List of Titles

American National Standard

ANSI/AAMI/ISO 7198:1998/2001

Cardiovascular implants—Tubular vascular prostheses

AAMI Association for the Advancement of Medical Instrumentation

The Objectives and Uses of AAMI Standards and Recommended Practices

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

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

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

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

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

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

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

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

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

List of Titles

American National Standard

ANSI/AAMI/ISO 7198:1998/2001
(Revision of ANSI/AAMI VP20:1994)

Cardiovascular implants—
Tubular vascular prostheses

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

Approved 17 October 2001 by
American National Standards Institute, Inc.

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

Keywords: biological, component, leakage, permeability, material

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AAMI Standard

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

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Glossary of equivalent standards

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

Note—Documents are sorted by international designation.

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

International designation	U.S. designation	Equivalency
IEC 60601-2-21:1994 and Amendment 1:1996	ANSI/AAMI/IEC 60601-2-21 & Amendment 1:2000 (consolidated texts)	Identical
IEC 60601-2-24:1998	ANSI/AAMI ID26:1998	Major technical variations
ISO 5840:1996	ANSI/AAMI/ISO 5840:1996	Identical
ISO 7198:1998	ANSI/AAMI/ISO 7198:1998/2001	Identical
ISO 7199:1996	ANSI/AAMI/ISO 7199:1996	Identical
ISO 10993-1:1997	ANSI/AAMI/ISO 10993-1:1997	Identical
ISO 10993-2:1992	ANSI/AAMI/ISO 10993-2:1993	Identical
ISO 10993-3:1992	ANSI/AAMI/ISO 10993-3:1993	Identical
ISO 10993-4:1992	ANSI/AAMI/ISO 10993-4:1993	Identical
ISO 10993-5:1999	ANSI/AAMI/ISO 10993-5:1999	Identical
ISO 10993-6:1994	ANSI/AAMI/ISO 10993-6:1995	Identical
ISO 10993-7:1995	ANSI/AAMI/ISO 10993-7:1995	Identical
ISO 10993-8:2000	ANSI/AAMI/ISO 10993-8:2000	Identical
ISO 10993-9:1999	ANSI/AAMI/ISO 10993-9:1999	Identical
ISO 10993-10:1995	ANSI/AAMI/ISO 10993-10:1995	Identical
ISO 10993-11:1993	ANSI/AAMI 10993-11:1993	Minor technical variations
ISO 10993-12:1996	ANSI/AAMI/ISO/CEN 10993-12:1996	Identical
ISO 10993-13:1998	ANSI/AAMI/ISO 10993-13:1999	Identical
ISO 10993-14:200x[1]	ANSI/AAMI/ISO 10993-14:2001	Identical
ISO 10993-15:2000	ANSI/AAMI/ISO 10993-15:2000	Identical
ISO 10993-16:1997	ANSI/AAMI/ISO 10993-16:1997	Identical
ISO 11134:1994	ANSI/AAMI/ISO 11134:1993	Identical
ISO 11135:1994	ANSI/AAMI/ISO 11135:1994	Identical
ISO 11137:1995	ANSI/AAMI/ISO 11137:1994	Identical
ISO 11138-1:1994	ANSI/AAMI ST59:1999	Major technical variations
ISO 11138-2:1994	ANSI/AAMI ST21:1999	Major technical variations
ISO 11138-3:1995	ANSI/AAMI ST19:1999	Major technical variations
ISO 11140-1:1995 and Technical Corrigendum 1:1998	ANSI/AAMI ST60:1996	Major technical variations

International designation	U.S. designation	Equivalency
ISO 11607:200x[1]	ANSI/AAMI/ISO 11607:2000	Identical
ISO 11737-1:1995	ANSI/AAMI/ISO 11737-1:1995	Identical
ISO 11737-2:1998	ANSI/AAMI/ISO 11737-2:1998	Identical
ISO TR 13409:1996	AAMI/ISO TIR 13409:1996	Identical
ISO 13485:1996	ANSI/AAMI/ISO 13485:1996	Identical
ISO 13488:1996	ANSI/AAMI/ISO 13488:1996	Identical
ISO 14155:1996	ANSI/AAMI/ISO 14155:1996	Identical
ISO 14160:1998	ANSI/AAMI/ISO 14160:1998	Identical
ISO 14161:2000	ANSI/AAMI/ISO 14161:2000	Identical
ISO 14937:2000	ANSI/AAMI/ISO 14937:2000	Identical
ISO 14969:1999	ANSI/AAMI/ISO 14969:1999	Identical
ISO 14937:2000	ANSI/AAMI/ISO 14937:2000	Identical
ISO 14971:2000	ANSI/AAMI/ISO 14971:2000	Identical
ISO 15223:2000	ANSI/AAMI/ISO 15223:2000	Identical
ISO 15225:2000	ANSI/AAMI/ISO 15225:2000	Identical
ISO 15674:2001	ANSI/AAMI/ISO 15674:2001	Identical
ISO 15675:2001	ANSI/AAMI/ISO 15675:2001	Identical
ISO TS 15843:2000	ANSI/AAMI/ISO TIR15843:2000	Identical
ISO TR 15844:1998	AAMI/ISO TIR15844:1998	Identical
ISO TR 16142:1999	ANSI/AAMI/ISO TIR16142:2000	Identical

[1] FDIS approved; being prepared for publication.

Committee representation

Association for the Advancement of Medical Instrumentation

Vascular Prostheses Committee

The adoption of ISO 7198:1998 as an American National Standard was initiated by the AAMI Vascular Prostheses Committee. The AAMI Vascular Prostheses Committee also functions as a U.S. Technical Advisory Group to the relevant work in the International Organization for Sterilization (ISO). U.S. representatives from the AAMI Vascular Prostheses Committee (U.S. Sub-TAG for ISO/TC 150/SC 2/WG 3) played an active part in developing the ISO standard.

At the time this document was published, the **AAMI Vascular Prostheses Committee** had the following members:

Cochairs:	Dorothy Abel Louis Smith
Members:	Dorothy Abel, Center for Devices and Radiological Health, U.S. Food and Drug Administration Richard Bianco, University of Minnesota Mark Dehdashtian, Edwards LifeSciences Dennis Genito, Cordis Corporation Kristen Honl, Guidant Endovascular Solutions Martin King, North Carolina State University College of Textiles John Riolo, Medtronic A.V.E. Louis Smith, W.L. Gore & Associates Inc. Ann Tunstall, PhD, Salamandra LLC Frank Veith, MD, Montefiore Medical Center Cynthia Walcott, RN, C.R. Bard Steven Weinberg, PhD, Biomedical Consultants & Labs Rodney White, MD, Harbor – UCLA Medical Center Christopher Zarins, Stanford University Hospital
Alternates:	Brian Hudson, C.R. Bard Mike Morton, W.L. Gore & Associates Inc. Megan Moynahan, Office of Device Evaluation, Center for Devices and Radiological Health, U.S. Food and Drug Administration James Shy, Medtronic Interventional

NOTE—Participation by federal agency representatives in the development of this standard does not constitute endorsement by the federal government or any of its agencies.

