IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA
(Alexandria Division)

SCOTT WADLEY
20933 Rootstown Terrace
Ashburn, Virginia 20147

Plaintiff,

v.

MEDTRONIC, INC.,

Serve Registered Agent: CT Corporation System
4701 Cox Road, Suite 301
Glen Allen, Virginia 23060

And; MEDTRONIC SOFAMOR DANEK USA, INC.,

Serve Registered Agent: CT Corporation System
4701 Cox Road, Suite 301
Glen Allen, Virginia 23060

Defendants.

Civil Action No.: 1:12CV1397 CMH/TRJ

COMPLAINT FOR DAMAGES

Plaintiff SCOTT WADLEY("Plaintiff"), by and through her counsel, C. Lowell Crews, Attorney at Law, PLLC and, alleges as follows:

I. INTRODUCTION

1. This case involves a spinal surgery in which a bio-engineered bone graft device known as the Infuse® Bone Graft ("Infuse®") was used in a posterior-approach spine surgery for Plaintiff, SCOTT WADLEY.

2. Infuse® was made by MEDTRONIC, INC., and MEDTRONIC SOFAMOR DANEK, USA, INC. (collectively "the Medtronic Defendants" or "Medtronic") and was

promoted and sold by Medtronic to be used off-label in SCOTT WADLEY's posterior lumbar fusion (L4-L5) on January 15, 2003.

3. Infuse® is approved and indicated for lumbar surgery that is performed through the abdomen (anterior). It is not approved for use in lumbar surgery through the back (posterior). When Infuse It is used off-label, such as in a posterior-approach spine surgery, it often causes "ectopic" or "exuberant" bone growth onto or around the spinal cord. When nerves are compressed by ectopic/exuberant bone growth or neural foraminal narrowing, a patient can experience, among other side effects, intractable pain, paralysis, spasms and cramps in limbs, as did in SCOTT WADLEY in his legs, back and foot.

4. Medtronic either recklessly or intentionally minimized and/or downplayed the risks of serious side effects related to the use of Infuse®, including but not limited to the risk of ectopic or uncontrolled bone growth. According to articles in the June 2011 issue of The Spine Journal (an international medical journal that publishes peer-reviewed research articles related to evidence-based spine care), earlier Medtronic-sponsored studies and articles inaccurately reported the safety of rhBMP-2 (the active fusion ingredient in infuse®) by underestimating its risks.

5 For example, these Medtronic-sponsored articles omitted mention of adverse effects seen in the earliest trials of Infuse®, such as uncontrolled or ectopic bone growth, inflammatory reactions, adverse back and leg pain events, radiculitis, retrograde ejaculation, urinary retention, bone resorption, and implant displacement. They also omitted mention of the risks of sterility and cancer associated with rhBMP-2 use, as reported in Food and Drug Administration documents and hearings.

6 The actual rate of incidence of these serious side effects is much greater than the rate disclosed by Medtronic or these Medtronic-sponsored studies to physicians or to the public. With

respect to posterior lumbar interbody fusion—which Plaintiff SCOTT WADLEY underwent—Medtronic failed to disclose significant risks that it knew of or should have known of including ectopic bone formation, radiculitis, neural foraminal narrowing, osteolysis, and worse overall outcomes.

7. Because of Medtronic's wrongful conduct, hundreds of patients, like SCOTT WADLEY, underwent surgeries without knowing the risks created by off-label use of Infuse®. These patients' doctors were persuaded by Medtronic and Medtronic's consultant "opinion leaders," who are paid physician promoters, and Medtronic sales representatives, to use Infuse® for dangerous off-label uses such as posterior lumbar fusion surgery.

8. As a result of this off-label, posterior-approach Infuse® spine surgery, SCOTT WADLEY suffered severe bodily injuries and lost wages. He has also suffered intractable leg pain and back pain two days after the surgical event and had to be transported via ambulance back to the hospital where he received morphine intravenous

9. SCOTT WADLEY is disabled due to this surgical event. Because of his off-label surgery using Infuse®, he has been unable to find meaningful employment. He suffers continuous pain in hisr back and legs from everyday activities, such as sitting or standing for even small amounts of time.

II. PARTIES

10. Plaintiff SCOTT WADLEY is an individual who is a resident of Loudoun County, Virginia.

11. Defendant MEDTRONIC, INC. is a Minnesota corporation, with its principal place of business at 710 Medtronic Parkway, Minneapolis, Minnesota 55432.

12. Defendant MEDTRONIC SOFAMOR DANEK USA, INC. is a Tennessee corporation,

with its principal place of business at 1800 Pyramid Place, Memphis, Tennessee 38132.

13. Plaintiff, by and through his undersigned counsel, hereby institutes this civil action against MEDTRONIC, INC., and MEDTRONIC SOFAMOR DANEK, USA, INC.

III. JURISDICTION AND VENUE

14. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. § 1332 because there is complete diversity of citizenship between Plaintiff and the Defendants, and because Plaintiff alleges an amount in controversy in excess of $75,000, exclusive of interest and costs.

15. This Court has personal jurisdiction over Defendants because at all relevant times they have engaged in substantial business activities in the State of Virginia. Upon information and belief, at all relevant times Defendants transacted, solicited, and conducted business in Virginia through their employees, agents, and/or sales representatives, and derived substantial revenue from such business causing injuries to Plaintiff in Virginia.

16. Venue is proper in this District pursuant to 28 U.S.C. § 1391(a) because Plaintiff is a Virginia resident in this District and the Defendants are Tennessee and Minnesota corporations.

IV. BACKGROUND

A. The Infuse® Bone Graft Device

17. Medtronic designed and marketed Infuse 1z for lumbar spine fusion surgery.

18. Infuse® is a bio-engineered bone filling material containing a bone morphogenetic protein ("BMP"), and is used as an alternative to grafting a patient's own bone, typically from the patient's hip. The purpose of Infuse® is to accomplish the same clinical outcomes as grafting a patient's own bone into these locations but without the difficulties of grafting bone from the hip and other sites, since grafting sites sometimes have side effects such as pain.

19. It uses a genetically engineered protein — rhBMP — to help fuse vertebrae in the lower (lumbar) spine in order to treat degenerative disc disease.

20. The device consists of three components split among two parts: (1) a metallic spinal fusion cage; and, (2) the bone graft substitute which consists of a genetically-engineered human protein (rhBMP-2) along with a sponge-like carrier or scaffold for the protein (manufactured from bovine collagen) that is placed inside the fusion cage.

