLY *(such as pacemakers, breast implants, etc.)*

Date the implant was put in *(mm/dd/yyyy)*	Date the implant was taken out *(If relevant) (mm/dd/yyyy)*
prior to 2004	too dangerous to remove 11/2015

➡ ***Go to Section D***

Section D – About the Person Who Had the Problem

Person's Initials	Sex	Age *(at time the problem occurred)* or Birth Date	Weight *(Specify lbs or kg)*	Race
MJ	☑ Female ☐ Male	7-28-58	154	Black

List known medical conditions *(such as diabetes, high blood pressure, cancer, heart disease, or others)*
high blood pressure, stage III breast cancer, peptic ulcer, adhesions stomach x 9, gall bladder, Tuberculosis

Please list all allergies *(such as to drugs, foods, pollen, or others)*.
aspirin, latex, Codeine, Morphine

List any other important information about the person *(such as smoking, pregnancy, alcohol use, etc.)*
never used drugs, alcohol

List all current prescription medications and medical devices being used.
umbrella catheter, surgical staples, lisinopril, albuterol, Zopedesm, prevacid

Continuation Page

List all over-the-counter medications and any vitamins, minerals, supplements, and herbal remedies being used.
tylenol

Continuation Page

➪ **Go to Section E**

Section E – About the Person Filling Out This Form

We will contact you only if we need additional information. Your name will not be given out to the public.

Last name	First name
Jeffries	Monica
Number/Street	City and State/Province
Monica Jeffries 414 Winslow Rd Oxon Hill, MD 20745-1432	
Country	ZIP or Postal code

Telephone number	Email address	Today's date *(mm/dd/yyyy)*
3014851659	JeffriesMonica2@yahoo.com	11/6/15

Did you report this problem to the company that makes the product (the manufacturer)?	May we give your name and contact information to the company that makes the product (manufacturer) to help them evaluate the product?
☑ Yes ☐ No	☑ Yes ☐ No

Send This Report by Mail or Fax

Keep the product in case the FDA wants to contact you for more information. Please do not send products to the FDA. Mail or fax the form to:

Mail:	**Fax:**
MedWatch Food and Drug Administration 5600 Fishers Lane Rockville, MD 20857	1-800-332-0178 (toll-free)

Thank you for helping us protect the public health.

For more information, visit *http://www.fda.gov/MedWatch*

Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

Patient Discharge Instructions for: MONICA JEFFRIES

Attending Physician: ESSAM TELLAWI, MD **Discharging Physician:** Cc System, Id , UNK

Allergies: ASPIRIN, codeine

Most Recent Vital Signs: BP (NIBP): 155/73 O2 Sat %: 100 % Pulse: 89
Respirations: 18 Temp #1: 97.6F Temporal scanner

Discharge Instructions Outline

Discharge: To Home.

Discharge Diagnosis Atrophic-hyperplastic gastritis (K29.40).
Discharge Diagnosis.

Discharge: Activity No Driving until Follow-up w/ MD.

Discharge: Diet Regular Diet.

Discharge: Work/School Restricitons None.

Discharge: F/U Appointment Within 2 weeks.

Discharge: F/U Lab/Tests/Procedures None.

Discharge: Dressing Care N/A.

Discharge: Incision Care N/A.

Discharge: Services None.

Discharge: Instructions None.

Discharge: Prescriptions Written .

Discharge Medication List

CONTINUE taking these medications at these doses following discharge

Drug Name	Instructions	Rx
acetaminophen oral 500 mg (Tylenol Extra Strength oral)	2 Oral	
dicyclomine 20 mg tablet (dicyclomine Oral)	1 tablet(s) By Mouth 4 times a day As needed Reason for Taking: Abdominal pain	
lisinopril oral 10 mg	Oral Every morning	

Patient Health Summary

Compile Date: 11/02/15 12:01 EST

Patient Name	Address/Phone	Sex	Marital Status	Date of Birth	Medical Record #
MONICA JEFFRIES	414 WINSLOW RD OXON HILL, MD 20745 301-485-1659	F	DIVORCED	July 28, 1958	M000528937

Pregnant	Language	Ethnicity	Race	Additional Races	Religion
NA	English	NOT SPANISH/HISPANIC ORIG	BLACK	None Recorded	Baptist

Support

Next of Kin	Relationship	Address	Phone Number
ASHLEY THOMAS	Daughter	414 WINSLOW RD OXON HILL, MD 20745	301-996-3323

Encounters

Encounter	Location	Register/Admit
Reg Surgical Day Care	Doctors Community Hospital	11/02/15 03:24

Care Team Providers

Care Team Provider Name	Role	Phone	Provider Type
Laeeq Ahmad	Attending Provider	(301)345-8400	GENERAL STAFF
Ibrahim Salih	Primary Care Provider	(301)817-3001	UNKNOWN

