

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.: 1:22-md-03044-NGG-MMH  
MDL No. 3044  
**PROTECTIVE ORDER**

Judge Nicholas G. Garaufis  
Magistrate Judge Marcia M. Henry

*This Document Applies To:*

*All Cases*

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By approval of this Court, to preserve, protect and maintain the confidentiality and protected status of certain confidential, commercial, and/or proprietary documents and information produced or to be produced in the above-captioned litigation (“Litigation”), the Court hereby enters the following Protective Order governing the disclosure of confidential Discovery Material by a producing party (“Producing Party”) to a receiving party (“Receiving Party”) in this Litigation.

HAVING FOUND GOOD CAUSE, THIS COURT HEREBY ORDERS, ADJUDGES, and DECREES that the following Protective Order (“Protective Order”) shall govern the exchange of confidential information in this Litigation, as follows:

1. **Scope.** The terms and conditions of this Protective Order shall govern documents, depositions, deposition exhibits, discovery responses, written material, electronic data, graphic data, excerpts or summaries of documents disclosed as required by Rule 26(a) and all other tangible items, produced in whatever format (e.g., hard copy, electronic, digital, etc.) and on whatever

media (e.g., hard copy, videotape, computer disk, CD-ROM, DVD, by secure electronic transmission, hard drive, USB drive, or otherwise), given or exchanged by and among any and all of the parties and non-parties to this Litigation, whether gathered through informal requests or communications between the parties or their counsel or gathered through formal discovery conducted pursuant to Federal Rules of Civil Procedure (“Rule” or “Rules”) 30 through 36 and 45 (“Discovery Material”).

2. The term “Designating Party” as used herein shall mean the person or party who produces the Discovery Material or the party who chooses to designate Discovery Material produced by or originating with any other party or non-party.

3. **Confidential Material.** As used in this Protective Order, “Confidential Material” means Discovery Material labeled as “CONFIDENTIAL” produced by the Designating Party in this case and designated as follows:

- a. The Designating Party shall have the right to designate any Discovery Material as “CONFIDENTIAL” to the extent it believes in good faith that such Discovery Material contains or reflects information subject to protection under Federal Rule of Civil Procedure 26(c)(1)(G), or other federal or state statute or regulation, or contains or reflects other confidential, commercially sensitive, proprietary, or privileged information, or which is protected by a right to privacy.
- b. Mass, indiscriminate, global, or routinized designations and designation challenges are prohibited. If it comes to a Designating Party’s attention that information or items that it designated for protection do not qualify for protection, the Designating Party must promptly notify all other Parties that

it is withdrawing the mistaken designation. Counsel for Challenging Party has an obligation to ensure there is a good faith basis for each Designation Challenge.

4. **Designations.** Confidential Material shall be designated by the Designating Party by placing the legend “CONFIDENTIAL” on each page of the document containing Confidential Material prior to production. The Designating Party shall employ reasonable efforts to ensure that substantive content of any document is not obscured through the application of such legend.

- a. With respect to documents produced by a non-party, either party may designate such documents as Confidential Material by (i) placing the legend “CONFIDENTIAL” on each page containing Confidential Material after receiving the production from the non-party or the party who directly receives the production from the non-party; or (ii) identifying in writing, by Bates number, the documents to be treated as Confidential Material. The failure of a non-party to designate a document it produces as Confidential Material shall in no way affect the right of either party to so designate the document.
- b. With respect to deposition transcripts and hearing transcripts, designation of the transcript or a portion of the transcript (including exhibits) that contains Confidential Material shall be made by a statement on the record during the course of the deposition or hearing as to which portion(s) are being designated as Confidential Material. Deposition transcripts and hearing transcripts shall also be provisionally deemed confidential in their entirety, inclusive of exhibits, for a period of thirty (30) days after the

certified transcript is released to the Parties by the court reporter. To retain any designations not otherwise asserted on the record, beyond the provisional period, the Designating Party shall identify which portions of the transcript (by page and line designations) contain Confidential Material before the provisional period of thirty (30) days has expired. Such designations must be made in writing such that counsel and court reporters may append the designation to all copies of the transcripts. The parties may modify this procedure for any deposition or hearing transcript through agreement on the record at such deposition or hearing, or by separate agreement among counsel for the parties, without further court order.

