SLOVENSKI STANDARD
oSIST prEN ISO 7198:2026

01-julij-2026

Vsadki (implantati) za srce in ožilje ter zunajtelesni pretočni sistemi - Žilne proteze - Cevasti vsadki s srčnimi zaklopkami (tubularni grafti) in žilne proteze (ISO/DIS 7198:2026)

Cardiovascular implants and extracorporeal systems - Vascular prostheses - Tubular vascular grafts and vascular patches (ISO/DIS 7198:2026)

Kardiovaskuläre Implantate und extrakorporale Systeme - Vaskuläre Prothesen - Tubulare vaskuläre Transplantate und Gefäßpatches (ISO/DIS 7198:2026)

Implants cardiovasculaires et systèmes extracorporels - Prothèses vasculaires - Greffons vasculaires tubulaires et pièces vasculaires (ISO/DIS 7198:2026)

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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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Foreword

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This document was prepared by Technical Committee ISO/TC 150, Implants for surgery, Subcommittee SC 2, Cardiovascular implants and extracorporeal systems.

This third edition cancels and replaces the second edition (ISO 7198:2016), which has been technically revised

Any feedback or questions on this document should be directed to the user’s national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

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 7198:2016.

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).

This revised document introduces methodology to identify appropriate testing and analyses for a specific vascular prosthesis, designated as the device evaluation strategy. The requirement regarding the device evaluation strategy is in Clause 8.1. Annex A provides guidance for developing a focused device evaluation strategy table that is specific to the unique characteristics of a device, device design modifications, or changes in intended use. Annex A also provides guidance for the development of a comprehensive device evaluation strategy table that may be used when it is not sufficient to focus only on the unique characteristics or changes.

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. Guidance is provided for using a comprehensive device evaluation strategy for approval or reapproval of a device where previous nonclinical testing and historical clinical data are available. Thus, nonclinical testing data obtained according to a previous version of this standard and historical clinical data may be justified to be used to satisfy the new version of this standard.

The requirements regarding sampling have been updated with clarification for selecting device sizes or portions of the device to be tested.

A requirement for a durability assessment, including creep evaluation and/or cyclic pressurization was added. The durability assessment may include the totality of the available information regarding the vascular prosthesis (e.g. historical clinical data, literature, material data, comparison to a commercially available device) in place of testing.

A requirement for evaluation of visibility of vascular prostheses that are intended to be visible with imaging techniques post-implantation was added. A requirement for determination of the appropriate MR safety term as defined by ASTM 2503 was added.

A requirement and associated test method for tubular vascular prostheses indicated for vascular access using needle puncture for evaluation of integral water permeability/leakage after dialysis puncture were added. A maximum area of puncture was added to the test methods related to repeated puncture (i.e. strength and permeability).

Additional elastic mechanics equations have been added, as an option, to convert the measured external diameter to the internal diameter associated with the measurement of dynamic radial compliance.

For coated vascular prostheses, Annex D was added to aid the user in meeting the requirements of ISO 17327-1. ISO 17327-1 has a broad scope, including all non-active surgical implants, and thus only some of the requirements in ISO 17327-1 are applicable to coated vascular prostheses. Annex D clarifies how ISO 12417-1, ISO/TS 17137, and ISO 7198 satisfy the requirements of ISO 17327-1.

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 are referred to in the text in such a way that some or all of their content constitutes requirements of this document. 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 — Requirements for the development, validation and routine control of a sterilization process for medical devices*

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
compliance
ability of a prosthesis to elastically expand and contract in the circumferential direction in response to a pulsatile pressure

3.6
component
substance used during manufacture whether or not it is intended to remain as a consistent element of the device

3.7
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* (3.8).

3.8
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* (3.7).

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.

3.9
configuration
geometry of prosthesis

EXAMPLE Straight, bifurcated, tapered.

3.10
construction
type of structure of a prosthesis

EXAMPLE Knitted, woven, nonwoven, expanded polymer.

3.11
crimp
creases or folds manufactured into a prosthesis to permit elongation and reduce kinking

3.12
determine
quantitatively appraise or analyse

3.13
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

3.14
evaluate
qualitatively appraise or analyse

3.15
factory anastomosis
factory manufactured seam-line in which two or more edges of graft material are joined (e.g. sewn) together

3.16
fibril
strand of material which originates from one or more nodes and terminates at one or more nodes

3.17
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

3.18
host
recipient of an implant in a preclinical *in vivo* study

3.19
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.

3.20
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

3.21
inter-nodal distance
distance between two nodes of expanded polymers

3.22
implant coating
surface coating (3.29) or *surface modification* (3.30)

Note 1 to entry: Implant coating is considered a constituent of an implant.

Note 2 to entry: A laminate, i.e. a composite material made of multiple layers of the same or different materials with the same or different internal structures assembled sandwich-like and bonded by heat, pressure, welding, soldering or adhesives, is not in itself considered an implant coating. But the exposed surface of the laminate can be an implant coating.

Note 3 to entry: A covering, for example additional material (e.g. a graft) added to a structure (e.g. a stent) specifically to bridge elements of the structure for the sole purpose of reducing the permeability of the structure, is not considered an implant coating.

[SOURCE: ISO 17327-1:2018, 3.1]

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* (3.39).

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* (3.41).

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 *implantcoating* (3.22) is applied to result in a compound prosthesis

3.29
surface coating
layer of material with any different property than the substrate that is intentionally added to the substrate

Note 1 to entry: The coating can partially or fully cover the substrate surface.

Note 2 to entry: The term includes surface coatings created as a result of additive manufacturing.

[SOURCE: ISO 17327-1:2018, 3.1]

3.30
surface modification
intentional conversion or reconstruction of the surface of the original substrate to form a new surface material consisting of components of the substrate's own material and possibly foreign material and forming a surface layer with different properties

[SOURCE: ISO 17327-1:2018, 3.1]

3.31
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.

3.32
synthetic nontextile prosthesis
vascular prosthesis manufactured made from synthetic materials using nontextile processes

EXAMPLE Prostheses made from extruded polymer, expanded polymer.

3.33
synthetic textile prosthesis
vascular prosthesis made from synthetic yarns using textile fabrication methods

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

3.34
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.

3.36
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.

3.37
vascular patch
non-tubular prosthesis intended for repair and reconstruction of the vascular system

EXAMPLE Flat sheet of material.

3.38
vascular prosthesis
tubular vascular graft or vascular patch

3.39
void
proportion of the wall of a vascular prosthesis that is not occupied by the material of construction.

3.40
water entry pressure
pressure at which water passes from the inner wall to the outer wall of a vascular prosthesis

3.41
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).

3.42
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.