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

Implants cardiovasculaires et systèmes extracorporels — Prothèses vasculaires — Greffons vasculaires tubulaires et pièces vasculaires

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ISO copyright office
Ch. de Blandonnet 8 • CP 401
CH-1214 Vernier, Geneva, Switzerland
Tel. +41 22 749 01 11
Fax +41 22 749 09 47
copyright@iso.org
www.iso.org

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Foreword

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The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: Foreword - Supplementary information

The committee responsible for this document is ISO/TC 150, *Implants for surgery*, Subcommittee SC 2, *Cardiovascular implants and extracorporeal systems*.

This second edition cancels and replaces the first edition (ISO 7198:1998), which has been technically revised.

Introduction

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

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

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

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

1 Scope

1.1 This International Standard specifies requirements for the evaluation of vascular prostheses and requirements with respect to nomenclature, design attributes and information supplied by the manufacturer, based upon current medical knowledge. Guidance for the development of *in vitro* test methods is included in an informative annex to this International Standard. This International Standard can be considered as a supplement to ISO 14630:2012, which specifies general requirements for the performance of non-active surgical implants.

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

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

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

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

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

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

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

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

1.8 Cardiac and pericardial patches, vascular stents, accessory devices such as anastomotic devices, staplers, tunnelers and sutures, and pledgets are excluded from the scope of this International Standard.

NOTE Requirements for vascular stents are specified in ISO 25539-2.

1.9 Requirements regarding cell seeding are excluded from the scope of this International Standard. Tissue engineered vascular prostheses that contain or are manufactured using cells present many distinct manufacturing (e.g. aseptic processing, cell seeding, etc.) and testing issues than those produced with synthetic or non-viable biological materials. The *in vitro* testing requirements that are outlined in this International Standard can be a useful guide for certain testing requirements for these cell-based products.

1.10 Pharmacological aspects of drug-eluting or drug-coated vascular prostheses are not addressed in this International Standard.

NOTE Requirements for vascular device-drug combination products are specified in ISO 12417-1.

1.11 Degradation, tissue ingrowth and/or tissue replacement, and other time-dependent aspects of absorbable vascular prostheses are not addressed in the standard.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 10993 (all parts), *Biological evaluation of medical devices*

ISO 11135, *Sterilization of health-care products — Ethylene oxide — Requirements for the development, validation and routine control of a sterilization process for medical devices*

ISO 11137 (all parts), *Sterilization of health care products — Radiation*

ISO 11607-1, *Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems*

ISO 14155, *Clinical investigation of medical devices for human subjects — Good clinical practice*

ISO 14160, *Sterilization of health care products — Liquid chemical sterilizing agents for single-use medical devices utilizing animal tissues and their derivatives — Requirements for characterization, development, validation and routine control of a sterilization process for medical devices*

ISO 14630:2012, *Non-active surgical implants — General requirements*

ISO 14937, *Sterilization of health care products — General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices*

ISO 14971, *Medical devices — Application of risk management to medical devices*

ISO 17665 (all parts), *Sterilization of health care products — Moist heat*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 14630:2012 and the following apply.

3.1
adverse event
adverse change in health that occurs in a subject who participates in a study while receiving the treatment or within a specified time after receiving treatment

Note 1 to entry: Adverse events are categorized by the system affected (e.g. cardiac, vascular, respiratory, neurological, renal, gastro-intestinal).

Note 2 to entry: This definition is not applicable for routine, post-approval event reporting.

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

3.4
biostability
ability of a material to maintain its physical and chemical integrity after implantation in living tissue

3.5
coating
organic or inorganic material, other than living cells, intentionally applied by a manufacturer to substrate prosthesis

Note 1 to entry: This coating can be intended to be permanent or temporary, can be applied to the external and/or internal surface, and/or can be impregnated into the structure of the *substrate prosthesis* (3.30).

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

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

Note 1 to entry: It is important to note the difference between a composite and *compound prosthesis* (3.9).

3.9
compound prosthesis
vascular prosthesis whose wall is constructed of materials from more than one source which is of uniform construction along the length of the prosthesis

Note 1 to entry: It is important to note the difference between a compound and *composite prosthesis* (3.8).

Note 2 to entry: A substrate prosthesis with a coating, that is, a coated vascular prosthesis, is an example of a compound prosthesis. This type of vascular prosthesis is commonly referred to as coated prosthesis rather than a compound prosthesis.

3.10
configuration
geometry of prosthesis

EXAMPLE Straight, bifurcated, tapered.

3.11
construction
type of structure of a prosthesis

EXAMPLE Knitted, woven, nonwoven, expanded polymer.

3.12
crimp
creases or folds manufactured into a prosthesis to permit elongation and reduce kinking

3.13
determine
quantitatively appraise or analyse

3.14
endovascular prosthesis
endovascular graft
endovascular implant
prosthesis (including modular components) delivered and deployed using a delivery system, which resides partially or completely within a blood vessel or vascular conduit to form an internal bypass or shunt between sections of the vascular system

3.15
evaluate
qualitatively appraise or analyse

3.16
factory anastomosis
factory manufactured seam-line in which two or more edges of graft material are joined (e.g. sewn) together

3.17
fibril
strand of material which originates from one or more nodes and terminates at one or more nodes

3.18
graft material
textile or non-textile, non-metallic material [e.g. polyethylene terephthalate (PET), polytetrafluoroethylene (PTFE), polyurethane] used in the construction of a vascular prostheses or to line or cover the mechanical support structures of an endovascular prosthesis or to provide a vascular conduit for blood flow

3.19
host
recipient of an implant in a preclinical *in vivo* study

3.20
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 1 to entry: Preparation does not include *preclotting* (3.26) but does include any recommended method of washing or soaking.

3.21
integral water permeability
volume of water which passes through the wall of a tubular vascular graft, or representative tubular segment, in a specified time under a specified pressure

3.22
inter-nodal distance
distance between two nodes of expanded polymers

3.23
leakage
volume of water which passes through flaws in a water-impermeable vascular prosthesis in a specified time under a specified pressure

Note 1 to entry: Leakage may be either through small defects in the wall of a continuous tube or through an anastomosis constructed by the manufacturer.

Note 2 to entry: Leakage is not the same as *porosity* (3.25).

3.24
node
solid region within a material at which fibrils originate and converge

3.25
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 to entry: See *void* (3.36).

Note 2 to entry: Porosity may be expressed as the percentage void to the total area of volume, mean distance between nodes, or mean pore diameter.

Note 3 to entry: Porosity is not the same as *leakage* (3.23) or *water permeability* (3.38).

3.26
preclotting
procedure whereby blood or blood fractions are allowed to penetrate and coagulate within the interstices of a porous prosthesis to decrease the permeability

3.27
prosthesis
device which replaces or substitutes for an anatomical part or deficiency

3.28
substrate prosthesis
vascular prosthesis to which a coating meeting the definition of *coating* (3.5) is applied to result in a compound prosthesis

3.29
synthetic material
substance of nonbiological source that is produced and/or polymerized by chemical or physical means

Note 1 to entry: Chemically modified materials derived from fossil biological remains (e.g. petroleum or oil) are considered to be synthetic.

3.30
synthetic nontextile prosthesis
vascular prosthesis manufactured made from synthetic materials using nontextile processes

EXAMPLE Prostheses made from extruded polymer, expanded polymer.

3.31
synthetic textile prosthesis
vascular prosthesis made from synthetic yarns using textile fabrication methods

EXAMPLE Prostheses made by knitting, weaving, or braiding of synthetic yarns.

3.32
tubular vascular graft
prosthesis used to replace, bypass, or form shunts between sections of the vascular system, implanted using direct visualization surgical techniques as opposed to fluoroscopic or other non-direct imaging

Note 1 to entry: Examples of non-direct imaging are computerized tomography and magnetic resonance imaging.

3.33
usable length
length of a prosthesis available for implantation, determined under a specified fixed load

Note 1 to entry: The load may be zero for certain prostheses.

3.34
vascular patch
non-tubular prosthesis intended for repair and reconstruction of the vascular system

EXAMPLE Flat sheet of material.

3.35
vascular prosthesis
tubular vascular graft or vascular patch

3.36
void
proportion of the wall of a vascular prosthesis that is not occupied by the material of construction.

3.37
water entry pressure
pressure at which water passes from the inner wall to the outer wall of a vascular prosthesis

3.38
water permeability
volume of water that passes during a specified period through a unit area of the graft material under a specified pressure

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

Note 2 to entry: Water permeability is not the same as *porosity* (3.25).

3.39
xenograft
heterograft
implant material made from the tissues of an animal of a different species from the host or patient

4 General requirements

4.1 Configuration designation for tubular vascular grafts

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

Some prostheses can be manufactured for specific applications, such as an axillo-bifemoral prosthesis, and shall be designated by their intended clinical use, not as “bifurcated.”

