

**American
National
Standard**

ANSI/AAMI VP20:1994

**Cardiovascular
implants—Vascular graft
prostheses**

AAMI

Association for the
Advancement of Medical
Instrumentation



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Cardiovascular implants—Vascular prostheses

AMERICAN NATIONAL STANDARD

ANSI/AAMI VP20—1994

(Revision of ANSI/AAMI VP20—1986)

Cardiovascular implants—Vascular prostheses

Developed by
Association for the Advancement of Medical Instrumentation

Approved 30 August 1994 by
American National Standards Institute, Inc.

Abstract:

This standard establishes requirements for testing synthetic textile, synthetic non-textile, biologic, composite, and compound vascular prostheses. It includes requirements for labeling, testing the physical and mechanical properties of the device, and for *in vivo* testing and clinical assessment.

Association for the Advancement of Medical Instrumentation

Vascular Prostheses Committee

This standard was developed by the AAMI Vascular Prostheses Committee. Committee approval of this standard does not necessarily imply that all committee members voted for its approval. The AAMI Vascular Prostheses Committee has the following members:

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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.

Foreword

This standard was developed by the AAMI Vascular Prostheses Committee.

This standard is a modification and expansion of *Vascular graft prostheses* (ANSI/AAMI VP20—1986) and was developed by the AAMI Vascular Prostheses Committee. The objective of this standard is to define general, material, sterility, labeling, and finished product requirements, as well as test methods for synthetic textile, synthetic non-textile, biological, composite, and compound vascular prostheses.

This document differs from the *Vascular graft prostheses* (ANSI/AAMI VP20—1986) in that it includes additional information on the testing and requirements for vascular access prostheses, composite prostheses, compound prostheses, and biologic prostheses, and additional requirements on animal and clinical studies. Further, information and format were taken from drafts of ISO/DIS 7198-1, *Cardiovascular implants—Tubular vascular prostheses—Part 1: Synthetic vascular prostheses* and ISO/CD 7198-2, *Cardiovascular implants—Tubular vascular prostheses—Part 2: Sterile vascular prostheses of biological origin—specification and methods of test* and incorporated into this document in order to formulate a more universally applicable document.

The concepts incorporated in this standard should be considered flexible and dynamic. To remain relevant, this standard, like any other, must be reviewed and updated periodically to assimilate new data and to reflect advances in the technology.

This standard reflects the conscientious efforts of concerned physicians, engineers, and other health care professionals, in cooperation with manufacturers, to develop a standard for those characteristics of vascular prostheses that could be addressed at this time, in view of new technology and information.

As used within the context of this document, "shall" indicates requirements strictly to be followed in order 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 a course of action is permissible within the limits of the standard; and "can" is used as a statement of possibility and capability. "Must" is used only to describe "unavoidable" situations, including those mandated by government regulation.

Suggestions for improving this standard are invited. These should be sent to AAMI, 3330 Washington Boulevard, Suite 400, Arlington, VA 22201-4598.

NOTE —This foreword is not a part of the American National Standard, *Cardiovascular implants—Vascular prostheses* (ANSI/AAMI VP20—1994).

Cardiovascular implants—Vascular prostheses

1 Scope

1.1 General

This standard has been prepared in order to provide basic guidance for characterization of vascular prostheses that are intended to replace, bypass portions of, or form shunts between, segments of the vascular system in humans. The standard addresses vascular prostheses that are made wholly or partly of: materials of biologic origin; synthetic textile materials; and synthetic non-textile materials. In addition, guidance for characterization of compound and composite prostheses is provided.

The design characteristics of the vascular prostheses must be verified to be representative of the devices to be released for distribution. Within the requirements of Good Manufacturing Practices (GMP), it will be the responsibility of the manufacturer to determine which tests and methods are required in order to assure consistent performance according to design characteristics.

For characterization purposes, the methods in this document shall be used unless adequate justification is provided for use of an alternative method. Alternative methods must be validated.

Retesting shall be performed whenever significant changes are made in materials, construction, configuration, application, or processing methods.