21. The fusion cage component maintains the spacing and temporarily stabilizes the diseased region of the spine, while the Infuse® bone graft component is used to form bone, which is intended to permanently stabilize (fuse) this portion of the spine. During surgery, rhBMP-2 is soaked onto and binds with the absorbable collagen sponge that is designed to resorb, or disappear, over time. As the sponge dissolves, the rhBMP-2 stimulates the cells to produce new bone.

B. Background on Bone Morphogenetic Proteins in the infuse 1z Bonc Graft

22. The active ingredient in the INFUSE® Bone Graft is rhBMP-2, a manufactured version of a protein already present in the human body that promotes new bone growth.

23. Certain BMPs have been studied for decades because of their ability to heal bone and eliminate the need for bone graft harvesting from other parts of the body. Approximately twenty (20) BMPs have been discovered, but only six appear capable of initiating bone growth. Of these, rhBMP-2 has been studied more than any other BMP and is FDA-approved for use only in the lower (lumbar) spine, some types of tibia fractures, and some dental surgeries.

25. Naturally-occurring BMP is found within the bone itself, but only in small amounts. To provide clinically useful and reproducible amounts of isolated, human BMP, it must be manufactured in a special facility.

26. Scientists isolated the gene for one protein (BMP-2) from bone tissue and used molecular biology techniques to create genetically engineered cells. These cells then produce large quantities of rhBMP-2. A similar process is used to manufacture other proteins, such as insulin.

C. The FDA Approval Process

27. Infuse© was approved by the United States Food and Drug Administration ("FDA") on July 2, 2002, for use only in the lower, or lumbar, region of the spine (at levels L4 through S I) to treat degenerative disc disease, and was approved only for anterior-approach surgeries at L4 through S 1. That meant that it was initially approved only to be used by surgeons in spinal fusions when going in through the patient's abdomen.

28. Infuse® is also used to fill space where bone is needed in order to place dental implants (for example, dental implants with an exposed head used to secure dental devices such as crowns, fixed bridges, or dentures.) In dental surgeries, Infuse® is used to make enough bone in the sinus area to place dental implants in the upper jaw. Infuse© is also used to increase bone in extraction sites prior to implant placement.

29. Infuse® was approved by the FDA on March 9, 2007, for dental use.

30. In addition to use in lower spine fusion surgeries and dental surgeries, Infuse® has been approved for only one other use: repair of tibial fractures that have already been stabilized with IM nail fixation after appropriate wound management.

31. Infuse® has never been approved by the FDA for use in other parts of the body or for use in any other type of procedure. Any such uses are "off-label" uses.

32. Physicians may use FDA-approved medical devices in any way they see fit, but companies are not permitted to promote off-label uses for their medical devices or to pay doctors inducements or kickbacks to promote off-label uses or to perform procedures using the devices off-label.

33. The use of Infuse® for posterior lumbar fusion surgery has never been approved by the FDA, and the use of this product through a posterior approach is an off-label use.

D. Infuse® is a Very Profitable Part of Medtronic's Business

34. Infuse® has become a best seller for Medtronic. One market analyst has publicly estimated that the product's sales were approximately $815 million for the fiscal year ending in April 2008. Medtronic has been depending heavily on Infuse® since sales in so many of its other products, such as cardiac defibrillators, have slowed because of the recalls of those defective defibrillators.

E. Off-Label Use of Infuse® in the Lumbar Spine is Not Safe or Effective

35. Susan Levine, a Vice President at Hayes, Inc., a company which evaluates medical technologies for insurers, has reported that she has reviewed the research work on Infuse®, and finds it "really distressing to see something like this used in a potentially harmful way and without adequate evidence." Ms. Levine has reportedly said that, when used properly, Infuse© can be "good for a patient."

36. Questions about off-label use cropped up before the product was approved. For example, in early 2002, one member of an FDA advisory committee reviewing Infuse® asked agency staff for recommendations on "guarding against off-label use of this product."

37. A number of patients say they have been harmed in off-label uses of Infuse®, which is approved by the FDA only for anterior-approach surgery in a small section of the spine in the lower, or lumbar, region. At least 280 reports of adverse events involving Infuse® have been made to the FDA. Approximately 75% of those reports involve off-label use.

F. Despite Lack of Safety and Effectiveness, Medtronic Improperly Promoted and Marketed to Physicians the Off-Label Use of Infuse « Through a Posterior Approach

38. Medical device companies look for surgeons who are known as "Opinion Leaders" and who will use a high volume of their devices. Opinion leaders are physicians whose opinions on medical procedures and medical devices are held in high regard. If these influential physicians are willing to promote the use of a certain device, then other surgeons are likely to follow suit and use that device, sometimes including the improper promotion of off-label uses.

39. Many medical device companies, including Medtronic, cultivate relationships with these opinion leaders, paying them handsome (and in the case of Infuse®, sometimes seven-figure) consulting fees, travel expenses for seminars, and other perks, to encourage these physicians to promote the use of a particular medical device.

40. Not only did Medtronic engage in such activities with respect to Infuse®, it improperly paid doctors to promote, both directly and indirectly, the off-label use of Infuse® through the posterior and lateral approaches in lumbar spine fusions.

41. The Wall Street Journal, for example, has reported that Timothy Kuklo, M.D., while an orthopedic surgeon at Walter Reed Army Hospital, submitted an article to a British medical journal with fabricated claims of the efficacy of Infuse® and forged the signatures of four "co-authors." Medtronic confirmed that Dr. Kuklo was a paid consultant for Medtronic and that the company has paid him over $800,000.

42. The Defendants here, MEDTRONIC, INC. and MEDTRONIC SOFAMOR DANEK USA, INC., have been named as defendants in two prior qui tam actions, United States ex rel. (UNDER SEAL) v. Medtronic. Inc., et al., Civil Action No. 02-2709 (W. D. Tenn.), and United States ex rel. Poteet v. Medtronic, Inc., et al., Civil Action No. 03-2979 (W. D. Tenn.) (collectively the "qui tam lawsuits"), both of which allege that Medtronic violated the False Claims Act, 31 U.S.C. § 3729, et seq., by paying illegal kickbacks to certain physicians in connection with promoting the off-label use of Infuse® in the spine, which resulted in the submission of false or fraudulent claims to federal health care programs.