4.2 Size designation

4.2.1 Uniform straight tubular vascular grafts

The size of a straight uniform tubular vascular graft 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;

c) minimum usable length, expressed in centimeters.

4.2.2 Uniform bifurcated tubular vascular grafts

The size of uniform bifurcated tubular vascular graft shall be designated by the nominal relaxed internal diameters and the minimum usable overall length of the main tube and its branches. Pressurized internal diameters shall also be designated if required [see 4.2.1 b)]. Diameters shall be expressed in millimetres and length expressed in centimeters.

4.2.3 Tapered tubular vascular grafts

The size of a tapered tubular vascular graft shall be designated by the nominal relaxed internal diameters of its ends and its minimum usable length. Nominal pressurized internal diameters shall also be designated if required [see 4.2.1 b)]. Diameters shall be expressed in millimeters and length expressed in centimeters.

4.2.4 Other configurations of tubular vascular grafts

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. Diameter shall be expressed in millimetres and length expressed in centimetres.

4.2.5 Vascular patches

The size of a vascular patch shall be designated by its nominal length and width. It shall also be identified by its wall thickness, if appropriate.

4.3 Materials

4.3.1 General

Vascular prostheses and their materials of construction shall be described according to the applicable clauses below.

4.3.2 Classification of tubular vascular grafts and vascular patches

The classification of a tubular vascular graft or a vascular patch 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. xenograft, human tissues with and without viable cells);

d) compound, (i.e. other than coated);

e) composite;

f) coated.

NOTE Although a coated vascular prosthesis is a type of compound prosthesis, the term coated is more specific and more commonly used.

4.3.3 Nomenclature

4.3.3.1 General

Materials shall be described according to the applicable clauses below.

4.3.3.2 Synthetic materials

Synthetic materials shall be described by the following:

a) their generic or chemical name;

b) the general nature of any chemical treatment or modification.

4.3.3.3 Biological materials

Biological materials shall be described by the following information:

a) the origin of the material as the genus of the donor animal, in adjectival form;

b) the type and site of the tissue (e.g. umbilical vein, carotid artery) or the type of material (e.g. collagen, albumin);

c) the general nature of any chemical treatment or modification;

d) the specific characterization of any biological material (e.g. the degree of crosslinking).

4.3.3.4 Coatings

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

a) the nomenclature of any synthetic component(s) in accordance with 4.3.3.2;

b) the nomenclature of any biological component(s) in accordance with 4.3.3.3;

c) for other types of coatings, such as pharmaceutical coatings, the generic or chemical name.

4.3.3.5 Storage fluids

Storage fluids shall be described by the generic or chemical name of the principal component(s).

4.4 Intended clinical use designation

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

a) thoracic aorta;

   1) ascending aortic;

   2) aortic arch;

   3) descending thoracic aortic;

4) thoraco-abdominal aortic;

b) abdominal aortic and/or aorto-iliac and/or aorto-femoral;

c) peripheral arterial, including extra-anatomic (e.g. axillo-bifemoral arterial);

d) coronary;

e) arterio-venous shunt for vascular access;

f) other vessels to be specified.

5 Intended performance

The requirements of ISO 14630:2012, Clause 4 apply.

6 Design attributes

6.1 General

The requirements of ISO 14630:2012, Clause 5 apply. The tests considered and the rationale for selection and/or waiving of tests shall be documented.

6.2 Tubular vascular grafts

The design attributes to meet the intended performance of the tubular vascular graft shall additionally take into account at least the following:

a) the ability to be anastomosed to a blood vessel;

b) the ability to maintain adequate patency;

c) the ability to prevent blood from flowing through the implant wall as appropriate to its intended use;

NOTE Changes in wall permeability after implantation can be taken into account;

d) the ability to maintain adequate material and structural integrity;

e) the consistency of the implant dimensions and its design for compatibility for use in specified vessel diameters;

f) compliance with the requirements of ISO 10993-1 and other parts of the ISO 10993 series.

6.3 Vascular patches

The design attributes to meet the intended performance of the vascular patches shall additionally take into account at least the following:

a) the ability to be anastomosed to a blood vessel or a vascular prosthesis;

b) the ability to not adversely affect patency;

c) the ability to prevent blood from flowing through the implant wall as appropriate to its intended use;

NOTE Changes in wall permeability after implantation can be taken into account;

d) the ability to maintain adequate material and structural integrity;

e) compliance with the requirements of ISO 10993-1 and other parts of the ISO 10993 series.

6.4 Coatings

The design attributes to meet the intended performance of the coating shall additionally take into account at least the following:

a) the ability of the coating to maintain adequate integrity over time according to design specifications (e.g. freedom from significant delamination, flaps and bare spots);

b) the appropriate interaction between the coating and the prosthesis (e.g. absence of coating induced degradation of the prostheses material);

c) the ability of the coating to maintain adequate resistance to unintended particulate generation;

d) the conformance of the coating parameters to the design requirements (e.g. porosity, density, distribution).

6.5 Drug coatings and drug-eluting coatings

The design attributes to meet the intended performance of the vascular prosthesis if the coating contains a drug shall additionally take into account the information provided in ISO 12417-1.

7 Materials

The requirements of ISO 14630:2012, Clause 6 shall apply. Additional testing specific to certain materials should be performed to determine the appropriateness of the material for use in the design. For example, polyurethanes and materials of biologic origin should be subjected to testing in order to assess biostability.

8 Design evaluation

8.1 General

The requirements of ISO 14630:2012, Clause 7 shall apply. A risk assessment shall be carried out in accordance with the requirements of ISO 14971.

Not all requirements are applicable to all vascular prosthesis designs or intended clinical uses. For a tubular vascular graft or vascular patch, justification shall be provided for any design characteristics that are not evaluated from the list below.

Tubular vascular grafts or vascular patches incorporating new or emerging technologies (e.g. absorbable materials) should be evaluated following this International Standard, as appropriate. Testing beyond the scope of this International Standard might also be necessary to characterize these vascular prostheses. Consideration shall be given to the potential failure modes of the vascular prostheses and their effects on the performance of the implant 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 an absorbable component, the non-absorbable 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 factory manufactured anatomises shall satisfy the requirements of this International Standard relating to leakage and factory anastomotic strength.

Whenever changes are made in materials, construction, configuration, implantation site, or processing methods, an appropriate analysis of the possible impact of the change on the potential failure modes and performance of the vascular prosthesis shall be completed. Appropriate testing shall be conducted as deemed necessary based on this analysis.

The use of a control device for comparison may be considered in the evaluation of certain design attributes, particularly for design iterations.

Testing to establish the labelled shelf-life shall be conducted by repeating appropriate tests. Justification for the selection of tests shall be provided.

8.2 Sampling

A sampling plan shall be utilized which will ensure that adequate representation (e.g. multiple sizes) has been obtained for each characteristic measured. The test samples shall be representative, with respect to the design attribute under evaluation, of the devices to be released for distribution.

Sampling should ensure adequate representation of the potential variability (e.g. a minimum of three samples from a minimum of three lots) in device characteristics.

A rationale should be provided for sample selection. For all tests, the number of samples shall be justified.

8.3 Conditioning of test samples

All samples should be subjected to sterilization, including multiple sterilizations if appropriate, unless justification is provided for use of nonsterilized products for the evaluation of specific attributes.

Samples should be subjected to conditions that are normally encountered during clinical use that might affect the test results, including preparation as stated in the instructions for use (IFU), where appropriate.

Tubular vascular grafts and vascular patches whose material properties are sensitive to temperature and/or hydration should consider these conditions during testing.

8.4 Reporting

For the purposes of this International Standard, reporting refers to submission to a regulatory authority.

The design evaluation report should include an appropriate table of contents (including appendices) and three main sections: a) an executive summary; b) individual test summaries; c) detailed reports. Pages should be numbered sequentially throughout the document (including appendices).

a) The executive summary should include

   1) a description of the bench and nonclinical *in vivo* testing and analyses that have been performed and any relevant clinical information,

   2) justification for the selection of tests, and

   3) a table to summarize the testing completed, with the following columns: name of test, test purpose, test sample description, number of samples, acceptance criteria, summary of results, and cross references to the test summary and full test report.

b) Individual test summaries should include

   1) a brief summary of the purpose, methods, and results, and

   2) the significance of the test results

      i) for tests with acceptance criteria, justification for the criteria, or

      ii) for characterization tests, an explanation of the relevance of the results.

      These results can provide a baseline for comparison with design iterations, when applicable.