5. **Use at Trial.** Except for trial, Confidential Material shall be used, shown, or disclosed only as provided in this Protective Order. However, nothing in this Protective Order shall limit a Party's use or disclosure of its, his, or her own information designated as Confidential Material. The use of Confidential Information at trial shall not be governed by this Protective Order except that any party to this Litigation may request the Court to preserve the confidentiality of Confidential Material at trial as the Court deems appropriate.

6. **Challenge to Confidentiality Designation.** A Party receiving Discovery Material shall not be obligated to challenge its designation as Confidential Material under this Protective Order at the time the designation is made, and a failure to do so shall not preclude a subsequent challenge thereto. If any party elects to challenge the designation of any Discovery Material as Confidential Material, such party ("Challenging Party") shall do so in good faith and must begin the process through notice provided in writing to counsel for the Designating Party identifying the challenged documents with specificity, including Bates-number where available, and identifying

the basis for each challenge. After receipt of this written notification, the Designating Party will have an opportunity to review the designated material, to reconsider the circumstances, and, if no change in designation is offered, to explain, in writing within fourteen (14) days of receiving such a challenge, the basis of the designation. If that does not resolve the dispute over the designation, then the dispute will be presented to the Court by notice and motion as set forth below. Until the filing of a motion occurs, and during the pendency of any such motion, the designated document or item shall continue to be treated as Confidential Material and subject to the provisions of this Protective Order until determination by the Court as to the confidential status, including as to any appellate remedies, or until the designation is withdrawn by the Designating Party. The burden of proof as to a designation of Confidential Material rests on the Designating Party to establish that such designation is proper and should be deemed Confidential Material.

- a. The Challenging Party must file a Notice of Challenged Information with the Court identifying by Bates number the specific documents being challenged, with a short description of the document and the good faith basis for the challenge to each. The Challenging Party will use its best efforts to consolidate challenges into as few notices as practicable to save resources both for the Parties and the Court.
- b. Within fourteen (14) days of the Notice of Challenged Information, the parties shall file a joint letter Motion to Protect Confidentiality Designation of no more than six (6) pages with supporting authority for their respective positions and shall specify, if any, which documents are no longer being maintained as confidential.

7. Confidential Material, their contents, and any copies thereof shall be maintained and remain confidential by the persons authorized to receive the documents pursuant to Paragraph 8, with the persons agreeing to the terms of this MDL protective order, and shall be used only for prosecuting, defending, or attempting to settle any Exactech medical device case coordinated with this MDL involving a hip or knee, or ankle implant, subject to the limitations set forth herein.

8. Information designated as Confidential Material may be disclosed only to the following qualified persons:

- a. Exactech's in-house attorneys working on this matter, including those working under their supervision and direction;
- b. The parties in this Litigation, including their present officers, directors and employees deemed necessary to aid counsel in the prosecution or defense of this Litigation;
- c. The Parties' counsel of record in this Litigation, and attorneys, paralegals and other support staff employed by such counsel who are assisting in the conduct of this Litigation;
- d. Professional vendors and other persons providing litigation support services to any party to this litigation or its counsel, including translators, photocopying, data processing and hosting, document review, graphic production, jury research, or trial preparation services;
- e. Experts or non-attorney consultants (and employees of such experts or consultants) retained by any party or attorney to assist with the Litigation, provided that no disclosure shall be made to any expert or consultant who