43. In these lawsuits, the United States Department of Justice ("DOJ") contends that between January 1, 1998 and April 30, 2003, Medtronic made payments and provided other remuneration to a number of physicians and entities in connection with its spinal products in the form of (1) payments and other remuneration for physicians' attendance and expenses at medical education events, "think tanks", VIP/opinion leader events, and meetings at resort locations; (2) services and payments for services to physicians through Medtronic's Healthcare Economic Services and eBusiness Departments; and (3) payments made pursuant to consulting, royalty, fellowship and research agreements with various physicians and entities

44. Based on its investigation, the DOJ contends that certain of the payments, services, and remuneration mentioned above were improper and resulted in the submission of false or fraudulent claims.

45. In July 2006, Medtronic agreed to pay $40 million to the United States of America to settle these lawsuits under the False Claims Act, 31 U.S.C. §§ 3729-3733, the Civil Monetary Penalties Law, 42 U.S.C. § 1320a-7a, and the Program Fraud Civil Remedies Act, 31 U.S.C. §§ 3801-12.

46. As a result of this settlement, Medtronic and Medtronic Sofamor Danek agreed to enter into a Corporate Integrity Agreement with the Department of Health and Human Services Office of Inspector General.

47. Also, as a result of this settlement, Medtronic agreed to negotiate with representatives of the National Association of Medicaid Fraud Control Units to reach an agreement that provides for distribution of certain sums to the several states with which Medtronic agreed to a settlement concerning the conduct at issue in the lawsuits.

48. Despite its 2006 settlement with the DOJ, and on information and belief, Medtronic has continued from 2006 to the present to improperly and illegally promote the off-label use of Infuse® in non-FDA-approved spine surgeries.

G. September 30, 2008 Letters from United States Senators Herb Kohl and Charles Grassley to Medtronic Regarding Ongoing Concerns over Medtronic's Payments to Doctors Related to the Promotion and Marketing of Infuse®

49. Despite this July 2006 Settlement with the DOJ, concerns regarding Medtronic's off-label marketing activities and related payments to doctors continued.

50. On September 30, 2008, U.S. Senator Herb Kohl sent a letter to Medtronic noting that earlier in 2008, Medtronic's outside counsel provided to the Special Committee on Aging a written account of Medtronic's efforts to comply with the July 2006 Settlement Agreement it reached with the DOJ concerning allegations that Medtronic and its subsidiary improperly compensated surgeons and physicians in connection with the Infuse® device.

51. Senator Kohl's letter expressed several concerns, including the following:

> That account also addressed the corporate integrity agreement (CIA) that Medtronic and its subsidiary entered into with the Office of the Inspector General of the United States Department of Health and Human Services stemming from those same

> allegations. In that same letter to the Committee, Medtronic and its subsidiary both denied that "improper payments were made to physicians in the first place (Medtronic's agreement with DOJ does not contain any admission of liability), much less that improper payments `have continued." Consequently, it was with concern that I read recent articles, in the Wall Street Journal and elsewhere, which outlined highly disturbing allegations of improper, if not illegal, payments by Medtronic to surgeons and physicians.
>
> These continuing allegations are directly relevant to the Committee's oversight of inappropriate physician compensation practices within the medical device industry. All of the major orthopedic device companies that settled with DOJ over such allegations were required to publicly reveal information related to their payments to physicians. Medtronic's response to the Committee's initial inquiry articulated no specific reasons as to why Medtronic has yet to voluntarily make the same disclosures.

52. In this letter, Senator Kohl requested both documentation of Medtronic's efforts to comply with the July 2006 Settlement Agreement and interviews with corporate witnesses and documents "given the ongoing, serious concerns publicly raised regarding the integrity and transparency of Medtronic's physician compensation practices."

53. Senator Kohl also asked Medtronic to explain "the circumstances that led Medtronic's former counsel to file suit against the company [alleging improper payments to physicians] and how that matter was subsequently settled."

54. Also on September 30, 2008, U.S. Senator Charles Grassley sent a similar letter to Medtronic pertaining to the marketing of Infuse® and allegations of related kickbacks to physicians regarding the sale of Infuse®, noting that:

> Last week, the Wall Street Journal (WSJ) reported on allegations of financial perks provided to doctors that included "entertainment at a Memphis strip club, trips to Alaska and patent royalties on inventions they played no part in." I would appreciate your assistance in better understanding these allegations and would like to take this opportunity to lay out my specific concerns and questions.[1]

[1] 'David Armstrong, Lawsuit Says Medtronic Gave Doctors Array of Perks, Wall St. J., Sept. 25, 2008.

55. Senator Grassley went on to express his concern over the Wall Street Journal's reports "that one of the incentives Medtronic provided physicians was to include them on patents for medical devices and reward them with royalties, even though the physicians may not have contributed to the development of the product."

56. This letter specifically addressed issues related to Medtronic's marketing of Infuse®:

> Fourth, earlier this month the WSJ reported on problems with off-label use of Medtronic's Infuse®. Infuse® is a bone graft replacement technology that uses a protein which creates bone. Specifically, it was reported that Medtronic gave payments to physicians, in the form of consulting agreements, as a means of increasing sales of Infuse®. The allegations that Medtronic has been disguising these consulting agreements as inducements or kickbacks for physicians to use Infuse® are equally troubling. Likewise, this is a practice that I would like to better understand and I would like to know what if anything has changed since these reported events.

57. Senator Grassley, in his September 30, 2008 letter, also questioned why several lawsuits against Medtronic pertaining to Infuse® remained under seal, and indicated that he would like to "better understand the status of these lawsuits and the procedural process that has led to the current situation."

H. June 21, 2011 Letter from United States Senators Charles Grassley and Max Baucus to Medtronic Regarding Continuing Concerns

58. The Senate Committee on Finance currently is investigating whether Medtronic has continued to misrepresent the adverse events that result from Infuse® and rhBMP-2, as well as the possibility that Medtronic improperly influenced clinical trials and reporting regarding rhBMP-2. On June 21, 2011, Senators Charles Grassley and Max Baucus sent a letter to Medtronic on behalf of the Senate Committee on Finance requesting Medtronic produce documents and communication pertaining to "adverse postoperative events and/or medical

complications" resulting from the use of rhBMP-2.[2] The letter also requests Medtronic provide "[a] detailed account of payments that Medtronic made to all Infuse clinical investigators."