Clinical applicability of the acceptance criteria, or the relevance of characterization results, shall take into consideration the anatomical and physiological conditions of the intended use.

c) Individual test reports should include the following information:

1) purpose: state the purpose of the test as it corresponds to this International Standard;

2) materials: list significant materials (e.g. test articles with lot/serial numbers or other appropriate means of traceability, critical equipment) used in performing the test, using figures and diagrams as appropriate;

3) sampling: state the sampling plan, including the basis for and the number of samples tested and justification for the selection of test articles (e.g. sizes, conditioning);

4) acceptance criteria, if applicable: state the criteria for the test results, including justification and/or clinical relevance;

5) test method: describe in detail the method used to perform the test, including any prospectively defined inspection procedures, and provide a justification for relevant test parameters;

6) protocol deviations: describe any deviations and their potential significance on the interpretation of the results;

7) expression of results: report testing results expressed in units as indicated in the test method;

8) conclusions: state conclusions, based on comparing results to acceptance criteria or provide an explanation of the relevance of the results for characterization tests and, if appropriate, include a discussion on the potential clinical significance of the results.

8.5 Biocompatibility

8.5.1 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.

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

8.5.2 Biocompatibility

The biocompatibility of the vascular prosthesis shall be tested in accordance with ISO 10993-1 and appropriate other parts of the ISO 10993 series of International standards.

8.6 Biostability

When the design of a vascular prosthesis and its intended use as a chronic implant require that the prosthesis maintain some minimum level of physical and chemical integrity (i.e. durability) after implant in living tissue for some time interval, the materials of which the prosthesis is made shall be evaluated.

Testing for biostability might be necessary for materials not previously used for implantable vascular prostheses (e.g. new formulations of polyurethane). Methods used for *in vitro* and/or preclinical *in vivo* testing shall be disclosed by the manufacturer and justified.

A rationale for the evaluation of biostability shall be disclosed by the manufacturer and may include the following:

a) the biostability 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 or not there are currently prostheses or other forms of treatment for the targeted indication that use the same materials.

8.7 Bench and analytical tests

8.7.1 General

Testing of the tubular vascular graft or vascular patch shall be conducted to evaluate the design attributes described in Clause 6, as applicable.

Test method guidance is provided in Annex A. Alternative methods from those described in Annex A can be used and shall be justified.

8.7.2 Tubular vascular grafts

8.7.2.1 Permeability

8.7.2.1.1 General

Determine the porosity, water permeability, integral water permeability/leakage, and/or water entry pressure as appropriate to the tubular vascular graft. The selection of appropriate tests from those listed below shall be justified based on the material of construction.

8.7.2.1.2 Integral water permeability/leakage

Determine the rate of water leakage through the tubular vascular graft or a representative segment in tubular form. This requirement is applicable to grafts with a coating that is intended to reduce the leakage and grafts with regions where leakage is of concern (e.g. sewn or sutured anastomosis or seam in the graft material).

8.7.2.1.3 Porosity (non-textile materials)

Determine the porosity of a tubular vascular graft constructed of synthetic, non-textile materials.

8.7.2.1.4 Water entry pressure (non-textile materials)

Determine the pressure required to force water through a synthetic non-textile tubular vascular graft.

8.7.2.1.5 Water permeability (textile materials)

Determine the rate of water flow through the graft wall of a tubular vascular graft constructed with a water permeable material. When applicable, the manufacturer shall provide recommendations whereby the water permeability can be reduced by preclotting. Regions where leakage is of concern may also be evaluated using this test.

8.7.2.2 Strength

8.7.2.2.1 General

Determine the longitudinal tensile strength, burst strength and, if applicable, factory anastomotic strength of the vascular prosthesis. For burst strength, pressurized burst strength is the preferred method. If pressurized burst strength cannot be readily measured, circumferential tensile strength or

probe burst are alternatives. For factory anastomotic strength, a region incorporating the anastomosis shall be tested using the longitudinal tensile strength or a burst method.

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

For tubular 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.

8.7.2.2.2 Circumferential tensile strength

Determine the circumferential tensile strength of the tubular vascular graft in its tubular form.

8.7.2.2.3 Diaphragm pressurized burst strength

Determine the burst strength of the tubular vascular graft in a flat form.

8.7.2.2.4 Longitudinal tensile strength

Determine the longitudinal tensile strength of the tubular vascular graft in tubular form.

8.7.2.2.5 Pressurized burst strength

Determine the pressurized burst strength of the tubular vascular graft in its tubular form.

8.7.2.2.6 Probe burst strength

Determine the probe burst strength of the tubular vascular graft in flat form.

8.7.2.2.7 Strength after repeated puncture

Determine the strength of the tubular vascular graft following repeated dialysis-needle punctures.

8.7.2.3 Length

Determine the usable length of the tubular vascular graft. The usable length of the prosthesis shall be no less than that declared by the manufacturer.

8.7.2.4 Relaxed internal diameter

Determine the relaxed internal diameter of the tubular vascular graft.

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 or less;

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 or less;

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 % or less.

Alternative limits for acceptance may be used and shall be justified.

8.7.2.5 Pressurized internal diameter

Determine the pressurized internal diameter of the tubular vascular graft under clinical conditions, if applicable.

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.

8.7.2.6 Wall thickness

Determine the wall thickness of the tubular vascular graft.

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

8.7.2.7 Suture retention strength

Determine the force required to pull a suture through the wall of a tubular vascular graft.

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

8.7.2.8 Kink diameter/radius

Determine the radius of curvature required to kink a tubular vascular graft.

NOTE This test might not be applicable to all tubular vascular grafts (e.g. crimped textile graft).

8.7.2.9 Dynamic radial compliance

Determine the dynamic radial compliance of a tubular vascular graft constructed of an elastomeric material (e.g. polyurethane).

8.7.3 Vascular patches

8.7.3.1 Permeability

8.7.3.1.1 General

Determine the porosity, water permeability, and/or water entry pressure as appropriate to the vascular patch. The selection of appropriate tests from those listed below shall be justified based on the material of construction.

8.7.3.1.2 Porosity

Determine the porosity of a vascular patch constructed of synthetic, non-textile materials.

8.7.3.1.3 Water entry pressure

Determine the pressure required to force water through a synthetic non-textile vascular patch.

8.7.3.1.4 Water permeability

Determine the rate of water flow through the material of a vascular patch constructed with a water permeable material. When applicable, the manufacturer shall provide recommendations whereby the water permeability can be reduced by preclotting. Regions where leakage is of concern may also be evaluated using this test.

8.7.3.2 Strength

8.7.3.2.1 General

Determine the tensile strength and burst strength of the vascular patch. For burst strength, select one of the following: diaphragm pressurized burst strength or probe burst strength.

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

8.7.3.2.2 Diaphragm pressurized burst strength

Determine the burst strength of the vascular patch.

8.7.3.2.3 Longitudinal tensile strength

Determine the longitudinal tensile strength of the vascular patch. For vascular patches, testing might be appropriate in both the longitudinal and transverse directions.

8.7.3.2.4 Probe burst strength

Determine the probe burst strength of the vascular patch.

8.7.3.3 Length and width

Determine the usable length and width of the vascular patch. The usable length and width of the prosthesis shall be no less than that declared by the manufacturer.

8.7.3.4 Wall thickness

Determine the wall thickness of the vascular patch.

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

8.7.3.5 Suture retention strength

Determine the force required to pull a suture through the wall of a vascular patch.

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

9 Preclinical *in vivo* evaluation test methods for vascular prostheses

9.1 Preclinical *in vivo* evaluation

9.1.1 Purpose

The purpose of preclinical *in vivo* testing is to evaluate the biological response of the host to the vascular prosthesis and the effect of the implant environment on the prosthesis. If the objective of an animal study can be met through alternative means (e.g. through reference to previously conducted animal and/or clinical studies), justification for use of previously obtained data shall be provided and shall be based on an appropriate risk assessment.

Although the principles of this Clause may be applied for the preclinical *in vivo* evaluation of a vascular patch, if such a study is deemed necessary, specific aims and reporting for vascular patch studies are not specified below.

9.1.2 Specific aims

Specific aims of the study shall be based on an appropriate risk assessment for the vascular prosthesis and shall be stated in the protocol. More than one study may be used to address these aims, which can include the following:

a) evaluate the handling of the vascular prosthesis;

b) evaluate the suture-ability of the vascular prosthesis;

c) evaluate histology and pathology (e.g. inflammation, downstream findings) of explants and pertinent tissues/organs;

d) record failure modes and adverse events.

9.1.3 Protocol considerations

Each type of vascular prosthesis shall be tested by implantation at the intended, or an analogous, vascular site in a reasonable number of animals (i.e. at least six) for an adequate duration (e.g. 20 weeks), justified through an appropriate risk assessment for the given vascular prosthesis. A control might be appropriate for comparison purposes. The type and intervals of interim assessments shall be specified and justified. As far as permitted by the limitations of the animal model, all devices used should be of clinical quality and size and of the design intended for clinical use.

All animals in the study shall be regularly examined. Histological and pathological assessment of explants and appropriate tissues/organs shall be provided. If an animal either dies or must be sacrificed prior to scheduled termination, it shall be subjected to immediate post-mortem examination. The cause of death or illness, and the extent to which the implant was implicated, shall be documented. All animals implanted with either test or control prostheses, including those excluded from the final analyses, shall be recorded and reported.

