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**Cardiovascular implants — Tubular
vascular prostheses**

Implants cardiovasculaires — Prothèses vasculaires tubulaires



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Contents

1 Scope 1

2 Normative references 1

3 Terms and definitions 2

4 General requirements 5

5 Requirements for finished prosthesis 10

6 Requirements for *in vivo* preclinical and clinical evaluation 14

7 Sampling 15

8 Test methods for vascular prostheses 16

9 *In vivo* preclinical and clinical test methods for vascular prostheses 42

10 Information to be recorded and disclosed by the manufacturer on request 48

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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*.

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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.

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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