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

IN RE: DEPUY ORTHOPAEDICS, INC., PINNACLE HIP IMPLANT PRODUCTS LIABILITY LITIGATION	§ § § §	MDL Docket No. 3:11-MD-2244-K
This Document Relates to all Cases	§ §	

CASE MANAGEMENT ORDER NO. 9
[EXPLANT PRESERVATION ORDER]

Upon the stipulation of the Parties and for good cause shown,

IT IS HEREBY ORDERED that:

Pursuant to the Court's duty to supervise pretrial proceedings in this case, including discovery, and pursuant to the Court's inherent power, the Court hereby orders, effective immediately, that DePuy Orthopaedics, Inc. ("Defendant") and Plaintiffs (collectively, "the Parties") shall comply with the following directives relating to the preservation of explants in the above-captioned matter:

A. Definitions

1. "*DePuy Ultamet Device*" means a metal-on-metal hip implant using an Ultamet or Ultamet XL insert.

2. "*Explanted DePuy Ultamet Device*" means any DePuy Ultamet Device that is explanted from a plaintiff in the United States, as well as any other hip replacement

components that were used with the DePuy Ultamet Device and any tissue samples, synovial fluid and/or whole blood/serum that are retrieved during the surgery. The provisions of this Order shall also pertain to any other DePuy Ultamet Device, and any tissue samples, synovial fluid and/or whole blood/serum that are retrieved during the surgery, that have been explanted and returned to any of the Parties that, through reasonable efforts, can be identified as having been implanted in any patients in the United States.

B. Preservation Protocol

The Parties agree that the "Procedure for the Decontamination and Preservation of Retrieved DePuy Ultamet Device Components and Preservation of Tissue Samples by the Hospital or Healthcare Center and Prior to the Shipment to the Storage Facility or Contract Laboratory Retained by Either Plaintiff or DePuy" ("Decontamination Protocol"), attached as Exhibit A, the "Procedure for the Initial Receipt, Photography, and Decontamination of DePuy Ultamet Device Components and the Initial Receipt and Photography of Tissue Samples, if any, at the Contract Laboratory and/or Storage Facility" ("Initial Receipt Protocol"), attached as Exhibit B, and the "Procedure for the Storage of Retrieved DePuy Ultamet Components and/or Tissue Samples at a Contract Laboratory and/or Storage Facility" ("Storage Protocol"), attached as Exhibit C (collectively, the "Preservation Protocols"), represent reasonable protocols designed for the preservation, receipt and storage of Explanted DePuy Ultamet Devices which may

constitute evidence related to any claim or defense which the Parties may assert in this litigation. The Parties will not object to the request by or on behalf of any other party that the explanting surgeon and/or hospital retain and preserve synovial fluid and/or whole blood/serum pursuant to procedures consistent with the Preservation Protocols.

Recognizing that each explant procedure is within the purview and control of non-party medical practitioners and hospitals where surgeries occur, any departure from the Preservation Protocols by non-party medical practitioners and hospitals shall not constitute the spoliation of evidence by a party, provided that the party has not promoted or encouraged third parties, including but not limited to physicians and hospital personnel, to act in a way that is inconsistent with this Order or the Preservation Protocols.

C. Physical Evidence

A Plaintiff shall make good faith efforts with non-party medical practitioners and hospitals to preserve his or her Explanted DePuy Ultamet Devices that may be relevant to the claims, defenses, or subject matter of his or her case pursuant to the Preservation Protocols. Defendant will not take steps which interfere with requests by or on behalf of a Plaintiff to have their surgeon and/or hospital retain and preserve any Explanted DePuy Ultamet Device, tissue or any other physical evidence.

1. Non-Destructive Inspection and Analysis.

Unless otherwise ordered by the Court, any inspection and analysis shall be non-destructive. Non-destructive inspection and analysis by the Parties or their designated contract laboratory(s) of Explanted DePuy Ultamet Devices are allowed. The Parties agree that the "Procedure for Laboratory Inspection of Ultamet and Related Components" ("Inspection Protocol"), appended hereto as Exhibit D, represents one reasonable non-destructive protocol designed for the inspection of Explanted DePuy Ultamet Devices which may constitute evidence related to any claim or defense asserted in this litigation. The Parties will not object to any inspection of Explanted DePuy Ultamet Devices which is reasonably consistent with the Inspection Protocol, and this Order, and any inspection of Explanted DePuy Ultamet Devices which is reasonably consistent with the Inspection Protocol, and this Order, shall not constitute the spoliation of evidence by any of the Parties. If counsel of record for a Plaintiff so chooses, a Plaintiff's Explanted DePuy Ultamet Device may be obtained from the Plaintiff's surgeon or the hospital where the surgery occurred and sent to a contract laboratory(s) of Plaintiff's choice, or a designated storage facility, subject to the requirement that the explant shall be preserved in a manner that does not change or alter its condition or characteristics, or in accordance with the Preservation Protocols. The production of any report generated from an inspection of an Explanted DePuy Ultamet Device by a party shall be governed by the scheduling order entered in a particular Plaintiff's case or by such other orders as the Court may enter.

Consistent with the Preservation Protocols and Inspection Protocol, the Parties will take reasonable measures with their respective contract laboratories and/or designated storage facilities to maintain the Explanted DePuy Ultamet Devices, including all component parts, in the same condition as they were in when received, including refraining from altering the appearance, structure, existence, integrity and nature of the device surfaces as explanted. Except as otherwise permitted by this Order, all Explanted DePuy Ultamet Devices obtained by the Parties from surgeons or from the hospital where a Plaintiff's surgery occurred shall be retained by the receiving party, its designated contract laboratory(s) or designated storage facility unless otherwise agreed by the Parties or ordered by the Court.

2. Explanted DePuy Ultamet Device in Plaintiffs' or Defendant's Possession.

In the event that prior to the entry date of this Order, an Explanted DePuy Ultamet Device has been obtained by a party, the Parties agree as follows:

(i) For each Plaintiff who has obtained an Explanted DePuy Ultamet Device, notice of that fact will be provided to Defendant, along with information as to the date of the explantation, the location of the explant, whether tissues, synovial fluid and/or whole blood/serum were retained, and an acknowledgment that the explant will be preserved in its present condition consistent with the Preservation Protocols, and that any further inspection

and testing shall be in accordance with the provisions of this Order and the Inspection Protocol.