The design of the preclinical *in vivo* testing, including the experimental protocol, measurement methods and data analysis, shall be justified. In addition, the choice of animal model, such as species, sex, age, and whether or not a lesion is created, shall be justified and shall be consistent with the study objectives. Implantation shall be consistent with the recommended instructions for use as far as permitted by the limitations of the animal model.

Appropriate quality management practices should be followed in the execution of an animal study.

9.1.4 Data acquisition

The following minimum data shall be recorded for each animal receiving a prosthesis:

a) identification data:

   1) animal identification;

   2) sex;

   3) approximate age;

   4) mass;

b) pre-operative data:

   1) verification of satisfactory health status;

   2) medications (e.g. prophylactic antibiotics);

c) operative data:

   1) date of procedure;

2) name of person(s) performing the procedure;

3) prosthesis identification;

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

5) use of systemic antiplatelet/anticoagulant therapy;

6) assessment of the handling and suture-ability of the vascular prosthesis;

7) observed adverse peri-operative events;

8) any deviations from the protocol;

d) post-operative and follow-up data:

1) medications, including those that affect coagulation;

2) patency assessment, method, and date;

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

4) any deviations from the protocol;

e) termination data:

1) date of sacrifice;

2) patency assessment and method;

3) gross alteration in the dimensional and physical properties of the prosthesis;

4) histological and pathological assessment of explants and appropriate surrounding and distal tissues/organs.

9.1.5 Test report and additional information

Results of all animals enrolled in the protocol shall be recorded and reported, even if excluded from the final analysis.

The test report shall include the following:

a) study protocol;

b) rationale, including information from the risk assessment, for selection of the following:

1) animal model;

2) implantation site;

3) control;

4) implantation periods;

5) method of patency assessment;

6) intervals of observation;

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

c) summary of results:

1) animal accountability, including rationale for exclusion of data from the primary analysis;

2) number of animals for which there was successful implantation of the prosthesis;

3) operator assessment of handling and suture-ability;

4) summary of structural and material integrity and patency of the prosthesis;

5) summary of failure modes and adverse events;

6) significant and/or relevant deviations from the protocol;

7) summary of pathology and histology of explants and appropriate tissues/organs, including representative gross photographs and micrographs;

8) comparison of outcomes for test and control groups, if applicable;

9) conclusions from study;

10) summary of quality assurance and data auditing procedures.

10 Clinical investigation methods for vascular prostheses

10.1 Clinical investigation

10.1.1 Purpose

The purpose of clinical investigation is to assess the safety and effectiveness of a vascular prosthesis. This investigation 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 market approval, using the principles given in ISO 14155 or an equivalent publication. Significant design changes that can impact safety and performance shall require clinical investigation if determined to be necessary based on an appropriate risk assessment.

If an objective of a clinical investigation can be met through alternative means (e.g. through reference to previously conducted clinical studies), justification for use of previously obtained data shall be provided based on an appropriate risk assessment.

Although the principles of this subclause may be applied for the clinical investigation of a vascular patch, if such a study is deemed necessary, specific objectives and reporting for vascular patch studies are not specified below.

10.1.2 Specific aims

Specific aims of the study shall be based on an appropriate risk assessment for the vascular prosthesis and shall be stated in the protocol. The specific aims can include the following.

a) Evaluate the effectiveness of the vascular prosthesis, such as the

   1) structural and material integrity of the prosthesis over time,

   2) patency of the prosthesis over time, and

   3) failure modes;

b) Evaluate the safety of the vascular prosthesis, such as the adverse events.

10.1.3 Protocol considerations

A multicentre study, at a minimum of three investigational sites, shall be performed. A justification for the number of investigational sites shall be provided.

A specific question or set of questions (i.e. hypotheses) shall be defined prospectively. These questions shall delineate the appropriate primary safety and effectiveness endpoints to be evaluated. Definitions

of success and failure for each endpoint and the duration of follow-up needed to assess each endpoint shall be specified. A definition for the study success shall also be specified (e.g. meeting both the safety and effectiveness primary endpoints).

A statistical justification for the number of patients studied shall be provided based upon the primary hypotheses. No investigational site should enroll more than 50 percent of the total number of study subjects.

The clinical investigation shall be continued for a minimum of 12 months for each patient unless a justification for a different study duration is provided. Patient follow-up intervals shall include a minimum of a baseline assessment at discharge and an assessment at the specified study duration. A justification will be required for follow-up intervals. All patients enrolled in the study, including those excluded from the primary endpoint analyses, shall be recorded and reported. The final report shall include current follow-up data on all patients when the required number of patients to test the hypotheses have reached the specified study duration.

A control should be included in the study to appropriately address the questions postulated. If an appropriate control is not or cannot be identified, or if a concurrent control is unnecessary, a method for evaluating the clinical outcomes shall be prospectively defined and justified (e.g. through use of a performance goal).

The study design shall be designated by the following terms:

— randomized, multi-arm, “unblinded” study with a concurrent control using an alternative or no treatment;

— non-randomized study with concurrent control;

— single-arm study with patient serving as own control (include designed single-arm crossover);

— single-arm study with historical control using patient-level data;

— single-arm study with literature control;

— single-arm study with performance goals.

Patient inclusion and exclusion criteria shall be clearly identified.

Definitions, primary and secondary clinical endpoints, measurement methods and data analysis shall be specified in the clinical protocol.

10.1.4 Data acquisition

At least the following data shall be recorded for each patient in the study:

a) identification and demographic data:

   1) patient identification;

   2) indication for treatment (e.g. aneurysm, dissection, occlusion), if the selection criteria for the study is not limited to one indication;

   3) patient demographics:

      i) date of birth;

      ii) sex;

      iii) race;

      iv) mass;

   4) name of implanting physician;

5) name of institution;

b) pre-operative data:

1) risk factors, such as hypertension, diabetes, coronary artery disease, hyperlipidemia, tobacco use, obesity, anaesthesia risk and any other cardiovascular risk factors;

2) summary of previous vascular interventions at the same or other relevant vascular sites, including nonsurgical interventions and previously implanted vascular devices (e.g. stents, endovascular prostheses, surgically placed vascular prostheses);

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;

vi) failure date and mode;

3) relevant medications;

4) 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);

For arteriovenous shunts, an objective assessment may not be applicable;

c) operative data:

1) date of procedure;

2) identification data for the vascular prosthesis including identification number, configuration, and diameter;

3) information regarding the procedure:

i) identity of native vessel(s) treated or location of anastomoses for an arteriovenous access prosthesis;

ii) details of anastomoses [e.g. type (e.g. end-to-end), location];

iii) length of prosthesis implanted;

iv) adjunctive vascular procedures;

4) relevant medications (e.g. heparin, other anticoagulants);

5) assessment of prosthesis function and mode of assessment (e.g. intraoperative angiography, intraoperative Doppler);

6) failure modes and adverse operative events;

d) post-operative data for arteriovenous access:

1) assessment at dialysis session:

i) interval of follow-up (e.g. initial prosthesis dialysis session and 1, 3, 6, and 12 months after initial prosthesis use);

ii) date of dialysis session;

iii) size and type of needles;

iv) ability to dialyze during the session;

v) time to hemostasis after needle withdrawal, if applicable;

vi) observations at implant site;

vii) adverse events;

2) assessment at the investigational site:

i) interval of follow-up (e.g. discharge or 7 d to 14 d after surgery and 3, 6 and 12 months after surgery);

ii) date of follow-up;

iii) patency of prosthesis;

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

v) relevant medications;

vi) adverse events;

vii) information obtained during any unscheduled follow-up visit:

I) date;

II) reason for visit;

e) post-operative data for all other clinical uses (i.e. non-arterialvenous access):

1) interval of follow-up (e.g. discharge or 7 d to 14 d after surgery and 6 and 12 months after surgery);

2) date of follow-up visit;

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

4) clinical evaluation:

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

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

5) relevant medications (e.g. anticoagulants or antiplatelets);

6) adverse events:

i) if an adverse event is suspected, appropriate objective assessment should be conducted;

f) adverse events data:

1) type of effect or event, date of occurrence, severity, management (e.g. none, medical treatment, endovascular procedure, open surgery), outcome (e.g. continuing, resolved, unknown, death);

2) documentation of prosthesis involvement;

3) documentation of probable causative factors (e.g. caused by the prosthesis, patient factors, technical factors);

g) explant data:

1) date;

2) whether the subject is living or deceased;

3) reason for explant, if applicable;

4) relevant observations (e.g. device integrity, device positioning, tissue incorporation, vascular tissue erosion), if available;

h) patient withdrawal:

1) date;

2) months of study completed;

3) reason for withdrawal (e.g. lost to follow-up, withdrew consent, removed from study per physician recommendation).

