The 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, directions 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 fume of reference for device evaluation. Similarly, even though a recommended practice is usually oriented towards health care 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:

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 Manager for Technical Development. 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.
American National Standard

(Revision of ANSI/AAMI VP20:1994)

Cardiovascular implants—Tubular vascular prostheses

Approved 24 September 2001 by
Association for the Advancement of Medical Instrumentation

Approved 17 October 2001 and reaffirmed 22 April 2010 by
American National Standards Institute, Inc.

Abstract: This American National Standard provides basic requirements for sterile vascular prostheses and the methods of test which will enable evaluation of vascular prostheses.

Keywords: biological, component, leakage, permeability, material
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.

CAUTION NOTICE: This AAMI standard may be revised or withdrawn at any time. AAMI procedures require that action be taken to reaffirm, revise, or withdraw this standard no later than 5 years from the date of publication. Interested parties may obtain current information on all AAMI standards by calling or writing AAMI.

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.

Published by

Association for the Advancement of Medical Instrumentation
1110 N. Glebe Road, Suite 220
Arlington, VA 22201-4795

© 2001 by the Association for the Advancement of Medical Instrumentation

All Rights Reserved

This publication is subject to copyright claims of ISO, ANSI, and AAMI. No part of this publication may be reproduced or distributed in any form, including an electronic retrieval system, without the prior written permission of AAMI. All requests pertaining to this draft should be submitted to AAMI. It is illegal under federal law (17 U.S.C. § 101, et seq.) to make copies of all or any part of this document (whether internally or externally) without the prior written permission of the Association for the Advancement of Medical Instrumentation. Violators risk legal action, including civil and criminal penalties, and damages of $100,000 per offense. For permission regarding the use of all or any part of this document, contact AAMI, 1110 N. Glebe Road, Suite 220, Arlington, VA 22201-4795. Phone: (703) 525-4890; Fax: (703) 525-1067.

Printed in the United States of America

6.1  In vivo preclinical testing .............................................................................................. 11
6.2  Clinical evaluation .......................................................................................................... 11

7  Sampling .............................................................................................................................................. 12
7.1  Sampling for characterization .............................................................................................. 12
7.2  Sampling for quality control .............................................................................................. 12
  7.2.1  Random sampling .............................................................................................................. 12
  7.2.2  Time interval sampling .................................................................................................... 12
  7.2.3  Number of samples ........................................................................................................... 12

