

**UNITED STATES DISTRICT COURT FOR
THE SOUTHERN DISTRICT OF FLORIDA
Case No. 14-cv-61086**

PEGGY PADUDA,)	
)	
Plaintiff,)	
)	
v.)	
)	
KARL STORZ ENDOSCOPY-AMERICA,)	
INC., a California corporation; KARL)	
STORZ ENDOVISION, INC., a)	
Massachusetts corporation; and KARL)	JURY TRIAL DEMANDED
STORZ GMBH & CO. KG, organized in)	
Germany,)	
)	
Defendants.)	
)	

COMPLAINT

COMES NOW Peggy Paduda, a citizen and resident of the State of Florida, by and through her undersigned counsel, and brings this action against the foreign corporations Karl Storz Endoscopy-American, Inc., Karl Storz Endovision, Inc., and Karl Storz GMBH & Co. KG ("Defendants"), for all damages allowed by law for injuries she suffered from the Defendants' surgical product known as the Storz Rotocut Morcellator. The parties are diverse within the meaning of 28 U.S.C. § 1332, and the amount in controversy exceeds \$75,000 (seventy-five thousand dollars), exclusive of interest and costs, so this Court has subject-matter jurisdiction to hear and decide this tort and products liability case.

1. The Plaintiff is entitled to the relief she seeks because the Defendants (a) negligently failed to warn Plaintiff and her doctor about the true risks of the Storz Rotocut Morcellator, (b) made the instrument unsafe for its intended use, (c) breached warranties of the instrument, and (d) fraudulently misrepresented the risks of the instrument. These acts and omissions of the Defendants gravely injured the Plaintiff, causing her to suffer upstage endometrial stromal sarcoma, a cancer which causes her pain and suffering and drastically shortens her life expectancy.

PARTIES, JURISDICTION, AND VENUE

2. Plaintiff Peggy Paduda is an adult resident and citizen of the State of Florida who resides, and resided at all times material, in Oakland Park, Florida, which is Broward County, Florida.

3. Paduda, on or about April 8, 2013, underwent a surgical procedure known as a supra-cervical hysterectomy during which the surgeon removed one or more fibroids from her uterus using a powered surgical instrument known as a Storz Rotocut Morcellator ("Storz Morcellator"). She was injured by the instrument.

4. Defendant Karl Storz Endoscopy-America, Inc., is incorporated in the state of California, and together with the other Defendants, it is responsible for the

sale, marketing, promotion, and distribution of Storz instruments, including the Storz Morcellator, throughout the United States and the State of Florida, directly and indirectly through its agents and distributors to such an extent that it avails itself of the jurisdiction of this court. It maintains its principal place of business in El Segundo, California, and is a citizen of the state of California, according to 28 U.S.C. § 1332.

5. Defendant Karl Storz Endovision, Inc., is incorporated in the state of Massachusetts, and it manufactures Storz instruments distributed throughout the United States and the State of Florida, directly and indirectly through its agents and distributors to such an extent that it avails itself of the jurisdiction of this court. It maintains its principal place of business in Charlton, Massachusetts, and is a citizen of the state of Massachusetts, according to 28 U.S.C. § 1332.

6. Defendant Karl Storz GMBH & Co. KG, is organized in Germany and maintains its principal place of business in Tuttlingen, Germany. It is the parent company of Karl Storz Endovision, Inc., and Karl Storz Endoscopy-American, Inc., and is diverse from Plaintiff Paduda within the meaning of 28 U.S.C. § 1332. Together with the other Defendants, it is responsible for the design, production, marketing, and sale of the Storz Morcellator throughout the United States and the State of Florida, directly and

indirectly through its agents and distributors to such an extent that it avails itself of the jurisdiction of this court, and for all information about the Storz Morcellator product, including warnings and instructions to surgeons about its use and risks.

7. All Defendants are diverse from the Plaintiff and are subject to service of process. This Court properly may exercise personal jurisdiction over them. Each Defendant has sufficient minimum contacts with the state of Florida to be sued and be required to defend here.

