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Cardiovascular implants — Endovascular devices —

Part 1: Endovascular prostheses

*Implants cardiovasculaires — Dispositifs endovasculaires —
Partie 1: Prothèses endovasculaires*



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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.

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ISO 25539-1 was prepared by Technical Committee ISO/TC 150, *Implants for surgery*, Subcommittee SC 2, *Cardiovascular implants*.

ISO 25539 consists of the following parts, under the general title *Cardiovascular implants — Endovascular devices*:

- *Part 1: Endovascular prostheses*
- *Part 2: Vascular stents*
- *Part 3: Vena cava filters*

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Introduction

This part of ISO 25539 has been prepared in order to provide minimum requirements for endovascular prostheses and the methods of test that will enable their evaluation. It is the first part of a proposed three-part International Standard. ISO/TS 15539, from which this part of ISO 25539 is derived, serves as a rationale for the requirements. The Technical Specification was developed by first identifying the design requirements for endovascular implants and listing the potential implant and clinical failure modes. Tests were then identified to address each of the failure modes. The requirements provided in this part of ISO 25539 are based on that assessment.

Due to the variations in the design of implants covered by this part of ISO 25539 and in some cases due to the relatively recent development of some of these implants, acceptable standardized *in vitro* tests and clinical results are not always available. As further scientific and clinical data become available, appropriate revision of this part of ISO 25539 will be undertaken.