10.1.5 Final report

The final clinical report shall include the following:

a) study protocol, including the following at a minimum:

1) study description (e.g. study design designation, control arm, number of sites, number of patients);

2) primary and secondary endpoints, hypotheses and definitions of success;

3) definition of study success;

4) subject population (i.e. selection criteria);

5) follow-up intervals;

6) methods of assessment (e.g. clinical, CTA, MRA, duplex ultrasound);

7) data analysis plan;

8) definitions of adverse events;

b) rationale, based on the risk assessment and questions to be answered, for selection of the following:

1) study size;

2) choice of control;

3) measurement methods;

4) statistical analyses employed;

5) patient follow-up intervals;

c) number of patients treated at each investigational site;

d) follow-up accountability (e.g. numbers of patients eligible for each follow-up interval and the number with specified follow-up data), including a rationale for the exclusion of data from the primary endpoint analyses;

e) demographics and risk factors;

f) diameters of devices used;

g) significant and/or relevant deviations from the protocol;

h) results:

1) primary and secondary outcomes:

i) safety;

ii) effectiveness;

2) comparison of results for test and control groups;

i) conclusions from study, including results of hypothesis testing and achievement of success as defined by the protocol.

10.2 Post market surveillance

A systematic procedure to review post market experience gained from implants should be in place using the principles given in ISO 14630:2012 and ISO 14971.

11 Manufacturing

Tubular vascular grafts and vascular patches shall be manufactured in such a way that the specified design attributes are achieved. Requirements are specified in other related International Standards (e.g. ISO 13485).

12 Sterility

The prosthesis shall be supplied sterile.

For terminally sterilized products, a sterility assurance level (SAL) of 10^{-6} shall be obtained.

a) If vascular prostheses are to be sterilized by ethylene oxide, ISO 11135 shall apply.

b) If vascular prostheses are to be sterilized by moist heat, ISO 17665 shall apply.

c) If vascular prostheses are to be sterilized by radiation, ISO 11137 (all parts) shall apply.

d) If single-use vascular prostheses incorporating animal tissue are to be sterilized using liquid chemical sterilants, ISO 14160 shall apply.

e) If vascular prostheses are to be sterilized by other sterilization processes, ISO 14937 shall apply.

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

13 Packaging and labelling

13.1 General

The requirements of ISO 14630:2012 shall apply.

13.2 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.

13.3 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.

13.4 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.

13.5 Maintenance of sterility in transit

The unit container shall be designed to maintain the sterility of the endovascular system under nominal conditions of handling, transit, and storage and to permit the contents to be presented for use in an aseptic manner.

The packaging shall conform to ISO 11607-1.

13.6 Marking

13.6.1 Container label

Each vascular patch or tubular vascular graft 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) material of construction and type of construction;

c) configuration (see 4.1). A symbol may be substituted for a written description of the prosthesis (e.g. I = straight, Y = bifurcated, ⊢ = axillo-bifemoral), □ = rectangular for vascular patches);

d) minimum usable length for tubular vascular grafts;

e) nominal relaxed internal diameter(s) for tubular vascular grafts;

f) if appropriate, the nominal pressurized internal diameter(s) for tubular vascular grafts;

g) minimum usable length and width for vascular patches;

h) if appropriate, the porosity, mean water permeability, integral water permeability/leakage, and/or water entry pressure;

i) the words STERILE DO NOT RESTERILIZE SINGLE USE ONLY, or equivalent phrase or symbols, in prominent form;

j) method of sterilization;

k) manufacturer's batch or lot number;

l) sterile lot number;

NOTE If the manufacturer's batch or lot number (k) and the sterile lot number (l) can be traced to the same information, only one number need be given;

m) date of sterilization and/or the expiry/expiration date;

n) a warning against the use of the device if the package is open or damaged;

o) manufacturer's recommendations for storage, when applicable;

p) chemical nature of any storage fluid in the unit container, with any appropriate hazard warning;

q) if appropriate, a prominent statement regarding preclotting requirements or restrictions.

13.6.2 Record label

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

a) manufacturer's name and address;

b) product name;

c) manufacturer's batch or lot number and/or sterile lot number;

d) part or model number (i.e. manufacturer's catalog number).

13.6.3 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 or instructions on how to access an electronic version of the IFU. The instructions shall include the following information:

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;

e) notification of additives and/or leachable components, if applicable;

f) recommendations for storage, if applicable;

g) date of, or reference relating to, the publication of the text, indicating if the text has been revised.

Annex A
(informative)

Test methods

A.1 General

The information included in this Annex is intended to provide guidance for pre-clinical *in vitro* testing performed in order to verify the design of the vascular prostheses. Guidance for reporting the test results is also provided. It is recognized that not all of the tests described in this Annex are applicable for each type of tubular vascular graft or vascular patch (biological, synthetic textile, synthetic non-textile, coated). It is also recognized that testing intended to assure that the device meets specifications during manufacture can be conducted in a manner other than those outlined in this Annex.

Complete test methods are not included in this Annex due to the need for flexibility in designing appropriate methodologies for specific device designs and indications for use. To enhance consistency in the testing of devices, use of methods developed based on the steps and concepts outlined in this Annex is recommended. If alternative methods are employed, these methods should be justified.

It is recognized that some methods may be combined when testing is conducted for a specific tubular vascular graft or vascular patch. For those tests performed simultaneously, the report should provide the individual test results for each of the tests listed in the body of the standard.

Modifications to existing test methods or inclusion of additional test methods might be required for various tubular vascular graft or vascular patch designs. Further, when identifying testing conditions, attention should be made to physiological conditions in the vasculature.

To ensure valid results, measurement equipment used during testing should have appropriate precision and accuracy and be calibrated or verified against traceable measurement standards as appropriate. The precision and accuracy should be adequate to determine the measured value relative to the acceptance criteria.

NOTE Although this is an informative Annex, the use of the terms "should" and "shall" are intended to differentiate between considerations and essential components of the methods, respectively.

A.2 Sampling

A sampling plan shall be utilized which will ensure that adequate representation (e.g. multiple sizes) has been obtained for each characteristic measured. The test samples shall be representative, with respect to the design attribute under evaluation, of the devices to be released for distribution.

Sampling should ensure adequate representation of the potential variability (e.g. a minimum of three samples from a minimum of three lots) in device characteristics.

A rationale should be provided for sample selection. For all tests, the number of samples shall be justified.

NOTE The information included in this subclause is identical to the requirements for sampling in 8.2.

A.3 Conditioning of test samples

All samples should be subjected to sterilization, including multiple sterilizations, if appropriate, unless justification is provided for use of nonsterilized products.

Samples should be subjected to conditions that are normally encountered during clinical use that might affect the test results, including preparation as stated in the instructions for use (IFU), where appropriate.

Tubular vascular grafts and vascular patches whose material properties are sensitive to temperature and/or hydration should consider these conditions during testing.

NOTE The information included in this subclause is identical to the requirements for conditioning of test samples in 8.3.

A.4 Reporting

For the purposes of this International Standard, reporting refers to submission to a regulatory authority.

The design evaluation report should include an appropriate table of contents (including appendices) and three main sections: a) an executive summary; b) individual test summaries; c) detailed reports. Pages should be numbered sequentially throughout the document (including appendices).

a) The executive summary should include

   1) a description of the bench and nonclinical *in vivo* testing and analyses that have been performed and any relevant clinical information,

   2) justification for the selection of tests, and

   3) a table to summarize the testing completed, with the following columns: name of test, test purpose, test sample description, number of samples, acceptance criteria, summary of results, and cross references to the test summary and full test report.

b) Individual test summaries should include

   1) a brief summary of the purpose, methods, and results, and

   2) the significance of the test results

      i) for tests with acceptance criteria, justification for the criteria, or

      ii) for characterization tests, an explanation of the relevance of the results.

      These results can provide a baseline for comparison with design iterations, when applicable.

      Clinical applicability of the acceptance criteria, or the relevance of characterization results, shall take into consideration the anatomical and physiological conditions of the intended use.

3) Individual test reports should include the following information:

   1) purpose: state the purpose of the test as it corresponds to this International Standard;

   2) materials: list significant materials (e.g. test articles with lot/serial numbers or other appropriate means of traceability, critical equipment) used in performing the test, using figures and diagrams as appropriate;

   3) sampling: state the sampling plan, including the basis for and the number of samples tested and justification for the selection of test articles (e.g. sizes, conditioning);

   4) acceptance criteria, if applicable: state the criteria for the test results, including justification and/or clinical relevance;

   5) test method: describe in detail the method used to perform the test, including any prospectively defined inspection procedures, and provide a justification for relevant test parameters;

6) protocol deviations: describe any deviations and their potential significance on the interpretation of the results;

7) expression of results: report testing results expressed in units as indicated in the test method;

8) conclusions: state conclusions, based on comparing results to acceptance criteria or provide an explanation of the relevance of the results for characterization tests and, if appropriate, include a discussion on the potential clinical significance of the results.