(ii) For each Plaintiff for whom DePuy has obtained an Explanted DePuy Ultamet Device, notice of that fact will be provided to that Plaintiff's counsel of record, along with information as to the date of the explantation, the location of the explant, whether tissues, synovial fluid and/or whole blood/serum were retained, and an acknowledgment that the explant will be preserved in its present condition consistent with the Preservation Protocols, and that any further inspection and testing shall be in accordance with the provisions of this Order and the Inspection Protocol. Upon request, DePuy will return the explant to Plaintiff's counsel of record upon receipt of an acknowledgment that the explant will be preserved, inspected and tested in accordance with the provisions of this Order and the Protocols. If the request for forwarding arrives prior to the completion of the testing and inspection, then (a) the inspection shall stop immediately and (b) DePuy shall seek approval to either complete the inspection or will forward the device as requested. The Parties agree that the mere failure to follow the Protocols attached to this Order for such Explanted DePuy Ultamet Devices received prior to the entry of this Order shall not, in and of itself, constitute the spoliation of evidence.

D. Sharing of Devices for Inspection

1. For Defendant-Obtained Explanted DePuy Ultamet Devices.

For Explanted DePuy Ultamet Devices obtained from surgeons or hospitals by Defendant, upon request, a Plaintiff has the right, at his or her expense, to request that his or her Explanted DePuy Ultamet Device be sent to a custodian of Plaintiff's choice for further inspection and testing.

In addition, the Court orders that the Parties may, at their own expense, examine for purposes of this litigation Explanted DePuy Ultamet Devices as well as relevant medical records (with identifying information redacted) obtained by Defendant from non-Parties either in connection with the explant study mandated by the FDA pursuant to Section 522 of the Food, Drug and Cosmetic Act, 21 U.S.C. 360l or otherwise, provided that such examinations are conducted in accordance with this Order or subsequent orders of the Court. Defendant is not required to provide Plaintiffs with access to a Explanted DePuy Ultamet Device and relevant medical records until those materials have been examined for purposes of the Section 522 explant study.

2. For Plaintiff-Obtained Explanted DePuy Ultamet Devices.

For Explanted DePuy Ultamet Devices obtained from surgeons or hospitals by Plaintiff, upon request and after initial inspection and testing by Plaintiff's consultants or laboratories, Defendant has the right, at its expense, to request that the Explanted

DePuy Ultamet Device be sent to a contract laboratory of Defendant's choice for further inspection and testing.

If Plaintiff has taken possession of an Explanted DePuy Ultamet Device and has chosen not to conduct an inspection or testing, Defendant shall have the right, at its expense, to request that the Explanted DePuy Ultamet Device be sent to a contract laboratory of Defendant's choice for inspection and testing. Upon completion of Defendant's inspection and testing, the device shall be returned to Plaintiff in the same condition as Defendant received it.

E. Court Oversight of the Process

The process of obtaining from surgeons and hospitals Explanted DePuy Ultamet Devices and sending them for inspection and testing at contract laboratories may encounter complications which the parties and this Court cannot anticipate at this time. The Court shall retain an active involvement in this process and the Parties shall keep the Court advised of complications encountered that are not resolved by agreement of the Parties. In the event a dispute arises between the hospital and a Plaintiff or a Plaintiff's counsel regarding a DePuy Ultamet Device, the Plaintiff or Plaintiff's counsel has the right to seek relief in this Court and this Court and/or the Special Master will intervene to resolve the dispute. To facilitate the Court's involvement in resolving any complications arising from this Order, the Court designates Plaintiffs' Executive Committee member Richard Arsenault and Defense Counsel Stephen J. Harburg as the

contact persons to field any questions and who will bring to the Court those issues requiring Court involvement.

SO ORDERED.

Signed January 23, 2013.

Ed Kinkeade

ED KINKEADE
UNITED STATES DISTRICT JUDGE

EXHIBIT A

Procedure for the Decontamination and Preservation of Retrieved DePuy Ultamet Components and Preservation of Tissue Samples by the Hospital or Healthcare Center and Prior to the Shipment to the Storage Facility or Contract Laboratory Retained by Either DePuy or the Patient.

1. PURPOSE:
   The following is an agreed upon protocol for giving instruction to outside parties for the decontamination of retrieved DePuy Ultamet components and the preservation of possible tissue sample(s).

2. SCOPE:
   - 2.1 THIS PROCEDURE ONLY APPLIES TO ALL DEVICES AND POSSIBLE TISSUE SAMPLE(S) THAT ARE RETRIEVED DURING AND LEADING UP TO THE REVISION SURGERY FOR DEPUY ULTAMET COMPONENTS.
   - 2.2 While not being requested by DePuy, DePuy does not object to a patient or the patient's counsel of record making other arrangements for the retention, preservation and shipping by a surgeon and/or the hospital of synovial fluid and whole blood serum for an individual patient.
   - 2.3 Decontamination, preservation and shipment of DePuy devices that do not involve the revision of DePuy Ultamet components are to be handled in the customary manner.

3. PRECAUTIONS:
   - 3.1 Only personnel trained in handling and shipping infectious substances shall perform this procedure.
   - 3.2 Standard precautions for biological materials must be used when handling the retrieved components and possible tissue samples.

4. DECONTAMINATION OF EXPLANTS AND PRESERVATION OF TISSUE SAMPLES:
   - 4.1 Retrieved components shall be decontaminated in accordance with hospital procedures unless a Patient or Patient's counsel of record requests that it be done in a different fashion. DePuy does not object to a patient or a patient's counsel of record making other arrangements with the patient's surgeon and/or the hospital for the fixation or decontamination of retrieved components in a manner other than in accordance with hospital procedures so long as the retrieved components are appropriately decontaminated and preserved.
     - 4.1.1 In the event that a dispute arises between a hospital and Patient or Patient's counsel regarding the manner in which the retrieved components should be decontaminated, preserved and/or shipped, until resolved, the retrieved components shall remain completely immersed in 10% Neutral Buffered Formalin without any alteration or decontamination. If the Patient or Patient's counsel objects to

autoclaving, autoclaving should not take place without an order from the Court permitting same.

4.2 Tissue samples are to be fixed according to hospital pathology procedures, remain soaked in the fixative and retained in a leak proof container marked as “biohazard” and “hazardous” in accordance with hospital procedures for the fixative unless a patient or a patient’s counsel of record requests that it be done in a different fashion. DePuy does not object to a patient or a patient’s counsel of record making other arrangements with the patient’s surgeon and/or the hospital for the fixation of tissue samples in a manner other than in accordance with hospital procedures so long as the tissue samples are appropriately preserved.

4.3 The total sample volume should not be larger than a golf ball in size and should only be taken from tissue removed from areas adjacent to the revised implant that may contain debris from the subject device.

4.4 DePuy does not object to a patient or a patient’s counsel of record requesting the retention and preservation of synovial fluid and/or whole blood to be packaged, preserved, and shipped in accordance with procedures to be agreed upon by the patient, her counsel of record, and the surgeon and/or hospital.