It is impossible, when writing this standard, to take into consideration all future and emerging technologies. These emerging-technology prostheses will need to follow the basic test protocols of this standard to characterize the device. Testing beyond the scope of this standard may also be necessary to characterize new emerging technology prostheses. Consideration shall be given to the failure modes of the prostheses and their effects on the performance of the device in identifying the appropriate testing.

For the purpose of this standard, the "disclosure of test methods and results on request" relates solely to information requested by an appropriate regulatory authority. Reports of test methods and results obtained shall be made available to appropriate regulatory authorities on request, or shall be disclosed with the product supplied or in the product literature as specified elsewhere in this standard.

1.2 Inclusions

Included in the scope of this standard are requirements for testing of synthetic textile, synthetic non-textile, biologic, composite, and compound vascular prostheses. Also included are requirements for *in vivo* preclinical and clinical testing, requirements for labeling, and definitions of the terms used in this standard.

1.3 Exclusions

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

This standard does not establish end-product performance criteria *per se* for these devices, but presents a series of standard test methods so that various devices can be compared.

2 Normative references

The following standards contain provisions, which, through reference in this text, constitute provisions of this AAMI Standard. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this AAMI Standard are encouraged to investigate the possibility of applying the most recent editions of the standards listed below.

- 2.1 AMERICAN NATIONAL STANDARDS INSTITUTE. *Test for density of plastics by the density gradient technique*. ANSI/ASTM D1503-68.
- 2.2 AMERICAN SOCIETY FOR TESTING AND MATERIALS. *Specification for tensile testing machines for textiles*. ASTM D 76-77. ASTM, 1977.
- 2.3 AMERICAN SOCIETY FOR TESTING AND MATERIALS. *Terminology relating to textile materials*. ASTM D 123-84. ASTM, 1984.
- 2.4 INTERNATIONAL ORGANIZATION FOR STANDARDIZATION. *Plastics—Vocabulary*. ISO 472. ISO, 1988.
- 2.5 INTERNATIONAL ORGANIZATION FOR STANDARDIZATION. *Textiles—Man-made fibres—Generic names*. ISO 2076. ISO, 1989.
- 2.6 INTERNATIONAL ORGANIZATION FOR STANDARDIZATION. *Textiles—Determination of bursting strength and bursting distension—Diaphragm method*. ISO 2960. ISO, 1974.
- 2.7 INTERNATIONAL ORGANIZATION FOR STANDARDIZATION. *Textiles—Woven fabrics—Determination of breaking strength and elongation (strip method)*. ISO 5081. ISO, 1977.
- 2.8 INTERNATIONAL ORGANIZATION FOR STANDARDIZATION. *Textiles—Determination of thickness of woven and knitted fabrics (other than textile floor coverings)*. ISO 5084. ISO, 1977.
- 2.9 INTERNATIONAL ORGANIZATION FOR STANDARDIZATION. *Biological testing of medical devices—Part 1: Guidance on selection of tests*. ISO 10993-1. ISO, 1992 (or U.S. equivalent; see 2.9.2).
- 2.9.1 INTERNATIONAL ORGANIZATION FOR STANDARDIZATION. *Technical Corrigendum 1:1992 to ISO 10993-1:1992*. ISO, 1992.
- 2.9.2 ASSOCIATION FOR THE ADVANCEMENT OF MEDICAL INSTRUMENTATION. *Biological testing of medical devices—Part 1: Guidance on selection of tests*. ANSI/AAMI 10993-1. AAMI, 1994. IN: *AAMI Standards and Recommended Practices, Volume 4: Biological Evaluation of Medical Devices* (1994).
- 2.10 INTERNATIONAL ORGANIZATION FOR STANDARDIZATION. *Clinical investigations of medical devices*. ISO 14155 (redesignation of ISO/CD 10993-8). ISO.1)

3 Definitions

For purposes of this standard, the following definitions should apply.

For definition of textile terms, reference can be made to ASTM D 123–84. For definition of tensile-testing terms, reference can be made to ASTM D 76–77.