NOTE The information included in this subclause is identical to the requirements for reporting in 8.4.

A.5 Test methods

Table A.1 contains a listing of the test methods contained in Annex A cross referenced to the design evaluation requirements of this International Standard.

Table A.1 — Index of test methods

Design Evaluation Section	Tests	Annex A Subclause
8.7	Bench and analytical tests	
8.7.2	Tubular vascular grafts	
8.7.2.1	Permeability	A.5.1
8.7.2.1.3	Porosity (non-textile materials)	A.5.1.1
	Planimeteric porosity	A.5.1.1.1
	Gravimetric porosity	A.5.1.1.2
	Microscopic porosity (inter-nodal distance)	A.5.1.1.3
8.7.2.1.5	Water permeability (textile materials, biologic)	A.5.1.2
8.7.2.1.2	Integral water permeability/leakage	A.5.1.3
8.7.2.1.4	Water entry pressure (non-textile materials)	A.5.1.4
8.7.2.2	Strength	A.5.2
8.7.2.2.5	Pressurized burst strength	A.5.2.2
8.7.2.2.4	Longitudinal tensile strength	A.5.2.3
8.7.2.2.2	Circumferential tensile strength	A.5.2.4
8.7.2.2.3	Diaphragm pressurized burst strength	A.5.2.5
8.7.2.2.6	Probe burst strength	A.5.2.6
8.7.2.2.7	Strength after repeated puncture	A.5.2.7
8.7.2.3	Length	A.5.3
8.7.2.4	Relaxed internal diameter	A.5.4
8.7.2.5	Pressurized internal diameter	A.5.5
8.7.2.6	Wall thickness	A.5.6
8.7.2.7	Suture retention strength	A.5.7
8.7.2.8	Kink diameter/radius	A.5.8
8.7.2.9	Dynamic radial compliance	A.5.9
8.7.3	Vascular patches	
8.7.3.1	Permeability	A.5.1
8.7.3.1.2	Porosity	A.5.1.1
	Planimeteric porosity	A.5.1.1.1
	Gravimetric porosity	A.5.1.1.2

Table A.1 *(continued)*

Design Evaluation Section	Tests	Annex A Subclause
	Microscopic porosity (inter-nodal distance)	A.5.1.1.3
8.7.2.1.4	Water permeability	A.5.1.2
8.7.2.1.3	Water entry pressure	A.5.1.4
8.7.2.2	Strength	A.5.2
8.7.2.2.3	Longitudinal tensile strength	A.5.2.3
8.7.2.2.2	Diaphragm pressurized burst strength	A.5.2.5
8.7.2.2.4	Probe burst strength	A.5.2.6
8.7.3.3	Length and width	A.5.3
8.7.3.4	Wall thickness	A.5.6
8.7.3.5	Suture retention strength	A.5.7

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

A All material types

B Biological

C Coated

N Non-textile synthetic

T Textile synthetic

Compound or composite prostheses may encompass one or more of the above categories.

A.5.1 Permeability

A.5.1.1 Porosity (N)

One of the following methods shall be used:

a) planimetric porosity;

b) gravimetric porosity;

c) microscopic porosity.

NOTE The planimetric and gravimetric methods provide a measurement of effective porosity, while the microscopic method provides an index of effective 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.

A.5.1.1.1 Planimetric porosity

A.5.1.1.1.1 Purpose

The purpose of this test is 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.

A.5.1.1.1.2 Materials

Materials to be used include the following:

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 measuring device capable of measuring the area of the voids and/or the area of the material.

A.5.1.1.1.3 Sampling

Sampling shall be in accordance with A.2.

A.5.1.1.1.4 Test procedure

From each sample prosthesis, either

a) prepare a scanning electron micrograph(s), or

b) prepare a photograph(s) or digital image for optical examination of the surface of the sample (see NOTE).

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

Examine the electron micrographs or the photographs using the measuring apparatus and determine the size of the voids, the number of voids per square millimeter, and the area of the material. The surface examined (inner or outer) shall be recorded.

Calculate and record the porosity (P) of each test specimen from Formula (A.1):

$$P = 100 \times \frac{\text{total area of voids}}{\text{total area of voids} + \text{total area of materials}} \quad \text{(A.1)}$$

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

A.5.1.1.1.5 Expression of results

Porosity shall be expressed as a percentage.

A.5.1.1.1.6 Test report and additional information

The test report shall be in accordance with A.4. The test report shall include the surface examined, its dimensions, and the mean and standard deviations of the porosity of the sample prostheses.

A.5.1.1.2 Gravimetric porosity

A.5.1.1.2.1 Purpose

The purpose of this test is to compare the measured mass per unit area of the sample prosthesis with the product density and the wall thickness of the sample.

A.5.1.1.2.2 Materials

Materials to be used include the following:

a) a balance, capable of weighing with an accuracy of ±0,1 % of the mean sample mass;

b) equipment for determining of the volume of the sample with an accuracy of ±5 %;

NOTE The measurement of area can be derived from separate determinations of length and diameter, as described in A.5.3 and either A.5.4 or A.5.5; alternatively, a cut, flat sample can be used. The pressurized internal diameter need only be used if it is to be disclosed in accordance with 8.7.2.5.

c) equipment for determination of non-porous material density.

A.5.1.1.2.3 Sampling

Sampling shall be in accordance with A.2.

A.5.1.1.2.4 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 material volume (V) in cubic centimeters;

c) 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.

Calculate and record the porosity (P) of each sample from Formula (A.2):

$$P = 100 \times \left(1 - \frac{(m)}{V\rho}\right) \tag{A.2}$$

Calculate and record the mean and standard deviation of porosity.

A.5.1.1.2.5 Expression of results

Porosity shall be expressed as a percentage.

A.5.1.1.2.6 Test report and additional information

The test report shall be in accordance with A.4. The test report shall include the mean and standard deviation of the porosity of the sample prostheses.

A.5.1.1.3 Microscopic porosity (inter-nodal distance)

A.5.1.1.3.1 Purpose

The purpose of this test is to determine the main inter-nodal distance in stretched or expanded polymers by means of measurements made on a scanning electron micrograph or microscopic images. If there is a difference between the inner and outer surfaces, both should be characterized unless a justification is provided for the surface measured.

A.5.1.1.3.2 Materials

Materials to be used include the following:

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

b) a device capable of measuring inter-nodal distance.

NOTE As part of samples preparation, the test sample can be placed under moderate tension if it is extensible under clinical conditions.

A.5.1.1.3.3 Sampling

Sampling shall be in accordance with A.2.

A.5.1.1.3.4 Test procedure

Prepare a scanning electron micrograph of a section of the test specimen or visualize (image) the sample under magnification.

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

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

A.5.1.1.3.5 Expression of results

The mean and standard deviation of the inter-nodal distance shall be expressed in micrometers (μm).

A.5.1.1.3.6 Test report and additional information

The test report shall be in accordance with A.4. The test report shall include the surface examined, its dimensions, the inter-nodal distance mean of each sample, and the mean and standard deviations of the porosity of the sample prostheses.

A.5.1.2 Water permeability (B, T, C)

A.5.1.2.1 Purpose

The purpose of this test is to measure the rate of flow of water through a given area of the sample prosthesis under a given hydrostatic pressure.

A.5.1.2.2 Materials

Materials to be used include the following:

a) a flow measuring device or with an accuracy of ±5 % reported value;

   More than one such device may be required to cover the range of flow rates encountered during testing. A fluid collection device capable of measuring the volume used in conjunction with a calibrated timing device may be substituted for the flow measuring device;

b) a pressure measuring device capable of measuring hydrostatic pressures 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 %, and

   2) the configuration of the aperture is circular (see 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;

d) a means of supplying clean, filtered, room-temperature (or otherwise specified) water to the sample holding device to a pressure of 16,0 kPa (120 mmHg) for the duration of the test.

Water shall be filtered such that particles are removed that would affect the results of the test.

A.5.1.2.3 Sampling

Sampling shall be in accordance with A.2.

A.5.1.2.4 Test procedure

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

Load the sample into the holder, manipulating to remove any wrinkles or folds, but do not stretch the sample so as to apply a net load in any direction.

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 flow rate 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.

Calculate and record the water permeability from Formula (A.3):

$$\text{Water permeability} = Q/A \tag{A.3}$$

where

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

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

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

A.5.1.2.5 Expression of results

Water permeability shall be expressed in milliliters per centimeter squared per minute (mL cm^{-2} min^{-1}).

A.5.1.2.6 Test report

The test report shall be in accordance with A.4. The test report shall include mean and standard deviations of the measured water permeability of the sample prostheses, and the dimensions of the aperture, if rectangular.

