List of Titles

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 prothesis 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
mL $\cdot$ cm^{-2} $\cdot$ 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, Ã = 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 ± 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

reported.

A prosthesis shall not be tested in a species from which it was derived unless justification is provided.

The prosthesis shall be shown to be suitable for its intended use based on the objectives declared and justified in the *in vivo* preclinical testing protocol (see 9.1.2).

Testing shall be performed in accordance with 9.1, or by a validated alternative test method, which shall be disclosed by the manufacturer of the prosthesis. The design of *in vivo* preclinical testing shall be justified: in particular, the experimental protocol, measurement methods, and data analysis. Consideration shall be given to the objectives of the study in this justification.

6.2 Clinical evaluation

The purpose of clinical evaluation is to assess the short-term (up to 1 year) safety and efficacy of a vascular prosthesis for a particular clinical application. This evaluation is not intended to demonstrate the long-term performance of the prosthesis.

A clinical evaluation shall be carried out for each new prosthesis or new clinical application of a prosthesis prior to general marketing, using the principles given in ISO 14155 or an equivalent publication.

The prosthesis shall have satisfied all appropriate requirements of sections 4, 5, and 6.1 of this standard before starting clinical evaluation.

NOTE—Clinical evaluation conducted in the thoracic aortic implant site may be used to support straight abdominal aortic applications.

The clinical evaluation shall be conducted at a minimum of three institutions, each of which shall implant a minimum of 10 of the prostheses. The smallest diameter of a prosthesis, with a representative sample of all other diameters to be marketed for the particular clinical application, shall be included in the clinical evaluation (see NOTES).

For a prosthesis that is infrequently used, a clinical evaluation using an appropriate smaller number of patients shall be conducted at a minimum of three institutions. A justification of the numbers studied shall be provided.

NOTE—Additions of diameters to a marketed prosthesis for the same clinical application may require further clinical evaluation.

NOTE—For a compound prosthesis constructed of a biological resorbable component and a currently marketed substrate (e.g., knitted or woven fabric), the smallest diameter of the prosthesis is not required to be included in the clinical evaluation, provided that this diameter of the substrate is marketed.

The clinical evaluation shall be continued for a minimum of 12 months in each patient. Loss of patency before the intended study duration does not necessarily exclude the patient from the study population used to assess prosthetic function. All patients implanted with either test or control prostheses, including those excluded from the final analysis, shall be recorded and reported.

NOTE—It is advisable to continue the follow up until at least 24 months after the last prosthesis has been implanted.

NOTE—For a new prosthesis constructed of a biologic resorbable component used in a currently marketed prosthesis and a different currently marketed substrate, a 6-month study duration may be appropriate.

Objective evidence of safety and efficacy shall be provided. This evidence shall be compared to data collected and analyzed in an equivalent manner from patients managed by currently accepted medical and/or surgical treatment (control group). Justification shall be provided for the choice of control group, measurement methods, and statistical analyses employed.

The clinical data shall be collected, analyzed, and recorded in accordance with 9.2, or by a validated alternative test method, which shall be disclosed by the manufacturer of the prosthesis on demand.

The design of the clinical evaluation shall be justified: the total number of recipients of the prosthesis, the protocol, measurement methods, and data analysis being justified according to appropriate statistical methods. Consideration shall be given to the objectives of the study in this justification.

7 Sampling

During development, a sampling plan should be utilized which will ensure that an adequate representation of the data has been obtained for each parameter under evaluation. The number of samples for testing shall not be less than three random samples taken from each of three lots.

8 Test methods for vascular prostheses

NOTE—Each test method may not be appropriate for all prosthesis designs. The codes given below will give guidance as to which test methods are appropriate:

A All type prostheses
B Biologic
C Coated
N Synthetic non-textile
T Synthetic textile

NOTE—Compound or composite prosthesis may encompass one or more of the above categories.

8.1 Visual inspection (A)

8.1.1 Principle

The prosthesis is examined visually for defects.

8.1.2 Apparatus

Apparatus to be used include:

a) a controlled air environment, e.g., a clean room or cabinet;

b) a source of diffuse back illumination, and/or direct illumination.

8.1.3 Sampling

Sampling shall be in accordance with section 7.

8.1.4 Test procedure

Examine the prosthesis by unmagnified, corrected vision under illumination for the presence of holes and other discontinuities or imperfections of fabrication, and for the presence of dirt, soiled areas, spots, stains, loose particles, or other defects that would render the prosthesis unsuitable for its intended use.

8.1.5 Expression of results

The number of units accepted and rejected shall be recorded.

8.1.6 Test reports and additional information

A test report is not normally required (see NOTE in 4.9).

8.2 Determination of porosity, water permeability, integral water permeability/leakage, and water entry pressure

8.2.1 Determination of porosity

One of the following methods shall be used:

a) planimetric porosity;

b) gravimetric porosity;

c) microscopic porosity.

NOTE—The planimetric and gravimetric methods provide a direct measurement of porosity, while the microscopic method provides an index of porosity in terms of internodal distance or mean pore diameter.

An alternative method may be used provided that there is documented evidence that it is equivalent.

8.2.1.1 Method for planimetric determination of porosity (N)

8.2.1.1.1 Principle

This test is intended to determine the area of the voids and/or the area of the material on the sample prosthesis by means of measurements made on a scanning electron micrograph or optical micrograph. If there is a difference between the inner and outer surface, both should be characterized unless justification is provided for the surface measured.

8.2.1.1.2 Apparatus

Apparatus to be used include:

a) equipment for preparing a scanning electron micrograph of a section of the prosthesis, or equipment to enable visual examination and/or photography of the specimen or a section of the specimen by light microscopy;

b) a device such as micro-planimeter, micrometer, or computer digitizing table capable of measuring to an accuracy of ± 1% of the manufacturer's declared mean pore diameter or internodal distance.

8.2.1.1.3 Sampling

Sampling shall be in accordance with section 7.

8.2.1.1.4 Test procedure

From each sample prosthesis, either:

a) prepare a scanning electron micrograph(s);

b) prepare a photograph(s) for optical examination of the surface of the sample (see NOTE). The surface examined (inner or outer) shall be recorded.

NOTE—The degree of magnification is dependent upon the nature of the sample and the measuring apparatus (8.2.1.1.2) available.

Examine the electron micrographs or the photographs using the measuring apparatus (8.2.1.1.2) and determine the size of the voids, the number of voids per square millimeter, and the area of the material.

8.2.1.1.5 Expression of results

Porosity shall be expressed as a percentage. Calculate and record the porosity (P) of each test specimen from the equation:

$$P = 100 * \frac{Total\ areas\ of\ voids}{Total\ areas\ of\ voids + Total\ areas\ of\ materials}$$

Calculate and record the mean and standard deviation of the porosity.

8.2.1.1.6 Test report and additional information

The test report shall include the surface examined, its dimensions, and the mean and standard deviation of the porosity of the sample prostheses, and the details required by 4.9.1.

Additional information shall be recorded in accordance with 4.9.2.

8.2.1.2 Method for gravimetric determination of porosity (N)

8.2.1.2.1 Principle

The measured mass per unit area of the sample prosthesis is compared with the product density and the wall thickness of the sample.

8.2.1.2.2 Apparatus

Apparatus to be used include:

a) a balance, capable of weighing with an accuracy of ± 0.1% of the mean sample weight;

b) equipment for measurement of the area of the sample with an accuracy of ± 2% of the test area.

NOTE—The measurement of area may be derived from separate determinations of length and diameter, as described in 8.4 and either 8.5 or 8.6; alternatively a cut, flat sample may be used. The pressurized internal diameter need only be used if it is to be disclosed in accordance with 5.6;

c) equipment for measurement of wall thickness, as described in 8.7;

d) equipment for density gradient column determination.

NOTE—The equipment described in ANSI/ASTM D1503-68 has been found to be suitable.

8.2.1.2.3 Sampling

Sampling shall be in accordance with section 7.

8.2.1.2.4 Test procedure

Each sample should not be less than 100 mm in length. Determine the following:

a) the total mass (M) in grams;

b) the total area (A) in mm^2;

NOTE—If the usable length (L) and the internal diameter (D) are measured separately, then $A = \pi * D * L$.

c) the wall thickness (t) of both specimens in mm, using the method given in 8.7;

d) the density (ρ) of the fibrous or polymeric material in each specimen in g/cm^3 by means of a suitable density gradient method (see for example, ANSI/ASTM D1503-68).

