UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF ARKANSAS
CENTRAL DIVISION

IN RE: PROFEMUR HIP IMPLANT	**)**	**MDL NO. 2949**
PRODUCTS LIABILITY LITIGATION	**)**	**ALL CASES**

EXPLANT PRESERVATION AGREEMENT

The following shall govern the handling and preservation of available explanted medical devices that are at issue in any individual case as part of MDL 2949.

1. Scope

This Agreement shall pertain to hip components received by Plaintiffs in this MDL. The term "Explanted Hip System Device" means any preserved hip implant components explanted from Plaintiffs made the subject of their claims against Defendants in this MDL and tissue and fluid samples, if retrieved, during surgery and preserved with the device(s).[1]

2. Physical Evidence

A. Non-Destructive Inspection and Analysis

Non-destructive inspection and analysis by the parties or their designated contract laboratory(ies) or expert(s) of Explanted Hip System Devices are allowed. The "Procedure for the Inspection and Documentation of Explanted Devices and Tissue Samples by Laboratories" ("Inspection Protocol"), contained within Exhibit A hereto, represents a reasonable non-

[1] This Agreement does not address the procedures for processing, dividing and analyzing tissue samples preserved from any surgery at issue. To the extent any party has unprocessed tissue (i.e. tissue blocks), the parties agree to meet and confer on an agreed to protocol for processing and dividing the tissue into slides for microscopic review.

destructive protocol for the inspection of Explanted Hip System Devices. Any inspection of Explanted Hip System Devices which is reasonably consistent with the Inspection Protocol attached as Exhibit A as outlined in Section II therein and this Agreement shall not constitute the spoliation of evidence by any party. However, inspection pursuant to methods or procedures other than those reasonably consistent with Exhibit A, Section II, Inspection Protocol and this Agreement shall not in itself constitute spoliation of evidence, nor be considered evidence of spoliation.

Unless and until otherwise agreed to by all parties in writing, any inspection and analysis of any Explanted Hip System Device shall be non-destructive. Except as permitted in Exhibit A, Section II, Inspection Protocol, the parties will take reasonable measures with their respective contract laboratories, expert(s), and/or designated storage facilities to maintain the Explanted Hip System Devices, including all component parts, in the same condition as they were in when received, including refraining from altering the structure, existence, integrity and nature of the device surfaces as explanted.

Should a party wish to conduct an inspection that potentially may alter the explanted device or components other than as provided in Exhibit A, or deviates materially from the inspection protocol as provided in Exhibit A, Section II, Inspection Protocol, Subsection 12.1, all parties to the specific Plaintiff's case shall be notified of the proposed inspection prior to it taking place. Such notice shall contain a copy of a detailed written Proposed Destructive Inspection Protocol, and state what, if any, changes to the device/components are potentially a result of, or expected as a result of, the inspection. Any objection to this proposed inspection must be made in writing and served on opposing counsel within 7 business days of receipt of the notice. Failure to raise an objection that the proposed inspection should not take place will be deemed a waiver of the

objection. If a party does object to the notice, the parties shall, within 5 business days of receipt of the objection, conduct a meet and confer conference in an attempt to resolve the dispute. If the meet and confer efforts are unsuccessful, the party seeking to conduct the inspection shall notify the Court and request a telephone conference to seek its guidance in resolving the issue before the inspection may occur. On request by any party, the party conducting the inspection shall make arrangements that allows for the in-person or remote attendance at the inspection by representatives and experts of any party(ies) to the specific Plaintiff's case.

B. Explanted Hip System Device Controlled by a Plaintiff

In the event that an Explanted Hip System Device is obtained or controlled by a plaintiff or plaintiff's counsel or that its availability was made known to a Plaintiff or Plaintiff's counsel, the plaintiff shall, within 30 days, provide notice to Defendants, along with information as to the date of the explantation, the present location of the explant, whether tissue, synovial fluid and/or whole blood/serum were retained, an acknowledgement that the explant will be preserved, and that any further inspection and testing shall be in accordance with the provisions of this Agreement.

