



Standard Practice for Corrosion Fatigue Testing of Metallic Implant Materials¹

This standard is issued under the fixed designation F1801; 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 practice covers the procedure for performing corrosion fatigue tests to obtain S - N fatigue curves or statistically derived fatigue strength values, or both, for metallic implant materials. This practice describes the testing of axially loaded fatigue specimens subjected to a constant amplitude, periodic forcing function in saline solution at 37°C and in air at room temperature. The environmental test method for implant materials may be adapted to other modes of fatigue loading such as bending or torsion. While this practice is not intended to apply to fatigue tests on implantable components or devices, it does provide guidelines for fatigue tests with standard specimens in an environment related to physiological conditions.

1.2 The values stated in either SI units or inch-pound units are to be regarded separately as standard. The values stated in each system may not be exact equivalents; therefore, each system shall be used independently of the other. Combining values from the two systems may result in non-conformance with the standard.

1.3 *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
- E466 Practice for Conducting Force Controlled Constant Amplitude Axial Fatigue Tests of Metallic Materials
- E467 Practice for Verification of Constant Amplitude Dynamic Forces in an Axial Fatigue Testing System
- E468 Practice for Presentation of Constant Amplitude Fa-

tigue Test Results for Metallic Materials

- E739 Practice for Statistical Analysis of Linear or Linearized Stress-Life (S - N) and Strain-Life (ϵ - N) Fatigue Data
 - E1012 Practice for Verification of Testing Frame and Specimen Alignment Under Tensile and Compressive Axial Force Application
 - E1150 Definitions of Terms Relating to Fatigue (Withdrawn 1996)³
 - F86 Practice for Surface Preparation and Marking of Metallic Surgical Implants
 - F601 Practice for Fluorescent Penetrant Inspection of Metallic Surgical Implants
 - G15 Terminology Relating to Corrosion and Corrosion Testing (Withdrawn 2010)³
- 2.2 ANSI Standard:
ANSI B46.1 Surface Texture⁴

3. Terminology

3.1 Definitions:

3.1.1 The terminology used in conjunction with this practice complies to Terminology E1150 and Terminology G15.

3.2 Definitions of Terms Specific to This Standard:

3.2.1 S - N curves— S - N curves (also known as Wöhler-curves) show the correlation between the applied stress (S) and the counted number (N) of cycles to failure.

4. Significance and Use

4.1 Implants, particularly orthopedic devices, are usually exposed to dynamic forces. Thus, implant materials must have high fatigue resistance in the physiological environment.

4.1.1 This practice provides a procedure for fatigue testing in a simulated physiological environment. Axial tension-tension fatigue tests in an environmental test chamber are recommended as a standard procedure. The axial fatigue loading shall comply with Practice E466 and Practice E467.

4.1.1.1 Bending and rotating bending beam fatigue tests or torsion tests may be performed in a similar environmental cell.

4.1.2 This practice is intended to assess the fatigue and corrosion fatigue properties of materials that are employed or

¹ This practice is under the jurisdiction of ASTM Committee F04 on Medical and Surgical Materials and Devices and is the direct responsibility of Subcommittee F04.15 on Material Test Methods.

Current edition approved Oct. 1, 2014. Published November 2014. Originally approved in 1997. Last previous edition approved in 2009 as F1801 – 97(2009)^{ε1}. DOI: 10.1520/F1801-97R14.

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.

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