



Standard Guide for Testing Absorbable Stents¹

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1. Scope

1.1 This Guide covers select physical and mechanical characterizations of vascular stents with one or more absorbable components. Such absorbable stents (also referred to as vascular scaffolds) are used to provide temporary luminal support of the coronary and peripheral vasculature following interventional revascularization procedures. This Guide covers devices that are fabricated from one or more degradable polymers and/or metals (from this point on referred to as “absorbable”). This Guide provides a framework for evaluating the change in select physical and mechanical characteristics of absorbable stents from manufacture through their intended degradation *in vivo*. Specific testing recommendations are limited to existing ASTM standards for stent evaluation.

1.2 Recommendations specific to non-absorbable stents with absorbable coatings are not within scope.

1.3 Recommendations specific to testing absorbable stent grafts are not provided here, however this standard has many elements applicable to testing absorbable stent grafts.

1.4 Clinical need dictates that absorbable stents initially possess the same general dimensions and mechanical function as their non-absorbable counterparts. Thus, utilization of already established mechanical stent evaluation methods is possible when absorbable test specimens are previously conditioned under physiologically relevant temperature and humidity. As a result, this standard addresses absorbable-specific testing issues related to the mechanical and physical evaluation of these devices. This standard is limited to providing absorbable-specific testing recommendations for evaluations where an ASTM method for durable (i.e., non-absorbable) stents is already available. Specifically, this standard provides testing recommendations for adapting the elastic recoil (ASTM F2079), securement/dislodgement (ASTM F2394), and three-point bending (ASTM F2606) tests to fully absorbable devices. This guide generally describes specimen conditioning, as appropriate, for absorbable devices, which can range from none to extensive – depending on the measured attribute and

relevant clinical exposure conditions, including time in the in-use environment. There are additional stent evaluation methods that are not addressed explicitly in this guide, e.g., chronic durability, that may require absorbable-specific provisions. The user should justify the appropriate testing for the specific polymer and device.

1.4.1 While the primary purpose of this guide is to address absorbable stent-related issues specific to the tests described in Section 1.3, additional testing (e.g., radial strength) will likely also be needed. Thus, aspects of what is presented herein may be applicable to additional relevant device attributes, such as those described in ISO 25539-1 and/or 25539-2.

1.5 This Guide may not be appropriate for all absorbable devices, for example those that possess limited hydrolytic or corrosion 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.

1.6 This Guide does not address the methods necessary to characterize the chemical degradation of the absorbable stent (e.g., changes in mass, molecular weight, or degradants). However, this type of characterization does represent an important component of the degradation profile and mechanism of the device. These characterizations are addressed in ASTM F1635.

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

1.8 *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.*

2. Referenced Documents

2.1 ASTM Standards:²

D618 Practice for Conditioning Plastics for Testing
E6 Terminology Relating to Methods of Mechanical Testing

¹ This test method is under the jurisdiction of ASTM Committee F04 on Medical and Surgical Materials and Devices and is the direct responsibility of Subcommittee F04.30 on Cardiovascular Standards.

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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.