C. Receipt and Shipment of Explanted Hip System Device

Upon the receipt of an Explanted Hip System Device from any source, the receiving party, its designated contract laboratory(ies), expert(s), or designated storage facility shall photograph each component of the Explanted Hip System Device as received and in a manner which provides a readable photograph of the product identification number or some other unique patient identification number.

However, nothing in this Agreement requires a receiving counsel to open a package containing an Explanted Hip System Device and, in the event counsel elects to re-ship a received package as received, counsel are not required to take any photographs.

When shipping an Explanted Hip System Device, the parties shall send the Explanted Hip System Device by overnight delivery, for delivery on a regular business day, during regular business hours, signature upon receipt required, via any method of shipping that provides location tracking of the shipment.

D. Access for Inspections of Explanted Hip System Devices

For Explanted Hip System Devices obtained from surgeons or hospitals by a Plaintiff, upon request and after initial inspection by a Plaintiff's consultants or laboratories, Defendants have the right, on seven days or more advance notice, at Defendants' expense, to request that the Explanted Hip System Device and tissue, synovial fluid and/or whole blood/serum, if retained and if any remains after a Plaintiff's testing, be sent to a contract laboratory, expert, or counsel of Defendants' choice for further inspection on a designated date or dates.

If a Plaintiff has taken possession of an Explanted Hip System Device and has chosen not to conduct an inspection, Defendants shall have the right to request that the Explanted Hip System Device be sent to requesting Defendants' counsel or to a contract laboratory or expert of Defendants' choice for inspection. Once the inspection is completed, the Explanted Hip System Device shall be sent in the same condition as Defendants received it to a recipient as directed by Plaintiff's counsel. Nothing in this Agreement prevents Defendants from requesting re-examination of an Explanted Hip System Device, including after an initial examination and/or after the Explanted Hip System Device has been returned to a recipient directed by Plaintiff's counsel. Defendants specifically reserve the right to request and inspect the Explanted Hip System Device at any point, and regardless of any prior inspections, in accordance with the applicable deadlines.

PLAINTIFFS' LEADERSHIP COUNSEL

By: */s/ N. Kirkland Pope, Esq.*

Dated: February 16, 2021

By: */s/ George E. McLaughlin, Esq.*

Dated: February 16, 2021

WRIGHT MEDICAL TECHNOLOGY, INC.

By: */s/ Sean K. Burke, Esq.*

Dated: February 16, 2021

MICROPORT ORTHOPEDICS INC.

By: */s/ Julie Y. Park, Esq.*

Dated: February 16, 2021

Exhibit A

SECTION I

Procedure of the Initial Receipt, Photography, and Decontamination of Hip Devices

Procedure of the Initial Receipt, Photography, and Decontamination of Hip Devices and the Initial Receipt and Photography of Tissue Samples, if any.

1. PURPOSE:

The following protocol describes the processes for the initial receipt of the package, photographing of the contents, and decontamination of the retrieved devices.

2. PRECAUTIONS:

2.1 Tracking and maintaining the integrity of the retrieved devices and other package contents is critical.

2.2 Only one package should be handled at a time for each stage of the process to prevent sample mix-up.

2.3 Personnel performing these procedures shall be trained in handling and disposal of infectious substances, chemical handling, and photography.

2.4 Standard precautions for biological materials must be used when handling the retrieved devices, possible tissue samples, and inner-most packaging.

2.5 Although the retrieved devices may be labeled as having been previously decontaminated, the devices may be decontaminated according to this procedure prior to detailed analysis for personnel safety if required.

