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ΓΙL Ε U
11/13/2024
Tina Henry

Cascade County District Court STATE OF MONTANA By: <u>Jammie Jacobson</u> DV-7-2024-000563-OC Kutzman, John A.

4.00

John M. Fitzpatrick, Esq. TOWE & FITZPATRICK, PLLC 619 S.W. Higgins, Suite O P.O. Box 1745 Missoula, MT 59806

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Attorneys for Plaintiffs

MONTANA EIGHTH JUDICIAL DISTRICT COURT, CASCADE COUNTY

HANNAH and KEVIN DIETERLE,) Cause No. DV-7-2024-0000563-
individually and as natural parents of) OC
SOPHIE DIETERLE,) Hon. John A. Kutzman
Plaintiffs,) FIRST AMENDED
) COMPLAINT AND DEMAND
-vs-) FOR JURY TRIAL
)
ETHICON, INC., GREAT FALLS)
CLINIC, LLC, and JOHN DOE)
PERSONS, CORPORATIONS AND)
ENTITIES 1-10,)
)
Defendants.)
)

For their claims against the Defendants, the Plaintiffs allege as follows:

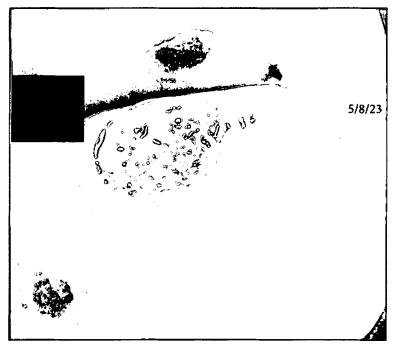
FACTS COMMON TO ALL CLAIMS

1. Hannah and Kevin Deiterle are the natural parents of Sophie Diterle, and are residents of Great Falls, Cascade County, Montana.

- 2. Defendant Ethicon, Inc., is a foreign profit corporation headquartered in Raritan, New Jersey. Defendant Ethicon is a surgical technology company whose business is to manufacture and sell surgical devices, including MEGADYN patient return electrode pads used in electrosurgery. Defendant Ethicon is registered to do business in the State of Montana.
- 3. In 2017, Ethicon acquired Megadyne Medical Products, Inc., and continues to manufacture, supply and sell Megadyne products under that name. As a result of the acquisition, Ethicon is legally liable and responsible for Megadyn products.
- 4. Defendant Great Falls Clinic, LLC (GFC), is a Montana LLC with its principal place of business in business in Great Falls, Cascade County, Montana.
- 5. John Doe Persons, Corporations and Business Entities 1-10 are persons, corporations, or entities who may qualify as "sellers" of the defective product that is at issue in this case, or may otherwise be liable for Plaintiffs' injuries, harms and losses.
- 6. On April 20, 2023, 5-year-old Sophie Deiterle underwent a routine tonsillectomy surgery at GFC.
- 7. During the surgery, the doctor used electrosurgical instruments, including a MEGADYN patient return electrode pad manufactured, sold and/or supplied to GFC by Defendant Ethicon, Inc.

FIRST AMENDED COMPLAINT AND DEMAND FOR JURY TRIAL - PAGE 2

- 8. The morning after the procedure, Sophie's mom noticed blistering on areas of her bottom. Hannah brought Sophie in to be seen by the doctor and he prescribed burn cream and referred her to wound care.
- 9. The wound care provider documented three burn wounds on Sophie's backside. She described two as 2^{nd} degree and the larger one $(4 \times 4 \text{ cm})$ as 3^{rd} degree.
- 10. Sophie received mentally and physically painful wound care for the next three months. Her wounds interfered with her activities and quality of life. Her wounds were severe and painful, as demonstrated in the following photo from May 8, 2023:



11. On May 18, 2023, Sophie was seen by dermatologist Jonathan Bingham, MD. Dr. Bingham concluded that the wounds were burns and noted "the findings are concerning for possible burn injury from the electrosurgical unit."

FIRST AMENDED COMPLAINT AND DEMAND FOR JURY TRIAL - PAGE 3

- 12. Sophie's injuries are thermal burns.
- 13. Sophie's injuries are thermal burns from the Megadyn electrode grounding pad.
- 14. Sophie will have scarring from her burns for the rest of her life, and the associated psychological and physiological impacts that go along with them.
- 15. Sophie's parents sustained and continue to sustain mental distress as a result of seeing their little girl go through this horrific situation and knowledge she will have permanent scarring.
- 16. Return electrode alternative site burns can be caused by inappropriate placement and use of the grounding pad and/or a defective grounding pad.
- 17. According to a notice from the U.S. Food and Drug Administration, on May 10, 2024, MEGADYNE initiated a global discontinuation and voluntary recall of all MEGADYNE MEGA SOFT Pediatric Patient Return Electrodes.