8.2.1.2.5 Expression of results

Porosity shall be expressed as a percentage.

Calculate and record the porosity (P) of each sample from the equation:

$$P = *[(1 - \frac{1000 * M}{A * t * \rho})]$$

Calculate and record the mean and standard deviation of the porosity.

8.2.1.2.6 Test report and additional information

The test report shall include the mean and standard deviation of the porosity of the sample prostheses and the details required by 4.9.1.

Additional information shall be recorded in accordance with 4.9.2.

8.2.1.3 Method for microscopic determination of porosity (N)

8.2.1.3.1 Principle

This test is intended to determine the main internodal distance in stretched or expanded polymers or mean pore diameter and number of pores per square millimeter in cast or dipped polymers by means of measurements made on a scanning electron micrograph or optical micrograph. If there is a difference between the inner and outer surface, both should be characterized unless a justification is provided for the surface measured.

NOTE—This is an index of porosity, rather than a direct measure of porosity.

8.2.1.3.2 Apparatus

Apparatus to be used include:

a) equipment for preparing a scanning electron micrograph of a section of the prosthesis, or equipment to enable visual examination and/or photography of the specimen or a section of the specimen by light microscopy;

b) a device such as a steel ruler, micrometer, measuring eyepiece, or computer digitizing table capable of measurement to an accuracy of ± 1% of the manufacturer's declared mean pore diameter or internodal distance.

8.2.1.3.3 Sampling

Sampling shall be in accordance with section 7.

8.2.1.3.4 Test procedure

Prepare a scanning electron micrograph of a section of the test specimen or examine and photograph under optical magnification.

NOTE—The degree of magnification is dependent upon the nature of the sample and the measuring apparatus (8.2.1.3.2) available.

Determine the distance between the inner edges of neighboring nodes in the direction of the filaments or fibrils. Perform this determination on at least six locations from each photomicrograph.

Alternatively, determine the diameter of a pore. Repeat this measurement on at least six representative pores from each photomicrograph. Count the number of pores in a known area.

NOTE—Internodal distances of 5 microns (M) or less are not considered nodal separation, i.e., only internodal distances of 6 M or greater should be recorded.

8.2.1.3.5 Expression of results

Mean and standard deviation of the internodal or mean and standard deviation of the pore diameter shall be expressed in micrometers (M).

Calculate and record the mean and standard deviation of the internodal distance or the mean and standard deviation of the pore diameter, and the number of pores per unit area.

8.2.1.3.6 Test report and additional information

The test report shall include the surface examined, its dimensions, the mean and standard deviation of the internodal distance of the sample prostheses or the mean and standard deviation of the pore diameter of the sample prostheses, and the details required by 4.9.1.

Additional information including, where appropriate, the mean and standard deviation of the number of pores per unit area, shall be recorded with the details required by 4.9.2. When a pore is not circular, a description of the "diameter" measured shall be provided.

8.2.2 Method for determination of water permeability (T,C)

8.2.2.1 Principle

This test is intended to measure the rate of flow of water through a given area of the sample prosthesis under a given hydrostatic pressure.

8.2.2.2 Apparatus

Apparatus to be used include:

a) a flow measuring device, such as a weighted receptacle or an integrating flowmeter, capable of being read to within 2% of the full scale range and to an accuracy of ± 2% of the full scale reading;

NOTE—More than one such device may be required to cover the range of flow rates encountered during testing.

b) a pressure measuring device, such as a pressure transducer, a manometer, or a vertical standard column, capable of measuring hydrostatic pressures of up to 140 mmHg (19.0 kPa) to an accuracy of ± 2 mmHg (± 0.3 kPa);

c) a sample holding device, designed so that:

i) the area of the aperture of the holding device is between 0.5 cm^2 and 1.0 cm^2, measured with a precision of ± 1%;

ii) the configuration of the aperture is circular (see NOTE);

NOTE—If a narrow sample is to be tested, the aperture may be in the form of a rectangle. When this form of aperture is used, it should be stated in the test report, together with its dimensions measured to a precision of ± 1%.

iii) there are no bends or changes in diameter of the flow pathway within a distance from the test sample of six diameters of the test area;

iv) leaks around the sample are not obscured;

NOTE—Examples of suitable holders are given in figures 1, 2, and 3.

d) a means of supplying clean, filtered, room-temperature water to the sample holding device to a pressure of 120 mmHg (16.0 kPa) for the duration of the test.

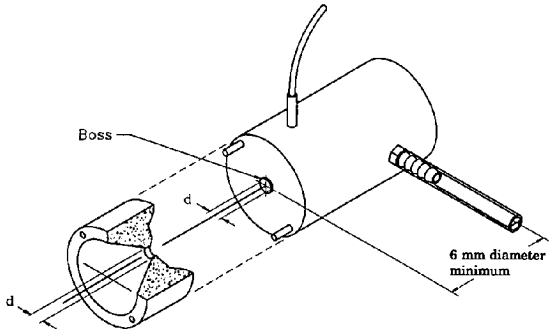

Figure 1—Porosity tester: Sample holding device (example 1)

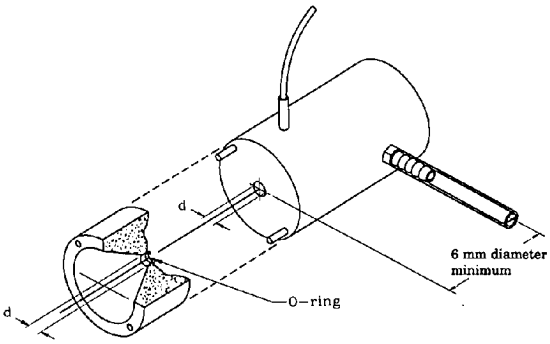

Figure 2—Porosity tester: Sample holding device (example 2)

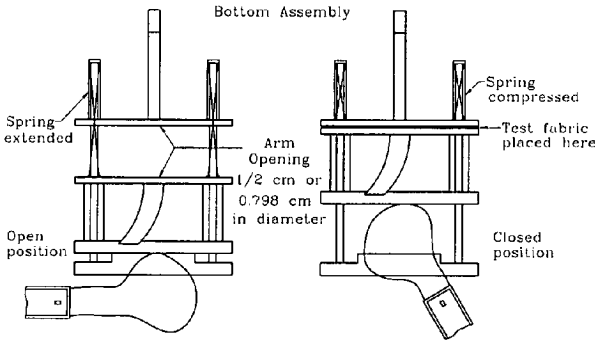

Figure 3—Porosity tester: Sample holding device (example 3)

8.2.2.3 Sampling

Sampling shall be in accordance with section 7.

8.2.2.4 Test procedure

The sample prosthesis may be submerged in clean, filtered water at room temperature to wet the sample prior to testing.

Load the sample into the holder, stretching the sample sufficiently without distorting the material.

NOTE—Stretching may be accomplished by means of clips and weights or by flattening the sample with a narrow spatula. This stretching of the sample should approximate the usable length conditions (see 8.4) and in the case of crimped constructions will remove most of the crimp.

Turn on the water flow system and adjust until a pressure of 120 ± 2 mmHg (16.0 ± 0.3 kPa), as indicated on the pressure measuring device, is obtained. Measure the flow rate of water passing through the sample for a

period of 60 ± 1 seconds, during which the system is operating under steady flow (steady state) conditions.

8.2.2.5 Expression of results

Water permeability shall be expressed in mL • cm^{-2} • min^{-1}

Calculate and record the water permeability from the equation:

Water permeability = Q/A

where

Q = flow rate through the sample in mL • min^{-2}

A = cross-sectional area of the aperture in the sample holder in cm^2

Record the area and, if appropriate, dimensions of the aperture.

8.2.2.6 Test report and additional information

The test report shall include mean and standard deviation of the measured water permeability of the sample prostheses, the dimensions of the aperture, if rectangular, and the details required by 4.9.1.

Additional information, including the area of the aperture, shall be recorded together with the details required by 4.9.2.

8.2.3 Method for determination of integral water permeability/leakage (B, C)

8.2.3.1 Principle

This test is intended to measure the rate of water leakage through the entire prosthesis wall, or to measure a representative segment in tubular form under a pressure of 120 mmHg (16 kPa). The test segment shall include any areas where leakage is of concern (e.g., factory anastomoses). The test will accommodate both straight and bifurcated configurations.

8.2.3.2 Apparatus

Clean, filtered, room-temperature water should be used.

