INTERNATIONAL STANDARD

ISO 7198

Second edition
2016-08-01

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

Reference number
ISO 7198:2016(E)

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

Contents

Page

Foreword

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

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).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

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)]. Diameter 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;

