



Designation: F 1800 – 97 (Reapproved 2003)

Standard Test Method for Cyclic Fatigue Testing of Metal Tibial Tray Components of Total Knee Joint Replacements¹

This standard is issued under the fixed designation F 1800; 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 covers a procedure for the fatigue testing of metallic tibial trays used in knee joint replacements. This test method covers the procedures for the performance of fatigue tests on metallic tibial components using a cyclic, constant-amplitude force. It applies to tibial trays which cover both the medial and lateral plateaus of the tibia. This test method may require modifications to accommodate other tibial tray designs.

1.2 This test method is intended to provide useful, consistent, and reproducible information about the fatigue performance of metallic tibial trays with one unsupported condyle.

1.3 The values stated in SI units are regarded as the standard. The inch-pound units given in parentheses are for information only.

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:

- E 4 Practices for Force Verification of Testing Machines²
- E 467 Practice for Verification of Constant Amplitude Dynamic Loads in an Axial Load Fatigue Testing System²
- E 468 Practice for the Presentation of Constant Amplitude Fatigue Results for Metallic Materials²
- E 1150 Definitions of Terms Relating to Fatigue²

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 *Annual Book of ASTM Standards*, Vol 03.01.

3. Terminology

3.1 Definitions:

3.1.1 *R value*—The R value is the ratio of the minimum load to the maximum load.

$$R = \frac{\text{minimum load}}{\text{maximum load}} \quad (1)$$

3.2 Definitions of Terms Specific to This Standard:

3.2.1 *anteroposterior centerline*—a line that passes through the center of the tibial tray, parallel to the sagittal plane and perpendicular to the line of load application. For asymmetric tibial tray designs, the appropriate center of the tibial tray shall be determined by the investigator and the rationale reported.

3.2.2 *fixture centerline*—a line that passes through the center of the fixture, parallel to the anteroposterior centerline. This line represents the separation between the supported and unsupported portions of the test fixture.

3.2.3 *mediolateral centerline*—a line that passes through the center of the tibial tray, parallel to the coronal, or frontal, plane and perpendicular to the line of load application. For asymmetric tibial tray designs, the appropriate center of the tibial tray shall be determined by the investigator and the rationale reported.

3.2.4 *moment arm “d_{ap}”*—the perpendicular distance between the mediolateral centerline of the tibia component and the line of load application.

3.2.5 *moment arm “d_{ml}”*—the perpendicular distance between the anteroposterior centerline of the tibia component and the line of load application.

4. Significance and Use

4.1 This test method can be used to describe the effects of materials, manufacturing, and design variables on the fatigue performance of metallic tibial trays subject to cyclic loading for relatively large numbers of cycles.