NOTE—Other solutions, such as buffered saline, may be used.

A set of adapters specific for the internal diameter of the prostheses to be tested are used to mount the sample. The seal between the sample prosthesis and the adapters must be water-tight. The prosthesis adapter assembly is connected to a fixture which allows one end of the prosthesis to extend freely while pressurized. The fixture is connected to a pressure-regulated system capable of delivering water at greater than 120 mmHg (16.0 kPa). A pressure measuring device, e.g., a transducer, gauge, or standard column, is configured to measure the intraluminal pressure of the prosthesis during the test. A means for measuring the volumetric flow of water through the prosthesis wall, and/or a means for collecting the leakage from a factory anastomosis will be employed. This may be accomplished by a flowmeter, displacement, or collection method. A timer is used to time the test. A means of determining the test length of the prosthesis in centimeters from seal to seal is used.

8.2.3.3 Sampling

Sampling shall be in accordance with section 7.

8.2.3.4 Test procedure

The prosthesis should be tested in its implantable state.

Seal distal end(s) with a plug or tightly fold or roll the distal end(s) approximately 2 cm and clamp to

maintain a water-tight seal.

Connect the sample prothesis to the adapters specific for the internal diameter using a water-tight sealing technique. Connect the adapters and prosthesis to the pressure delivery and measurement fixture. Gradually increase the intraluminal pressure in the sample, bleeding off entrapped air. Pressurize to 120 mmHg ± 2 mmHg (16.0 ± 0.3 kPa). Allow the flow to stabilize and measure the leakage through the prothesis wall for 60 seconds. If a water collection method is used, leakage through the body and legs of bifurcates may be measured separately.

8.2.3.5 Expression of results

The surface area of the prosthesis or segment is calculated, and the water permeability expressed as mL • cm^{-2} • min^{-1}. For anastomotic leakage, the leakage in the region of the anastomosis shall be expressed as mL • min^{-1}.

8.2.3.6 Test report and additional information

The test report shall include the mean and standard deviation of the water permeability and/or anastomotic leakage of the sample prostheses, and the details required by 4.9.1.

Additional information shall be recorded in accordance with 4.9.2.

8.2.4 Method for determination of water entry pressure (N)

8.2.4.1 Principle

This test is intended to determine the water entry pressure of vascular prostheses.

8.2.4.2 Apparatus

Apparatus to be used include a machine capable of incrementally pressurizing samples until leakage occurs. An appropriate pressure transducer should also be used.

8.2.4.3 Sampling

Sampling shall be in accordance with section 7.

8.2.4.4 Test procedure

Samples are filled with water and pressurized to an initial value determined by the manufacturer. The pressure is then increased gradually. Once water is observed on the external surface, the pressure is recorded and the test terminated. This is the water entry pressure.

8.2.4.5 Expression of results

The pressure shall be recorded in mmHg (kPa).

8.2.4.6 Test report and additional information

The test report shall include the mean and standard deviation of the water entry pressure of the sample prostheses, and the details required by 4.9.1.

Additional information, including the pressure rate, shall be recorded together with the details required by 4.9.2.

8.3 Determination of strength

NOTE—Separate tests, applying a unidirectional stress, are required for determining the longitudinal and the circumferential tensile strengths of a sample prosthesis. Both tests shall be applied when appropriate.

8.3.1 Method for determination of circumferential tensile strength (A)

8.3.1.1 Principle

The sample prosthesis in its tubular form is placed onto two rounded pins. It is then stretched at a uniform rate until the yield and/or break point is reached. The test is a modification of ISO 5081.

8.3.1.2 Apparatus

Apparatus to be used include:

a) a tensile testing machine meeting the requirements of ISO 5081, having a constant rate of traverse, and with a pair of pins and suitable holders over which the sample prosthesis may be threaded: a suitable example is given in figure 4 (a and b; see next page);

b) a measuring device accurate to ± 0.5 mm, e.g., a ruler or vernier calipers;

c)apparatus to measure the relaxed internal diameter (see 8.5).

8.3.1.3 Sampling

Sampling shall be in accordance with section 7.

8.3.1.4 Test procedure

Cut a test specimen from the sample prosthesis with a usable length not less than the nominal relaxed internal diameter (section 8.5). After careful removal of any crimp, measure and record the length of the specimen (L) in mm to an accuracy of ± 0.5 mm. Thread the specimen over the two pins. Care should be taken to ensure that the specimen is not stretched or twisted, and slack should be kept to a minimum. Stretch the specimen at a steady rate of 50 to 200 mm • min^{-1} until the break point is reached. Determine the load at yield or break, i.e., the maximum load (Tmax), to an accuracy of ± 2 %, and record the rate of extension (see figure 5, next page), if appropriate.

8.3.1.5 Expression of results

Calculate the circumferential tensile strength of each sample by dividing the maximum load (Tmax) by the original length of the sample.

$$\textit{Maximum Load/Lenght} = \frac{Tmax}{(2 * L)}\ , \textit{expressed in kN/mm}$$

8.3.1.6 Test report and additional information

The test report shall include the mean and standard deviation of the circumferential strength of the sample prostheses, the strain rate with rationale if not within the specified range (see 8.3.1.4), and the details required by 4.9.1.

Additional information shall be recorded in accordance with 4.9.2.

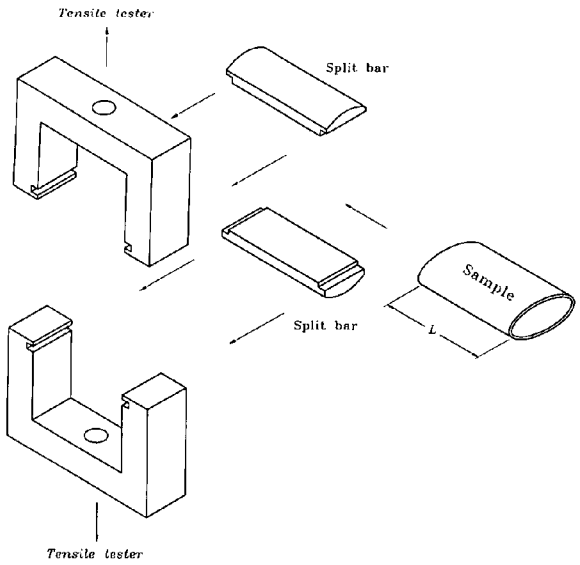

Figure 4(a)—Schematic of a split bar tester

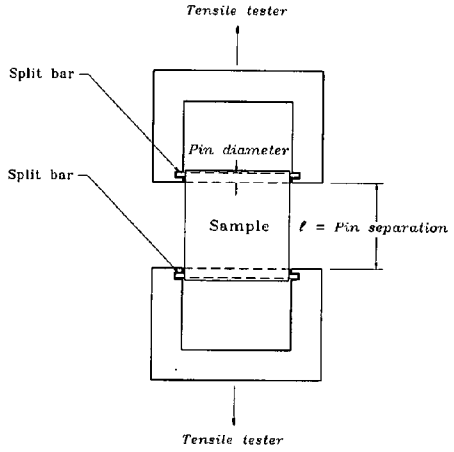

Figure 4(b)—Front view of split bar tester

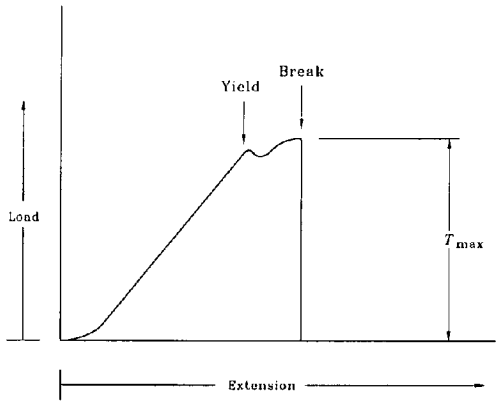

Figure 5—Load/extension curve

8.3.2 Method for determination of longitudinal tensile strength (A)

8.3.2.1 Principle

The sample prosthesis in its tubular form is placed with its ends in suitable jaws. It is then stretched at a uniform rate until the yield and/or break point is reached. The test is a modification of ISO 5081.

8.3.2.2 Apparatus

Apparatus to be used include:

a) a tensile strength machine meeting the requirements of ISO 5081, having a constant rate of traverse and suitable jaws to hold the sample prosthesis firmly without damaging its structure (because such damage might cause the break to occur prematurely at the jaw margins);

b) a measuring device accurate to ± 0.5 mm, for example, a ruler or vernier calipers.

