IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND
(Baltimore Division)

IN RE: SMITH & NEPHEW BIRMINGHAM HIP RESURFACING (BHR) HIP IMPLANT PRODUCTS LIABILITY LITIGATION	MDL No. 2775 Master Docket No. 1:17-md-2775 JUDGE CATHERINE C. BLAKE **THIS DOCUMENT RELATES TO ALL ACTIONS**

[redacted] CASE MANAGEMENT ORDER NO. 9
Protocol For Explanted Devices

Plaintiffs and Defendant Smith & Nephew, Inc. (collectively, the "Parties") hereby submit this Stipulated Order regarding the identification, preservation, and handling of explanted devices.

I. DEFINITIONS

The following definitions pertain to this Order:

1. "BHR System" means the Birmingham Hip Resurfacing ("BHR") Femoral Head and the Birmingham Hip Resurfacing Acetabular Cup, and only these components.

2. "THA System" means a BHR component used as part of a total hip replacement construct. Components may include but are not limited to various femoral hip stems, the Smith & Nephew Modular Femoral Head, the Smith & Nephew Modular Head Sleeve Adapter, and the BHR Acetabular Cup (when used in a total hip replacement construct). The parties agree that constructs involving the R3 acetabular shell and metal liner, which were PMA-approved as part of the BHR, should also be considered a "THA System," when used in a total hip replacement construct.

3. "Defendant" means Smith & Nephew, Inc., and any of its officers, directors, and employees in possession of explanted devices from Plaintiffs in this litigation.

4. "Explanted BHR System" means the BHR System, or any component of the BHR System, explanted from a Plaintiff in this litigation, and tissue, fluid, and/or whole blood/serum samples, if any, that were retrieved during the explant surgery.

5. "Explanted THA System" means the THA System, or any component of the THA System, explanted from a Plaintiff in this litigation, and tissue, fluid, and/or whole blood/serum samples, if any, that were retrieved during the explant surgery.

6. "Explanted System" means Explanted BHR System and/or Explanted THA System.

7. "BHR Plaintiff" means a named plaintiff with a matter involving a BHR System that is currently pending in MDL No. 2775 or will be filed in, removed to, or transferred to MDL No. 2775.

8. "THA Plaintiff" means a named plaintiff with a matter involving a THA System that is currently pending in MDL No. 2775 or will be filed in, removed to, or transferred to MDL No. 2775.

9. "Non-Destructive Explant Inspection, Testing, or Analysis" refers to any analysis, inspection, preparation, or any other handling of an Explanted System that maintains and does not alter the as-received nature, state, and/or condition of the Explanted System.

10. "Destructive Explant Testing or Analysis" refers to any analysis, inspection, preparation, or any other handling of an Explanted System that alters or has the significant potential to alter the as-received nature, state, and/or condition of the Explanted System. Examples of Destructive Analysis include but are not limited to:

- Cutting or sectioning any component of the Explanted System;
- Removal of biological tissue that is affixed to any component of the Explanted System;
- Separation of a Smith & Nephew Modular Head Sleeve Adapter from a Smith & Nephew Modular Femoral Head into which it is seated;
- Separation of a R3 metal liner from an R3 acetabular shell into which it is seated;
- Any cleaning whatsoever of the taper surfaces of any components, including the taper surfaces between:
    - The R3 metal liner and R3 acetabular shell;
    - The femoral stem and the Modular Head Sleeve Adaptor;
    - The Modular Head Sleeve Adapter and the Modular Femoral Head;
- Application of any preparation, treatment, powder or coating to any component of the Explanted System that may be required to perform additional analysis and cannot be completely removed under the permissible cleaning methods described in Section VI.F below; and
- Any analysis of tissue, fluid, whole blood, and/or serum samples that results in the consumption or destruction of any portion of the sample.

