UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NEW YORK

IN RE: EXACTECH POLYETHYLENE ORTHOPEDIC PRODUCTS LIABILITY LITIGATION	**MDL No. 3044** **Case No. 1:22-md-3044 (NGG) (MMH)**
This Document Applies to All Cases	**PATHOLOGY AND MEDICAL DEVICE PRESERVATION PROTOCOL**

AMENDED CASE MANAGEMENT ORDER NO. 3
PATHOLOGY AND MEDICAL DEVICE PRESERVATION PROTOCOL

I. SCOPE OF THE ORDER

Discovery in this proceeding may involve the collection, storage, preservation, and production of pathology specimens and/or retrieved or explanted medical devices, evidence for which special handling, storage, and preservation procedures may be warranted. Therefore, the Court enters this stipulated pathology and medical device preservation protocol order ("Pathology and Medical Device Preservation Protocol Order" or "Order") in the matters consolidated in MDL 3044.

II. THE ORDER

It is hereby **ORDERED** as follows:

A. Definitions

"Explanted Product" is defined as any Exactech knee, hip, or ankle replacement component, including but not limited to polyethene component, that has been explanted from a Plaintiff in a revision surgery that is the subject of that Plaintiff's claims in this litigation.

"Material" or "Materials" is defined as any Explanted Products or any portion thereof retrieved, explanted, or excised from a Plaintiff, and gross and microscopic specimens, which may contain portions of an Explanted Product, pathology evidence, histology slides, paraffin blocks, and/or stock jars containing tissue, synovial fluid, blood serum, gross material, and/or an Explanted Product.

"Destructive Testing" is defined as any testing or inspection methods that in any way alter the structure, existence, integrity, appearance, or nature of the Materials—including their surfaces—from their explanted condition.

"Facility" is defined to include health care facilities where a Plaintiff underwent a surgery or procedure involving extraction of Materials, and facilities responsible for the preservation and/or maintenance of retrieved, explanted, or excised Materials.

"Non-Destructive Testing" is defined as any testing or inspection methods that will not alter the structure, existence, integrity, appearance, or nature of the Materials—including their surfaces—from their explanted condition.

"Plaintiff" means an individual with a filed lawsuit pending before this Court as part of MDL 3044.

"Plaintiff's Counsel" means a lawyer representing an individual with a filed lawsuit pending before this Court as part of MDL 3044.

"Exactech Defendants' Counsel" means a single lawyer, at a single address, that the Exactech Defendants so designate to receive notice of Plaintiff's preservation efforts consistent with this Order.

B. Intent

It is the intention of the parties that all Materials be preserved in a manner that permits the Parties access to and analysis of the Materials, that Materials will be preserved in a manner to preserve their time-of-explant condition to the extent practicable, that the chain of custody of the Materials will be documented, and that neither Party will alter the Materials in any way prior to reaching an agreement in writing regarding the testing or inspection of the Materials. Only if no such agreement can be reached will the Parties seek the Court's guidance. The Materials remain at all times the property of the Plaintiff.

C. Third-Party Medical Evidence Storage Provider

To further their intent described above, the Parties will utilize third-party medical evidence storage providers to store and facilitate the inspection of the Materials.[1] The Parties will direct the third-party medical evidence storage provider to handle, store, and release the Materials pursuant to the protocol set forth in **Attachment A.** Any departure from this Order, including the protocol set forth in **Attachment A**, by the third-party medical evidence storage provider shall not constitute spoliation of evidence by any of the Parties, provided that proper instructions for the maintenance of the Materials, consistent with this Order, have been provided by the Party providing the Materials to the storage provider.

D. Protocol for Preservation of Materials from Future Procedures

Upon receiving information that a Plaintiff with a filed lawsuit within the scope of MDL 3044 has scheduled a procedure involving extraction of Materials, Plaintiff's Counsel shall send a letter, with a copy to the Exactech Defendants' Counsel, to the Facility where the revision or explant surgery is to occur in the form attached hereto as **Attachment B**, or in a form that is

[1] To the extent that Plaintiff's device and pathology specimens are being maintained, per a substantially similar protocol, by the clinical facility where the revision surgery took place, that will suffice.

substantially similar such that it is sufficient to advise the Facility of the need to collect, preserve, and document the Material as potential evidence in the litigation. Plaintiff's Counsel shall also include with the letter a Chain of Custody form in the form attached hereto as **Attachment C**, or in a form substantially similar such that it provides sufficient information to track the transfer of custody of the Materials, which the Parties shall request that the Facility execute for any Material leaving the possession of the Facility. Additionally, Plaintiff's Counsel shall provide to the Facility a HIPAA-compliant authorization and any other form requiring a Plaintiff's signature for the collection of the Material.