Background of ANSI/AAMI adoption of ISO 7198:1998

As indicated in the foreword to the main body of this document (page x), the International Organization for Standardization (ISO) is a worldwide federation of national standards bodies. The United States is one of the ISO members that took an active role in the development of this standard, which was developed by ISO Technical Committee 150/SC 2/WG 3, *Vascular prostheses*, to fill a need for basic requirements for sterile vascular prostheses and the methods of test which will enable evaluation of vascular prostheses.

U.S. participation in this ISO TC is organized through the U.S. Technical Advisory Group for ISO/TC 150/SC 2, administered by the Association for the Advancement of Medical Instrumentation (AAMI).

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

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

AAMI (and ANSI) have adopted other ISO standards. See the Glossary of equivalent standards for a list of ISO standards adopted by AAMI, which gives the corresponding U.S. designation and the level of equivalency with the ISO standard.

The concepts incorporated in this standard should not be considered inflexible or static. This standard, like any other, must be reviewed and updated periodically to assimilate progressive technological developments. To remain relevant, it must be modified as technological advances are made and as new data comes to light.

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

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

Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

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

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

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

Introduction

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

List of Titles

Cardiovascular implants—Tubular vascular prostheses

1 Scope

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

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

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

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

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

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

2 Normative references

The following normative documents contain provisions which, through reference in this text, constitute provisions of this International Standard. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent editions of the normative documents indicated below. For undated references, the latest edition of the normative document referred to applies. Members of ISO and IEC maintain registers of currently valid International Standards.

ISO 472:1988, *Plastics—Vocabulary.*

ISO 2076:1989, *Textiles—Man-made fibers—Generic names.*

ISO 2859-1:1989, *Sampling procedures for inspection by attributes—Part 1: Sampling plans indexed by acceptable quality level (AQL) for lot-by-lot inspection.*

ISO 2859-2:1985, *Sampling procedures for inspection by attributes—Part 2: Sampling plans indexed by limiting quality (LQ) for isolated lot inspection.*

ISO 2960:1974, *Textiles—Determination of bursting strength and bursting distension—Diaphragm method.*

ISO 5081:1977, *Textiles—Woven fabrics—Determination of breaking strength and elongation (Strip method).*

ISO 5084:1977, *Textiles—Determination of thickness of woven and knitted fabrics (other than textile floor coverings).*

ISO 10993-1:1977, *Biological evaluation of medical devices—Part 1: Evaluation and testing.*

ISO 14155:1996, *Clinical investigation of medical devices.*

ASTM D 76-93, *Specification for tensile testing machines for textiles.*

ASTM D 123-94, *Terminology relating to textiles.*

3 Terms and definitions

For the purposes of this International Standard, the terms and definitions given in ASTM D 76-93, ASTM D 123-94, and the following apply.

3.1 allograft (adj.: alloplast): 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 excluding any material derived from fossil biological remains (e.g., petroleum oil).

3.4 biostability: 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 substrate prosthesis.

NOTE—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: 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. cf. **Compound prosthesis** (3.9)

EXAMPLE—Prosthesis in which the proximal portion is of crimped knitted fabric and the distal portion is of an aldehyde-treated animal vascular tube.

3.9 compound prosthesis: Vascular prosthesis whose wall is uniformly constructed of materials from more than one source. cf. **Composite prosthesis** (3.8)

3.10 configuration: Geometry of prosthesis.

EXAMPLES—Straight, bifurcated, tapered.

3.11 construction: Type of structure of a prosthesis.

EXAMPLES—Knitted, woven, nonwoven, 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: 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: 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: 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 1—Leakage may be either through small defects in the wall of a continuous tube or through an anastomosis constructed by the manufacturer.

NOTE 2—Leakage is not the same as **porosity** (3.19).

3.18 node: 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 1—Porosity may be expressed as the percentage void to the total area of volume, mean distance between nodes, or mean pore diameter.

NOTE 2—Porosity is not the same as **leakage** (3.17) or **water permeability** (3.34).

3.20 preclotting: Procedure whereby blood or blood fractions are allowed to penetrate and coagulate within the interstices of a porous prosthesis to decrease the permeability.

3.21 primary component: Substance incorporated into the finished prosthesis whose addition is designed by the manufacturer to improve the performance of the device**.**

3.22 prosthesis (plural: prostheses, adj.: prosthetic): Any device which replaces or substitutes for an anatomical part or deficiency.

3.23 residual material: Substance that is employed in the manufacture of the prosthesis, but is intended to be removed or is 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: Vascular prosthesis to which a coating meeting the definition of 3.5 is applied.

3.26 synthetic material: Substance of nonbiological 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 nontextile prosthesis: Vascular prosthesis manufactured using nontextile processes.

EXAMPLES—Prostheses made from extruded polymer, expanded polymer.

3.28 synthetic textile prosthesis: Vascular prosthesis made from synthetic yarns using textile fabrication methods.

EXAMPLES—Prostheses made by knitting, weaving, braiding of synthetic yarns.

3.29 usable length: Length of a prosthesis available for implantation, determined under a specified fixed load.

NOTE—The load may be zero for certain prostheses.

3.30 vascular prosthesis (vascular graft): 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. cf. **Porosity** (3.19)

NOTE—This is, the interstices of a knitted or woven structure.

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

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

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

NOTE 2—Water permeability is not the same as **porosity** (3.19).

3.35 xenograft (adj.: xenoplast) (heterograft): 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 16 kPa (120 mmHg), 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 nontextiles (e.g., extruded polymer, expanded polymer);

c) biological (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 methods

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 crosslinking) that shall be disclosed by the manufacturer on request.

4.3.2.3 Coatings

For a coating, the amount, permanence, and 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.

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

Materials of which the prosthesis is made shall have been evaluated for biocompatibility in the implantable state either individually or as part of the finished prothesis in accordance with the principles and methods recommended in ISO 10993-1.

Details of test methods and the results obtained shall be disclosed by the manufacturer of the prosthesis on request.

Reassessment shall be made whenever changes are made in materials or in significant processing methods.

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 disclosed by the manufacturer on request 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 prosthesis shall be supplied sterile.

NOTE—The particular problems of transfer of infective agents by prostheses of animal, including human, tissue should be taken into account when validating sterilization processes.

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 has been opened.

For prostheses supplied sterile, 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);

NOTE—The intention of clause references is to assist in adequately describing the device. It is not necessary to be redundant (e.g., porcine xenograft, synthetic polyester).

c) the configuration (see 4.1). A symbol may be substituted for a written description of the prosthesis (e.g., | = straight, 人 = bifurcated, ├ = 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 three adhesive record labels 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 clause of this International Standard.

