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# Cardiovascular implants — Endovascular devices —

## Part 4: Application of ISO 17327-1 for coated endovascular devices



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# Foreword

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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 of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 150, *Implants for surgery*, Subcommittee SC 2, *Cardiovascular implants and extracorporeal systems*.

A list of all parts in the ISO 25539 series can be found on the ISO website.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

# Introduction

ISO 17327-1 has a broad scope, including all non-active surgical implants, and thus only some of the requirements in ISO 17327-1 are applicable to coated endovascular devices. This document clarifies how ISO 12417-1, ISO/TS 17137, ISO 25539-1, ISO 25539-2, and ISO 25539-3 satisfy the requirements of ISO 17327-1. A device evaluation strategy is needed to identify the appropriate evaluation of specific coated devices.

It is recognized by this ISO committee that many coated endovascular devices have been shown to be safe and effective in clinical use. This document does not intend to require additional evaluation of these devices to comply with this document as the testing does not provide useful information regarding the expected clinical performance of the device. Manufacturers may rely on historical data gathered under the guidance of ISO 25539-1, ISO 25539-2, and ISO 25539-3. Similarly, for device modifications or changes in intended clinical use, this document does not intend to require additional evaluation of any aspects of the device that are not expected to change the clinical performance.

# Cardiovascular implants — Endovascular devices —

# Part 4: Application of ISO 17327-1 for coated endovascular devices



## 1 Scope

This document specifies the appropriate application of ISO 17327-1:2018 to coated endovascular prostheses, vascular stents, and vena cava filters. This document is intended to be used as a supplement to ISO 25539-1, ISO 25539-2, ISO 25539-3, ISO 12417-1 and ISO/TS 17137.

The following coatings are within the scope of ISO 17327-1 and addressed in this document for endovascular devices: drug coatings (eluting and non-eluting), non-drug coatings (absorbable and non-absorbable), and chemistry-related surface modifications (oxide, such as $TiO_2$, and non-oxide, such as amorphous silicon carbide and diamond-like carbon).

This document is not applicable to coated delivery systems or coated ancillary devices (e.g. guidewires), as these coatings are not within the scope of ISO 17327-1, which is specifically directed to implant coatings.

This document is not applicable to coverings of endovascular devices; however, if the covering of a device is coated, it is within the scope of this document.

This document does not address the requirements for, and the evaluation of, viable tissues and non-viable biologic materials used as implant coatings.

## 2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 12417-1:2015, *Cardiovascular implants and extracorporeal systems — Vascular device-drug combination products — Part 1: General requirements*

ISO/TS 17137:2021, *Cardiovascular implants and extracorporeal systems — Cardiovascular absorbable implants*

ISO 17327-1:2018, *Non-active surgical implants — Implant coating — Part 1: General requirements*

ISO 25539-1:2017, *Cardiovascular implants — Endovascular devices — Part 1: Endovascular prostheses*

ISO 25539-2:2020, *Cardiovascular implants — Endovascular devices — Part 2: Vascular stents*

ISO 25539-3:2011, *Cardiovascular implants — Endovascular devices — Part 3: Vena cava filters*

## 3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 12417-1:2015, ISO/TS 17137:2021, ISO 17327-1:2018, ISO 25539-1:2017, ISO 25539-2:2020, ISO 25539-3:2011 and the following apply.