59. In the June 21 letter, Senators Grassley and Baucus state: "We are extremely troubled by press reports suggesting that doctors conducting clinical trials examining the safety and effectiveness of Infuse on behalf of Medtronic were aware that Infuse, a treatment commonly used in spinal surgery, may cause medical complications, but failed to report this in the medical literature. This issue is compounded by the fact that some clinical investigators have substantial financial ties to Medtronic."

60. The letter further states: "We are also concerned that other severe side-effects of Infuse and similar bone-growth products developed by Medtronic may have been unreported or under-reported in clinical literature. Reports have linked Infuse to potentially fatal swelling in the neck and throat, and radiating leg pain. Concerns have also been expressed about a potential link to cancer."

I. June 1, 2011 Issue of The Spine Journal

61. On June 1, 2011, The Spine Journal, a leading medical journal in the United States, published a special edition dedicated to addressing serious patient safety concerns and ethical concerns related to the use of rhBMP-2 (Infuse®) in the spine.

62. This special edition reviewed thirteen peer-reviewed articles about rhBMP-2 by industry-sponsored authors, including many sponsored by Medtronic, and found that these articles had inaccurately reported the safety of rhBMP-2 applications by underestimating its risks.

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2 Letter from Charles Grassley & Max Baucus to Medtronic (June 21, 2011), available at http://finance.senate.gov/newsroom/chairman/release.

63. In an editorial summarizing the findings of the special issue, five prominent physicians, including spine surgeons at Stanford University, wrote that the earlier industry-sponsored trials and reports were "remarkable for the complete absence of reported rhBMP-2-related clinical adverse events." For example, the industry-sponsored articles omitted mention of indications from the earliest trials of inflammatory reactions, adverse back and leg pain events, radiculitis, retrograde ejaculation, urinary retention, bone resorption, and implant displacement. They also omitted mention of sterility and cancer risks associated with rhBMP-2, as reported in FDA documents and hearings. The trials and reports suffered from idiosyncratic trial design, reporting bias, and peer-review/publication shortfalls.

64. According to this editorial and several of the accompanying articles, the thirteen industry-sponsored articles reported only successful fusions and low rates of complications with Infuse®, which led to the "off-label" use of Infuse® as an adjunct to increase early fusion rates in lumbar fusion procedures. The articles "may have promoted widespread poorly considered on- and off-label use, eventual life-threatening complications and deaths."

65. Contrary to the conclusions of the earlier industry-sponsored trials and articles, an article in the special issue suggested "an estimate of adverse events associated with rhBMP-2 use in spine fusion ranging from 10% to 50% depending on approach."

> Anterior cervical fusion with rhBMP-2 has an estimated 40% greater risk of adverse events with rhBMP-2 in the early postoperative period, including life-threatening events. After anterior interbody lumbar fusion rates of implant displacement, subsidence, infection, urogenital events, and retrograde ejaculation were higher after using rhBMP-2 than controls. Posterior lumbar interbody fusion was associated with radiculitis, ectopic bone . formation, osteolysis, and poorer global outcomes. In posterolateral fusions, the risk of adverse effects associated with rhBMP-2 use was equivalent to or greater than that of iliac crest bone graft harvesting, and 15% to 20% of subjects reported early back pain and leg pain adverse events; higher doses of rhBMP-2 were also associated with a greater apparent risk of new malignancy."

Eugene J. Carragee, Eric L. Hurwitz & Bradley K. Weiner, A critical review of recombinant human bone morphogenetic protein-2 trials in spinal surgery: emerging safety concerns and lessons learned, 11 Spine J. 471, 471-72 (2011) (emphasis added).

66. This article also reported that ten of the earlier industry-sponsored rhBMP-2 trials were funded in whole or in part by the manufacturer of rhBMP-2 (Infuse®), Medtronic, Inc. Furthermore, in twelve of these earlier studies, the median-known financial association between the authors and Medtronic Inc. was approximately $12,000,000-$16,000,000 per study (range, $560,000-$23,500,000). Id. at 475.

J. SCOTT WADLEY's Initial Surgery and Emergency Intervention

67. On January 15, 2003, SCOTT WADLEY was admitted to George Washington University Hospital in Washington, D.C. for spine surgery to address disk herniation and stenosis.

68 During the surgery, Dr. Warren Yu used an off-label posterior approach to place the Medtronic Infuse® bone graft into the lumbar region of Mr. Wadley's spine in order to attempt to fuse vertebrae L4- L5, lumbar laminectomy with fusinon and instrumentation.

69. Mr. Wadley's post-operative period was marked by increasingly severe pain and weakness in her left leg.

70. Less than 48 hours after surgery, Mr. Wadley had severe back pain and was taken via ambulance back to George Washington University Hospital for intravaneous induced pain medication.

71. Since the surgical event, SCOTT WADLEY continues to suffer significant pain, cramping and spasms going up his back, leg and foot numbness as well as weakness in his left leg.

72. A MRI study conducted on November 9, 2011 shows Mr. Wadley shows "evidence of right

neural foraminal narrowing at L4-L5."

V. SUMMARY OF ALLEGATIONS

73 Plaintiff, SCOTT WADLEY, suffered grievous personal injuries as a direct and proximate result of Defendants' misconduct.

74. SCOTT WADLEY would not have chosen to be treated with Infuse® had he known of or been informed by Defendants of the true risks of the off-label use of Infuse®.

75. At all relevant times, Infuse® was researched, developed, manufactured, marketed, promoted, advertised and sold by the Medtronic Defendants.

76. At all times relevant, the Medtronic Defendants misrepresented the safety of Infuse® to physicians and patients, including SCOTT WADLEY, and recklessly, willfully, or intentionally failed to alert SCOTT WADLEY or his physicians of the extreme danger to patients of the off-label use of Infuse® through a posterior approach.

77. At all times relevant, the Medtronic Defendants negligently manufactured, marketed, advertised, promoted, sold and distributed Infuse® as a safe and effective device to be used for spinal fusion surgery. Medtronic negligently, recklessly, and/or intentionally overpromoted Infuse® to physicians and consumers, including to Dr. Amos Dare and Jennifer English, and downplayed to physicians and consumers its dangerous effects, including but not limited to the overpromotion and downplaying of the dangerous effects of Infuse® in off-label posterior approach spine surgeries.

78. Any warnings Medtronic may have issued concerning the dangers of off-label use of Infuse© through a posterior approach were insufficient in light of Medtronic's contradictory prior, contemporaneous and continuing promotional efforts and overpromotion of Infuse® for off-label posterior-approach use in the lumbar spine.