5. PACKAGING AND TRACKING:

5.1 After the decontamination and preservation of retrieved components and after the preservation of tissue, hospitals and health care centers are, to the extent possible, to follow the packaging, tracking and shipment instructions provided by either:

5.1.1 DePuy’s procedure for shipment of retrieved DePuy Ultamet components from the hospital or Healthcare center to the DePuy contract laboratory **OR**

5.1.2 Per the patient or patient’s counsel seeking transfer of these materials pursuant to a duly executed authorization.

5.2 When handling, packaging and shipping the retrieved components, avoid putting all the components in the same container without separate packaging. Ideally, each retrieved component should be individually wrapped and stored in its own container, then placed in a larger container with all the other retrieved components.

6. STORAGE:

6.1 The retrieved components and possible tissue samples should be stored in a secured location until a shipping kit and instructions arrive from DePuy, the patient or a representative of the patient.

7. REFERENCES:

7.1 Title 21 CFR, Part 803, *Medical Device Reporting*

7.2 Title 29 CFR, Part 1910, *Occupational Safety and Health Standards*

7.3 ANSI/AAMI ST79, *Comprehensive guide to steam sterilization and sterility assurance in health care facilities*

EXHIBIT B

Procedure for the Initial Receipt, Photography, and Decontamination of DePuy Ultamet Components and the Initial Receipt and Photography of Tissue Samples, if any, at the Contract Laboratory or Storage Facility

1. PURPOSE:
   The following protocol to describes the processes for the initial receipt of the package, taking photographs of the contents, and decontamination of the retrieved components at the storage facility or contract laboratory retained by the Patient and/or DePuy.

2. PRECAUTIONS:
   - 2.1 Tracking and integrity of the retrieved components 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 components, possible tissue samples, and inner-most packaging.
   - 2.5 Although the retrieved components may be labeled as having been previously decontaminated, the components must be decontaminated according to this procedure prior to detailed analysis for personnel safety.

3. RECEIPT OF PACKAGE BY DEPUY CONTRACT LABORATORY:
   - 3.1 Do not open the package until instructed to do so within this procedure.
   - 3.2 Inspect the package for shipping damage.
   - 3.3 Identify the DePuy Retrieval number and the tracking number on the package's shipping label (air waybill). These two numbers shall be used for tracking of all retrieved components and possible tissue samples
   - 3.4 Create a label containing both the DePuy Retrieval number and the package's tracking number, which shall be included in the initial macro photographs.

4. RECEIPT OF PACKAGE BY PATIENT"S CONTRACT LABORATORY OR STORAGE FACILITY:
   - 4.1 Do not open the package until instructed to do so within this procedure.
   - 4.2 Inspect the package for shipping damage.
   - 4.3 Identify the assigned unique patient identification number and the tracking number on the package's shipping label (air waybill). These two numbers shall be used for tracking of all retrieved components and possible tissue samples
   - 4.4 Create a label containing both the assigned unique patient identification number and the package's tracking number, which shall be included in the initial macro photographs

5. PHOTOGRAPHY OF THE AS-RECEIVED PACKAGE AND CONTENTS:
   - 5.1 Standard precautions for biological materials must be used per local lab procedures.
   - 5.2 Photography shall be performed with a digital camera, SLR preferred, 8.0 Megapixel minimum, greater than or equal to 12 Megapixel preferred.
   - 5.3 Macro photographs shall include the label with the DePuy Retrieval number or some other unique patient identification number along with the package's tracking number.
   - 5.4 Photography of the outer packaging shall include:
     - 5.4.1 An overall image of the package;
     - 5.4.2 A readable image of the package's air waybill;
     - 5.4.3 And, any significant damage to the outer package.
   - 5.5 Carefully open the outer package, so as to not damage the contents.
   - 5.6 At each step of unpacking the contents of the package, take photographs of the packing materials and labels.
   - 5.7 Retain the outer-most package for future storage, and the cardboard tray with plastic film for future shipping.
   - 5.8 Take a readable photograph of the paperwork found inside the package and any other paperwork in the air waybill pouch that was not visible when photographing the outside of the package.
     - 5.8.1 Confirm that the DePuy Retrieval number or some other unique patient identification number listed in the paperwork matches that on the package's air waybill.
     - 5.8.2 If the DePuy Retrieval number or some other unique patient identification number listed in the paperwork does not match that on the package's air waybill, create a label containing both numbers plus the package tracking number which shall be included in the initial macro photographs from this point forward. DePuy contract laboratories should report any such discrepancy in the regular Transmission of Information to DePuy. A patient retained contract laboratory or storage facility should report such a discrepancy to the patient.
     - 5.8.3 If the DePuy Retrieval number or some other unique patient identification number was not shown on the shipping label (air waybill), and is now found on the paperwork or component labels, create a label containing the DePuy Retrieval number or some other unique patient identification number along with the package's tracking number which shall be included in the initial macro photographs from this point forward.
   - 5.9 Inspect the package containing the tissue sample(s), if provided.
     - 5.9.1 Take photographs of the packing materials and labels at each step of opening the contents of the package.

5.9.2 Transfer the tissue sample(s) to a new, labeled leak-proof container, and add 10% neutral buffered formalin solution until the sample is submerged.

5.10 As-received photography of the retrieved components shall include:

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

5.10.2 At least two overall images (opposing views) of all retrieved components together, on a plain background, with a scale to indicate size. The Pinnacle Acetabular Cup must be positioned with the DP or DEPUY identification marking at the 12 o'clock position in both images. The Ultamet Metal Insert must be positioned with the identification marking aligned left to right when the marking is in view or right to left (when the marking is face down). The Metal Head must be positioned with the identification marking aligned left to right (when the marking is in view) or right to left (when the marking is face down);

5.10.3 At least two overall images (opposing views) of each individual retrieved component, on a plain background, with a scale to indicate size. The Pinnacle Acetabular Cup must be positioned with the DP or DEPUY identification marking at the 12 o'clock position in both images. The Ultamet Metal Insert must be positioned with the identification marking aligned left to right when the marking is in view or right to left (when the marking is face down). The Metal Head must be positioned with the identification marking aligned left to right (when the marking is in view) or right to left (when the marking is face down);

5.10.4 Readable images of each component's identification (laser) markings;

5.10.5 And, images of each component at various magnifications to document noteworthy features.

5.11 Components with attached tissue, including femoral surface replacement components with contained femoral head bone should be transferred to a new, labeled leak proof container, and add 10% neutral buffered formalin solution until each component is submerged.

