



Standard Guide for Characterization of Material Loss from Conical Taper Junctions in Total Joint Prostheses¹

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1. Scope

1.1 This guide specifies a method to measure the surface and estimate the *in-vivo* material loss from the conical taper junctions, such as the femoral head/stem junction or adapter sleeve from explanted modular hip prosthesis, modular knee or shoulder joints. This guide is applicable to any articulating bearing material, stem material and conical taper size. The principles in this guide may be applied to other designs of taper junction, such as the modular stem/neck junction found in some hip joints.

1.2 This guide covers the measurement of the surface and estimation of depth of material loss and volume of material loss and taper geometry using a Roundness Machine (1-4), Coordinate Measuring Machine (CMM) (5) and Optical Coordinate Measuring Machine (6, 7).² Other measurement equipment may be used to measure the surface 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.

NOTE 1—The maximum depth of material loss is sensitive to the number and spacing of data points.

1.3 The measurement techniques in this standard guide use measurements taken on the surface of the taper using stylus instruments. The material loss/corrosion mechanisms in the taper junction may lead to oxide layers or corrosion products deposited on the surface of the taper. These layers may lead to an underestimation of the volume of material loss.

1.4 The explants may have debris or biological deposits on the surfaces of the taper junctions. These deposits will prevent the measurement of the actual surface of the taper junction and their effect on the measurement must be considered when deciding the cleaning protocol. Normally, the taper surfaces will be cleaned before measurements are taken.

1.5 *This standard may involve hazardous materials, operations and equipment. As a precautionary measure, explanted devices should be sterilized or minimally 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:³

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

2.2 ISO Standards:⁴

ISO 12181-1-2003 Geometrical Product Specifications (GPS)—Roundness Part 1: Vocabulary and Parameters of Roundness

ISO 12181-2-2003 Geometrical Product Specifications (GPS)—Roundness Part 2: Specification Operators

ISO 4287:1997 Geometrical Product Specifications (GPS)—Surface Texture: Profile Method—Terms, Definitions and Surface Texture Parameters

ISO 4287:1997/Cor 1:1998 Geometrical Product Specifications (GPS)—Surface Texture: Profile Method—Surface and its Parameters

ISO 4287:1997/Cor 2:2005 Geometrical Product Specifications (GPS)—Surface Texture: Profile Method—Measurement of Surface Roughness Parameters

ISO 25178-2 Geometric Product Specifications (GPS)—Surface Texture: Areal—Part 2: Terms, Definitions and Surface Texture Parameters

¹ This guide 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 The boldface numbers in parentheses refer to the list of references at the end of this standard.

³ 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.

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