American National Standard

ANSI/AAMI/ISO 25539-1:2017

Cardiovascular implants—Endovascular devices—Part 1: Endovascular prostheses

AAMI
Advancing Safety in Healthcare Technology

Objectives and uses of AAMI standards and recommended practices

It is most important that the objectives and potential uses of an AAMI product standard or recommended practice are clearly understood. The objectives of AAMI's technical development program derive from AAMI's overall mission: the advancement of medical instrumentation. Essential to such advancement are (1) a continued increase in the safe and effective application of current technologies to patient care, and (2) the encouragement of new technologies. It is AAMI's view that standards and recommended practices can contribute significantly to the advancement of medical instrumentation, provided that they are drafted with attention to these objectives and provided that arbitrary and restrictive uses are avoided.

A voluntary *standard* for a *medical device* recommends to the manufacturer the information that should be provided with or on the product, basic safety and performance criteria that should be considered in qualifying the device for clinical use, and the measurement techniques that can be used to determine whether the device conforms with the safety and performance criteria and/or to compare the performance characteristics of different products. Some standards emphasize the information that should be provided with the device, including performance characteristics, instructions for use, warnings and precautions, and other data considered important in ensuring the safe and effective use of the device in the clinical environment. Recommending the disclosure of performance characteristics often necessitates the development of specialized test methods to facilitate uniformity in reporting; reaching consensus on these tests can represent a considerable part of committee work. When a drafting committee determines that clinical concerns warrant the establishment of *minimum* safety and performance criteria, referee tests must be provided and the reasons for establishing the criteria must be documented in the rationale.

A *recommended practice* provides guidelines for the use, care, and/or processing of a medical device or system. A recommended practice does not address device performance *per se*, but rather procedures and practices that will help ensure that a device is used safely and effectively and that its performance will be maintained.

Although a device standard is primarily directed to the manufacturer, it may also be of value to the potential purchaser or user of the device as a frame of reference for device evaluation. Similarly, even though a recommended practice is usually oriented towards healthcare professionals, it may be useful to the manufacturer in better understanding the environment in which a medical device will be used. Also, some recommended practices, while not addressing device performance criteria, provide guidelines to industrial personnel on such subjects as sterilization processing, methods of collecting data to establish safety and efficacy, human engineering, and other processing or evaluation techniques; such guidelines may be useful to health care professionals in understanding industrial practices.

In determining whether an AAMI standard or recommended practice is relevant to the specific needs of a potential user of the document, several important concepts must be recognized:

All AAMI standards and recommended practices are *voluntary* (unless, of course, they are adopted by government regulatory or procurement authorities). The application of a standard or recommended practice is solely within the discretion and professional judgment of the user of the document.

Each AAMI standard or recommended practice reflects the collective expertise of a committee of health care professionals and industrial representatives, whose work has been reviewed nationally (and sometimes internationally). As such, the consensus recommendations embodied in a standard or recommended practice are intended to respond to clinical needs and, ultimately, to help ensure patient safety. A standard or recommended practice is limited, however, in the sense that it responds generally to perceived risks and conditions that may not always be relevant to specific situations. A standard or recommended practice is an important *reference* in responsible decision-making, but it should never *replace* responsible decision-making.

Despite periodic review and revision (at least once every five years), a standard or recommended practice is necessarily a static document applied to a dynamic technology. Therefore, a standards user must carefully review the reasons why the document was initially developed and the specific rationale for each of its provisions. This review will reveal whether the document remains relevant to the specific needs of the user.

Particular care should be taken in applying a product standard to existing devices and equipment, and in applying a recommended practice to current procedures and practices. While observed or potential risks with existing equipment typically form the basis for the safety and performance criteria defined in a standard, professional judgment must be used in applying these criteria to existing equipment. No single source of information will serve to identify a particular product as "unsafe". A voluntary standard can be used as one resource, but the ultimate decision as to product safety and efficacy must take into account the specifics of its utilization and, of course, cost-benefit considerations. Similarly, a recommended practice should be analyzed in the context of the specific needs and resources of the individual institution or firm. Again, the rationale accompanying each AAMI standard and recommended practice is an excellent guide to the reasoning and data underlying its provision.

