

**UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF LOUISIANA
LAFAYETTE DIVISION**

MARY LACASSIN

V.

COVIDIEN LP AND MEDTRONIC, INC.

CIVIL ACTION NUMBER:

SECTION:

DIVISION:

JUDGE:

MAGISTRATE JUDGE:

JURY DEMAND

COMPLAINT

NOW INTO COURT, through undersigned counsel, comes Plaintiff, **MARY LACASSIN** (“Plaintiff”), to file this Complaint against Defendants, **COVIDIEN LP AND MEDTRONIC, INC.** (“Defendants”).

PARTIES

1. Plaintiff is an individual of the full age of majority domiciled in Saint Landry Parish, Louisiana, who was injured as a result of receiving defective hernia mesh researched, designed, developed, tested, manufactured, labeled, packaged, promoted, advertised, marketed, supplied, sold, and/or distributed by Defendants.
2. The following parties are made Defendants:
 - A. **COVIDIEN LP** (“Covidien”) is a for-profit limited partnership organized under the laws of Delaware with its principal place of business in Massachusetts at 15 Hampshire Street, Mansfield, Massachusetts 02048. At all relevant times, Covidien conducted business in Louisiana including, but not limited to, business related to surgical products and medical devices involved in hernia repair such as Parietex

Composite Mesh. All acts and omissions of Covidien were done on behalf of Covidien by its owners, employees, agents, representatives, and servants in the course and scope of their ownership, employment, agency, representation, and service. The general partner of Covidien is Covidien Holding Inc., a for-profit corporation organized under the laws of Delaware with its principal place of business in Massachusetts at 15 Hampshire Street, Mansfield, Massachusetts 02048.

- B. **MEDTRONIC, INC.** (“Medtronic”) is a for-profit corporation organized under the laws of Minnesota with its principal place of business in Minnesota at 710 Medtronic Parkway Northeast, Minneapolis, Minnesota 55432. At all relevant times, Medtronic conducted business in Louisiana including, but not limited to, business related to surgical products and medical devices involved in hernia repair such as Parietex Composite Mesh. All acts and omissions of Medtronic were done on behalf of Medtronic by its owners, employees, agents, representatives, and servants in the course and scope of their ownership, employment, agency, representation, and service.

JURISDICTION AND VENUE

3. This Court has jurisdiction pursuant to 28 U.S.C. § 1332 because the amount in controversy exceeds \$75,000.00, exclusive of interest and costs, and Plaintiff and Defendants are citizens of different states.
4. Venue is proper in this Court pursuant to 28 U.S.C. § 1391 because a substantial part of the acts or omissions giving rise to this claim occurred in the Western District of Louisiana including the surgery implanting Defendants’ hernia mesh products into Plaintiff and the resulting injuries suffered by Plaintiff.
5. Defendants conducted substantial business through the distribution of surgical mesh products as well as received significant compensation and profits from sales of surgical mesh products in Louisiana and the Western District of Louisiana. While conducting substantial business in Louisiana and the Western District of Louisiana, Defendants also made material misrepresentations and omissions of fact with regard to the effectiveness, safety, risks, side

effects, contraindications, and complications related to surgical mesh products. In addition, Defendants directly or indirectly promoted, advertised, marketed, supplied, sold, and/or distributed surgical mesh products in Louisiana and the Western District of Louisiana.

GENERAL ALLEGATIONS

6. In approximately November of 2011, Plaintiff underwent surgery to repair a hernia and Parietex Composite Mesh was implanted during the surgery.
7. As a result of the implantation of the unreasonably dangerous and defective Parietex Composite Mesh, Plaintiff suffered injuries including, but not limited to, scarring, pain, recurrence, and additional surgery.
8. Covidien and Medtronic researched, designed, developed, tested, manufactured, labeled, packaged, promoted, advertised, marketed, supplied, sold, and/or distributed Parietex Composite Mesh.
9. Parietex Composite Mesh is a two-sided composite mesh with an absorbable collagen barrier on the visceral side and a hydrophilic three-dimensional polyester textile on the parietal side used in the treatment of hernias such as laparoscopic ventral hernia repair.
10. The absorbable collagen barrier on the visceral side of Parietex Composite Mesh fails to protect the body from the hydrophilic three-dimensional polyester textile on the parietal side because the absorbable collagen barrier breaks down after coming in contact with moisture and tears easily during handling. The composition of polyester is also weak and Parietex Composite Mesh is known to unravel causing the polyester fiber to detach and travel to other parts of the body inciting an inflammatory response. Parietex Composite Mesh further contracts over time causing tension to increase where secured by tacks and sutures resulting

in tearing.

