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Standard Guide for Metallurgical Characterization of Absorbable Metallic Materials for Medical Implants[1]

This standard is issued under the fixed designation F3160; 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 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

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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.

B557M Test Methods for Tension Testing Wrought and Cast Aluminum- and Magnesium-Alloy Products (Metric)
B661 Practice for Heat Treatment of Magnesium Alloys
B949 Specification for General Requirements for Zinc and Zinc Alloy Products
B953 Practice for Sampling Magnesium and Magnesium Alloys for Spectrochemical Analysis
B954 Test Method for Analysis of Magnesium and Magnesium Alloys by Atomic Emission Spectrometry
D3648 Practices for the Measurement of Radioactivity
E8/E8M Test Methods for Tension Testing of Metallic Materials
E18 Test Methods for Rockwell Hardness of Metallic Materials
E29 Practice for Using Significant Digits in Test Data to Determine Conformance with Specifications
E45 Test Methods for Determining the Inclusion Content of Steel
E112 Test Methods for Determining Average Grain Size
E290 Test Methods for Bend Testing of Material for Ductility
E340 Practice for Macroetching Metals and Alloys
E354 Test Methods for Chemical Analysis of High-Temperature, Electrical, Magnetic, and Other Similar Iron, Nickel, and Cobalt Alloys
E384 Test Method for Microindentation Hardness of Materials
E407 Practice for Microetching Metals and Alloys
E536 Test Methods for Chemical Analysis of Zinc and Zinc Alloys
E1245 Practice for Determining the Inclusion or Second-Phase Constituent Content of Metals by Automatic Image Analysis
E1382 Test Methods for Determining Average Grain Size Using Semiautomatic and Automatic Image Analysis
E1441 Guide for Computed Tomography (CT) Imaging
E2627 Practice for Determining Average Grain Size Using Electron Backscatter Diffraction (EBSD) in Fully Recrystallized Polycrystalline Materials
F601 Practice for Fluorescent Penetrant Inspection of Metallic Surgical Implants
F629 Practice for Radiography of Cast Metallic Surgical Implants
F2052 Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment
F2119 Test Method for Evaluation of MR Image Artifacts from Passive Implants
F2182 Test Method for Measurement of Radio Frequency Induced Heating On or Near Passive Implants During Magnetic Resonance Imaging
F2213 Test Method for Measurement of Magnetically Induced Torque on Medical Devices in the Magnetic Resonance Environment
F2229 Specification for Wrought, Nitrogen Strengthened 23Manganese-21Chromium-1Molybdenum Low-Nickel Stainless Steel Alloy Bar and Wire for Surgical Implants (UNS S29108)
F2393 Specification for High-Purity Dense Magnesia Partially Stabilized Zirconia (Mg-PSZ) for Surgical Implant Applications
F2581 Specification for Wrought Nitrogen Strengthened 11Manganese-17Chromium-3Molybdenum Low-Nickel Stainless Steel Alloy Bar and Wire for Surgical Implants (UNS S29225)
F2902 Guide for Assessment of Absorbable Polymeric Implants
IEEE/ASTM SI 10 American National Standard for Metric Practice

2.2 *Aerospace Material Standards (AMS):*[3]

AMS 2248 Chemical Check Analysis Limits Corrosion and Heat Resistant Steels and Alloys, Maraging and Other Highly-Alloyed Steels, and Iron Alloys
AMS 2630 Inspection, Ultrasonic Product Over 0.5 inch (12.7 mm) Thick
AMS 2632 Ultrasonic Inspection of Thin Materials

2.3 *ISO Standards:*[4]

