ANSI/AAMI/ISO TIR37137:2014
Cardiovascular biological evaluation of medical devices — Guidance for absorbable implants
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Cardiovascular biological evaluation of medical devices — Guidance for absorbable implants

Abstract: provide interim part-by-part guidance on potential adjustments to various test methods within the 10993 series to account for the intentional release of soluble components or degradation products from absorbable medical devices.

Keywords: biological evaluation, absorbable implants, cardiovascular
AAMI Technical Information Report

A technical information report (TIR) is a publication of the Association for the Advancement of Medical Instrumentation (AAMI) Standards Board that addresses a particular aspect of medical technology.

Although the material presented in a TIR may need further evaluation by experts, releasing the information is valuable because the industry and the professions have an immediate need for it.

A TIR differs markedly from a standard or recommended practice, and readers should understand the differences between these documents.

Standards and recommended practices are subject to a formal process of committee approval, public review, and resolution of all comments. This process of consensus is supervised by the AAMI Standards Board and, in the case of American National Standards, by the American National Standards Institute.

A TIR is not subject to the same formal approval process as a standard. However, a TIR is approved for distribution by a technical committee and the AAMI Standards Board.

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All standards, recommended practices, technical information reports, and other types of technical documents developed by AAMI are voluntary, and their application is solely within the discretion and professional judgment of the user of the document. Occasionally, voluntary technical documents are adopted by government regulatory agencies or procurement authorities, in which case the adopting agency is responsible for enforcement of its rules and regulations.

Comments on this technical information report are invited and should be sent to AAMI, Attn: Standards Department, 4301 N. Fairfax Dr., Suite 301, Arlington, VA 22203-1633.

ANSI Technical Report

This AAMI TIR has been registered by the American National Standards Institute as an ANSI Technical Report. Publication of this ANSI Technical Report has been approved by the accredited standards developer (AAMI). This document is registered as a Technical Report series of publications according to the Procedures for the Registration of ANSI Technical Reports. This document is not an American National Standard and the material contained herein is not normative in nature.
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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
Biological Evaluation Committee

The adoption of ISO/TR 37137:2014 as an AAMI Technical Information Report was initiated by the AAMI Biological Evaluation Committee, which also functions as a U.S. Technical Advisory Group to the relevant work in the International Organization for Standardization (ISO) and the AAMI Strategic Approach to Biological Assessment Working Group.

At the time this document was published, the AAMI Biological Evaluation Committee had the following members:

**Co-chairs**
- Ronald P. Brown, FDA/CDRH
- Jon Cammack, PhD DABT, Medimmune LLC

**Members**
- James M. Anderson, MD PhD, Case Western Reserve Univ
- Joseph Carraway, DVM, NAMSA
- Philippe Hasgall, Zimmer Inc
- Richard W. Hutchinson, DVM PhD DABT, Johnson & Johnson
- Laurence Lister, BS, Toxikon Corporation
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- Yijun Lu, PhD, Johnson & Johnson
- Larry J. Thompson, Zimmer Inc

**NOTE**—Participation by federal agency representatives in the development of this standard does not constitute endorsement by the federal government or any of its agencies.

At the time this document was published, the AAMI Strategic Approach to Biological Assessment Working Group had the following members:

**Chair**
- Jon Cammack, PhD DABT, Medimmune LLC

**Members**
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- David J. Brodersen, Covidien
- Ronald P. Brown, FDA/CDRH
- Jon Cammack, PhD DABT, Medimmune LLC
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- John Dooley, PhD DABT, Johnson & Johnson
- Gloria H. Frost, PhD DABT, Cardinal Health (MP&S)
- Joel R. Gorski, PhD, NAMSA
- Niranjan Goud, PhD, Boston Scientific Corporation
- John Iannone, BME, Toxikon Corporation
- Keith A. Knisley, PhD, WL Gore & Associates Inc
- Mollie Love, Smiths Medical
- Richard Lukacovic, Baxter Healthcare Corporation
- Lori H. Mollanen, PhD DABT, 3M Healthcare
- Dave Parente, Ecolab
- Rodney D. Parker, Stryker Instruments Division
- Deanna Porter, St Jude Medical Inc
- Karen Sargsis, CareFusion
- Sharmilee Sawant, PhD, Halyard Health
- Anita Y. Sawyer, Becton Dickinson & Company
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- Nancy J. Stark, PhD, Clinical Device Group Inc
- April T. Veeoukas, JD, Abbott Laboratories
- Brian Wallace, Intuitive Surgical Inc
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Background of AAMI adoption of ISO/TR 37137:2014

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.

U.S. participation in ISO/TC 194 is organized through the U.S. Technical Advisory Group for ISO/TC 194, administered by the Association for the Advancement of Medical Instrumentation (AAMI) on behalf of the American National Standards Institute (ANSI). U.S. experts made a considerable contribution to this standard.

AAMI encourages its committees to harmonize their work with international standards as much as possible. Upon review of ISO/TR 37137:2014, the AAMI Biological Evaluation Committee and the AAMI Strategic Approach to Biological Assessment Working Group decided to adopt 37137, verbatim, as an AAMI Technical Information Report.

AAMI (and ANSI) have adopted other ISO documents. 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 into 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 comes to light.

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

NOTE—Beginning with the ISO foreword on page ix, this AAMI Technical Information Report is identical to ISO/TR 37137:2014.
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

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

The committees responsible for this document are ISO/TC 194, Biological evaluation of medical devices and ISO/TC 150/SC 2, Cardiovascular implants and extracorporeal systems.

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1 Scope

The objective of this Technical Report is to provide interim Part-by-Part guidance on potential adjustments to various test methods within the 10993 series to account for the intentional release of soluble components or degradation products from absorbable medical devices. The content is intended to add clarity and present potentially acceptable approaches for reducing the possibility of erroneous or misleading results due to the nature of the absorbable material. All suggestions should be considered as preliminary and subject to change, with final dispositions implemented through direct modification to the respective parts of ISO 10993. Thus, interim adoption of any of the described adjustments requires an accompanying written justification.