8. Venue is proper here because all or a substantial part of the events at issue occurred within this U.S. Judicial District, and in Broward County, Florida, specifically.

ALLEGATIONS

9. In April, 2013, the Plaintiff had surgery at the Cleveland Clinic in Weston, Florida, which is in Broward County. Prior to this surgery, there was no evidence that she suffered endometrial stromal sarcoma, which is rare type of uterine cancer.

10. The surgeon who performed the surgery utilized the Storz Morcellator to cut, shred, and remove Ms. Paduda's uterus. The Storz Morcellator is a cutting instrument, and in cutting, shredding, and removing the uterus and fibroid(s) from Paduda, the Storz Morcellator disseminated and

fulminated an endometrial stromal sarcoma cancer throughout her abdominal cavity, worsening her long term prognosis and the natural course of this cancer. She was diagnosed with endometrial stromal sarcoma after the surgery based on an analysis of her uterine tissues by the pathologist.

11. Had the Storz Morcellator not disseminated and fulminated the cancer cells throughout Paduda's abdomen, she would not have suffered and been diagnosed with advanced stage endometrial stromal sarcoma. The instrument caused this specific cancerous condition, profoundly and gravely injuring her. At her initial hysterectomy surgery washing were performed which did not reveal any sign of cancer cells in the peritoneal cavity. At her second staging surgery after the dissemination of the endometrial stromal sarcoma via the morcellator, Ms. Paduda had cancer calls all over the peritoneal cavity.

12. Had the Storz Morcellator not disseminated and fulminated cancer throughout Paduda's abdomen, cancerous tissue in her uterus would have remained well confined to uterus and fallopian tube, and not in the abdomen generally and posing almost no danger of dissemination, fulmination, and upstage cancer. Storz knew, or should have known, of the risk of disseminating unsuspected/undiagnosed cancers with the normal and customary use of their morcellator.

13. On or about May 9, 2013, Paduda underwent a second surgery -- this time to treat the spread of the endometrial stromal sarcoma induced and caused by the Storz Morcellator. To have her upstage cancer treated, she has undergone aggressive radiation treatment and drug therapy since May of 2013. She has had 31 radiation treatments and has experienced on a daily basis the following adverse effects the cancer, of the radiation, and of the cancer drug therapy: fatigue, joint pain, inflammation, swelling, insomnia, and gastrointestinal distress. Her treatments continue, and her pain and suffering continue. Without the “upstaging” of her cancer by the morcellator she would not have required this extensive and debilitating radiation treatment.

14. The Plaintiff, as a result of the upstage cancer induced and caused by the Storz Morcellator, has incurred out of pocket expenses for treatment, lost employment compensation, and has had her employment impaired and adversely affected. Her life expectancy is drastically reduced.

15. The Defendants failed to adequately warn about the true risk of dissemination and fulmination of cancer from the use of the Storz Morcellator. Despite their knowledge of that true risk and of their own failure to adequately warn of it, they failed to make the instrument safe for its intended use, making it unsafe for that use.

16. The Defendants designed, manufactured, marketed, and sold the Storz Morcellator for uterine surgery, specifically for cutting, shredding, and removing the uterus and uterine fibroids. Storz therefore knew that they had marketed and promoted the use of their morcellator for surgical cases specifically consistent with Ms. Paduda's April, 2013, surgery. Because of Storz's failure to adequately warn surgeon of the risk of morcellator use and Storz's failure to provide a safe, closed system for use with their morcellator to prevent dissemination of an unsuspected cancer, Ms. Paduda's prognosis went from highly favorable to poor and changed the natural course of treatment requiring advanced cancer treatment and significantly decreased her quality of life. And this was completely avoidable.

COUNT I – NEGLIGENCE

The allegations above are incorporated by reference to support this Count.