3. RECEIPT OF PACKAGE BY ANY PARTY:

3.1 Do not open the package until instructed to do so within this procedure.

3.2 Inspect the package for shipping damage.

4. PHOTOGRAPHY OF THE AS-RECEIVED PACKAGE AND CONTENTS:

4.1 Standard precautions for biological materials must be used per local lab procedures.

4.2 Photographs shall include the label with the package's tracking number.

4.3 Photography of the outer packaging shall include:

4.3.1 An overall image of the package;

4.3.2 A readable image of the package's shipping label; and

4.3.3 Any significant damage to the outer package.

4.4 Carefully open the outer package, so as to not damage the contents.

4.5 At each step of unpacking the contents of the package, take photographs of the packing materials and labels.

4.6 Retain all innermost packaging in direct contact with device components and any packaging that includes patient-specific labelling or information. Outer packaging may be discarded. Retained packaging must be kept with the device components.

4.7 Take a readable photograph of the paperwork found inside the package and any other paperwork in the shipping label pouch that was not visible when photographing the outside of the package.

4.8 Inspect the package containing the tissue sample(s), if provided.

4.8.1 Take photographs of the packing materials and labels at each step of opening the contents of the package.

4.8.2 If necessary, transfer the tissue sample(s) to a new, labeled leak-proof container, and if appropriate, add 10% neutral buffered formalin solution until the sample is submerged. Old formalin solution may be disposed of upon transfer of a sample to fresh formalin solution.

4.9 Photography of the as-received retrieved devices should include:

4.9.1 An image of each device with the inner-most packaging in which it was contained;

4.9.2 At least two overall images (opposing views) of all retrieved devices; and

4.9.3 Readable images of each device's identification (laser) markings if they are visible.

4.10 Acetabular cups or femoral stems with attached bone may be allowed to dry after decontamination and do not need to be stored in formalin.

4.11 If appropriate, a label containing either the retrieval number or some other unique patient identification number should be affixed to each new leak-proof container.

4.12 A Chain of Custody record must be maintained. The Chain of Custody record must include the dates the components were received and dispatched, the details of the organization responsible for the custody of the components, and the name of the person responsible for the receipt and dispatch.

4.13 When components are dispatched, the packing process must be documented using the reverse procedure to the unpacking process.

5. DECONTAMINATION OF RETRIEVED DEVICES:

5.1 Decontamination of the retrieved devices may be performed if appropriate before further analysis is conducted.

5.2 A 10% neutral buffered formalin solution may be prepared for decontaminating the retrieved devices. Ensure that the formalin has not surpassed its expiration date. Refer to the manufacturer's material safety datasheet (MSDS) and instructions for safe handling, personal protective equipment, storage, and disposal.

5.3 Retrieved devices must be placed individually into separate containers labeled with the retrieval number or some other unique patient identification number as well as the package's tracking number. Add enough formalin solution to cover the devices. Record information requested on the attached certification.

5.4 The retrieved devices shall soak in the formalin solution for a minimum of 12 hours in a laboratory vented fume hood for the purpose of decontamination.

5.4.1 Once the retrieved devices are removed from soaking, they shall be rinsed with running water for approximately 1 minute and allowed to dry.

5.4.2 Dried decontaminated, retrieved devices should be transferred into individual plastic bags or containers to prevent the devices from contacting each other. The individual bags or containers shall be labeled with the retrieval number or some other unique patient identification number.

5.4.3 Once the decontamination is complete, the Certification of Decontamination and Component Identification (attached) should be completed and signed. A copy of the Certification of Decontamination should be included when shipping components.

6. REFERENCES

6.1 ASTM F561-19, Standard Practice for Retrieval and Analysis of Medical Devices, and Associated Tissues and Fluids

6.2 ISO 12891-1:2015, Retrieval and Analysis of Surgical Implants – Part 1: Retrieval and Handling

6.3 ISO 12891-2:2020, Retrieval and Analysis of Surgical Implants – Part 2: Analysis of Retrieved Surgical Implants

6.4 ASTM E860-07, Standard Practice for Examining and Preparing Items That Are Or May Become Involved In Criminal or Civil Litigation

7. ATTACHMENTS

7.1 Certification of Decontamination and Component Identification

Laboratory Certification of
Decontamination and Component Identification

10% Neutral Buffered Formalin Used: _____

Vendor: _____ Solution Lot#: _____

Expiration Date: _____ Activation Date: _____

Soak Start Date: _____ Soak Start Time: _____ AM/PM

Soak End Date: _____ Soak End Time: _____ AM/PM

Total Soak Time: _____

Minimum soak 12 hours for decontamination.