After the letter has been sent to a Facility, Plaintiff's Counsel will pay any costs or fees associated with the preservation and shipment of Materials to an appropriate third-party medical evidence storage provider of Plaintiff's choice. Plaintiffs shall provide the third-party medical evidence storage provider with proper instructions for the maintenance of the Materials, consistent with the protocol in **Attachment A** of this Order.

E. Protocol for Identification and Handling of Materials Currently Available at a Facility

Unless Plaintiff's Counsel has already done so, within thirty (30) days of entry of this Order, Plaintiff's Counsel shall send a letter, with a copy to the Exactech Defendants' Counsel, to any Facility at which Plaintiff's Counsel knows a Plaintiff in this litigation underwent a procedure that potentially involved extraction of Materials, to determine whether the Facility maintains possession of Materials. The letter shall be in the form attached hereto as **Attachment D**, or in a form that is substantially similar such that it is sufficient to advise the Facility of the need to collect, preserve, and document the Material as potential evidence in the Litigation. Plaintiff's Counsel shall also include with the letter a Chain of Custody form in the form attached hereto as **Attachment C**, or in a form substantially similar such that it provides sufficient information to

track the transfer of custody of the Materials, which the Parties shall request that the Facility execute for any Material leaving the possession of the Facility. Additionally, Plaintiff's Counsel shall provide to the Facility a HIPAA-compliant authorization and any other form requiring a Plaintiff's signature for the collection of the Material.

After a letter in the form set forth in **Attachment D** has been sent to a Facility, Plaintiff's Counsel will pay any costs or fees associated with the preservation and shipment of Materials from the Facility to a third-party medical evidence storage provider of Plaintiff's choice. Plaintiffs shall provide the third-party medical evidence storage provider with proper instructions for the maintenance of the Materials, consistent with **Attachment A** of this Order.

F. Protocol for Handling of Currently Available Materials Existing in Possession or Control of the Parties, and Future Obtained Materials

1. Notice of Available Material

If Plaintiffs are already in possession of any Materials as of the date of this Order, that information should be noted in the Plaintiff Preliminary Disclosure, governed by separate order.

Similarly, if the Exactech Defendants are already in possession of any Materials as of the date of this Order, the Exactech Defendants shall notify Plaintiff's Counsel in writing of the existence of the Materials and the present location of the Materials in the Defendant Fact Sheet.

2. Preservation of Materials

Parties agree to utilize reasonable efforts to safeguard the Materials by utilizing appropriate methods – including but not limited to those methods outlined in **Attachment A** – in all aspects of shipping, handling, inspection, and testing to avoid alteration of the Materials in any manner not agreed to herein. Consistent with **Attachment A,** Materials should be handled one at a time at each stage of the handling process to prevent errors in identifying, handling, labeling, or packaging Materials, and standard precautions for handling biological materials should be used when

handling Materials and their innermost packaging. Recognizing that each explant procedure is within the purview and control of non-party medical practitioners and hospitals, any departure from this Order by non-party practitioners and hospitals shall not constitute spoliation of evidence by any of the Parties, provided that proper instructions for the maintenance of the Materials, consistent with **Attachment A** to this Order, have been provided by the Party providing the Materials to the storage provider. Likewise, reasonable compliance with this Order shall not constitute spoliation of evidence. The Parties will not object to retrieval and analysis of Materials that is reasonably consistent with this Order.

3. Shipment of Materials

Upon request of the Plaintiff's Counsel (with copy to the opposing Party), the third-party evidence storage facility described in paragraph C shall release Materials pursuant to the protocol set forth in **Attachment A paragraph 4.**[2] However, the Parties agree that no Destructive Testing will be done by any Party without the written agreement of Exactech and the Plaintiff. Further, to preserve the time-of-explant condition of polyethylene components of the Explanted Products, the time such components are out of the freezer should be minimized to the greatest extent practicable. All release of materials must be documented in the Chain of Custody Form in the form attached hereto as **Attachment C**

G. No Waiver

Nothing herein shall be construed to preclude a Party from challenging the method of preservation of any Materials.

