IN THE UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF TEXAS
DALLAS DIVISION

IN RE: DEPUY ORTHOPAEDICS,	§	
INC. PINNACLE HIP IMPLANT	§	MDL Docket No.
PRODUCTS LIABILITY LITIGATION	§	
	§	3:11-MD-2244-K
	§	
--	§	
This Document Relates to all Cases	§	
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AGREED ORDER GRANTING LEAVE OF COURT TO CONDUCT TRANSMISSION ELECTRON MICROSCOPY/ FOCUSED ION BEAM EXAMINATION

In addition to the inspection and analysis permitted pursuant to Case Management Order No. 9, entered Jan. 23, 2013, the Court hereby grants leave for the Plaintiffs' Executive Committee (or their designees) and the Defendants (or their designees) to conduct examination and testing of the explanted components of potential bellwether plaintiffs Michael Hodges, Jean Garvin, Gerald Jones, Toni Lay, Edward McKee, Carol Mello, Kathy Paoli, and Byron Rowe, in accordance with the protocol attached hereto as Exhibit A.

SO ORDERED.

Signed on September 20th, 2013.

ED KINKEADE
UNITED STATES DISTRICT JUDGE

<u>**EXHIBIT A**</u>

Protocol for Focused Ion Beam (FIB) Microscopy and Sample Preparation for Transmission Electron Microscopy

A microscopic piece of material may be removed from the worn areas of the surface region of the femoral heads and acetabular liners in order to perform high-resolution Transmission Electron Microscopy (TEM) of these surfaces. The technique used to prepare these TEM samples is termed Focused Ion Beam (FIB) milling. In FIB milling a "slice" of material approximately 0.6 thousandths of an inch (15 μm) in width and depth and approximately 4 millionths of an inch (100 nm) in thickness is lifted from the surface. This microscopic slice of material is carefully prepared and handled within a Scanning Electron Microscope that is equipped with a focused ion beam. This ion beam knocks atoms off of the surface of the metal forming a "trench" on both sides of the TEM "slice", which enables the slice to be freed from the surface and "lifted" out of the metal component. The total area of the trenches is approximately 0.7 millionths of a square inch (about 450 um2) and is invisible to the naked eye (a relatively high magnification optical microscope approximately 400x to 1,000x would be needed to optically examine the trench).

Samples may be prepared from any of the components removed from the plaintiffs identified in the Order to which this protocol is appended, including the femoral heads, acetabular liners, and acetabular shells. The specific components from which samples are prepared will be identified, including the plaintiff's name, which component, which side, and any part or lot number on the component.

Components will be wiped dry with a lint free laboratory wipe, and placed into a Scanning Electron Microscope with a Focused Ion Beam (SEM-FIB). The component will be imaged under non-destructive electron microscopy and a region of interest will be determined during this examination. Once a region of interest is determined, the exact area will be documented through images recorded at increasing magnifications so that the exact location of the sample can be determined. A TEM sample will be prepared from this location using FIB milling.

The TEM "slicing" or sample preparation will be done using standard, validated automated processes, such as those which have been developed by reputable microscope manufacturers. The specific equipment and automated processes used will be identified. The entire process must take place within a Scanning Electron Microscope following the specific steps listed below:

a) Platinum Deposition: A thin protective layer of platinum is deposited directly over the site of interest.

b) Trenching: The focused ion beam sputters atoms off of the surface on both sides of the site of interest. Once completed, a thin and freestanding "sheet" of material will remain at the surface.

c) Undercutting: The sample will be tilted in the microscope and the ion beam will be used to cut the "sheet" away from the surface forming a "slice" of material, which is no longer attached to the component.

d) Lift-Out: A micromanipulator within the SEM will be used to gently lift the TEM slice from the component.

e) Mounting: Using the ion beam, the sample may be attached to a post or grid for transferring the sample from the SEM to the TEM.

f) Thinning and Cleaning: Once attached to the post or grid, further "thinning" and "cleaning" of the TEM slice can be performed using the FIB to sputter away atoms from the slice.

Images will be collected prior and after sample preparation by using the imaging capability of the Scanning Electron Microscope (SEM). A variety of magnifications will be used to enable others to navigate back through the various magnifications to return to the exact site from which the sample was taken.

Images will be collected prior to and after sample preparation and saved as high resolution standard microscope images.

The SEM images collected prior and after sample preparation will provide a "map" to the location of sample preparation. Samples may be taken from any location on the components.

At least 72 hours prior to performing the testing set forth in this protocol, a party shall advise the other parties of the location and equipment to be used, and the person under whose supervision the testing will be performed.

The parties have agreed to share the results of their respective testing as soon as practicable after the testing is completed.

End of protocol