11. Covidien and Medtronic applied for clearance from the United States Food and Drug Administration (“FDA”) to market Parietex Composite Mesh pursuant to Section 510(k) of the Food, Drug, and Cosmetic Act. The Section 510(k) process allowed Covidien and Medtronic to skip pre-market clinical studies and research intended to ensure the safety of Parietex Composite Mesh . The approval of Parietex Composite Mesh was based on a substantial equivalence to legally marketed predicate devices.
12. The FDA maintains a database of adverse incidents related to medical implants and devices and there are numerous reports documenting serious adverse events associated with Parietex Composite Mesh.
13. Covidien and Medtronic misrepresented Parietex Composite Mesh as a safe and effective treatment for hernias; wrongly marketed Parietex Composite Mesh as safer and more effective than other meshes or methods for hernia repair; and improperly minimized the adverse effects of Parietex Composite Mesh.
14. Covidien and Medtronic knew or should have known that Parietex Composite Mesh was not a safe and effective treatment for hernias. Covidien and Medtronic also knew or should have known that Parietex Composite Mesh was considerably more harmful and inadequate than other meshes or methods for hernia repair. Additionally, Covidien and Medtronic knew or should have known that Parietex Composite Mesh was unreasonably dangerous as well as defective and likely to cause severe complications.
15. Covidien and Medtronic knew or should have known of the defective nature of Parietex Composite Mesh but continued to research, design, develop, test, manufacture, label,

package, promote, advertise, market, supply, sell, and/or distribute Parietex Composite Mesh so as to maximize sales and profits at the expense of the health and safety of the general public and Plaintiff. Covidien and Medtronic acted in conscious disregard for the foreseeable harm caused by Parietex Composite Mesh in not adequately warning the FDA, the general public, the medical community, or Plaintiff of the numerous side effects, complications, and contraindications of Parietex Composite Mesh.

16. Contrary to the representations of Covidien and Medtronic, Parietex Composite Mesh has a high rate of failure, injury, and complication; fails to perform as intended; and causes severe and irreversible injuries like those suffered by Plaintiff.
17. Parietex Composite Mesh is unreasonably dangerous and defective including, but not limited to, as follows:
 - A. The absorbable collagen barrier on the visceral side of Parietex Composite Mesh fails to protect the body from the hydrophilic three-dimensional polyester textile on the parietal side.
 - B. Parietex Composite Mesh unravels causing the polyester fiber to detach and travel to other parts of the body inciting an inflammatory response.
 - C. Parietex Composite Mesh contracts over time causing tension to increase where secured by tacks and sutures resulting in tearing.
 - D. Parietex Composite Mesh is defective in shape, composition, weight, chemical, material, physical properties, pore size, mechanical properties, biomechanical properties, elasticity, and engineering.
 - E. The design of Parietex Composite Mesh is more dangerous and less effective than other meshes or methods for hernia repair and causes injury.
 - F. Covidien and Medtronic failed to provide adequate warning of the numerous side effects, complications, and contraindications of Parietex Composite Mesh.

- G. Parietex Composite Mesh is not a safe and effective treatment for hernias as represented by Covidien and Medtronic.

CAUSES OF ACTION

CONSTRUCTION OR COMPOSITION DEFECT PURSUANT TO LA. R.S. 9:2800.55

18. Plaintiff reavers and realleges each and every allegation of this Complaint.
19. Pursuant to La. R.S. 9:2800.55,
- A product is unreasonably dangerous in construction or composition if, at the time the product left its manufacturer's control, the product deviated in a material way from the manufacturer's specifications or performance standards for the product or from otherwise identical products manufactured by the same manufacturer.
20. The danger to people including Plaintiff resulting from the construction or composition defects in Parietex Composite Mesh was foreseeable by Defendants.
21. Parietex Composite Mesh is unreasonably dangerous in construction or composition pursuant to La. R.S. 9:2800.55 and damaged Plaintiff.