Insurance Providers

Payer Name	Group #	Policy #	Subscriber	Relationship	Address/ Phone
AETNA EL PASO			MONICA JEFFRIES	Self	None Recorded None Recorded
PRI PARTNR J HOPKINS		00091444101	MONICA JEFFRIES	18 SELF/SAME AS PATIENT	414 WINSLOW RD OXON HILL, MD 20745 301-485-1659

Guarantor Information

Guarantor Name	Address	Phone
JEFFRIES,MONICA	414 WINSLOW RD	301-485-1659

	OXON HILL, MD 20745	

Allergies, Adverse Reactions, Alerts

Allergen	Type	Severity	Reaction	Last Updated
aspirin	Adverse Reaction	Severe		03/07/14
codeine	Adverse Reaction	Severe		03/07/14

Problems

Active Problems	Diagnosis Date
Right lower quadrant pain	Not Recorded

Medications

Medication	Dose	Route	Directions	Days	Qty
Lisinopril* [Prinivil*,Zestril] 10 MG Tab	10 Milligram	Oral	twice a day (0900,2100)		
Propranolol HCl 120 MG Cap.Sa.24h	120 Milligram	Oral	every morning (0900)		
Zolpidem Tartrate [Ambien Cr] 12.5 MG Tab.Mphase	12.5 Milligram	Oral	at bedtime (2200) as needed for insomnia		
Acetaminophen* [Tylenol*] 325 MG Tab	500 Milligram	Oral	prn, as needed		
Diphenhydramine HCl* [Benadryl*] 25 MG Tab	25 Milligram	Oral	prn, as needed		
Albuterol [Proventil] 17 GM Aerosol	2 Puff(S)	Inhalation	prn, as needed as needed for Allergic Symptoms		
Omeprazole Magnesium [Prilosec Otc] 20 MG Tablet.Dr	20 Milligram	Oral	prn, as needed as needed for Indigestion/Upset Stomach		

Advanced Directives

Directive	Response	Recorded Date/Time
If None, Information Offered	Yes	11/02/15 09:17
Comment	copy at home-speak w/son in emergency	03/07/14 11:29
If Legal Indicator/s Not On Chart, Request to Bring In	No	11/02/15 09:17
Legal Indicator/s	None	11/02/15 09:17
Legal Indicator/s on Chart	None	11/02/15 09:17

Immunizations

No Immunizations Recorded

Vital Signs

Vital Sign	Result	Reference	Recorded Date/Time
Temperature (F)	97.6 F	97.6 F-99.6 F	11/02/15 11:46
Pulse Rate	76 BPM	60-100	11/02/15 11:46
Respiratory Rate	16 RPM	12-18	11/02/15 11:46
Blood Pressure	144/84	96/60-140/90	11/02/15 11:46
O2 Sat by Pulse Oximetry	98 %	95-100	11/02/15 11:46

Measurement	Result	Reference	Recorded Date/Time
Height	5 ft 8 in		11/02/15 10:21
Weight	154 lb		11/02/15 10:21
BMI	23.4		11/02/15 10:21

Encounter Diagnoses

Diagnosis	Diagnosis Date
Right lower quadrant abdominal pain	Not Recorded

Procedures

Procedure	Date	Status	Provider(s)
VENA CAVAGRM, INF OR SUP	11/02/15	active	Ahmad,Laeeq

Lab Results

Test Name	Result/Comment	Unit	Reference	Date/Time
White Blood Count	3.7 L	K/CMM	4.3-10.5	11/02/15 08:07 EST
Red Blood Count	2.99 L	M/CMM	4.5-5.3	11/02/15 08:07 EST
Hemoglobin	9.4 L	GM/DL	11.7-15.7	11/02/15 08:07 EST
Hematocrit	29.1 L	%	36.0-46.0	11/02/15 08:07 EST
Mean Corpuscular Volume	97	FL	80.0-100	11/02/15 08:07 EST
Mean Corpuscular Hemoglobin	31	PG	26-33	11/02/15 08:07 EST
Mean Corpuscular Hemoglobin Concent	32	G/DL	31-35	11/02/15 08:07 EST
RDW Coefficient of Variation	12.9	%	12-15	11/02/15 08:07 EST
Platelet Count	333	K/CMM	140-450	11/02/15 08:07 EST
Sodium Level	144	MMOL/L	134-146	11/02/15 08:07 EST
Potassium Level	3.4 L	MMOL/L	3.5-5.0	11/02/15 08:07 EST