- 3.1 **allograft**: (adjective: alloplast). An implant material made from tissues of an animal of the same species.
- 3.2 **bifurcation**: Site of division of one vascular tube (trunk or body) into two branches (limbs).
- 3.3 **biological material**: Material of animal or vegetable origin that may have been modified or treated by chemical processes, but excludes any material derived from fossil biological remains (e.g., petroleum oil).
- 3.4 **biostability**: The ability of a material to maintain its physical and chemical integrity after implantation in living tissue.
- 3.5 **coating**: Any organic or inorganic material, other than living cells, intentionally applied by a manufacturer to a substrate prosthesis. This coating may be intended to be permanent or temporary, may be applied to the external and/or internal surface, and/or may be impregnated into the structure of the substrate.
- 3.6 **compliance**: The ability of a prosthesis to elastically expand and contract in the circumferential direction in

response to a pulsatile pressure.

- 3.7 component:** Substance used during manufacture whether or not it is intended to remain as a consistent element of the device.
- 3.8 composite prosthesis:** Vascular prosthesis in which the construction and/or material of construction varies in a segmental manner along the length (e.g., a prosthesis where the proximal portion is of crimped knitted fabric and the distal portion is of an aldehyde-treated animal vascular tube). (See also 3.9.)
- 3.9 compound prosthesis:** Vascular prosthesis whose wall is uniformly constructed of materials from more than one source. (See also 3.8.)
- 3.10 configuration:** Geometry of prosthesis (e.g., straight, bifurcate, tapered).
- 3.11 construction:** Type of structure of a prosthesis (e.g., knitted, woven, non-woven, expanded polymer).
- 3.12 crimp:** Creases or folds manufactured into a prosthesis to permit elongation and reduce kinking.
- 3.13 fibril:** Strand of material which originates from one or more nodes and terminates at one or more nodes.
- 3.14 host: The recipient of an implant**
- 3.15 implantable state:** Condition of a prosthesis that has been prepared in accordance with the manufacturer's instruction prior to implantation, or of a material of construction that has undergone the same process of sterilization and/or preparation.
- NOTE—Preparation does *not* include preclotting (see 3.20), but does include any recommended method of washing or soaking.
- 3.16 integral water permeability:** The volume of clean, filtered liquid (with a viscosity approximating that of water) which passes through the wall of a prosthesis in a specified time under a specified pressure.
- 3.17 leakage:** The volume of clean, filtered liquid (with a viscosity approximating that of water) which passes through flaws in a water-impermeable vascular prosthesis in a specified time under a specified pressure.
- NOTE—Leakage may be either through small defects in the wall of a continuous tube or through an anastomosis constructed by the manufacturer.
- 3.18 node:** The solid region within a material at which fibrils originate and converge.
- 3.19 porosity:** Estimate or index of the ratio of the void within a material to the total volume occupied by the material including the voids.
- NOTE—Porosity may be expressed as the percentage void to the total area of volume, mean distance between nodes, or mean pore diameter.
- 3.20 preclotting:** Procedure whereby blood or blood fractions are allowed to penetrate and coagulate within the interstices of a porous prosthesis to decrease the permeability.
- 3.21 primary component:** Substance incorporated into the finished prosthesis whose addition is designed by the manufacturer to improve the performance of the device.
- 3.22 prosthesis:** (plural: prostheses, adjective: prosthetic). Any device which replaces or substitutes for an anatomical part or deficiency.
- 3.23 residual materials:** Substances that are employed in the manufacture of the prosthesis, but are intended to be removed or are not required in the finished prosthesis.
- 3.24 secondary component:** Substance that may be incorporated into the finished prosthesis, but is not primarily responsible for the stated function.

3.25 substrate prosthesis: A vascular prosthesis to which a coating meeting the definition of is applied.

3.26 synthetic material: Substance of non-biological source that is produced and/or polymerized by chemical or physical means.

NOTE—Chemically modified materials derived from fossil biological remains, e.g., petroleum or oil, are considered to be synthetic.