8  Test methods for vascular prostheses ...................................................................................... 12
8.1  Visual inspection (A) .............................................................................................................. 13
  8.1.1  Principle .............................................................................................................................. 13
  8.1.2  Apparatus ............................................................................................................................ 13
  8.1.3  Sampling ............................................................................................................................. 13
  8.1.4  Test procedure .................................................................................................................... 13
  8.1.5  Expression of results .......................................................................................................... 13
  8.1.6  Test reports and additional information .......................................................................... 13
8.2  Determination of porosity, water permeability, integral water permeability/leakage, and water entry pressure ...................................................................................................................... 13
  8.2.1  Determination of porosity (N) ........................................................................................... 13
  8.2.2  Determination of water permeability (T, C) .................................................................... 16
  8.2.3  Determination of integral water permeability/leakage (B, C) .......................................... 19
  8.2.4  Determination of water entry pressure (N) .................................................................... 19
8.3  Determination of strength ......................................................................................................... 20
  8.3.1  Determination of circumferential tensile strength (A) ....................................................... 20
  8.3.2  Determination of longitudinal tensile strength (A) .......................................................... 22
  8.3.3  Determination of burst strength (A) .................................................................................. 23
  8.3.4  Determination of strength after repeated puncture (A, if applicable) ............................. 27
8.4  Determination of usable length (A) ....................................................................................... 28
  8.4.1  Principle .............................................................................................................................. 28
  8.4.2  Apparatus ............................................................................................................................ 28
  8.4.3  Sampling ............................................................................................................................. 29
  8.4.4  Test procedure .................................................................................................................... 29
  8.4.5  Expression of results .......................................................................................................... 29
  8.4.6  Test report and additional information .......................................................................... 29
8.5  Determination of relaxed internal diameter (A) .................................................................... 29
  8.5.1  Principle .............................................................................................................................. 29
  8.5.2  Apparatus ............................................................................................................................ 29
  8.5.3  Sampling ............................................................................................................................. 29
  8.5.4  Test procedure .................................................................................................................... 31
  8.5.5  Expression of results .......................................................................................................... 31
  8.5.6  Test report and additional information .......................................................................... 31
8.6  Determination of pressurized internal diameter (A) .............................................................. 31
  8.6.1  Principle .............................................................................................................................. 31
  8.6.2  Apparatus ............................................................................................................................ 31
  8.6.3  Sampling ............................................................................................................................. 31
  8.6.4  Test procedure .................................................................................................................... 31
  8.6.5  Expression of results .......................................................................................................... 32
  8.6.6  Test report and additional information .......................................................................... 32
8.7  Determination of wall thickness (A) ...................................................................................... 33
  8.7.1  Principle .............................................................................................................................. 33
  8.7.2  Apparatus ............................................................................................................................ 33
  8.7.3  Sampling ............................................................................................................................. 33
  8.7.4  Test procedure .................................................................................................................... 33
  8.7.5  Expression of results .......................................................................................................... 33
  8.7.6  Test report and additional information .......................................................................... 33
8.8  Determination of suture retention strength (A) ..................................................................... 33
  8.8.1  Principle .............................................................................................................................. 33
  8.8.2  Apparatus ............................................................................................................................ 34
  8.8.3  Sampling ............................................................................................................................. 34
  8.8.4  Test procedure .................................................................................................................... 34
  8.8.5  Expression of results .......................................................................................................... 34
  8.8.6  Test report and additional information .......................................................................... 34
8.9 Determination of kink diameter/radius (A) ........................................................................ 35
  8.9.1 Principle ...................................................................................................................... 35
  8.9.2 Apparatus .................................................................................................................. 35
  8.9.3 Sampling .................................................................................................................... 35
  8.9.4 Test procedure .......................................................................................................... 35
  8.9.5 Expression of results ................................................................................................. 35
  8.9.6 Test report and additional information ......................................................................... 35
8.10 Determination of dynamic compliance ......................................................................... 35
  8.10.1 Principle .................................................................................................................. 35
  8.10.2 Apparatus ................................................................................................................ 35
  8.10.3 Sampling ................................................................................................................ 36
  8.10.4 Test procedure ......................................................................................................... 36
  8.10.5 Expression of results ............................................................................................... 36
  8.10.6 Test report and additional information ..................................................................... 37
9 In vivo preclinical and clinical test methods for vascular prostheses ................................. 37
  9.1 Trial design, data acquisition, and data analysis for in vivo preclinical animal studies .......... 37
   9.1.1 Principle .................................................................................................................. 37
   9.1.2 Protocol ................................................................................................................... 37
   9.1.3 Data acquisition ....................................................................................................... 37
   9.1.4 Test report and additional information .................................................................... 38
  9.2 Trial design, data acquisition, and data analysis for clinical evaluation ............................. 38
   9.2.1 Principle .................................................................................................................. 38
   9.2.2 Protocol ................................................................................................................... 38
   9.2.3 Data acquisition ....................................................................................................... 38
   9.2.4 Test report ............................................................................................................... 38
10 Information to be recorded and disclosed by the manufacturer on request ......................... 41
  10.1 General ......................................................................................................................... 41
  10.2 Conformity to general requirements (see clause 4) ........................................................ 41
  10.3 Conformity to requirements for finished product (see clause 5) ....................................... 42
  10.4 Conformity to requirements for in vivo testing and clinical evaluation (see clause 6) ........ 42

Table
1 Suggested appropriate tests .................................................................................................. 8

Figures
1 Water permeability tester—Sample holding device (example 1) ........................................... 17
2 Water permeability tester—Sample holding device (example 2) ........................................... 17
3 Water permeability tester—Sample holding device (example 3)—Bottom assembly .............. 18
4 Split bar tester .................................................................................................................... 21
5 Load/extension curve ........................................................................................................ 22
6 Example of a probe burst test sample holder—Center opening to 0.445 in diameter, recessed gasket of fiber-rubber composition 1 in o.d., ¾ in i.d................................................................. 25
7 Example of a probe burst tester ........................................................................................ 26
8 Illustration of graft puncture test ...................................................................................... 28
9 Conical gauge for relaxed internal diameter ...................................................................... 30
10 Example of a balloon burst test device ............................................................................. 32
11 Example of suture retention strength test—Side view ....................................................... 34
Glossary of equivalent standards

International Standards adopted in the United States may include normative references to other International Standards. For each International Standard that has been adopted by AAMI (and ANSI), the table below gives the corresponding U.S. designation and level of equivalency to the International Standard.

Note—Documents are sorted by international designation.

Other normatively referenced International Standards may be under consideration for U.S. adoption by AAMI; therefore, this list should not be considered exhaustive.