NOTE—For the purposes of this International Standard, the unit gram is sometimes used as a representation of force, even though it is recognized that gram 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 clauses in this International 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 observations per sample;

h) the minimum and maximum values observed.

5 Requirements for finished prosthesis

NOTE—Suggestions concerning appropriate tests for characterization, quality control testing, and 100 % inspections may be found in Table 1.

Table 1—Suggested appropriate tests

<table>
<tr><th>TEST</th><th>CHARACTERIZATION</th><th>QC TESTING</th><th>100 % INSPECTIONS</th></tr>
<tr><td>Surface properties</td><td>x</td><td></td><td>x</td></tr>
<tr><td>Porosity</td><td rowspan="5">Select appropriate test(s)</td><td rowspan="5">Select appropriate test(s)</td><td rowspan="14">Select appropriate test(s)</td></tr>
<tr><td>Water permeability</td></tr>
<tr><td>Integral water permeability</td></tr>
<tr><td>Leakage</td></tr>
<tr><td>Water entry pressure</td></tr>
<tr><td>Strength after repeated puncture</td><td>x</td><td></td></tr>
<tr><td>Tensile strength</td><td>x</td><td rowspan="2">Select appropriate test(s)</td></tr>
<tr><td>Bursting strength</td><td>x</td></tr>
<tr><td>Usable length</td><td>x</td><td>x</td></tr>
<tr><td>Relaxed inner diameter</td><td>x</td><td>x</td></tr>
<tr><td>Pressurized inner diameter</td><td>x</td><td></td></tr>
<tr><td>Wall thickness</td><td>x</td><td></td></tr>
<tr><td>Suture retention strength</td><td>x</td><td></td></tr>
<tr><td>Knit resistance</td><td>x</td><td></td></tr>
</table>

All testing may not be appropriate for all prosthesis designs. See NOTE in clause 8.

Justification shall be provided for the properties not measured for characterization.

It is impossible, at publication of this International Standard, to take into consideration all future and emerging-technologies. These emerging-technology prostheses will need to follow the basic protocols of this International

Standard to characterize the device. Testing beyond the scope of this International 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 compound prostheses, although it may be appropriate to conduct some of the testing described in this International 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 nonresorbable 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 International Standard relating to leakage (5.2.3) and factory anastomotic strength (either 8.3.2 or 8.3.3.3).

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

The test methods in this International 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—When applicable, the manufacturer shall provide recommendations whereby the water permeability can be reduced by preclotting.

The water permeability of the sample prosthesis shall be less than the maximum, or within the tolerance, of 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 strength, 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 of 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 disclosed 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 %.

Alternative 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 be tested by implantation at the intended, or an analogous, vascular site in at least six animals for at least 20 weeks in each animal unless a justification for a shorter term study is provided. Appropriate controlled *in vivo* preclinical studies shall be used to collect comparable information, unless the absence of a control group is 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 (minimum 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.

An investigation 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 clauses 4 and 5 and 6.1 of this International Standard before starting clinical evaluation.

NOTE 1—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 2—Additions of diameters to a marketed prosthesis for the same clinical application may require further clinical evaluation.

NOTE 3—For a compound prosthesis constructed of a biological absorbable 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 4—It is advisable to continue the follow-up until at least 24 months after the last prosthesis has been implanted.

NOTE 5—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.

7.1 Sampling for characterization

The design characteristics of the vascular prostheses must be verified to be representative of the devices to be released for distribution. For characterization, a minimum of three random samples from each of three random batches or lots shall be used.

7.2 Sampling for quality control

7.2.1 Random sampling

Where a prosthesis is manufactured by a discontinuous or individual process (i.e., where the process is of a lot or batch type), then random samples shall be taken from each lot or batch.

7.2.2 Time interval sampling

Where a prosthesis is manufactured by a continuous process, the batch may be designated by an elapsed period of production, when samples shall be taken at fixed time intervals during the production run.

7.2.3 Number of samples

The number of samples taken for a test shall be in accordance with ISO 2859-1 and ISO 2859-2, having regard to a declared AOQL (Average Outgoing Quality Limit) and the number of items in the lot or batch (see NOTES).

NOTE 1—Alternatively, it may be preferable to use AQL (Acceptance Quality Level) in place of AOQL.

NOTE 2—The number of samples may alternatively be determined by the manufacturer if the sampling plan is based on a validated process with historical data showing the validity of their alternate sampling plan.

8 Test methods for vascular prostheses

NOTE 1—Each test method may not be appropriate for all prosthesis designs. The codes given below will give guidance as to which test methods may be appropriate.

A All type prostheses

B Biological

C Coated

N Synthetic nontextile

T Synthetic textile

NOTE 2—Compound or composite prostheses 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 cleanroom or cabinet;

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

8.1.3 Sampling

Sampling shall be 100 %.

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 (N)

One of the following methods shall be used:

a) planimetric porosity;

b) gravimetric porosity; or

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 intermodal 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 Planimetric determination of porosity

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 a microplanimeter, 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 clause 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:

$$P = 100 \times \frac{\text{total area of voids}}{\text{total area of voids + total area of materials}}$$

Calculate and record the mean 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 deviations 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 Gravimetric determination of porosity

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 mass;

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.

8.2.1.2.3 Sampling

Sampling shall be in accordance with clause 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 square millimeters;

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 millimeters, using the method given in 8.7;

d) the density of (ρ) of the fibrous or polymeric material in each specimen, in grams per cubic centimeter, by means of a suitable density gradient method.

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:

$$P = 100 \times \left(1 - \frac{(1000\, m)}{At\, \rho} \right)$$

Calculate and record the mean and standard deviation of 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 Microscopic determination of porosity

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 surfaces, 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 clause 7.

8.2.1.3.4 Test procedure

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

NOTE 1—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 2—Internodal distances of 5 µm or less are not considered nodal separation, i.e., only internodal distances of 6 µm 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 (μm).

Calculate and record the mean and standard deviations of the internodal distance or the mean and standard deviations 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 deviations of the internodal distance of the sample prostheses or the mean and standard deviations 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 deviations 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 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 flowrates 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 19 kPa (140 mmHg) to an accuracy of ± 0.3 kPa (± 2 mmHg);

c) a sample holding device, designed so that:

1) 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 %;

2) 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 %. The orientation of the sample shall also be noted.

3) 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;

4) leaks around the sample are not observed;

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 16.0 kPa (120 mmHg) for the duration of the test.