3.27 synthetic non-textile prosthesis: A vascular prosthesis manufactured using non-textile processes, e.g., extruded polymer, expanded polymer.

3.28 synthetic textile prosthesis: A vascular prosthesis made from yarns using textile fabrication methods, e.g., knitted, woven, braided.

3.29 usable length: Length of a prosthesis available for implantation, determined under a specified fixed load (which may be zero for certain prostheses).

3.30 vascular prosthesis (vascular graft—deprecated): Prosthesis used to replace, bypass, or form shunts between sections of the vascular system.

3.31 velour: Fabric with a cut or looped pile or with a napped surface.

3.32 void: Proportion of the wall of a vascular prosthesis that is not occupied by the material of construction.

NOTE—That is, the interstices of a knitted or woven structure. (See also [3.19](#))

3.33 water entry pressure: The pressure at which water passes from the inner wall to the outer wall of a vascular prosthesis.

3.34 water permeability (water porosity—deprecated): The volume of clean, filtered water that passes during a specified period through a unit area of the prosthetic material under a specified pressure.

NOTE—The water permeability is usually determined as $\text{mL} \cdot \text{cm}^{-2} \cdot \text{min}^{-1}$ at an applied pressure of 120 mmHg (16 kiloPascals [kPa]).

3.35 xenograft (heterograft—deprecated, adjective: xenoplast): An implant material made from the tissues of an animal of a different species from the host.

4 General requirements

The following requirements should apply to all vascular prostheses, regardless of origin.

4.1 Configuration and size designation

The configuration of a vascular prosthesis shall be designated by its geometry, e.g., straight, bifurcated, or tapered.

NOTE—Some prostheses may be manufactured for specific applications, such as an axillo-bifemoral prosthesis, and should be designated by their intended clinical use, not as 'bifurcated.'

4.1.1 Uniform straight vascular prostheses

The size of a straight uniform vascular prosthesis shall be designated by the following characteristics:

a) nominal relaxed internal diameter of the device, expressed in millimeters;

b) nominal pressurized internal diameter of the device, expressed in millimeters, under a distending pressure of at least 120 mmHg (16 kPa), if this diameter changes by more than 10% while under pressure (see [5.6](#));

c) minimum usable length, expressed in centimeters.

4.1.2 Bifurcated uniform vascular prostheses

The size of bifurcated uniform vascular prostheses shall be designated by the nominal relaxed internal diameters and the minimum usable overall length of the main tube and its branches, expressed in centimeters. Pressurized internal diameters shall also be designated if required (see 4.1.1[b]).

4.1.3 Tapered vascular prostheses

The size of a tapered vascular prosthesis shall be designated by the nominal relaxed internal diameters of its ends and its minimum usable length, both expressed in centimeters. Nominal pressurized internal diameters shall also be designated if required (see 4.1.1[b]).

4.1.4 Other configurations

For other configurations (e.g., an axillo-bifemoral prosthesis), the principal length(s), the nominal relaxed internal diameter(s), and the nominal pressurized internal diameter(s), if required, shall be designated, and expressed in millimeters or centimeters as required.

4.2 Intended clinical use designation

The intended clinical use shall be designated by one or more of the following:

- a) thoracic aortic and/or thoraco-abdominal;
- b) abdominal aortic and/or aorto/iliac, and/or aorto-femoral;
- c) peripheral arterial, including extra-anatomic (e.g., axillo-femoral arterial);
- d) coronary arterial;
- e) arterio-venous shunt for vascular access;
- f) other vessels to be specified.

4.3 Materials and construction

4.3.1 Classification

The classification of a prosthesis shall be designated by one of the following:

- a) synthetic textile (e.g., knitted, woven);
- b) synthetic non-textiles (e.g., extruded polymer, expanded polymer);
- c) biologic (e.g., allograft, xenograft);
- d) compound;
- e) composite.

4.3.2 Nomenclature

4.3.2.1 Synthetic materials

Synthetic materials shall be described by:

- a) their generic or chemical name, in accordance with ISO 472 or ISO 2076;
- b) the general nature of any chemical treatment or modification.