17. The Defendants owed a duty to manufacture, compound, label, market, distribute, and supply and/or sell products, including instruments for uterine morcellation, specifically the Storz Morcellator, in such a way as to avoid harm to persons upon whom they are used, such as Plaintiff herein, and to refrain from such activities following knowledge and/or constructive knowledge that such product is harmful to persons upon whom it is used.

18. Defendants owed a duty to warn of the hazards and dangers associated with the use of its products for patients such as Plaintiff herein, so as to avoid harm.

19. Defendants, acting by and through their authorized divisions, subsidiaries, agents, servants, and employees, were guilty of carelessness, recklessness, negligence, gross negligence and willful, wanton, outrageous and reckless disregard for human life and safety in manufacturing, designing, labeling, marketing, distributing, supplying and/or selling and/or placing into the stream of commerce, the Storz Morcellator, both generally and in the following particular respects:

- a. failing to conduct adequate and appropriate testing of instruments such as the Storz Morcellator, specifically including, but not limited to, products used for uterine morcellation;
- b. putting products used for uterine morcellation such as the Storz Morcellator on the market without first conducting adequate testing to determine possible side effects;
- c. putting products used for uterine morcellation such as the Storz Morcellator on the market without adequate testing of its dangers to humans;
- d. failing to recognize the significance of their own and other testing of, and

information regarding, products used for uterine morcellation, such as the Storz Morcellator, which testing evidenced such products potential harm to humans;

e. failing to respond promptly and appropriately to their own and other testing of, and information regarding products used for uterine morcellation, such as the Storz Morcellator which indicated such products potential harm to humans;

f. failing to promptly and adequately warn of the potential of the products used for uterine morcellation to be harmful to humans;

g. failing to promptly and adequately warn of the potential for the metastases of cancer when using products used for uterine morcellation, such as Storz Morcellator;

h. failing to promptly, adequately, and appropriately recommend testing and monitoring of patients upon whom products used for uterine morcellation in light of such products potential harm to humans;

i. failing to properly, appropriately, and adequately monitor the post-market performance of products used for uterine morcellation and such products effects on patients;

j. concealing from the FDA, National Institutes of Health, the general medical community and/or physicians, their full knowledge and experience regarding the potential that products used for uterine morcellation, specifically the Storz

Morcellator, are harmful to humans;

k. promoting, marketing, advertising and/or selling products used for uterine morcellation such as the Storz Morcellator, for use on patients given their knowledge and experience of such products' potential harmful effects;

l. failing to withdraw products used for uterine morcellation from the market, restrict its use and/or warn of such products' potential dangers, given their knowledge of the potential for its harm to humans;

m. failing to fulfill the standard of care required of a reasonable, prudent, minimally invasive gynecological surgical products manufacturer engaged in the manufacture of said products, specifically including products used for uterine morcellation such as the Storz Morcellator;

n. placing and/or permitting the placement of the products used for uterine morcellation, specifically the Storz Morcellator, into the stream of commerce without warnings of the potential for said products to be harmful to humans and/or without properly warning of said products' dangerousness;

o. failing to disclose to the medical community in an appropriate and timely manner, facts relative to the potential of the products used for uterine morcellation, including the Storz Morcellator, to be harmful to humans;

p. failing to respond or react promptly and appropriately to reports of products

used for uterine morcellation causing harm to patients, including the Storz Morcellator;

q. disregarding the safety of users and consumers of products used for uterine morcellation, including plaintiff herein, under the circumstances by failing adequately to warn of said products' potential harm to humans;

r. disregarding the safety of users and consumers of the products used for uterine morcellation, including plaintiff herein, and/or her physicians' and/or hospital, under the circumstances by failing to withdraw said products from the market and/or restrict their usage;

s. disregarding publicity, government and/or industry studies, information, documentation and recommendations, consumer complaints and reports and/or other information regarding the hazards of the products used for uterine morcellation and their potential harm to humans;

t. failing to exercise reasonable care in informing physicians and/or hospitals using the products used for uterine morcellation about their own knowledge regarding said products' potential harm to humans;