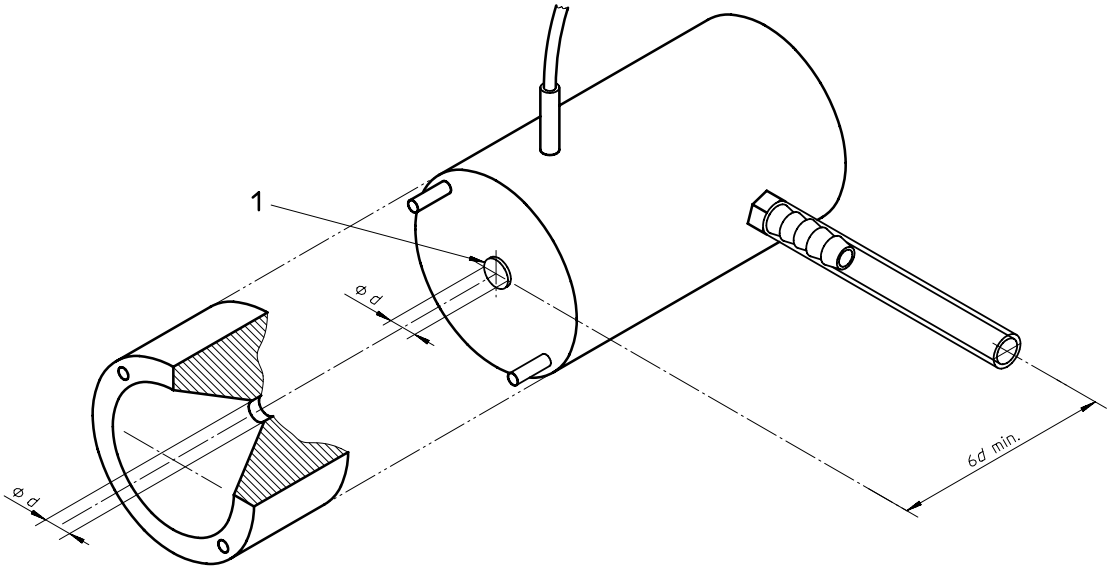
8.2.2.3 Sampling

Sampling shall be in accordance with clause 7.

8.2.2.4 Test procedure

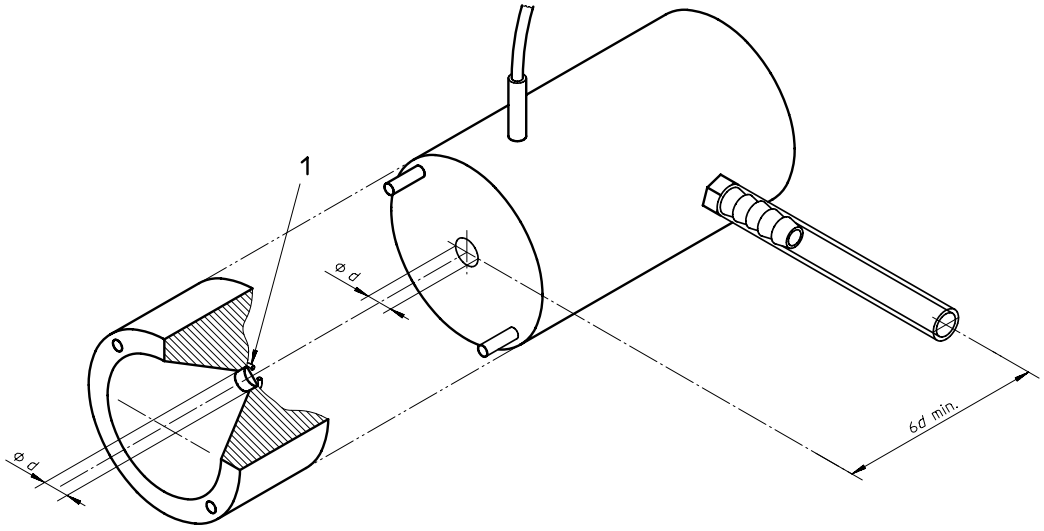
The sample prosthesis may be submerged in clean, filtered water at room temperature to wet the sample prior to testing.

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



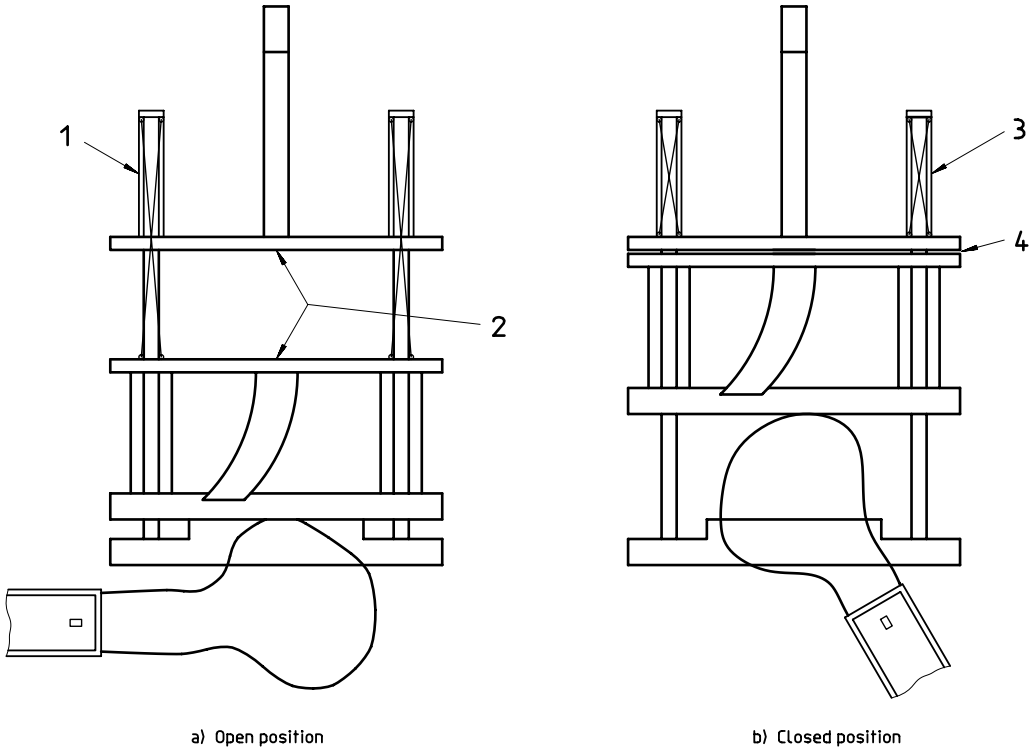
Key
1 Boss

Figure 1—Water permeability tester—Sample holding device (example 1)



Key
1 O-ring

Figure 2—Water permeability tester—Sample holding device (example 2)



Key

1 Spring extended
2 Arm opening 0.5 cm or 0.798 cm in diameter
3 Spring compressed
4 Test fabric placed here

Figure 3—Water permeability tester—Sample holding device (example 3)—Bottom assembly

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 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 16.0 kPa ± 0.3 kPa [(120 ± 2) mmHg], as indicated on the pressure-measuring device, is obtained. Measure the flowrate of water passing through the sample for a period of 60 s ± 1 s, 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 milliliters per centimeter squared per minute (mL cm^{-2} min^{-1}).

Calculate and record the water permeability from the equation:

$$\text{Water permeability} = Q/A$$

where:

Q = flowrate through the sample, in milliliters per minute;

A = cross-sectional area of the aperture in the sample holder, in square centimeters.

