Zimmer, Inc.
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March 31, 2013

SUBJECT: Zimmer Metal-on-Metal Section 522 Post-Market Surveillance Explant Retrieval Study

Dear Surgeon:

The Food and Drug Administration (FDA), pursuant to Section 522 of the Food, Drug and Cosmetic Act, 21 USC § 3601, has ordered medical device manufacturers, including Zimmer, Inc. ("Zimmer"), to conduct post market surveillance studies of their metal-on-metal hip implants. Part of the post-market surveillance includes the study of explanted retrievals when made available after medically necessary surgical intervention.

You are being notified about this study as you may have implanted a Zimmer metal-on-metal device or may be involved in a revision of a Zimmer metal-on-metal device. In order for Zimmer to comply with the FDA order, we are asking that explanted components be sent back to Zimmer for analysis. We have arranged for Exponent, Inc. ("Exponent") in Philadelphia, PA, to analyze any collected tissue and fluid samples. In order for the Section 522 retrieval study to be conducted, Zimmer requests that you obtain authorization from the patients for the following:

1. Return to Zimmer any explanted Zimmer metal-on-metal device and all associated components;
2. Collection of tissue and fluid samples;
3. Release of medical records necessary for the study; and
4. Shipment of tissue and fluid samples to Exponent.

You should follow your standard procedures for obtaining approval from the patient for retention and shipment to third parties of explanted components and any related tissue and fluid samples.

Since the explanted devices belong to the patient, Zimmer recognizes that the patient has the right to refuse permission for the explanted component and any related tissue and fluid samples to be shipped to and analyzed by Zimmer or its designated laboratory. The patient may make other arrangements for the retention, preservation, and analysis of explanted components and any related tissue or fluid samples. However, Zimmer requests that you try to obtain the necessary authorizations so that the explants and any related tissues and fluid samples are preserved and can be analyzed as part of the FDA-mandated explant study. Attached you will find a letter which provides additional information on the Section 522 study to share with patients.

ACTION REQUESTED:

When any Zimmer metal-on-metal device is revised, it is important that you preserve all of the explanted components. The following points provide an overview of what is requested of you to help us fulfill the requirements set forth by FDA:

1. Obtain authorization from the patient for release of explanted components, tissue and fluid samples, and medical records.

2. Contact the Zimmer Call Center at 1-877-946-2761 to request shipping containers and labels for explanted components and tissue and fluid samples.

3. During surgery:

    a. Note and record any observations related to reasons for revision – including fluid accumulations, metallosis, location and extent of any tissue damage, position of implants, loosening, etc.;

    b. Photograph the implants *in-situ*;

    c. Mark the implants to indicate orientation *in-situ*;

    d. Photograph the implants after removal; and

    e. Note and record any damage to the implant caused by the removal.

4. After surgery, ensure that the components are delivered to the appropriate department for preservation and shipment.

5. Ensure copies of patient medical records have been requested for shipment to Zimmer.

We are including a flow chart for you to reference and post in your office that will guide you through the retrieval process.

Thank you for your assistance in helping to ensure that explanted Zimmer metal-on-metal devices, associated components, and any related tissue and fluid samples are properly preserved and shipped to Zimmer or Exponent. If you have any questions about compliance with this important request or about shipment of the retained components, or if you would like copies of the Procedures for the analyses of Zimmer Metal on metal explant components and Associated Tissues and Fluids, please contact Zimmer at 1-877-946-2761.

Thank you for your assistance with this important study.

Sincerely,

Erin Osborn
Director of Clinical Affairs
Zimmer Inc

Enclosures:

a. Informed Consent for the Use of Retrieved Implants, Tissue/Fluid Samples and Medical Records
b. Explanted Letter for Patients; and
c. Flow Charts of Explants Process (4).

Copies of the enclosed documents and the explants protocol are available at the following website: www.522.zimmer.com.