



Standard Guide for Characterization of Wear from the Articulating Surfaces in Retrieved Metal-on-Metal and other Hard-on-Hard Hip Prostheses¹

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1. Scope

1.1 This guide specifies a method to measure the *in-vivo* wear of explanted Metal-on-Metal (MoM) and other “hard” (e.g., ceramic) hip components. The guide covers the measurement of acetabular cups and femoral heads using a dimensional change method and is applicable to all prosthetic hip types, including stemmed (modular) and resurfacing hip systems.

1.2 The methods specified in this guide are not applicable for measuring the *in-vivo* wear from non-articulating surfaces, for example modular connections (at the stem/neck, neck/head or cup liner/shell interface) or at acetabular cup rim.

1.3 The parameters (wear depth and volumetric wear) evaluated and reported in this guide are estimated from the assumed as-manufactured shape of the components. The wear volume is calculated using a numerical integration method and the wear depth is the difference between the assumed as-manufactured shape and the measured surface.

1.4 This guide covers the measurement of the depth of wear and the volumetric wear using a Coordinate Measuring Machine (CMM) and the depth of wear using a Roundness Machine. Other metrology measurement equipment may be used to measure the wear depth or volume if the resolution and accuracy of the measurements are comparable with the instruments detailed in this standard. The measurement and analysis protocols should be based on those described in this standard.

1.5 This guide is applicable to hip joints which are nominally spherical at the time of manufacture. Form deviations resulting from manufacturing or deformation may occur and may necessitate the use of a non-spherical surface to represent the unworn surface of the component. Hip joints designed with asymmetry are considered beyond the scope of this guide, although the principles and techniques may be applicable to the characterization of wear from the articulating surfaces.

1.6 This guide is intended as an extension to ASTM F561 as a Stage II nondestructive test.

1.7 *This standard may involve hazardous materials, operations and equipment. As a precautionary measure, explanted devices should be sterilized or disinfected by an appropriate means that does not adversely affect the implant or the associated tissue that may be the subject of subsequent analysis. A detailed discussion of precautions to be used in handling human tissues can be found in ISO 12891-1. This standard does not purport to address all of the safety concerns, if any, associated with its use. It is the responsibility of the user of this standard to establish appropriate safety and health practices and determine the applicability of regulatory limitations prior to use.*

2. Referenced Documents

2.1 ASTM Standards:²

F561 Practice for Retrieval and Analysis of Medical Devices, and Associated Tissues and Fluids

F2033 Specification for Total Hip Joint Prosthesis and Hip Endoprosthesis Bearing Surfaces Made of Metallic, Ceramic, and Polymeric Materials

2.2 ISO Standard:³

ISO 12181-1-2003 Part 1 – Geometrical product specifications roundness, vocabulary and parameters of roundness

3. Terminology

3.1 Definitions:

3.1.1 For the purposes of this standard the following definitions shall apply.

3.1.2 *cup rim*—the circle formed by the intersection of the articulating surface and the plane normal to the revolution axis that lies coincident with the extreme point of the open cup face.

¹ This test method is under the jurisdiction of ASTM Committee F04 on Medical and Surgical Materials and Devices and is the direct responsibility of Subcommittee F04.22 on Arthroplasty.

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² For referenced ASTM standards, visit the ASTM website, www.astm.org, or contact ASTM Customer Service at service@astm.org. For *Annual Book of ASTM Standards* volume information, refer to the standard's Document Summary page on the ASTM website.

³ Available from American National Standards Institute (ANSI), 25 W. 43rd St., 4th Floor, New York, NY 10036, <http://www.ansi.org>.