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 deviations 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 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 16 kPa (120mmHg). 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 16 kPa (120 mmHg). 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, shall 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 clause 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 prosthesis 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 16.0 kPa ± 0.3 kPa (120 mmHg ± 2 mmHg). Allow the flow to stabilize and measure the leakage through the prosthesis wall for 60 s. 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 milliliters per centimeter squared per minute. For anastomotic leakage, the leakage in the region of the anastomosis shall be expressed as milliliters per minute.

8.2.3.6 Test report and additional information

The test report shall include the mean and standard deviations of 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 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 clause 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 kilopascals (millimeters mercury).

8.2.4.6 Test report and additional information

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

Additional information, including the rate of pressure increase, 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 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:

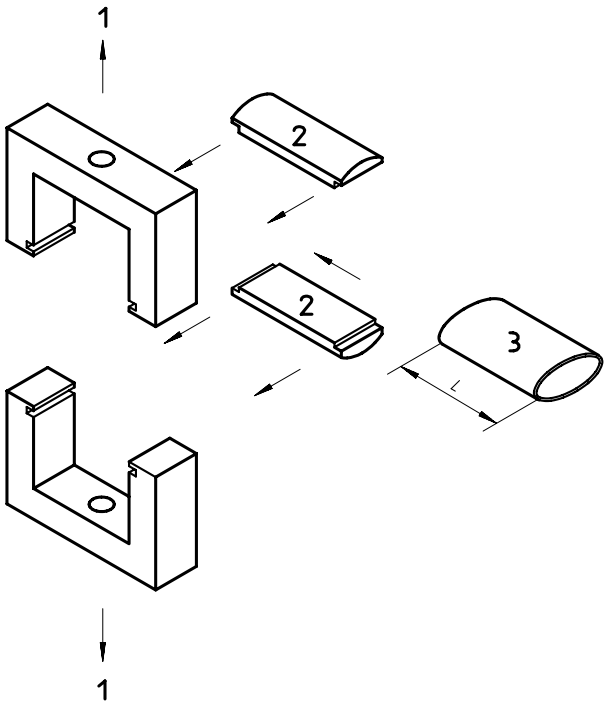
a) a tensile testing machine meeting the requirements of ISO 5081, having a constant rate of traverse, and with appropriately sized pins and suitable holders over which the sample prosthesis may be threaded: a suitable example is given in Figure 4 a) and b);

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

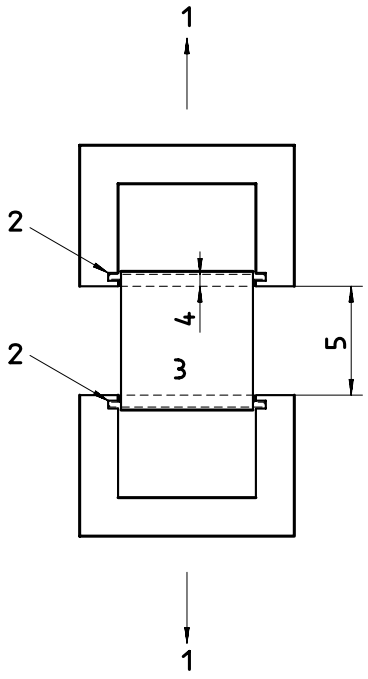
c) apparatus to measure the relaxed internal diameter (see 8.5).

8.3.1.3 Sampling

Sampling shall be in accordance with clause 7.



a) Schematic



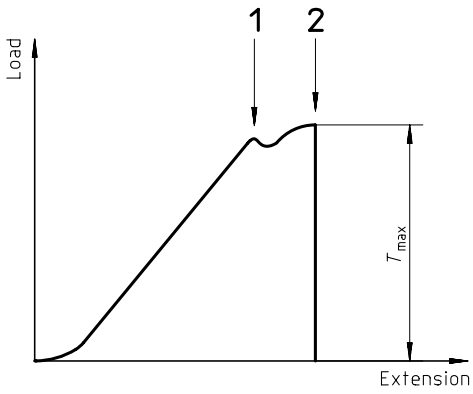
b) Front view

Key
1 Tensile tester
2 Split bar
3 Sample
4 Pin diameter
5 Pin separation

Figure 4—Split bar tester

8.3.1.4 Test procedure

Cut a test specimen from the sample prosthesis with a length not less than the nominal relaxed internal diameter (8.5). After careful removal of any crimp, measure and record the length of the specimen (L) in millimeters 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 $mm \cdot min^{-1}$ to 200 $mm \cdot min^{-1}$ until the break point is reached. Determine the load at yield or break, i.e., the maximum load (T_{max}), to an accuracy of ± 2 %, and record the rate of extension (see Figure 5), if appropriate.



Key

1 Yield

2 Break

Figure 5—Load/extension curve

8.3.1.5 Expression of results

Calculate the circumferential tensile strength of each sample, expressed as kilonewtons per millimeter, by dividing the maximum load (T_{max}) by the original length of the sample.

$$Maximum\ load\ /\ Length = \frac{T_{max}}{2\,L}$$

8.3.1.6 Test report and additional information

The test report shall include the mean and standard deviations 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.

8.3.2 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 clause 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 mm 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 $mm \cdot min^{-1}$ to 200 $mm \cdot min^{-1}$ until the break point is reached. Determine the load at yield or break, i.e., the maximum load (T_{max}), 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 in kilonewtons as:

Maximum load = T_{max}

8.3.2.6 Test report and additional information

The test report shall include the mean and standard deviations 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 Determination of burst strength (A)

NOTE—The tests described in this subclause are alternatives to those in 8.3.1. Attention is drawn to the NOTES 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 the pressurized burst strength (8.3.3.3) shall be the preferred method for characterization.

8.3.3.1 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 clause 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 baseplate 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 square milliliters, 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 deviations 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 with the details required by 4.9.2.

8.3.3.2 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;

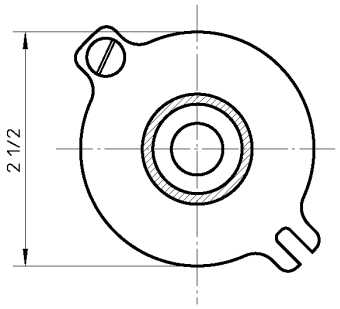
b) a sample holder with a clamping ring and a traversing probe. A suitable apparatus, including the dimensions, is given in Figures 6 and 7.

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

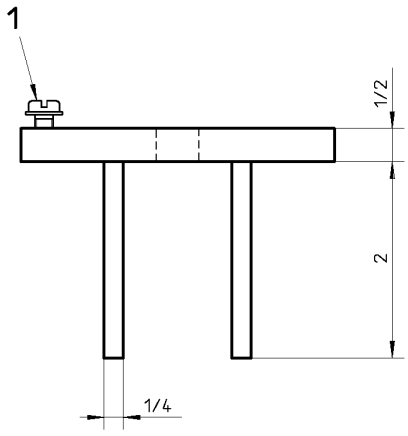
8.3.3.2.3 Sampling

Sampling shall be in accordance with clause 7.