5.12 A label containing either the DePuy Retrieval number or some other unique patient identification number should be affixed to each new leak-proof container.

6. <u>DECONTAMINATION OF RETRIEVED COMPONENTS</u>:

6.1 Decontamination of the retrieved components shall be performed before further analysis is conducted.

6.2 A 10% neutral buffered formalin solution shall be prepared for decontaminating the retrieved components. 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.

6.3 Place the retrieved components individually into separate containers labeled with the DePuy retrieval number or some other unique patient identification number as well as the package's tracking number. Add enough formalin solution to cover the components. Record information requested on the attached certification.

6.4 Allow the retrieved components to soak in the formalin solution for a minimum of 12 hours in a laboratory vented fume hood for the purpose of decontamination.

6.5 Components with no attached tissue proceed with steps below else go to step 6.6.

- 6.5.1 Remove the retrieved components from soaking, rinse with running water for approximately 1 minute. Allow products to dry.
- 6.5.2 Transfer the dry, decontaminated, retrieved components into individual plastic bags to prevent the components from contacting each other. The individual bags shall be labeled with the DePuy retrieval number or some other unique patient identification number as well as the package's tracking number.
- 6.5.3 Place the individual bags into a larger plastic bag also labeled with the DePuy retrieval number or some other unique patient identification number as well as the package's tracking number.
- 6.5.4 Complete and sign the Certification of Decontamination and Component Identification.
- 6.5.5 Place a copy of the Certification of Decontamination and Component Identification in the larger plastic bag labeled with the DePuy retrieval number or some other unique patient identification number as well as the package's tracking number, alongside the small bags containing the decontaminated retrieved components.
- 6.5.6 Go to step 6.7

6.6 Components with attached tissue, including femoral surface replacement components with contained femoral head bone, proceed with the steps below

- 6.6.1 After the initial decontamination period of 12 hours, store the components in individual containers submerged in fresh formalin solution until further testing is to be performed.
- 6.6.2 Each individual container shall be labeled with either, the DePuy retrieval number or some other unique patient identification number as well as the package's tracking number.
- 6.6.3 Complete and sign the Certification of Decontamination and Component Identification.
- 6.6.4 Place a copy of the Certification of Decontamination and Component Identification with the collection of individual containers for each patient.
- 6.6.5 Components should not be handled until the tissue is properly fixed. Tissue fixation can take a few days for small pieces of tissue covering acetabular components, up to a few weeks for femoral

surface replacements components with contained femoral head bone.

6.6.6 Should an inspection require the components to be dry, those components should be rinsed with water and the surfaces dried at room temperature under a vented fume hood. Care should be taken to minimize the time that the implants are out of formalin to avoid tissue damage.

6.6.7 At the completion of any testing, components should be returned to their individual containers submerged in formalin solution.

6.7 For cleanup after photography, the inner-most and biohazardous-labeled packaging shall be disposed of as biohazardous waste.

7. VERIFY THAT THE RETRIEVED COMPONENTS ARE ULTAMET:

7.1 Use the attached “Identification of DePuy Ultamet Components” document in order to determine if any of the retrieved components are Ultamet.

7.2 If none of the retrieved components are believed to be Ultamet, notify DePuy during the regular Transmission of Information.

8. REFERENCES:

8.1 Title 29 CFR, Part 1910, *Occupational Safety and Health Standards*

8.2 Centers for Disease Control, Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008

9. ATTACHMENTS:

9.1 Certification of Decontamination and Component Identification

9.2 Identification of DePuy Ultamet Components

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.

DePuy 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:

Ultamet Insert: _____


or

or

or


Cup: _____

Head: _____

Hip Stem: _____

Other components: _____

Other components: _____

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

Signature of laboratory representative: _____Date:_____

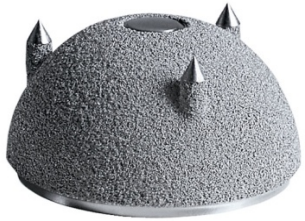
PRINT NAME & TITLE: _____

Identification of DePuy Ultamet Metal-on-Metal Articulation Coupled with the Pinnacle Acetabular Cup System

Ultamet Metal Insert 28mm, 36mm, 40mm, or 44mm

Confirm that there is an Ultamet Metal Insert. The Ultamet Metal Insert may be coupled with one of the Pinnacle Acetabular Cups shown below.

Pinnacle 100



Pinnacle 300

Pinnacle Sector

Pinnacle Multi-Hole

EXHIBIT C

Procedure for the Storage of Retrieved Components and/or Tissue Samples at the Contract Laboratory and/or Storage Facility

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

2. PRECAUTIONS:
   - 2.1 Tracking and integrity of the retrieved components and other package contents is critical.
   - 2.2 Only personnel trained in handling biological materials and chemical handling shall perform this procedure.
   - 2.3 The retrieved components shall have already been decontaminated by the DePuy procedure.
   - 2.4 The inner-most and biohazardous-labeled packaging around the retrieved components shall have been properly disposed of upon decontamination of the retrieved components. This particular packaging shall not be retained and shall not be stored with the decontaminated retrieved components.
   - 2.5 Standard precautions for biological materials must be used when handling the possible tissue sample(s).

3. ITEMS TO STORE:
   - 3.1 When handling, packaging and shipping the retrieved components, avoid putting all the components in the same container without separate packaging. Ideally, each retrieved component should be individually wrapped and stored in its own container, then placed in a larger container with all the other retrieved components. The following items for each patient may be stored in the outer-most shipping package labeled with the corresponding DePuy Retrieval number or some other unique patient identification number along with the package's tracking number:
     - 3.1.1 The decontaminated retrieved components in their individual containers and inside a larger container, all labeled with either the DePuy Retrieval number or some other unique patient identification number along with the package's tracking number;
     - 3.1.2 The copy of the Certification of Decontamination and Component Identification with the retrieved components;
     - 3.1.3 The package shipment paperwork;
     - 3.1.4 Retrieved component(s) with fixed tissue, if any, shall be retained in biohazardous packaging;
     - 3.1.5 The tissue sample(s), if any, in biohazardous packaging;
     - 3.1.6 A copy of the inspection report and all supporting documentation including images;
     - 3.1.7 And, other possible package contents received such as medical records, x-rays, etc….

