



Standard Test Methods for Determination of Static and Cyclic Fatigue Strength of Ceramic Modular Femoral Heads¹

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1. Scope

1.1 These test methods cover the evaluation of the static and cyclic fatigue strength of ceramic modular femoral heads, mounted on a cone as used on the femoral stem of the total hip arthroplasty.

1.2 These test methods were primarily developed for evaluation of ceramic (Specifications **F603** and **F1873**) head designs on metal cones but may have application to other materials.

1.3 The values stated in SI units are to be regarded as standard. No other units of measurement are included in this standard.

1.4 *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

- E4 Practices for Force Verification of Testing Machines**
- F603 Specification for High-Purity Dense Aluminum Oxide for Medical Application**
- F1873 Specification for High-Purity Dense Yttria Tetragonal Zirconium Oxide Polycrystal (Y-TZP) for Surgical Implant Applications (Withdrawn 2007)**³
- F1875 Practice for Fretting Corrosion Testing of Modular Implant Interfaces: Hip Femoral Head-Bore and Cone Taper Interface**

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 The last approved version of this historical standard is referenced on www.astm.org.

2.2 Other Documents:

- DIN 4768 Determination of Surface Roughness R_a , R_z , and R_{max} with Electric Stylus Instruments; Basic Data**⁴
- FDA Guidance Document for the Preparation of Premarket Notifications for Ceramic Ball Hip Systems (draft Jan. 10, 1995)**⁵

3. Terminology

3.1 Definitions:

- 3.1.1 *circularity*—deviations of taper cross section from a perfect circle.
- 3.1.2 *cone*—the proximal end of the femoral component fabricated as a truncated right cone and used to engage with a mating conical bore of the modular femoral head.
- 3.1.3 *cone angle*—included angle of cone (**Fig. 1**).
- 3.1.4 *femoral neck-axis*—centerline or axis of symmetry of the femoral cone.
- 3.1.5 *head size*—nominal spherical diameter of the head (generally standardized, but not limited to 22, 26, 28, 32, and 36 mm for total hips.)
- 3.1.6 *installation load*—the force, applied at 0° from femoral neck axis, used to settle the head on the cone prior to testing.
- 3.1.7 *load axis*—line of action of the compressive force applied to the head.
- 3.1.8 *load axis angle*—the measured angle “L” between the line of action of the applied force and femoral neck axis (see **Fig. 5**).
- 3.1.9 *load magnitude*—the peak (absolute value) compressive force of the applied constant amplitude cyclic force.
- 3.1.10 *load rate*—rate of applied compressive force.
- 3.1.11 *stroke rate*—the rate of the stroke displacement of the force applicator.
- 3.1.12 *surface finish*—measured roughness of surface of taper cone or head bore as determined by DIN 4768.

⁴ Available from Beuth Verlag GmbH (DIN—DIN Deutsches Institut für Normung e.V.), Burggrafenstrasse 6, 10787, Berlin, Germany.

⁵ Available from Food and Drug Administration (FDA), 5600 Fishers Ln., Rockville, MD 20857.