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

Implants cardiovasculaires et systemes extracorporels — Prothèses vasculaires

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ISO/CEN PARALLEL PROCESSING

This draft has been developed within the International Organization for Standardization (ISO), and processed under the **ISO lead** mode of collaboration as defined in the Vienna Agreement.

This draft is hereby submitted to the ISO member bodies and to the CEN member bodies for a parallel five month enquiry.

Should this draft be accepted, a final draft, established on the basis of comments received, will be submitted to a parallel two-month approval vote in ISO and formal vote in CEN.

To expedite distribution, this document is circulated as received from the committee secretariat. ISO Central Secretariat work of editing and text composition will be undertaken at publication stage.

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Foreword

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

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

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

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.

ISO 7198 was prepared by Technical Committee 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. It is an update of ISO 7198:1998, necessary given the introduction of new standards for endovascular prostheses and vascular device-drug combination products.

This 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). The ISO 25539 series of standards (Parts 1, 2 and 3) specify requirements and testing guidelines for endovascular devices, including 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 standard (ISO 7198) 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 these devices have been evaluated, or to add new requirements. Therefore, manufacturers may rely on historical methods of evaluation and historical data gathered under the guidance of the previous version of ISO 7198 in cases where the prostheses design is essentially unchanged.

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 standard. This standard should be considered as a supplement to ISO 14630, 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 document 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 nontextile materials are within the scope of this 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 standard does not address sourcing, harvesting, manufacturing and all testing requirements for biological materials. It is further noted that different regulatory requirements may 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 standard. This 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 standard. This 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 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 standard. Tissue engineered vascular grafts 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 standard may 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 standard.

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

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 11135 (all parts), *Medical devices — Validation and routine control of ethylene oxide sterilization*

ISO 11137 (all parts, *Sterilization of health care products — Requirements for validation and routine control — Radiation sterilization*

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

ISO 11607, *Packaging for terminally sterilized medical devices*

ISO 13485, *Medical devices — Quality management systems — Requirements for regulatory purposes*

ISO 13488, Quality systems — Medical devices — Particular requirements for the application of ISO 9002

ISO 14155 , *Clinical investigation of medical devices for human subjects*

ISO 14160, *Sterilization of single-use medical devices incorporating materials of animal origin — Validation and routine control of sterilization by liquid chemical sterilants*

ISO 14630 , *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*

3 Definitions

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

3.1
adverse event
an 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 Adverse events are categorized by the system affected (e.g., cardiac, vascular, respiratory, neurological, renal, gastro-intestinal).

NOTE 2 This definition is not applicable for routine, post-approval event reporting.

3.2
allograft (adj.: alloplast)
implant material made from tissues of an animal of the same species

3.3
bifurcation
site of division of one vascular tube (trunk or body) into two branches (limbs)

3.4
biological material
material of animal or vegetable origin that may have been modified or treated by chemical processes, but excluding any material derived from fossil biological remains (e.g., petroleum oil)

3.5
biostability
ability of a material to maintain its physical and chemical integrity after implantation in living tissue

3.6
coating
any organic or inorganic material, other than living cells, intentionally applied by a manufacturer to substrate prosthesis

NOTE 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** (3.27).

3.7
compliance
ability of a prosthesis to elastically expand and contract in the circumferential direction in response to a pulsatile pressure

3.8
component
substance used during manufacture whether or not it is intended to remain as a consistent element of the device

3.9
composite prosthesis
vascular prosthesis in which the construction and/or material of construction varies in a segmental manner along the length. cf. **compound prosthesis** (3.10)

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

3.10
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. composite prosthesis (3.9)

NOTE 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.

3.11
configuration
geometry of prosthesis

EXAMPLES Straight, bifurcated, tapered.

3.12
construction
type of structure of a prosthesis

EXAMPLES Knitted, woven, nonwoven, expanded polymer.

