

Technical Information Report

AAMI/ISO TIR17137: 2014

Cardiovascular implants
and extracorporeal
systems — Cardiovascular
absorbable implants

Cardiovascular implants and extracorporeal systems — Cardiovascular absorbable implants

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Abstract: Outlines design verification and validation considerations for absorbable cardiovascular implants. Applies to implants in direct contact with the cardiovascular system, where the intended action is upon the circulatory system.

Keywords: biocompatibility, classification, clinical, degrade, design, leachable, risk

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Glossary of equivalent standards

International Standards adopted in the United States may include normative references to other International Standards. AAMI maintains a current list of each International Standard that has been adopted by AAMI (and ANSI). Available on the AAMI website at the address below, this list gives the corresponding U.S. designation and level of equivalency to the International Standard.

www.aami.org/standards/glossary.pdf

Committee representation

Association for the Advancement of Medical Instrumentation

Cardiovascular Absorbable Implants Committee

This adoption of ISO Technical Specification (TS) 17137 as an AAMI Technical Information Report (TIR) was initiated by the AAMI Cardiovascular Absorbable Implants Committee. Approval of the TIR does not necessarily imply that all working group members voted for its approval.

At the time this document was published, the **AAMI Cardiovascular Absorbable Implants Committee** had the following members:

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NOTE Participation by federal agency representatives in the development of this technical information report does not constitute endorsement by the federal government or any of its agencies.

Background on ANSI/AAMI adoption of ISO/TS 17137:2014

As indicated in the foreword to the main body of this document (page ix), the International Organization for Standardization (ISO) is a worldwide federation of national standards bodies. The United States is one of the ISO members that took an active role in the development of this standard, which was developed by ISO Technical Committee 150, Subcommittee 2, *Cardiovascular implants and extracorporeal systems*, to fill a need for outlining design verification and validation considerations for absorbable cardiovascular implants.

U.S. participation in this ISO TC is organized through the U.S. Technical Advisory Group for ISO/TC 150/SC 2, administered by the Association for the Advancement of Medical Instrumentation (AAMI). The U.S. TAG for ISO/TC 150/SC 2 supports the guidance provided in this document.

The AAMI adoption of AAMI/ISO 17137:2014 was approved by AAMI on 10 March 2014. The AAMI Cardiovascular Absorbable Implants Committee (U.S. sub-TAG for ISO/TC 150/SC 2/WG 7, Cardiovascular Absorbable Implants) initiated the U.S. adoption of ISO/TS 17137:2014.

AAMI procedures require that Technical Information Reports be reviewed and, if necessary, revised every three years to reflect technological advances that may have occurred since publication.

AAMI has adopted other ISO standards. See the Glossary of Equivalent Standards for a list of ISO standards adopted by AAMI which gives the corresponding U.S. designation and the level of equivalency with the ISO standard.

The concepts incorporated in this standard should not be considered inflexible or static. This standard, like any other, must be reviewed and updated periodically to assimilate progressive technological developments. To remain relevant, it must be modified as technological advances are made and as new data come to light.

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Suggestions for improving this document are invited. Comments and suggested revisions should be sent to Standards Department, AAMI, 4301 N. Fairfax Drive, Suite 301, Arlington, VA 22203-1633.

NOTE Beginning with the ISO foreword on page ix, this AAMI TIR is identical to ISO/TS 17137:2014.

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. 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. www.iso.org/patents

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The committee responsible for this document is ISO/TC 150, *Implants for surgery*, sous-comité SC 2, *Cardiovascular implants and extracorporeal systems*.

The following definitions apply in understanding how to implement an ISO International Standard and other normative ISO deliverables (TS, PAS, IWA):

- “shall” indicates a requirement;
- “should” indicates a recommendation;
- “may” is used to indicate that something is permitted;
- “can” is used to indicate that something is possible, for example, that an organization or individual is able to do something.

3.3.1 of the ISO/IEC Directives, Part 2 (sixth edition, 2011) defines a requirement as an “expression in the content of a document conveying criteria to be fulfilled if compliance with the document is to be claimed and from which no deviation is permitted.”

3.3.2 of the ISO/IEC Directives, Part 2 (sixth edition, 2011) defines a recommendation as an “expression in the content of a document conveying that among several possibilities one is recommended as particularly suitable, without mentioning or excluding others, or that a certain course of action is preferred but not necessarily required, or that (in the negative form) a certain possibility or course of action is deprecated but not prohibited.”

Introduction

Absorbable cardiovascular implants are medical devices with various clinical indications for use in the human cardiovascular blood system. An absorbable cardiovascular implant, or at least a portion thereof, is designed to intentionally degrade over time into products that are absorbed by the body through metabolism, assimilation, and/or excretion (elimination). Such implants can be either surgically or interventionally introduced to the site of treatment.

This Technical Specification outlines requirements for intended performance, design attributes, materials, design evaluation, manufacturing, sterilization, packaging, and information supplied by the manufacturer. This Technical Specification should be considered as a supplement to ISO 14630, which specifies general requirements for the performance of non-active surgical implants. This Technical Specification should also be considered as a supplement to relevant device-specific standards such as the ISO 25539 series specifying requirements for endovascular devices, which do not address degradation and other time dependent aspects of absorbable implants and coatings.

This Technical Specification is not comprehensive with respect to the pharmacological evaluation of cardiovascular absorbable implants. More detailed safety and performance requirements for pharmacological agents included in the absorbable cardiovascular implant are described in ISO/TS 12417.

Only issues related to absorption combined with the cardiovascular implant are covered by this Technical Specification.

NOTE For issues related to the common mechanical function of the cardiovascular implant, the reader might find it useful to consider a number of other International Standards (see Bibliography).