- is a current employee of a competing manufacturer or distributor of orthopedic implants;
- f. The Court, court personnel, including stenographers, and the jury in this Litigation;
  - g. Court reporters or videographers involved in a deposition in this matter;
  - h. Any mediator, settlement master, facilitator or special master and their direct staff agreed upon by the parties;
  - i. Noticed or subpoenaed witnesses (and their counsel) at any deposition or trial in this Litigation but with respect to non-party witnesses, the sharing of confidential documents will be the subject of a future order of this Court.
  - j. Custodians, authors, and recipients of an item designated as “CONFIDENTIAL”;
  - k. In the case of an item designated as “CONFIDENTIAL” by or originating with a non-party, the non-party who produced such Discovery Material;
  - l. Counsel in this coordinated proceeding may share documents marked as “CONFIDENTIAL” with: (1) other counsel in this coordinated proceeding; and (2) with any counsel with cases coordinated with this MDL and who agree to the terms of the MDL protective order and provided counsel have signed the attached Agreement to Maintain Confidentiality;
  - m. Any other persons to whom the Designating Party agrees after meeting and conferring, or to whom the Court specifically allows disclosure after application by the party seeking such disclosure and an opportunity to reply by the Designating Party.

9. Persons identified in Paragraphs 8(d), (e), (g), (h), (i), (j), (k), (l), and (m) above shall not be granted access to Confidential Material, as permitted herein, until such persons have read this Protective Order and agreed to be bound by its provisions by signing the Agreement to Maintain Confidentiality attached hereto as Exhibit A or testifying on the record at a deposition or hearing that they have read and agree to be bound by the terms of this Protective Order. Counsel for the party providing such persons who are required to sign Exhibit A with access to Confidential Material shall be responsible for maintaining copies of the Agreement to Maintain Confidentiality executed by them along with a record of documents provided to each such person(s). Except as to privileged information, the Designating Party may move this Court for disclosure of the names of witnesses to whom Confidential Material was shown, along with a record of documents provided, upon a showing of good cause of a violation of this Protective Order. Each person executing the Agreement to Maintain Confidentiality attached hereto as Exhibit A, submits to the jurisdiction of this Court for the purposes of enforcement of this Protective Order, either prior to or following the completion of this action. Jurisdiction of this action is to be retained by this Court after final determination for purposes of enabling any party or persons affected by this Protective Order to apply to the Court at any time for such direction or further decree as may be appropriate for the construction or enforcement of this Protective Order or for such additional relief as may become appropriate.

10. A party producing documents (“Producing Party”), whether or not such documents contain Confidential Material, may produce documents in this litigation that contain Personally Identifying Information (“PII”) of certain individuals. While a Producing Party may but is not required to redact PII, redacting certain PII may be unduly burdensome, and thus such Party may choose to not redact PII in all documents produced. The parties agree that any PII contained in



documents produced in this litigation shall be treated as containing Confidential Material, pursuant to the terms of this Protective Order and that a failure to redact PII shall not be construed as a waiver by the parties of their position that PII is and will be considered Confidential in this case.

11. All documents filed with the Court that contain any portion of Confidential Material or information taken from any Confidential Material shall be filed under seal by following the protocols for sealing in this Court.

- a. The Party filing the motion containing Confidential Material (hereafter referred to as “underlying motion”) is required to file the confidential information under seal in accordance with the Court’s rules and electronic docketing procedures regarding the sealing of records, including for filing motions for leave to file under seal.
- b. To the extent any Party or other entity challenges whether such information should be treated as confidential or should otherwise be sealed from the public, the Designating Party shall have the burden of justifying that the materials should be sealed.
- c. Except for good cause, the Parties agree not to oppose motions to seal under this Paragraph.

12. The production of documents or information containing Confidential Material that should have been designated as such, but were not when initially produced, shall not be deemed a waiver in whole or in part of the Designating Party’s claims of confidentiality. If a party produces a document without a confidentiality designation as permitted by this Protective Order, such party shall, within fourteen (14) days of the discovery of the disclosure, notify the other parties in writing and provide a replacement production for the document and an overlay with the new confidentiality

designation in the appropriate metadata field. The party receiving such notice shall promptly certify destruction of the improperly designated document, including all copies thereof. The production of such document does not constitute a waiver of any claim of confidentiality unless otherwise ordered by the Court.