MEGADYNE removed the product because it received reports of patient burn injuries in procedures where the return electrodes were used.

- 18. A root cause investigation on the reports included testing which showed a combination of factors that, when present together, can result in burn injuries.
- 19. The combination of these conditions may be more likely when the pad is used with infants and small children.
- 20. The FDA identified this as a Class I recall, "the most serious type of FIRST AMENDED COMPLAINT AND DEMAND FOR JURY TRIAL PAGE 4

recall. Use of these devices may cause serious injuries or death."

21. According to the FDA recall notice:

Megadyne has received reports of patient burn injuries, including third-degree burns requiring intervention. Burn injuries may lead to extended hospital stay, scarring, and additional surgeries in both pediatric and adult patients. Severe burns could lead to potentially long-lasting impacts on patients especially under the age of 12 years.

* * *

There have been 99 reported injuries.

- 22. The pad used during Sophie's tonsillectomy was one of the defective pads recalled by Ethicon/Megadyne and the FDA.
- 23. Sophie was badly burned by MEGADYNE'S return pad, went through extraordinary pain and suffering as a result, and will have to live with the consequences of the burns for the rest of her life.
- 24. Sophie's burns were caused by a defective product or a combination of a defective produce and improper use by the surgical team.
- 25. GFC alleges that Sophie's burn injuries were caused by the defective Megadyne return electrode pad.
- 26. Ethicon/Megadyne allege that Sophie's burns were caused by GFC's improper use of the Megadyne return electrode pad.

COUNT I: Ethicon/Megadyne (Strict Product Liability)

- 27. Plaintiffs reallege the allegations contained in the preceding paragraphs and incorporate them here by reference.
- 28. Ethicon designed, manufactured, distributed and/or sold the Megadyne return electrode pad that was used in Sophie's tonsillectomy.
- 29. Ethicon placed the defective product into the stream of commerce in the State of Montana.
- 30. Ethicon's return electrode pad was by design, manufacture and/or lack of warning, in a defective condition unreasonably dangerous to Sophie, as evidenced by its failure and the fact that it was recalled for this very issue.
- 31. The failure of the product was beyond that which would be expected by an ordinary user.
- 32. The product was unreasonably unsuitable for its intended and foreseeable purpose.
- 33. Defendant Ethicon is strictly liable for all of Plaintiffs' injuries, damages, harms and losses caused by the failure of its defective product.

COUNT II: Ethicon/Megadyne (Breach of Warranty)

34. Plaintiffs reallege the allegations contained in the preceding paragraphs and incorporate them here by reference.

- 35. Under Montana law, implicit in every sale of goods is an implied warranty of merchantability, Mont. Code Ann. § 30-2-314, which warrants that the goods sold are fit for the ordinary purpose for which they are intended. Additionally, where the seller of goods has reason to know that they will be used for a particular purpose, a warranty that the goods will be fit for that purpose is implied in the sale, Mont. Code Ann. § 30-2-315.
- 36. Implicit in the sale and purchase of the product at issue in this action were warranties of merchantability and fitness for a particular purpose. These warranties warranted that the product would be fit and safe for the ordinary and particular purpose for which it was to be used.
- 37. The product was defective in design, material, manufacture and/or workmanship and was not fit for the use for which it was intended, as evidenced by the failure of the product and, therefore, Defendant Ethicon breached the implied warranties of merchantability and fitness for a particular purpose. As a result, Defendant Megadyne is liable for all of Plaintiffs' injuries, damages, harms and losses caused by the failure of the product.

COUNT III: GFC (Negligence)

- 38. Plaintiffs reallege the allegations contained in the preceding paragraphs and incorporate them here by reference.
- 39. According to Ethicon, Sophie's burn injuries were caused by improper FIRST AMENDED COMPLAINT AND DEMAND FOR JURY TRIAL PAGE 7

use and/or placement of the return pad by GFC agents, employees and staff during Sophie's procedure.

- 40. To the extent Ethicon establishes that GFC provided substandard care and was negligent, Plaintiff also asserts those positions and GFC is liable for Plaintiffs' injuries, damages, harms and losses.
- 41. Defendants are jointly and severally liable to Plaintiffs for damages caused by the defective product and/or negligence.

Count IV (Damages)

- 42. Plaintiffs reallege the allegations contained in the preceding paragraphs and incorporate them here by reference.
- 43. Plaintiffs seek all special and general damages allowed under Montana law including, without limitation, the following losses and damages:
 - (a) Medical and supportive care expenses, past and future;
 - (b) Disfigurement, mental and physical pain and suffering, past and future;
 - (c) Loss of established course of life and quality of life;
- (d) Anxiety, worry, fright, horror, grief, shame, humiliation, embarrassment, anger, chagrin, disappointment and mental and emotional suffering and distress, past and future; and
 - (e) All other special and general damages proved at trial.