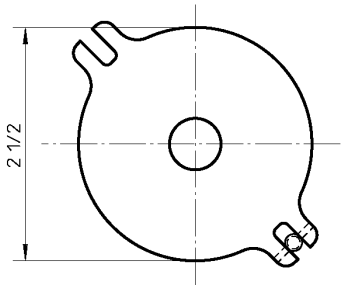
Dimensions in inches



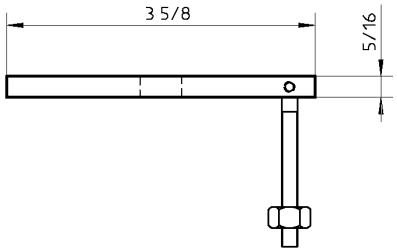
a) Base of holder, top view



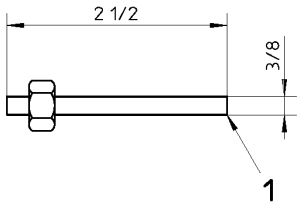
b) Base of holder, side view



c) Top of holder, top view



d) Top of holder, side view



e) Probe

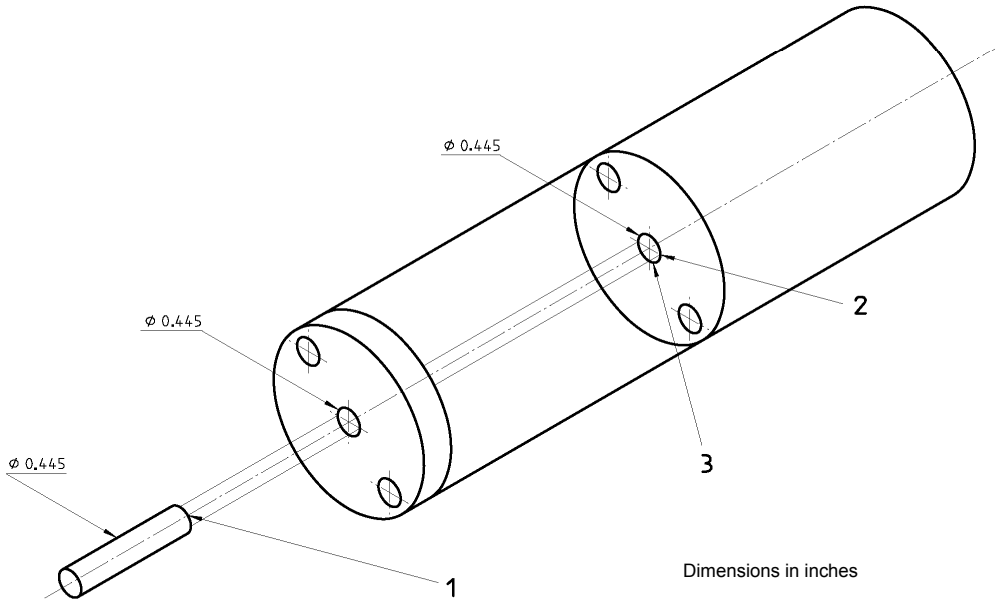
Key

1 1/4 in screw, sides flattened

2 Turn hemisphere and polish

NOTE 3 5/8 in = 92 mm 2 in = 51 mm 5/16 in = 7.9 mm
2 1/2 in = 64 mm 3/8 in = 9.5 mm 1/4 in = 6.4 mm

Figure 6—Example of a probe burst test sample holder—Center opening to 0.445 in diameter, recessed gasket of fiber-rubber composition 1 in o.d., ¾ in i.d.



Key

1 Hemispherical radius
2 Gasket
3 Break sharp edge

NOTE—0.445 in = 11.3 mm

Figure 7—Example of a probe burst tester

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 baseplate 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 baseplate 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 millimeters per minute, and the bursting load in kilonewtons.

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 require by 4.9.1.

Additional information shall be recorded in accordance with 4.9.2.

8.3.3.3 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 clause 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 prosthesis 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 deviations 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 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 prosthesis repeatedly. For other test equipment, refer to appropriate strength test (see 8.3.1 or 8.3.3.3).

8.3.4.3 Sampling

Sampling shall be in accordance with clause 7.

8.3.4.4 Test procedure

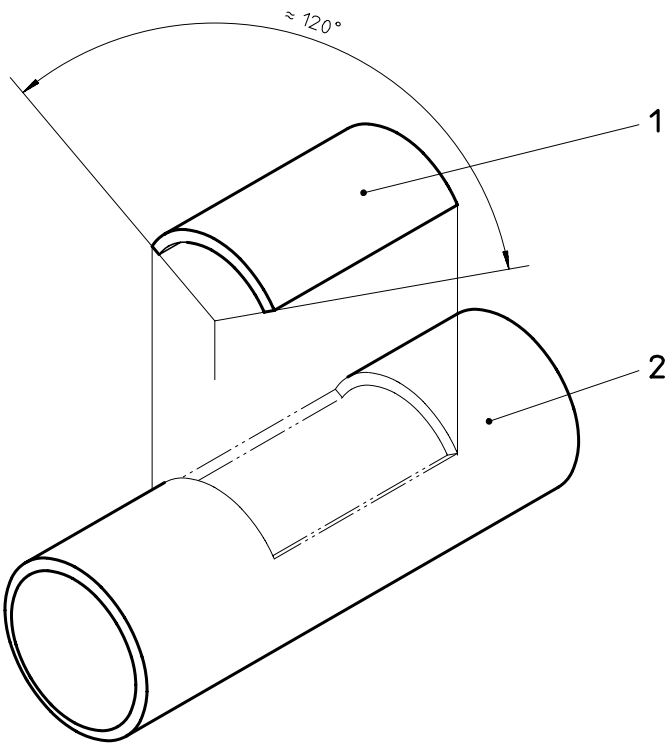
Samples are punctured 0, 8, 16, and 24 times per square centimeter of prosthesis external surface area (see NOTE). Puncturing shall be limited to one-third of the prosthesis circumference (see Figure 8).

NOTE—The values 8, 16, and 24 punctures per square centimeter 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.



Key

1 Puncture test section

2 Graft

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 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:

   1) a manual grip;

   2) 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 clause 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, and the applied load in newtons.