4.3.2.2 Biological materials

Biological materials shall be described by the following information:

- a) the origin of the material as the genus of the donor animal, in adjectival form;
- b) the type and site of the tissue (e.g., umbilical vein; carotid artery) or the type of material (e.g., collagen, albumin);
- c) the general nature of any chemical treatment or modification;
- d) the specific characterization of any biological material (e.g., the degree of cross-linking) that shall be disclosed by the manufacturer on request.

4.3.2.3 Coatings

For a coating, the amount, permanence, uniformity shall be determined.

Coatings shall be described by the following information, as appropriate:

- a) the nomenclature of any synthetic component(s) in accordance with [4.3.2.1](#);
- b) the nomenclature of any biological component(s) in accordance with [4.3.2.2](#).

4.3.2.4 Storage fluids

Storage fluids shall be described by the following information:

- a) the generic or chemical name of the principal component(s);
- b) the nature and type of possible toxic hazards.

NOTE—Attention is drawn to the existence of various international and national requirements with respect to maximum permitted levels of potentially toxic materials (e.g., ISO 10993-7; see section [10](#)).

4.3.2.5 Residual chemicals

NOTE—Residual chemicals refer to those processing and/or storage fluids or their derivatives that can be extracted from a prosthesis in the implantable state (see [3.15](#)).

Residual chemicals shall be described by their specific chemical names wherever possible; otherwise, their general chemical nature shall be used.

4.4 Biocompatibility and biostability

4.4.1 Biocompatibility

Tests shall be conducted during development and on a routine basis, or as specified by a manufacturer, in order to ensure biocompatibility parameters.

According to the classification scheme in [2.9](#), all vascular prostheses are "implant devices principally contacting blood." For most vascular prostheses, the intended implantation duration is permanent contact (greater than 30 days.) Therefore, the following tests should be considered for biocompatibility testing: cytotoxicity; sensitization; irritation or intracutaneous reactivity; and systemic toxicity (acute), including pyrogenicity, subchronic toxicity, genotoxicity, implantation, and hemocompatibility. In some cases, it may not be necessary to conduct all of the listed tests. A rationale for the test selection criteria, as well as a justification for pass/fail criteria, shall be provided where applicable.

The potential immunological response to biologic components and potential allergic response to drug components shall be analyzed. Pharmacology and toxicology of any drug component shall be fully characterized as a separate entity.

Risk of disease transmission to humans shall be evaluated. The manufacturing process shall ensure no

transmission of HIV, hepatitis viruses, bovine spongiform encephalitis, or other diseases that may be transmitted through biologic components.

4.4.2 Biostability

When the design of a prosthesis and its intended use as a chronic implant require that the prosthesis maintain some minimum level of physical and chemical integrity after implant in living tissue for some time interval, the materials of which the prosthesis is made shall be tested either individually or as part of the finished prosthesis.

A rationale for the test methods and the measured biostability shall be provided and may include:

- a) the durability of materials currently used for the same indication;
- b) the amount of time such a prosthesis is expected to perform in its indication for use, with consideration given to the performance and clinical utility of other prostheses and other forms of treatment currently available to treat the targeted indication;
- c) whether there are currently prostheses or other forms of treatment for the targeted indication.

These considerations would, in some cases, be addressed by some form of risk-to-benefit analysis.

4.5 Sterility

The results of a validation study shall be provided that show: (a) the sterilization process to be used in manufacturing provides a sterility assurance level (SAL) of at least 10^{-6} ; (b) the process does not adversely affect the product and/or package functionally.

If the prosthesis is intended for sterilization by the user, full details of the recommended procedure shall be provided and its efficacy demonstrated.

If resterilization instructions are to be included in the device labeling, data shall be provided to demonstrate that subjecting the prosthesis to the maximum number of sterilization cycles recommended does not adversely affect the properties of the device. Full details of the recommended sterilization procedure(s) must be provided and included in the device labeling.

NOTE—Section 10 contains a list of useful references regarding sterilization and package validation.

NOTE—Repackaging/sterilization of unused portions of a prosthesis is not recommended.