DESIGN DEFECT PURSUANT TO LA. R.S. 9:2800.56

22. Plaintiff reavers and realleges each and every allegation of this Complaint.
23. Pursuant to La. R.S. 9:2800.56,
- A product is unreasonably dangerous in design if, at the time the product left its manufacturer's control: (1) There existed an alternative design for the product that was capable of preventing the claimant's damage; and (2) The likelihood that the product's design would cause the claimant's damage and the gravity of that damage outweighed the burden on the manufacturer of adopting such alternative design and the adverse effect, if any, of such alternative design on the utility of the product. An adequate warning about a product shall be considered in evaluating the likelihood of damage when the manufacturer has used reasonable care to provide the adequate warning to users and handlers of the product.
24. The danger to people including Plaintiff resulting from the design defects in Parietex Composite Mesh was foreseeable by Defendants.

25. Parietex Composite Mesh is unreasonably dangerous in design pursuant to La. R.S. 9:2800.56 and damaged Plaintiff.

INADEQUATE WARNING PURSUANT TO LA. R.S. 9:2800.57

26. Plaintiff reavers and realleges each and every allegation of this Complaint.

27. Pursuant to La. R.S. 9:2800.57,

A product is unreasonably dangerous because an adequate warning about the product has not been provided if, at the time the product left its manufacturer's control, the product possessed a characteristic that may cause damage and the manufacturer failed to use reasonable care to provide an adequate warning of such characteristic and its danger to users and handlers of the product....A manufacturer of a product who, after the product has left his control, acquires knowledge of a characteristic of the product that may cause damage and the danger of such characteristic, or who would have acquired such knowledge had he acted as a reasonably prudent manufacturer, is liable for damage caused by his subsequent failure to use reasonable care to provide an adequate warning of such characteristic and its danger to users and handlers of the product.

28. The danger to people including Plaintiff resulting from the lack of adequate warning related to Parietex Composite Mesh was foreseeable by Defendants.

29. Parietex Composite Mesh is unreasonably dangerous because of the lack of adequate warning pursuant to La. R.S. 9:2800.57 and damaged Plaintiff.

BREACH OF EXPRESS WARRANTY PURSUANT TO LA. R.S. 9:2800.58

30. Plaintiff reavers and realleges each and every allegation of this Complaint.

31. Pursuant to La. R.S. 9:2800.58,

A product is unreasonably dangerous when it does not conform to an express warranty made at any time by the manufacturer about the product if the express warranty has induced the claimant or another person or entity to use the product and the claimant's damage was proximately caused because the express warranty was untrue.

32. The danger to people including Plaintiff resulting from the failure to conform to express warranties related to Parietex Composite Mesh was foreseeable by Defendants.

33. Parietex Composite Mesh is unreasonably dangerous because of the failure to conform to express warranties pursuant to La. R.S. 9:2800.58 and damaged Plaintiff.

NEGLIGENCE

34. Plaintiff reavers and realleges each and every allegation of this Complaint.
35. Pursuant to Article 2315 of the Louisiana Civil Code,
Every act whatever of man that causes damage to another obliges him by whose fault it happened to repair it.
36. The danger to people including Plaintiff related to Parietex Composite Mesh resulting from negligence was foreseeable by Defendants.
37. Defendants were negligent in researching, designing, developing, testing, manufacturing, labeling, packaging, promoting, advertising, marketing, supplying, selling, and/or distributing Parietex Composite Mesh and damaged Plaintiff.

REDHIBITION

38. Plaintiff reavers and realleges each and every allegation of this Complaint.
39. Pursuant to Article 2520 of the Louisiana Civil Code,
The seller warrants the buyer against redhibitory defects, or vices, in the thing sold. A defect is redhibitory when it renders the thing useless, or its use so inconvenient that it must be presumed that a buyer would not have bought the thing had he known of the defect. The existence of such a defect gives a buyer the right to obtain rescission of the sale. A defect is redhibitory also when, without rendering the thing totally useless, it diminishes its usefulness or its value so that it must be presumed that a buyer would still have bought it but for a lesser price. The existence of such a defect limits the right of a buyer to a reduction of the price.
40. The danger to people including Plaintiff resulting from the redhibitory defects or vices related to Parietex Composite Mesh was foreseeable by Defendants.
41. Parietex Composite Mesh contains redhibitory defects or vices and damaged Plaintiff.

BREACH OF WARRANTY OF FITNESS FOR ORDINARY USE

42. Plaintiff reavers and realleges each and every allegation of this Complaint.

43. Pursuant to Article 2524 of the Louisiana Civil Code,

The thing sold must be reasonably fit for its ordinary use. When the seller has reason to know the particular use the buyer intends for the thing, or the buyer's particular purpose for buying the thing, and that the buyer is relying on the seller's skill or judgment in selecting it, the thing sold must be fit for the buyer's intended use or for his particular purpose. If the thing is not so fit, the buyer's rights are governed by the general rules of conventional obligations.