8.4.6 Test report and additional information

The test report shall include the mean and standard deviations 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 Determination of relaxed internal diameter (A)

8.5.1 Principle

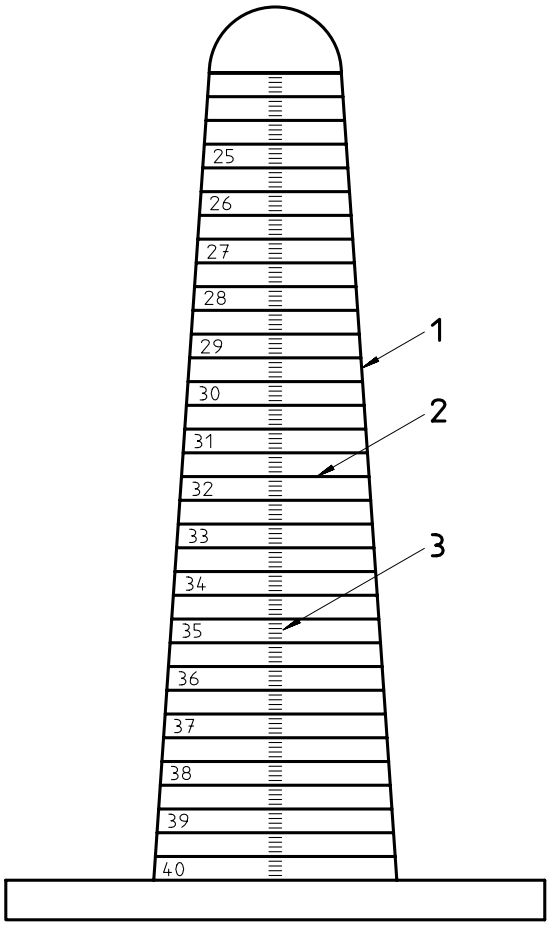
This test is intended to determine the relaxed internal diameter of a prosthesis either by fitting it over a conical gauge or by inserting a series of cylindrical mandrels.

8.5.2 Apparatus

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

8.5.3 Sampling

Sampling shall be in accordance with clause 7.



Key

1 Taper 1 in 10

2 0.5 mm rings

3 0.1 mm calibration marks

Figure 9—Conical gauge for relaxed internal diameter

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.

Record the 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 deviations 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 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 16 kPa (120 mmHg).

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.

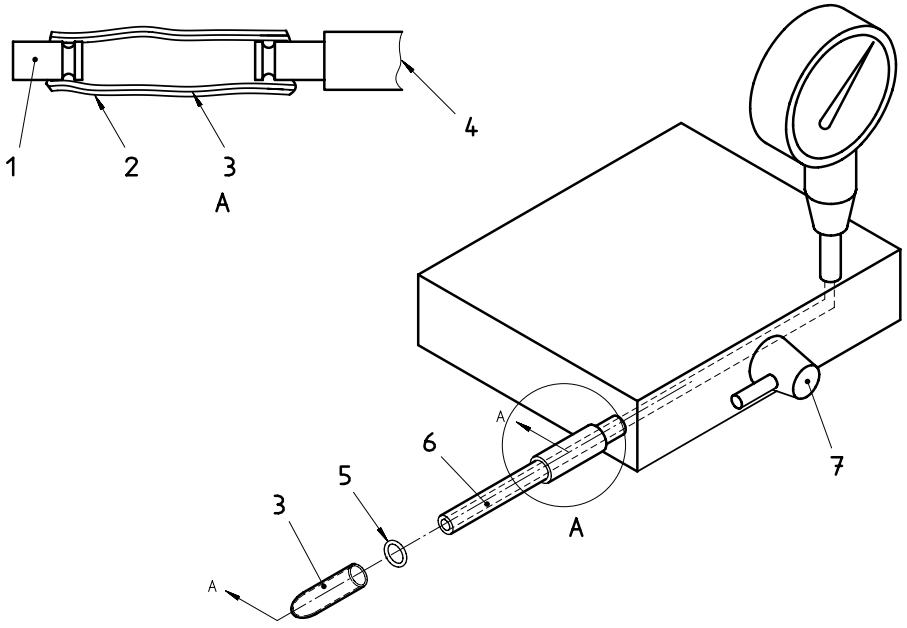
   If a balloon is required, a suitable apparatus is shown in Figure 10, which consists of a cylindrical balloon with a diameter at 16 kPa (120 mmHg) pressure of at least 1.05 times the nominal pressurized diameter of the prosthesis to be measured. This balloon is mounted over a cylindrical mandrel, the 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 26.7 kPa (200 mmHg) to an accuracy of ± 0.3 kPa (± 2 mmHg);

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

8.6.3 Sampling

Sampling shall be in accordance with clause 7.



Key

1 Plug
2 Graft
3 Balloon
4 Pressure source
5 O-ring
6 Mandrel
7 Valve

Figure 10—Example of a balloon burst test device

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 16 kPa (120 mmHg). 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} is the mean measured external diameter of the inflated prosthesis (in millimeters);

t_{meas} is the mean measured wall thickness of the prosthesis (in millimeters).

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 deviations 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 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 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;

b) a constant-load thickness gauge as specified in ISO 5084, with a foot area not less than 0.5 cm^2 and a pressure of 981 Pa (10 $g \cdot cm^{-2}$); or

c) a calibrated load thickness gauge with a foot area and pressure appropriate to the test sample.

8.7.3 Sampling

Sampling shall be in accordance with clause 7.

8.7.4 Test procedure

One of the two methods below for determination of wall thickness shall be used.

8.7.4.1 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 deviations of the values for each sample prosthesis.

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

8.7.4.2 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 deviations of the value for each sample prosthesis.

8.7.5 Expression of results

The wall thickness shall be expressed in micrometers or millimeters.

8.7.6 Test report and additional information

The test report shall include the nominal wall thickness, the individual mean and standard deviations of the measured wall thickness, the overall mean and standard deviations 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 Determination of suture retention strength (A)

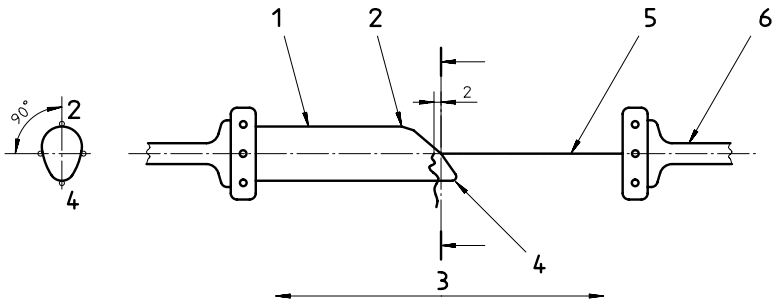
8.8.1 Principle

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. 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 (made of, e.g., polypropylene, polyester, or stainless steel).

Dimensions in millimeters



Key

1 Vascular graft
2 Heel
3 Force
4 Toe
5 Suture
6 Clamp

Figure 11—Example of suture retention strength test—Side view

8.8.3 Sampling

Sampling shall be in accordance with clause 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.

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 50 $mm \cdot min^{-1}$ to 200 $mm \cdot min^{-1}$. The force required to pull the suture through the prosthesis or cause the wall of the prosthesis to fail, and 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 shall 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 deviations of the suture retention strength of the sample prostheses, the type and size 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 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

Templates of radius ranging from 4 mm to 50 mm in increments of 1.5 mm are used. Alternatively, cylindrical mandrels of known diameter may be used.

