Designation: F1264 – 24

Standard Specification and Test Methods for Intramedullary Fixation Devices[1]

This standard is issued under the fixed designation F1264; 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 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 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.

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.

1.7 *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.*

1.8 *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]

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 Calibration and 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]

[1] This specification and test methods are under the jurisdiction of ASTM Committee F04 on Medical and Surgical Materials and Devices and are 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 www.astm.org/contact. 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.

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 (Withdrawn 2019)[3]

2.2 *AMS Standard:*[4]
AMS 5050 Steel Tubing, Seamless, 0.15 Carbon, Maximum Annealed

2.3 *SAE Standard:*[4]
SAE J524 Seamless Low-Carbon Steel Tubing Annealed for Bending and Flaring

3. Terminology

3.1 *Definitions—Geometric:*

3.1.1 *closed section, n*—any cross section perpendicular to the longitudinal axis of a solid or hollow IMFD in which there is no discontinuity of the outer wall.

3.1.1.1 *Discussion*—To orient the IMFD for testing and for insertion, the desired relationship of any irregularities, asymmetries, and so forth, to the sagittal and coronal planes for the intended applications should be described.

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.

3.1.2.1 *Discussion*—To orient the IMFD for testing and for insertion, the desired relationship of the curvature to the sagittal and coronal planes for the intended applications should be described.

3.1.3 *IMFD diameter, n*—diameter of the circumscribed circle that envelops the IMFD's cross section when measured along its working length. If the diameter is not constant along the working length, then the site of measurement should be indicated.

3.1.4 *IMFD length, n*—length of a straight line between the most proximal and distal ends of the IMFD.

3.1.5 *open section, n*—any cross section perpendicular to the longitudinal axis of a hollow IMFD in which there is a discontinuity of the outer wall.

3.1.5.1 *Discussion*—To orient the IMFD for testing and insertion, the desired relationship of the discontinuity to the sagittal and coronal planes for the intended applications should be described.

3.1.6 *potential critical stress concentrator (CSC), n*—any change in section modulus, material property, discontinuity, or other feature of a design expected to cause a concentration of stress in a region of the IMFD expected to be highly stressed under the normal anticipated loading conditions.

3.1.7 *tolerance, n*—acceptable deviations from the nominal size of any dimension describing the IMFD.

3.1.8 *working length, n*—length of uniform cross section of the IMFD intended to obtain some type of fit to the medullary canal in the area of the diaphysis.

3.2 *Definitions—Mechanical/Structural:*

3.2.1 *bending compliance, n*—reciprocal of the stiffness of the IMFD under a bending load in a specified plane as defined and determined in the static four-point bend test described in Annex A1.

3.2.2 *failure strength, n*—the force parameter (for example, load, moment, torque, stress, and so forth) required to meet the failure criteria, as defined and measured according to the test conducted. (See Note 1.)

NOTE 1—No present testing standard exists related to this term for IMFDs.

3.2.3 *fatigue strength at N cycles, n*—the maximum cyclic force parameter (for example, load, moment, torque, stress, and so forth) for a given load ratio, which produces device structural damage or meets some other failure criterion in no less than *N* cycles as defined and measured according to the test conducted.

3.2.4 *N*—a variable representing a specified number of cycles.

3.2.5 *no load motion, n*—relative motion between the IMFD and the bone that occurs with no elastic strain in the device and no (or minimal) change in load. (See Note 1.)

3.2.6 *structural stiffness, n*—the maximum slope of the elastic portion of the load-displacement curve as defined and measured according to the test conducted.

3.2.6.1 *Discussion*—For bending in a specified plane, this term is defined and determined in the static four-point bend test described in Annex A1.

3.2.7 *ultimate strength, n*—maximum force parameter (for example, load, moment, torque, stress, and so forth) which the structure can support, defined and measured according to the test conducted.

3.2.8 *yield strength, n*—the force parameter (for example, load, moment, torque, stress, and so forth) which initiates permanent deformation as defined and measured according to the test conducted.

4. Classification

4.1 The following IMFDs may be used singly, multiply, and with or without attached supplemental fixation: solid cross section, hollow cross section (open, closed, or a combination).

4.2 Intended application or use for particular IMFD designs:
4.2.1 *Preferred Orientation:*
4.2.1.1 Right versus left,
4.2.1.2 Sagittal versus coronal plane,
4.2.1.3 Proximal versus distal, and
4.2.1.4 Universal or multiple options.
4.2.2 *Preferred Anatomic Location:*
4.2.2.1 Specific bone,
4.2.2.2 Proximal versus distal versus midshaft, and
4.2.2.3 Universal or multiple options.
4.2.3 *Preferred Use Limited to Specific Procedures:*
4.2.3.1 Acute care of fractures,

[4] Available from Society of Automotive Engineers (SAE), 400 Commonwealth Dr., Warrendale, PA 15096-0001, http://www.sae.org.