44. The danger to people including Plaintiff resulting from the breach of warranty of fitness for ordinary use related to Parietex Composite Mesh was foreseeable by Defendants.

45. Parietex Composite Mesh is not reasonably fit for ordinary use and damaged Plaintiff.

BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY AND FITNESS

46. Plaintiff reavers and realleges each and every allegation of this Complaint.

47. Defendants knew or should have known of the uses for which Parietex Composite Mesh was intended and impliedly warranted that Parietex Composite Mesh would be of merchantable quality and safe and fit for such uses.

48. The danger to people including Plaintiff resulting from the breach of implied warranty of merchantability and fitness related to Parietex Composite Mesh was foreseeable by Defendants.

49. Parietex Composite Mesh is not of merchantable quality or safe and fit for intended uses and damaged Plaintiff.

DAMAGES

50. Plaintiff reavers and realleges each and every allegation of this Complaint.

51. Plaintiff alleges entitlement to such damages as are reasonable including, but not limited to, the following:
- A. Past, present, and future medical expenses;
 - B. Past, present, and future physical pain and suffering;
 - C. Past, present, and future mental anxiety and anguish;
 - D. Past, present, and future lost wages and earnings;
 - E. Past, present, and future loss of earning capacity;
 - F. Past, present, and future loss of enjoyment of life; and
 - G. All reasonable damages as will be more fully shown at trial.

JURY DEMAND

52. Plaintiff reavers and realleges each and every allegation of this Complaint.
53. Plaintiff is entitled to and demands a trial by jury.

WHEREFORE, Plaintiff, **MARY LACASSIN**, prays that there be a judgment against Defendants, **COVIDIEN LP AND MEDTRONIC, INC.**, for all reasonable damages, legal interest, attorney's fees, and costs.

DATED: JANUARY 12, 2018

Respectfully Submitted,

/s/ Jessica W. Hayes, Trial Attorney (#28927)

Jessica W. Hayes, Trial Attorney (#28927)

MURRAY LAW FIRM

650 Poydras Street, Suite 2150

New Orleans, Louisiana 70130

Telephone: (504) 525-8100

Facsimile: (504) 584-5249

E-mail: jhayes@murray-lawfirm.com

CIVIL COVER SHEET

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

I. (a) PLAINTIFFS

MARY LACASSIN

(b) County of Residence of First Listed Plaintiff Saint Landry Parish, LA (EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorneys (Firm Name, Address, and Telephone Number) Jessica W. Hayes, Trial Attorney (#28927) / Murray Law Firm 650 Poydras Street, Suite 2150 / New Orleans, Louisiana 70130 Telephone: (504) 525-8100 / Facsimile: (504) 584-5249

DEFENDANTS

COVIDIEN LP AND MEDTRONIC, INC.

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

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

Attorneys (If Known)

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

- 1 U.S. Government Plaintiff, 2 U.S. Government Defendant, 3 Federal Question (U.S. Government Not a Party), 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)

Table with columns for Plaintiff (PTF) and Defendant (DEF) citizenship and business location (Citizen of This State, Citizen of Another State, Citizen or Subject of a Foreign Country, Incorporated or Principal Place of Business In This State, Incorporated and Principal Place of Business In Another State, Foreign Nation).

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

Large table with categories: CONTRACT, REAL PROPERTY, CIVIL RIGHTS, TORTS, PRISONER PETITIONS, FORFEITURE/PENALTY, LABOR, IMMIGRATION, BANKRUPTCY, SOCIAL SECURITY, FEDERAL TAX SUITS, OTHER 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 - Transfer, 8 Multidistrict Litigation - Direct File

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing (Do not cite jurisdictional statutes unless diversity): 28 U.S.C. § 1332 - Diversity of citizenship. Brief description of cause: Plaintiffs suffered damages related to defective mesh manufactured by Defendants implanted during hernia repair

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 01/12/2018 SIGNATURE OF ATTORNEY OF RECORD /s/ Jessica W. Hayes, Trial Attorney (#28927)

FOR OFFICE USE ONLY

RECEIPT # AMOUNT APPLYING IFP JUDGE MAG. JUDGE

INSTRUCTIONS FOR ATTORNEYS COMPLETING CIVIL COVER SHEET FORM JS 44

Authority For Civil Cover Sheet

The JS 44 civil cover sheet and the information contained herein neither replaces nor supplements the filings and service of pleading 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. Consequently, a civil cover sheet is submitted to the Clerk of Court for each civil complaint filed. The attorney filing a case should complete the form as follows:

- I.(a) Plaintiffs-Defendants.** Enter names (last, first, middle initial) of plaintiff and defendant. If the plaintiff or defendant is a government agency, use only the full name or standard abbreviations. If the plaintiff or defendant is an official within a government agency, identify first the agency and then the official, giving both name and title.
- (b) County of Residence.** For each civil case filed, except U.S. plaintiff cases, enter the name of the county where the first listed plaintiff resides at the time of filing. In U.S. plaintiff cases, enter the name of the county in which the first listed defendant resides at the time of filing. (NOTE: In land condemnation cases, the county of residence of the "defendant" is the location of the tract of land involved.)
- (c) Attorneys.** Enter the firm name, address, telephone number, and attorney of record. If there are several attorneys, list them on an attachment, noting in this section "(see attachment)".
- II. Jurisdiction.** The basis of jurisdiction is set forth under Rule 8(a), F.R.Cv.P., which requires that jurisdictions be shown in pleadings. Place an "X" in one of the boxes. If there is more than one basis of jurisdiction, precedence is given in the order shown below.
 United States plaintiff. (1) Jurisdiction based on 28 U.S.C. 1345 and 1348. Suits by agencies and officers of the United States are included here.
 United States defendant. (2) When the plaintiff is suing the United States, its officers or agencies, place an "X" in this box.
 Federal question. (3) This refers to suits under 28 U.S.C. 1331, where jurisdiction arises under the Constitution of the United States, an amendment to the Constitution, an act of Congress or a treaty of the United States. In cases where the U.S. is a party, the U.S. plaintiff or defendant code takes precedence, and box 1 or 2 should be marked.
 Diversity of citizenship. (4) This refers to suits under 28 U.S.C. 1332, where parties are citizens of different states. When Box 4 is checked, the citizenship of the different parties must be checked. (See Section III below; **NOTE: federal question actions take precedence over diversity cases.**)
- III. Residence (citizenship) of Principal Parties.** This section of the JS 44 is to be completed if diversity of citizenship was indicated above. Mark this section for each principal party.
- IV. Nature of Suit.** Place an "X" in the appropriate box. If there are multiple nature of suit codes associated with the case, pick the nature of suit code that is most applicable. Click here for: [Nature of Suit Code Descriptions](#).
- V. Origin.** Place an "X" in one of the seven boxes.
 Original Proceedings. (1) Cases which originate in the United States district courts.
 Removed from State Court. (2) Proceedings initiated in state courts may be removed to the district courts under Title 28 U.S.C., Section 1441. When the petition for removal is granted, check this box.
 Remanded from Appellate Court. (3) Check this box for cases remanded to the district court for further action. Use the date of remand as the filing date.
 Reinstated or Reopened. (4) Check this box for cases reinstated or reopened in the district court. Use the reopening date as the filing date.
 Transferred from Another District. (5) For cases transferred under Title 28 U.S.C. Section 1404(a). Do not use this for within district transfers or multidistrict litigation transfers.
 Multidistrict Litigation – Transfer. (6) Check this box when a multidistrict case is transferred into the district under authority of Title 28 U.S.C. Section 1407.
 Multidistrict Litigation – Direct File. (8) Check this box when a multidistrict case is filed in the same district as the Master MDL docket.
PLEASE NOTE THAT THERE IS NOT AN ORIGIN CODE 7. Origin Code 7 was used for historical records and is no longer relevant due to changes in statute.
- VI. Cause of Action.** Report the civil statute directly related to the cause of action and give a brief description of the cause. **Do not cite jurisdictional statutes unless diversity.** Example: U.S. Civil Statute: 47 USC 553 Brief Description: Unauthorized reception of cable service
- VII. Requested in Complaint.** Class Action. Place an "X" in this box if you are filing a class action under Rule 23, F.R.Cv.P.
 Demand. In this space enter the actual dollar amount being demanded or indicate other demand, such as a preliminary injunction.
 Jury Demand. Check the appropriate box to indicate whether or not a jury is being demanded.
- VIII. Related Cases.** This section of the JS 44 is used to reference related pending cases, if any. If there are related pending cases, insert the docket numbers and the corresponding judge names for such cases.

Date and Attorney Signature. Date and sign the civil cover sheet.