



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

This standard is issued under the fixed designation F 2345; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon (ε) indicates an editorial change since the last revision or reapproval.

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 F 603 and F 1873) 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 the 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

- E 4 Practices for Force Verification of Testing Machines
- F 603 Specification for High-Purity Dense Aluminum Oxide for Surgical Implant Application
- F 1873 Specification for High-Purity Dense Ytria Tetragonal Zirconium Oxide Polycrystal (Y-TZP) for Surgical Implant Applications
- F 1875 Practice for Fretting Corrosion Testing of Modular Implant Interfaces: Hip Femoral Head-Bore and Cone Taper Interface

2.2 Other Documents:

- DIN 4768 Determination of Surface Roughness R_a , R_z , and R_{max} with Electric Stylus Instruments; Basic Data³
- FDA Guidance Document for the Preparation of Premarket

Notifications for Ceramic Ball Hip Systems (draft Jan. 10, 1995)⁴

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.

3.1.13 *test frequency*—the rate of cyclic repetition of fatigue loading in cycles per second.

3.1.14 *THR*—total hip replacement.

4. Significance and Use

4.1 These test methods can be used to determine the effects of head and cone materials, design variables, manufacturing,

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.

Current edition approved Nov. 1, 2003. Published January 2004.

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

⁴ Available from Food and Drug Administration (FDA), 5600 Fishers Ln., Rockville, MD 20857.