4. STORAGE:
   4.1 Storage of retrieved components shall occur in a secured location.

EXHIBIT D

PROCEDURE FOR LABORATORY INSPECTION OF PINNACLE ULTAMET 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	
Decontamination in 10% buffered formalin	
Photography of decontaminated components:	
Overall view of each component	
Bearing surfaces	
Bone ingrowth/cemented surfaces	
Bone and/or Implant fracture surfaces if present	
Detailed photos of burnishing, damage to bearings or fixation surfaces, extent of wear scar, corrosion, etc	
Macro, Stereomicroscopic and SEM examination of component	
General shape, damage, retrieval and/or post-retrieval artefacts, wear, burnishing, scratches, corrosion, embedded material/particles, discoloration, staining, polishing or hazing of original features, etc	
Identification and description of bone and/or soft tissue present on ingrowth surfaces	
Observations of porous and/or HA coated surfaces: damage, missing, etc	
Identification and description of bone and/or cement present on cemented surfaces	
Metrology:	
Coordinate Measurement Machine (CMM) surface profiling for component dimensions.	
Surface Finish measurement (R_a) with an appropriate non-contact and/or contact profilometry method per ASME B46.1 and surface profiling.	

1.0 PURPOSE

The purpose of this document is to provide a protocol for inspection of PINNACLE ULTAMET and related retrieved components at external facilities.

2.0 SCOPE

This work instruction to laboratories details the steps required to inspect PINNACLE ULTAMET and related components at external test facilities. It applies to components previously decontaminated, with stepwise photography of the unpacking procedure. A verification of the complaint number, patient

information, product information, and patient authorization/consent must also have been completed prior to performing this inspection.

3.0 REFERENCES

3.1 ASME B46.1, Surface Texture (Surface Roughness, Waviness, and Lay)
3.2 ASTM F561, Standard Practice for Retrieval and Analysis of Medical Devices, and Associated Tissues and Fluids
3.3 ASTM F 2033, Standard Specification for Total Hip Joint Prosthesis and Hip Endoprosthesis Bearing Surfaces Made of Metallic, Ceramic, and Polymeric Materials
3.3 ISO 7206-2, Implants for Surgery - Partial and Total Hip Joint Prostheses - Part 2: Articulating Surfaces Made of Metallic, Ceramic and Plastics Materials
3.4 ISO 12891-1, Retrieval and Analysis of Surgical Implants - Part 1: Retrieval and Handling
3.5 ISO 12891-2, Retrieval and Analysis of Surgical Implants - Part 2: Analysis of Retrieved Metallic Surgical Implants

4.0 MATERIALS

4.1 Retrieved components supplied with a DePuy Retrieval identifier
4.2 Digital camera, SLR preferred; 8.0 Megapixel minimum, ≥12 Megapixel preferred
4.3 Optical Stereomicroscope
4.4 Coordinate Measurement Machine (CMM) of sufficient accuracy to determine spherical diameters and sphericity per ASTM F2033 or ISO 7206-2.
4.5 Non-contact or Contact Profilometer – capable of R_a measurements on the order of 5-100 nm per ASME B46.1.

5.0 PROCEDURE

5.1 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.

5.2 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.

5.3 Verify overview photography of components from unpacking and prior to decontamination (photos shall include in view: DePuy retrieval identification and tracking number).
- 5.3.1 Sequential images of unpacking of received components
- 5.3.2 Overall image of all components received, two orientations
- 5.3.3 Individual image of each component received, two orientations
- 5.3.4 Images of each component with readable laser mark identifications
- 5.3.5 Images of any noteworthy features

5.4 Obtain a set of standard detailed photos. Articular surfaces may be wiped with isopropyl alcohol and a cotton ball or swab, or lint-free cloth to remove dried fluid or water spot artefact that may obscure features of the articular surface.

5.4.1 Group and individual overall views of the components shall be obtained (entire component in view within the image). ULTAMET insert and PINNACLE shell must be positioned with the "DP" or "DePuy" lasermark at the 12 o'clock position, refer to Appendix 1 and Appendix 2 for schematics. Head shall be oriented with the lasermark information aligned left to right (lasermark in view) or right to left (lasermark face down), refer to Appendix 3 for schematics. Images shall contain DePuy Retrieval identification and scale in each view.

5.4.1.1 Once oriented, using a "sharpie" style marker, marks may be drawn only on non-articulating, smooth surfaces (ie on the rim or edges of either the heads or the cups) of each component in order to delineate the quadrants or sectors as specified in the Appendices 1, 2, 3, and 4. Do not draw lines on any coated or articulating surface.

5.4.1.2 At least two overall images (opposing views) of all retrieved components together, on a plain background.

5.4.1.3 At least two overall images (opposing views) of each individual retrieved component, on a plain background. If a hip stem is included, overall images of the medial and lateral aspects of the stem are also required (in addition to Side A and Side B, as shown in Appendix 4).

5.4.2 Detailed photography shall also be performed (only a portion of the component in view within the image). The images shall be saved with file name information indicating location information (Example: Cup_Articular3R.jpg). When feasible, images shall contain DePuy Retrieval identification and scale in each view. Otherwise, the file name of the image shall also identify the DePuy Retrieval number.

5.4.2.1 Clear images of lasermark identification of each component

5.4.2.2 Quadrant views of each component, following the reference quadrants defined in Appendices 1-4 (minimum 8 views).

5.4.2.3 Additionally, the features of each component shall be photodocumented at appropriate magnifications. Examples of features to be noted if they exist include, but are not limited to, bone fracture surfaces, implant fracture surfaces, burnishing, damage, wear scar, corrosion, foreign material, discoloration, and missing porous coating.

5.5 A component specific form shall be completed for each component received to detail the specific observations for that component, see Appendices 1 - 4. Record the DePuy Retrieval Number, Patient Name, Patient Date of Birth (DOB), Revising Institution, and laser marking information on each component form.

5.6 Macro and stereomicroscopic examination

5.6.1 Perform macroscopic examination with the unaided eye or with the aid of an optical stereomicroscope. Examine all surfaces of each component for evidence of

in-service, retrieval and/or post-retrieval damage. Record observations with a score (herein referred to as Area Score) to indicate the amount of area affected by the observed feature on a zero to three scale, with "0" indicating none of surface affected, "1" indicating greater than none but less than 25% of the area affected, "2" indicating between 25% and 75%, inclusive, of the area affected, and "3" indicating greater than 75% of the area affected.

5.6.2 Every effort should be made to photo-document every feature noted. The images shall be saved with file name information indicating location information (Example: ComponentX_Area3A_burnishing.jpg). In the instance that a feature cannot be made apparent in an image, the feature shall be fully characterized: described in words, sketched, and noted with size and location information. The amount of area affected by an observed feature shall be scored.

5.6.3 Articular surfaces may be wiped with alcohol and a cotton ball or swab, or lint-free cloth to remove dried fluid or water spot artefact that may obscure features of the articular surface.

