
**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

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.