Chloride Level	110	MMOL/L	97-110	11/02/15 08:07 EST
Carbon Dioxide Level	25	MMOL/L	20-32	11/02/15 08:07 EST
Anion Gap	12	MMOL/L	10-20	11/02/15 08:07 EST
Blood Urea Nitrogen	13	MG/DL	8-22	11/02/15 08:07 EST
Creatinine	0.70 PLEASE NOTE NEW REFERENCE RANGE.	MG/DL	0.51-1.17	11/02/15 08:07 EST
Estimated GFR (African American)	> 60 Unit of measure for eGFR: ML/MIN/ 1.73 SQUARE METERS Reference Range: >60 mL/min/1.73 square meters **The calculated eGFR result should only be applied to patients 18 years and older. The calculation is derived using the IDMS-Traceable MDRD Study Equation.			11/02/15 08:07 EST
Estimated GFR (Non-African American	> 60 Unit of measure for eGFR: ML/MIN/ 1.73 SQUARE METERS Reference Range: >60 mL/min/1.73 square meters **The calculated eGFR result should only be applied to patients 18 years and older. The calculation is derived using the IDMS-Traceable MDRD Study Equation.			11/02/15 08:07 EST
Glucose Level	97 Criteria for the diagnosis of diabetes mellitus Fasting plasma glucose >= 126 mg/dL 2-hour plasma glucose >= 200 mg/dL during an OGTT A1C >= 6.5% Random plasma glucose >= 200 mg/dL in a patient with classic symptoms of hyperglycemia or hyperglycemic crisis Reference: Diabetes Care 33:S67, January 2010	MG/DL	60-125	11/02/15 08:07 EST
Calcium Level	8.7	MG/DL	8.7-10.5	11/02/15 08:07 EST
Calcium Adjusted for Albumin	Not Reportable			11/02/15 08:07 EST

Micro Results

No Micro Results Recorded

Radiology Procedures

Category	Procedure	Date/Time	Status
HEMATOLOGY	CBC WITH PLATELET, NO DIFF	11/02/15 08:05	Completed
CHEMISTRY	BASIC METABOLIC CHEM PROFILE	11/02/15 08:05	Completed

Social History

History	Response	Recorded Date/Time
Alcohol Use	none	11/02/15 08:13
Drug Use	none	03/07/14 10:55
Drug Use	No	11/02/15 08:13

Cognitive Status

Cognitive Observation	Response	Recorded Date/Time
Patient Orientation	x 3	11/02/15 09:17

Functional Status

Functional Observation	Response	Recorded Date/Time
Assistive Devices	None	11/02/15 09:17
Patient Requires Assistance With the Following Activities	None	11/02/15 09:17

Family History

No Family History Queries Recorded

Discharge Care Plan

Reason for Visit	R1031 RIGHT LOWER QUADRANT
Condition At Discharge	STABLE
Instructions/Education Provided	Angiography (DC)
Forms Provided	NUR Discharge Surgical
Prescriptions	see Medication section
Referrals	Salih,Ibrahim [Primary Care Provider] - 3 Days

Additional Instructions/ Education	KEEP DRESSING ON FOR 24 HOURS, TN REMOVE DRESSING AND APPLY BANDAID ON SITE. FOLLOW UP WITH YOUR DOCTOR AS OUT PATIENT IN 3 WORKING DAYS.

Report(s)

No Reports Entered

Radiology Imaging Associates
8926 Woodyard Road, Suite 301, Clinton, MD 20735
PHONE: (301) 856-3670 | FAX: (301) 868-0129
www.riassociates.com

DAVID HAIDAK MD
WEB PORTAL ONLY
CLINTON, MD 20735

PHONE: (301) 868-7912
FAX: (301) 868-0893

PERFORMED AT: **RIA at Heritage**

PATIENT:	**JEFFRIES, MONICA**	PATIENT ID#:	1043173
DOB:	07/28/1958	EXAM DATE:	09/22/15
SEX:	FEMALE	PHONE:	(240) 605-7781

CT ABDOMEN AND PELVIS WITH IV CONTRAST

HISTORY: Left breast cancer 2009, status post mastectomy and chemotherapy. Severe right lower quadrant pain 6 months. Status post subtotal gastrectomy due to ulcer.

TECHNIQUE: Helical multidetector imaging performed with 0.625 mm thin slices acquired from the dome of the diaphragm to the pubic symphysis. Images reviewed in reformatted axial, coronal and sagittal planes. Imaging was performed with low-dose technique and the latest generation iterative reconstruction and dose-reduction technology.

CONTRAST: 100 cc Optiray 320 intravenously. Patient also received oral contrast. No immediate contrast reaction.

COMPARISON: 1/30/2015 CT abdomen pelvis, additional multiple CT abdomen pelvis exams dating back to 6/3/2008

FINDINGS:

Minimal bibasilar atelectasis. No pleural effusion. Heart size normal. Status post left mastectomy, bilateral saline implants are in place.

