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Cardiovascular implants — Endovascular devices — Part 2: Vascular stents

Part 2: Vascular stent

*Implants cardiovasculaires — Dispositifs endovasculaires —
Partie 2: Endoprothèses 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.

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 25539-2 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 25539-2:2008), of which it constitutes a minor revision. This minor revision updates the normative references and provides minor editorial changes to Clause 8 and Annex D for clarification.

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 devices and the methods of test that will enable their evaluation. It is the second part of a three-part standard. ISO 25539-1 addresses endovascular prostheses and ISO 25539-3 addresses vena cava filters. ISO/TS 15539, from which this part of ISO 25539 is derived, serves as a rationale for the requirements of this part of ISO 25539. The Technical Specification ISO/TS 15539 was developed by first identifying the design requirements for these devices and listing the potential device 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.