INTERNATIONAL STANDARD

ISO 7198

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Cardiovascular implants — Tubular vascular prostheses

Implants cardiovasculaires — Prothèses vasculaires tubulaires

Contents

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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 3.

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

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

Introduction

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

Cardiovascular implants — Tubular vascular prostheses

1 Scope

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

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

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

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

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

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

2 Normative references

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

ISO 472:1988, *Plastics — Vocabulary*.

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

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

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

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

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

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

ISO 10993-1:1997, *Biological evaluation of medical devices — Part 1: Evaluation and testing*.

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

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

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

3 Terms and definitions

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

3.1
allograft (adj.: alloplast)
implant material made from tissues of an animal of the same species

3.2
bifurcation
site of division of one vascular tube (trunk or body) into two branches (limbs)

3.3
biological material
material of animal or vegetable origin that may have been modified or treated by chemical processes, but excluding any material derived from fossil biological remains (e.g. petroleum oil)

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

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

NOTE This coating may be intended to be permanent or temporary, may be applied to the external and/or internal surface, and/or may be impregnated into the structure of the substrate

3.6
compliance
ability of a prosthesis to elastically expand and contract in the circumferential direction in response to a pulsatile pressure

3.7
component
substance used during manufacture whether or not it is intended to remain as a consistent element of the device

3.8
composite prosthesis
vascular prosthesis in which the construction and/or material of construction varies in a segmental manner along the length

cf. **compound prosthesis** (3.9)

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

3.9
compound prosthesis
vascular prosthesis whose wall is uniformly constructed of materials from more than one source

cf. **composite prosthesis** (3.8)

3.10
configuration
geometry of prosthesis

EXAMPLES Straight, bifurcate, tapered.

3.11
construction
type of structure of a prosthesis

EXAMPLES Knitted, woven, nonwoven, expanded polymer.

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

3.13
fibril
strand of material which originates from one or more nodes and terminates at one or more nodes

3.14
host
recipient of an implant

3.15
implantable state
condition of a prosthesis that has been prepared in accordance with the manufacturer's instruction prior to implantation, or of a material of construction that has undergone the same process of sterilization and/or preparation

NOTE Preparation does not include preclotting (see 3.20), but does include any recommended method of washing or soaking.

3.16
integral water permeability
volume of clean, filtered liquid (with a viscosity approximating that of water) which passes through the wall of a prosthesis in a specified time under a specified pressure

3.17
leakage
volume of clean, filtered liquid (with a viscosity approximating that of water) which passes through flaws in a water-impermeable vascular prosthesis in a specified time under a specified pressure

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

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

3.18
node
solid region within a material at which fibrils originate and converge

3.19
porosity
estimate or index of the ratio of the void within a material to the total volume occupied by the material including the voids

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

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

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

3.21
primary component
substance incorporated into the finished prosthesis whose addition is designed by the manufacturer to improve the performance of the device

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

3.23
residual material
substance that is employed in the manufacture of the prosthesis, but is intended to be removed or is not required in the finished prosthesis

3.24
secondary component
substance that may be incorporated into the finished prosthesis, but is not primarily responsible for the stated function

3.25
substrate prosthesis
vascular prosthesis to which a coating meeting the definition of 3.5 is applied

3.26
synthetic material
substance of nonbiological source that is produced and/or polymerized by chemical or physical means

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

3.27
synthetic nontextile prosthesis
vascular prosthesis manufactured using nontextile processes

EXAMPLES Prostheses made from extruded polymer, expanded polymer.

3.28
synthetic textile prosthesis
vascular prosthesis made from synthetic yarns using textile fabrication methods

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

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

NOTE The load may be zero for certain prostheses.

3.30
vascular prosthesis
vascular graft
prosthesis used to replace, bypass, or form shunts between sections of the vascular system

3.31
velour
fabric with a cut or looped pile or with a napped surface

3.32
void
proportion of the wall of a vascular prosthesis that is not occupied by the material of construction

cf. **porosity** (3.19)

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

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

3.34
water permeability
water porosity
volume of clean, filtered water that passes during a specified period through a unit area of the prosthetic material under a specified pressure

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

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

3.35
xenograft (adj.: xenoplast)
heterograft
implant material made from the tissues of an animal of a different species from the host

4 General requirements

The following requirements should apply to all vascular prostheses, regardless of origin.