A.5.1.3 Integral water permeability/leakage (A)

A.5.1.3.1 Purpose

The purpose of this test is 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 (120 mmHg). The test segment shall include any areas where leakage is of concern (e.g. factory anastomoses, suture fixation points). The test will accommodate both straight and bifurcated configurations.

A.5.1.3.2 Materials

Materials to be used include the following:

a) clean, filtered, room-temperature (or otherwise specified) water;

   Water shall be filtered such that particles are removed that would affect the results of the test. Water viscosity is dependent upon temperature and should be considered.

b) a set of adapters specific for the internal diameter of the prostheses to be tested to mount the sample;

   The seal between the sample prosthesis and the adapters shall be water-tight. The prosthesis adapter assembly is connected to a fixture which allows one end of the prosthesis to extend freely while pressurized;

c) a pressure-regulated system capable of delivering and maintaining water at greater than 16 kPa (120 mmHg);

d) a pressure-measuring device (e.g. a transducer or gauge), configured to measure the intraluminal pressure of the prosthesis during the test [to an accuracy of ±0,3 kPa (±2 mmHg)];

e) a means for measuring the volumetric flow (with an accuracy of ±5 % reported value) of water through the prosthesis wall and/or a means for collecting the leakage;

   This may be accomplished by a flowmeter or collection method;

f) a timer;

g) a means of determining the test length of the prosthesis, in centimeters, from seal to seal.

A.5.1.3.3 Sampling

Sampling shall be in accordance with A.2.

A.5.1.3.4 Test procedure

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

The prosthesis should be tested in its implantable state.

Seal the distal end(s) of test sample with the plug or adaptor appropriately sized to the inner diameter of the test prosthesis.

Connect the proximal end(s) of the sample prosthesis to the adapter(s) 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 pressure or flow to stabilize and measure the leakage through the prosthesis wall for 60 s or an appropriately determined time to provide an accurate measurement. Leakage through the body and legs of bifurcates or other branched configurations may be measured separately.

Calculate the surface area of the prosthesis or segment.

A.5.1.3.5 Expression of results

Integral water permeability shall be expressed as milliliters per centimeter squared per minute ($mL \cdot cm^{-2} \cdot min^{-1}$). For anastomotic leakage, the leakage in the region of the anastomosis shall be expressed as milliliters per minute.

A.5.1.3.6 Test report and additional information

The test report shall be in accordance with A.4. The test report shall include the mean and standard deviations of integral water permeability and/or anastomotic leakage of the sample prostheses.

A.5.1.4 Water entry pressure (N)

A.5.1.4.1 Purpose

The purpose of this test is to determine the water entry pressure of the vascular prostheses.

A.5.1.4.2 Materials

Materials to be used include the following:

a) a machine capable of incrementally pressurizing samples until leakage occurs;

b) an appropriate pressure transducer should also be used with an accuracy of ±5 % of the reported value.

A.5.1.4.3 Sampling

Sampling shall be in accordance with A.2.

A.5.1.4.4 Test procedure

Samples are filled with water and pressurized to an initial value determined by the manufacturer. The pressure is then increased incrementally and held for a period of time no less than 30 seconds. Once water is observed on the external surface, the pressure is recorded and the test terminated. This is the water entry pressure.

NOTE Inspection for the water is done without magnification.

A.5.1.4.5 Expression of results

The pressure shall be recorded in kilopascals (kPa).

A.5.1.4.6 Test report and additional information

The test report shall be in accordance with A.4. The test report shall include the mean and standard deviations of water entry pressure of the sample prostheses.

Additional information, including the incremental rate of pressure increase, shall be reported.

A.5.2 Strength

A.5.2.1 General

Pressurized burst strength and longitudinal tensile strength are the preferred methods to evaluate strength for tubular vascular prostheses. Diaphragm pressurized burst strength or probe burst strength and tensile strength are the preferred methods to evaluate strength for vascular patches.

If pressurized burst cannot be readily measured, circumferential strength or probe burst are acceptable alternatives for tubular vascular prostheses.

Viscoelastic materials (e.g. biological) have strain rate dependent mechanical properties. Testing should be done at the same conditions (e.g. strain rate, temperature) between tests in order to make meaningful comparisons of results.

A.5.2.2 Pressurized burst strength (A)

A.5.2.2.1 Purpose

The purpose of this test is to determine the pressurized burst strength by either

a) filling the prosthesis directly with fluid or gas at a measured rate of pressure change until bursting of the sample prosthesis takes place, or

b) placing an elastic, non-permeable liner inside the prosthesis and filling the liner with fluid or gas at a measured rate of pressure change until bursting of the sample prosthesis takes place.

A.5.2.2.2 Materials

The materials to be used include

a) a system capable of measuring and recording pressure to greater than the bursting pressure to an accuracy of ±5 % of the reported value,

b) an apparatus capable of applying a steadily increasing at a controlled rate fluid or gas pressure to the inside of the sample prosthesis extended, and

c) if applicable, an elastic, non-permeable liner distension apparatus with a diameter notably greater than the nominal pressurized diameter of the sample at 16 kPa (120 mmHg).

A.5.2.2.3 Sampling

Sampling shall be in accordance with A.2.

A.5.2.2.4 Procedure

Carefully insert the elastic, non-permeable liner through the sample prosthesis or attach the sample prosthesis directly to the pressurization apparatus.

It might be necessary to lubricate the liner to facilitate insertion; however, effect of the liner and lubricant on the test results shall be considered. In addition, the loading sharing of the elastic, non-permeable liner shall be considered in context of the strength of the test sample.

The pressure-measuring device shall record the pressure that exists inside the sample prosthesis. Feed fluid or gas to produce a steady rise in pressure at a controlled rate 10 kPa/s and 70 kPa/s. 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.

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

A.5.2.2.5 Expression of results

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

A.5.2.2.6 Test report and additional information

The test report shall be in accordance with A.4. The test report shall include the mean and standard deviation of the bursting pressure of the sample prostheses.

Additional information, including the method of testing and the rate of pressurization, shall be reported.

A.5.2.3 Longitudinal tensile strength (A)

A.5.2.3.1 Purpose

The purpose of this test is to determine the longitudinal tensile strength of the sample prosthesis in its tubular form when loaded longitudinally along its centerline. For vascular patches, an appropriate tensile sample (e.g. with a reduced cross section) can be used. The sample is stretched at a uniform rate until the yield and/or break point is reached.

NOTE For vascular patches, testing might be appropriate in both the longitudinal and transverse directions.

A.5.2.3.2 Materials

Materials to be used include the following:

a) a tensile strength machine having a constant rate of traverse and suitable jaws to hold the sample prosthesis firmly without damaging its structure (i.e. because such damage might cause the break to occur prematurely at the jaw margins), with the accuracy of the load measurement device of ±2 % of the reported load at yield or break;

b) a length measuring device accurate to ±0,5 mm.

A.5.2.3.3 Sampling

Sampling shall be in accordance with A.2.

A.5.2.3.4 Test procedure

If testing factory anastomotic strength, a region incorporating the anastomosis (i.e. factory suture-line or seam in the fabric or graft material) 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 (e.g. between 50 mm·min^{-1} and 200 mm·min^{-1}) until the break point is reached. Determine the load at yield or break, i.e. the maximum load (T_{max}) and the rate of extension.

A.5.2.3.5 Expression of results

The longitudinal tensile strength of each sample is expressed in kilonewtons as:

Maximum load = T_{max}

A.5.2.3.6 Test report and additional information

The test report shall be in accordance with A.4. The test report shall include the mean and standard deviations of the longitudinal tensile strength of the sample prostheses and the rate of extension and the test sample gauge length (with rationale, if not within the specified range).

A.5.2.4 Circumferential tensile strength – tubular vascular graft only (A)

A.5.2.4.1 Purpose

The purpose of this test is to determine the circumferential tensile strength of the sample prosthesis in its tubular form when placed onto two rounded pins and stretched at a uniform rate until the yield and/or break point is reached.

