UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF INDIANA
SOUTH BEND DIVISION

IN RE: BIOMET M2a MAGNUM HIP IMPLANT PRODUCTS LIABILITY LITIGATION (MDL 2391)	)	CAUSE NO. 3:12-md-2391
This Document Relates to All Cases	)	

EXPLANT PRESERVATION ORDER

The court ORDERS, effective immediately, that defendants and plaintiffs (collectively, the "Parties") shall comply with the following directives relating to the preservation of explanted metal-on-metal hip prostheses in the above-captioned case. This order does not address or resolve issues relating to admissibility under FED. R. EVID. 702, or any other state or federal rules of evidence or procedure.

I. DEFINITIONS

A. Biomet Devices Subject to this Order

The provisions of this order shall pertain to the following:

1. "M^2a Device" means the following Biomet M^2a Hip System Device and components marketed and sold by defendants to plaintiffs in the United States: M^2a Magnum and M^2a 38.

2. "Explanted M^2a Device" means the M^2a Device explanted from a plaintiff in this litigation, and tissue samples, if any, that were retrieved during the explant surgery.

II. RETRIEVAL ANALYSIS PROTOCOL

Pursuant to Section 522 of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360*l*, Biomet is required by the Food and Drug Administration ("FDA") to conduct post-market surveillance on the M^2a Devices at issue in this litigation ("Section 522 Postmarket Surveillance"). "Biomet's Retrieval Analysis Protocol," attached hereto as Exhibit A, represents a reasonable protocol (though not necessarily the only reasonable protocol) designed to enable preservation and analysis of Explanted M^2a Devices and surrounding tissues.

Any initial inspection and analysis shall be non-destructive except to the extent Biomet might be required to conduct destructive testing under the Biomet Retrieval Analysis Protocol set forth in Exhibit A. Neither party will conduct destructive testing on an Explanted M^2a Device without prior written consent of the other party or by order of this court. A party intending on

performing destructive testing shall provide written notice of said intention to the opposing counsel set forth in Paragraph VIII herein and to the opposing party's Lead MDL Counsel. If the party seeking destructive testing does not receive any objection to said destructive analysis within 30 days of issuing the initial notice in writing, that party may proceed. Any disagreement between the parties regarding destructive testing shall be resolved by the court.

Reasonable compliance with Biomet's Retrieval Analysis Protocol, or 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 orthopaedic devices, and with this Order shall not constitute spoliation of evidence.

III. OBTAINING EXPLANTED M^{2}a DEVICES

A. M^{2}a Devices that have not been explanted or are not in either party's possession

With respect to M^{2}a Devices that have not yet been explanted or have been explanted but are not in either party's possession, counsel for a plaintiff may elect to obtain plaintiff's Explanted M^{2}a Device from plaintiff's surgeon or the hospital where the surgery occurred and send it to a contract laboratory of plaintiff's choice or a designated storage facility. If plaintiff's counsel does not elect to obtain an Explanted M^{2}a Device within 60 days of the revision surgery, Biomet will make arrangements for it to be sent to Malcolm Naylor of Biomet in Warsaw, Indiana.

The party that obtains the Explanted M^{2}a Device shall comply with the requirement that the explant shall be preserved in accordance with either Biomet's Retrieval Analysis Protocol or another retrieval analysis protocol used by an individual or institution in the field of orthopaedic device retrieval and analysis that uses a non-destructive method of explant retrieval and analysis.

The Parties shall take reasonable measures to ensure that their respective contract laboratories and/or designated storage facilities maintain the Explanted M^{2}a Devices, including all component parts, in the same condition as they were in when received, which includes refraining from altering the structure, existence, integrity, and nature of the device surfaces as explanted.

B. Explanted M^{2}a Devices in a Party's Possession

With respect to Explanted M^{2}a Devices that were obtained by either party prior to the entry date of this Order:

1. A party that has an Explanted M^{2}a Device in its possession shall provide notice to the other party, including information as to the corresponding plaintiff's name and surgeon, date of explantation, location of explant, and whether synovial fluid and/or whole blood/serum was retained.

2. To the extent that plaintiff's counsel has a reasonable belief that Biomet, directly or indirectly through an independent distributor or associated third party, retrieved a plaintiff's Explanted M^2a Device after removal, plaintiff's counsel may send a written request to Biomet for information relating to the location and condition of said removed device components and any related pathology or specimens. Biomet shall undertake a reasonable search for the location of such plaintiff's Explanted M^2a Device and shall make good faith efforts to ensure the same is preserved consistent with this order including, refraining from destructive testing without notice and the opportunity to object.