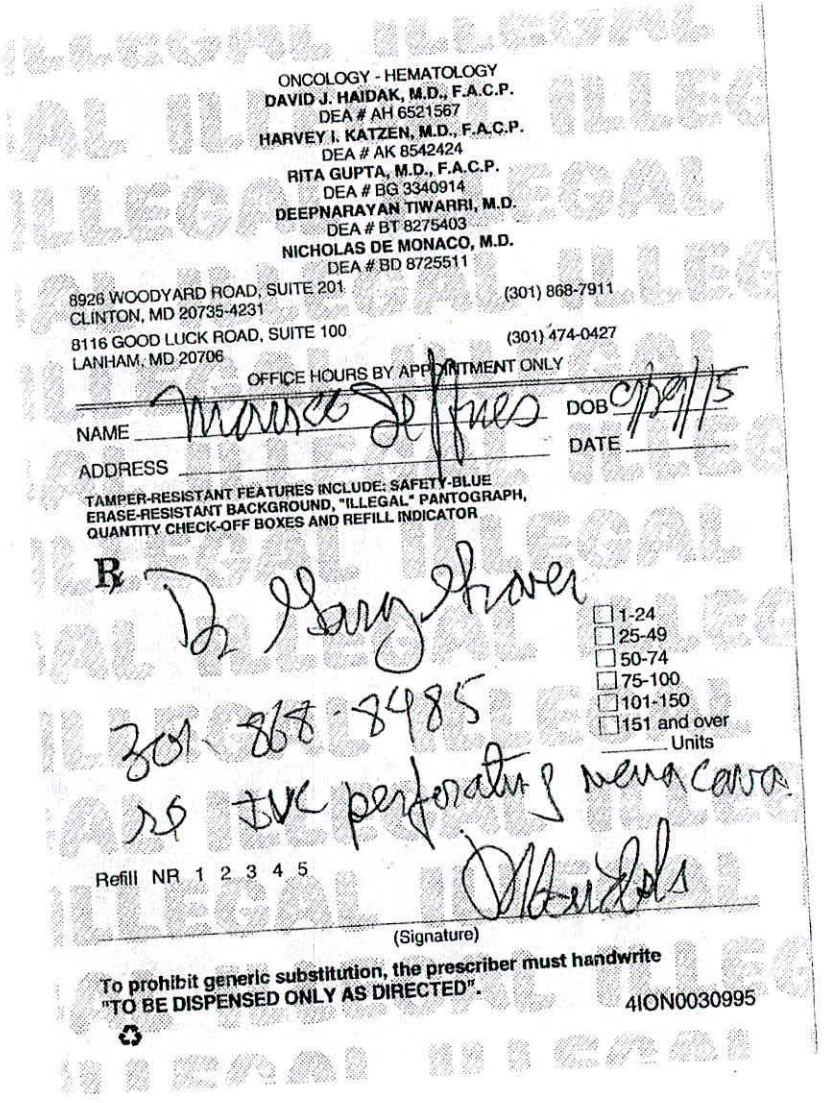
There is dilatation of intrahepatic and extrahepatic biliary tree, similar when compared to previous exam from 1/2015, common bile duct measures 1.1 cm at the porta hepatis, tapering down to 4 to 5 mm distally close to ampulla. Surgical clips in the gallbladder fossa, suggestive of cholecystectomy. Multiple surgical clips in the epigastric region, stable post subtotal gastrectomy changes. Spleen, pancreas, adrenal glands are unremarkable. 3 mm calyceal calculus lower pole of the left kidney, no hydronephrosis, kidneys otherwise unremarkable, symmetrical nephrogram.

Abdominal aorta is normal in caliber, there is IVC filter, however multiple struts of the IVC filter appeared outside the partially decompressed lumen of the inferior vena cava, the IVC distal to the filter is partially collapsed, enlarged bilateral internal iliac veins, left more than right. Multiple prominent and mildly enlarged porta hepatis, portacaval, aortocaval lymph nodes, for example aortocaval lymph node 1.3 x 1.4 cm on series 3, image 46, not substantially changed when compared to 1/2015.

The oral contrast has reached the proximal ascending colon, no bowel obstruction or ileus, redundant sigmoid colon. No obvious diverticulosis. There is long narrowing appearance of the terminal ileum, felt to be related to underdistention, the terminal ileum appeared normal on the last exam from January 2015, appendix is not seen, no pericecal inflammation. Bladder is unremarkable, status post hysterectomy.

Review of bone window demonstrates stable circumscribed sharply marginated sclerotic lesion left iliac crest since 2008. Degenerative spondylosis at L5-S1.

IMPRESSION:



ONCOLOGY - HEMATOLOGY
DAVID J. HAIDAK, M.D., F.A.C.P.
DEA # AH 6521567
HARVEY I. KATZEN, M.D., F.A.C.P.
DEA # AK 8542424
RITA GUPTA, M.D., F.A.C.P.
DEA # BG 3340914
DEEPNARAYAN TIWARRI, M.D.
DEA # BT 8275403
NICHOLAS DE MONACO, M.D.
DEA # BD 8725511

8926 WOODYARD ROAD, SUITE 201
CLINTON, MD 20735-4231
(301) 868-7911

8116 GOOD LUCK ROAD, SUITE 100
LANHAM, MD 20706
(301) 474-0427

OFFICE HOURS BY APPOINTMENT ONLY

NAME Marisol Reyes DOB 6/24/15

ADDRESS DATE

TAMPER-RESISTANT FEATURES INCLUDE: SAFETY-BLUE ERASE-RESISTANT BACKGROUND, "ILLEGAL" PANTOGRAPH, QUANTITY CHECK-OFF BOXES AND REFILL INDICATOR

℞ Dr Mary Shaver

301-858-8485

26 IVC perforating hemangioma.

☐ 1-24
☐ 25-49
☐ 50-74
☐ 75-100
☐ 101-150
☐ 151 and over
_____ Units

Refill NR 1 2 3 4 5

(Signature)

To prohibit generic substitution, the prescriber must handwrite "TO BE DISPENSED ONLY AS DIRECTED".