II. PRESERVATION OF EXPLANTED SYSTEMS

A. Plaintiffs shall make good faith efforts, including with non-party medical practitioners and hospitals, to preserve any Explanted System within their possession, custody, or control. To the extent that non-party medical practitioners and hospitals have preserved tissue, fluid, whole blood, and/or serum samples – in addition to the BHR or THA System components themselves – Plaintiffs shall make good faith efforts to have those samples preserved as well. Ideally, all separate tissue samples and components with affixed tissue or bone will be immediately rinsed in 0.9% saline and then placed in 10% neutral buffered formalin at the time of the revision surgery. Plaintiffs shall request that Explanted Systems with affixed tissue or bone and any separate tissue samples be preserved in this way, but the Parties recognize that Plaintiffs cannot compel non-party medical practitioners and hospitals to comply with the request, and that non-party medical practitioners and hospitals may have their own internal procedures for the handling and preservation of explanted components, tissue, and other samples.

Plaintiffs also shall request that such non-parties in possession of any Explanted System comply with guidelines for Shipping and Handling set forth in Section IV below.

B. Defendant also shall make good faith efforts to preserve any Explanted System identified pursuant to Section III below, that is presently in its possession or custody.

C. The procedures set forth in this protocol represent one reasonable protocol for retrieval, handling, and packaging of Explanted System devices; the collection of clinical history of the Plaintiff and the device; collection of tissue and fluid samples near the device; photographic record of the device and tissues; containing, labeling, cleaning, decontaminating, packaging, and shipping of retrieved implant, tissue, or fluid samples; analysis of tissue and fluids; and analysis of retrieved components. Following the entry of this Order, the Parties and their testifying and consulting experts shall comply with this protocol and Order. Reasonable compliance with this protocol and with this Order by the Parties and their testifying and consulting experts shall not constitute spoliation of evidence. Noncompliance with this protocol and with this Order by non-party medical practitioners and hospitals shall not be attributed to any Party, nor shall it constitute spoliation of evidence, provided the Parties have complied with the requirements set forth herein.

D. To the extent that – and only to the extent that – either Party or their testifying or consulting experts were in possession of a Plaintiff's Explanted System prior to the entry of this Order, the Parties will not object to prior retrieval and analysis of an Explanted System that is either reasonably consistent with this protocol or that was performed under another retrieval analysis protocol that is non-destructive and consistent with methods and practices accepted by those in the field of the inspection and testing of orthopedic devices. This provision, however, only applies to actions before the entry of this Order.

E. When individual circumstances so warrant, by mutual prior consent, the Parties may adopt an alternative, written retrieval analysis protocol to better accommodate the shipping, handling, inspection, and analysis of any Explanted System with unique circumstances.

F. The protocol in this CMO applies to Explanted Systems from individuals who are Plaintiffs in cases pending in MDL No. 2775 as of the date of this Order. The protocol also applies to any individual whose case is filed in, removed to, or transferred to MDL No. 2775 after entry of this Order, as of the date of filing, removal, or transfer. However, the Parties may not circumvent the obligations set forth in this protocol and Order by delaying the filing, removal, or transfer of a lawsuit until an explant inspection and analysis has been performed in a manner contrary to this protocol and Order.

III. IDENTIFICATION OF EXPLANTED SYSTEMS

A. Any BHR Plaintiff who has an Explanted BHR System in his or her possession, custody, or control shall provide information as to the explanting surgeon, date of explantation, location of the Explanted BHR System, and other requested information regarding the Explanted BHR System to Defendant pursuant to the procedures, time periods, and Plaintiff Fact Sheet ("PFS") form in Case Management Order 8 for Plaintiff Fact Sheets in BHR Track Cases.

B. Any BHR Plaintiff who does not know the location of the Explanted BHR System or whether it was preserved following explant, must inquire with the applicable healthcare provider(s) and/or medical facility(ies) about the location of the explanted device and disclose details about the inquiry and any response, as well as provide a copy of any written inquiry and responses, pursuant to the procedures, time periods, and PFS form in Case Management Order 8 for Plaintiff Fact Sheets in BHR Track Cases. Thereafter, if the Explanted BHR System is in the possession of Defendant, or has been in the possession of Defendant at any time, Defendant shall

notify Plaintiffs' Lead Counsel via the Defendant Fact Sheet ("DFS") process.