8.9.3 Sampling

Sampling shall be in accordance with clause 7.

8.9.4 Test procedure

The kink radius, to the nearest increment of the gauge, 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 template radius is decreased until slight narrowing or kinking of the prosthesis is determined.

Alternatively, a cylindrical mandrel may be used to determine kink radius. This is accomplished by forming a loop out of the test sample, and 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 millimeters.

8.9.6 Test report and additional information

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

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

8.10 Determination of dynamic compliance

8.10.1 Principle

This procedure will outline the test methods for measurement of dynamic circumferential compliance of a vascular prosthesis. 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 16 kPa (120 mmHg) 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 26.7 kPa (200 mmHg) to an accuracy of ± 0.3 kPa (± 2 mmHg); and

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

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 implants manufactured from biological material, volume methods which provide an average compliance are inappropriate due to inherent biological variability.

Distilled water shall be the test fluid, but alternative solutions can be utilized, if justified.

8.10.3 Sampling

Sampling shall be in accordance with clause 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 alternative temperature can be justified;

c) A longitudinal preload of 0.294 N to 0.588 N (suspended mass 30 g to 60 g) should be applied to the test segment;

d) If the radii will be calculated from the volume change, measurements of 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 nonlinear behavior, the tests should be conducted at three minimum-maximum pressure ranges [i.e., 7 kPa to 12 kPa (50 mmHg to 90 mmHg), 10.7 kPa to 16.0 kPa (80 mmHg to 12 mmHg), and 14.7 kPa to 20 kPa (110 mmHg to 150 mmHg)].

8.10.5 Expression of results

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

$$R_p = (D_p / 2) - t$$

where:

R_p is the pressurized internal radius;

D_p is the measured pressurized external diameter; and

t is the graft wall thickness.

NOTE—In biological 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.

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

$$\% \text{ compliance} = \frac{R_{p_2}\,(-R_{p_1}) / R_{p_1}}{p_2 - p_1} \times 10^4$$

where:

p_1 is the lower pressure valve, in mmHg; and

p_2 is the 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 deviations of the measured compliance at each pressure range, the overall mean and standard deviations 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 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:

   1) sex and mass;

   2) verification of satisfactory health status; and

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

c) operative data:

   1) date of procedure;

   2) implanting surgeon;

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

   4) prosthesis identification number;

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

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

d) post-operative data:

   1) medications, including those that affect coagulation;

   2) patency assessment, method, and date;

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

   4) any deviations from protocol;

e) termination data:

1) assessment of potency, method; and

2) 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:

1) animal species;

2) implantation site;

3) control;

4) method of patency assessment;

5) intervals of observation; and

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

c) summary of results:

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

2) patency rates;

3) adverse events;

4) investigator opinion of handling characteristics;

5) significant and/or relevant deviations from protocol;

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

7) comparison of results for test and control groups;

8) conclusions from study; and

9) summary of data auditing procedures.

9.2 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:

1) patient identification;

2) sex and date of birth;

3) name of investigator; and

4) name of institution;

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

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

2) summary of previous vascular interventions, including nonsurgical interventions, and vascular prostheses implanted;

NOTE—For arteriovenous shunts, this should include a summary of previous dialysis shunts. For example:

i) material;

ii) site and vessel anastomoses;

iii) implant date;

iv) frequency of use;

v) revision date(s) and type; and

vi) failure date and mode.

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

4) indications for procedure;

5) diagnostic criteria:

i) clinical assessment (e.g., noninvasive hemodynamic assessment);

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

NOTE—For arteriovenous shunts, an objective assessment may not be applicable.

c) operative data:

1) name of surgeon;

2) date of procedure;

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

4) identity of native vessel(s) treated or location of arteriovenous access prosthesis;

5) details of anastomoses [e.g., type (e.g., end-to-end), location, length, suture size and material, suture line (i.e., continuous, interrupted, both), reinforcement];

6) length of prosthesis implanted;

7) details of procedure (e.g., location, reimplantation of branches, circulatory support, adjunctive vascular procedures);

8) relevant medications;

9) assessment of prosthesis function (e.g., intraoperative angiography, intraoperative Doppler);

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

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

1) date of dialysis session;

2) frequency of use since last follow-up;

3) status of region over implant site;

4) patency of prosthesis;

5) dialysis:

i) size and type of needles;

ii) blood flow (mL/min);

iii) duration of dialysis (h);

iv) venous line pressure; and

v) duration of needle withdrawal site compression;

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

7) relevant medications;

8) adverse events;

9) 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):

1) date of follow-up visit;

2) 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;

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

4) clinical evaluation:

i) clinical assessment (e.g., noninvasive hemodynamic assessment) including progression of vascular disease; and

ii) 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.

5) relevant medications;

6) adverse events;

f) adverse events data:

1) definitions of complications;

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

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

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

g) patient withdrawal:

1) date;

2) months of study completed;

3) status:

i) lost to follow-up;

ii) prosthesis failure; and

iii) death (including date and cause of death 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:

1) study size;

2) choice of control;

3) measurement methods; and

4) statistical analysis employed;

c) summary of results:

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

2) significant and/or relevant deviations from protocol;

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

4) summary of adverse events;

5) summary of deaths;

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

7) patency rates and adverse event rates;

NOTE—For the post-operative period (a minimum of 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.

8) comparison of results for test and control groups; and

9) conclusions from study.

10 Information to be recorded and disclosed by the manufacturer on request

10.1 General

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

10.2 Conformity to general requirements (see clause 4)

Test method, justification, results, and additional information used to determine the following shall be recorded and shall be disclosed by the manufacturer on request:

a) characteristics of, and compliance with the limits declared by the manufacturer for, coatings, if appropriate (see 4.3.2.3);

b) biocompatibility and biostability (see 4.4); and

c) sterility (see 4.5).

10.3 Conformity to requirements for finished product (see clause 5)

Test reports and additional information for the determination of the following shall be recorded and shall be disclosed by the manufacturer on request:

a) visual inspection (see 5.1);

b) porosity, water permeability, integral water permeability/leakage, and water entry pressure, if appropriate (see 5.2);

c) strength (see 5.3);

d) length (see 5.4);

e) relaxed internal diameter (see 5.5);

f) pressurized internal diameter, if appropriate (see 5.6);

g) wall thickness (see 5.7);

h) suture retention strength (see 5.8);

i) kink diameter/radius (see 5.9); and

j) compliance (see 5.10).

10.4 Conformity to requirements for *in vivo* testing and clinical evaluation (see clause 6)

Test method, justification, results, and additional information used to determine the following shall be recorded and shall be disclosed by the manufacturer on request:

a) *in vivo* pre-clinical testing (see 6.1); and

b) clinical evaluation (see 6.2).