WHEREFORE, Plaintiffs request judgment against the Defendants as

follows:

- 1. For all special, general and compensatory damages in a sum to be proven at the trial of this action;
 - 2. For all costs and expenses of suit as are allowed by law;
 - 3. For any and all interest allowed by law; and
- 4. For such other and further relief against the Defendants which this Court deems just and proper.

Dated this 13th day of November, 2024.

/s/ John M. Fitzpatrick
John M. Fitzpatrick
TOWE & FITZPATRICK, PLLC
Attorneys for Plaintiffs

DEMAND FOR JURY TRIAL

Plaintiffs demand trial by jury of all issues of fact in this case.

Dated this 13th day of November, 2024.

/s/ John M. Fitzpatrick
John M. Fitzpatrick
TOWE & FITZPATRICK, PLLC
Attorneys for Plaintiffs

CERTIFICATE OF SERVICE

I, John M. Fitzpatrick, hereby certify that I have served true and accurate copies of the foregoing Complaint - Amended Complaint to the following on 11-13-2024:

Ethicon, Inc (Defendant)
Service Method: Certified Mail

Great Falls Clinic, LLC (Defendant) PO Box 5012 Great Falls MT 59403 Service Method: Certified Mail

Electronically signed by Mary Brown on behalf of John M. Fitzpatrick Dated: 11-13-2024

W. W.

John M. Fitzpatrick, Esq. TOWE & FITZPATRICK, PLLC 619 S.W. Higgins, Suite O P.O. Box 1745 Missoula, MT 59806 Telephone: (406) 829-1669

Fax No.: (406) 493-0538

Email: jfitz@towefitzlaw.com

Attorneys for Plaintiffs

MONTANA EIGHTH JUDICIAL DISTRICT COURT, CASCADE COUNTY

HANNAH and KEVIN DIETERLE, individually and as natural parents of SOPHIE DIETERLE,)))	Cause No. DV-7-2024-0000563-O Judge John A. Kutzman
Plaintiffs,))	,
-vs-)	
ETHICON, INC., GREAT FALLS CLINIC, LLC, and JOHN DOE PERSONS, CORPORATIONS AND ENTITIES 1-10,)))	
Defendants.) _) _)	•

To: ETHICON, INC.

A lawsuit has been filed against you.

Within 21 days after service of this summons on you or (42 days if you are the State of Montana, a state agency, or a state officer or employee), you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Montana Rules of Civil Procedure. Do not include the day you were served in your calculation of time. The answer or motion must be served on the plaintiff or plaintiff's attorney, if plaintiff is represented by an attorney, whose name and address are listed above.

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint.

You also must file your answer or motion with the court.

CLERK OF THE DISTRICT COURT

Date: November 12, 2024

By:

John M. Fitzpatrick, Esq. TOWE & FITZPATRICK, PLLC 619 S.W. Higgins, Suite O P.O. Box 1745 Missoula, MT 59806 Telephone: (406) 829-1669

Fax No.: (406) 493-0538

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Attorneys for Plaintiffs

MONTANA EIGHTH JUDICIAL DISTRICT COURT, CASCADE COUNTY

HANNAH and KEVIN DIETERLE,) Cause No. DV-7-2024-0000563-
individually and as natural parents of .) OC
SOPHIE DIETERLE,) Hon. John A. Kutzman
Plaintiffs,)
) PLAINTIFFS' FIRST
-vs-) COMBINED DISCOVERY
•) REQUESTS TO DEFENDANT
ETHICON, INC., GREAT FALLS) ETHICON, INC.
CLINIC, LLC, and JOHN DOE)
PERSONS, CORPORATIONS AND)
ENTITIES 1-10,)
)
Defendants.)
	_)

TO: Ethicon, Inc.:

In answering these Interrogatories, Requests for Admission, and Requests for Production, you are required not only to furnish such information as you know

of your own personal knowledge, but also information available to you including, but not limited to, information in the possession of your attorneys, investigators, insurance carriers, or anyone else acting on your behalf or their behalf.

These Interrogatories, Requests for Admission, and Requests for Production shall be deemed continuing and supplemental answers shall be required to be filed promptly if Defendant directly or indirectly obtains further information of the nature sought herein between the time answers are served and time of trial.

DEFINITIONS

The following definitions shall be used herein absent clear indication to the contrary:

- 1. "Document" means any written, recorded, or graphic material of any kind, whether prepared by you or by any other person, that is in your possession, custody, or control. The term "document" also includes electronically stored data from which information can be obtained either directly or by translation through detection devices or readers; any such document is to be produced in a reasonably legible and usable form. The term "document" includes all drafts of a document and all copies that differ in any respect from the original, including any notation, underlining, marking, or information not on the original. A document is deemed to be in your control if you have the right to secure the document or a copy thereof from another person
- 2. The term "files" as used herein shall mean the envelope, folder, file or other container in which documents are found.
- 3. To "identify" a person means to state the person's name, last known business address, telephone number and, if a natural person, last known residential address and telephone number and to state the employment positions held by such person at all times pertinent to this controversy.

