

Selected Technical Papers



STP 1560

Metal-On-Metal Total Hip Replacement Devices

Editors:

Steven M. Kurtz

A. Seth Greenwald

William M. Mihalko

Jack E. Lemons

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Foreword

THIS COMPILATION OF *Selected Technical Papers*, STP1560, on *Metal-On-Metal Total Hip Replacement Devices*, contains 20 papers presented at a symposium with the same name held in Phoenix, AZ, USA on May 8, 2012. The symposium was sponsored by ASTM International Committee F04 on Medical and Surgical Materials and Devices and Subcommittee F04.22 on Arthroplasty.

The Symposium Co-Chairs and STP Editors are Steven M. Kurtz, A. Seth Greenwald, William M. Mihalko, and Jack E. Lemons.

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Overview

One step forward, two steps back is a concerning assessment of the currency of contemporary metal-on-metal (MOM) total and surface replacement hip systems employed as a remedy in the treatment of degenerative arthritis. First introduced almost four decades ago, MOM bearings have represented as much as 40% of the primary total hip systems utilized in the United States as of 2008. Since then, they have received growing attention in the peer reviewed literature, by orthopedic registries, and in international press coverage, much of it with a negative slant, describing adverse local tissue reactions (*ALTR*) and the risk of revisions associated with certain designs of MOM bearings.

The combination of mounting scientific evidence and growing public scrutiny has triggered recent United Kingdom Medicines and Healthcare Products Regulatory Agency (MHRA) warnings on the use of MOM articulations and a series of regulatory actions by the United States Food and Drug Administration (US FDA). On May 6, 2011, the FDA issued a 522 ruling ordering the submission of post-market surveillance studies, and on January 17, 2013, the FDA issued a proposed order requiring the submission of PMA applications for MOM total hip replacement designs in the US Market. It seems the world of MOM articulations is at a watershed as a bearing couple for total hip and surface replacement designs.

This ASTM special technical publication (STP) is an outgrowth of an ASTM Symposium held on May 8, 2012, in Phoenix, Arizona. The purpose of this Symposium was to provide a forum for consensus development and scientific exchange on the needs for characterization and standardized testing related to MOM hip replacement devices. The main focus of this Symposium was to address unmet standardization needs and to help establish best testing practices in the following four areas:

- Characterization of Adverse Local Tissue Reactions
- Wear/Corrosion: Metallic Product Measurement in Fluid and Tissue Samples
- Analyses of Retrieved MOM Implants
- In Vitro Testing of MOM Implants under Adverse Conditions

This STP contains 20 papers from clinicians and scientists whose goal was to provide contemporary insight into the evolving knowledge base of MOM hip implants.

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