79. At all relevant times, Medtronic knew, and/or had reason to know, that Infuse® was not safe for off-label use on patients because it had not been approved for posterior-approach use; and its safety and efficacy for posterior-approach use was either unknown, or was known by these Defendants to be unsafe and ineffective.

80. In posterior-approach lumbar spine surgeries, Infuse® often leads to serious complications including, but not limited to, radiculitis, ectopic bone formation, osteolysis, and poorer global outcomes, and as in Plaintiff SCOTT WADLEY's case, pain and/or weakness in limbs caused by ectopic bone growth.

81. When used in posterior-approach lumbar spine surgery, Infuse® has often failed to work in a safe and effective manner, and was defective, thereby causing serious medical problems and, in some patients, like SCOTT WADLEY, catastrophic injuries.

82. At all relevant times, Medtronic knew, and/or had reason to know, that its representations and suggestions to physicians that Infuse® was safe and effective for use in posterior-approach lumbar spine surgery were materially false and misleading.

83. The off-label posterior-approach use of Infuse® can cause serious physical injuries and/or death.

84. Medtronic knew and/or had reason to know of this likelihood and the resulting risk of injuries and deaths, but concealed this information and did not warn Plaintiff Jennifer English or her physicians, preventing Plaintiff and her physicians from making informed choices in selecting other treatments or therapies.

85. Plaintiff and her physicians relied on Medtronic's misrepresentations regarding the safety and efficacy of Infuse® in connection with their decisions to use Infuse® off-label in Plaintiff's spine surgery. Plaintiff and her physicians did not know of the specific risks, and/or

were misled by Medtronic as to the nature and incidence of the true specific risks, and/or knew of the true risks and chose to not inform Plaintiff of those risks, related to the use of Infuse® in posterior-approach lumbar spine surgeries.

86. The Medtronic Defendants improperly promoted and marketed Infuse® to Plaintiff's physicians for off-label use in the spine, and this promotion and marketing caused Plaintiff's physicians to decide to implant Infuse® in Plaintiff's spine using a posterior approach.

87. At all times herein mentioned, each of the Defendants was the agent, servant, partner, aider and abettor, co-conspirator and/or joint venturer 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 breach of duty owed to the Plaintiff.

88. At all times herein mentioned, Defendants were fully informed of the actions of their agents and employees, and thereafter no officer, director or managing agent of Defendants repudiated those actions, which failure to repudiate constituted adoption and approval of said actions and all Defendants and each of them, thereby ratified those actions.

89. 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 has ceased and these Defendants are the alter-ego of the other certain Defendants and exerted control over those Defendants. Adherence to the fiction of the separate existence of these 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.

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

91. The harm which has been caused to Plaintiff resulted from the conduct of one, or various combinations of the Defendants, and, through no fault of the Plaintiff. There may be uncertainty as to which one or a combination of Defendants caused the harm. Defendants have superior knowledge and information on the subject of which one or a combination of Defendants caused Plaintiff's injuries.

92. Thus, the burden of proof should be upon each Defendant to prove that the Defendant has not caused the harms suffered by Plaintiff.

VI. PLAINTIFF IS ENTITLED TO PUNITIVE DAMAGES

93. As a result of Defendants' oppression, fraudulent concealment, wantonness, malice, and reckless disregard for Plaintiff's safety, Plaintiff is entitled to punitive or exemplary damages to the fullest extent necessary and punitive as plead in detail below.

VII. CLAIMS FOR RELIEF

FIRST CAUSE OF ACTION

Fraudulent Misrepresentation and Fraud in the Inducement

94. Plaintiff incorporates by reference all previous paragraphs of this Complaint as if fully set forth here and further alleges as follows:

95. In connection with their Infuse® products, Defendants fraudulently and

intentionally misrepresented material and important health and safety product risk information from Plaintiff and her physicians, all as alleged in this Complaint. Plaintiff and her physicians would not have made off-label use of Infuse® for posterior-approach lumbar spine fusion surgery had they known of the safety risks related to Infuse®.

96. Any of the following is sufficient to independently establish Defendants' liability for fraudulent misrepresentation and/or fraud in the inducement:

a. Defendants fraudulently concealed and misrepresented the health and safety hazards, symptoms, constellation of symptoms, diseases and/or health problems associated with the off-label posterior-approach use of their Infuse® product;

b. Defendants fraudulently concealed and misrepresented their practice of promoting and marketing to physicians, including Plaintiff's physician, the off-label use of Infuse® in posterior-approach lumbar spine surgery;

c. Defendants fraudulently concealed and misrepresented information about the known comparative risks and benefits of the use of Infuse® and the relative benefits and availability of alternate products, treatments and/or therapies.

97. Defendants knew, or should have known, that they were concealing and misrepresenting true information about the known comparative risks and benefits of the use of Infuse® and the relative benefits and availability of alternate products, treatments and/or therapies.

98. Defendants knew that Plaintiff and her physicians would regard the matters Defendants concealed and misrepresented to be important in determining the course of treatment for the Plaintiff, including Plaintiff and her physician's decision whether or not to use Infuse® in Plaintiff's posterior-approach spine surgery.

99. Defendants intended to cause Plaintiff and her physicians to rely on their concealment of information and misrepresentations about the safety risks related to Infuse® to induce them to make off-label use of Infuse® for posterior-approach lumbar spine fusion surgery.

100. Plaintiff and her physicians were justified in relying, and did rely, on Defendants' concealment of information and misrepresentations about the safety risks related to Infuse® in deciding to make off-label use of Infuse® for posterior-approach lumbar spine fusion surgery.

101. As a direct and proximate result of Defendants' fraudulent concealment and misrepresentations and suppression of material health and safety risks relating to Infuse® and Defendants' dangerous and irresponsible off-label promotion and marketing practices, Plaintiff suffered injuries, and economic loss, and Plaintiff will continue to suffer injuries, damages and economic loss.

102. As the direct, proximate and legal cause and result of the Defendants' fraudulent concealment and misrepresentations and suppression of material health and safety risks relating to Infuse® and Defendants' dangerous and irresponsible marketing and promotion practices, plaintiff has been injured and has incurred damages, including but not limited to medical and hospital expenses, physical and mental pain and suffering, and loss of the enjoyment of life.

103. Plaintiff is therefore entitled to damages in an amount to be proven at trial, together with interest thereon and costs.