u. failing to remove products used for uterine morcellation from the stream of commerce;

v. failing to test products used for uterine morcellation properly and/or

adequately so as to determine its safety for use;

w. promoting the products used for uterine morcellation as safe and/or safer than other comparative methods;

x. promoting the products used for uterine morcellation on websites aimed at creating user and consumer demand;

y. failing to conduct and/or respond to post-marketing surveillance of complications and injuries;

z. failing to use due care under the circumstances; and,

aa. such other acts or omissions constituting negligence and carelessness as may appear during the course of discovery or at the trial of this matter.

bb. failing to develop a closed morcellator system with the deployment of an intraperitoneal ballistic bag in order to prevent this known risk of disseminating an unsuspected cancer.

20. As a direct and proximate result of the negligent and/or reckless and/or wanton acts and/or omissions of Defendants, Plaintiff suffered serious injuries, and/or financial losses and harm.

21. Wherefore, on this Court, Plaintiff respectfully requests that the Court enter judgment in her favor against Defendants for all damages allowed by law, compensatory and punitive, in the utmost amounts allowed by law, to be decided

by a jury, plus interest, costs, and attorneys' fees.

COUNT II – STRICT PRODUCTS LIABILITY

Paragraphs 1 through 16 above are incorporated by reference to support this Count.

22. As a result of the unreasonably dangerous and defective condition of the products used for uterine morcellation, specifically the Storz Morcellator, which Defendants manufactured, designed, labeled, marketed, distributed, supplied and/or sold, and/or placed into the stream of commerce, they are strictly liable to the Plaintiff for her injuries which they directly and proximately caused. They proximately and directly caused her injuries by failing to properly and adequately design the products used for uterine morcellation, specifically the Storz Morcellator, in order to prevent the potential spread of malignancy.

23. In addition, the Plaintiff's injuries and losses were the direct and proximate result of Defendants' manufacturing, designing, labeling, marketing, distributing, supplying and/or selling and/or placing into the stream of commerce the products used for uterine morcellation, specifically the Storz Morcellator, without proper and adequate warnings regarding the potential for said products' harm to humans and as otherwise set forth supra, when said Defendants knew or should have known of the need for such warnings and/or recommendations.

24. Wherefore, on this Court, Plaintiff respectfully requests that the Court enter judgment in her favor against Defendants for all damages allowed by law, compensatory and punitive, in the utmost amounts allowed by law, to be decided by a jury, plus interest, costs, and attorneys' fees.

COUNT III - BREACH OF EXPRESS WARRANTY

Paragraphs 1 through 16 above are incorporated by reference to support this Count.

25. In the advertising and marketing of the products used for uterine morcellation which was directed to both physicians and hospitals and consumers, Defendants warranted that said product or products, including the Storz Morcellator, were safe for intended use, which induced physicians and hospitals to use the same for procedures such as the surgery Plaintiff Paduda underwent in April, 2013.

26. The aforesaid warranties were breached by Defendants in that the Storz Morcellator products used for uterine morcellation constituted a serious danger to the patient.

27. As a direct and proximate result of Defendants' breach of express warranty, Plaintiff suffered serious injuries, financial losses, and other harm.

28. Wherefore, on this Court, Plaintiff respectfully requests that the Court

enter judgment in her favor against Defendants for all damages allowed by law, in the utmost amounts allowed by law, to be decided by a jury, plus interest, costs, and attorneys' fees.

COUNT IV – BREACH OF IMPLIED WARRANTIES

Paragraphs 1 through 16 above are incorporated by reference to support this Count.

29. At all relevant and material times, Defendants manufactured, distributed, advertised, promoted, and sold the Storz Morcellator used for uterine morcellation.

30. At all relevant times, Defendants intended that the products used for uterine morcellation, including the Storz Morcellator, be used in the manner that the Plaintiff's surgeon in fact used it and Defendants impliedly warranted the product to be of merchantable quality, safe and fit for such use, and was adequately tested.

