INTERNATIONAL STANDARD

ISO 17327-1

First edition
2018-02

Non-active surgical implants — Implant coating —

Part 1: General requirements

Implants chirurgicaux non actifs — Revêtement de l'implant —

Partie 1: Exigences générales

Reference number
ISO 17327-1:2018(E)

© ISO 2018



COPYRIGHT PROTECTED DOCUMENT

© ISO 2018

All rights reserved. Unless otherwise specified, or required in the context of its implementation, no part of this publication may be reproduced or utilized otherwise in any form or by any means, electronic or mechanical, including photocopying, or posting on the internet or an intranet, without prior written permission. Permission can be requested from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva, Switzerland
Tel. +41 22 749 01 11
Fax +41 22 749 09 47
copyright@iso.org
www.iso.org

Published in Switzerland

Contents

Page

Foreword ..... **iv**
Introduction ..... **v**
1 Scope **1**
2 Normative references **2**
3 Terms and definitions **2**
4 General Requirements **4**
4.1 General description of the coating 4
4.2 Generic coating properties 4
4.2.1 General 4
4.2.2 Chemical composition 5
4.2.3 Phase composition 5
4.2.4 Surface texture 6
4.2.5 Coating coverage integrity 6
4.2.6 Dissolvability 6
4.2.7 Coating thickness 7
4.2.8 Adhesion strength 7
4.2.9 Abrasion resistance 7
4.2.10 Porosity and pore size 8
4.2.11 Surface wettability 8
Annex A (informative) **Coating technology examples** **9**
Annex B (informative) **Examples of intended functions of implant coatings** **11**
Annex C (informative) **Standards with information related to coatings** **12**
Bibliography **14**

© ISO 2018 – All rights reserved

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 on 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 the following URL: 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.

© ISO 2018 – All rights reserved

Introduction

A wide variety of coatings are applied to numerous types of non-active surgical implant substrates. These coated implant substrates have a diversity of functionalities and intended uses and exhibit a plurality of mechanical, physical, chemical, biological and morphological/structural properties. Even though there are diversities among the types of coating applied to surgical implants, there are common attributes that can be used to define, evaluate and understand these implant coatings within a surgical implant application. This document defines general principles to be followed by manufacturers of coatings for non-active surgical implants. As the coating can represent the direct interface of the implant with the human body, the coating and its interface with the substrate can contribute to the potential failure of the intended function of the implant. A coating possesses unique features, properties and risks for its interaction with the tissue, which may not have been considered in detail in existing standards.

The role of this document is to provide a framework of design principles and evaluation guidelines for coatings on non-active surgical implants, hereafter referred to as implant coatings. Because similar basic principles can be applied to different technologies for implant coatings, this is a comprehensive document and is not limited to specific types of non-active surgical implants or to particular materials. Accordingly, this document can be applied, yet is not restricted to, metallic, ceramic, drug and polymeric coatings used in implants across a variety of applications.

This document provides guidance on generic coating properties and the potential methods that can be used to assess them. This document is not intended as a performance standard and provides neither a set of device performance criteria nor rigidly held test methods, including pass/fail criteria, as this might result in either an unnecessary constraint on the development and use of novel implant coatings, or a false sense of security in their general use for implants.

In some cases, national and international standards are available and can be used to show compliance with essential requirements for specific coating/substrate combinations, and these standards are referenced in Annex C. Beyond these available application and performance standards, this document provides general guidance and generic principles for the evaluation of non-standardized implant coating combinations.

© ISO 2018 – All rights reserved

Non-active surgical implants — Implant coating —

Part 1: General requirements

1 Scope

This document specifies general requirements for implant coatings, comprising both surface coatings and surface modifications, applied to non-active surgical implants. This document specifies requirements concerned with generic coating properties including chemical and phase compositions, surface texture, coating coverage integrity, dissolvability, coating thickness, adhesion strength, abrasion resistance, porosity and pore size, and surface wettability.

This document is applicable to surface coatings, which are defined as layers of material with any different property than the natural surface of the substrate which are intentionally added to the substrate.