8.3.2.3 Sampling

Sampling shall be in accordance with section 7.

8.3.2.4 Test procedure

If testing factory anastomotic strength, a region incorporating the anastomosis should be tested.

Soak sample prosthesis to manufacturer's specifications, if applicable. Remove synthetic mesh covering the prosthesis before testing, if appropriate.

Place the ends of the sample prosthesis in the jaws with an initial separation of between 50 and 150 mm. Care should be taken to ensure that the sample is not stretched, twisted, or damaged by the jaws, and slack should be kept to a minimum. Stretch the specimen at a steady rate of 50 to 200 mm • min^{-1} until the break point is reached. Determine the load at yield or break, i.e., the maximum load (Tmax), to an accuracy of ± 2 % and the rate of extension (see figure 5), if appropriate.

8.3.2.5 Expression of results

The longitudinal tensile strength of each sample is expressed as:

Maximum Load = Tmax, expressed in kilonewtons (kN)

8.3.2.6 Test report and additional information

The test report shall include the mean and standard deviation of the longitudinal tensile strength of the sample prostheses, the strain rate (with rationale, if not within the specified range, see 8.3.2.4), and the details required by 4.9.1.

Additional information shall be recorded in accordance with 4.9.2.

8.3.3 Method for determination of burst strength (A)

NOTE—The tests described in this section are alternatives to those in 8.3.1. Attention is drawn to the NOTE in 8.3.

One of the three following methods shall be used:

a) diaphragm burst strength (this is a modification of the method specified in ISO 2960);

b) probe burst strength;

c) pressurized burst strength.

All have equal validity, but in case of dispute, the pressurized burst strength (8.3.3.3) shall be the referee method.

8.3.3.1 Method for determination of diaphragm burst strength

8.3.3.1.1 Principle

An area of the sample prosthesis to be tested is clamped over an elastic diaphragm by means of a flat annular clamping ring, and an increasing fluid pressure is applied to the underside of the diaphragm until the specimen bursts.

NOTE—This method is usually not appropriate for tightly woven fabrics.

8.3.3.1.2 Apparatus

Apparatus to be used include a bursting strength tester in accordance with ISO 2960, but with a clamping ring of a diameter such that the area under test is normally 100 mm^2. For prostheses of small nominal relaxed internal diameter, it may be necessary to use a tester with a smaller orifice. In this case, the size of the orifice shall be reported.

8.3.3.1.3 Sampling

Sampling shall be in accordance with section 7.

8.3.3.1.4 Test procedure

Cut a length from the sample prosthesis along its longitudinal axis and flatten it to form a single thickness sheet. Place the flat sample over the orifice in the base plate of the test apparatus so that the sample completely covers the diaphragm and, for crimped constructions, remove the crimp without distorting the fabric structure. Secure the clamping ring. Increase the pressure at a uniform rate. Record the bursting pressure.

8.3.3.1.5 Expression of results

The bursting pressure of each sample shall be expressed in kilopascals (kPa), the size of the orifice in mm^2, and the nominal inside diameter of the prosthesis tested in millimeters.

8.3.3.1.6 Test report and additional information

The test report shall include the mean and standard deviation of the bursting pressure of the sample prostheses and the size of the orifice if the test area was less than 100 mm^2 and the details required by 4.9.1.

If not in the test report, additional information, including the method of testing, the pressurization rate, and the size of the orifice, shall be recorded together with the details required by 4.9.2.

8.3.3.2 Method for determination of probe burst strength

8.3.3.2.1 Principle

An area of the sample of the prosthesis to be tested is clamped over an orifice by means of a flat annular clamp ring, and a cylindrical probe with a hemispherical head is traversed through the specimen until it ruptures. The applied load is measured continuously during this procedure.

8.3.3.2.2 Apparatus

Apparatus to be used include:

a) a tensile testing machine, having a constant rate of traverse and meeting the requirements of ISO 5081, and capable of operation in the compression mode or fitted with a suitable compression cage;

b) a sample holder with a clamping ring and a traversing probe. A suitable apparatus, including the dimensions, is given in figures 6 and 7 (see following pages).

The complete test equipment shall have an accuracy of ± 5%.

8.3.3.2.3 Sampling

Sampling shall be in accordance with section 7.

8.3.3.2.4 Test procedure

Cut a length from the sample prosthesis along its longitudinal axis and flatten it to form a single thickness sheet. Place the flat sample over the orifice in the base plate of the test apparatus so that the sample completely covers the orifice. For crimped constructions, remove the crimp without distorting the fabric structure. Secure the clamping ring. Align the base plate and the probe, either in the jaws of the tensile tester or in the compression cage, so that the two orifices and the probe are all concentric. Lower the probe until it just touches the test sample. Traverse the probe through the sample at a constant rate until it bursts. Record the probe diameter, the rate of traverse, and the maximum bursting load for each sample.

8.3.3.2.5 Expression of results

The probe diameter shall be expressed in millimeters, the rate of traverse in millimeters per minute and the bursting load in kilonewtons.

