March 31, 2013

Information for Patients

The US Food and Drug Administration (FDA) is conducting a nationwide study which requires all orthopaedic medical device manufacturers, including Zimmer, Inc., to collect, analyze and provide information on metal-on-metal hip implants. This is considered a post market surveillance study.

A key part of this study involves the examination of retrieved metal-on-metal hip implants that are replaced with new devices. The hip implants that are removed are called "explants". The explants, tissue and fluid, and medical records are yours and Zimmer requires an authorization by you to collect these items for analysis and reporting to FDA. If explants are available and you have signed the authorization form, then they will be shipped to Zimmer and any tissue/fluid samples will be shipped to Exponent, Inc., a laboratory that Zimmer uses for analysis and storage. The explants will be analyzed according to a protocol approved by FDA. The explants can be returned to you or your physician upon request.

Clinical information related to the surgical procedure and the patient's medical background may also be helpful to the analysis of the retrieved components and tissues, so Zimmer is requesting that medical records be sent to Zimmer, Inc. The clinical information may include, but is not limited to: demographics (age, weight, etc.), clinical history, activity level, diagnostic imaging, any operative reports of the original and revision surgery, and office reports.

To participate, you simply complete the Patient Authorization forms and leave them with your surgeon. By participating in this study and allowing your explants to be examined, you are contributing to the knowledge base for orthopaedic healthcare.

Thank you for your consideration in participating in this study. You are not required to sign the Patient Authorization Form or to provide the medical information to Zimmer, but your participation in this study is greatly appreciated. If you have additional questions, please feel free to call Zimmer at 1-877-946-2761.

If you would like to learn more about post market surveillance studies, please visit www.fda.gov and enter "522" in the search bar on their website. The first entry in the search results will direct you to a Frequently Asked Questions page. You can also copy the link listed at the end of this letter.

Thank you for your assistance with this very important study.

Sincerely,

Erin Osborn

Erin Osborn
Director of Clinical Affairs
Zimmer, Inc.

Link to FDA website:

www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/PostmarketSurveillance