31. Defendants breached various implied warranties with respect to the products used for uterine morcellation, including:

a. Defendants represented through their labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions that the products used for uterine morcellation, including

the Storz Morcellator, were safe, and withheld and concealed information about the substantial risks of serious injury associated with using the products used for uterine morcellation;

b. Defendants represented that the products used for uterine morcellation, including, the Storz Morcellator, were as safe and/or safer than other alternative surgical approaches that did not include the use of the said products, and concealed information, which demonstrated that said products were not safer than alternatives available on the market; and,

c. Defendants represented that the products used for uterine morcellation, including the Storz Morcellator, were more efficacious than other alternative surgical approaches and techniques and concealed information, regarding the true efficacy of said products.

32. In reliance upon Defendants' implied warranties, Plaintiff's surgeons used said Storz Morcellator as prescribed and in the foreseeable manner normally intended, recommended, promoted, instructed, and marketed by Defendants.

33. Defendants breached their implied warranties to Plaintiff in that said Storz Morcellator used for uterine morcellation was not of merchantable quality, was not safe and fit for intended use, and was not adequately tested.

34. As a direct and proximate consequence of Defendants' breach of

implied warranties and/or intentional acts, omissions, misrepresentations and/or otherwise culpable acts described herein, the Plaintiff sustained injuries and damages alleged herein including pain and suffering.

35. Wherefore, on this Court, Plaintiff respectfully requests that the Court enter judgment in her favor against Defendants for all damages allowed by law, in the utmost amounts allowed by law, to be decided by a jury, plus interest, costs, and attorneys' fees.

COUNT V - FRAUDULENT MISREPRESENTATION AND OMISSION

Paragraphs 1 through 16 above are incorporated by reference to support this Count.

36. Defendants, having undertaken design, formulation, testing, manufacture, marketing, sale, and distribution of devices used for uterine morcellation, including the Storz Morcellator, owed a duty to provide accurate and complete information regarding said instruments.

37. Prior to Plaintiff's surgery in April, 2013, Defendants fraudulently misrepresented that the use of their Storz Morcellator for uterine morcellation was safe and effective.

38. Defendants had a duty to provide Plaintiff, her physicians, and other patients and doctors concerned with true and accurate information regarding the

devices for uterine morcellation it manufactured, marketed, distributed and sold, including the Storz Morcellator. They failed to perform that duty, omitting material information about the instrument's risks.

39. Defendants made representations and failed to disclose material facts with the intent to induce consumers, including Plaintiff, and the medical community to act in reliance by purchasing and using the Storz Morcellator. The Plaintiff's doctor, the Plaintiff, and the medical community justifiably relied on Defendants' representations and omissions by purchasing and using the Storz Morcellator, including for Plaintiff's surgery in April, 2013.

40. Defendants' representations and omissions regarding use of its uterine morcellation device were a direct and proximate cause of the Plaintiff's injuries, specifically the disseminated and fulminated cancer she suffered and was diagnosed with one month after the surgery.

41. Wherefore, on this Court, Plaintiff respectfully requests that the Court enter judgment in her favor against Defendants for all damages allowed by law, compensatory and punitive, in the utmost amounts allowed by law, to be decided by a jury, plus interest, costs, and attorneys' fees.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for relief as follows:

- A. Compensatory damages in excess of the jurisdictional amount, including, but not limited to, damages for bodily injury, pain, suffering, emotional and mental distress, loss of enjoyment of life, loss of society, aggravation of a previously existing condition and other non-economic damages in an amount to be determined by a jury at trial of this action;
- B. Medical expenses, loss of earnings, loss of the ability to earn money and other economic damages in an amount to be determined by a jury at trial of this action;
- C. All punitive damages allowed by law, to the utmost amount, to be determined by a jury at trial of this action;
- D. Restitution and disgorgement of profits;
- E. Reasonable attorneys' fees;
- F. The costs of these proceedings; and
- G. Such other and further relief as this Court deems just and proper.