4.5.1 Shelf life

A description of the protocol for shelf life studies must be provided with justification of the sample size and the results of the study. Shelf life must be based on the ability of both the vascular prosthesis and the package to maintain their integrity. Studies must include the effects of temperature, humidity, pressure, and light exposure, as well as shipping and handling (dropping and vibration). After subjecting the packaged devices to a simulated or real-time environment, the devices shall be tested for sterility and functionality.

4.6 General information and instructions for use

Each unit container or outer container of which the contents are identical shall be supplied with instructions for the use of the prosthesis. The instructions shall include the following:

- a) indications for use;
- b) contraindications, cautions, and warnings that are applicable;
- c) recommended methods for the aseptic presentation and the preparation of the prosthesis for implantation, including any pretreatment such as prewashing, preclotting, and/or implantation techniques, if applicable;

- d) the statement "STERILE—DO NOT RESTERILIZE—SINGLE USE ONLY" in prominent form, if applicable;
- e) resterilization information, if applicable;
- f) notification of additives and/or leachable components, if applicable;
- g) recommendations for storage, if applicable;
- h) date of or reference relating to the publication of the text, indicating if the text has been revised.

4.7 Packaging

4.7.1 Unit container

Each prosthesis shall be packaged in a unit container. The unit container shall be so designed that it shall be readily apparent once the unit container is opened.

For prostheses supplied sterile (see 4.5), the unit container shall be designed to maintain the sterility of the prosthesis under nominal conditions of handling, transit, and storage, and to permit the contents to be presented for use in an aseptic manner.

4.7.2 Outer container

Each unit container shall be packaged in an outer container. This outer container shall be designed so as to protect the inner container from damage due to storage.

4.7.3 Shipping container

Each unit container, or a number of unit containers not necessarily of the same type, may be packaged in a shipping container designed to protect the contents under normal conditions of handling, transit, and storage.

4.8 Marking

4.8.1 Container label

Each prosthesis shall be accompanied by a label(s) on an appropriate container(s). At least the following information shall be provided on the label(s):

- a) name, address, and/or trademark of the manufacturer;
- b) the material of construction and type of construction (see 4.3);
- c) the configuration (see 4.1). A symbol may be substituted for a written description of the prosthesis (e.g., I = straight,  = bifurcated, Å = axillo-bifemoral);
- d) the nominal usable length (see 5.4);
- e) the nominal relaxed internal diameter(s) (see 5.5);
- f) if appropriate, the nominal pressurized internal diameter(s) (see 5.6);
- g) if appropriate, porosity, mean water permeability, integral water permeability/leakage, and/or water entry pressure (see 5.2);
- h) the words "STERILE—DO NOT RESTERILIZE—SINGLE USE ONLY", or equivalent phrase or symbols, in prominent form, if applicable; (see 4.5);
- i) manufacturer's batch or lot number;
- j) sterile lot number;

NOTE—If the manufacturer's batch or lot number (i) and the sterile lot number (j) can be traced to the same information, only one number need be given.

- k) date of sterilization and/or the expiry/expiration date;
- l) for prostheses supplied sterile, a warning against the use of the device if the package is open or damaged;
- m) manufacturer's recommendations for storage, when applicable;
- n) the chemical nature of any storage fluid in the unit container, with any appropriate hazard warning;
- o) if appropriate, a prominent statement regarding preclotting requirements or restrictions.

4.8.2 Record label

Each prosthesis shall be supplied with at least one adhesive record label suitable for attachment to the records of the patient receiving the implant. The record label shall include the following information:

- a) manufacturer's name and address;
- b) product name;
- c) manufacturer's batch and/or sterile lot number;
- d) part or model number (manufacturer's catalog number).

4.9 Test reports

NOTE—With some tests, reports may not be required.

4.9.1 General

When requested, test methods and results shall be disclosed in the form of a test report.

A test report shall provide at least the following information:

- a) manufacturer's or distributor's name;
- b) location and date of test;
- c) batch and/or lot number(s);
- d) manufacturer's or distributor's specifications;
- e) test results;
- f) statement of compliance or noncompliance with the test methods specified in the appropriate section of this AAMI standard.