A.5.2.4.2 Materials

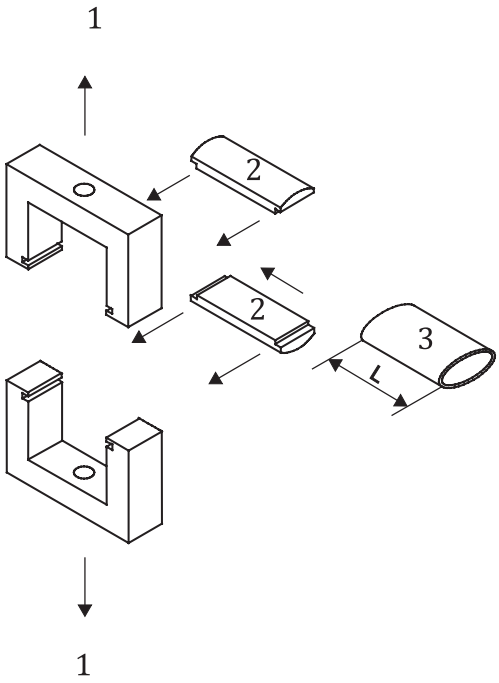
Materials to be used include the following:

a) a tensile testing machine having a constant rate of traverse, and with appropriately sized pins and suitable holders over which the sample prosthesis may be placed, with the accuracy of the load measurement device of ±2 % of the reported load at yield or break;

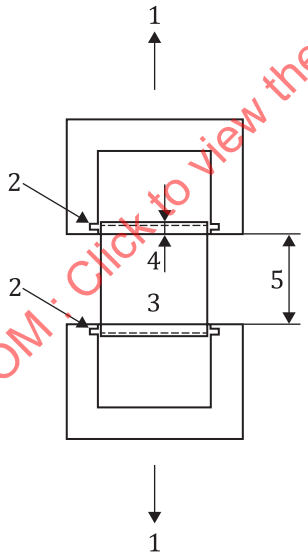
   A suitable example is given in Figure A.1 a) and b);

b) a length measuring device accurate to ±0,5 mm;

c) apparatus to measure the relaxed internal diameter.



a) Schematic



b) Front view

Key

1 tensile tester
2 split bar
3 sample
4 pin adapter
5 pin separation

Figure A.1 — Split bar tester

A.5.2.4.3 Sampling

Sampling shall be in accordance with A.2.

A.5.2.4.4 Test procedure

Cut a test specimen from the sample prosthesis with a length not less than the nominal relaxed internal diameter. After careful removal of any crimp, measure and record the length of the specimen (L) in millimeters to ±0,5 mm. Place 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·min^{-1} to 200 mm·min^{-1} until the break point is reached. Determine the load at yield or break, i.e. the maximum load (T_{max}), and record the rate of extension, if appropriate.

Calculate the circumferential tensile strength of each sample by dividing the maximum load (T_{max}) by the original length of the sample.

$$\text{Maximum load/Length} = \left(\frac{T_{max}}{2L} \right) \tag{A.4}$$

A.5.2.4.5 Expression of results

The circumferential tensile strength shall be expressed as kilonewtons per millimetre.

A.5.2.4.6 Test report and additional information

The test report shall be in accordance with A.4. The test report shall include the mean and standard deviations of the circumferential strength of the sample prostheses and the rate of extension (with rationale, if not within the specified range).

A.5.2.5 Diaphragm pressurized burst strength (A)

A.5.2.5.1 Purpose

The purpose of this test is to determine the burst strength of the prosthesis when loading an area of the sample that is clamped over an elastic diaphragm with an increasing fluid pressure that is applied to the underside of the diaphragm.

NOTE 1 This method is usually not appropriate for tightly woven fabrics.

NOTE 2 This method is similar to the pressurized burst test method and can be used for flat samples such as vascular patches.

A.5.2.5.2 Materials

Materials to be used include the following:

a) a bursting strength tester with a clamping ring of a diameter such that the area under test is nominally 100 mm^2;

b) for prostheses of small nominal relaxed area or inner diameter, it may be necessary to use a tester with a smaller orifice. In this case, the size of the orifice shall be reported. A system capable of measuring and recording pressure to greater than the bursting pressure to an accuracy of ±5 % of the reported value;

c) if deflection is desired, a system capable of measuring sample deflection at burst to an accuracy of ±5 %.

The material used for the diaphragm shall be able to extend notably beyond the failure deflection of the test sample at 120 mmHg.

The loading sharing of the diaphragm shall be considered in context of the strength of the test sample.

The load sharing of the deflection measurement equipment shall be considered in context of the strength of the sample.

A.5.2.5.3 Sampling

Sampling shall be in accordance with A.2.

A.5.2.5.4 Test procedure

If the test sample is a tubular prosthesis, cut a length from the sample prosthesis and then cut 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 between 10 kPa/s and 70 kPa/s. Record the bursting pressure and the deflection, if appropriate.

A.5.2.5.5 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.

A.5.2.5.6 Test report and additional information

The test report shall be in accordance with A.4. The test report shall include the mean and standard deviations of the bursting pressure and if appropriate, the deflection at burst of the sample prostheses and the size of the orifice in the test area.

Additional information, including the method of testing and the rate of pressurization, shall be reported.

A.5.2.6 Probe burst strength (A)

A.5.2.6.1 Purpose

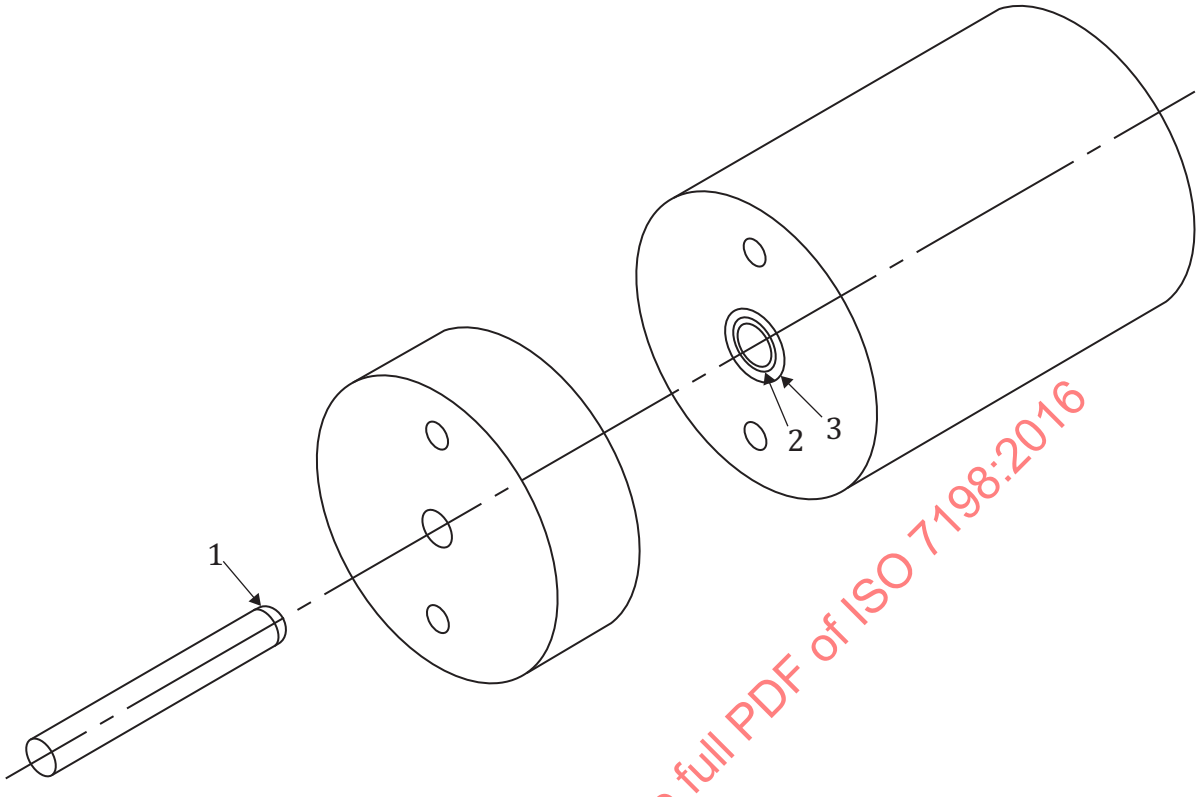
The purpose of this test is to determine the strength of an area of the sample prosthesis that is clamped over an orifice when a cylindrical probe is traversed through the specimen until it ruptures.

A.5.2.6.2 Materials

Materials to be used include the following:

a) a tensile testing machine, having a constant rate of traverse and capable of operation in the compression mode or fitted with a suitable compression cage, with measurement of the compressive load should be of an accuracy of ±5 % of the reported value;

b) a sample holder with a clamping ring and a traversing probe. The center opening of the sample holder should be 11,3 mm (0,445 in) in diameter. The traversing probe should have a hemispherical radius with a diameter of 9,5 mm (3/8 in). A suitable apparatus is given in Figure A.2.



Key

1 hemispherical radius
2 break sharp edges
3 o-ring gasket

Figure A.2 — Example of a probe burst tester

A.5.2.6.3 Sampling

Sampling shall be in accordance with A.2.

A.5.2.6.4 Test procedure

If the test sample is a tubular prosthesis, cut a length from the sample prosthesis and then cut 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 of 50 mm·min^{-1} to 200 mm·min^{-1} until it bursts. Record the probe diameter, the rate of traverse, and the maximum bursting load for each sample.

A.5.2.6.5 Expression of results

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

A.5.2.6.6 Test report and additional information

The test report shall be in accordance with A.4. The test report shall include the mean and standard deviations of the bursting load, the probe diameter, and the rate of traverse.