In summary, a standard or recommended practice is truly useful only when it is used in conjunction with other sources of information and policy guidance and in the context of professional experience and judgment.

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Requests for interpretations of AAMI standards and recommended practices must be made in writing, to the AAMI Vice President, Standards Policy and Programs. An official interpretation must be approved by letter ballot of the originating committee and subsequently reviewed and approved by the AAMI Standards Board. The interpretation will become official and representation of the Association only upon exhaustion of any appeals and upon publication of notice of interpretation in the "Standards Monitor" section of the *AAMI News*. The Association for the Advancement of Medical Instrumentation disclaims responsibility for any characterization or explanation of a standard or recommended practice which has not been developed and communicated in accordance with this procedure and which is not published, by appropriate notice, as an *official interpretation* in the *AAMI News*.

Cardiovascular implants—Endovascular devices—Part 1: Endovascular prostheses

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AAMI

Approved 25 May 2017 by
American National Standards Institute

Abstract: Specifies requirements for the evaluation of endovascular systems (prostheses and delivery systems) and requirements with respect to nomenclature, design attributes and information supplied by the manufacturer based upon current medical knowledge. Guidance for the development of *in vitro* test methods is included in an informative annex to this document.

Keywords: attachment system, delivery system, design, manufacturing, materials, packaging, performance, sterilization, surveillance

AAMI Standard

This Association for the Advancement of Medical Instrumentation (AAMI) standard implies a consensus of those substantially concerned with its scope and provisions. The existence of an AAMI standard does not in any respect preclude anyone, whether they have approved the standard or not, from manufacturing, marketing, purchasing, or using products, processes, or procedures not conforming to the standard. AAMI standards are subject to periodic review, and users are cautioned to obtain the latest editions.

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Contents

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

Vascular Prostheses Committee

The adoption of ISO 25539-1:2017 as an American National Standard was initiated by the AAMI Vascular Prostheses Committee. The AAMI Vascular Prostheses Committee also functions as the U.S. Technical Advisory Group to the relevant work in the International Organization for Standardization (ISO). U.S. representatives from the AAMI Vascular Prostheses Committee (U.S. Sub-TAG for ISO/TC 150/SC 2/WG 3) played an active part in developing the ISO standard.

At the time this document was published, the **AAMI Vascular Prostheses Committee** (U.S. Sub-TAG for ISO/TC 150/SC 2/WG 3) had the following members:

Cochair:
Dorothy Abel
Patrick Norris

Members:
Dorothy Abel, FDA/CDRH/ODE/DCD/PVDB
Richard Bianco, Fairview Health Services
Yolanda Bolanos, Johnson & Johnson/Cordis Corporation
Brian Choules, PhD, Embry-Riddles Aeronautical University
James Conti, PhD, Dynatek Labs
Xiao-Yan Shawn Gong, PhD, Medical Implant Mechanics
Michael Hallisey, MD, Jefferson Radiology
Martin King, PhD, Hopital Saint Francois D'Assise/Quebec Biomaterials Institute
Evan Lipsitz, MD, Montefiore Medical Center
Troy Nickel, TA Instruments – Electroforce Group
Patrick Norris, W.L. Gore & Associates
Jorge Ochoa, PhD PE, Exponent
Ning Pan, Boston Scientific
Santosh Prabhu, PhD, Abbott Vascular
Anthony Ragheb, PhD, Cook Research
Sam Robaina, Medtronic
Ann Tunstall, PhD, SciLucent LLC
Matthew Wanninger, PhD, MED Institute
Craig Weinberg, PhD, Biomedical Device Consultants & Laboratories
Rodney White, MD, Harbor-UCLA Medical Center

Alternates:
Jane Bohn, W.L. Gore & Associates
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Elaine Strope, PhD, Dynatek Labs
Steven Weinberg, PhD, Biomedical Device Consultants & Laboratories
Michael Wolf, Medtronic

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.

Background of AAMI adoption of ISO 25539-1:2017

As indicated in the foreword to the main body of this document (page vii), 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 (TC) 150 Subcommittee (SC) 2, *Cardiovascular implants and extracorporeal systems,* to specify requirements for intended performance, design attributes, materials, design evaluation, post-market surveillance, manufacturing, sterilization, and packaging for endovascular prostheses.