ISO 404 Steel and Steel Products—General Technical Delivery Requirements
ISO 643 Steels—Micrographic Determination of the Apparent Grain Size
ISO 3116 Magnesium and Magnesium Alloys—Wrought Magnesium Alloys—Fourth edition
ISO 3815-1 Zinc and Zinc Alloys—Part 1: Analysis of Solid Samples by Optical Emission Spectrometry
ISO 3815-2 Zinc and Zinc Alloys—Part 2: Analysis by Inductively Coupled Optical Emission Spectrometry
ISO 4967 Steel—Determination of Content of Nonmetallic Inclusions—Micrographic Method Using Standard Diagrams
ISO 6892-1 Metallic Materials—Tensile Testing—Part 1: Method of Test at Room Temperature
ISO 10993-15 Biological Evaluation of Medical Devices—Part 15: Identification and Quantification of Degradation Products from Metals and Alloys
ISO 10993-17 Biological Evaluation of Medical Devices—Part 17: Establishment of Allowable Limits for Leachable Substances
ISO 10993-18 Biological Evaluation of Medical Devices—Part 18: Chemical Characterization of Materials
ISO/TS 10993-19-Part 19 Physico-chemical, Morphological and Topographical Characterization of Materials
ISO 13067 Microbeam Analysis—Electron Backscatter Diffraction—Measurement of Average Grain Size
ISO 13485 Medical Devices Quality Management Systems—Requirements for Regulatory Purposes—Second edition
ISO 16220 Magnesium and Magnesium Alloys—Magnesium Alloy Ingots and Castings
ISO/TS 17137 Cardiovascular Implants and Extracorporeal Systems—Cardiovascular Absorbable Implants

[3] Available from SAE International (SAE), 400 Commonwealth Dr., Warrendale, PA 15096, http://www.sae.org.
[4] Available from American National Standards Institute (ANSI), 25 W. 43rd St., 4th Floor, New York, NY 10036, http://www.ansi.org.

ISO 24173 Microbeam Analysis—Guidelines for Orientation Measurement Using Electron Backscatter Diffraction
ISO/TR 37137 Biological Evaluation of Medical Devices—Guidance for Absorbable Implants
ISO 9001 Quality Management Systems—Requirements

3. Terminology

3.1 *Definitions:*

3.1.1 *absorbable, adj—in the body*, an initially distinct foreign material or substance that either directly or through intended degradation can pass through or be metabolized or assimilated by cells and/or tissue. **F2902**

4. Summary of Guide

4.1 Novel absorbable metallic implant materials that do not yet have industry standards are being developed for use in applications such as cardiovascular, orthopedic, general surgical, and diagnostic. The lack of a standard guide for the metallurgical characterization of these new materials may contribute to material property non-uniformity which could create variation in the observed performance of the final product. It is the intent of this guide to provide material property information, corresponding test methods, and relevant medical product standards to serve as a guide for the metallurgical characterization of new or modified materials. These guidelines are tabulated to assist with the development of specifications for new or modified absorbable metallic materials.

4.2 This guide is focused on providing a characterization scheme for materials prior to their fabrication into a finished medical implant. The characterization and testing of absorbable metallic materials after they have been manufactured into finished and sterilized medical implants will depend on the design, mass, shape, anatomic location, and end-use application.

5. Significance and Use

5.1 The metallurgical properties of materials used to manufacture absorbable metallic implants can influence biological reactions and mechanical interaction with soft and hard tissue in the body. This standard guide describes a suggested material characterization scheme for absorbable metallic materials to ensure reproducibility of properties prior to their manufacture into medical implants.

6. Characterization

6.1 *Overview:*

6.1.1 The metallurgical characterization of absorbable metallic materials includes the influence of chemical, microstructural, physical, and mechanical properties in addition to material inspection methods that are utilized to document initial material quality and uniformity.

6.1.2 This metallurgical characterization guide will focus on magnesium (Mg)-base, iron (Fe)-base, and zinc (Zn)-base alloys since these are the main classes of metallic materials that have been documented in the literature for potential absorbable metallic implant applications. This guide may be applicable to other absorbable alloy systems.

6.1.3 The below described evaluations are general in their scope, with additional unlisted material assessments potentially needed to address the performance requirements of a specific implant application.

