Designation: F2502 – 24

Standard Specification and Test Methods for Absorbable Plates and Screws for Internal Fixation Implants[1]

This standard is issued under the fixed designation F2502; 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 and test methods cover the mechanical characterization of plates and screws for orthopedic internal fixation. Covered devices are fabricated from one or more hydrolytically degradable polymer (from this point on referred to as "absorbable") resins or resin composites.

1.2 This specification establishes a common terminology to describe the size and other physical characteristics of absorbable implants and performance definitions related to the performance of absorbable devices.

1.3 This specification establishes standard test methods to consistently measure performance-related mechanical characteristics of absorbable devices when tested under defined conditions of pretreatment, temperature, humidity, and testing machine speed.

1.4 This specification may not be appropriate for all absorbable devices, especially those that possess limited hydrolytic susceptibility and degrade *in vivo* primarily through enzymatic action. The user is cautioned to consider the appropriateness of the standard in view of the particular absorbable device and its potential application.

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

1.6 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 test methods described herein.

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]

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

E6 Terminology Relating to Methods of Mechanical Testing

E122 Practice for Calculating Sample Size to Estimate, With Specified Precision, the Average for a Characteristic of a Lot or Process

E1823 Terminology Relating to Fatigue and Fracture Testing

F116 Specification for Medical Screwdriver Bits

F382 Specification and Test Method for Metallic Bone Plates

F543 Specification and Test Methods for Metallic Medical Bone Screws

F565 Practice for Care and Handling of Orthopedic Implants and Instruments

F1088 Specification for Medical-Grade Beta-Tricalcium Phosphate Raw Material for Implantable Medical Devices

F1185 Specification for Composition of Medical-Grade Hydroxylapatite for Surgical Implants

F1635 Test Method for ***in vitro*** Degradation Testing of Hydrolytically Degradable Polymer Resins and Fabricated Forms for Surgical Implants

F1839 Specification for Rigid Polyurethane Foam for Use as a Standard Material for Testing Orthopaedic Devices and Instruments

[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.

F1925 Specification for Semi-Crystalline Poly(lactide) Polymer and Copolymer Resins for Surgical Implants
F2313 Specification for Poly(glycolide) and Poly(glycolide-co-lactide) Resins for Surgical Implants with Mole Fractions Greater Than or Equal to 70 % Glycolide
F2503 Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment
F2579 Specification for Amorphous Poly(lactide) and Poly(lactide-co-glycolide) Resins for Surgical Implants
F2902 Guide for Assessment of Absorbable Polymeric Implants
F3160 Guide for Metallurgical Characterization of Absorbable Metallic Materials for Medical Implants

2.2 *ISO Standards:*[3]

ISO 13781 Poly (L-Lactide) Resins and Fabricated Forms for Surgical Implants—In Vitro Degradation Testing
ISO 14630 Non-Active Surgical Implants—General Requirements
ISO 15814 Copolymers and Blends Based on Polylactide—In Vitro Degradation Testing

3. Terminology

3.1 *Definitions:*

3.1.1 Unless otherwise defined in this specification, the terminology related to mechanical testing that is used in these test methods will be in accordance with the definitions of Terminologies E6 and E1823, and Specifications F382 and F543.

3.2 *General Definitions:*

3.2.1 *absorbable, adj*—in the body, referring to an initially distinct foreign material or substance that either directly or through intended degradation can pass through or be assimilated by cells and/or tissue.

NOTE 1—See X1.5 for a discussion regarding the usage of "absorbable" and other related terms.

3.2.2 *absorbable composite*—an absorbable polymer resin or construct incorporating a particulate and/or fibrous bioactive and/or absorbable filler material.

3.2.3 *bone plate*—a device, when affixed with screws or cerclage wire, intended to provide alignment of two or more bone sections, primarily by spanning the fracture or defect. A bone plate has two or more holes. Its width and thickness usually are not the same in magnitude.

3.2.4 *deterioration*—the reduction or worsening of mechanical or other functional performance properties of a device.

3.2.5 *hydrolytically degradable polymer*—any polymeric material in which the primary mechanism of chemical degradation in the body is by hydrolysis (water reacting with the polymer resulting in cleavage of the chain).

3.3 *Definitions of Terms Specific to This Standard:*

3.3.1 *insertion depth (mm)*—the linear advancement of a device into the test block measured relative to its seated position at the test block's surface prior to testing.

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

4. Significance and Use

4.1 Absorbable devices are intended to degrade and absorb over time once they are implanted into the body. This makes a removal operation unnecessary, which is especially advantageous for pediatric patients.

4.2 While the polymer degrades due to hydrolytic reaction with the environment, the mechanical performance of the device also deteriorates. The key to developing mechanically effective fracture fixation systems based on absorbable devices is to provide an adequate level of fixation strength and stiffness for a time frame that exceeds that expected for fracture healing. Once the fracture is healed, the device can be completely absorbed by the body. The biological performance of the device, particularly for application at a bony site, may be enhanced by incorporation of bioactive fillers in the polymer.

4.3 Absorbable devices will be tested using test methods that are similar to those used to evaluate conventional metallic devices. The pre-test conditioning requirements, handling requirements, and time-dependent mechanical property evaluations for absorbable devices shall be considered.

4.4 This specification and accompanying test methods are intended to complement the more general considerations for the assessment of absorbable polymeric implants that are described within Guide F2902.

5. Materials and Manufacture

5.1 Absorbable devices may be fabricated from one of the following materials:

5.1.1 L-lactide, D-lactide, D, L-lactide, glycolide, or other known hydrolytically degradable polymer resins or copolymers. (For additional information, see complementary test methods found in ISO 13781, ISO 15814, and Test Method F1635, and in related Specifications F1925, F2313, and F2579.)

5.1.2 Other absorbable polymeric, ceramic, or metallic based constructs that degrade through non-hydrolytic means, such as those described in Specifications F1088 and F1185, and Guide F3160 may be considered, but precautions should be undertaken to ensure a materials-appropriate degradation environment is maintained.

5.2 The manufacturer shall ensure that materials used to manufacture absorbable implants are suitable for implanting into the body. Methods to evaluate a material's suitability are described in ISO 14630.

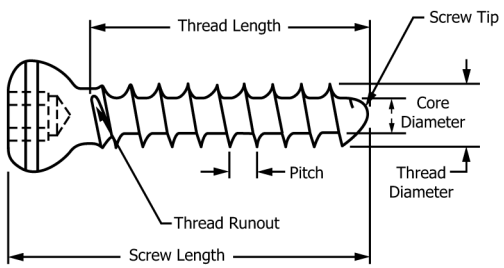

FIG. 1 Screw Parameters