U.S. participation in this ISO SC 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).

AAMI encourages its committees to harmonize their work with international standards as much as possible. ANSI/AAMI/ISO 25539-1 was approved by the AAMI Standards Board on 14 April 2017. The AAMI Vascular Prostheses Committee (U.S. Sub-TAG for ISO/TC 150/SC 2/WG 3, Vascular prostheses) initiated the U.S. adoption of ISO 25539-1.

AAMI (and ANSI) have 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.

As used within the context of this document, "shall" indicates requirements strictly to be followed to conform to the standard. "Should" indicates 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 should be avoided but is not prohibited. "May" is used to indicate that a course of action is permissible within the limits of the standard. "Can" is used as a statement of possibility and capability. Finally, "must" is used only to describe "unavoidable" situations, including those mandated by government regulation.

NOTE Users of this standard are advised that this document is an AAMI identical adoption of an ISO document and that the following international conventions have been carried over to the AAMI publication:

- British English spelling (e.g. colour instead of color)
- Use of SI units (e.g. metres instead of feet, Celsius instead of Fahrenheit, etc.)
- Decimal comma instead of a decimal point (e.g. 1 000,15 instead of 1,000.15)

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.

Suggestions for improving this standard 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 vii, this American National Standard is identical to ISO 25539-1:2017.

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 on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: Foreword—Supplementary information

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

This second edition cancels and replaces the first edition (ISO 25539-18:2003), which has been technically revised.

It also incorporates the Amendment ISO 25539-1:2003/Amd1:2005.

A list of all the parts of ISO 25539 can be found on the ISO website.

Introduction

This document was prepared to provide minimum requirements for endovascular prostheses. The normative requirements are provided in the main body. The rationale for the requirements for bench tests and analyses to assess device performance, guidance on the identification of appropriate testing to evaluate a specific device design and guidance for developing test methods are provided in informative annexes. Further clarification of terminology and a cross reference between the main body and these annexes are provided in additional informative annexes.

This document has been updated to reflect current knowledge regarding the testing and clinical use of endovascular prostheses, reflected in modifications to the requirements in the main body and in the guidance for developing test methods in Annex D. In addition, revisions have been made to improve consistency in nomenclature and reporting and to enhance the utility of this document.

This document introduces methodology to identify appropriate testing and analyses for specific endovascular prosthesis, designated as the device evaluation strategy (DES). The requirement regarding the DES is in the main body, with informative guidance for the preparation of a DES table included in Annex A. Annex A also provides guidance for developing a DES for device design modifications and changes in intended use.

The other significant modifications in the requirements include the addition of non-radial durability testing, with guidance on the selection of appropriate testing, and specific requirements for testing to evaluate patency-related characteristics. Guidance for the development of appropriate tests to meet these requirements is included in Annex D.

The guidance on the development of methods to address the requirement for evaluating fatigue and durability through computational analyses has been modified significantly to include recommendations regarding verification of the solution and validation of the computational model, as well as reporting. The guidance on the model development for simulated use has also been significantly revised to improve the clinical relevance of this testing.

New requirements also include the evaluation of leakage at a seal zone and dislodgement force of endovascular prosthesis from a balloon. Guidance for the development of appropriate tests to meet these requirements is included in Annex D.

The requirement for evaluating the strength of the connection(s) between the graft material and a discrete fixation system(s) has been clarified with respect to the applicability of this requirement, that is, this requirement is only applicable for prostheses with a fixation system that is discrete from any stent(s) intended to provide structural support within the prosthesis [e.g. suprarenal stent that is not continuous with the stent(s) in the prosthesis body].

The specific requirements to evaluate pushability, flexibility, torquability, trackability and deployment accuracy of an endovascular system have been removed and incorporated within the simulated use evaluation requirement to better reflect how these attributes are evaluated. Similarly, the requirement to evaluate tubing tensile strength has been removed and incorporated within the evaluation of tensile bond strength.

The requirement to evaluate stent-free surface area has been removed as this attribute is not relevant for endovascular prostheses, which includes covered stents.

