



Designation: **F2009–00 (Reapproved 2011) F2009 – 20**

Standard Test Method for Determining the Axial Disassembly Force of Taper Connections of Modular Prostheses¹

This standard is issued under the fixed designation F2009; 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 This test method establishes a standard methodology for determining the force required, under laboratory conditions, to disassemble tapers of implants that are otherwise not intended to release. Some examples are the femoral components of a total or partial hip replacement or shoulder in which the head and base component are secured together by a self-locking taper.

1.2 This test method has been developed primarily for evaluation of metal and ceramic head designs on metal tapers but may have application to other materials and designs.

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, health, and environmental practices and determine the applicability of regulatory limitations prior to use.*

1.5 *This international standard was developed in accordance with internationally recognized principles on standardization established in the Decision on Principles for the Development of International Standards, Guides and Recommendations issued by the World Trade Organization Technical Barriers to Trade (TBT) Committee.*

2. Referenced Documents

2.1 *ASTM Standards:*²

[E4 Practices for Force Verification of Testing Machines](#)

~~[F1636 Specification for Bores and Cones for Modular Femoral Heads \(Withdrawn 2001\)](#)~~³

3. Summary of Test Method

3.1 The axial disassembly test method provides a means to measure the axial locking strength of the taper connection for modular prostheses.

3.2 Following assembly, an axial tensile force is applied to disassemble the taper connection and the maximum force is recorded.

4. Significance and Use

4.1 This test method helps to assess the axial locking force of a modular taper. ~~Examples of these devices are described in Specification F1636.~~ Some types of devices that may utilize this type of connection are the modular shoulder and modular hip prostheses. Additional means of evaluating the locking mechanisms of tapers may be appropriate, depending upon the design of the device.

4.2 This test method may not be appropriate for all implant applications. The user is cautioned to consider the appropriateness of the practice in view of the materials and design being tested and their potential application.

4.3 While this test method may be used to measure the force required to disengage tapers, any comparison of such data for various component designs must take into consideration the size of the implant and the type of locking mechanism evaluated.

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.

5. Apparatus

5.1 The cone portion of the assembly shall be constrained by suitable fixtures that can sustain high loads.

5.2 The fixtures shall be constructed so that the line of load application is aligned with the axes of the male and female taper components within $\pm 1^\circ$.

5.2.1 For example, modular heads may be assembled by a solid metal 100° cone as shown in Fig. 1. The cone should provide line contact around the diameter of the head.

5.2.2 For example, modular heads may be disassembled with a metal cage that surrounds the head and provides even contact around the inferior edge of the head as shown in Fig. 2.

5.2.3 One method to minimize misalignment and off-axis loading during constant rate assembly is to include thrust bearing for self-centering of the taper with the assembly cone.

5.2.4 One method to minimize misalignment and off-axis loading during disassembly is to attach both the disassembly cage and trunnion to the testing machine with universal joints.

5.3 The testing machine shall conform to the requirements of Practices E4. The loads used to determine the attachment strength shall be within the range of the testing machine as defined in Practices E4.

5.4 The test machine should be capable of delivering a compressive and tensile force at a constant displacement rate or constant force rate. The test machine should have a load monitoring and recording system.

6. Sampling and Test Specimens

6.1 The male and female taper components can be finished implants or they can be simplified test specimens. The test specimens shall have tapers manufactured to the specifications of a finished implant, including material, and preferably manufactured with the same equipment.

6.2 The supporting material around the female taper shall be similar in size and shape to the finished implant.

6.3 A minimum of five taper assemblies shall be tested to determine the axial disassembly force between the tapered components. Pairing of the components shall be random unless otherwise reported. The appropriateness of performing multiple tests on the same taper connection will depend on the design and application of the device.

6.4 Sterilization of test components is not required unless it has known effects on the parts being evaluated. Generally, sterilization does not have an effect on metallic materials.