C. Any THA Plaintiff who has an Explanted THA System in his or her possession, custody, or control shall provide information as to the explanting surgeon, date of explantation, location of the Explanted THA System, and other requested information regarding the Explanted THA System to Defendant pursuant to the procedures, time periods, and PFS form to be subsequently determined by the parties and entered by the Court in a Case Management Order for Plaintiff Fact Sheets in THA Track Cases.

D. Any THA Plaintiff who does not know the location of the Explanted THA System or whether it was preserved following explant, must inquire with the applicable healthcare provider(s) and/or medical facility(ies) about the location of the explanted device and disclose details about the inquiry and any response, as well as provide a copy of any written inquiry and responses, pursuant to the procedures, time periods, and PFS form to be subsequently determined by the parties and entered by the Court in a Case Management Order for Plaintiff Fact Sheets in THA Track Cases. If the Explanted THA System is in the possession of Defendant, or has been in the possession of Defendant at any time, Defendant shall notify Plaintiffs' Lead Counsel via the DFS process for THA Track Cases to be subsequently determined by the parties and entered by the Court.

E. Any Plaintiff who has a BHR or THA explant surgery subsequent to the date of his or her PFS submission must supplement his or her PFS with information about the explant procedure, including location of the Explanted System or inquiry about the location if the location is unknown and other applicable information, within thirty (30) days from the date of the procedure.

F. The deadline for submitting a PFS in either a BHR or THA Track Case in no way alters or extends the requirement to preserve Explanted Systems as of the date of this Order, or as of the date of filing, removal, or transfer to this MDL for cases not currently pending in MDL 2775.

IV. SHIPPING AND HANDLING OF EXPLANTED SYSTEMS

The Parties acknowledge the importance of proper shipping and handling of an Explanted System to prevent any damage to or alteration of the nature, state, and/or condition of the System. To that end, the Parties shall use the following procedures:

A. Nothing in this protocol and Order shall be interpreted to require the Parties or their counsel to open any inner, sealed packaging containing an Explanted System. Nor shall this protocol and Order be interpreted to require that any Party or their counsel inspect and repackage any Explanted System that has been received from a non-party medical practitioner or hospital. Preserving and maintaining an Explanted System in the same packaging and condition that it was in upon receipt from a non-party medical practitioner or hospital shall not constitute evidence of spoliation. However, the Parties and their respective consulting and testifying experts are obligated to comply with the following procedures in the event that they open the inner, sealed packaging of an Explanted System that has been received. They shall also request that non-party medical practitioners and hospitals do the same.

B. All components of the Explanted System shall be individually packaged with padded packaging as needed to avoid contact or damage to the Explanted System during shipping and handling.

C. Shipping shall occur by any method of shipping that provides location tracking of the shipment.

D. Upon inspection by a Party's testifying or consulting expert, if the Explanted System has not been decontaminated, the inspection shall immediately stop, and the Parties shall confer regarding the development of a mutually agreeable protocol for further shipping, handling, and analysis of that specific Explanted System. In the event that decontamination already has taken place, the following procedures apply.

E. In the event that separate tissue specimens exist, or in the event that bone is attached to the explanted femoral component(s) of an Explanted System, upon inspection by a Party's testifying or consulting expert, the System shall be fixed using 10% neutral buffered formalin and/or ethanol and/or other fixative before further analysis is performed.

F. Any component with affixed tissue or separate tissue that has been fixed as described in subparagraph E above, as well as any fluid, whole blood, and/or serum shall be placed in sterile, leak-proof containers and shipped in accordance with all applicable laws, rules, and regulations. ASTM F2995 - 13 Standard Guide for Shipping Possibly Infectious Materials, Tissues, and Fluids offers guidance on safe shipping of biological materials.

G. Any testifying or consulting expert receiving or in possession of an Explanted System shall photo-document the as-received condition of the Explanted System before any inspection, testing, or analysis is performed. As described in subparagraph A above, Counsel for the Parties are not subject to this requirement so long as Counsel does not open the inner, sealed packaging that contains the Explanted System.

H. Photo-documentation shall include:

1. Use of a digital camera with a minimum resolution of 8.0 megapixels. An SLR digital camera with resolution of greater than or equal to 12.0 megapixels is preferred. The photographs shall be date and time stamped, either visibly on the image itself or in the name of

the digital file. Alternatively, the unpackaging process may be recorded by video provided that a camera with an equal or greater resolution is used.