6.2 *General:*

6.2.1 General requirements are specified in B90/B90M and B107/B107M for wrought Mg-base product forms; A480/A480M, A484/A484M, and A555/A555M for wrought Fe-base product forms; and B949 for Zn-base product forms.

6.2.2 Requirements are specified in B403 for Mg-base castings; A957 for Fe-base castings; and B86 for Zn-base castings.

6.3 *Chemical:*

6.3.1 Some examples of absorbable Mg compositions that have been investigated to date include pure Mg, conventional Mg alloys, and experimental Mg alloys containing combinations of aluminum (Al), calcium (Ca), lithium (Li), manganese (Mn), neodymium (Nd), rare earth (RE), silver (Ag), yttrium (Y), zinc (Zn), or zirconium (Zr).

6.3.2 Some examples of absorbable Fe compositions that have been investigated to date include pure Fe, a range of Fe-Mn alloys with and without silicon (Si) or palladium (Pd), and novel binary Fe compositions containing either aluminum (Al), boron (B), carbon, (C), cobalt (Co), sulfur (S), or tungsten (W).

6.3.3 Some examples of absorbable Zn compositions that have been investigated to date include pure Zn, commercial Zn alloys, and binary Zn-Mg combinations.

6.3.4 Relevant technical information[5] has been published for the majority of the absorbable alloy compositions documented in 6.3.1 and 6.3.2.

6.3.5 Elemental concentrations present at specified major, minor, residual, or trace levels are defined in A751 and ISO 3116. Within this context, a trace classification does not include elements that are a specified component of the alloy, regardless of concentration.

NOTE 1—For the materials covered by this standard, no biocompatibility assessment is required since this standard focuses on characterization of materials that are subject to further fabrication into a final device. However, since the overall composition of any absorbable implant can be expected to have a significant impact on its biocompatibility, the entire composition of materials covered by this standard (including the intended composition, metallic degradation species, and any residual or trace metallic or non-metallic impurities) should be preliminarily assessed for their potential impact on any later ISO 10993 risk assessment of the final device. In addition to the ISO 10993 series, additional supplemental guidance specific for the biological evaluation of absorbable implants can be found in ISO TR37137.

6.3.6 Chemical analysis may be performed according to E354 for Fe-base materials, B954 for Mg-base materials, and E536 for Zn-base materials.

6.3.7 Chemical check analysis tolerance limits specified in AMS 2248 may be used to verify heat analysis of Fe-base materials.

[5] Hendra Hermawan, Biodegradable Metals from Concept to Applications, Spinger, 2012, ISSN 2192-1091; ISSN 2192- 1105 (electronic).

6.3.8 Rare earth (RE) elements[6] include the fifteen lanthanide elements (atomic number 57 to 71) plus the transition metals scandium (Sc) and yttrium (Y).

6.3.9 Processing aids and binders that may be used with powder metallurgy materials shall be documented in order to evaluate the residual composition of additives that are present after final powder consolidation and heat treatment processes.

6.4 *Physical:*

6.4.1 Magnetic permeability of metallic implant materials should be assessed to determine the potential for a magnetic response. The magnetic permeability is a function of the final implant's size, dimensions, and placement within the intended application. The possibility of selective dealloying may occur during degradation and periodic magnetic permeability measurements during *in-vitro* absorption testing may be used to determine nonmagnetic retention properties. The magnetic response of low permeability materials may be measured in accordance with A342/A342M.

6.4.2 The minerals and any ensuing extraction and refining process should be assessed for the potential presence of radioactivity in the absorbable metallic device. If the assessment determines that a risk of potentially significant radioactive carryover is present, the radioactivity, defined as the sum of the mass activity of U238, Ra226, and Th232, as determined by γ-spectroscopy on the material, should meet the suggested limits of ASTM F2393, unless justified otherwise. Radioactivity measurements may be conducted according to D3648.

6.5 *Microstructural:*

6.5.1 Microstructural features will primarily depend on the chemical composition and the level of processing (e.g. whether the material is wrought or cast).

