



Standard Specification and Test Methods for Intramedullary Fixation Devices¹

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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 criteria and methods for measurement of 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 is available to predict the consequences of the use of any of these devices in individual patients for specific activities of daily living. 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 IFMD 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 This specification includes four standard test methods:

1.3.1 Static Four-Point Bend Test Method—Annex A1, and

1.3.2 Static Torsion Test Method—Annex A2.

1.3.3 Bending Fatigue Test Method—Annex A3.

1.3.4 Test Method for Bending Fatigue of IMFD Locking Screws—Annex A4.

1.4 A Rationale is given in Appendix X1.

1.5 The values stated in SI units are to be regarded as the standard.

2. Referenced Documents

2.1 ASTM Standards:

A 214/A 214M Specification for Electric-Resistance-Welded Carbon Steel Heat Exchanger and Condenser Tubes²

A 450/A 450M Specification for General Requirements for

Carbon, Ferritic Alloy, and Austenitic Alloy Steel Tubes²
D 790 Test Methods for Flexural Properties of Unreinforced and Reinforced Plastics and Electrical Insulating Materials²

E 4 Practices for Force Verification of Testing Machines³

E 691 Practice for Conducting an Interlaboratory Study to Determine the Precision of a Test Method⁴

F 86 Practice for Surface Preparation and Marking of Metallic Surgical Implants⁵

F 138 Specification for Wrought-18 Chromium-14 Nickel-12.5 Molybdenum Stainless Steel Bar and Wire for Surgical Implants (UNS S31673)⁵

F 339 Specification for Cloverleaf Intramedullary Pins^{6,7}

F 383 Practice for Static Bend and Torsion Testing of Intramedullary Rods⁵

F 565 Practice for Care and Handling of Orthopaedic Implants and Instruments⁵

F 1611 Terminology for Sizing of IMFDs for Application to Reamed Diaphyseal Bone and Associated Instrumentation⁵

2.2 AMS Standard:

AMS 5050⁸ Steel Tubing, Seamless, 0.15 Carbon, Maximum Annealed

2.3 SAE Standard:

SAE J524⁹ Seamless Low-Carbon Steel Tubing Annealed for Bending and Flaring

3. Terminology

3.1 Definitions for Geometric:

3.1.1 *closed section, n*—any cross section perpendicular to the longitudinal axis of a solid IMFD, or hollow IMFD where there is no discontinuity of the outer wall. In order to orient the IMFD for testing and for insertion, the desired relationship of any irregularities, asymmetries, etc., to the sagittal and coronal planes should be described for the intended applications.

3.1.2 *IMFD curvature, n*—dimensions of size and locations of arcs of the curvature, or mathematical description of the curvature, or other quantitative descriptions to which the curvature is manufactured along with tolerances. In order to

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² Annual Book of ASTM Standards, Vol 08.01.

³ Annual Book of ASTM Standards, Vol 03.01.

⁴ Annual Book of ASTM Standards, Vol 14.02.

⁵ Annual Book of ASTM Standards, Vol 13.01.

⁶ Discontinued; see 1998 Annual Book of ASTM Standards, Vol 13.01.

⁷ Discontinued; see 1996 Annual Book of ASTM Standards, Vol 13.01.

⁸ Available from the Society of Automotive Engineers, 400 Commonwealth Dr., Warrendale, PA 15096.

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