NOTE—For the purposes of this standard, the unit "grams" is used as a representation of force, even though it is recognized that "grams" is a unit of mass.

4.9.2 Additional information

In addition to the test report, the following information shall be recorded:

- a) material(s) of manufacture, in accordance with [4.3](#);
- b) the configuration and type of construction of the prosthesis;
- c) the dimensions of the prosthesis in accordance with [4.1](#), [4.1.2](#), [4.1.3](#), [4.1.4](#);

- d) a statement indicating whether each sample prosthesis has or has not been sterilized and, if appropriate, the method of sterilization used;
- e) the test method(s) in accordance with the appropriate sections in this standard;
- f) the atmosphere, including mean and tolerance for controlled environments, in which the prosthesis was conditioned and/or tested;
- g) the number of samples and the observations per sample;
- h) the minimum and maximum values observed.

5 Requirements for finished prosthesis

All testing may not be appropriate for all prosthesis designs. See NOTES in section 8.

Justification shall be provided for the properties not measured.

For compound prostheses, although it may be appropriate to conduct some of the testing described in this standard on components of the prosthesis, testing of the device as a whole is also required. In addition, if the compound prosthesis is partially constructed of a resorbable component, the non-resorbable portion of the device shall be characterized as well as the device as a whole.

Each segment of a composite prosthesis shall be tested. In addition, any manufactured anastomosis shall satisfy the requirements of this standard relating to leakage (5.2.3) and factory anastomotic strength (either 8.3.2 or 8.3.3.3).

The test methods in this standard shall be used unless the design of the prosthesis is such that alternative methods must be employed. An alternative method shall be validated and disclosed by the manufacturer of the prosthesis with a justification for the method selected.

5.1 Visual inspection

The prosthesis shall show no discontinuities in construction, and shall show no dirt, soiled areas, spots, stains, loose particles, or other defects that would render the prosthesis unsuitable for its intended use.

Testing shall be performed in accordance with 8.1.

5.2 Porosity, water permeability, integral water permeability/leakage, and water entry pressure

Porosity, water permeability, integral water permeability/leakage, and/or water entry pressure shall be evaluated as appropriate to the device. Justification shall be provided for the property(ies) selected to be measured.

5.2.1 Porosity

The mean porosity of the sample prosthesis shall be measured using one of the methods given in 8.2.1.

The mean porosity of the sample prosthesis shall be within the nominal range declared by the manufacturer.

5.2.2 Water permeability

The mean water permeability of the sample prosthesis shall be measured using the method given in 8.2.2.

NOTE—If applicable, the manufacturer should provide recommendations whereby the water permeability can be reduced by pre-clotting.

The water permeability of the sample prosthesis shall be less than the maximum, or within the tolerance for, the nominal water permeability disclosed by the manufacturer.

5.2.3 Integral water permeability/leakage

The mean integral water permeability/leakage and/or the anastomotic leakage of the sample prosthesis shall be measured using the method given in [8.2.3](#).

The integral water permeability/leakage of the sample prosthesis shall be less than the maximum disclosed by the manufacturer.

5.2.4 Water entry pressure

The mean water entry pressure of the sample prosthesis shall be measured using the method given in [8.2.4](#).

The water entry pressure of the sample prosthesis shall be greater than the minimum or within the tolerance disclosed by the manufacturer.

5.3 Strength

The sample prosthesis shall be tested for longitudinal tensile strength in accordance with [8.3.2](#), for burst strength in accordance with [8.3.3](#) and factory anastomotic strength in accordance with either [8.3.2](#) or [8.3.3.3](#), if applicable. Circumferential tensile strength (see [8.3.1](#)) is only required if burst strength cannot be readily measured.

The value of tensile, burst strength, and factory anastomotic strength shall be greater than the minimum values disclosed by the manufacturer.