5.6.4 Scratches may be defined into three categories:

5.6.4.1 Light: Can be seen but not felt/detected with a fingernail or a 0.18 mm thickness acetate gage.

5.6.4.2 Moderate: Can be seen and felt/detected with a fingernail or a 0.18 mm thickness acetate gage.

5.6.4.3 Heavy: Distinctly seen, felt/detected and will catch or stop a fingernail or 0.18 mm acetate gage.

5.6.5 Disassembly of components may only be performed after the party who has not yet had an opportunity to inspect and test has been notified and been given an opportunity to first perform any/all non-destructive testing on the explants.

5.6.5.1 A party may not proceed with disassembly until notification is provided to, and authorization is received from, the opposing party or the applicable court.

5.6.6 Scanning electron microscopy (SEM) may be used to further examine certain features of the retrieved components at a higher magnification and to allow interpretation of the cause of features seen at the gross level (for example third body wear, fatigue mechanisms, corrosion, etc.).

5.7 Metrology

5.7.1 For PINNACLE ULTAMET components, CMM measurements shall be made (see Appendices 1-3). Spherical diameter and the circularity, also called Sphericity, shall be measured following the methods of ISO 7206-2 (Method A.1 for a femoral head and A.2 for an acetabular cup) or ASTM F2033. Additionally, true position of the sphere center with respect to two defined datums shall be made for acetabular components only. Results shall be recorded and a report of the raw CMM data shall be attached to the component specific form.

5.7.3 For PINNACLE ULTAMET components, contacting and/or non-contacting surface profilometry measurements shall be made according to ASME B46.1. Measurements shall be taken in the three defined locations shown in the Appendices 2 and 3. The three locations shall be: one at the pole of the articular

surface; and two locations 30° from the pole, 180° from each other. The results may be suitably filtered in order to appropriately separate roughness, waviness and form.

5.7.3.1 Non contacting profilometry surface roughness (S_a) shall be measured for acetabular and femoral components in accordance with the default parameters of ASME B46.1 for non-contacting optical equipment. The surface scan shall be taken using a nominal 20 times objective lens and examine an area for each measurement of between 225-340 microns by 225-340 microns. Results shall be recorded on the component specific form (see Appendices 2 and 3) and a report of the raw profilometry data shall be attached to the component specific form.

5.7.3.2 Contacting profilometry surface roughness (R_a) shall be measured for the acetabular and femoral components in accordance with ASME B46.1. The stylus shall have a diamond tip and a nominal spherical tip radius of 2.0 (two) microns. The scans shall start with a cut-off length of 0.08 mm and a minimum evaluation length of 0.40 mm. For higher surface R_a results, adjustments to the cut-off and evaluation length shall be made according to ASME B46.1 Table 3.2 and the scan repeated. Results shall be recorded on the component specific form (see Appendices 2 and 3) and a report of the raw profilometry data shall be attached to the component specific form.

5.7.4 A coordinate measuring machine or surface profiling machine shall be used to assess the form of available taper surfaces.

5.8 Tissue samples

5.8.1 If available, a minimum sample of 5mm in greatest diameter will be cut from each available piece of tissue, such that a portion of the tissue, representing approximately 50% of the original sample is retained in formalin for future or additional analysis.

5.8.2 Tissue will be processed into paraffin wax and 3 sections of approximately 3-5 microns in thickness should be cut from each block. Any block and sections shall be retained for

5.8.3 One section should be stained with haematoxylin and eosin (H&E) for routine histology analysis.

5.8.4 Have an experienced investigator examine the stained section using a light microscope. The features of the tissue should be noted with particular attention to the presence and extent of inflammatory cells, necrosis, fibrosis, and wear debris.

5.8.5 Rate the tissue using the 10 point ALVAL score which consists of three parts: the synovial lining, the inflammatory cells, and the tissue organization.

Synovial lining

0 intact, cellular, normal
1 Focal loss, some fibrin attachment may occur
2 Moderate to marked loss, fibrin attachment
3 Complete loss, abundant fibrin and/or necrosis

Inflammatory Infiltrate

0 Minimal inflammatory cell infiltrates
1 Predominantly macrophages
2 Macrophages & diffuse and/or small pv lymphocytic aggregates
3 Macrophages & lymphocytes, large (>50% hpf) pv aggregates may occur
4 Predominantly lymphocytes, mostly in multiple, large pv aggregates

Tissue Organization

0 Normal capsule/bursa arrangement
1 Mostly normal, small areas of hyperplasia, focal necrosis may occur
2 Markedly abnormal, distinct acellular or fibrous layers may occur
3 PV aggregates distally, thick acellular areas may occur

Sum Low=0 -4, Moderate=5 – 8, High=9 – 10
pv=perivascular hpf=high power field (~400x)

5.8.6 The block and any sections and any other tissue samples received shall be retained per DePuy "Procedure for the Storage of Retrieved Components at the Contract Laboratory".

5.9 Storage of components and associated documentation shall be per DePuy "Procedure for the Storage of Retrieved Components at the Contract Laboratory"

6.0 REPORT

6.1 Each component specific form shall be signed and dated by the associate. The compiled report of forms, attachments, and acquired images shall be signed and dated upon completion by a reviewer.

6.2 The results of the inspection will be provided in a formal report using the completed forms and required attachments and submitted to DePuy. The report will be reviewed and additional inspection may be requested.

Appendix 1: *Laboratory Retrieval Inspection Form**: ACETABULAR SHELL***

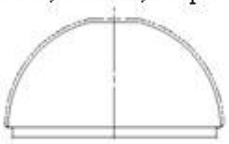
DePuy Retrieval Number:_____

TITLE: FORM FOR LABORATORY INSPECTION OF ACETABULAR SHELL

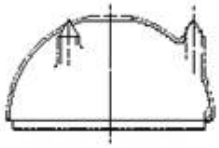
Patient Name: _____
DOB: _____
Revising Institution: _____

Acetabular shell type

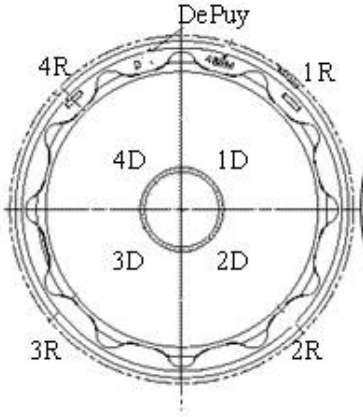
100 Series
Porocoat, Duofix, Gription



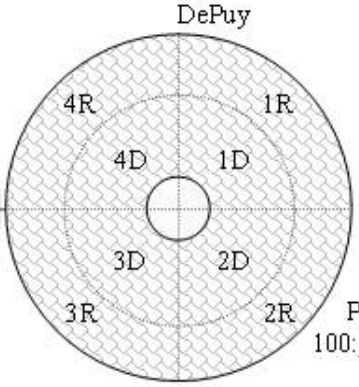
300 Series
Porocoat



Quadrant reference system for internal surface

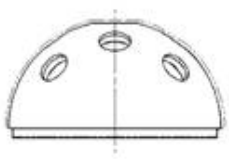


Quadrant reference system for fixation surface



Sector
Porocoat, Duofix, Gription

Multi-Hole
Porocoat
Gription



CHECK TYPE:
Porocoat:___ Duofix:___ Gription: ___
100:___ 300: ___Sector:___ Multi-hole: ___

Laser mark: D T SIZE: _____
Lot ID: _____

NOTE: Orient with "DP" or "DePuy" at 12 o'clock position, for consistency of location references.