- 4. The terms "you" and "your" include the named Defendant, its agents, employees, insurance companies, attorneys of any one else acting for or on its behalf.
- 5. The term "person" as used herein shall mean any natural person, company, corporation, association, partnership, joint venture, proprietorship, cooperative or other entity.

INTERROGATORY NO. 1: Do you expect to call any expert witness or witnesses at the trial of this action? If so, please provide the following additional information:

- (a) Identify each and every such expert;
- (b) State the subject matter on which the expert is expected to testify;
- (c) State the substance of the facts and opinions to which each such expert is to testify;
 - (d) State a summary of the grounds for each opinion of each such expert.

If such expert maintains a resume or curriculum vitae, please produce true and correct copy of such document, pursuant to Rule 34, M.R.Civ.P.

ANSWER:

<u>INTERROGATORY NO. 2</u>: Please identify any and all policies of liability insurance that potentially cover, in whole or in part, the acts, errors and omissions alleged in the Complaint. Please also provide the following additional information:

(a) Identify the insurance company providing coverage applicable to this PLAINTIFFS' FIRST COMBINED DISCOVERY REQUESTS TO DEFENDANT ETHICON, INC. - PAGE 3

claim;

- (b) State the limits of all insurance available to indemnify you against the claims (or any of them) asserted herein; and
- (c) State a summary of the insurer's position with regard to coverage (i.e., if there is a coverage dispute, please state what the basis and or grounds for that dispute are).

ANSWER:

REQUEST FOR PRODUCTION NO. 1: Please produce a true and correct copy of each insurance policy, including the declarations page, identified in your answer to the preceding Interrogatory.

RESPONSE:

REQUEST FOR PRODUCTION NO. 2: Please produce true and correct copies of any and all reservation of rights letters, non-waiver letters/agreements, or other correspondence evidencing any coverage issue.

RESPONSE:

INTERROGATORY NO. 3: Identify any person who you believe or know to have knowledge of any facts relating to any allegation, contention or issue in this case and with respect to such persons, please identify any such person that you intend to call as a witness in the event of trial of this matter.

ANSWER:

<u>INTERROGATORY NO. 4</u>: With regard to the return electrode pad in the photographs attached as **Exhibit 1**, please:

- (a) Identify it by name, model number and product code;
- (b) Identify where and by whom it was manufactured;
- (c) State who distributed it;
- (d) State the identity of all retailers through whom it was marketed;
- (e) State the inclusive dates in which this model was manufactured;
- (f) If this model was discontinued, state when and why; and
- (g) State the most similar models to the model shown in the attached photos.

ANSWER:

REQUEST FOR ADMISSION NO. 1: Please admit the return electrode pad in the photographs attached as **Exhibit 1** is a Medadyne return electrode pad subject to recall because of reports of burn injuries.

RESPONSE:

REQUEST FOR PRODUCTION NO. 3: Please produce all documents, photographs, videos, records, complaints, correspondence, internal investigative reports, investigations, lawsuits, spreadsheets, files, and/or materials of any kind pertaining to reports of burn injuries involving Megadyne Mega Soft patient return electrodes.

PLAINTIFFS' FIRST COMBINED DISCOVERY REQUESTS TO DEFENDANT ETHICON, INC. - PAGE 5

RESPONSE:

<u>REQUEST FOR PRODUCTION NO. 4</u>: Please produce all files, documents, and materials of any kind pertaining to communications between you and the FDA regarding issues involving Megadyne Mega Soft patient return electrodes.

RESPONSE:

<u>REQUEST FOR PRODUCTION NO. 5</u>: Please produce all files, documents, or materials of any kind pertaining to communications between you and customers regarding issues involving Megadyne Mega Soft patient return electrodes.

RESPONSE:

<u>REQUEST FOR PRODUCTION NO. 6</u>: Please produce the original IFU for the patient return electrode pad depicted in the photographs attached as Exhibit 1.

RESPONSE:

REQUEST FOR PRODUCTION NO. 7: Please produce all corrections the the IFU for the patient return electrode pad depicted in the photographs attached as Exhibit 1.

RESPONSE:

REQUEST FOR PRODUCTION NO. 8: Please produce the "Cleaning and Care Visual Aid and Placement and Setup Aid" associated with Megadyn Mega Soft patient return electrodes.