Retrieval Number or Patient assigned identification number: _____

Package's tracking number: _____

Was a separate tissue sample included? YES [ ] NO [ ]

Tissue Sample Label Information: _____

Record each component's identification (laser) marking information:

Head: _____

Cup: _____

Sleeve Adapter: _____

Stem: _____

Neck: _____

Other components: _____

Other components: _____

These retrieved components have been decontaminated per the procedure specified in this protocol.

Signature of Laboratory Representative:

_____ Date: _____

PRINT NAME & TITLE: _____

SECTION II

Procedure for the Inspection and Documentation of Explanted Devices and Tissue Samples by Laboratories.

PROCEDURE FOR LABORATORY INSPECTION OF HIP AND RELATED COMPONENTS

SUMMARY OF REQUESTED INSPECTIONS AND REQUESTED CAPABILITIES

Requested Capabilities:	
Metal Component Inspection	
Photography of received biohazardous components as received:	
Sealed package as received + each opening step	
Overall view of all components	
Identification markings on all components (if visible)	
Decontamination in 10% buffered formalin (optional)	
Photography of decontaminated components	
Macro and Optical microscopic examination of each component	
Scanning Electron Microscopy (SEM) and Energy Dispersive X-ray Spectroscopy (EDS)	
Metrology (possibly including: Coordinate measurement Machine (CMM), Roundness Machine, Contact and/or Non-Contact Profilometry)	
Other Techniques including MicroCT, X-ray, or Fourier-transform infrared spectroscopy (FTIR)	

8. PURPOSE:

The purpose of this document is to provide a protocol for inspection of Explanted Hip System Devices and related retrieved components at external facilities.

9. SCOPE:

This work instruction applies to received explant components, with stepwise photography of the unpacking procedure.

10. REFERENCES:

10.1 ASTM F561-19, Standard Practice for Retrieval and Analysis of Medical Devices, and Associated Tissues and fluids

10.2 ISO 12891-1:2015, Retrieval and Analysis of Surgical Implants – Part 1: Retrieval and Handling

10.3 ISO 12891-2:2020, Retrieval and Analysis of Surgical Implants – Part 2: Analysis of Retrieved Surgical Implants

10.4 ASTM F3129-16, Standard Guide for Characterization of Material Loss from Conical Taper Junctions in Total Joint Prostheses

10.5 ASTM F2979-14, Standard Guide for Characterization of Wear from the Articulating Surfaces in Retrieved Metal-on-Metal and other Hard-on-Hard Hip Prostheses

10.6 ASTM E860-07, Standard Practice for Examining and Preparing Items That Are Or May Become Involved In Criminal or Civil Litigation

11. MATERIALS:

11.1 Retrieved components

11.2 Digital camera; 8.0 Megapixel minimum, ≥12 Megapixel preferred

11.3 Optical Microscope

11.4 Coordinate Measurement Machine (CMM)

11.5 Non-contact Profilometer

11.6 Roundness Machine

11.7 Scanning electron microscope (SEM) equipped with energy dispersive X-ray spectroscopy (EDS)

11.8 MicroCT/X-ray equipment

11.9 Fourier-transform infrared spectroscope (FTIR)

12. PROCEDURE:

12.1 Except as specifically set forth in this Laboratory Retrieval Inspection Procedure, all handling of implants must be performed non-destructively; this includes all inspection, examination or other actions that may alter the original, as-found nature, state or condition of components.

12.2 Tracking and integrity of the retrieved components is critical. Appropriate segregation and handling procedures shall be performed to prevent the possibility of mixing multiple retrieval cases.

