

EXHIBIT C

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK
BROOKLYN DIVISION

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*IN RE: EXACTECH POLYETHYLENE
ORTHOPEDIC PRODUCTS LIABILITY
LITIGATION*

Case No.: 22-md-3044-NGG-MMH
MDL No. 3044

DEFENDANT’S FACT SHEET

This Document Applies To:

Judge Nicholas G. Garaufis
Magistrate Judge Marcia M. Henry

All Cases

.....X

Plaintiff(s):

Civil Action Number:

INSTRUCTIONS

Defendant shall prepare and serve the completed Defendant Fact Sheet and documents responsive to requests in the Defendant Fact Sheet within 15 days of receipt of a substantially completed¹ Plaintiff Fact Sheet. If Defendant for good cause requires additional time to provide the Defendant Fact Sheet within the required deadlines, Defendant’s Lead Counsel will contact the individual Plaintiff’s counsel or a *pro se* plaintiff, request additional time, and explain the basis for good cause. No objections may be made to the questions.

Please provide the following information for Plaintiff (or Plaintiff’s decedent) (hereinafter “Plaintiff”) who was implanted with an Exactech device or any components thereof (hereinafter “Device”) that is the subject of Plaintiff’s Complaint in the above-referenced action, and who

¹ “Substantially complete” shall mean that the Plaintiff Fact Sheet shall be complete enough such that Defendant has the information from Plaintiff and time sufficient to conduct its search to complete a Defendant Fact Sheet. All of Defendant’s other rights are reserved, including the right to send deficiency letters where appropriate.

subsequently had a revision of said implantation. In filling out any section or sub-section of this form, please submit additional sheets as necessary to provide complete information.

In filling out this form, please respond on the basis of information and/or documents that are reasonably available to each Defendant. Also, please use the following definition for “Healthcare Providers”: All Persons and Hospitals identified in Section III and IV of the Preliminary Disclosure Form or Plaintiff Fact Sheet submitted by Plaintiff in the above-referenced action who surgically implanted and/or surgically explanted the Device(s) or any component thereof.

“Produce” shall be defined as to identify where in the general document production the documents requested may be located, either by Bates number or by some other unique identifier specific to the responsive document.

In completing this Defendant Fact Sheet, You are under oath and must provide information that is true and correct to the best of Your knowledge, information and belief. If the response to any question is that You do not know the information requested, that response should be entered in the appropriate location(s). Defendant may refer Plaintiff(s) to a Document(s) produced in Exactech’s document production in MDL 3044 so long as Defendant references the document(s) by Bates number or by some other unique identifier specific to the responsive document.

I. COMMUNICATIONS AND RELATIONSHIPS WITH PLAINTIFF'S HEALTHCARE PROVIDERS

A. Dear Healthcare Provider Letters and Other Communications with Plaintiff's Implanting and Revising Orthopedic Surgeons

1. State whether a "Dear Doctor" or "Dear Healthcare Provider" letter, or any other written communication, whether correspondence or emails, related to a recall, was sent to Plaintiff's implanting and/or Plaintiff's revising orthopedic surgeon, regarding the Exactech Implant implanted into Plaintiff and upon which the claims in the above-referenced action are based.

Yes _____ No _____

- a. If yes, please identify the date(s) the communication was/were sent, its manner of transmission (type of mail, email, etc.) and state whether proof of receipt was required and received, including but not limited to Dear Healthcare Profession Letter Response Forms.
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- b. If yes, produce a copy of the letter sent by Defendants to the healthcare provider.

3. Did Plaintiff's orthopedic surgeons who implanted and/or explanted the Device(s) ever attend any education courses in the five (5) years before or after Plaintiff's implant surgery sponsored by Defendant?

- a. If yes, indicate which courses, dates and locations of said courses, and whether Defendants paid any travel costs or provided remuneration of said costs.

4. Were Plaintiff(s)' orthopedic surgeons who implanted and/or explanted the Device(s) ever listed on Exactech's "Surgeon Locator" on the Exactech website <https://www.exac.com/surgeon-locator/#/> (or any predecessor address) in the five (5) years before Plaintiff's implant surgery?

Yes _____ No _____

- a. If yes, provide the dates the surgeon(s) was listed, and if the surgeon(s) are no longer listed on the Surgeon Locator, set forth the reason, and who initiated the removal of the Surgeon's name(s).

B. Consulting Relationships with Plaintiff's Implanting and Revising Orthopedic Surgeons

1. Identify whether any of Plaintiff's orthopedic surgeons who implanted and/or explanted the Device(s) has or had a Consulting Agreement with Defendant or other similar arrangement that relates to serving as a consultant as a thought leader, opinion leader, design surgeon, or member of a speaker's bureau regarding any of Defendant's hip replacement, knee replacement and/or ankle replacement systems in the five (5) years before Plaintiff's implant surgery.