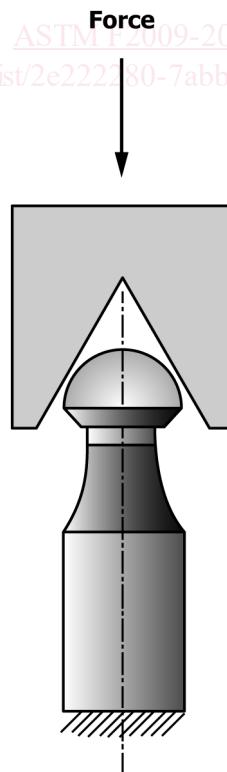


FIG. 1 Modular Head Assembly

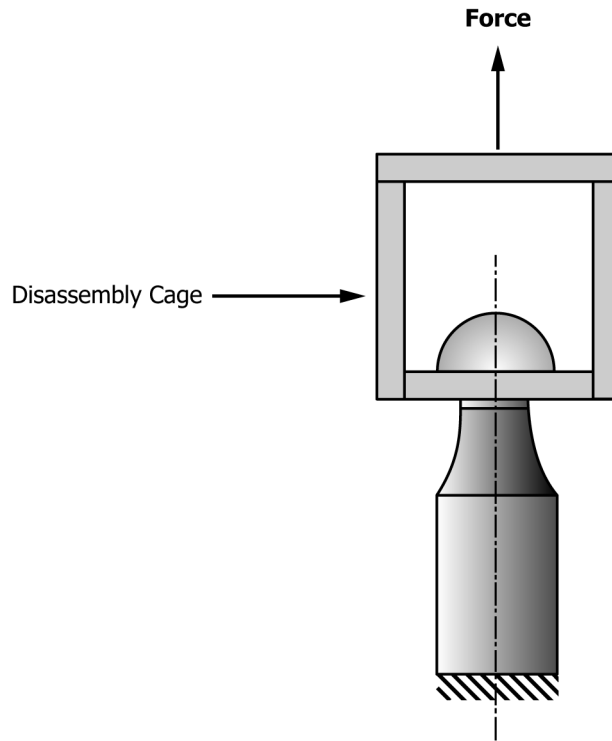


FIG. 2 Modular Head Disassembly

7. Procedure

7.1 Following normal laboratory cleaning procedures to remove any debris or other surface contaminants, the taper components are assembled on a suitable test machine. A suggested procedure for cleaning and drying of the specimens is given in [Appendix XI](#).

7.2 Each specimen should be characterized prior to testing. This information may include, but is not limited to, the following: material, hardness, bore and taper diameters, concentricity, surface roughness, taper angle, and length of engagement.

7.3 Tapers can be assembled using two methods. Depending on the intended use, the user may use the assembly method that best suits the taper application.

7.3.1 *Constant Rate Assembly Method*—A 2 kN peak static load is applied to the taper component along the long axis of the taper within $\pm 1^\circ$; the load may be applied using a constant displacement rate until the maximum load (2 kN) is achieved. A suggested displacement rate is 0.05 mm/s.

7.3.2 *Drop Weight Assembly Method*—The two components may be assembled with an impact load, that is, a 907-g weight dropped from a 254-mm height.

7.4 *Disassembly Procedure*—The taper assembly should be placed in appropriate fixtures in a qualified test machine. The fixture should be capable of maintaining the load axis angle to within $\pm 1^\circ$. Special care should be taken to ensure that no artificial hoop stresses or bending moments are placed on the taper assembly while disassembling the tapers. ~~A displacement rate of 0.05 mm/s may be used.~~ The testing may be performed in displacement-control or force-control. The load and displacement should be recorded continuously until the test is terminated.

7.4.1 For displacement-controlled testing a rate of 0.05 mm/s may be used.

7.4.2 For force-controlled testing a rate of 20 N/s may be used.

7.5 Testing of each specimen shall be terminated when ~~the disassembly load drops by~~ dissociation is evident. This may be indicated by a load drop of at least 90 % of the peak load; load or 1 mm displacement at the taper junction.

8. Report

8.1 The test report shall include the following:

8.1.1 The device name, materials, assembly method, load versus displacement graph, sample size, and manufacturer and lot number, if applicable. Additional information pertaining to the drop weight method is desirable and may include, but is not limited to, the following: description of the drop weight apparatus, drop weight mass, and drop height.

8.1.2 Description of the pre-assembly cleaning method.

8.1.3 The maximum load required to disassemble the tapers.