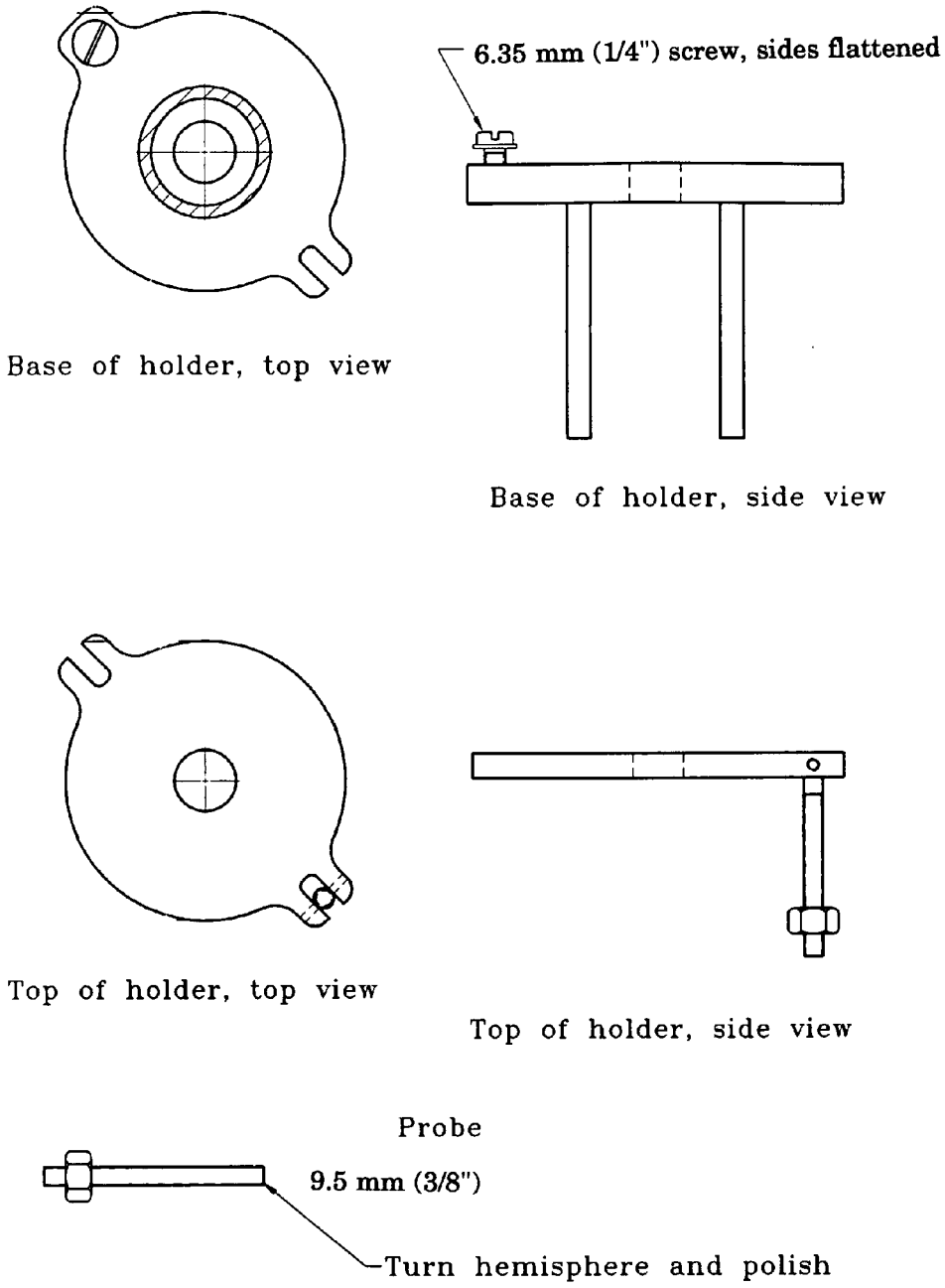

Figure 6—Example of a probe burst test sample holder

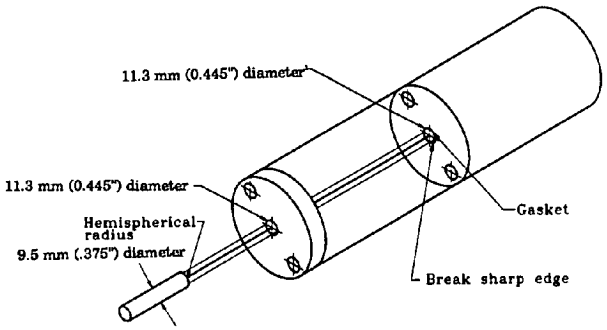

Figure 7—Example of a probe burst tester

8.3.3.2.6 Test report and additional information

The test report shall include the mean and standard deviation of the bursting load, the probe diameter, the rate of traverse, and the details required by 4.9.1.

Additional information shall be recorded in accordance with the details by 4.9.2.

8.3.3.3 Method for determination of pressurized burst strength

8.3.3.3.1 Principle

The sample prosthesis is distended by either:

a) filling the prosthesis directly with fluid; or

b) placing a balloon inside the prosthesis and filling the balloon with fluid at a measured rate of pressure change until bursting of the sample prosthesis takes place.

8.3.3.3.2 Apparatus

The apparatus to be used includes a system capable of measuring and recording pressure to greater than the bursting pressure of the sample with either:

a) an apparatus capable of applying a steadily increasing fluid or gas pressure to the inside of the sample prosthesis extended to its usable length; or

b) a balloon distension apparatus as described in 8.6.2.

NOTE—For either method, several devices may be required to cover the range of samples to be measured.

8.3.3.3.3 Sampling

Sampling shall be in accordance with section 7.

8.3.3.3.4 Procedure

Carefully insert the balloon through the sample prosthesis or attach the sample prosthesis directly to the pressurization apparatus.

NOTE—It may be necessary to lubricate the balloon with a light silicone grease to facilitate insertion.

Attach the pressure measuring device so that it will record the pressure inside the sample prosthesis. Feed fluid or gas to produce a steady rise in pressure. Measure the pressure inside the sample prosthesis. Record the rate of pressure rise and the pressure at which either the sample prostheses bursts or the test is discontinued.

8.3.3.3.5 Expression of results

The rate of pressure rise shall be expressed in kilopascals per second and the bursting pressure in kilopascals.

Calculate and record the mean and the standard deviation for the bursting pressure.

8.3.3.3.6 Test report and additional information

The test report shall include the mean and standard deviation of the bursting pressure of the sample prostheses and the details required by 4.9.1.

Additional information, including the method of testing and the rate of pressurization, shall be recorded, together with the details required by 4.9.2.

8.3.4 Method for determination of strength after repeated puncture (A, if applicable)

8.3.4.1 Principle

This test is intended to determine the strength of a prosthesis after repeated puncture to simulate dialysis use. Samples are punctured repeatedly and then tested for pressurized burst strength according to 8.3.3.3 or circumferential tensile strength according to 8.3.1.

8.3.4.2 Apparatus

A 16-gauge dialysis needle shall be used to puncture the sample prothesis repeatedly. For other test equipment, refer to appropriate strength test (see 8.3.1, Method for determination of circumferential tensile strength, or 8.3.3.3, Method for determination of pressurized burst strength).

8.3.4.3 Sampling

Sampling shall be in accordance with section 7.

8.3.4.4 Test procedure

Samples are punctured 0, 8, 16, and 24 times per square centimeter of prosthesis external surface area (see NOTE). Puncturing shall be limited to one-third of the prosthesis circumference (see figure 8, next page).

NOTE—The values 8, 16, and 24 punctures per cm^2 of external surface area correspond to approximately 6, 12, and 18 months of clinical use. This assumes 6 punctures per week on one-third of the outer surface area of a 30 cm long prosthesis.

Samples should be tested for strength.

8.3.4.5 Expression of results

The strength before and after puncturing is reported in the same manner as the appropriate test section.

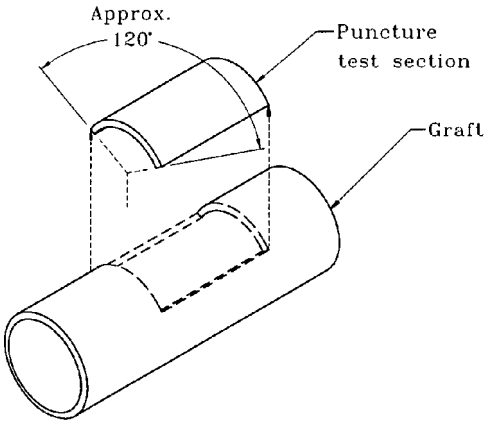

Figure 8—Illustration of graft puncture test

8.3.4.6 Test report and additional information

The test report shall include the mean and standard deviation of the strength before and after puncturing of the sample prostheses, and the details required by 4.9.1.

Additional information, including the test method and the number of samples, shall be recorded with the details required by 4.9.2.

8.4 Method for determination of usable length (A)

8.4.1 Principle

The usable length of the prosthesis shall be measured. The length shall be measured under a prescribed load, which may be zero.

8.4.2 Apparatus

Apparatus to be used include:

a) a tape or scale of adequate length having an accuracy of ± 1 mm, graduated in millimeters, to permit measurements of various lengths of prostheses and where appropriate;

b) a suitable device to clamp the prosthesis at one end (fixed clamp) and a means of applying a specified tension (e.g., via a movable clamp) to the other end of the sample, such as:

i) a manual grip;

ii) a spring-loaded scale or balance pan and a series of weights having an accuracy of ± 0.5 g.

8.4.3 Sampling

Sampling shall be in accordance with section 7.

8.4.4 Test procedure

If appropriate, place the sample prosthesis in the fixed clamp so that a minimum amount of sample is in the clamp. Apply tension to the other end of the sample by a suitable means (e.g., via a movable clamp), again involving a minimum amount of sample. Allow the sample to extend. The applied load shall not be greater than that intended to be applied at implantation.

Record load applied and length.

8.4.5 Expression of results

The usable length of each prosthesis shall be expressed in centimeters (cm), and the applied load in grams

(g).

8.4.6 Test report and additional information

The test report shall include the mean and standard deviation of the usable length of the sample prostheses, and the details required by 4.9.1.

Additional information, including the load applied, shall be recorded, with the details required by 4.9.2.

8.5 Method for determination of relaxed internal diameter (A)

8.5.1 Principle

This test is intended to determine the relaxed internal diameter of a prosthesis either by fitting it over a conical gauge or by inserting a series of cylindrical mandrels.

8.5.2 Apparatus

Apparatus to be used includes conical gauges or cylindrical mandrels, having dimensions capable of measuring to the accuracy specified in 5.5 (see figure 9, next page).

8.5.3 Sampling

Sampling shall be in accordance with section 7.

8.5.4 Test procedure

Either:

a) place the sample prosthesis or a small specimen length of the sample prosthesis loosely over the conical gauge, without stretching; or

b) starting from a small size, insert a mandrel into the sample prosthesis or a small specimen length of the sample prosthesis of increasing diameter until the largest size which does not cause stretching is reached.

Measure and record the relaxed internal diameter.

8.5.5 Expression of results

The relaxed internal diameter of each prosthesis shall be expressed in millimeters (mm).

Record the relaxed internal diameter.