4ION0030995

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PHONE: (301) 868-7912
FAX: (301) 868-0893

PERFORMED AT: **RIA at Heritage**

PATIENT:	**JEFFRIES, MONICA**	PATIENT ID#:	1043173
DOB:	07/28/1958	EXAM DATE:	09/22/15
SEX:	FEMALE	PHONE:	(240) 605-7781

1. No acute finding, stable exam.
2. CT findings raise the concern for IVC filter perforation, chronic appearance. Recommend surgical or interventional radiology consultation.
3. Mild porta hepatus and retroperitoneal lymphadenopathy, stable.
4. Nonobstructive left nephrolithiasis.
5. Mild biliary dilatation even for post cholecystectomy status, no substantial change, perhaps due to benign post inflammatory stenosis distally.
6. Status post hysterectomy.

Findings were discussed with DAVID HAIDAK MD at 9/23/2015 10:25 AM.

Approved by Fang Yu MD on 9/23/2015 10:25 AM

Thank you for your referral.

Call Us For Online Access Via Our New Portal for Physicians!

RIA at Pembrooke
11335 Pembrooke Sq. #101
WALDORF, MD 20603-4845
www.riassociates.com
(301) 870-8434

RITA GUPTA MD
8926 WOODYARD RD 101/FAX
CLINTON, MD 20735 Phone: (301) 868-1702 Fax: (301) 868-2285

PATIENT: MONICA JEFFRIES
DOB: 07/28/1958
Sex: Female

DATE OF SERVICE: 10/10/12
PATIENT#: 1043173
Phone: (240) 605-7781

EXAMINATION: CT SCAN OF THE CHEST, ABDOMEN AND PELVIS

CLINICAL HISTORY: Breast cancer. Neutropenia. Anemia.

TECHNIQUE:
IV access could not be obtained. Thin contiguous axial images were obtained from the thoracic inlet to the pubis symphysis. Multiplanar reformations were obtained. Delayed imaging through the kidneys was obtained.

FINDINGS:

Comparison is made to prior study from 6/3/2008.

CHEST:
There is no axillary, mediastinal or hilar adenopathy. There is minimal atelectasis at the lung bases. There is no pleural or pericardial effusion. Port-A-Cath is noted in place. Breast implants are noted.

ABDOMEN:
The liver, spleen, adrenal glands and pancreas are unremarkable. Patient status post cholecystectomy. The kidneys concentrate and excrete contrast into nondilated collecting systems bilaterally and symmetrically. The abdominal aorta is unremarkable. There is no retroperitoneal adenopathy. IVC filter is noted in place.

PELVIS:
The pelvis is unremarkable. Patient is status post hysterectomy. Degenerative change the spine are noted most pronounced at the level of L5/S1.

IMPRESSION:
Unremarkable unenhanced CT scan of the chest, abdomen and pelvis.

Thank you for your referral

BENJAMIN W. EDINGER, MD
BE/ 10/10/2012 1:13 PM

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PATIENT: MONICA JEFFRIES
DOB: 07/28/1958
Sex: Female

DATE OF SERVICE: 10/10/12
PATIENT#: 1043173
Phone: (240) 605-7781

Approved by BENJAMIN W. EDINGER on 10/10/2012 1:13 PM

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JUN SUN MD
8926 WOODYARD RD #101/FAX
CLINTON, MD 20735 Phone: (301) 868-1702 Fax: (206) 309-0200

PATIENT: MONICA JEFFRIES
DOB: 07/28/1958
Sex: Female

DATE OF SERVICE: 01/23/12
PATIENT#: 1043173
Phone: (301) 894-1999

EXAM: COMPREHENSIVE CT OF THE SINUSES

HISTORY: Migraines, ear infections, completed antibiotics. Left breast cancer 2008.

COMPARISON: MRI brain, 11/4/2010.

TECHNIQUE: Spiral scanning was performed through the sinuses with coronally and sagittally reformatted images obtained from the axial data.

FINDINGS:
In the right maxillary sinus, there is a lobular broad-based retention cyst, 3.2 x 2.2 x 3 cm. A 2.3 cm retention cyst is present in the inferior aspect of the left maxillary sinus. There is mild mucosal thickening more anteriorly. No gas fluid levels are identified. The sphenoid and frontal sinuses are clear. The ethmoid air cells demonstrate mild mucosal thickening. The osteomeatal complexes are patent. Small concha bullosa are noted in the right middle turbinate. There is paradoxical rotation of this turbinate. A mild leftward septal deviation is noted. The anterior cartilaginous septum is deviated to the right. No bony erosions or lesions are demonstrated. The mastoid air cells are well aerated and clear.

