



Standard Specification and Test Methods for Absorbable Plates and Screws for Internal Fixation Implants¹

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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 *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.*

¹ This specification and test methods 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. 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 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 Beta-Tricalcium Phosphate for Surgical Implantation

F1185 Specification for Composition of 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

F1925 Specification for Semi-Crystalline Poly(lactide) Polymer and Copolymer Resins for Surgical Implants

2.2 ISO Standards:³

ISO 13781 Poly (L-Lactide) Resins and Fabricated Forms for Surgical Implants—In Vitro Degradation Testing

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