DRAFT INTERNATIONAL STANDARD

ISO/DIS 25539-4

ISO/TC **150**/SC **2**

Secretariat: **ANSI**

Voting begins on:
2020-12-07

Voting terminates on:
2021-03-01

Cardiovascular implants — Endovascular devices —

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

ICS: 11.040.40

This document is circulated as received from the committee secretariat.

Reference number
ISO/DIS 25539-4:2020(E)

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Published in Switzerland

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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 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.

ISO 25539-4 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. 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*

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

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

This standard specifies the application of ISO 17327-1:2018, *Non-active surgical implants — Implant coating —Part 1: General requirements* to coated endovascular prostheses, vascular stents, and vena cava filters. Examples of coatings include: drug coatings (i.e. eluting and non-eluting), non-drug coatings (i.e. absorbable and non-absorbable), and chemistry-related surface modifications (i.e. oxide (e.g. TiO2) and non-oxide (e.g. amorphous silicon carbide, diamond-like carbon)). ISO 17327-1 has a broad scope, including all nonactive surgical implants, and thus only some of the requirements in that standard are applicable to coated endovascular devices. ISO 25539-4 clarifies how ISO 12417-1, ISO 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 standard is not intended to require additional evaluation of these devices to be in compliance with this standard as the testing would 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 standard is not intended to require additional evaluation of any aspects of the device that are not expected to change clinical performance.

Cardiovascular implants — Endovascular devices —

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

1 Scope

Part 4 of ISO 25539 specifies the appropriate application of ISO 17327-1:2018, *Non-active surgical implants — Implant coating —Part 1: General requirements,* to coated endovascular prostheses, vascular stents, and vena cava filters. Part 4 of ISO 25539 should be considered as a supplement to ISO 25539-1, ISO 25539-2, ISO 25539-3, ISO 12417-1 and ISO 17137.

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

This standard 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 part of ISO 25539.

This standard 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 below, only the edition cited applies.

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*

ISO 12417-1:2011, *Cardiovascular implants and extracorporeal systems – Vascular device-drug combination products*

ISO/TS 17137:2014, *Cardiovascular implants and extracorporeal systems -- Cardiovascular absorbable implants*

3 Terms and definitions

3.1
Implant coating
Refer to ISO 17327-1.
For the purposes of this document, the terms and definitions in the normative references apply.

4 Requirements for coating properties

Clauses 4.1, 4.2, and 4.3 address the requirements as related to ISO 17327-1 for vascular stents, endovascular protheses and vena cava filters, respectively. The coating types identified in Table 1 are addressed in this standard. A device may have multiple coatings each of which could be identified as different or multiple coating sub-types. For example, a drug eluting stent with an absorbable matrix would fit into eluting and absorbable coating sub-types.

Table 1 — Coating Types Addressed by this Standard

Coating Category	Coating Sub-Type I	Coating Sub-Type II
Drug	Eluting	Non-eluting
Non-Drug	Absorbable	Non-absorbable
Chemistry-related surface modifications	Oxide	Non-oxide

All evaluations identified in ISO 17327-1 might not be appropriate for all coated endovascular prostheses, vascular stents and vena cava filters. The device evaluation strategy described in ISO 25539-1 and ISO 25539-2 guides the development of the rationale for the testing selected to evaluate the endovascular device based on the requirements of the device design and potential failure modes. Evaluation of generic coating properties listed in ISO 17327-1 and identified as necessary by the device evaluation strategy shall be completed. Evaluation of coating properties listed in ISO 17327-1 deemed as not necessary by the device evaluation strategy do not need to be completed.

Due to the broad scope of ISO 17327-1, some terminology and associated requirements in that standard are appropriate for other types of nonactive surgical implants, but inconsistent with standard terminology and requirements for endovascular devices. In these cases, more relevant terminology and requirements are presented in this standard and correlated to the requirements in ISO 17327-1. This includes the requirements for the consideration of adhesion strength and coating abrasion resistance. For the coatings and implants addressed in this standard, these generic coating properties are evaluated by other tests. For example, adhesion strength is defined in ISO 17327-1 as the "load per unit area required to separate the coating from the substrate." For the coatings and implants addressed in this standard, coating adhesion is considered part of the assessment of maintenance of coating integrity which is evaluated through other means such as simulated use, durability, and particulate generation. Thus, the specific characterization of the adhesion strength (i.e. load per unit area required to separate the coating from the substrate) is not required. Similarly, coating abrasion resistance is considered part of the assessment of maintenance of coating integrity.

For chemistry-related surface modifications on the devices within the scope of ISO 25539, coating coverage integrity evaluation is addressed through corrosion testing, while corrosion resistance is not identified as a generic coating property in ISO 17327-1.

Evaluation of porosity and pore size, surface wettability, and surface texture are generally not applicable to coatings on endovascular devices. The potential need to evaluate these properties would be identified through the device evaluation strategy.

4.1 Vascular stents

In order to conform to the requirements of ISO 17327-1, evaluation of drug coatings, non-drug coatings, and chemistry-related surface modifications of stents shall be conducted for the properties as outlined in Tables 3, 4, and 5, respectively. The standards listed in Tables 3, 4, and 5 refer to the dated versions in clause 2. A description of column headings associated with Tables 3, 4, and 5 is provided in Table 1. The available test methods (non-mandatory) that may be of use in meeting the applicable requirements are provided in Tables 3, 4, and 5.

Table 2 — Description of Table 3, 4, and 5 column headings

ISO 17327-1 Generic Coating Property	Design Attributes from Other Relevant ISO Standards Corresponding to Generic ISO 17327-1 Coating Properties	Coating Type			
		Coating Sub-Type I		Coating Sub-Type II	
		Applicable Requirement	*Applicable Test Method*	*Applicable Requirement*	*Applicable Test Method*
Each generic coating property from ISO 17327-1 to be considered for characterization or evaluation.	Design attributes identified in the applicable ISO standards that correspond to the ISO 17327-1 generic coating property.	The requirements identified in the applicable ISO standard that correspond to the generic coating property or design attribute. Requirements that do not align with the ISO 17327-1 generic coating properties are not listed. Some requirements indicate the need to consider the evaluation of a property, while others indicate that the property shall be evaluated, as required by the applicable standard.	The available test methods that may be of use in meeting the applicable requirement. These test methods are not mandatory and are not limited to ISO standardized methods.	see column 3	see column 4