IMPRESSION:
1. Bilateral maxillary retention cyst, larger on the right. Mild chronic inflammatory changes left maxillary sinus.
2. Mild septal deviation.
3. Right middle turbinate with concha bullosa and paradoxical rotation.
4. Clear mastoids.

Thank you for your referral

NINA J. GORDON, MD
NG/ 01/24/2012 5:19 PM

Approved by NINA J. GORDON on 01/24/2012 5:19 PM

RIA at Heritage
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JUN SUN MD
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PATIENT: MONICA JEFFRIES
DOB: 07/28/1958
Sex: Female

DATE OF SERVICE: 01/23/12
PATIENT#: 1043173
Phone: (301) 894-1999

BRAIN CT

HISTORY: Breast cancer, otitis media.

COMPARISON: Heritage brain MRI 11/4/2010.

Contiguous 5 mm axial sections were obtained from the base to vertex. Slices were visualized on bone and soft tissue windows.

The inferior aspect of the maxillary sinuses are not visualized. Certainly the previous noted retention cyst in the right maxillary sinus is smaller. The mastoids are well aerated. The ventricles are normal and symmetric in size and the sulci preserved. No extra-axial fluid collections are present. The pineal is calcified and midline. No intra-axial masses are present. The bony calvarium is unremarkable.

IMPRESSION: Incompletely imaged right maxillary sinus but certainly the previously noted retention cyst is at least smaller.

COMMENT: If clinically indicated, mastoid CT would be useful in further evaluation.

Thank you for your referral

VERNE F. KEMERER, JR, MD
VK/ 01/24/2012 10:29 AM

Approved by VERNE F. KEMERER, JR on 01/24/2012 10:29 AM

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PATIENT: MONICA JEFFRIES
DOB: 07/28/1958 Phone: (301) 856-3282

DATE OF SERVICE: 06/03/08
PATIENT#: 1043173

EXAM: CT OF THE CHEST, ABDOMEN, AND PELVIS.

HISTORY: Recently diagnosed left breast cancer. Patient is referred for staging.

Technique: High-resolution CT exams were performed with multichannel helical acquisition and multiplanar reformats. 100 cc of intravenous nonionic contrast and oral contrast was administered without untoward reaction.

FINDINGS: CT OF THE CHEST:

There is a low density collection in the left anterior lateral chest wall most consistent with a postoperative collection, probably a seroma. It measures approximately 8 x 6 x 3 cm in size. There are no enlarged axillary, hilar, or mediastinal lymph nodes. There is an area of mild parenchymal pleural scarring and nodularity in the left lower lobe, most consistent with chronic postinflammatory change. Otherwise there are no pulmonary infiltrates or nodules. There are no pleural effusions. The tracheobronchial tree is patent. A Mediport catheter is present. There are a few less than 1 cm lymph nodes seen in the visualized lower neck on the left, not likely to be pathologic.

IMPRESSION:
1. Low density collection in the left anterior lateral chest wall, most consistent with a postoperative seroma.
2. Pleural-parenchymal scarring in the left lower hemithorax posteriorly, most consistent with a postoperative seroma.
3. There are no findings which strongly suggest metastatic disease in the thorax.

CT OF THE ABDOMEN:

There are no space-occupying lesions in the liver or spleen. The gallbladder has been removed. The common duct is slightly prominent, but probably normal for a postcholecystectomy state. The pancreas, aorta, adrenal glands and kidneys appear normal. There is an inferior vena cava filter present. There is no retroperitoneal adenopathy.

CT OF THE PELVIS:

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PATIENT: MONICA JEFFRIES **DATE OF SERVICE:** 06/03/08
DOB: 07/28/1958 Phone: (301) 856-3282 **PATIENT#:** 1043173

There is no ascites, adenopathy, or pelvic mass. The uterus is absent. The bladder, perirectal space, and ischiorectal fossa are normal. There is a loop of sigmoid which appears to demonstrate some mild mucosal thickening but more likely due to incomplete distention with oral contrast.

There are no significant osseous abnormalities other than degenerative changes at the L5-S1 level.

IMPRESSION:
1. There are no findings in the abdomen or pelvis which strongly suggest metastatic disease.
2. Further evaluation with PET-CT imaging, would be helpful, if felt clinically needed.

Thank you for your referral

ROBERT S. FRANKEL, MD
RF/ 06/03/2008 2:38 PM

Approved by ROBERT S. FRANKEL on 06/03/2008 2:38 PM

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DAVID HAIDAK MD
WEB PORTAL ONLY
CLINTON, MD 20735

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PERFORMED AT: **RIA at Heritage**

PATIENT:	**JEFFRIES, MONICA**	PATIENT ID#:	1043173
DOB:	07/28/1958	EXAM DATE:	09/22/15
SEX:	FEMALE	PHONE:	(240) 605-7781

CT ABDOMEN AND PELVIS WITH IV CONTRAST

HISTORY: Left breast cancer 2009, status post mastectomy and chemotherapy. Severe right lower quadrant pain 6 months. Status post subtotal gastrectomy due to ulcer.

