TECHNICAL REPORT

ISO/TR 17327-2

First edition
2021-04

Non-active surgical implants — Implant coating —

Part 2: Reference standards related to coatings

Reference number
ISO/TR 17327-2:2021(E)

ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Email: copyright@iso.org
Website: www.iso.org

Published in Switzerland

Contents

Page

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.

This document was prepared by Technical Committee ISO/TC 150, *Implants for surgery*.

A list of all parts in the ISO 17327 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

Implant coatings have a broad range of functions and an innumerable variety of thicknesses, compositions, densities, other properties and characteristics. Depending on the intended function, an implant coating can be a highly important, potentially critical, component of the device's overall design or performance criteria, or both.

ISO 17327-1 provides an overview of generic coating properties, some of which are relevant to a particular implant design and function in relation to its intended use. If these generic properties are pertinent to a coating's performance within its intended application, ISO 17327-1 requires the coating to be assessed and potentially characterized to assure its proper function.

This document identifies International Standards and national documents that address requirements for specific coating/substrate/product combinations. These reference standards contain guidance on assessing and addressing the general coating requirements described in ISO 17327-1. The device-specific implant reference standards provide guidance on the application of the characterization requirements defined in ISO 17327-1. Likewise, general standards and material-specific standards provide guidance on how to apply these characterizations as defined in ISO 17327-1.

This document provides tables that are grouped by generalized applications consistent with ISO/TC 150. Each table contains lists of applicable reference standards and indicates their relationship to the 10 properties introduced in ISO 17327-1. The relationship between the reference standard and the property is defined as a description of a test methodology (TM), an indication of a requirement (R) for evaluation, or a source of general information (GI) about the property. Additional footnotes provide greater specificity of the relationship between the reference standard and the generalized property.

A reference standard with a (TM) designation describes a method by which the specific property can be evaluated or applied.

A reference standard with an (R) designation contains a requirement regarding the specific property, or that it is required to be evaluated, either to comply with design criteria or to complete a characterization methodology.

A reference standard with a (GI) designation considers the specific property generally. It can indicate that the reference standard requires or recommends the property to be characterized under only specific circumstances. It can also indicate that the reference standard requires or recommends the design attributes to meet their intended performance in the context of the property, but no methodology or performance requirement is otherwise given.

NOTE The purpose of Tables 1 through 5 is to point to reference standards related to coatings and to provide an initial impression of the relevant content included in these documents. However, the information contained in the tables is not exhaustive and this initial impression will not be sufficient to evaluate if any of the reference standards are relevant for a specific coating or device. This information is offered as a starting point, while the documents themselves offer detailed content.

Non-active surgical implants — Implant coating —

Part 2: Reference standards related to coatings

1 Scope

This document provides lists of reference standards which contain general information, implant device or application-specific information, material specifications, or test methods related to coatings. These reference standards can be used to develop product coatings for specified applications when using ISO 17327-1 to address general coating requirements.

This document is applicable to coatings on non-active surgical implants.

2 Normative references

There are no normative references in this document.

3 Terms and definitions

No terms and definitions are listed in this document.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at http://www.electropedia.org/

4 Reference standards for coatings

4.1 General standards

Table 1 contains references to applicable general standards and indicates their relationship to the 10 properties introduced in ISO 17327-1.

Table 1 — General standards

Reference standard	Chemical composition	Phase composition	Surface texture	Coating integrity	Dissolvability	Coating thickness	Adhesion strength	Abrasion resistance	Porosity and pore size	Surface wettability	Other
ISO 10993-18	TM, R	GI									
ISO/TR 14283	GI							GI			GI[e]
ASTM F86											GI[d]
ASTM F1801			R	R							TM[d]
ASTM F1877	TM, R										TM[e]
ASTM F2129			GI								R[h], TM[d]
ASTM F2847	TM, R	GI									TM[e], R[e]
ASTM F3044	R										TM[d], R[b,d,h], GI[h]

Key

GI General information

TM Test method

R Requirement

---

[a] Chemical ratio required.

[b] Colour.

[c] Density.

[d] Corrosion.

[e] Particle sizing.

[f] Dissolution.

[g] Surface discontinuity evaluation.

[h] Surface area.

[i] Thermal properties.