<table>
<thead>
<tr>
<th>International designation</th>
<th>U.S. designation</th>
<th>Equivalency</th>
</tr>
</thead>
<tbody>
<tr>
<td>International designation</td>
<td>U.S. designation</td>
<td>Equivalency</td>
</tr>
<tr>
<td>--------------------------</td>
<td>---------------------------</td>
<td>---------------</td>
</tr>
</tbody>
</table>

1 FDIS approved; being prepared for publication.
Committee representation

Association for the Advancement of Medical Instrumentation

Vascular Prostheses Committee

The adoption of ISO 7198:1998 as an American National Standard was initiated by the AAMI Vascular Prostheses Committee. The AAMI Vascular Prostheses Committee also functions as a U.S. Technical Advisory Group to the relevant work in the International Organization for Sterilization (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 had the following members:

Co-chairs:  Dorothy Abel  Louis Smith

Members:  Dorothy Abel, Center for Devices and Radiological Health, U.S. Food and Drug Administration
            Richard Bianco, University of Minnesota
            Mark Dehdashtian, Edwards Lifesciences
            Dennis Genito, Cordis Corporation
            Kristen Honl, Guidant Endovascular Solutions
            Martin King, North Carolina State University College of Textiles
            John Riolo, Medtronic AVE
            Louis Smith, W.L. Gore & Associates Inc.
            Ann Tunstall, PhD, Salamandra LLC
            Frank Veith, MD, Montefiore Medical Center
            Cynthia Walcott, RN, C.R. Bard
            Steven Weinberg, PhD, Biomedical Consultants & Labs
            Rodney White, MD, Harbor-UCLA Medical Center
            Christopher Zarins, Stanford University Hospital

Alternates:  Brian Hudson, C.R. Bard
            Mike Morton, W.L. Gore & Associates Inc.
            Megan Moynahan, Office of Device Evaluation, Center for Devices and Radiological Health, U.S. Food and Drug Administration
            James Shy, Medtronic Interventional

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 ANSI/AAMI adoption of ISO 7198:1998

As indicated in the foreword to the main body of this document (page x), 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/SC 2/WG 3, Vascular prostheses, to fill a need for basic requirements for sterile vascular prostheses and the methods of test which will enable evaluation of vascular prostheses.

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).

This document is based on ANSI/AAMI VP20:1994, Cardiovascular implants—Vascular prostheses, and is technically identical to that document except in the following clauses: 4.5, Sterility (including subclauses); 5, Requirements for finished products (clause 5 paragraphs only); and 7, Sampling (including subclauses).

AAMI and ANSI procedures require that standards be reviewed and, if necessary, revised every five years to reflect technological advances that may have occurred since publication.

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.

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 comes to light.

Suggestions for improving this standard are invited. Comments and suggested revisions should be sent to Standards Department, AAMI, 1110 N. Glebe Road, Suite 220, Arlington, VA 22201-4795.

NOTE—Beginning with the foreword on page x, this American National Standard is identical to ISO 7198:1998.
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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 3.

Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75% of the member bodies casting a vote.

International Standard ISO 7198 was prepared by Technical Committee ISO/TC 150/SC 2, Cardiovascular implants.
Introduction

ISO 7198 has been prepared in order to provide basic requirements for sterile vascular prostheses and the methods of test which will enable evaluation of vascular prostheses.
Cardiovascular implants—Tubular vascular prostheses

1 Scope

1.1 This International Standard specifies requirements relating to testing, packaging, labeling, and terminology for sterile tubular vascular prostheses intended to replace, bypass, or form shunts between segments of the vascular system in humans.

This International Standard addresses vascular prostheses that are made wholly or partly of materials of: biological origin; synthetic textile materials; and synthetic non-textile materials. In addition, guidance for characterization of compound and composite prostheses is provided. It specifies the designation of materials of manufacture and the construction, and specifies the designation of sizes and dimensions of vascular prostheses. It refers to biological requirements of the materials of construction and of the finished product, taking into account the appropriate part of the horizontal International Standard ISO 10993.

This International Standard also specified the designation of mechanical properties. It describes methods for the measurement and verification of the dimensions and mechanical properties declared by the manufacturer. It refers to sterilization of prostheses and specifies requirements for labeling and packaging. It also provides definitions of terms in common use.

1.2 This International Standard does not specify all the performance or dimensional characteristics, but it does include methods for verifying that the nominal values disclosed by the manufacturer are within the permitted tolerances. These recommendations do not purport to comprise a complete test program.

1.3 For the purposes of this International Standard, the disclosure of test methods, results, and other information on request shall relate solely to requests from a National Regulatory Authority with responsibility for surgical implants.

This International Standard does not apply to human donor tissue devices such as cryopreserved vessels. Also excluded are all patches, pledgets, and stents.