Yes _____ No _____

2. If yes, please identify the date(s) the agreement and produce copies.
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C. Financial Compensation and other things of value provided to Plaintiff's orthopedic surgeons who implanted and/or explanted the Device(s).

1. Identify whether you have provided to any of Plaintiff's orthopedic surgeons who implanted and/or explanted the Device(s) financial compensation or other things of value in the five (5) years before Plaintiff's implant surgery.

Yes _____ No _____

2. If yes, please provide copies of consulting agreements or other agreements memorializing terms of compensation and the amount of compensation.
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II. BROADSPIRE CLAIM DOCUMENTS

A. Claim Documents

1. State whether Plaintiff has a Broadspire claim, which means a claim that has been assigned a claim number.

Yes _____ No _____

III. RETAINED SURGICAL SPECIMEN

1. Please state whether Exactech has received or retained any specimens (e.g. explanted device, pathology) from any of Plaintiff's surgeries.

Yes _____ No _____

- a. If yes to 1, please identify the specimens received or retained and identify all locations where any of Plaintiff’s removed specimens are, or at any time have been stored, with the limitation that consulting expert/expert witness names and locations need not be identified, to preserve privilege.

- b. If yes to 1, please produce all chain of custody forms, photos, and documents relating to any testing or examination of any retained specimens, except for any documents prepared by consulting experts or expert witnesses.
- c. Produce any complaint files, retrieval analysis or reports of any inspections and/or done of any such devices, including but not limited to Product Evaluation Engineering Forms and Memos regarding Device(s) implanted and/or explanted into the above-referenced, except for any documents prepared by consulting experts or expert witnesses.
- d. Produce any documentation of retrieval analysis findings submitted to the FDA of said revision surgery if the documentation exists.

IV. SALES REPRESENTATIVES/DISTRIBUTORS

- 1. As to the implant procedure(s) where the Device(s) were implanted in Plaintiff, where Sales Representatives/Distributors were present for any amount of time, identify all Sales Representatives or any other Representatives, including the name of their affiliated distributor, who provided the implanted components to the Health Care Providers and/or who attended the implantation procedures.

Sales Representative(s)	Distributor	Component	Surgeon	Whether Representative Attended Implantation Procedure	To Defendant’s knowledge, is Sales Representative Still Employed with Employer

- 2. As to any subsequent revision surgery on the same joint as Plaintiff’s implanting surgery, state whether Exactech components were implanted in the revision surgery.

Yes _____ No _____

3. If yes, as to any subsequent revision surgery on the same joint as Plaintiff’s implanting surgery, identify the Sales Representatives, or Distributors who provided the implanted Exactech components to the health care providers and/or who attended the revision procedure.

Sales Representative(s)	Distributor	Component	Surgeon	Whether Representative Attended Implantation Procedure	To Defendant’s knowledge, is Sales Representative Still Employed with Employer

- a. Indicate if the Sales Representative or Distributor took any photos or videos during the revision surgery of the Plaintiff or of the explanted device during and following the completion of the surgery. If so, produce said photos and/or videos.

Yes _____ No _____

V. COMPLAINT FILES AND ADVERSE EVENT REPORTS

1. Produce all Complaint File records for Plaintiff in Defendant’s possession.
2. Produce copies of any Adverse Event Reports/Medical Device Reports (MDRs) pertaining to Plaintiff submitted to the FDA pursuant to the Manufacturer and User Facility Device Experience (MAUDE) requirements or submitted to any other entity or person.

VI. COMMUNICATIONS WITH PLAINTIFF AND ABOUT PLAINTIFF

1. Produce copies of documents reflecting any direct contact, either written or oral, between Plaintiff and/or Plaintiff’s representative and any employee and/or representative of Defendants.

VIII. DEVICE MANUFACTURER INFORMATION

For each Device identified by Plaintiff in response to Section III of Plaintiff's Preliminary Disclosure Form, please provide the following:

- a. Final Goods Release Date
- b. Identity of supplier of the packaging for the Polyethylene components implanted in Plaintiff and whether the packaging was within the scope of the recall.
- c. Expiration Date of each Polyethylene Component(s) implanted in Plaintiff
- d. Date of Shipment of each Polyethylene Component(s) implanted in Plaintiff to the geographical region where it was implanted

IX. RESEARCH

State whether Plaintiff's Implanting or Revision Surgeons Participated in Post-Market Clinical Follow-Up Studies.

VERIFICATION

I am employed by Exactech, Inc., one of the Defendants in this action. I am authorized by Defendants to make this Verification on each corporation's behalf. The foregoing answers were prepared with the assistance of a number of individuals, including counsel for Defendants, upon whose advice and information I relied. I declare under penalty of perjury that all of the information as to the foregoing Defendants provided in this Defendant' Fact Sheet is true and correct to the best of my knowledge upon information and belief.

Date: _____

Signature

Name: _____

Employer: _____

Title: _____