American National Standard

ANSI/AAMI/ISO 7198:2016

Cardiovascular implants and extracorporeal systems—Vascular prostheses—Tubular vascular grafts and vascular patches

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.

INTERPRETATIONS OF AAMI STANDARDS AND RECOMMENDED PRACTICES

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 and extracorporeal systems—Vascular prostheses—Tubular vascular grafts and vascular patches

Approved 5 June 2016 by
AAMI

Approved 2 August 2016 by
American National Standards Institute

Abstract: Specifies requirements for the evaluation of vascular prostheses 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 International Standard.

Keywords: attribute, configuration, design, evaluation, materials, packaging, performance, test

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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All AAMI 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.

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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

Vascular Prostheses Committee

The adoption of ISO 7198:2016 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

Members
Dorothy Abel, FDA/CDRH/ODE/DCD/PVDB
Richard Bianco, Fairview Health Services
Yolanda Bolanos, Johnson & Johnson/Cordis Corporation
James Conti, PhD, Dynatek Labs
Xiao-Yan Shawn Gong, PhD, Medical Implant Mechanics
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Ann Tunstall, PhD, Sciucent LLC
Matthew Waninger, PhD, MED Institute
Craig Weinberg, PhD, Biomedical Device Consultants & Laboratories
Rodney White, MD, Harbor-UCLA Medical Center

Alternates
Jane Bohn, W.L. Gore & Associates
Jennifer Goode, FDA/CDRH/ODE/DCD
Thomas Herbst, PhD, Boston Scientific
Thomas Nickel, TA Instruments – Electroforce Group
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 7198:2016

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 (TC) 150 Subcommittee (SC) 2, *Cardiovascular implants and extracorporeal systems,* to specify requirements for intended performance, design attributes, materials, design evaluation, manufacturing, sterilization, packaging and information supplied by the manufacturer for vena cava filters.

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 7198 was approved by the AAMI Standards Board on 5 June 2016. 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 7198.

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.

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 7198:2016.

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 7198:1998), which has been technically revised.

Introduction

This International Standard has been prepared in order to provide minimum requirements for tubular vascular grafts and vascular patches, including guidance on the methods of test that will enable their evaluation. This International Standard is an update of ISO 7198:1998, necessary given the introduction of new standards for endovascular prostheses, vascular stents and vascular device-drug combination products.

This International Standard covers vascular prostheses implanted using direct visualization surgical techniques as opposed to fluoroscopic or other non-direct imaging (e.g. computerized tomography or magnetic resonance imaging). ISO 25539-1 specifies requirements and testing guidelines for endovascular prostheses, implanted using catheter delivery and non-direct visualization. Since the design of endovascular prostheses often involves the use of materials that are used in traditional vascular prostheses, some of the methods to evaluate these materials are contained in this International Standard and referenced in the endovascular prostheses standard (ISO 25539-1).

It is recognized by this ISO committee that many forms of tubular vascular grafts and vascular patches have been shown to be a safe and effective means to surgically restore blood flow in various indications over many years. This update is not intended to significantly change the manner in which tubular vascular grafts have been evaluated or to add new requirements. Therefore, manufacturers can rely on evaluation and historical data gathered under ISO 7198:1998 to meet the requirements that have not changed in the current standard. The committee recognizes that, with the addition of requirements for vascular patches and references to device-drug combination requirements in other ISO documents, a reasonable amount of time (e.g. one to three years) might be needed to become fully compliant with this International Standard.

Cardiovascular implants and extracorporeal systems—Vascular prostheses—Tubular vascular grafts and vascular patches

1 Scope

1.1 This International Standard specifies requirements for the evaluation of vascular prostheses 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 International Standard. This International Standard can be considered as a supplement to ISO 14630:2012, which specifies general requirements for the performance of non-active surgical implants.

NOTE Due to the variations in the design of implants covered by this International Standard and, in some cases, due to the relatively recent development of some of these implants (e.g. bioabsorbable vascular prostheses, cell based tissue engineered vascular prostheses), acceptable standardized *in vitro* tests and clinical results are not always available. As further scientific and clinical data become available, appropriate revision of this International Standard will be necessary.

1.2 This International Standard is applicable to sterile tubular vascular grafts implanted by direct visualization surgical techniques as opposed to fluoroscopic or other non-direct imaging (e.g. computerized tomography or magnetic resonance imaging), intended to replace, bypass, or form shunts between segments of the vascular system in humans and vascular patches intended for repair and reconstruction of the vascular system.

1.3 Vascular prostheses that are made of synthetic textile materials and synthetic non-textile materials are within the scope of this International Standard.

1.4 While vascular prostheses that are made wholly or partly of materials of non-viable biological origin, including tissue engineered vascular prostheses are within the scope, this International Standard does not address sourcing, harvesting, manufacturing and all testing requirements for biological materials. It is further noted that different regulatory requirements might exist for tissues from human and animal sources.

1.5 Compound, coated, composite, and externally reinforced vascular prostheses are within the scope of this standard.

1.6 Endovascular prostheses implanted using catheter delivery and non-direct visualization are excluded from the scope of this International Standard. This International Standard includes information on the development of appropriate test methods for graft materials, referenced in ISO 25539-1 for materials used in the construction of endovascular prostheses (i.e. stent-grafts).

NOTE Requirements for endovascular prostheses are specified in ISO 25539-1.

1.7 The valve component of valved conduits constructed with a tubular vascular graft component, and the combination of the valved component and the tubular vascular graft component, are excluded from the scope of this International Standard. This International Standard can be helpful in identifying the appropriate evaluation of the tubular vascular graft component of a valved conduit but specific requirements and testing are not described for these devices.