The Court DIRECTS the Clerk to file a copy of this Order in MDL 3044, and it shall apply to all cases that are or become a part of MDL 3044 or are coordinated with MDL 3044.

[2] Upon request of the Exactech Defendants, Plaintiff's counsel shall timely provide authorization to the Third-Party Medical Evidence Storage Provider to authorize release pursuant to this protocol.

DATED: Brooklyn, New York
November 6, 2023

Marcia M. Henry

The Honorable Judge Marcia M. Henry
United States Magistrate Judge

ATTACHMENT A

PROTOCOL FOR HANDLING AND STORAGE OF MATERIALS

IMPORTANT: DO NOT autoclave implant components. Doing so may change the material properties of the components.

1. Unboxing
    a. Universal Precautions should be observed throughout the unboxing process.
        i. Universal Precautions are an approach to infection control to treat all body fluids as if they contain bloodborne pathogens.
        ii. Double gloves, and proper personal protection equipment should be worn at all times when handling biohazard specimens. Although optional, puncture proof gloves are recommended.
        iii. Shared surfaces (e.g., door handles and pens) should never be touched with a gloved biohazard hand.
    b. Separate pathology specimens from the implant device.
        i. Pathology specimens to include histology slides and paraffin blocks might be boxed with an implant but should not be in contact with the implant.
        ii. If pathology specimens are boxed so as to be in contact with an implant, contact counsel for further instructions before proceeding.
        iii. If pathology specimens to include histology slides and paraffin blocks are boxed without being in contact with implant:
            1. Photo-document the "as received" condition of the pathology specimens;
            2. Place the pathology specimens in plastic bag labeled with full name of Plaintiff;
            3. Record the pathology specimens in the Chain of Custody Form.
        iv. If pathology specimens include items other than histology slides and/or paraffin blocks, contact counsel for further instruction before proceeding.

2. Decontamination
    a. Universal Precautions, as outlined above, should be observed throughout the decontamination process.
    b. Remove the implant device from its inner-most packaging.
        i. Properly dispose of the packaging in a biohazard trash bag.
    c. Photo-document the "as received" condition of the implant. For specimens that arrive in 10% diluted formalin, remove the specimens from the formalin, rinse with water, air dry for a day, then pat dry with a microfiber cloth or paper towel.
    d. For specimens that are received dry, submerge the implant components in one of the following solutions:
        i. Formalin for 2 hours
        ii. 10% Bleach Solution for 30 minutes (2x)
        iii. 10% Discide solution for 30 minutes (2x)
    e. Remove the implant components from the solution and allow to air dry overnight, then pat dry with a microfiber cloth or paper towel.
    f. **IMPORTANT: DO NOT** sterilize the implant components in any other manner, as doing so could change the material properties of the components.

3. Storage
    a. Separate the metal from the polyethylene implant components and place them in separate plastic bags.
        i. Ensure the Plaintiff's full name is on each bag.
        ii. Record all device components in the Chain of Custody Form.
    b. Metallic implant components can be stored on the shelf in air in a secure location.
    c. Polyethylene implant components should be stored in at least a -15º C freezer.
        i. Storage in an at least -15º C freezer to preserve the oxidative state of the implant at revision.

4. Release for Inspection

   a. With the consent of the Plaintiff, the Plaintiff's implant and/or pathology specimens can be released and shipped for inspection.

   b. If boxed without being in contact with implant, pathology specimens to include histology slides and paraffin blocks can be released and shipped without being treated as biohazards.

   c. Once the decontamination process described in paragraph 2 above has been completed, all implant components can be released and shipped without being treated as biohazards.

   d. Polyethylene implant components can be released and shipped without remaining frozen, but the date of removal from and return to the freezer should be recorded in the Chain of Custody Form. Time out of the -15º C freezer should be minimized to preserve the time-of-explant oxidative state.

   e. Any release of materials must be recorded in the Chain of Custody Form.

   f. No destructive testing of any materials is permitted without the written consent of Exactech and Plaintiff.

   g. No Materials shall be disposed of—by destructive testing or otherwise—absent a separate written agreement by the Parties or a Court order.