6.5.2 Wrought materials may exhibit a refined microstructure and the grain size should be evaluated and reported according to E112 as equiaxed, uniform, mixed, or duplex. If analytically beneficial, a more precise grain boundary determination should be considered through utilization of one of the electron backscatter diffraction (EBSD) methods that are described in ASTM E1382, E2627, and ISO 13067, all of which are suited for both cast and wrought alloys.

6.5.3 Casting alloy is usually in the form of shot, bar or ingots and may exhibit lamellar, dendritic, and/or equiaxed microstructural characteristics after melting into castings followed by heat treating.

6.5.4 Metastable martensitic phase transformations such as (γFe,γMn $\rightarrow$ α') may occur in specific Fe-Mn compositions during cold working and magnetic permeability measurements may be used to verify nonmagnetic stability.

6.5.5 A magnetic surface layer may be formed on high manganese (Mn) containing alloys as a result of thermal oxidation of Mn during hot working or annealing operations and may increase the magnetic permeability. The magnetic surface layer shall be removed from the finished product prior to its use as a medical device (see material standards F2229 Appendix X1.7 and F2581 Appendix X1.6).

6.5.6 The presence of nonmetallic inclusion types such as sulfide, alumina, silicate, and globular oxides in the microstructure of Fe-base materials may affect localized corrosion resistance and absorption rate. Such inclusions may be classified according to E45 and/or E1245 in order to allow assessment of their potential effect on localized corrosion resistance and absorption rate.

6.5.7 The presence of a cold worked, annealed, or thermally aged metallurgical condition shall be documented, since these factors influence the initial mechanical, physicochemical, and degradation properties.

6.5.8 Metallographic etching methods, such as E407 or E340, may be used to detect decarburization (superficial carbon oxidation) due to high-temperature thermal processing in order to evaluate compositional uniformity and the reduction in initial surface hardness.

6.5.9 The presence of a carbide network in the microstructure may affect the localized absorption rate. The carbide network can be evaluated according to A262.

6.5.10 Other unique microstructures obtained by nanoprocessing, metal injection molding, powder consolidation, hot isostatic pressing, or additive manufacturing methods, may influence the overall absorption rate and should be specified accordingly.

6.6 *Mechanical:*

6.6.1 Tensile properties of bar, wire, sheet, strip, plate, tubing or forged wrought material and castings produced from casting alloy may be determined according to ASTM E8/E8M, ASTM B557M, or ISO 6892-1 in order to determine initial mechanical properties.

6.6.2 Hardness testing according to E18 or E384 may be used to characterize initial wear resistance or abrasion properties.

6.6.3 Bend mandrel diameter testing of sheet, strip, and tubing materials according to E290 may be useful to verify that materials intended for medical device applications have satisfactory formability for fabrication into surgical implants.

6.7 *Inspection:*

6.7.1 Visual inspection of wrought materials may be used to characterize surface discontinuities and surface finish.

6.7.2 Visual inspection of castings may be used to characterize the presence of surface discontinuities, scale, casting shell, and weld repair.

6.7.3 Fluorescent penetrant inspection (FPI) of castings according to F601 may be used to evaluate surface and sub-surface discontinuities.

6.7.4 Radiographic evaluation of castings according to F629 may be used to evaluate internal porosity and differential density indications. Computed Tomography (CT) imaging in accordance with the methodology described in E1441 may also be considered as an alternative means to evaluate internal porosity.

6.7.5 Contact and immersion ultrasonic examination of wrought materials according to AMS 2630 and AMS 2632 may be used to characterize internal porosity and sub-surface discontinuities.

6.7.6 It is recognized that absorbable metallic materials may be intentionally designed to provide a level of surface or

[6] Rare Earth Technology Alliance & American Chemical Council, *The Economic Benefits of the North American Rare Earth Industry*, Report, April 2, 2014.

internal porosity in order to influence absorption rate and other types of non-visual inspection methods may be appropriate under these circumstances.