JURY DEMAND

Plaintiff demands a jury to decide all triable issues.

Dated: May 7, 2014

Respectfully submitted,

/s/ Phillip Holden

Phillip E. Holden

Fla. Bar No. 14395

Email: phillip@integrityforjustice.com

Alex Alvarez

Fla. Bar No. 946346

E-mail: alex@integrityforjustice.com

THE ALVAREZ LAW FIRM

355 Palermo Avenue

Coral Gables, FL 33134

Telephone: (305) 444-7675

Facsimile: (305) 444-0075

Of Counsel:

François M. Blaudeau, MD JD FACHE

FCLM

Alabama Bar No. 7722-D32F

Southern Institute for Medical & Legal
Affairs

Of Counsel: HENINGER GARRISON

DAVIS, LLC

2224 1st Avenue North

Birmingham, Alabama 35203

francois@southernmedlaw.com

Phone: (205) 547.5525

Fax: (205) 547.5526

W. Lewis Garrison, Jr.

Alabama Bar No. 3591-N74W

Christopher B. Hood

Alabama Bar No. 2280-S35H

HENINGER GARRISON DAVIS, LLC

2224 1st Avenue North

Birmingham, AL 35203

wgarrison@hgdlawfirm.com
chood@hgdlawfirm.com

Tel: (205) 326 3336

Fax: (205) 326 3332

Attorneys for Plaintiff

JS 44 (Rev. 12/12)

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) NOTICE: Attorneys MUST Indicate All Re-filed Cases Below.

I. (a) PLAINTIFFS

PEGGY PADUA

DEFENDANTS

KARL STORZ ENDOSCOPY-AMERICA, INC.

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

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

(c) Attorneys (Firm Name, Address, and Telephone Number) The Alvarez Law Firm 355 Palermo Avenue, Coral Gables, FL 33134 (305) 444-7675

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED. Attorneys (If Known)

(d) Check County Where Action Arose: MIAMI-DADE MONROE BROWARD PALM BEACH MARTIN ST. LUCIE INDIAN RIVER OKEECHOBEE HIGHLANDS

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)

- Citizen of This State
Citizen of Another State
Citizen or Subject of a Foreign Country
PTF DEF
1 1
2 2
3 3
4 4
5 5
6 6

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

Table with columns: CONTRACT, REAL PROPERTY, CIVIL RIGHTS, TORTS, PRISONER PETITIONS, FORFEITURE/PENALTY, LABOR, IMMIGRATION, BANKRUPTCY, SOCIAL SECURITY, FEDERAL TAX SUITS, OTHER STATUTES. Includes various legal categories like Personal Injury, Property Damage, and Labor.

V. ORIGIN

- 1 Original Proceeding
2 Removed from State Court
3 Re-filed (See VI below)
4 Reinstated or Reopened
5 Transferred from another district (specify)
6 Multidistrict Litigation
7 Appeal to District Judge from Magistrate Judgment
8 Remanded from Appellate Court

VI. RELATED/ RE-FILED CASE(S)

a) Re-filed Case YES NO b) Related Cases YES NO

JUDGE DOCKET NUMBER

VII. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing and Write a Brief Statement of Cause (Do not cite jurisdictional statutes unless diversity):

28 U.S.C. Section 1332 - Defective Product LENGTH OF TRIAL via days estimated (for both sides to try entire case)

VIII. REQUESTED IN COMPLAINT:

CHECK IF THIS IS A CLASS ACTION UNDER F.R.C.P. 23 DEMAND \$ CHECK YES only if demanded in complaint: JURY DEMAND: Yes No

ABOVE INFORMATION IS TRUE & CORRECT TO THE BEST OF MY KNOWLEDGE

DATE SIGNATURE OF ATTORNEY OF RECORD

May 7, 2014

FOR OFFICE USE ONLY

RECEIPT # AMOUNT IFP JUDGE MAG JUDGE