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Standard Specification and Test Methods for Intramedullary Fixation Devices¹

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^{ε1} NOTE—Editorial changes were made throughout in November 2016.

1. Scope

1.1 This specification is intended to provide a characterization of the design and mechanical function of intramedullary fixation devices (IMFDs), specify labeling and material requirements, provide test methods for characterization of IMFD mechanical properties, and identify needs for further development of test methods and performance criteria. The ultimate goal is to develop a standard which defines performance-related mechanical characteristics of IMFDs and their fixation to bone. It is not the intention of this specification to define levels of performance or case-specific clinical performance of these devices, as insufficient knowledge to predict the consequences of the use of any of these devices in individual patients for specific activities of daily living is available. It is not the intention of this specification to describe or specify specific designs for IMFDs.

1.2 This specification describes IMFDs for surgical fixation of the skeletal system. It provides basic IMFD geometrical definitions, dimensions, classification, and terminology; labeling and material specifications; performance definitions; test methods and characteristics determined to be important to *in-vivo* performance of the device.

1.3 *Multiple test methods are included in this standard. However, the user is not necessarily obligated to test using all of the described methods. Instead, the user should only select, with justification, test methods that are appropriate for a particular device design. This may be only a subset of the herein described test methods.*

1.4 This specification includes four standard test methods:

1.4.1 Static Four-Point Bend Test Method—[Annex A1](#) and

1.4.2 Static Torsion Test Method—[Annex A2](#).

1.4.3 Bending Fatigue Test Method—[Annex A3](#).

1.4.4 Test Method for Bending Fatigue of IMFD Locking Screws—[Annex A4](#).

1.5 A rationale is given in [Appendix X1](#).

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

2. Referenced Documents

2.1 *ASTM Standards*:²

[A214/A214M](#) Specification for Electric-Resistance-Welded Carbon Steel Heat-Exchanger and Condenser Tubes

[A450/A450M](#) Specification for General Requirements for Carbon and Low Alloy Steel Tubes

[D790](#) Test Methods for Flexural Properties of Unreinforced and Reinforced Plastics and Electrical Insulating Materials

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

[E691](#) Practice for Conducting an Interlaboratory Study to Determine the Precision of a Test Method

[F86](#) Practice for Surface Preparation and Marking of Metallic Surgical Implants

[F138](#) Specification for Wrought 18Chromium-14Nickel-2.5Molybdenum Stainless Steel Bar and Wire for Surgical Implants (UNS S31673)

[F339](#) Specification for Cloverleaf Intramedullary Pins (Withdrawn 1998)³

[F383](#) Practice for Static Bend and Torsion Testing of Intramedullary Rods (Withdrawn 1996)³

[F565](#) Practice for Care and Handling of Orthopedic Implants and Instruments

[F1611](#) Specification for Intramedullary Reamers

[F2503](#) Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment

[F2809](#) Terminology Relating to Medical and Surgical Materials and Devices

¹ This specification is under the jurisdiction of ASTM Committee F04 on Medical and Surgical Materials and Devices and is the direct responsibility of Subcommittee F04.21 on Osteosynthesis.

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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.