6.8 Metallurgical characterization and related topics that may be considered for absorbable metallic materials are listed in Table 1.

7. Reference Standards for Metallic Materials

7.1 ASTM reference standards for characterizing metallurgical properties are shown in Table 2.

7.2 ISO reference standards for characterizing metallurgical properties are shown in Table 3.

7.3 AMS reference standards for chemical check analysis and inspection test methods are listed in Table 4.

7.4 Appropriate selection from Table 2, Table 3, and Table 4 may be useful for initial characterization of metallic absorbable materials.

7.5 Many of the reference standards may be applicable for absorbable metallic compositions other than Mg-base, Fe-base, and Zn-base alloy systems.

8. Reference Standards for Metallic Medical Implants

8.1 ASTM test methods for semi-finished or finished metallic medical implants are listed in Table 5 for information purposes.

8.2 ISO standards for the biological evaluation of medical devices are listed in Table 6 for information purposes.

8.3 Appropriately finished absorbable metallic material specimens may also be evaluated according to the ASTM and ISO methods in Table 5 and Table 6 in order to screen potential new materials for medical implant applications.

9. Units of Measure

9.1 *Conversion of Units*—If the supplier's test equipment does not report in the selected units defined in the material specification, the test equipment units may be converted to the selected units for certification purposes. Accurate arithmetic conversion and proper use of significant digits should be observed when performing this conversion. IEEE/ASTM SI 10 provides guidelines for the use of SI units. Annex A provides conversion tables and Annex B provides rules for conversion and significant digits.

10. Significance of Numerical Limits

10.1 The following applies to all specified numerical limits that may be established in specifications that are created for absorbable metallic implant materials. To determine conformance to these limits, an observed or calculated value shall be rounded to the nearest unit in the last right-hand digit used in expressing the specification limit, in accordance with the rounding method of Practice E29.

11. Certification

11.1 The supplier of absorbable metallic implant materials shall provide a certification that the material was tested in accordance with the appropriate material and/or purchase specification and has met all requirements. A report of the test results shall be furnished at the time of shipment.

12. Quality Program Requirements

12.1 The supplier shall maintain a quality program such as defined in ISO 9001 or similar quality program. However, users of this standard are cautioned that the organization providing the medical device can be expected to be subject to the quality provisions of ISO 13485.

TABLE 1 Metallurgical Characterization and Related Topics for Absorbable Metallic Materials

Characterization	Related Topics
Chemical	Analytical measurement. Specified major, minor, residual, and trace element definition. Product analysis tolerances to verify heat or cast composition. Presence or absence of processing aid and binder.
Microstructural	Grain size measurement. Secondary Phase (particle, size, type, distribution, and area fraction). Cast lamellar or refined wrought structure documentation. Presence or absence of magnetic phase and nonmetallic inclusion. Confirmation of annealed or cold worked structure. Presence or absence of surface decarburization or carbide network. Porosity. Crystallographic texture.
Physical	Presence or absence of radioactivity. Magnetic permeability measurement.
Mechanical	Ultimate tensile strength, 0.2% yield strength, percent elongation. Percent reduction in area, elastic modulus, toughness, hardness, microhardness. Flexural strength, compressive strength, anisotrophy.
Inspection	Visual. Fluorescent penetrant. Radiographic. Contact and immersion ultrasonic.