104. Defendants' conduct, as alleged above, was malicious, oppressive, intentional and/or reckless, outrageous, and constituted willful and wanton disregard for the rights or safety of others. Such conduct was directed specifically at Plaintiff and warrants an award of punitive damages.

SECOND CAUSE OF ACTION
Constructive Fraud

105. Plaintiff incorporates by reference all previous paragraphs of this Complaint as if fully set forth here and further alleges as follows:

106. Defendants marketed their Infuse© product to and for the benefit of Plaintiff, and marketed it to her physicians, and Defendants knew or had reason to know of the unreasonable dangers and defects in their Infuse® product, and that Plaintiff and her physicians would use the product.

107. Defendants owed Plaintiff duties to exercise reasonable or ordinary care under the circumstances, in light of the generally recognized and prevailing best scientific knowledge, and to produce and market Infuse® in as safe a manner and condition as possible.

108. Specific defects, as specified above in this Complaint, in the Infuse® product, rendered it defective and unreasonably dangerous.

109. Through the conduct described in the foregoing and subsequent paragraphs of this Complaint, Defendants breached their duties to Plaintiff. Such breaches exhibited a reckless disregard for the safety of others and willful and wanton conduct.

110. By breaching their duties to Plaintiff, Defendants gain an advantage by profiting from the sale of Infuse® for off-label use.

111. Plaintiff and her physicians justifiably relied on Defendants' misrepresentations and concealment of the actual dangers of off-label use Infuse®.

112. As the direct, producing, proximate and legal cause and result of the Defendants' breach of their duties, Plaintiff has suffered severe physical pain and pecuniary loss.

113. As the direct, producing, proximate and legal cause and result of the Defendants' breach of their duties, Plaintiff has been injured and has incurred damages, including but not

limited to medical and hospital expenses, and pain and suffering.

114. Plaintiff is therefore entitled to damages in an amount to be proven at trial, together with interest thereon and costs.

115. Defendants' conduct, as alleged above, was malicious, oppressive, intentional and/or reckless, outrageous, and constituted willful and wanton disregard for the rights or safety of others. Such conduct was directed specifically at Plaintiff and warrants an award of punitive damages.

THIRD CAUSE OF ACTION
Strict Products Liability — Failure To Warn

116. Plaintiff incorporates by reference all previous paragraphs of this Complaint as if fully set forth here and further alleges as follows:

117. Medtronic had a duty to warn Plaintiff and her physicians about the dangers of Infuse® of which they knew, or in the exercise of ordinary care, should have known, at the time the Infuse© left the Defendants' control. The Medtronic Defendants did know of these dangers of off-label use of Infuse®, and breached this duty by failing to warn Plaintiff and her physicians of the dangers of its off-label use in posterior-approach lumbar spine surgery.

118. The warnings accompanying the Infuse® product did not adequately warn Plaintiff and her physicians, in light of its scientific and medical knowledge at the time, of the dangers associated with Infuse® when used off-label in posterior-approach lumbar spine surgery including, but not limited to, pain and weakness in limbs, radiculitis, ectopic bone formation, neural foraminal narrowing, osteolysis, and poorer global outcomes than alternative treatments.

119. The warnings accompanying the Infuse® product failed to provide the level of information that an ordinary physician or consumer would expect when using the product in a manner reasonably foreseeable to Medtronic. Medtronic either recklessly or intentionally

minimized and/or downplayed the risks of serious side effects related to the off-label use of Infuse®, including but not limited to these risks of ectopic or uncontrolled bone growth.

120. Plaintiff and her physicians relied on Medtronic's inadequate warnings in deciding to use Infuse® in an off-label manner. Plaintiff and her physicians would not have made off-label use of Infuse® for posterior-approach lumbar spine fusion surgery had they known of the safety risks related to Infuse®.

121. As a direct and proximate result of one or more of the above listed dangerous conditions and defects, and of Medtronic's failure to provide adequate warnings about them, Plaintiff sustained serious injuries of a personal and pecuniary nature from approximately August 2007 to the present.

122. Plaintiff has sustained extreme pain, suffering, and anguish from the date of her posterior-approach lumbar spine surgery with Infuse® until present.

123. Defendants' conduct, as alleged above, was malicious, oppressive, intentional and/or reckless, outrageous, and constituted willful and wanton disregard for the rights or safety of others. Such conduct was directed specifically at Plaintiff and warrants an award of punitive damages.

FOURTH CAUSE OF ACTION
Strict Products Liability — Manufacturing Defect

124. Plaintiff incorporates by reference all previous paragraphs of this Complaint as if fully set forth here and further alleges as follows:

125. Defendants' Infuse® device was defectively manufactured at the time that it left the Defendants' control and was placed into the stream of commerce in Florida. The device reached Plaintiff without a substantial change in the condition in which it was sold.

126. The Infuse® product was unreasonably dangerous in that it was unsafe when used

as it was promoted by Medtronic for use in off-label posterior-approach lumbar spine surgeries.

127. The Infuse® product was not manufactured in conformity with the manufacturer's design.

128. The Infuse® product failed to perform as safely as an ordinary consumer would expect.

129. Plaintiff and her physicians used the Infuse® product in the way Defendants intended and promoted it to be used.

130. Plaintiff and her physicians could not have discovered any defect in the Infuse® product through the exercise of due care.

131. Medtronic, as designer, manufacturer, marketer, and distributor of the Infuse® product, is held to a higher level of knowledge in their field.

132. Plaintiff and her physicians did not have substantially the same knowledge as the designer, manufacturer or distributor: Medtronic.

133. Defendants' unreasonably-dangerous and defectively-manufactured Infuse® was the direct, legal and proximate cause of Plaintiff's injuries and damages including, but not limited to, medical hospital expenses and lost wages.

134. As a direct and proximate result of one or more of the above-listed dangerous conditions and defects, Plaintiff has sustained serious injuries of a personal and pecuniary nature from approximately August 2007 to present.

135. Plaintiff has sustained extreme pain, suffering, and anguish from the date of her posterior-approach lumbar spine surgery with Infuse®.

136. Defendants' conduct, as alleged above, was malicious, oppressive, intentional and/or reckless, outrageous, and constituted willful and wanton disregard for the rights or safety

of others. Such conduct was directed specifically at Plaintiff and warrants an award of punitive damages.

