Second edition
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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

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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*

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.