RESPONSE:

PLAINTIFFS' FIRST COMBINED DISCOVERY REQUESTS TO DEFENDANT ETHICON, INC. - PAGE 6

REQUEST FOR PRODUCTION NO. 9: According to a FDA notice dated May 10, 2024:

A root cause investigation on the reports included testing which showed a combination of factors when present together may result in potential for thermal injuries.

Please produce all files, documents, or materials of any kind pertaining to root cause investigations and testing pertaining to reports of burn injuries from Megadyn Mega Soft patient return electrodes.

RESPONSE:

REQUEST FOR PRODUCTION NO. 10: Please Produce any photographs, videotapes, motion pictures or any similar photographic evidence which pertains in any way to the claims and defenses asserted in this case.

RESPONSE:

REQUEST FOR ADMISSION NO. 2: Please admit that Sophie Dieterle sustained burn injuries during her tonsillectomy surgery.

RESPONSE:

REQUEST FOR ADMISSION NO. 3: Please admit that the burn injuries Sophie Dieterle sustained during surgery are consistent with other burn injuries reported from Megadyn Mega Soft patient return electrodes.

RESPONSE:

REQUEST FOR ADMISSION NO. 4: Please admit that you recalled the PLAINTIFFS' FIRST COMBINED DISCOVERY REQUESTS TO DEFENDANT ETHICON, INC. - PAGE 7

Megadyn Mega Soft patient return electrode used in Sophie Dieterle's surgery because they were causing burns on children like the burns Sophie stustaind.

RESPONSE:

REQUEST FOR ADMISSION NO. 5: Please admit that a patient return electrode that causes burns to children is unreasonably unsuitable for its intended or foreseeable purpose.

RESPONSE:

INTERROGATORY NO. 5: Is it your contention that Sophie Dieterle's injuries were caused, in whole or in part, by something other than the Megadyn Mega Soft patient return electrode? If so, please identify each other such person or entity and describe how, or in what manner, such other person or entity caused or contributed to Sophie's injuries or damages.

ANSWER:

REQUEST FOR PRODUCTION NO. 11: Identify and produce all documents upon which your contentions in your answer to the preceding interrogatory are based, in whole or part.

RESPONSE:

INTERROGATORY NO. 6: Do you contend that any of Sophie's health care providers are at fault for causing Sophie's injuries or damages? If so, please identify each such health care provider and describe how, or in what manner, such health care

provider caused or contributed to Sophie's injuries or damages.

ANSWER:

REQUEST FOR PRODUCTION NO. 12: Identify and produce all documents upon which your contentions in your answer to the preceding interrogatory are based, in whole or part.

RESPONSE:

REQUEST FOR PRODUCTION NO. 13: If not already produced, please produce any and all files, records, or documents of any kind from any person or entity that you have received pertaining in any way to alleged burn injuries associated with use of Megadyn Mega Soft patient return electrodes, including the model shown in the photographs attached as Exhibit 1. [Note: this request includes, without limitation, production of information transmitted by any means, including writing and/or electronically, i.e., e-mail].

RESPONSE:

REQUEST FOR PRODUCTION NO. 14: If not already produced, please produce any and all complaints, formal or informal, or knowledge of any other incidents that you have ever received, in writing or otherwise, alleging (1) a defect or failure of a Megadyne Mega Soft patient return electrode and/or (2) injury or damage allegedly caused because of such defect or failure. (In your answer describe each complaint and/or incident separately and state the date of each and the name and

address of the individual making the complaint or sustaining the damage or injury).

RESPONSE:

REQUEST FOR PRODUCTION NO. 15: Please produce any and all advertising materials that you have produced or disseminated with respect to the Megadyne Mega Soft patient return electrode shown in the photographs attached as Exhibit 1.

RESPONSE:

REQUEST FOR PRODUCTION NO. 16: Please produce copies of exemplar package inserts that would have come with the Megadyne Mega Soft patient return electrode shown in the photographs attached as Exhibit 1.

RESPONSE:

REQUEST FOR PRODUCTION NO. 17: If you did not manufacture the Megadyne Mega Soft patient return electrode at issue, please produce copies of any agreements with the manufacturer pertaining to liability, indemnification or insurance.

RESPONSE:

REQUEST FOR PRODUCTION NO. 18: Please produce copies of any expert reports by both Plaintiffs and Defendants in litigation pertaining to burn injuries allegedly caused by Megadyne Mega Soft patient return electrodes.

RESPONSE:

REQUEST FOR PRODUCTION NO. 19: Please produce all pleadings and answers to discovery from any litigation involving burn injuries caused by the alleged failure or malfunction of a Megadyne Mega Soft patient return electrode.

RESPONSE:

REQUEST FOR PRODUCTION NO. 20: Please produce all documents pertaining in any way to settlement of claims alleging burn injuries caused by Megadyne Mega Soft patient return electrodes.