12.3 Destructive testing is defined as "testing, examination, reexamination, disassembly, or other actions likely to alter the original, as-found nature, state or condition of items of evidence so as to preclude or adversely affect additional examination and testing." [ASTM E860-07]

12.4 Examples of destructive testing or examination techniques include cleaning of fracture surfaces or the surfaces of taper junctions, disassembly of components, when two or more components are fixed and attached, hardness testing, coating surfaces of devices, cutting or sectioning of devices, or any process that materially alter the condition of the device.

12.5 Examples of non-destructive testing include decontamination according to the protocol in Section 5, visual inspection, photodocumentation, microscopy, SEM, EDS, profilometry, roundness measurements, CMM measurements, FTIR and CT. Articular surfaces may be wiped with isopropyl alcohol and a cotton ball or swab, or lint-free cloth to remove biological material, dried fluid or water spot artifact that may obscure features of the articular surface.

12.6 Obtain a set of standard detailed photos. Macrophotography of the whole components or groups of components may be performed. Detailed photography may also be performed (only a portion of the component in view within the image).

12.7 Macro and microscopic examination

12.7.1 Macroscopic examination may be performed with the unaided eye or with the aid of an optical microscope. All surfaces of each component should be examined for evidence of in-service, retrieval and/or post-retrieval damage. Detailed microscopy of the devices may also be performed to document condition of the devices.

12.7.2 Additionally, the features of each device may be documented with a scanning electron microscope (SEM). Further analysis of the surface and surface deposits may be performed with energy dispersive X-ray spectroscopy (EDS).

12.8 Metrology

12.8.1 The material loss from the cobalt chromium taper junction surfaces (including head/neck and stem/neck) may be characterized using a CMM or roundness machine as per ASTM F3129-16. The profilometer will touch the surface of the component using a 2 mm (or larger) diameter stylus.

12.8.2 The wear from the articulating surfaces may be characterized using a CMM or roundness machine as per ASTM F2979-14.

12.8.3 Non-contacting profilometry surface roughness may be measured. For the purposes of this protocol, when measuring explanted hip devices, contacting profilometry with a diamond stylus is considered destructive.

12.9 Other Analysis

12.9.1 Radiography or CT analysis may be performed on explanted devices.

12.9.2 FTIR (Fourier-transform infrared spectroscopy) may be performed on explanted devices.

12.10 Destructive Testing

12.10.1 Destructive testing may only be performed after a written protocol has been agreed to by all parties. All parties must be given the opportunity to attend the destructive testing and have the opportunity to inspect the components before and after destructive testing.

12.10.2 At a multi-party inspection, all parties will be permitted to take photographs of the device and its handling/processing as part of the inspection procedures. Audio and video recording will not be permitted, nor will photography of anything not directly related to the subject device or its examination be permitted.

SECTION III

Procedure for the Storage of Retrieved Components and/or Tissue Samples

Procedure for the Storage of Retrieved Components and/or Tissue Samples.

13. PURPOSE:

To describe the storage of retrieved components and/or tissue samples and other package contents received.

14. PRECAUTIONS:

14.1 Tracking and integrity of the retrieved components and other package contents is critical.

14.2 Only personnel trained in handling biological materials and chemical handling shall perform this procedure.

14.3 The retrieved components may have already been decontaminated. If so, a certificate of decontamination must be kept with the components.

14.4 Retain all innermost packaging in direct contact with device components and any packaging that includes patient specific labelling or information. Outer packaging may be discarded. Retained packaging must be kept with the device components.

14.5 Standard precautions for biological materials must be used when handling the possible tissue sample(s).

15. ITEMS TO STORE:

15.1 The following items for each patient should be stored:

15.1.1 The decontaminated retrieved components in their individual containers and inside a larger container, all labeled with either the Retrieval number or some other unique patient identification number;

15.1.2 Copy of Certification of Decontamination, if any;

15.1.3 The tissue sample(s), if any; and

15.1.4 Other possible package contents received, such as medical records, X-rays, shipment paperwork, or other items or papers.

16. STORAGE:

16.1 Storage of retrieved components shall occur in a secured location.