ATTACHMENT B

VERY IMPORTANT—REQUEST FOR PRESERVATION OF PATHOLOGY MATERIALS AND/OR MEDICAL DEVICES FROM UPCOMING PROCEDURE

[Date]

Attn: Departments of Surgery and Pathology
[Address of Retrieval/Explant Facility]

Re: [Case Caption]

Dear Departments of Surgery and Pathology:

I represent the Plaintiff, [Plaintiff's name], and the attorneys copied below represent the Exactech Defendants in the above-referenced lawsuit. There is no litigation pending against your facility or the treating physician in this matter. I write to request the preservation of medical devices and components (including but not limited to polyethylene components) and pathology material including tissue and bone cuts(collectively) ("Materials") from [Plaintiff's name]'s upcoming procedure, scheduled for [date] to be performed by Dr. [Retrieval/Explant Physician].

It is very important that any pathology and medical devices obtained during this upcoming procedure be preserved for future analysis by the parties' respective experts. The parties request that you preserve the Material(s) obtained as follows:

Instructions for Immediate Preservation of the Material(s):

1. Please preserve **all** retrieved or explanted Materials.

2. Medical Devices: **Do not autoclave or sterilize** explanted device components in a manner other than the disinfection techniques noted below, as this could change the material properties of the devices, which are at issue in this litigation. If device components cannot be released without disinfection, the following protocol is acceptable:

   - Submerge the implant components in one of the following solutions:
     - Formalin for 2 hours
     - 10% Bleach Solution for 30 minutes (2x)
     - 10% Discide solution for 30 minutes (2x)
   - Remove components from the solution and allow to air dry overnight.

3. Histology: Please process any pathology specimens according to your usual practice. (For example, preserve in formalin, place into paraffin blocks, and cut slides.)

Instructions for Shipping:

To assist with the preservation, we are working with a third party medical evidence storage facility _____, _____ who will be in touch and ship a collection kit directly to your facility to store and then ship the materials. Please complete the enclosed Chain of Custody form describing the Material(s). Be sure to describe the manner, if any, in which the Materials have been sterilized prior to shipment. Please forward it along with all of the Material(s) to:

[INSERT RECIPIENT]

Instruction for Reimbursement for Costs Incurred

For reimbursement of costs incurred in the collection, preservation, and shipping of the Material(s), please submit an itemized invoice to:

[Counsel for Plaintiff's contact information]

In order to facilitate this request, enclosed please find a HIPAA-compliant authorization for the release of the Material(s), signed by [Plaintiff's name].

Should you have any questions or concerns regarding this matter, please feel free to contact me.

If you are not the appropriate recipient of this request, please notify and forward a copy of this letter to the appropriate person or entity responsible for ensuring compliance with the terms of this request at your earliest convenience. Thank you very much for your assistance. To assist with the preservation, we are working with a third-party medical evidence storage facility _____, _____ who will be in touch and ship a collection kit directly to your facility to store and then ship the materials.

Very truly yours,

[Counsel for Plaintiff]

Enclosures

cc: *Exactech Defendants' Counsel*

ATTACHMENT C

CHAIN OF CUSTODY FORM

Case/Cause No.:

ENTRY NO. 1

RELEASING Party Information:

Person/Facility Name:_____

Person/Facility Address:_____

Description of Materials Being Released:

A. Name of patient/plaintiff from whom Materials were explanted:_____

B. Date of birth of patient:_____

C. General description of Material (including product/catalogue ID number if known and number of components and/or fragments separated from components):

_____

_____

D. Description of disinfection (specify component(s) and disinfection procedure):_____

_____

_____

Full Name of Person Releasing Material:_____

Title:_____

Date Released:_____ Time Released:_____

Released to:_____

Manner in which Released (FedEx, etc.):_____

Tracking or Shipping No.:_____

Signature:_____

RECEIVING Party Information:

Person/Facility Name:_____

Person/Facility Address:_____

Description of Materials Being Received:

A. Name of patient/plaintiff from whom Materials were explanted:_____

B. Date of birth of patient:_____

C. General description of Material (including product/catalogue ID number if known and number of components and/or fragments separated from components):

_____

_____

Full Name of Person Receiving Material:_____

Title:_____

Date Received:_____ Time Received:_____

Material Received from:_____

Manner in which Received (FedEx, etc.):_____

Tracking or Shipping No.:_____

Signature:_____

ENTRY NO. 2

RELEASING Party Information:

Person/Facility Name:_____

Person/Facility Address:_____

Description of Materials Being Released:

A. Name of patient/plaintiff from whom Materials were explanted:_____

B. Date of birth of patient:_____

C. General description of Material (including product/catalogue ID number if known and number of components and/or fragments separated from components):

_____

_____

D. Description of disinfection (specify component(s) and disinfection procedure):_____

_____

_____

Full Name of Person Releasing Material:_____

Title:_____

Date Released:_____ Time Released:_____

Released to:_____

Manner in which Released (FedEx, etc.):_____

Tracking or Shipping No.:_____

Signature:_____

RECEIVING Party Information:

Person/Facility Name:_____

Person/Facility Address:_____

Description of Materials Being Received:

A. Name of patient/plaintiff from whom Materials were explanted:_____

B. Date of birth of patient:_____

C. General description of Material (including product/catalogue ID number if known and number of components and/or fragments separated from components):

_____

_____

Full Name of Person Receiving Material:_____

Title:_____

Date Received:_____ Time Received:_____

Material Received from:_____

Manner in which Received (FedEx, etc.):_____

Tracking or Shipping No.:_____

Signature:_____

ATTACHMENT D

VERY IMPORTANT—REQUEST FOR PRESERVATION OF PATHOLOGY MATERIALS AND/OR MEDICAL DEVICES FROM PREVIOUS PROCEDURE

[Date]

Attn: Departments of Surgery and Pathology
[Address of Retrieval/Explant Facility]

Re: [Case Caption]

Dear Departments of Surgery and Pathology:

I represent the Plaintiff, [Plaintiff's name], and the attorneys copied below represent the Exactech Defendants in the above-referenced lawsuit. There is no litigation pending against your facility or the treating physician in this matter. I write to request the preservation of pathology materials, and/or medical devices (including but not limited to polyethene components) (collectively, "Materials") from [Plaintiff's name]'s previous procedure, which was performed by Dr. [Retrieval/Explant Physician] on [date].

It is very important that any pathology and/or medical devices obtained from this previous procedure be preserved for future analysis by the parties' respective experts. To the extent you have not already done so, the parties request that you preserve the Material(s) obtained as follows:

Instructions for Immediate Preservation of the Material(s):

1. Please preserve **all** retrieved or explanted Materials.

2. Medical Devices: **Do not autoclave or sterilize** explanted device components in a manner other than the disinfection techniques noted below, as this could change the material properties of the devices, which are at issue in this litigation. If device components cannot be released without disinfection, the following protocol is acceptable:

   - Submerge the implant components in one of the following solutions:
     - Formalin for 2 hours
     - 10% Bleach Solution for 30 minutes (2x)
     - 10% Discide solution for 30 minutes (2x)
   - Remove components from the solution and allow to air dry overnight, then pat dry with a microfiber cloth or paper towel.

3. Histology: Please process any pathology specimens according to your usual practice. (For example, preserve in formalin, place into paraffin blocks, and cut slides.)

4. If the Materials have already been preserved in a different manner, please keep the Materials in the manner that they are currently preserved.

Instructions for Shipping:

To assist with the preservation, we are working with a third-party medical evidence storage facility _____, _____ who will be in touch and ship a collection kit directly to your facility to store and then ship the materials. Please complete the enclosed Chain of Custody form describing the Material(s). Be sure to describe the manner, if any, in which the Materials have been sterilized prior to shipment. Please forward it along with all of the Material(s) to:

[INSERT RECIPIENT]

Instruction for Reimbursement for Costs Incurred

For reimbursement of costs incurred in the collection, preservation, and shipping of the Material(s), please submit an itemized invoice to:

[Counsel for Plaintiff's contact information]

In order to facilitate this request, enclosed please find a HIPAA-compliant authorization for the release of the Material(s), signed by [Plaintiff's name].

Should you have any questions or concerns regarding this matter, please feel free to contact me.

If you are not the appropriate recipient of this request, please notify and forward a copy of this letter to the appropriate person or entity responsible for ensuring compliance with the terms of this request at your earliest convenience. If you have any questions, or concerns, please do not hesitate to contact _____ ----at --#. Thank you very much for your assistance.

Very truly yours,

[Counsel for Plaintiff]

Enclosures

cc: *Exactech Defendants' Counsel*