RESPONSE:

REQUEST FOR PRODUCTION NO. 21: Please produce any inter-company files, documents or materials discussing or pertaining to the issue of Megadyne Mega Soft patient return electrodes allegedly causing burn injuries.

RESPONSE:

INTERROGATORY NO. 7: Do you intend to refer to any learned text, treatise, journal article or other such publication, within the meaning of M. R. Evid. 803(18) either in support of any contention asserted by you in this action or in examination of any expert witness who may be called or identified by the Plaintiff? If so, please identify by appropriate bibliography each and every such item.

ANSWER:

<u>REQUEST FOR PRODUCTION NO. 22</u>: Please produce all files, documents, photographs, video recordings, audio recordings and other records, including

electronically stored records and information, pertaining to the recall of Megadyne Mega Soft patient return electrodes.

RESPONSE:

REQUEST FOR PRODUCTION NO. 23: If not already produced, please produce all documents and records pertaining to investigation(s) of why Megadyne Mega Soft patient return electrodes were allegedly causing burn injuries.

RESPONSE:

<u>INTERROGATORY NO. 8</u>: When did you first become aware of reports of Megadyne Mega Soft patient return electrodes allegedly causing burn injuries?

ANSWER:

REQUEST FOR PRODUCTION NO. 24: Please produce all documents or materials pertaining to your response to the preceding interrogatory.

RESPONSE:

<u>INTERROGATORY NO. 9</u>: When did you first notify notify customers/health care providers that you had received reports of Megadyne Mega Soft patient return electrodes allegedly causing burn injuries?

ANSWER:

<u>REQUEST FOR PRODUCTION NO. 25</u>: Please produce all documents or materials pertaining to your response to the preceding interrogatory.

RESPONSE:

<u>REQUEST FOR ADMISSION NO. 6</u>: Please admit that you manufactured the Megadyne Mega Soft patient return electrode attached as Exhibit 1.

RESPONSE:

REQUEST FOR ADMISSION NO. 7: Please admit that you distributed the Megadyne Mega Soft patient return electrode attached as Exhibit 1.

RESPONSE:

REQUEST FOR ADMISSION NO. 8: Please admit that you sold the Megadyne Mega Soft patient return electrode attached as Exhibit 1.

RESPONSE:

INTERROGATORY NO. 10: If any of your answers to any of the Requests for Admission are anything other than an unqualified admission, please state, with particularity, the bases for your qualification or denial.

<u>ANSWER:</u>

<u>INTERROGATORY NO. 11:</u> Please state the name and position of all persons who helped in responding to these discovery requests.

ANSWER:

INTERROGATORY NO. 12: Please state and describe the factual and legal basis of each affirmative defense you contend you have to the claims asserted in Plaintiffs' Complaint and identify all facts, witnesses and documents supporting such affirmative defenses.

ANSWER:

REQUEST FOR PRODUCTION NO. 26: If any request for production is objected to based on a privilege, please provide in a privilege log:

- (a) a description of the material withheld;
- (b) the identity and position of its author;
- (c) the date it was written;
- (d) the identity and position of recipients;
- (e) the material's present location; and
- (f) the specific reasons for its being withheld, including the privilege invoked and the grounds thereof. [This is the minimum information needed to be responsive and compliant with Fed.R.Civ.P. 26(b)(5) see Kephart v. Natl. Union Fire Ins. Co. of Pitt. Pa., 2007 WL 2253608].

RESPONSE:

REQUEST FOR PRODUCTION NO. 27: Please provide all files, documents and materials pertaining to the acquisition of Megadyne Medical Products, Inc.

RESPONSE:

REQUEST FOR PRODUCTION NO. 28: Please provide all files, documents and materials pertaining to FDA approval of the Megadyne Mega Soft patient return electrodes subject to the recall.

RESPONSE:

Dated this $\frac{13}{2}$ day of November, 2024.

By:

John M. Fitzpatrick
TOWE & FITZPATRICK, PLLC

Attorneys for Plaintiffs

John M. Fitzpatrick, Esq. TOWE & FITZPATRICK, PLLC 619 S.W. Higgins, Suite O P.O. Box 1745 Missoula, MT 59806 Telephone: (406) 829-1669 Fax No.: (406) 493-0538

•

Attorneys for Plaintiffs

Email: jfitz@towefitzlaw.com

MONTANA EIGHTH JUDICIAL DISTRICT COURT, CASCADE COUNTY

HANNAH and KEVIN DIETERLE,) Cause No. DV-7-2024-0000563-
individually and as natural parents of) OC
SOPHIE DIETERLE,) Hon. John A. Kutzman
Plaintiffs,) ACKNOWLEDGMENT AND
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-VS-) SUMMONS (ETHICON, INC.)
ETHICON, INC., GREAT FALLS)
CLINIC, LLC, and JOHN DOE)
PERSONS, CORPORATIONS AND) · · · · · · · · · · · · · · · · · · ·
ENTITIES 1-10,)
Defendants.) ·

To: John M. Fitzpatrick
Towe & Fitzpatrick, PLLC
619 S.W. Higgins, Suite O
Missoula, MT 59806

I have received your request to acknowledge and waive service of a summons in this action along with a copy of the complaint, two copies of this

acknowledgment and waiver form, and a prepaid means of returning one signed copy of the form to you.