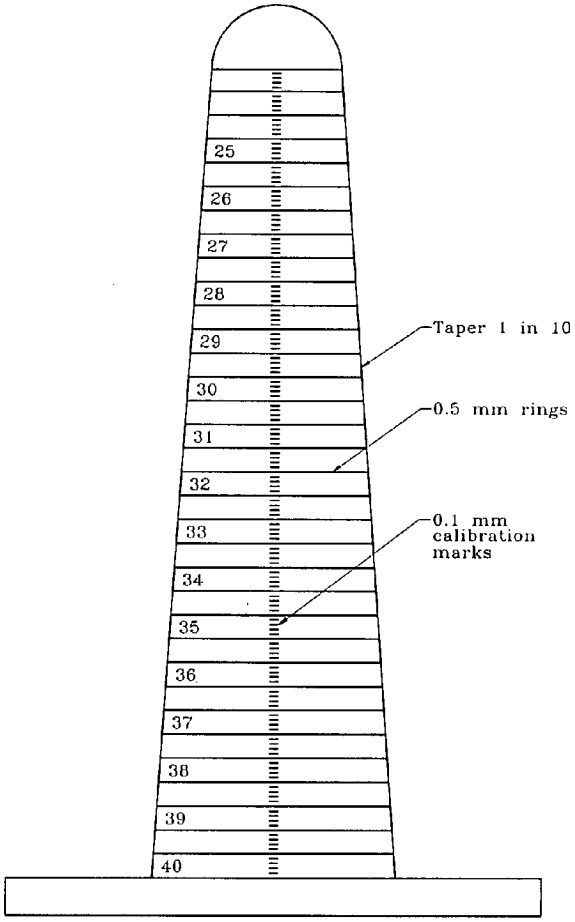

Figure 9—Conical relaxed internal diameter

8.5.6 Test report and additional information

The test report shall include the method of measurement used (i.e., conical gauge or mandrel), the measured mean and standard deviation of the relaxed internal diameter of the sample prostheses, and the details required by 4.9.1.

Additional information, including the number of observations, shall be recorded in accordance with the details required by 4.9.2.

8.6 Method for determination of pressurized internal diameter (A)

8.6.1 Principle

This test is intended to measure the internal diameter under approximately "in use" conditions, i.e., at the usable length and with a distending pressure of the same order of magnitude as the arterial blood pressure 120 mmHg (16.0 kPa).

8.6.2 Apparatus

Apparatus to be used include:

a) a machine or method capable of applying a specified pressure uniformly to the inside of a prosthesis which is extended to its usable length. The latter may be achieved either by applying a known load (see 8.4) without fixation of the distal end of the sample prosthesis, or by fixation of both ends of the sample prosthesis after extension to its usable length.

If a balloon is required, a suitable apparatus is shown in figure 10, which consists of a cylindrical balloon with a diameter at 120 mmHg (16 kPa) pressure, at least 1.05 times the nominal pressurized diameter of

the prosthesis to be measured. This balloon is mounted over a cylindrical mandrel, the greatest diameter of which (excluding all balloon fixing elements) does not exceed 0.95 times the nominal relaxed internal diameter;

b) a pressure measuring device, such as a transducer or manometer, capable of measurement of pressure up to 200 mmHg (19.0 kPa) to an accuracy of ± 2 mmHg (± 0.26 kPa);

c) a device capable of measuring diameter to an accuracy of ± 0.02 mm.

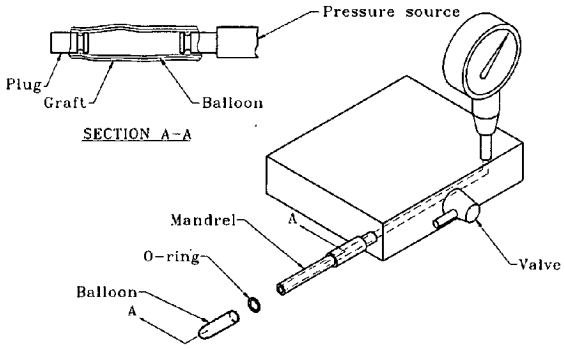

Figure 10—Example of a balloon burst test device

8.6.3 Sampling

Sampling shall be in accordance with section 7.

8.6.4 Test procedure

From the sample prosthesis, cut a sample length of at least 50 mm or at least five times the nominal relaxed internal diameter of the sample prosthesis, whichever is the greater.

Measure and record the wall thickness of the sample prosthesis (t_{meas}) (see 8.7).

If necessary, lubricate the balloon with a light silicone grease, and carefully insert it into the sample length. Stretch the sample length to its usable length (determined as described in 8.4), and inflate the balloon to 120 mmHg (16.0 kPa). Measure and record the external diameter (D_{meas}) to the nearest 0.1 mm at four points equidistant along the sample circumference.

8.6.5 Expression of results

The pressurized internal diameter of each specimen shall be expressed in millimeters.

Calculate the mean pressurized internal diameter (D_p) from the expression:

$$D_p = D_{meas} - (2 * t_{meas})$$

where

D_{meas} = mean measured external diameter of the inflated prosthesis (in mm)

t_{meas} = mean measured wall thickness of the prosthesis (in mm)

Record the mean pressurized internal diameter.

8.6.6 Test report and additional information

The test report shall include the method of measurement used, the mean and standard deviation of the measured pressurized internal diameter of the sample prostheses, and the details required by 4.9.1.

Additional information, including the number of observations, shall be recorded in accordance with the details required by 4.9.2.

8.7 Method for determination of wall thickness (A)

8.7.1 Principle

This test is intended to determine the thickness of the wall of the prosthesis under no load or minimal load.

8.7.2 Apparatus

Apparatus to be used include either:

a) a microscope with either a calibrated eyepiece or with a vernier stage and eyepiece cross-hairs, capable of measurement to an accuracy of 5.0 µm and with provision for direct and diffuse illumination; or

b) a constant load thickness gauge as specified in ISO 5081, with a foot area not less than 0.5 cm and a pressure of 10 g • cm^{-2}.

8.7.3 Sampling

Sampling shall be in accordance with section 7.

8.7.4 Test procedure

One of the two methods shall be used:

8.7.4.1 Method for microscopic determination of wall thickness

Transect the sample prosthesis with a sharp blade and mount a test specimen on the microscope stage with the cut end normal to the axis of the microscope and illuminated from above. Using the eyepiece scale, or the cross-hairs and vernier stage control, measure the thickness of the wall.

Make at least four measurements on each test specimen.

Record the individual measurements of wall thickness, and calculate the mean and standard deviation of the values for each sample prosthesis.

NOTE—For biological vascular tubes, the points measured must include the thinnest and thickest portions of the wall of the test specimen.

8.7.4.2 Method for constant load gauge determination of wall thickness

Perform the test as described in ISO 5084, using a constant pressure thickness gauge.

Make at least four measurements on each test specimen.

Record the individual measurements for wall thickness, and calculate the mean and standard deviation of the value for each sample prosthesis.

8.7.5 Expression of results

The wall thickness shall be expressed in micrometers (µm) or millimeters (mm).

8.7.6 Test report and additional information

The test report shall include the nominal wall thickness, the individual mean and standard deviation of the measured wall thickness, the overall mean and standard deviation of the results of the sample prostheses, and the details required by 4.9.1.

Additional information, including details of the measurement equipment used, shall be recorded with the details required by 4.9.2.

8.8 Method for determination of suture retention strength (A)

8.8.1 Principle

This test is intended to determine the force necessary to pull a suture from the prosthesis or cause the wall of the prosthesis to fail.

8.8.2 Apparatus

A tensile testing machine equipped with a suitable load cell and appropriate gripping mechanism shall be used as described in figure 11 (see next page). A suture as close in size to the typical clinical instrument as possible is selected. The suture should be sufficiently strong to pull through the prosthesis and not break (e.g., polypropylene, polyester, or stainless steel).

8.8.3 Sampling

Sampling shall be in accordance with section 7.

8.8.4 Test procedure

For reinforced prostheses (e.g., external mesh), if the reinforcement is not meant to be included in the anastomosis, the reinforcement should not be incorporated in the suture bite.

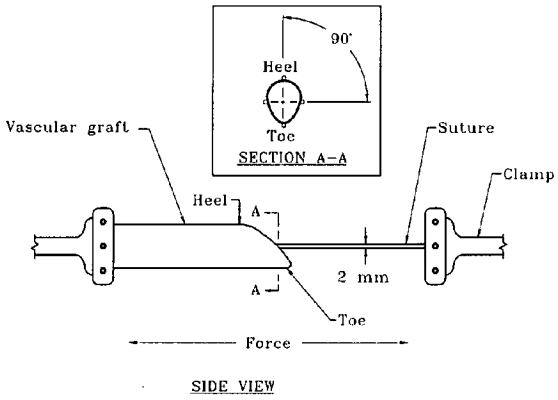

Figure 11—Example of suture retention strength test

8.8.4.1 Straight across procedure

The prosthesis is cut normal to the long axis. If the prosthesis is crimped, the end of the prosthesis must be gently stretched until the crimp has been removed. A suture is inserted 2 mm from the end of the stretched prosthesis through one wall of the prosthesis to form a half loop. The suture is pulled at the rate of 150 ± 50 mm per minute. The force required to pull the suture through the prosthesis or cause the wall of the prosthesis to fail and the suture size are recorded. A minimum of three tests per specimen shall be performed.