3.13
crimp
creases or folds manufactured into a prosthesis to permit elongation and reduce kinking

3.14
determine
quantitatively appraise or analyse

3.15
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

3.16
evaluate
qualitatively appraise or analyse

3.17
factory anastomosis
a factory manufactured seam-line in which two or more edges of graft material are joined (e.g., sewn) together

3.18
fibril
strand of material which originates from one or more nodes and terminates at one or more nodes

3.19
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

3.20
host
recipient of an implant

3.21
implantable state
condition of a prosthesis that has been prepared in accordance with the manufacturer's instruction prior to implantation, or of a material of construction that has undergone the same process of sterilization and/or preparation

NOTE Preparation does not include preclotting (see 3.26), but does include any recommended method of washing or soaking.

3.22
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

3.23
inter-nodal distance
The distance between two nodes of stretched or expanded polymers.

3.24
leakage
volume of water which passes through flaws in a water-impermeable vascular prosthesis in a specified time under a specified pressure

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

NOTE 2 Leakage is not the same as **porosity** (3.26).

3.25
node
solid region within a material at which fibrils originate and converge

3.26
porosity
estimate or index of the ratio of the void within a material to the total volume occupied by the material including the voids

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

NOTE 2 Porosity is not the same as **leakage** (3.24) or **water permeability** (3.43).

3.27
preclotting
procedure whereby blood or blood fractions are allowed to penetrate and coagulate within the interstices of a porous prosthesis to decrease the permeability

3.28
primary component
substance incorporated into the finished prosthesis whose addition is designed by the manufacturer to improve the performance of the device

3.29
prosthesis (plural: prostheses, adj.: prosthetic)
any device which replaces or substitutes for an anatomical part or deficiency

3.30
residual material
substance that is employed in the manufacture of the prosthesis, but is intended to be removed or is not required in the finished prosthesis

3.31
secondary component
substance that may be incorporated into the finished prosthesis, but is not primarily responsible for the stated function

3.32
substrate prosthesis
vascular prosthesis to which a coating meeting the definition of 3.6 is applied to result in a compound prosthesis

3.33
synthetic material
substance of nonbiological source that is produced and/or polymerized by chemical or physical means

NOTE Chemically modified materials derived from fossil biological remains, e.g., petroleum or oil, are considered to be synthetic.

3.34
synthetic nontextile prosthesis
vascular prosthesis manufactured using nontextile processes

EXAMPLES Prostheses made from extruded polymer, expanded polymer.

3.35
synthetic textile prosthesis
vascular prosthesis made from synthetic yarns using textile fabrication methods

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

3.36
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 (e.g., computerized tomography or magnetic resonance imaging)

3.37
usable length
length of a prosthesis available for implantation, determined under a specified fixed load

NOTE The load may be zero for certain prostheses.

3.38
vascular patch
a non-tubular prosthesis intended for repair and reconstruction of the vascular system

3.39
vascular prosthesis
tubular vascular graft or vascular patch

3.40
velour
fabric with a cut or looped pile or with a napped surface

3.41
void
proportion of the wall of a vascular prosthesis that is not occupied by the material of construction (see **porosity** 3.26).

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

3.42
water entry pressure
pressure at which water passes from the inner wall to the outer wall of a vascular prosthesis

3.43
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 The water permeability is usually determined as mL cm^{-2} min^{-1} at an applied pressure of 16 kPa (120 mmHg).

NOTE 2 Water permeability is not the same as **porosity** (3.26).

3.44
xenograft (adj.: xenoplast) (heterograft)
implant material made from the tissues of an animal of a different species from the host

4 General requirements

The following requirements apply to tubular vascular grafts or vascular patches, as appropriate.

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.

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

4.2 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. Diameters shall be expressed in millimetres and length expressed in centimeters. Pressurized internal diameters shall also be designated if required [see 4.2.1b)].

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. Diameter shall be expressed in millimeters and length expressed in centimeters. Nominal pressurized internal diameters shall also be designated if required [see 4.2.1 b)].

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.