13. If a party is served with a subpoena, court order, or administrative agency order issued in other proceedings that compels disclosure of any Confidential Material, that party must promptly notify in writing the Designating Party sufficient to allow the Designating Party to intervene to protect the Confidential Material, unless prohibited by law from doing so. Such notification shall include a copy of the subpoena or order promptly notify in writing the party who caused the subpoena or order to issue in the other proceeding that some or all of the material covered by the subpoena or order is subject to this Protective Order; and cooperate with respect to all reasonable procedures sought to be pursued by the Designating Party whose Confidential Material may be affected. If the Designating Party timely seeks a protective order, the party served with the subpoena or court order shall not produce any Confidential Material before a determination by the court from which the subpoena or order issued, unless the party has obtained the Designating Party's permission. The Designating Party shall bear the burden and expense of seeking protection of its Confidential Material, and nothing in these provisions should be construed as authorizing or encouraging a Receiving Party to disobey a lawful directive from another court.

14. If Confidential Material is disclosed to any person other than in the manner authorized by this Protective Order, the party responsible for the disclosure must immediately bring all pertinent facts relating to such disclosure to the attention of the Designating Party, and without prejudice to the rights and remedies of the Designating Party, make every effort to retrieve

the improperly disclosed material and to prevent further unauthorized disclosure on its own part or on the part of the recipient of such information or material.

15. The production of privileged or work-product protected documents, ESI, or information, whether inadvertent or otherwise, is not a waiver of the privilege or protection from discovery in this case or in any other federal or state proceeding. This Protective Order shall be interpreted to provide the maximum protection allowed by Federal Rule of Evidence 502(d). The provisions of Federal Rule of Evidence 502(b) do not apply. Nothing contained herein is intended to or shall serve to limit a party's right to conduct a review of evidence, ESI, or information (including metadata) for relevance, responsiveness and/or segregation of privileged and/or protected information before production. If the Receiving Party, upon review of the Producing Party's production locates documents or ESI that appear to be privileged or protected from discovery, it shall promptly notify the Producing Party, and it shall segregate such material and not further review or disseminate it, until the Producing Party responds. If a Producing Party produces to a Receiving Party any document, ESI, or information that the Producing Party later determines was subject to a claim of privilege or immunity from discovery (including but not limited to attorney-client privilege, work product protection, and immunities created by federal or state statute or regulation), the Producing Party shall, within thirty (30) days of the discovery of the inadvertent production, give notice to the Receiving Party in writing of the Producing Party's claim of privilege or immunity from discovery. Upon receipt of such notice, the Receiving Party shall immediately (but in no event, not later than five (5) days after receiving such notice) return or destroy the document or ESI at issue and all copies thereof and shall notify the Producing Party of such destruction. If the Receiving Party has any notes or other work product reflecting the contents of the privileged materials, the Receiving Party will not review or use those materials

unless the Court later designates the privileged materials as not privileged or protected. The Receiving Party also must take reasonable steps to retrieve the document or ESI from all to whom it disclosed the document or ESI before being notified of the claim of privilege. Such disclosure shall not be deemed a waiver in whole or in part of the Producing Party's claim of privilege or immunity from discovery either as to specific documents and information disclosed or on the same subject matter. In the event that the Receiving Party disagrees with the Producing Party's claim of privilege or immunity from discovery (for reasons other than the fact that it was produced, which does not provide a basis to challenge the privilege or protection), then the Receiving Party shall notify the Producing Party within five (5) days of receipt of the producing party's written notice of claim of privilege, and shall set forth the precise grounds upon which the Receiving Party's position rests. If the Parties cannot resolve the matter, then the dispute will be presented to the Court by motion or otherwise. Any document or ESI presented to the Court for *in camera* review shall be filed under seal pursuant to the rules and electronic filing procedures of this Court. The disputed document or ESI is considered and treated as privileged unless and until the Court orders otherwise. Nothing in this Protective Order limits or otherwise modifies an attorney's ethical responsibilities with respect to the review or disclosure of privileged information.

