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Implants for surgery — General guidelines and requirements for assessment of absorbable metallic implants

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ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Email: copyright@iso.org
Website: www.iso.org

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 150, *Implants for surgery*.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

This document provides a general introduction to the field of absorbable metals. It outlines design considerations which differ from non-absorbable metals and provides a detailed description of the absorption process.

Metallurgical evaluation of absorbable metals is discussed, with reference to ASTM F3160 and commentary on the impact of composition and production processes on final performance.

In vitro degradation corrosion testing is discussed, with reference to ASTM F3268 and commentary on the importance of environmental conditions in the tests.

Both *in vitro* and *in vivo* biological assessment are discussed, with reference to several parts of the ISO 10993 series, ISO/TS 37137-1[1)] and the under-development ISO/TR 37137-2[2)].

NOTE ISO/TS 37137-1 applies to all absorbable materials, including metals and polymers. ISO/TR 37137-2 is specific to absorbable magnesium-based materials.

The interrelation of the absorbable-specific reference documents can be viewed in Figure 1.

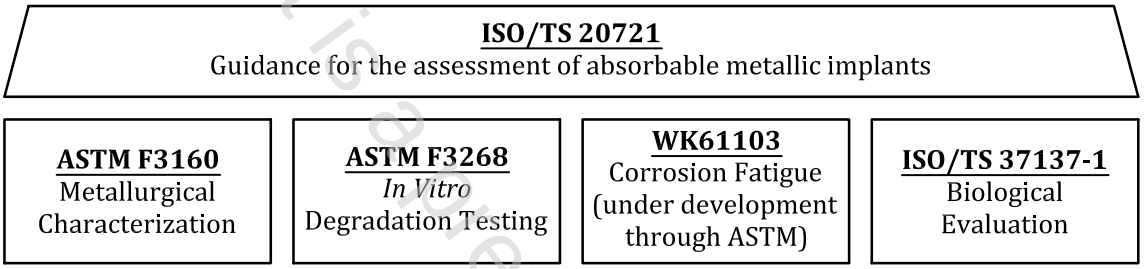

Figure 1 — Interrelation of standards specific to absorbable implants

The guide can be useful to both material suppliers and implant manufacturers.

Absorbable polymers used in conjunction with absorbable metals, either for performance modification or drug delivery, are not addressed. However, it is expected that a polymer coating, absorbable or non-absorbable, can influence absorption and performance of the underlying absorbable metal. ASTM F2902 addresses absorbable polymers.

Some existing standards address specific absorbable implants (e.g. ISO/TS 17137 addresses absorbable cardiovascular implants) made of either polymer or metal.

1) Under preparation. Stage at the time of publication: ISO/TS/CD 37137-1:2020.

2) Under preparation. Stage at the time of publication: ISO/TS/CD 37137-2:2020.

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1 Scope

This document established the currently recognized approaches and special considerations needed when evaluating the *in vitro* and *in vivo* performance of absorbable metals and implants fabricated, in whole or in part, from them. This document describes how the evaluation of these metals can differ from those utilized for permanent non-absorbable implantable implants (or subcomponents), in that absorbable metal implants (or subcomponents) are — by design — intended to be absorbed in their entirety by the host.

This document provides guidance regarding the materials considerations, *in vitro* degradation/fatigue characterization, and biological evaluation of medical implants made of absorbable metals. The provided content is intended to deliver added clarity to the evaluation of these materials and implants to increase awareness of critical factors and reduce potential for generation of erroneous or misleading test results.

While this document and the herein described referenced standards contain many suggested alterations or modifications to currently practiced procedures or specifications, the provided content is intended to complement, and not replace, current conventions regarding the assessment of implantable implants.

This document covers the evaluation of absorbable metal specific attributes in general and is not intended to cover application or implant specific considerations. Thus, it is important to consult relevant implant and/or application specific standards.

This document does not apply to non-absorbable or non-metallic components (e.g. polymeric coatings, pharmaceuticals, non-absorbable metals) used in conjunction with absorbable metal implants.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO/TS 37137-1, *Biological evaluation of medical devices — Part 1: Guidance for absorbable implants*[3)]

ASTM F3160, *Standard guide for metallurgical characterization of absorbable metallic materials for surgical implants*

ASTM F3268, *Standard guide for in vitro degradation testing of absorbable metals*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at http://www.electropedia.org/

3) Under preparation. Stage at the time of publication: ISO/TS/CD 37137-1:2020.