Proposed New ASTM Standard to Provide Guide for Collection and Analysis of Explanted Hip Implants

ASTM

An ASTM International symposium on metal-on-metal total hip replacement devices held in May 2012 identified unmet standardization needs. One such need was for a standard that deals with the collection and analysis of explanted hip implants in order to understand their in-vivo performance. In addition, the U.S. Food and Drug Administration Order 522 mandates orthopaedic companies to carry out retrieval analysis on all explanted metal-on-metal hip components. In response, a proposed new ASTM standard will provide a guide for the industry to follow covering the issue of material loss.

ASTM WK43442 [1], Guide for the Characterization of Material Loss from Conical Taper Junction Between Femoral Head and Stem in Retrieved Modular Hip Prostheses, is being developed by Subcommittee F04.22 on Arthroplasty [2], part of ASTM International Committee F04 on Medical and Surgical Materials and Devices [3].

Once approved, the proposed standard will give the user a series of options and increase awareness of information and approaches to researchers and companies that need to measure the material loss from taper joints in orthopaedic devices.

“In order to understand the in-vivo performance of hip joints, and to understand the mechanisms that lead to material loss, it is essential to be able to accurately and repeatedly measure the material loss from the components,” says Richard Underwood, associate, biomedical engineering practice, Exponent, and a member of F04.22. “This proposed standard will help researchers understand the in-vivo behavior of orthopaedic devices and ultimately design longer-lasting devices.”

Research laboratories and implant manufacturers will be the primary users of ASTM WK43442. Manufacturers are mandated by the U.S. Food and Drug Administration to analyze explanted hip components, and the proposed guide will be used as part of the FDA submission process.

All interested parties are invited to join in the standards developing activities of F04.22. The task group working on ASTM WK43442 [4], F04.22.29 on Metal-on-Metal Clinical Characterization, is also working on the following proposed standards:

- ASTM WK34551, Guide for Clinical Diagnostic Evaluation of Metal-on-Metal Hip Arthroplasty Devices Using Magnetic Resonance Imaging
- ASTM WK35939, Guide for the Characterization of Wear from the Articulating Surfaces in Retrieved Metal-on-Metal Hip Prostheses

- ASTM WK38566, Test Method for Measuring Metal Ions in Retrieved Fluid Samples from Total Joint Arthroplasty

ASTM International welcomes participation in the development of its standards. For more information on becoming an ASTM member, visit www.astm.org/JOIN. [5]

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