16. No provision of this Protective Order shall constitute a concession by any Party that any documents are subject to protection by the attorney-client privilege, the work product doctrine or any other potentially applicable privilege or doctrine. No provision of this Protective Order is intended to waive or limit in any way either Party's right to contest any privilege claims that may be asserted with respect to any of the documents produced except to the extent set forth herein.

17. This Order, insofar as it restricts the communication and use of Confidential Material, shall continue to be binding throughout and after the conclusion of this Litigation, including any appeals.

18. This Protective Order may not be waived, modified, abandoned, or terminated, in whole or part, except by an instrument in writing signed by counsel for Exactech and Co-Lead Counsel for Plaintiffs, or by order of the Court. If any provision of this Protective Order shall be held invalid for any reason whatsoever, the remaining provisions shall not be affected thereby.

19. Within ninety (90) calendar days of the final determination of this Litigation, all Confidential Material, including all hard and electronic copies, derivations, and summaries thereof, shall be destroyed or deleted, with a written certification, to be received no more than one hundred and twenty (120) days after final termination of this Litigation, of such secure destruction or deletion provided to the Designating Party or third party. This includes the secure destruction or deletion of Confidential Material provided to any person, including independent experts. Confidential Material that may exist on any back up media must also be destroyed or deleted within ninety (90) calendar days of the final determination of this Litigation.

- a. For purposes of this provision, the “final determination of this Litigation” shall mean the later of: (a) the date of a jury verdict or bench trial order in the last pending case filed by any particular law firm; (b) the day after an appeal of right is due for filing, if not filed in the last pending case filed by any particular law firm; (c) the day after a settlement in the last pending case file by any particular law firm.

20. For good cause, any Party may seek, by written agreement or motion, relief beyond that which is contemplated in this stipulation.

*--Signature to Follow--*

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***Counsel for Defendants Exactech, Inc. and  
Exactech U.S., Inc.***

**SO ORDERED:**

*Marcia M. Henry*

The Honorable Marcia M. Henry  
United States Magistrate Judge

Dated: January 25, 2023

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.: 1:22-md-03044-NGG-MMH  
MDL No. 3044

**EXHIBIT A - Agreement to Maintain  
Confidentiality**

Judge Nicholas G. Garaufis  
Magistrate Judge Marcia M. Henry

*This Document Applies To:*

*All Cases*

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1. I hereby acknowledge that I will be receiving Confidential Material pursuant to the terms of a Protective Order entered by the Court in the above-referenced litigation.
2. I have been given a copy of, and have read and understand, the Protective Order governing the use of Confidential Material in this litigation and I agree to be bound by the terms and conditions of that Protective Order.
3. I shall not use any document or information marked “CONFIDENTIAL” or other information subject to the Protective Order for any purpose other than this litigation or as permitted by the attached Protective Order or by further order of this Court. I further affirm that I will not reveal or share the Confidential Material to, nor discuss it with, anyone, except in accordance with the terms of the Protective Order or by further order of this Court.
4. I understand unauthorized disclosures of Confidential Material or the substance of Confidential Material may constitute contempt of court.



5. I understand that (a) I am to make no copies of any such Confidential Material except as necessary for exclusive use in the above-captioned MDL, and (b) such Confidential Material and any copies thereof must remain in my custody until I have completed my assigned duties, whereupon the Confidential Material, as well as any copies, summaries, or abstracts of them, and documents related to them, whether in hard copy, electronic, or digital format, are to be returned to counsel who provided me with such Confidential Material.

6. I agree not to disseminate any information derived from such Confidential Material to anyone, or disclose any such information, except for the purposes of the above-captioned litigation or as permitted by the attached Protective Order or by further order of this Court.

7. I agree that my signature below submits me to the jurisdiction of the United States District Court for the Eastern District of New York as necessary to enforce the provisions of this Protective Order and binds me to the provisions of the Protective Order, including to all promises undertaken in the Order, as if originally agreed by me.

Dated \_\_\_\_\_  
Signature \_\_\_\_\_  
Printed Name \_\_\_\_\_  
Address \_\_\_\_\_  
City, State, Zip \_\_\_\_\_  
Telephone \_\_\_\_\_