TABLE 2 ASTM Reference Standards for Mg, Fe, and Zn Metallic Materials

ASTM Standard	Base Alloy (Mg/Fe/Zn)	Subject Matter	Metallurgical Characterization
B90/B90M	Mg	Wrought sheet and plate	General
B107/B107M	Mg	Wrought extrusions	General
A480/A480M	Fe	Wrought plate, sheet, strip	General
A484/A484M	Fe	Wrought bar, billet, forging	General
A555/A555M	Fe	Wrought wire and rod	General
B949	Zn	Wrought and cast products	General
B69	Zn	Wrought sheet and coil	General
B80	Mg	Sand Castings	General
B199	Mg	Permanent Mold Castings	General
B403	Mg	Investment Castings	General
A957	Fe	Investment Castings	General
B86	Zn	Die Castings	General
B953	Mg	Sampling	Chemical
B954	Mg	Test method	Chemical
E354	Fe	Test methods	Chemical
E536	Zn	Test methods	Chemical
A751	All	Defines specified, major, minor residual, and trace elements	Chemical
F2393	All	Radioactivity limits	Chemical
D3648	All	Radioactivity measurement	Chemical
A342/A342M	All	Magnetic permeability measurement	Physical
E407	All	Etching test methods to reveal structure and decarburization	Microstructural
E112/E1382/E2627	All	Grain size test method	Microstructural
E45/E1245	Fe	Nonmetallic inclusion test method	Microstructural
F2229/F2581	Fe	Loss of surface Mn	Microstructural
A262	Fe	Intergranular carbide test method	Microstructural
E8/E8M	Fe/Zn	Tensile test method	Mechanical
B557M	Mg	Tensile test method	Mechanical
E18	All	Hardness test method	Mechanical
E290	All	Bending test method	Mechanical
B661	Mg	Heat Treating	Mechanical
E1441	All	Computed tomography imaging	Inspection

13. Keywords

13.1 absorbable; absorption; bioabsorbable; biodegradable; bioresorbable; degradable; degradation; metals (for surgical implants); resorbable; surgical implants

TABLE 3 ISO Reference Standards for Mg, Fe, and Zn Metallic Materials

ISO Standard	Base Alloy (Mg/Fe/Zn)	Subject Matter	Metallurgical Characterization
16220	Mg	Ingots and castings	General
3116	Mg	Alloy compositions	Chemical
404	Fe	Wrought products	General
3815-1	Zn	Test method	Chemical
3815-2	Zn	Test method	Chemical
643/13067	All	Grain size test method	Microstructural
4967	All	Nonmetallic inclusion test method	Microstructural
24173	All	Crystallographic texture	Microstructural
6892	All	Tensile test method	Mechanical

TABLE 4 AMS Reference Standards for Metallic Materials

Standard	Base Alloy (Mg/Fe/Zn)	Subject Matter	Metallurgical Characterization
AMS 2248	Fe	Check analysis limits	Chemical
AMS 2630	All	Ultrasonic test method	Inspection
AMS 2632	All	Ultrasonic test method	Inspection

TABLE 5 ASTM Reference Test Methods for Metallic Medical Implants

Standard	Base Alloy (Mg/Fe/Zn)	Subject Matter	Metallurgical Characterization
F601	All	Wrought and cast fluorescent penetrant	Inspection
F629	All	Cast radiographic	Inspection
F2052	All	Displacement force test method	MRI Response
F2119	All	Image artifact test method	MRI Response
F2182	All	RF induced heating test method	MRI Response
F2213	All	Torque test method	MRI Response

TABLE 6 ISO Reference Standards for Medical Devices

Standard	Base Alloy (Mg/Fe/Zn)	Subject Matter	Metallurgical Characterization
ISO 10993-15	All	Degradation products	Biological
ISO 10993-17	All	Leachable substances	Biological
ISO 10993-18	All	Chemical analysis methods	Biological
ISO/TS 10993-19	All	Physical chemistry, morphological, topographical features	Biological
ISO/TS 17137	All	Cardiovascular absorbable implants	General
ISO/TR 37137	All	Absorbable implants	Biological

APPENDIXES

(Nonmandatory Information)

X1. RATIONALE

X1.1 The investigation of absorbable metals for possible cardiovascular, orthopedic, general surgical, and diagnostic applications is an area of interest for medical implants.

X1.2 Absorbable metals are expected to corrode or degrade gradually *in vivo* with an appropriate host response elicited by released corrosion or degradation products.

X1.3 This standard guide is focused on the characterization of chemical, physical, microstructural, and mechanical properties for wrought and cast metallic materials that are used for medical implants designed to be absorbed in the body over a period of time. Important non-destructive test (NDT) guidelines are also included in order to characterize initial material quality and uniformity.

