



September 30, 2010

**ASR™ XL Acetabular System/DePuy ASR™ Hip Resurfacing System:  
Retention of Explanted Components**

Attention Doctors and Hospital Representatives:

DePuy Orthopaedics, Inc. requests your assistance in retaining explanted DePuy ASR™ and ASR™ XL Hip System components and related tissue samples.

When a femoral hip stem is removed during the revision of ASR XL components, please retain the hip stem with the ASR components. If the revision procedure requires removal of tissue adjacent to the ASR Hip System, samples of the removed tissue should be retained for inspection in addition to the hip stem and ASR components. The samples of the removed tissue should be obtained by routine procedures. 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. Collection and inspection of explanted components and tissue samples require prior written patient authorization.

DePuy is identifying third-party retrieval laboratories to receive and analyze explanted components and related tissue samples. In the interim, please retain these items in accordance with the following procedures until DePuy can arrange for their transport to the appropriate retrieval laboratory:

1. **Preservation:** All tissue samples should be placed in fixative and explanted components should be decontaminated in accordance with hospital procedures.
2. **Packaging:** After decontamination, place each component in a separate zip top style bag and then place all the components for the patient in one larger zip top style bag. Tissue samples should remain soaked in the fixative and retained in a leak-proof container marked as "biohazard" and "hazardous" per hospital procedures for the fixative.
3. **Tracking:** For tracking purposes, all retrieved components and tissue samples should be labeled either directly on the bag/bottle or on a tag firmly attached to the bag/bottle with the patient name, patient date of birth, hospital name, surgeon name, hospital patient identity number, date of original surgery and date of revision surgery. When available, the DePuy supplied complaint number, which is prefaced by the letters WPC or DINT, should also be included.

Thank you for your assistance in retaining explanted components and tissue samples. If you have any questions, please contact Dan Auger at 574-372-7551.