Shell interior surfaces	1D	1R	2D	2R	3D	3R	4D	4R
Generally hemi-spherical in shape: YES [ ] NO [ ]								
If NO, denote location of non-uniformity with "X"								
Wear or Burnishing								
Scratches (see section 5.6.4)								
Change of shape								
Impingement								
Mechanical/Retrieval damage								
Corrosion								
Embedded material/particles								
Discoloration/staining								
Polishing of non-polished surface features								
Hazing of surface features								
OTHERS:								

DePuy Retrieval Number:_____

TITLE: FORM FOR LABORATORY INSPECTION OF ACETABULAR SHELL

Non-articular fixation surfaces	1D	1R	2D	2R	3D	3R	4D	4R
Wear or Burnishing								
Scratches (see section 5.6.4)								
Change of shape								
Impingement								
Mechanical/Retrieval damage								
Corrosion								
Embedded material/particles								
Discoloration/staining								
Polishing of non-polished surface features								
Hazing of surface features								
For porous and/or HA coated surfaces								
damage to coating								
missing coating								
attachment of bone tissue								
attachment of soft tissue								
OTHERS:								

Signature:_____ Date:_____

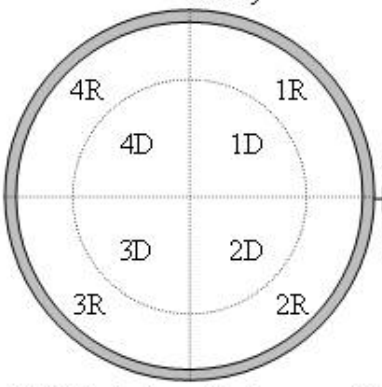
PRINT NAME & TITLE: _____

DePuy Retrieval Number:_____

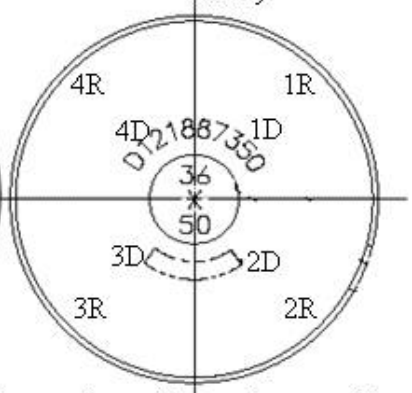
TITLE: FORM FOR LABORATORY INSPECTION OF ACETABULAR LINER

Patient Name: _____
DOB: _____
Revising Institution: _____

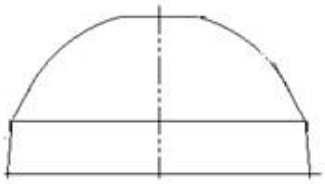
Quadrant reference system for articular surface



Quadrant reference system for backside surface



Metal Acetabular Liner



Laser mark: D_____
SIZE: _____
Lot Id: _____

NOTE: Orient with laser marking as shown, for consistency of location references.

Articular surfaces	1D	1R	2D	2R	3D	3R	4D	4R
Generally hemi-spherical in shape: YES [ ] NO [ ]								
If NO, denote location of non-uniformity with "X"								
Evidence of a clear wear zone? If YES, denote Location								
Area Score: (0: None, 1: <25%, 2: 25-75%, 3: >75%)								
Scratches: (See section 5.6.4) Light (visually apparent but no perceived depth)								
Moderate (slightly perceived depth)								
Heavy (Depth to scratch is evident)								
Impingement								
Corrosion								
Embedded Material/Particles								
Discoloration/Staining								
Hazy Appearance								
OTHERS:								

DePuy Retrieval Number:_____

TITLE: FORM FOR LABORATORY INSPECTION OF ACETABULAR LINER

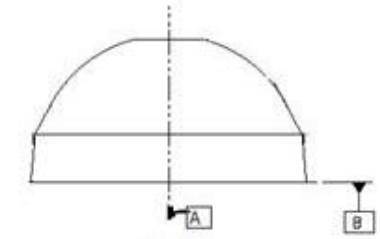
Non-articular surfaces	1D	1R	2D	2R	3D	3R	4D	4R
Wear or Burnishing								
Scratches (see section 5.6.4)								
Change of shape								
Impingement								
Mechanical/Retrieval damage								
Corrosion								
Embedded material/particles								
Discoloration/staining								
Polishing of non-polished surface features								
Hazing of surface features								
OTHERS:								

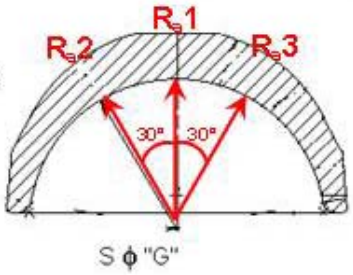
Metrology Evaluation

Measure and record the following dimensions in mm with CMM (see drawing for clarification):

SØ "G" _____ mm
Surface Profile (Sphericity) _____ mm
True Position-Datum A _____ mm
True Position-Datum B _____ mm

Position-Datum A refers to the position of the sphere center with respect to the central axis defined by the taper on the outside of the cup (i.e. distance of sphere center from the central axis). Position-Datum B refers to the position of the sphere center with respect the plane defined by the face of the rim of the cup (i.e. distance of sphere center to face of cup).