[j] Hardness/surface modulus.

[k] Electrical properties.

4.2 Implant-related standards

4.2.1 Cardiovascular implant standards

Table 2 contains references to applicable cardiovascular implant standards and indicates their relationship to the 10 properties introduced in ISO 17327-1.

Table 2 — Cardiovascular implant standards

Reference standard	Chemical composition	Phase composition	Surface texture	Coating integrity	Dissolvability	Coating thickness	Adhesion strength	Abrasion resistance	Porosity and pore size	Surface wettability	Other
ISO 5840-1	GI		GI			GI	GI	GI	GI	GI	GI[d]
ISO 5840-2											R[d], TM[d]
ISO 5840-3	GI										GI[d,e]
ISO 5910	GI										R[d,e], GI[k]
ISO 7198	R			R					R, GI		R[e]
ISO 10555-1	R										TM[d], R[g]
ISO 11070				R, TM							TM[d], R[g]
ISO 12417-1	R			R	GI	R	R	R	R		R[c,d,e,i], TM[d,e]
ISO/TS 17137	R										GI[d,e]
ISO 25539-1[l]	R										R[d], TM[d]
ISO 25539-2				R, TM	GI	R	R, TM	R, TM	R		GI[c,d], R[e]
ISO 25539-3											R[d], TM[d]
ISO 25539-4[m]											
ASTM F2394				GI, R, TM							
ASTM F2902	GI	GI				GI			GI		GI[b]
ASTM F2743	GI			GI			TM				TM[e]

Key

GI General information

TM Test method

R Requirement

---

[a] Chemical ratio required.

[b] Colour.

[c] Density.

[d] Corrosion.

[e] Particle sizing.

[f] Dissolution.

[g] Surface discontinuity evaluation.

[h] Surface area.

[i] Thermal properties.

[j] Hardness/surface modulus.

[k] Electrical properties.

[l] ISO 25539-4 clarifies which characterization requirements are applicable to cardiovascular implant coatings.

[m] Applies to coatings, e.g. drug coatings (eluting and non-eluting); non-drug coatings (absorbable and non-absorbable); and intentionally manufactured chemistry-related surface modifications that are not the natural surface; oxide (e.g. TiO_2) and non-oxide (e.g. anodization, diamond-like carbon).

4.2.2 Orthopaedic implant standards

Table 3 contains references to applicable orthopaedic implant standards and indicates their relationship to the 10 properties introduced in ISO 17327-1.

Table 3 — Orthopaedic implant standards

Reference standard/ guidance document/ regulatory information	Chemical composition	Phase composition	Surface texture	Coating integrity	Dissolvability	Coating thickness	Adhesion strength	Abrasion resistance	Porosity and pore size	Surface wettability	Other
ISO 19227	GI		GI								
ISO 21534				R			R				GI[e]
ISO 21536			GI					R			
ISO/AWI 23089-1[l]											TM[d]
ISO/DIS 23089-2[m]											TM[d]
ASTM F897											TM[d]
ASTM F1357											R[d]
ASTM F1378							R				R[d]
ASTM F1672							GI, R				R[d]
ASTM F1798											GI[d]
ASTM F1801			R	R							TM[d]
ASTM F2068				R		GI	R, TM	R	GI		R[d]
ASTM F2083	R						R				R[d]
ASTM F2091							R	R	R		R[d]
ASTM F2129			GI								R[h], TM[d]
ASTM F2665	R						R				R[d]
ASTM F2790											GI[d]
ASTM F2887	R						R				R[d]
ASTM F2902	GI	GI				GI			GI		GI[b]
ASTM F3044	R										TM[d] R[b,d,h], GI[h]

Key

GI General information

TM Test method

R Requirement

---

[a] Chemical ratio required.

[b] Colour.

[c] Density.

[d] Corrosion.

[e] Particle sizing.

[f] Dissolution.

[g] Surface discontinuity evaluation.

[h] Surface area.

[i] Thermal properties.

[j] Hardness/surface modulus.

[k] Electrical properties.

[l] Under preparation. Stage at the time of publication: ISO/AWI 23089-1:— new project registered.

[m] Under preparation. Stage at the time of publication: ISO/DIS 23089-2:2020.