NOTE—Although the test methods given in [8.3.3.1](#) and [8.3.3.2](#) may be of equal validity for quality assurance purposes, they are not necessarily equivalent. There are markedly different stress/strain relationships between uniaxial and biaxial stressing for many prostheses.

For vascular prostheses with a designated intended clinical use for vascular access, the strength after repeated puncture shall be measured. The measured value for the strength after repeated puncture of the sample prosthesis shall be greater than the minimum value declared by the manufacturer.

Testing for strength after repeated puncture shall be performed in accordance with [8.3.4](#), which shall be disclosed on demand by the manufacturer of the prosthesis with a justification for the method selected.

5.4 Length

The usable length shall be measured and disclosed. The usable length of the prosthesis shall be no less than that declared by the manufacturer.

Testing shall be performed in accordance with [8.4](#).

5.5 Relaxed internal diameter

The specified limits for acceptance shall be as follows:

- a) For prostheses of nominal relaxed internal diameter of 10 mm or less, the measured relaxed internal diameter shall equal the nominal relaxed internal diameter disclosed by the manufacturer, within a tolerance of ± 0.5 mm.
- b) For prostheses of nominal relaxed internal diameter of 20 mm or less but greater than 10 mm, the measured relaxed internal diameter shall equal the nominal relaxed internal diameter disclosed by the manufacturer, within a tolerance of ± 1.0 mm.
- c) For prostheses of nominal relaxed internal diameter greater than 20 mm, the measured relaxed internal diameter of the sample prosthesis shall equal the nominal relaxed internal diameter declared by the manufacturer, within a tolerance of $\pm 5\%$.

Alternate limits for acceptance shall be justified.

Testing shall be performed in accordance with 8.5, which shall be disclosed on demand by the manufacturer of the prosthesis with a justification for the method selected.

5.6 Pressurized internal diameter

If the pressurized internal diameter exceeds the nominal relaxed internal diameter declared by the manufacturer by more than 10%, the nominal pressurized internal diameter shall be declared by the manufacturer (see 4.8.1[f]).

Testing shall be performed in accordance with 8.6.

5.7 Wall thickness

The wall thickness shall be measured in accordance with 8.7.

The wall thickness shall be within the tolerance as specified by the manufacturer.

5.8 Suture retention strength

The suture retention strength shall be measured in accordance with 8.8.

The suture retention strength shall be greater than the minimum disclosed by the manufacturer.

5.9 Kink diameter/radius

The kink diameter/radius of vascular prostheses shall be measured and disclosed by the manufacturer.

Testing shall be performed in accordance with 8.9.

NOTE—This test may not be applicable to all vascular prostheses (e.g., crimped textile prostheses).

5.10 Compliance

Compliance shall be measured and disclosed as appropriate to the device and in accordance with 8.10.

6 Requirements for *in vivo* preclinical and clinical evaluation

In vivo preclinical and clinical evaluation may be necessary when safety and efficacy, or substantial equivalence, cannot be demonstrated solely through *in vitro* testing.

NOTE—Innovative products and/or products with specific claims, including a new clinical application, may require further testing, including a failure mode analysis and design assessment.

6.1 *In vivo* preclinical testing

The purpose of *in vivo* preclinical testing is to assess the short-term response and patency of the prosthesis, the response of the host tissues following implantation in a vascular site, and any gross alteration in the physical, chemical, and biological properties of the material(s) of construction, including any coatings, where appropriate. This testing is not intended to demonstrate the long-term performance of the prosthesis.

Each type of prosthesis shall have been tested by implantation at the intended, or at an analogous, vascular site in no less than six animals for no less than 20 weeks in each animal unless a justification for a shorter term study can be provided. Appropriate controlled *in vivo* preclinical studies shall be used to collect comparable information, unless the absence of a control group can be justified. The duration of patency for each prosthesis shall be monitored by appropriate periodic examination (e.g., angiography, Doppler) and the results recorded. Loss of patency before the intended study duration does not necessarily exclude the animal from the study population used to assess prosthetic function and host tissue response. All animals implanted with either test or control prostheses, including those excluded from the final analysis, shall be recorded and