Measure and record the surface roughness (S_a or R_a) in nm using a profilometer (see schematic for defined locations):

S_a1 _____ nm or R_a1_____nm
S_a2 _____ nm or R_a2_____nm
S_a3 _____ nm or R_a3_____nm

Signature:_____ Date:_____

PRINT NAME & TITLE: _____

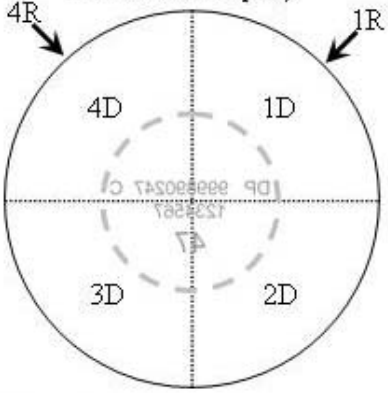
DePuy Retrieval Number:_____

TITLE: FORM FOR LABORATORY INSPECTION OF FEMORAL HEAD

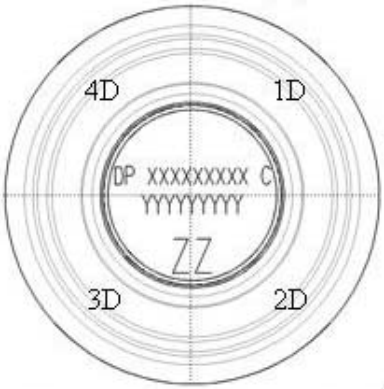
Patient Name: _____
DOB: _____
Revising Institution: _____

Femoral Head

Quadrant reference system (for articular surface viewed from apex)



Quadrant reference system (for opposite side viewed from female taper)



Lasermark: DP _____ C
_____
_____

Views 1-4 "R" are the areas below the equator of the articular surface (toward the rim) with the same numbering convention as 1-4 "D".

Orient with "DP" lasermark lines oriented left to right (lasermark in view) or right to left (lasermark face down), as applicable (see schematics), for consistency of location references.

Articular surfaces	1D	1R	2D	2R	3D	3R	4D	4R
Generally hemi-spherical in shape: YES [ ] NO [ ]								
If NO, denote location of non-uniformity with "X"								
Evidence of a clear wear zone? If YES, denote Location								
Area Score: (0: None, 1: <25%, 2: 25-75%, 3: >75%)								
Scratches: (See Section 5.6.4) Light (visually apparent but no perceived depth)								
Moderate (slightly perceived depth)								
Heavy (Depth to scratch is evident)								
Corrosion								
Embedded Material/Particles								
Discoloration/Staining								
Hazy Appearance								

DePuy Retrieval Number:_____

TITLE: FORM FOR LABORATORY INSPECTION OF FEMORAL HEAD

Articular surfaces, continued	1D	1R	2D	2R	3D	3R	4D	4R
OTHERS:								
Non-articular surfaces	1D	2D	3D	4D				
Area Score: (0: None, 1: <25%, 2: 25-75%, 3: >75%)								
Wear or Burnishing								
Scratches (See Section 5.6.4)								
Change of shape								
Mechanical/Retrieval damage								
Corrosion								
Embedded material/particles								
Discoloration/staining								
Polishing of non-polished surface features								
Hazing of surface features								
OTHERS:								

Metrology Evaluation

Measure and record the following dimensions in mm with CMM (see drawing for clarification):

SØ "C" _____ mm

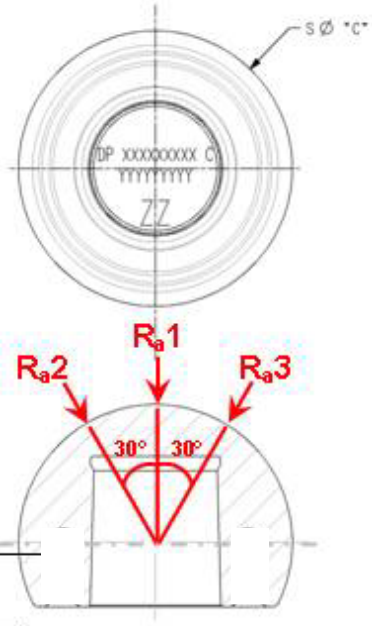
Circularity (Sphericity) _____ mm

Measure and record the surface roughness (S_a or R_a) in nm using a profilometer (see schematic for defined locations):

S_a1 _____ nm or R_a1_____nm

S_a2 _____ nm or R_a2_____nm

S_a3 _____ nm or R_a3_____nm



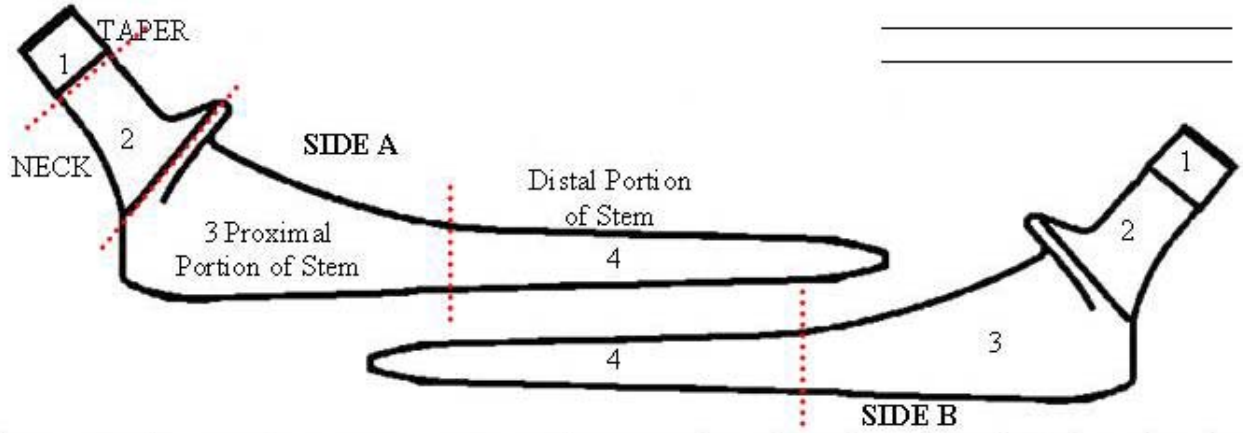
Signature:_____ Date:_____

PRINT NAME & TITLE: _____

DePuy Retrieval Number:_____

TITLE: FORM FOR LABORATORY INSPECTION OF HIP STEM

Patient Name: _____
DOB: _____
Revising Institution: _____ Lasermark: _____



Area Score: (0: None, 1: <25%, 2: 25-75%, 3: >75%)	1A	1B	2A	2B	3A	3B	4A	4B
Wear or Burnishing								
Scratches (See Section 5.6.4)								
Change of shape								
Impingement								
Mechanical/Retrieval damage								
Corrosion								
Embedded material/particles								
Discoloration/staining								
Polishing of non-polished surface features								
Hazing of surface features								
For porous and/or HA coated surfaces								
damage to coating								
missing coating								
attachment of bone tissue								
attachment of soft tissue								
OTHERS:								

Signature: _____ Date: _____

PRINT NAME & TITLE: _____