X1.4 The characterization scheme for absorbable metallic materials is applicable to product forms such as wire, bar, sheet, strip, plate, and tubing prior to fabrication into a finished medical implant. The characterization and testing of absorbable metallic materials after they have been manufactured into finished and sterilized medical implants will depend on the design, mass, shape, anatomic location, and end-use application.

X1.5 Alloy compositions containing tin (Sn), tantalum (Ta), tungsten (W), and gold (Au) are designated 3TG materials and implant producers must work with suppliers and subcontractors to determine the presence of 3TG materials in the supply chain, verify the country of origin, and establish the source of 3TG minerals used in the materials that are supplied. This is in response[7] to Section 1502 of the Dodd-Frank Wall Street Reform Act and Consumer Act of 2010 requiring companies to publicly report on their use and the source of "conflict minerals" originating from the Democratic Republic of Congo and adjoining countries (DRC region) which involve human rights violations.

[7] Securities and Exchange Commission, Conflict Minerals Final Rule, 17 CFR Parts 240 and 249b, August 22, 2012.

X2. NOMENCLATURE OF ABSORB, DEGRADE, AND RELATED TERMS[8]

X2.1 Synthetic implants fabricated from hydrolysable alpha-hydroxy polyesters have been described as "absorbable" since the first polyglycolide-based sutures were commercialized in the United States in the 1970s. At that time, both poly(glycolide) (DEXON—Davis and Geck) and poly(glycolide-co-lactide) copolymer (VICRYL—Ethicon) based sutures were classified as "Absorbable Surgical Suture" by the United States Pharmacopeia (USP) and the United States Food Drug Administration (US-FDA), a designation that remains to this day. In contrast with "Nonabsorbable Surgical Suture," synthetic glycolide-lactide and collagen-based sutures undergo hydrolytic and/or enzymatic driven chain scission, generating degradation products that are then absorbed by the body. Since this designation, other terms such as "degradable" and "resorbable" have been used interchangeably to describe absorbable implants, with the prefix "bio-" often applied to all these terms.

X2.2 Based on historical usage and regulatory precedent, this document preferentially utilizes the term absorb/absorbable/absorption to describe implantable synthetic hydrolysable polymers and devices. These same terms are also applied to natural polymers (e.g., collagen) and metals intended to undergo corrosion *in vivo*, since any degradation product—be it proteinaceous or ionic—will inherently be absorbed by the host organism. The prefix "bio" is avoided since it is redundant in the context of implant applications. "Resorb" and its derivatives are avoided since they are accepted medical terms routinely utilized to describe natural resorption processes present in dynamic tissue, such as osteoclastic driven bone remodeling. "Degrade" and its various derivatives are avoided when referring to either an implantable device or raw material since common utilization is routinely applied broadly to include composting and other natural processes (including ultra-violet radiation) that cause materials to either intentionally or unintentionally break down into chemical and/or particulate matter. However, use of the term "degrade" and its derivatives is considered acceptable when referring to breakdown processes (e.g. chain scission, corrosion) within the absorbable materials or implantable device (for example, "The absorbable implant degrades through hydrolysis" or "During extrusion, absorbable polyglycolide is prone to thermal degradation").

X2.3 Since the aforementioned variety of terms have been historically utilized interchangeably both within and across surgical disciplines (but intermittently with inferred differentiation), the user of this document is cautioned that effective searches of the published literature should include all potential terms used to describe an absorbable implant or material. These include, but are not limited to:

(1) Absorbable and its derivatives
(2) Bioabsorbable and its derivatives
(3) Degradable and its derivatives

[8] Adopted and modified with permission from ASTM International standard F2902-12. Copyright ASTM International. The most current edition can be obtained from www.astm.org.

(4) Biodegradable and its derivatives
(5) Resorbable and its derivatives
(6) Bioresorbable and its derivatives