TECHNIQUE: Helical multidetector imaging performed with 0.625 mm thin slices acquired from the dome of the diaphragm to the pubic symphysis. Images reviewed in reformatted axial, coronal and sagittal planes. Imaging was performed with low-dose technique and the latest generation iterative reconstruction and dose-reduction technology.

CONTRAST: 100 cc Optiray 320 intravenously. Patient also received oral contrast. No immediate contrast reaction.

COMPARISON: 1/30/2015 CT abdomen pelvis, additional multiple CT abdomen pelvis exams dating back to 6/3/2008

FINDINGS:

Minimal bibasilar atelectasis. No pleural effusion. Heart size normal. Status post left mastectomy, bilateral saline implants are in place.

There is dilatation of intrahepatic and extrahepatic biliary tree, similar when compared to previous exam from 1/2015, common bile duct measures 1.1 cm at the porta hepatis, tapering down to 4 to 5 mm distally close to ampulla. Surgical clips in the gallbladder fossa, suggestive of cholecystectomy. Multiple surgical clips in the epigastric region, stable post subtotal gastrectomy changes. Spleen, pancreas, adrenal glands are unremarkable. 3 mm calyceal calculus lower pole of the left kidney, no hydronephrosis, kidneys otherwise unremarkable, symmetrical nephrogram.

Abdominal aorta is normal in caliber, there is IVC filter, however multiple struts of the IVC filter appeared outside the partially decompressed lumen of the inferior vena cava, the IVC distal to the filter is partially collapsed, enlarged bilateral internal iliac veins, left more than right. Multiple prominent and mildly enlarged porta hepatis, portacaval, aortocaval lymph nodes, for example aortocaval lymph node 1.3 x 1.4 cm on series 3, image 46, not substantially changed when compared to 1/2015.

The oral contrast has reached the proximal ascending colon, no bowel obstruction or ileus, redundant sigmoid colon. No obvious diverticulosis. There is long narrowing appearance of the terminal ileum, felt to be related to underdistention, the terminal ileum appeared normal on the last exam from January 2015, appendix is not seen, no pericecal inflammation. Bladder is unremarkable, status post hysterectomy.

Review of bone window demonstrates stable circumscribed sharply marginated sclerotic lesion left iliac crest since 2008. Degenerative spondylosis at L5-S1.

IMPRESSION:

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PERFORMED AT: **RIA at Heritage**

PATIENT:	**JEFFRIES, MONICA**	PATIENT ID#:	1043173
DOB:	07/28/1958	EXAM DATE:	09/22/15
SEX:	FEMALE	PHONE:	(240) 605-7781

1. No acute finding, stable exam.
2. CT findings raise the concern for IVC filter perforation, chronic appearance. Recommend surgical or interventional radiology consultation.
3. Mild porta hepatus and retroperitoneal lymphadenopathy, stable.
4. Nonobstructive left nephrolithiasis.
5. Mild biliary dilatation even for post cholecystectomy status, no substantial change, perhaps due to benign post inflammatory stenosis distally.
6. Status post hysterectomy.

Findings were discussed with DAVID HAIDAK MD at 9/23/2015 10:25 AM.

Approved by Fang Yu MD on 9/23/2015 10:25 AM

Thank you for your referral.

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PERFORMED AT: **RIA at Heritage**

PATIENT:	**JEFFRIES, MONICA**	PATIENT ID#:	1043173
DOB:	07/28/1958	EXAM DATE:	01/30/15
SEX:	FEMALE	PHONE:	(240) 605-7781

EXAM: CT ABDOMEN AND PELVIS

HISTORY: Right lower quadrant pelvic pain for 6 months. History of left breast cancer in 2009 status post mastectomy.

COMPARISON: Abdominal ultrasound 1/31/2014 and CT abdomen and pelvis 1/27/2014

CONTRAST: Intravenous administration 100 cc of nonionic contrast was injected without reaction. Oral contrast was administered.

TECHNIQUE: Helical multidetector imaging performed with 0.625 mm thin slices acquired from the dome of the diaphragm to the pubic symphysis. Images reviewed in reformatted axial, coronal and sagittal planes. Imaging was performed with low-dose technique and the latest generation iterative reconstruction and dose-reduction technology.

FINDINGS:

CT ABDOMEN: The lung bases are clear. There is no pericardial or pleural effusion.

Breast implants present status post left mastectomy.

The liver, pancreas, spleen, adrenal glands, and kidneys are normal. There are postsurgical findings of a cholecystectomy. There is no mesenteric or retroperitoneal lymphadenopathy. No abdominal ascites. There is an IVC filter present.