I, or the entity I represent, agree to save the expense of serving a summons and complaint in this case.

I understand that I, or the entity I represent, will keep all defenses or objections to the lawsuit, the court's jurisdiction, and the venue of the action, but that I waive any objections to the absence of a summons or of service.

I also understand that I, or the entity I represent, must file and serve an answer or a motion under Montana Rule of Civil Procedure 12 within 21 days from the date I sign this acknowledgment and waiver form (or 42 days if I am signing on behalf of the State of Montana, a state agency, or a state officer or employee).

If I fail to do so, a default judgment will be entered against me or the entity I represent.

Date:				
				•
Signature		·		٠
Printed name				
Relationship to enti	ty or author	ority to rece	eive se	rvice

Address			٠.	
E-mail address				
		·		
Telephone number	er			

John M. Fitzpatrick, Esq. TOWE & FITZPATRICK, PLLC 619 S.W. Higgins, Suite O P.O. Box 1745 Missoula, MT 59806 Telephone: (406) 829-1669

Fax No.: (406) 493-0538

Email: ifitz@towefitzlaw.com

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To: John M. Fitzpatrick
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619 S.W. Higgins, Suite O
Missoula, MT 59806

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acknowledgment and waiver form, and a prepaid means of returning one signed copy of the form to you.

I, or the entity I represent, agree to save the expense of serving a summons and complaint in this case.

I understand that I, or the entity I represent, will keep all defenses or objections to the lawsuit, the court's jurisdiction, and the venue of the action, but that I waive any objections to the absence of a summons or of service.

I also understand that I, or the entity I represent, must file and serve an answer or a motion under Montana Rule of Civil Procedure 12 within 21 days from the date I sign this acknowledgment and waiver form (or 42 days if I am signing on behalf of the State of Montana, a state agency, or a state officer or employee).

If I fail to do so, a default judgment will be entered against me or the entity I represent.

Date:			
			1
Signature			
Printed name			
Relationship to entity of	r authority	to receive	

Case 4:24-cv-00116-JTJ Document 1-1 Filed 12/19/24 Page 41 of 41

Address	 	
E-mail address	 	
Telephone number	 <u> </u>	

EXHIBIT B

Maxon R. Davis
Davis, Hatley, Haffeman & Tighe, P.C.
The Milwaukee Station, 3rd Floor
101 River Drive N.
Great Falls, MT 59401
Telephone: 406-761-5243

Email: max.davis@dhhtlaw.com

Attorneys for Defendant

MEGADYNE MEDICAL PRODUCTS, INC. (Erroneously sued herein as ETHICON, INC.)

MONTANA EIGHTH JUDICIAL DISTRICT COURT, CASCADE COUNTY

HANNAH and KEVIN DIETERLE, individually and as natural parents of SOPHIE DIETERLE,

Plaintiffs,

V.

ETHICON, INC., GREAT FALLS CLINIC, LLC, and JOHN DOE PERSONS, CORPORATIONS AND ENTITIES 1-10,

Defendants

No. DV-7-2024-0000563-OC

NOTICE OF FILING NOTICE OF REMOVAL AND REQUEST FOR TRANSFER

TO: Plaintiffs Hannah and Kevin Dieterle; and the Clerk of the Eighth Judicial District Court, Cascade County, Montana, MT 59401

YOU, AND EACH OF YOU, WILL PLEASE TAKE NOTICE THAT on the 19th day of December, 2024, the above-named Defendants in this matter filed a Notice of Removal in the United States District Court for the District of Montana, for the removal of the above-entitled action from the Montana Eighth Judicial

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District Court, Cascade County, to the above-entitled District Court of the United

States, and filed with the Clerk of Court a copy of the Notice of Removal. A copy

of the Notice of Removal to the federal court is served upon you. See Exhibit A.

Pursuant to Rule 77(e), M. R. Civ. P., request is made upon the Clerk of the Eighth

Judicial District Court, Cascade County, Montana, that the file be transferred and

promptly delivered to the Clerk of Court, United States District Court for the District

of Montana.

Dated: December 19, 2024

Davis, Hatley, Haffeman & Tighe, P.C.

/s/ Maxon R. Davis

Maxon R. Davis Attorneys for Defendant MEGADYNE MEDICAL PRODUCTS, INC. (erroneously sued herein as ETHICON, INC.)