In addition to modifications to specific design evaluation requirements, guidance has been provided regarding the assessment of the acceptability of test results. When the requirement is to quantitatively appraise or analyse a parameter, test results generally may be compared to a quantitative value (i.e. acceptance criteria). For characterization tests, it is appropriate to provide an explanation of the relevance of the results. Additionally, some testing may include comparison to test data or existing data from a previously evaluated device.

For design evaluation, requirements regarding sampling, conditioning of test samples and reporting have been incorporated in the main body. Guidance on these elements of testing and documentation were previously included in Annex D.

The revisions to the titles of the annexes to this document are as follows.

Annex	ISO 25539-1:2003+A1:2005	ISO 25539-1:2017
A	Attributes of endovascular devices — Technical and clinical considerations	Relationship between testing requirements and device attributes and potential failure modes
B	Bench and analytical tests	Description of device and clinical effects of failure
C	Definitions of reportable clinical events	Bench and analytical tests
D	Test methods	Test methods
E	Sample equations as a supplement to the radial fatigue and durability test	There is no Annex E as this information was incorporated in Annex D

It is recognised by this ISO committee that many endovascular systems have been shown to be safe and effective in clinical use. This update is not intended to require additional evaluation of these devices to remain in compliance with this document as the testing would not provide useful information regarding the expected clinical performance of the device. Manufacturers may rely on historical data gathered under the guidance of the previous version of this document. Similarly, for device modifications or changes in intended clinical use, this update is not intended to require additional evaluation of any aspects of the device that are not expected to change clinical performance.

Cardiovascular implants—Endovascular devices—
Part 1:
Endovascular prostheses

1 Scope

This document specifies requirements for the evaluation of endovascular systems (prostheses and delivery systems) and requirements with respect to nomenclature, design attributes and information supplied by the manufacturer based upon current medical knowledge. Guidance for the development of *in vitro* test methods is included in an informative annex to this document. This document can be considered as a supplement to ISO 14630, which specifies general requirements for the performance of non-active surgical implants.

This document is applicable to endovascular systems used to treat aneurysms, stenoses or other vascular anomalies or pathologies (e.g. dissections, transections) or to create shunts between vessels [e.g. creation of transjugular intrahepatic portosystemic shunting (TIPS)]. Some of the requirements are specific to endovascular treatment of arterial aneurysms or stenoses. Although uses of endovascular systems other than treatment of arterial aneurysms or stenoses (e.g. dissections, transections, shunts) are within the scope of this document, the specific requirements and testing are not described. Similarly, specific prosthesis configurations (e.g. fenestrated, branched) are within the scope, but specific requirements and testing are not described for these devices.

This document is not applicable to vascular occluders, with the exception of contra-lateral iliac artery occluders when used as an integral part of aorto-uni-iliac endovascular prosthesis. Although contra-lateral iliac artery occluders when used as an integral part of aorto-uni-iliac endovascular prosthesis are within the scope of this document, specific requirements and testing are not described for these devices.

Balloons used to achieve adequate apposition of the prosthesis with the vessel wall or overlapping components are within the scope of this document, even if they are not integral to the endovascular system. This document provides requirements beyond the requirements of ISO 10555-4, specific to the use of balloons with endovascular prostheses.

This document is not applicable to procedures and devices used prior to the introduction of the endovascular system, such as balloon angioplasty devices.

The valve component of valved conduits constructed with an endovascular prosthesis component and the combination of the valved component and the endovascular prosthesis component are excluded from the scope of this document. This document can be helpful in identifying the appropriate evaluation of the endovascular prosthesis component of a valved conduit, but specific requirements and testing are not described for these devices.

NOTE 1 Cardiac valved conduits are within the scope of ISO 5840-1.

Pharmacological aspects of drug eluting or drug coated endovascular prostheses are not addressed in this document.

NOTE 2 Vascular device-drug combination products are within the scope of ISO 12417.

This document does not address the requirements for, and the evaluation of, viable tissues and non-viable biologic materials used in the construction of endovascular prostheses.

The requirements for, and the evaluation of, degradation and other time-dependant aspects of absorbable materials used in the construction of endovascular prostheses are not addressed in this document.

NOTE 3 Absorbable materials are within the scope of ISO/TS 17137 and ISO/TR 37137.