3. If a party inspected or tested an Explanted M^2a Device that was obtained prior to the entry of this Order, the results of such inspection and testing shall be provided to the other party pursuant to this Order or the Parties' mutual agreement.

C. Access to Explanted M^2a Devices

A party has the right to obtain an Explanted M^2a Device after the completion of inspection and testing by the other party's contract laboratory(s) or expert(s). Each party shall make reasonable efforts to assure that its testing is completed within a reasonable amount of time. Upon written request and at the expense of the requesting party, after the completion of the inspection and testing of the Explanted M^2a Device, the party in possession of the Explanted M^2a Device shall send the device to the requesting party. Handling and packaging of the Explanted M^2a Device by the plaintiff shall be performed either in accordance with Biomet's Retrieval Analysis Protocol or in accordance with 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 orthopaedic devices.

IV. RETRIEVAL AND ANALYSIS OF EXPLANTED M^2a DEVICES

The procedures set forth in Biomet's Retrieval Analysis Protocol represent one reasonable protocol for (1) retrieval, handling, and packaging of Explanted M^2a Devices; (2) the collection of clinical history of the plaintiff and the M^2a Device; (3) collection of tissue and fluid samples near the M^2a Device; (4) photographic record of the Explanted M^2a Device and tissues; (5) containing, labeling, cleaning, decontaminating, packaging, and shipping of retrieved implant, tissue, or fluid samples; (6) analysis of tissue and fluids; and (7) analysis of retrieved components.

The Parties will not object to retrieval and analysis of an Explanted M^2a Device that is either reasonably consistent with Biomet's Retrieval Analysis Protocol or 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 orthopaedic devices and with this Order.

V. INSPECTION RESULTS

The Parties shall exchange all inspection and analysis results including data, photographs, and other information generated as a result of the retrieval and analysis of the Explanted M^2a Devices conducted pursuant to the Case Management Order of this court and this Order. The agreement to exchange the results of inspection and analysis does not require the exchange of drafts, privileged communications, or facts or opinions of a consulting expert employed for trial preparation.

VI. COMPLIANCE

A plaintiff shall make good faith efforts to ensure that non-party medical practitioners, hospitals, and vendors engaged to facilitate device preservation preserve his or her Explanted M^2a Devices that may be relevant to the claims, defenses, or subject matter of his or her case consistent with this order. The defendants will not take steps that interfere with requests by or on behalf of a plaintiff to have the plaintiff's surgeon and/or hospital retain and preserve any Explanted M^2a Device(s), tissue, or any other physical evidence.

The Parties agree that they will not promote or encourage third parties, including, but not limited to, physicians and hospital personnel, to act in a way that is inconsistent with this Order.

VII. PROTOCOLS SHALL NOT BE BINDING

Neither party's protocols for the retrieval, transport, storage, inspection, and testing of the M^2a Devices shall be binding on the other party. As long as either party's protocols or practices for the retrieval, transport, storage, inspection, and testing of M^2a Devices are non-destructive and consistent with methods and practices accepted by those in the field of the inspection and testing of orthopaedic devices, that party shall be deemed to be in compliance with this Order and those actions shall not constitute spoliation of evidence.

VIII. COURT OVERSIGHT

The process of obtaining Explanted Biomet M^2a Devices from surgeons and hospitals and sending them to contract laboratories for inspection and testing is likely to involve complications that the Parties and this court have not anticipated. To assist in the resolution of potential complications, the court shall remain actively involved in this process, and the Parties shall keep the court apprised, in writing, of encountered complications. In the event a dispute arises between a surgeon or hospital and a party or a party's counsel regarding an Explanted M^2a Device, the party's counsel shall seek relief in this court, and this court will intervene, consistent with the Federal Rules of Civil Procedure, to resolve the dispute. To facilitate the court's involvement in resolving any complications arising from this Order, the court designates Plaintiff's Executive Committee Member

Douglass A. Kreis of Aylstock, Witkin, Kreis & Overholtz, PLLC, and Defendants' Liaison Counsel John LaDue of LaDue Curran & Keuhn LLC as the contact persons who will field any questions and bring to the court those issues requiring court involvement.

SO ORDERED.

ENTERED: March 7, 2013

/s/ Robert L. Miller, Jr.
Judge, United States District Court
Northern District of Indiana