FIFTH CAUSE OF ACTION
Strict Products Liability — Design Defect

137. Plaintiff incorporates by reference all previous paragraphs of this Complaint as if fully set forth here and further alleges as follows:

138. Defendants' Infuse® device was defectively designed at the time that it left the Defendants' control and was placed into the stream of commerce. The device reached Plaintiff without a substantial change in the condition in which it was sold.

139. Defendants' Infuse® device was defectively designed because the design was unsafe when used in the manner promoted by Defendants and in a manner reasonably foreseeable by Defendants. The Infuse® product failed to perform as safely as an ordinary consumer would expect when used, as it was promoted by Medtronic for use in off-label posterior-approach lumbar spine surgeries.

140. Defendants' Infuse® device was defectively designed because the risks of danger in the design outweigh the benefits of the design.

141. The Infuse® product was designed in a way that it caused users injuries including, but not limited to pain and weakness in limbs, radiculitis, ectopic bone formation, osteolysis, and poorer global outcomes than equally-effective, alternative designs and treatments.

142. The foreseeable risks of harm posed by using the Infuse© product in a manner promoted by Defendants could have been reduced or avoided by adopting a reasonably alternative design. Defendants did not adopt a design that would have rendered the Infuse® product reasonably safe.

143. Plaintiff and her physicians used Infuse® in a manner intended and reasonably

foreseeable by Defendants considering its 'off-label' promotion.

SIXTH CAUSE OF ACTION
Negligence

144. Plaintiff incorporates by reference all previous paragraphs of this Complaint as if fully set forth here and further alleges as follows:

145. Defendants marketed their Infuse® product to and for the benefit of Plaintiff, and additionally marketed it to her physicians, and these Defendants knew or should have known that plaintiff and her physicians would use their product, including for the off-label use of posterior-approach lumbar spine fusion.

146. Defendants owed Plaintiff and her physicians duties to exercise reasonable or ordinary care under the circumstances in light of the generally recognized and prevailing best scientific knowledge.

147. Defendants had a confidential and special relationship with Plaintiff due to (a) Defendants' vastly superior knowledge of the health and safety risks relating to Infuse®, and (b) Defendants' sole and/or superior knowledge of their dangerous and irresponsible practices of improperly promoting to physicians the off-label use of Infuse© for posterior-approach lumbar spine surgeries.

148. As a result, Defendants had an affirmative duty to fully and adequately warn Plaintiff and her physicians of the true health and safety risks related to the off-label use of Infuse®, and Defendants had a duty to disclose their dangerous and irresponsible practices of improperly promoting to physicians the off-label use of Infuse® for posterior-approach lumbar spine fusion surgery. Independent of any special relationship of confidence or trust, Defendants had a duty not to conceal the dangers of the off-label use of Infuse® to Plaintiff and her physicians.

149. Misrepresentations made by Defendants about the health and safety of Infuse® independently imposed a duty upon Defendants to fully and accurately disclose to Plaintiff and her physicians the true health and safety risks related to Infuse®, and a duty to disclose their dangerous and irresponsible off-label promotion and marketing practices.

150. Through the conduct described in the foregoing and subsequent paragraphs of this Complaint, Defendants breached their duties to Plaintiff and to her physicians.

151. The following sub-paragraphs summarize, in/er alia, Defendants' breaches of duties to Plaintiff and her physicians and describe categories of acts or omissions constituting breaches of duty by these Defendants. Each and/or any of these acts or omissions establishes an independent basis for these Defendants' liability in negligence:

a. Unreasonable and improper promotion and marketing of Infuse® to physicians, including but not limited to the promotion and marketing of Infuse® for off-label use in posterior-approach lumbar spine fusion surgeries;

b. Failure to warn physicians and Plaintiff of the dangers associated with Infuse® when used off-label in posterior-approach lumbar spine surgery including, but not limited to, pain and weakness in limbs, radiculitis, foraminal narrowing, osteolysis, and poorer global outcomes than alternative treatments.

c. Failure to exercise reasonable care by not complying with federal law and regulations applicable to the sale and marketing of Infuse®.

152. Defendants knew, or should have known, that, due to their failure to use reasonable care, Plaintiff and her physicians would use and did use Infuse®, to the detriment of Plaintiff's health, safety and well-being.

153. As the direct, producing, proximate and legal cause and result of the Defendants' negligence, Plaintiff suffered severe injuries.

154. Plaintiff is therefore entitled to damages in an amount to be proven at trial, together with interest thereon and costs.

155. Defendants' conduct, as alleged above, was malicious, intentional and outrageous and constituted willful and wanton disregard for the rights or safety of others. Such conduct was directed specifically at Plaintiff and warrants an award of punitive damages.

156. Defendants' conduct, as alleged above, was malicious, oppressive, intentional and/or reckless, outrageous, and constituted willful and wanton disregard for the rights or safety of others. Such conduct was directed specifically at Plaintiff and warrants an award of punitive damages.

SEVENTH CAUSE OF ACTION
Negligent Misrepresentation

157. Plaintiff incorporates by reference all previous paragraphs of this Complaint as if fully set forth here and further allege as follows:

158. Specific defects in the Infuse® product, as specified above in this Complaint, rendered it defective and unreasonably dangerous.

159. Defendants made untrue representations and omitted material information to Plaintiff and her physicians by sponsoring biased medical trials, reports, and articles that concluded that the dangers inherent to off-label use of Infuse® did not exist or were significantly less that the actual dangers.

160. Plaintiff and her physicians would not have made off-label use of Infuse® for posterior-approach lumbar spine fusion surgery had they known of the safety risks related to Infuse®.

161. Defendants were negligent in making the untrue misrepresentations and omitting material information because Defendants knew, or had reason to know, of the actual, unreasonable dangers and defects in their Infuse® product.

162. Defendants intended to induce Plaintiff and her physicians to rely on their misrepresentations and omissions to use Infuse® in an off-label manner.

163. Plaintiff and her physicians were justified in relying, and did rely, on the misrepresentations and omissions about the safety risks related to Infuse® in deciding to make off-label use of Infuse® for posterior-approach lumbar spine fusion surgery.

164. As the direct, producing, proximate and legal cause and result of the Defendants' misrepresentations, Plaintiff has suffered severe physical pain, medical and hospital expenses, pain and suffering, and pecuniary loss.

165. Plaintiff is therefore entitled to damages in an amount to be proven at trial, together with interest thereon and costs.

166. Defendants' conduct, as alleged above, was malicious, oppressive, intentional and/or reckless, outrageous, and constituted willful and wanton disregard for the rights or safety of others. Such conduct was directed specifically at Plaintiff and warrants an award of punitive damages.