8.8.4.2 Oblique procedure

The test is repeated as in 8.8.4.1 with the prosthesis cut at 45° to the long axis. One suture is to be placed at the base (heel) of the cut; for subsequent tests, sutures shall be placed at ± 90° from the base, and at the toe of the cut (see figure 11). The force required to pull the suture through the prosthesis or cause the wall of the prosthesis to fail and the suture size are recorded. A minimum of three tests per specimen will be performed.

8.8.5 Expression of results

The force is measured in grams.

8.8.6 Test report and additional information

The test report shall include the mean and standard deviation of the suture retention strength of the sample prostheses, the type of suture used, and details required by 4.9.1.

Additional information, including the number of samples, shall be recorded in accordance with the details required by 4.9.2.

8.9 Method for determination of kink diameter/radius (A)

8.9.1 Principle

This test is intended to determine the radius of curvature required to begin "kinking" a vascular prosthesis.

8.9.2 Apparatus

Radius templates ranging from 4 to 50 mm in increments of 1.5 mm are used. Alternately, cylindrical mandrels of known diameter may be used.

8.9.3 Sampling

Sampling shall be in accordance with section 7.

8.9.4 Test procedure

The kink radius is determined before and during pressurization as appropriate.

Since kink resistance may be affected by pressure, non-water-permeable prostheses should be tested at 100 mmHg internal pressure. Water at room temperature should be used unless kink behavior is affected by temperature. Water-permeable- constructions may be tested at ambient pressure. The radius of the mandrel that first causes graft kinking is recorded.

Samples are placed in a radius template that does not cause kinking or narrowing. The radius template is decreased until slight narrowing or kinking of the prosthesis is determined.

Alternately a cylindrical mandrel may be used to determine kink radius. This is accomplished by forming a loop out of the test sample, pulling the ends of the sample in opposite directions in order to reduce the loop until a kink is observed. The appropriate size cylindrical mandrel is placed within the loop to measure the kink radius.

8.9.5 Expression of results

The kink radius is measured in mm.

8.9.6 Test report and additional information

The test report shall include the mean and standard deviation of the kink radius of the sample prostheses, the test conditions of temperature and pressure, and details required by 4.9.1.

Additional information, including the number method of testing, shall be recorded together with the details required by 4.9.2.

8.10 Method for determination of dynamic compliance

8.10.1 Principle

This procedure will outline the test methods for measurement of dynamic circumferential compliance of a

vascular prostheses. This will be done by measuring the change in diameter (either directly or by measuring changes in volume/length and calculating the diameter) under dynamic cyclic simulated vessel loading. In principle, prostheses should be tested under conditions which approximate the *in vivo* preclinical environment.

8.10.2 Apparatus

Apparatus to be used include:

a) a machine or method capable of applying a reproducible dynamic pressure to the inside of a prosthesis under constant tension (isotonic) or at a fixed length (isometric) for testing at 37 ± 2°C. The apparatus must be capable of maintaining both the test sample and solution at 37 ± 2°C;

if a balloon is required, a suitable apparatus is shown in figure 10, which consists of a cylindrical balloon with a diameter at 120 mmHg (16 kPa) pressure, at least 1.05 times the nominal pressurized diameter of the prosthesis to be measured. This balloon is mounted over a cylindrical mandrel, the greatest diameter of which (excluding all balloon fixing elements) does not exceed 0.95 times the nominal relaxed internal diameter;

b) a pressure measuring device, such as a transducer, capable of measuring dynamic pressure up to 200 mmHG (27.2 kPa) to an accuracy of ± 2 mmHG (± 0.26);

c) a device capable of measuring diameter to an accuracy of ± 0.02 mm;

d) the apparatus should be capable of directly measuring diameter changes at multiple sites along the test specimen or of measuring the intraluminal volume and length changes thereby allowing the calculation of an average diameter;

NOTE—For biologics, volume methods which provide an average compliance are inappropriate due to inherent biologic variability.

e) distilled water shall be the test fluid, but alternate solutions can be utilized, if justified.

8.10.3 Sampling

Sampling shall be in accordance with section 7.

8.10.4 Test procedure

The following test procedure applies:

a) The length of the test segment shall be no less than 10 times its diameter;

b) The test shall be conducted at 37 ± 2°C unless an alternate temperature can be justified;

c) A longitudinal preload of 30–60 grams should be applied to the test segment;

d) If the radii will be calculated from the volume change, measurements of initial internal diameter and length should be taken prior to pressurization. For the volumetric method, calculate the initial intraluminal volume using the initial internal diameter and initial specimen length;

e) Pressurize the test specimen in a cyclic fashion at a rate of 60 beats per minute ± 10 beats per minute. To assess non-tension behavior, the tests should be conducted at three minimum-maximum pressure ranges (i.e., 50–90 mmHg, 80–120 mmHg, and 110–150 mmHg).

8.10.5 Expression of results

a) If the external diameter is directly measured, then the internal radius can be calculated as:

$Rp = (Dp/2) - t$

where

Rp = Pressurized internal radius

Dp = Measured pressurized external diameter

t = Graft wall thickness

NOTE—In biologic vessels, wall thickness may vary appreciably with pressure. If the wall is incompressible, thickness at any pressure may be calculated using the isovolumetric assumption.

b) If the volume and length are measured, then the pressurized radii at the specified pressure range must be calculated from the volume and length.

c) Once the internal radii at the specified pressure range are calculated, the circumferential compliance can be obtained from the following formula:

$$\%\ compliance = \frac{(Rp2 - Rp1)/Rp1}{p2 - p1} \times 10^4$$

where

p1 = lower pressure value in mmHg

p2 = higher pressure value in mmHg

The circumferential compliance as calculated above is expressed as a percentage of the diameter change per 100 mmHg.

8.10.6 Test report and additional information

The test report shall include the individual mean and standard deviation of the measured compliance, the overall mean and standard deviation of the compliance of the sample prostheses, and the details required by 4.9.1.

Additional information, including test methods used, shall be recorded with the details required by 4.9.2.

9 *In vivo* preclinical and clinical test methods for vascular prostheses

9.1 Method for trial design, data acquisition, and data analysis for *in vivo* preclinical animal studies

9.1.1 Principle

This test is intended to collect and analyze data from the assessment in animals to evaluate the capacity of the prosthesis to maintain physiologic function when used in the circulatory system, and to determine the response of the host and the response of the prosthesis.

9.1.2 Protocol

The intended clinical application and the biological characteristics of the animal shall be considered in the selection of the animal model. Consideration should be given to the intended diameter(s) and length(s) in selection of the appropriate animal model.

A specific question or set of questions to be answered by the study shall be defined prospectively (i.e., a clear statement of objectives). These questions shall delineate the appropriate endpoints to be measured.

9.1.3 Data acquisition

At least the following data shall be recorded for each animal receiving a prosthesis for any clinical application:

a) animal identification;

b) pre-operative data:

i) sex and weight;

ii) verification of satisfactory health status;

iii) medications (e.g., prophylactic antibiotics);

c) operative data:

i) date of procedure;

ii) implanting surgeon;

iii) description of the surgical procedure including type of proximal and distal anastomoses, and immediate post-operative care, including any deviations from study protocol;

iv) prosthesis identification number;

v) *in situ* length and diameter of prosthesis;

vi) adverse peri-operative events (e.g., transmural blood leakage);

d) post-operative data:

i) medications, including those that affect coagulation;

ii) patency assessment, method, and date;

iii) adverse events, date of occurrence, therapy, and outcome;

iv) any deviations from protocol;

e) termination data;

i) assessment of patency, method;

ii) assessment of prosthesis explant pathology.