2. The outer packaging of the Explanted System shall be photographed to document its condition and damage, if present. Photography of the outer packaging shall include an overall image of the package, a readable image of the package's air waybill, tracking number, and any damage to the outer package.

3. At each step of unpacking the contents of the package, the packing materials and labels shall be photographed, including any labels with unique patient identification numbers.

4. A readable photograph shall be taken of any paperwork inside the package and any paperwork in the air waybill that was not visible when photographing the outside of the package. If either party has any reason to suspect a discrepancy between the components enclosed in the package and the components explanted from the Plaintiff, that party shall immediately cease analysis and notify the opposing party.

5. If provided, any package containing a tissue, fluid, and/or whole blood/serum sample shall be inspected and photographed to document its condition and damage, if present. Again, the packing materials and labels shall be photographed at each step of opening the package contents as outlined in subparagraphs H.2, H.3, and H.4 above. If no analysis is being undertaken of the tissue, fluid, and/or whole blood/serum samples, it is not necessary to open the packages for photo-documentation purposes.

6. Upon final unpacking of the Explanted System by a testifying or consulting expert, each component shall be photographed to document its condition and damage, if present. Photography of the as-received components shall include the following:

a) An image of each component with the innermost packaging in which it was contained;

b) At least two overall images (opposing views) of all components together, on a plain background, with a scale to indicate size;

c) At least two overall images (opposing views) of each individual component, on a plain background, with a scale to indicate size;

d) Images of the bearing surface of each individual component;

e) Images of the visible surfaces of each taper interface, including, to the extent applicable, both femoral interfaces (i.e., femoral stem/modular head sleeve adapter interface and modular head sleeve adapter/modular femoral head interface) and the acetabular interface (e.g., R3 metal liner/R3 acetabular shell interface);[1]

f) Images of all non-articulating surfaces of each individual component; and

g) Readable images of each component's identification (laser) markings if visible.

I. All package materials shall be retained during and after the unpacking process.

J. Counsel for the Parties have a duty to maintain complete and accurate internal documentation of the current location and custodian of an Explanted System while under their control, whether it be in possession of Counsel or experts or consultants retained by the Parties. All such documentation shall be considered attorney work-product and not subject to production absent the required showing under the Federal Rules of Civil Procedure. Moreover, if produced, such documentation shall be redacted to remove any names or identifying information of non-testifying consultants and/or potential testifying experts whom have not already been disclosed in the litigation.

[1] This does not require that components seated into one another be separated. Rather, this requirement only applies to the extent that the taper surfaces are visible without separating components from one another. As previously described in Section I.10, separating components from one another that are seated is defined as Destructive Explant Testing or Analysis and is not allowed under this protocol without prior written consent of the parties or an Order from the Court. *See* Section VII.A.

V. ACCESS TO EXPLANTED SYSTEMS

Defendant has the right to obtain an Explanted System promptly after the completion of any Non-Destructive Explant Inspection, Testing, or Analysis by Plaintiff and before any Destructive Explant Testing or Analysis is proposed. Plaintiff shall make reasonable efforts to assure that such Non-Destructive Explant Inspection, Testing, or Analysis is completed within a reasonable amount of time. Upon written request by Defendant to the Plaintiff's individual counsel of record and Plaintiffs' Lead Counsel, Plaintiff shall send the Explanted System to Defendant as set forth in Section IV regarding the Shipping and Handling of Explanted Systems.

VI. NON-DESTRUCTIVE EXPLANT INSPECTION, TESTING, OR ANALYSIS

A. Testing and analysis, whether Non-Destructive or Destructive, on a non-decontaminated Explanted System shall not occur absent an agreement of the Parties or an Order by the Court.

B. Absent consent of all Parties or a governing order by the Court, all Non-Destructive Explant Inspection, Testing, or Analysis of Explanted Systems must be in accordance with a documented and identifiable retrieval analysis protocol that is non-destructive and consistent with this Order.