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JS 44 (Rev. 10/20)

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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

1. (a) PLAINTIFFS			DEFENDANTS						
Hannah and Kevin Dieterle, individually and as natural parents of Sophie Dieterle				Megadyne Medical Products, Inc., erroneously sued as Ethicon, Inc.					
(b) County of Residence of First Listed Plaintiff Cascade County, MT (EXCEPT IN U.S. PLAINTIFF CASES)			MT	County of Residence of First Listed Defendant (IN U.S. PLAINTIFF CASES ONLY) NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.					
	rick, TOWE & FITZ ns, Suite 0, P.O. Bo		MT	Attorneys (If Known Maxon R. Dav P.O. Box 2103 761-5243	is, Davis,). =
II. BASIS OF JURISD		in One Box Only)		FIZENSHIP OF	PRINCIPA	L PARTIES	Place on "X" in i	One Box fo	
1 U.S. Government Plaintiff	3 Federal Question (U.S. Governmen			(For Diversity Cases Only	PTF DEF		and One Box for Lincipal Place		
2 U.S. Government Defendant	× 4 Diversity (Indicate Citizen.	ship of Parties in Item III)		n of Another State	2 2	Incorporated and F of Business In A		5	× 5
***************************************				n or Subject of a eign Country	3 3	Foreign Nation		6	6
IV. NATURE OF SUIT						for: Nature of S	The state of the s	THE R. LEWIS CO., LANSING, MICH.	
110 Insurance	PERSONAL INJURY	ORTS PERSONAL INJURY		RFEITURE/PENALTY 5 Drug Related Seizure		KRUPTCY		STATUTI	
120 Marine 130 Miller Act 140 Negotiable Instrument 150 Recovery of Overpayment & Enforcement of Judgment 151 Medicare Act 152 Recovery of Defaulted Student Loans (Excludes Veterans) 153 Recovery of Overpayment of Veteran's Benefits 160 Stockholders' Suits 190 Other Contract 195 Contract Product Liability 196 Franchise REAL PROPERTY 210 Land Condemnation 220 Foreclosure 230 Rent Lease & Ejectment 240 Torts to Land 245 Tort Product Liability 290 All Other Real Property	310 Airplane 315 Airplane Product Liability 320 Assault, Libel & Slander 330 Federal Employers' Liability 340 Marine 345 Marine Product Liability 350 Motor Vehicle 355 Motor Vehicle Product Liability 360 Other Personal Injury 362 Personal Injury - Medical Malpractice CIVIL RIGHTS 440 Other Civil Rights 441 Voting 442 Employment 443 Housing/ Accommodations 445 Amer. w/Disabilities Employment 446 Amer. w/Disabilities Other 448 Education	365 Personal Injury - Product Liability 367 Health Care/	710 720 740 751 791	LABOR Fair Labor Standards Act Labor/Management Relations Railway Labor Act Family and Medical Leave Act Other Labor Litigation Employee Retirement Income Security Act IMMIGRATION Naturalization Application Other Immigration Actions	## 423 Witi 28 No. PROPER \$20 Cop 830 Pate 835 Pate New 840 Trace \$80 Defi Act \$60 Pate \$61 Pate \$64 Pate \$65 Pate \$70 Tax \$70 Tax \$71 Pate \$71	CTY RIGHTS Dyrights ent ent - Abbreviated v Drug Application	480 Consum (15 US) 485 Telephh Protect 490 Cable/S 850 Securiti Exchar 890 Other S 891 Agricul 893 Enviror 895 Freedon Act 896 Arbitral 899 Admini Act/Rev	m (31 USC)) eapportion: st and Bankin erce ation erce ation t Organizat mer Credit GC 1681 or one Consur- tion Act Sat TV ies/Common tuton istrative Preview or App Decision utionality of	ment ing iced and itions 1692) mer odities/ ictions atters mation ocedure
	n One Box Only) moved from 3 te Court	Remanded from Appellate Court	4 Reins Reope		ferred from ner District	6 Multidistri Litigation Transfer		Multidist Litigation Direct Fi	n -
VI. CAUSE OF ACTIO	DN 28 U.S.C. §§ 1332, 14 Brief description of c			o not cite jurisdictional st					
VII. REQUESTED IN COMPLAINT:		S IS A CLASS ACTION		MAND \$		HECK YES only i	-	complain	nt:
VIII. RELATED CASE IF ANY	(See instructions):	JUDGE			DOCKI	ET NUMBER			
DATE		SIGNATURE OF ATTO	RNEY O	FRECORD	1				
December 19, 2024		(7.5	J-Kh	14.1	Tan	10			
FOR OFFICE USE ONLY				03 (
RECEIPT # AM	10UNT	APPLYING IFP		JUDGE_		MAG. JUD	OGE		