4.1 Configuration and size designation

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

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

4.1.1 Uniform straight vascular prostheses

The size of a straight uniform vascular prosthesis shall be designated by the following characteristics:

a) nominal relaxed internal diameter of the device, expressed in millimetres;

b) nominal pressurized internal diameter of the device, expressed in millimetres, under a distending pressure of at least 16 kPa (120 mmHg), if this diameter changes by more than 10% while under pressure (see 5.6);

c) minimum usable length, expressed in centimetres.

4.1.2 Bifurcated uniform vascular prostheses

The size of bifurcated uniform vascular prostheses shall be designated by the nominal relaxed internal diameters and the minimum usable overall length of the main tube and its branches, expressed in centimetres. Pressurized internal diameters shall also be designated if required [see 4.1.1 b)].

4.1.3 Tapered vascular prostheses

The size of a tapered vascular prosthesis shall be designated by the nominal relaxed internal diameters of its ends and its minimum usable length, both expressed in centimetres. Nominal pressurized internal diameters shall also be designated if required [see 4.1.1 b)].

4.1.4 Other configurations

For other configurations (e.g. an axillo-bifemoral prosthesis), the principal length(s), the nominal relaxed internal diameter(s), and the nominal pressurized internal diameter(s), if required, shall be designated, and expressed in millimetres or centimetres as required.

4.2 Intended clinical use designation

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

a) thoracic aortic and/or thoraco-abdominal;

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

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

d) coronary arterial;

e) arterio-venous shunt for vascular access;

f) other vessels to be specified.

4.3 Materials and construction

4.3.1 Classification

The classification of a prosthesis shall be designated by one of the following:

a) synthetic textile (e.g. knitted, woven);

b) synthetic nontextiles (e.g. extruded polymer, expanded polymer);

c) biological (e.g. allograft, xenograft);

d) compound;

e) composite.

4.3.2 Nomenclature

4.3.2.1 Synthetic materials

Synthetic materials shall be described by:

a) their generic or chemical name, in accordance with ISO 472 or ISO 2076;

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

4.3.2.2 Biological 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) that shall be disclosed by the manufacturer on request.

4.3.2.3 Coatings

For a coating, the amount, permanence, uniformity shall be determined.

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

a) the nomenclature of any synthetic component(s) in accordance with 4.3.2.1;

b) the nomenclature of any biological component(s) in accordance with 4.3.2.2.

4.3.2.4 Storage fluids

Storage fluids shall be described by the following information:

a) the generic or chemical name of the principal component(s);

b) the nature and type of possible toxic hazards.

NOTE Attention is drawn to the existence of various international and national requirements with respect to maximum permitted levels of potentially toxic materials.

4.3.2.5 Residual chemicals

NOTE Residual chemicals refer to those processing and/or storage fluids or their derivatives that can be extracted from a prosthesis in the implantable state (see 3.15).

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

4.4 Biocompatibility and biostability

4.4.1 Biocompatibility

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

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

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

4.4.2 Biostability

When the design of a prosthesis and its intended use as a chronic implant require that the prosthesis maintain some minimum level of physical and chemical integrity after implant in living tissue for some time interval, the materials of which the prosthesis is made shall be tested either individually or as part of the finished prosthesis.

A rationale for the test methods and the measured biostability shall be disclosed by the manufacturer on request and may include:

a) the durability of materials currently used for the same indication;

b) the amount of time such a prosthesis is expected to perform in its indication for use, with consideration given to the performance and clinical utility of other prostheses and other forms of treatment currently available to treat the targeted indication;

c) whether there are currently prostheses or other forms of treatment for the targeted indication.

These considerations would, in some cases, be addressed by some form of risk-to-benefit analysis.

4.5 Sterility

The prosthesis shall be supplied sterile.

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

4.6 General information and instructions for use

Each unit container or outer container of which the contents are identical shall be supplied with instructions for the use of the prosthesis. The instructions shall include the following:

a) indications for use;

b) contraindications, cautions, and warnings that are applicable;

c) recommended methods for the aseptic presentation and the preparation of the prosthesis for implantation, including any pretreatment such as prewashing, preclotting, and/or implantation techniques, if applicable;

d) the statement STERILE DO NOT RESTERILIZE SINGLE USE ONLY in prominent form, if applicable;

e) resterilization information, if applicable;

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

g) recommendations for storage, if applicable;

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

4.7 Packaging

4.7.1 Unit container

Each prosthesis shall be packaged in a unit container. The unit container shall be so designed that it shall be readily apparent once the unit has been opened.

For prostheses supplied sterile, the unit container shall be designed to maintain the sterility of the prosthesis under nominal conditions of handling, transit, and storage, and to permit the contents to be presented for use in an aseptic manner.