C. If there is any question as to whether a particular form of testing or analysis is Destructive or Non-Destructive, the Party seeking to perform the testing shall advise the opposing party of the proposed testing. Such testing then shall not occur absent the consent of the opposing party or by Order of the Court.

D. To the extent that the Explanted System components were decontaminated and fixed in 10% neutral buffered formalin or other fixative prior to receipt, upon inspection by a testifying or consulting expert, the Party whose expert is inspecting the Explanted System shall

notify the opposing party of that fact, and the expert shall perform any Non-Destructive Explant Inspection, Testing, or Analysis in a manner to minimize the time that the components are outside the formalin to prevent potential damage to adherent tissue.

E. After unpacking, the Explanted System components shall be appropriately segregated and handled to prevent the possibility of mixing components from different patients or Plaintiffs during analysis.

F. An Explanted System may only be cleaned by wiping the bearing or articular surfaces with isopropyl alcohol and a cotton ball, cotton swab, soft bristled brush (e.g., a toothbrush), and/or lint-free cloth to remove dried fluid, artifact, or other substances that may obscure features of the bearing or articular surfaces. Such cleaning may not be used on any porous-coated surfaces, on any adherent biological material, or on any of the taper surfaces described in Section I.10. Any other form of cleaning shall be considered destructive testing and governed by the provisions of the following section entitled "Destructive Explant Testing or Analysis."

G. All preparation of an Explanted System for inspection, testing or analysis must be performed Non-Destructively. Any substance placed on the Explanted System in preparation for analysis must be capable of being removed by the cleaning procedures set forth in the preceding Subparagraph.

H. The results of the any Non-Destructive Explant Inspection, Testing, or Analysis shall not be discoverable unless performed or relied upon by a testifying expert, as set forth in the Federal Rules of Civil Procedure. Nothing in this Order is intended to alter the requirements or rules relating to expert disclosures contained in the Federal Rule of Civil Procedure 26.

VII. DESTRUCTIVE EXPLANT TESTING OR ANALYSIS

A. Destructive testing on any Plaintiff's Explanted System is prohibited without prior written consent of the Parties or by Order of this Court.

B. Any Plaintiff intending to perform Destructive Explant Testing or Analysis on his or her Explanted System shall provide written notice of said intention and a detailed destructive testing protocol to Defendant's Lead Counsel by email to bhr-mdl-ppd@irwinllc.com. If Defendant intends to perform Destructive Testing or Analysis on a Plaintiff's Explanted System, it shall provide written notice of said intention and a detailed destructive testing protocol to Plaintiff's individual counsel of record and Plaintiffs' Lead Counsel by email to bhr@jonesward.com. Any party receiving such written notice shall promptly confirm receipt of the notice.

C. If the party seeking destructive testing does not receive any objection to the destructive analysis within 30 days of the receiving party's confirmation of receipt of the initial notice, that party may proceed with the destructive testing.

D. If Destructive Explant Testing or Analysis occurs pursuant to subparagraph C above or otherwise permitted (including by prior written consent of the parties or order of this Court), the party performing the Destructive Explant Testing or Analysis must provide written notice to counsel of the opposing party (at the email addresses indicated in subparagraph B) indicating the date, time, and location of the testing or analysis. The party performing the Destructive Explant Testing or Analysis shall allow the opposing party, counsel, and their experts and consultants to attend the destructive portions of the testing, and must allow the opposing party access to all remnants of the Explanted System after the Destructive Explant Testing or Analysis is completed.

E. In the event of any disagreement between the parties regarding whether particular testing is Destructive or Non-Destructive, the testing shall not proceed until the dispute is resolved by the Court.

VIII. CONCLUSION

Nothing in this Order shall be construed to alter the applicable rules and procedures governing the disclosure of expert witnesses, the scope of permissible discovery of communications and file materials of both testifying experts and non-testifying consultants, and/or the admissibility of evidence at trial as set forth in the Federal Rules of Civil Procedure and Federal Rules of Evidence.

IT IS SO ORDERED, this 17th day of July 2018.

CCB

HON. CATHERINE C. BLAKE
UNITED STATES DISTRICT JUDGE