



Standard Guide for Metallurgical Characterization of Absorbable Metallic Materials for Medical Implants¹

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1. Scope

1.1 This guidance document provides metallurgical characterization information that may be beneficial in the evaluation of absorbable metallic materials intended for medical implant applications. This guide is primarily intended for absorbable metallic materials that undergo further processing into a fabricated final device. Therefore, this standard does not require assessments that are more appropriately conducted on the final device, such as biological evaluation. However, a few relevant standards for finished implant devices are included for information purposes.

1.2 The purpose of this guide is to identify appropriate test methods and relevant medical product standards that can be used to develop future standards for new or modified absorbable metallic materials.

1.3 This guide is not intended to cover other major classes of absorbable materials such as polymers, ceramics, composites, and tissue-engineered materials.

1.4 This standard guide is focused on the chemical, physical, microstructural, and mechanical properties plus inspection guidelines for metallic materials that are used for medical implants designed to be absorbed in the body over a period of time. This guide focuses on material characterizations and does not address device specific mechanical testing that may be necessary to determine safety and functionality of the implant.

1.5 Compliance with materials specifications developed in accordance with this standard may not necessarily result in a material suitable for its intended purpose. Additional testing specific to the intended use may be required.

1.6 Since surface modifications of medical implants are generally applied in the latter stages of manufacturing, this standard guide does not cover the characterization of either absorbable or non-absorbable surface coatings that are metallic in origin such as oxides or from the addition of other materials

such as ceramics or polymers. However, this standard does apply to absorbable metallic materials, regardless of the presence or absence of a coating.

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 and health practices and determine the applicability of regulatory limitations prior to use.

2. Referenced Documents

2.1 ASTM Standards:²

- A262 Practices for Detecting Susceptibility to Intergranular Attack in Austenitic Stainless Steels
- A342/A342M Test Methods for Permeability of Weakly Magnetic Materials
- A480/A480M Specification for General Requirements for Flat-Rolled Stainless and Heat-Resisting Steel Plate, Sheet, and Strip
- A484/A484M Specification for General Requirements for Stainless Steel Bars, Billets, and Forgings
- A555/A555M Specification for General Requirements for Stainless Steel Wire and Wire Rods
- A751 Test Methods, Practices, and Terminology for Chemical Analysis of Steel Products
- A957 Specification for Investment Castings, Steel and Alloy, Common Requirements, for General Industrial Use
- B69 Specification for Rolled Zinc
- B80 Specification for Magnesium-Alloy Sand Castings
- B86 Specification for Zinc and Zinc-Aluminum (ZA) Alloy Foundry and Die Castings
- B90/B90M Specification for Magnesium-Alloy Sheet and Plate
- B107/B107M Specification for Magnesium-Alloy Extruded Bars, Rods, Profiles, Tubes, and Wire
- B199 Specification for Magnesium-Alloy Permanent Mold Castings
- B403 Specification for Magnesium-Alloy Investment Castings

¹ This guide is under the jurisdiction of ASTM Committee F04 on Medical and Surgical Materials and Devices and is the direct responsibility of Subcommittee F04.12 on Metallurgical Materials.

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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.