4.7.2 Outer container

Each unit container shall be packaged in an outer container. This outer container shall be designed so as to protect the inner container from damage due to storage.

4.7.3 Shipping container

Each unit container, or a number of unit containers not necessarily of the same type, may be packaged in a shipping container designed to protect the contents under normal conditions of handling, transit, and storage.

4.8 Marking

4.8.1 Container label

Each prosthesis shall be accompanied by a label(s) on an appropriate container(s). At least the following information shall be provided on the label(s):

a) name, address, and/or trademark of the manufacturer;

b) the material of construction and type of construction (see 4.3);

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

c) the configuration (see 4.1). A symbol may be substituted for a written description of the prosthesis (e.g. | = straight, 人 = bifurcated, ⊢ = axillo-bifemoral);

d) the nominal usable length (see 5.4);

e) the nominal relaxed internal diameter(s) (see 5.5);

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

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

h) the words STERILE DO NOT RESTERILIZE SINGLE USE ONLY, or equivalent phrase or symbols, in prominent form, if applicable (see 4.5);

i) manufacturer's batch or lot number;

j) sterile lot number;

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

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

l) for prostheses supplied sterile, a warning against the use of the device if the package is open or damaged;

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

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

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

4.8.2 Record label

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

a) manufacturer's name and address;

b) product name;

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

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

4.9 Test reports

NOTE With some tests, reports may not be required.

4.9.1 General

When requested, test methods and results shall be disclosed in the form of a test report.

A test report shall provide at least the following information:

a) manufacturer's or distributor's name;

b) location and date of test;

c) batch and/or lot number(s);

d) manufacturer's or distributor's specifications;

e) test results;

f) statement of compliance or noncompliance with the test methods specified in the appropriate clause of this International Standard.

NOTE For the purposes of this International Standard, the unit grams is sometimes used as a representation of force, even though it is recognized that grams is a unit of mass.

4.9.2 Additional information

In addition to the test report, the following information shall be recorded:

a) material(s) of manufacture, in accordance with 4.3;

b) the configuration and type of construction of the prosthesis;

c) the dimensions of the prosthesis in accordance with 4.1, 4.1.2, 4.1.3, 4.1.4;

d) a statement indicating whether each sample prosthesis has or has not been sterilized and, if appropriate, the method of sterilization used;

e) the test method(s) in accordance with the appropriate clauses in this International Standard;

f) the atmosphere, including mean and tolerance for controlled environments, in which the prosthesis was conditioned and/or tested;

g) the number of samples and the observations per sample;

h) the minimum and maximum values observed.

5 Requirements for finished prosthesis

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

Table 1 — Suggested appropriate tests

TEST	CHARACTERIZATION	QC TESTING	100% INSPECTIONS
Surface properties	x		x
Porosity	Select appropriate test(s)	Select appropriate test(s)	Select appropriate test(s)
Water permeability			
Integral water permeability			
Leakage			
Water entry pressure			
Strength after repeated puncture	x		
Tensile strength	x	Select appropriate test(s)	
Bursting strength	x		
Usable length	x	x	
Relaxed inner diameter	x	x	
Pressurized inner diameter	x		
Wall thickness	x		
Suture retention strength	x		
Kink resistance	x		

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

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

It is impossible, at publication of this International Standard, to take into consideration all future and emerging technologies. These emerging-technology prostheses will need to follow the basic test protocols of this International Standard to characterize the device. Testing beyond the scope of this International Standard may also be necessary to characterize new emerging technology prostheses. Consideration shall be given to the failure modes of the prostheses and their effects on the performance of the device in identifying the appropriate testing. For compound prostheses, although it may be appropriate to conduct some of the testing described in this International Standard on components of the prosthesis, testing of the device as a whole is also required. In addition, if the compound prosthesis is partially constructed of a resorbable component, the nonresorbable portion of the device shall be characterized as well as the device as a whole.

Each segment of a composite prosthesis shall be tested. In addition, any manufactured anastomosis shall satisfy the requirements of this International Standard relating to leakage (5.2.3) and factory anastomotic strength (either 8.3.2 or 8.3.3.3).

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

The test methods in this International Standard shall be used unless the design of the prosthesis is such that alternative methods must be employed. An alternative method shall be validated and disclosed by the manufacturer of the prosthesis with a justification for the method selected.

5.1 Visual inspection

The prosthesis shall show no discontinuities in construction, and shall show no dirt, soiled areas, spots, stains, loose particles or other defects that would render the prosthesis unsuitable for its intended use.