9.1.4 Test report and additional information

The test report shall include the following:

a) study protocol;

b) rationale for selection of the following:

i) animal species;

ii) implantation site;

iii) control;

iv) method of patency assessment;

v) intervals of observation;

vi) sample size (i.e., number of animals and implants);

c) summary of results:

i) animal accountability, including rationale for exclusion of data;

ii) patency rates;

iii) adverse events;

iv) investigator opinion of handling characteristics;

v) significant and/or relevant deviations from protocol;

vi) summary of pathology, including representative gross photographs and micrographs;

vii) comparison of results for test and control groups;

viii) conclusions from study;

ix) summary of data auditing procedures.

9.2 Method for trial design, data acquisition, and data analysis for clinical evaluation

9.2.1 Principle

Collection and analysis of pre-operative, operative, and post-operative data from an initial clinical evaluation of a new prosthesis or a new clinical application of a prosthesis in order to establish the short-term safety and efficacy prior to general marketing.

9.2.2 Protocol

A specific question or set of questions to be answered by the study to demonstrate safety and effectiveness shall be defined prospectively (i.e., a clear statement of objectives). These questions shall delineate the appropriate endpoints to be measured and include definitions of success and failure for each endpoint.

Patient selection and exclusion criteria shall be clearly established. The criteria shall specify the target population (i.e., those for whom the device is intended) and the accessible population (i.e., those who agree to participate fully in the study). An appropriate epidemiological approach shall be utilized for recruiting subjects to minimize bias.

9.2.3 Data acquisition

At least the following data shall be recorded for each patient receiving a prosthesis:

a) identification data:

i) patient identification;

ii) sex and date of birth;

iii) name of investigator;

iv) name of institution;

b) pre-operative data (0–25 days prior to surgery):

i) risk factors such as hypertension, diabetes, hyperlipidemia, tobacco use, obesity, and any other cardiovascular risk factors, with some measure of severity and current treatment;

ii) summary of previous vascular interventions, including non-surgical interventions, and vascular prostheses implanted;

NOTE—For arterio-venous shunts this should include a summary of previous dialysis shunts. For example:

1) material;

2) site and vessel anastomoses;

3) implant date;

4) frequency of use;

5) revision date(s) and type;

6) failure date and mode.

iii) urgency of intervention (i.e., emergency or elective);

iv) indications for procedure;

v) diagnostic criteria:

1) clinical assessment (e.g., non-invasive hemodynamic assessment);

2) objective assessment (e.g., C.T. scanning, magnetic resonance imaging, ultrasonography, arteriography, duplex doppler);

NOTE—For arterio-venous shunts, an objective assessment may not be applicable.

c) operative data:

i) name of surgeon;

ii) date of procedure;

iii) identification data for prosthesis including identification number, configuration (i.e., as provided and also as used if different), and diameter;

iv) identify native vessel(s) treated or location of arterio-venous access prosthesis;

v) details of anastomoses (e.g., replacement or bypass, type (e.g., end to end), location, length, suture size and material, suture line (i.e., continuous, interrupted, both), reinforcement);

vi) length of prosthesis implanted;

vii) details of procedure (e.g., re-implantation of branches, circulatory support, adjunctive vascular procedures);

viii) relevant medications;

ix) assessment of prosthesis function (e.g., intra-operative angiography, intra-operative Doppler);

x) adverse operative events (e.g., transmural bleeding, prosthesis disruption, suture line bleeding);

d) post-operative data for arterio-venous access (initial prosthesis dialysis session, and 1, 3, 6, and 12 months after initial prosthesis use):

i) date of dialysis session;

ii) frequency of use since last follow-up;

iii) status of region over implant site;

iv) patency of prosthesis;

v) dialysis;

1) size and type of needles;

2) blood flow (ml/min);

3) duration of dialysis (hrs);

4) venous line pressure;

5) duration of needle withdrawal site compression;

vi) summary of vascular interventions since last follow-up;

vii) relevant medications;

viii) adverse events;

ix) reassessment of risk factors such as hypertension, diabetes, hyperlipidemia, tobacco use, obesity, and any other cardiovascular risk factors, with some measure of severity and current treatment, noting improvement/deterioration over pre-operative levels;

e) post-operative data for, all other clinical uses (discharge or 7-14 days after surgery and 3, 6, and 12 months after surgery):

i) date of follow-up visit;

ii) reassessment of risk factors such as hypertension, diabetes, hyperlipemia, tobacco use, obesity, and any other cardiovascular risk factors, with some measure of severity and current treatment, noting improvement/deterioration over pre-operative levels;

iii) summary of vascular interventions and nonsurgical vascular procedures, including minimally invasive procedures, since last follow-up;

iv) clinical evaluation:

1) clinical assessment (e.g., non-invasive hemodynamic assessment), including progression of vascular disease;

2) objective assessment of prosthesis (e.g., C.T. scanning, magnetic resonance imaging, ultrasonography, arteriography, duplex doppler) at 1 year;

NOTE—Should an adverse event be suspected, appropriate objective assessment should be conducted.

v) relevant medications;

vi) adverse events;

f) adverse events data:

i) definitions of complications;

ii) complication, date of occurrence, severity, management, outcome;

iii) documentation of prosthesis involvement (i.e., does the complication physically involve the prosthesis?);

iv) documentation of prosthesis relationship (i.e., is the complication caused by prosthesis, patient, or technical factors?), justified by pathogenesis;

g) patient withdrawal data:

i) date;

ii) months of study completed;

iii) status:

1) lost to follow-up;

2) prosthesis failure;

3) death (including date, cause, and status of prosthesis).

9.2.4 Test report

The test report shall include the following:

a) study protocol;

b) rationale for selection of the following:

i) study size;

ii) choice of control;

iii) measurement methods;

iv) statistical analyses employed;

c) summary of results:

i) patient accountability, including rationale for exclusion of data;

ii) significant and/or relevant deviations from protocol;

iii) summary of patients not completing study (e.g., lost to follow-up, death, or explant);

iv) summary of adverse events;

v) summary of deaths;

vi) summary of pathology, if appropriate, including representative gross, photographs and micrographs;

vii) patency rates and adverse event rates;

NOTE—For the post-operative period (up to 1 year), rates should be calculated as a simple percentage. For the late post-operative period, an estimate of average rates should be calculated. The linearized rates should be reported as the number of events per 100 years of patient exposure. An estimation of risk should be completed for all of the reported complications (i.e., early and late). An actuarial analysis should be used to construct life tables to show estimated probability of freedom from the complication at the end of each time interval.

viii) comparison of results for test and control groups;

ix) conclusions from study.

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Annex A
(Informative)

Rationale for requirements

A.1 Introduction

This AAMI Standard attempts to provide basic requirements for vascular prostheses and to ensure the

collection of accurate and reliable test data to characterize these devices. The intent of this standard is not to establish absolute pass/fail criteria, but to have manufacturers define their own criteria which must be justified. This committee believes that it is not appropriate to establish universal pass/fail criteria for vascular prostheses since the results of such testing cannot, at this time, be related to the clinical performance of these devices. It is nonetheless useful to define test methods in order to provide a uniform means of comparison. Specific performance expectations have not been addressed by this document. An ad hoc committee of the Joint Societies of the North American Chapter of the International Society for Cardiovascular Surgery and the Society for Vascular Surgery published its position on this subject in the June 1993 *Journal of Vascular Surgery* (vol. 17, pp. 746-756).

A.2 Need for the revision of ANSI/AAMI VP20-1986, *Vascular Graft Prostheses*

Revision of the standard is necessary because vascular prostheses have become more diverse and procedures for their analysis are better established. Furthermore, this standard:

i) provides guidance for establishing requirements for safety and efficacy;

ii) facilitates characterization of material properties;

iii) facilitates comparison of prostheses;

iv) assists in the design and development of future products.

A.3 Requirements

These requirements have been divided into the following categories (1) general requirements; (2) finished prostheses requirements; (3) *in vivo* preclinical and clinical requirements.

A.3.1 General requirements

In this document, the committee decided it was appropriate to define intended clinical uses. Different implant locations may necessitate different *in vivo* preclinical characterization. Furthermore, vascular prostheses have become more diverse and nomenclature has been included to assist in adequately describing the prostheses. This standard includes a section on biostability and biocompatibility.

A.3.2 Finished prosthesis requirements

The committee has listed these requirements with specific consideration to the various types of prostheses. Some modifications to the original tests and some additional tests have been included to address the diversity of vascular prostheses.

A.3.3 *In vivo* and clinical requirements

In vivo preclinical testing may be necessary when safety and efficacy, or substantial equivalence, cannot be demonstrated solely through *in vitro* testing. Guidance has been provided in this document for conducting such testing.