EIGHTH CAUSE OF ACTION
Breach of Implied Warranty for Merchantability

167. Plaintiff incorporates by reference all previous paragraphs of this Complaint as if fully set forth here and further allege as follows:

168. By virtue of the aforementioned acts of Defendants, Defendants have breach their implied warrant of merchantability. Defendants impliedly warranted that the Infuse product were of merchantable quality and would perform adequately under ordinary and expected usage.

169. Infuse is defective and did not perform as expected under ordinary and expected usage, thusly performed to such a degree causing irrepairable damage to Mr. Wadley's spine.

170. As a direct and proximate result of the aforementioned acts by Defendants they have been unjustly enriched.

171. As a direct and proximate result of the aforementioned acts of Defendants, Plaintiff has been harmed.

172. In addition, the aforementioned acts of Defendants were willful, wanton, malicious, oppressive, and justify the awarding of exemplary and punitive damages, including an award of attorney's fee, in an amount according to proof.

NINTH CAUSE OF ACTION
Breach of Implied Warranty of Fitness for a Particular Purpose

173. Plaintiff incorporates by reference all previous paragraphs of this Complaint as if fully set forth here and further allege as follows:

174. By virtue of the aforementioned acts of Defendants, Defendants have breach their implied warrant of merchantability. Defendants impliedly warranted that the Infuse product fit for the particular purpose for which it was marketed, on-label and off-label, advertised, and sold to Plaintiff. Infuse is not fit for such purpose.

175 As a direct and proximate result of the aforementioned acts by Defendants they have been unjustly enriched.

176. As a direct and proximate result of the aforementioned acts of Defendants, Plaintiff has been harmed.

177. In addition, the aforementioned acts of Defendants were willful, wanton, malicious, oppressive, and justify the awarding of exemplary and punitive damages, including an award of attorney's fee, in an amount according to proof.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for judgment against Defendants, and each of them, as follows:

1. For compensatory damages and general damages, economic and non-economic, sustained by Plaintiff against all Defendants, jointly and severally, in an amount to be determined at trial;

2. For punitive and exemplary damages according to proof against the Medtronic Defendants, for all causes of action, in an amount to be determined at trial;

3. For an award of prejudgment interest, costs, disbursements and reasonable attorneys' fees; and,

4. For such other and further relief as the Court deems equitable or appropriate under the circumstances.

DEMAND FOR JURY TRIAL

Plaintiff demands a trial by jury on all issues stated.

Respectfully submitted,
SCOTT WADLEY
C. Lowell Crews, Attorney at Law, PLLC

Virginia Bar No.: 42691
Attorney for SCOTT WADLEY
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1:12CV1397-CMH/TRT

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CIVIL COVER SHEET

Attachment 2

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 THE REVERSE OF THE FORM.)

I. (a) PLAINTIFFS
SCOTT WADLEY

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

(c) Attorney's (Firm Name, Address, and Telephone Number)
C. Lowell Crews, Attorney at Law, PLLC
1655 Fort Myer Drive, Suite 700
Arlington, Virginia 22209

DEFENDANTS
MEDTRONIC SOFAMOR DANEK USA, INC., a Tennessee Corporation and MEDTRONIC, INC, a Minnesota Corporation

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

Attorneys (If Known)

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

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

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

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

IV. NATURE OF SUIT (Place an "X" in One Box Only)

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 (Excl. 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

PERSONAL INJURY
- ☐ 362 Personal Injury - Med. Malpractice
- ☒ 365 Personal Injury - Product Liability
- ☐ 368 Asbestos Personal Injury Product Liability

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

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

PRISONER PETITIONS
- ☐ 510 Motions to Vacate Sentence

Habeas Corpus:
- ☐ 530 General
- ☐ 535 Death Penalty
- ☐ 540 Mandamus & Other
- ☐ 550 Civil Rights
- ☐ 555 Prison Condition

FORFEITURE/PENALTY
- ☐ 610 Agriculture
- ☐ 620 Other Food & Drug
- ☐ 625 Drug Related Seizure of Property 21 USC 881
- ☐ 630 Liquor Laws
- ☐ 640 R.R. & Truck
- ☐ 650 Airline Regs.
- ☐ 660 Occupational Safety/Health
- ☐ 690 Other

LABOR
- ☐ 710 Fair Labor Standards Act
- ☐ 720 Labor/Mgmt. Relations
- ☐ 730 Labor/Mgmt.Reporting & Disclosure Act
- ☐ 740 Railway Labor Act
- ☐ 790 Other Labor Litigation
- ☐ 791 Empl. Ret. Inc Security Act

IMMIGRATION
- ☐ 462 Naturalization Application
- ☐ 463 Habeas Corpus - Alien Detainee
- ☐ 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
- ☐ 400 State Reapportionment
- ☐ 410 Antitrust
- ☐ 430 Banks and Banking
- ☐ 450 Commerce
- ☐ 460 Deportation
- ☐ 470 Racketeer Influenced and Corrupt Organizations
- ☐ 480 Consumer Credit
- ☐ 490 Cable/Sat TV
- ☐ 810 Selective Service
- ☐ 850 Securities/Commodities Exchange
- ☐ 875 Customer Challenge 12 USC 3410
- ☐ 890 Other Statutory Actions
- ☐ 891 Agricultural Acts
- ☐ 892 Economic Stabilization Act
- ☐ 893 Environmental Matters
- ☐ 894 Energy Allocation Act
- ☐ 895 Freedom of Information Act
- ☐ 900 Appeal of Fee Determination Under Equal Access to Justice
- ☐ 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 ☐ 7 Appeal to District Judge from Magistrate Judgment

VI. CAUSE OF ACTION
Cite the U.S. Civil Statute under which you are filing (**Do not cite jurisdictional statutes unless diversity**):
28 U.S.C. 1332
Brief description of cause:
Medical Product Liability

VII. REQUESTED IN COMPLAINT:
☐ CHECK IF THIS IS A CLASS ACTION UNDER F.R.C.P. 23
DEMAND $ 75,000.00
CHECK YES only if demanded in complaint.
JURY DEMAND: ☑ Yes ☐ No

VIII. RELATED CASE(S) IF ANY (See instructions)
JUDGE _____ DOCKET NUMBER _____

DATE: 12/6/2012
SIGNATURE OF ATTORNEY OF RECORD

FOR OFFICE USE ONLY

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