CT PELVIS: There is no free fluid within the pelvis or bulky pelvic adenopathy. There is mild diffuse circumferential wall thickening involving the ascending colon and cecum. The appendix is normal.

The bladder is normal.

There are no suspicious lytic or sclerotic osseous lesions identified. There are spondylotic changes at L5-S1.

IMPRESSION:
1. Mild circumferential wall thickening involving the ascending colon and cecum. Although these findings may be related to underdistention, mild colitis could also have this appearance.
2. Postsurgical findings of a left mastectomy and reconstruction mammoplasty.
3. No evidence of metastatic disease within the abdomen or pelvis.
4. IVC filter present.

Approved by Kara J Waters MD on 1/30/2015 2:00 PM

Thank you for your referral.

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PERFORMED AT: **RIA at Heritage**

PATIENT:	**JEFFRIES, MONICA**	PATIENT ID#:	1043173
DOB:	07/28/1958	EXAM DATE:	01/30/15
SEX:	FEMALE	PHONE:	(240) 605-7781

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PERFORMED AT: **RIA at Heritage**

PATIENT:	**JEFFRIES, MONICA**	PATIENT ID#:	1043173
DOB:	07/28/1958	EXAM DATE:	02/20/14
SEX:	FEMALE	PHONE:	(240) 605-7781

EXAM: CT OF THE CHEST WITHOUT IV CONTRAST

HISTORY: Anemia, left breast cancer diagnosed in 2009, status post mastectomy, cough, followup abnormal chest x-ray.

COMPARISON: Chest x-ray 1/24/2014, CT chest abdomen and pelvis 10/10/2012, 6/3/2008

TECHNIQUE: Multislice axial CT images from the lung apices to the upper pole both kidneys are performed without intravenous contrast. Coronal and sagittal reconstruction images obtained.

FINDINGS:

Linear bandlike opacity left inferior lingula segment, and posterior left lung base, slightly increased from 2012, perhaps pleural parenchyma scarring and/or discoid atelectasis.. No significant pulmonary nodule or mass. No acute infiltrates. Tracheobronchial tree is patent. No pleural effusion.

Visualized thyroid gland is unremarkable, right Port-A-Cath in place with the tip in distal SVC. Heart size normal. No pericardial effusion. Great vessels normal in caliber. No significant mediastinal, hilar lymphadenopathy. Status post left mastectomy, bilateral breast implants, stable small bilateral axilla lymph nodes, left more than right.

Visualized small portion of the upper abdomen demonstrates multiple surgical clips in the epigastric region.

Review of bone window demonstrates multiple small subcentimeter lucencies in the thoracic vertebrae and sternum without obvious change.

IMPRESSION:

1. Probable pleural-parenchymal scarring and/or discoid atelectasis left lung base, slightly worse when compared to 2012.
2. Exam otherwise stable, however patient has innumerable subcentimeter lucencies in the vertebrae and sternum, although stable, not typical appearance for osteoporosis/osteopenia or metastasis from breast cancer, patient had negative bone scan 10/10/2012, clinical correlation, multiple myeloma needs to be ruled out..

Approved by Fang Yu MD on 2/20/2014 2:44 PM

Thank you for your referral.

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JS 44 (Rev. 12/12)

CIVIL COVER SHEET

RWT 15CV3480

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

Jeffries, Monica

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

(c) Monica Jeffries
414 Winslow Rd
Oxon Hill, MD 20745-1432
301-485-1659

DEFENDANTS

Boston Scientific et. al.
300 Boston Scientific Way
Marlborough, MA 01752-1234

County of Residence of First Listed Defendant MA
(IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.

Attorneys *(If Known)*

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DISTRICT OF MARYLAND
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BY

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)*

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

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

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
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- ☐ 371 Truth in Lending
- ☐ 380 Other Personal Property Damage
- ☐ 385 Property Damage Product Liability

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- ☐ 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

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

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

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

PROPERTY RIGHTS
- ☐ 820 Copyrights
- ☐ 830 Patent
- ☐ 840 Trademark

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

OTHER STATUTES
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- ☐ 400 State Reapportionment
- ☐ 410 Antitrust
- ☐ 430 Banks and Banking
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- ☐ 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
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- ☐ 895 Freedom of Information Act
- ☐ 896 Arbitration
- ☐ 899 Administrative Procedure Act/Review or Appeal of Agency Decision
- ☐ 950 Constitutionality of State Statutes

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

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing *(Do not cite jurisdictional statutes unless diversity)*:
28:1332 Diversity, Product Litigation

Brief description of cause:
Perforation Migration Defective Medical device

VII. REQUESTED IN COMPLAINT:

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

DEMAND $

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

VIII. RELATED CASE(S) IF ANY

(See instructions): JUDGE _____ DOCKET NUMBER _____

DATE 11/9/15

SIGNATURE OF ATTORNEY OF RECORD Monica Jeffries pro se

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