This document is applicable to surface modifications, which are defined as intentional conversion or reconstruction of the surface of the original substrate to form a new surface material consisting of components of the substrate's own material and possibly foreign material and forming a surface layer with different properties.

Since the pertinent properties of a coating and their needed level of characterization are highly dependent on the intended application of the implant, the generic nature of the general requirements in this document is not intended to either override or replace the provisions of application-specific performance standards.

This document is not applicable to surfaces modified by texturing with the exclusive intention to change the roughness of the surface or the strength of the raw material.

This document is not applicable to natively passivated metal surfaces. While this document is applicable to intentionally passivated metal surfaces, well-established materials passivated by conventional techniques, such as nitric acid immersion, are usually non-hazardous and can be described in a very basic manner.

This document is not applicable to implant coatings utilizing viable tissue.

This document is not applicable to laminates, i.e. composite materials made of multiple layers, e.g. vascular prosthesis constructed of different expanded polytetrafluoroethylene layers, except the exposed surface of the laminate, which can be an implant coating (see 3.1, note 2 to entry).

This document is not applicable to coverings, e.g. covered stents.

NOTE 1 This document does not contain requirements on biocompatibility. Nevertheless, this is a critical property of the device and coating and needs to be addressed during risk assessment.

NOTE 2 This document supplements applicable non-active surgical implant standards and ISO 14630.

NOTE 3 This document does not require that manufacturers have a quality management system in place. However, the application of a quality management system, such as that described in ISO 13485, could be appropriate to help ensure that the implant achieves its intended performance.

NOTE 4 Although fully porous implants are not coatings, some of the considerations in this document can also be applied to them.

© ISO 2018 – All rights reserved

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 14630, *Non-active surgical implants — General requirements*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 14630 and the following apply.

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

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

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

3.1
implant coating
surface coating (3.2) or *surface modification* (3.3)

Note 1 to entry: Implant coating is considered a constituent of an implant.

Note 2 to entry: A laminate, i.e. a composite material made of multiple layers of the same or different materials with the same or different internal structures assembled sandwich-like and bonded by heat, pressure, welding, soldering or adhesives, is not in itself considered an implant coating. But the exposed surface of the laminate can be an implant coating.

Note 3 to entry: A covering, for example additional material (e.g. a graft) added to a structure (e.g. a stent) specifically to bridge elements of the structure for the sole purpose of reducing the permeability of the structure, is not considered an implant coating..

3.2
surface coating
layer of material with any different property than the natural surface of the substrate that is intentionally added to the substrate

Note 1 to entry: The coating can partially or fully cover the substrate surface.

Note 2 to entry: The term includes surface coatings created as a result of additive manufacturing.

3.3
surface modification
intentional conversion or reconstruction of the surface of the original substrate to form a new surface material consisting of components of the substrate's own material and possibly foreign material and forming a surface layer with different properties

3.4
coating property
measurable characteristic of a coating

Note 1 to entry: A coating property can for example be mechanical, physical, chemical or morphological/microstructural in nature.

Note 2 to entry: In multi-layered coatings, one or more characteristics are designed to change along the coating depth with one or more corresponding interfaces. These characteristics are also considered coating properties.

Note 3 to entry: In gradient coatings, one or more characteristics are designed to change (increase or decrease in magnitude of a particular property) along the coating depth without interfaces. These characteristics are also considered coating properties.

© ISO 2018 – All rights reserved

3.5
generic coating property
coating property (3.4) generally of importance for most types of coatings

3.6
pertinent property
coating property (3.4) relevant to the safety and/or efficacy of the device when used in its intended application

3.7
abrasion resistance
resistance to mechanical damage exhibited by articulating against a surface

3.8
adhesion strength
load per unit area required to separate the coating from the substrate

3.9
chemical composition
type and ratio of the chemical constituents

Note 1 to entry: If the coating comprises multiple substances, the chemical composition of each substance and the ratio of these substances might also be important. The latter can be expressed as molar fraction, volume fraction, mass fraction, molality, molarity or normality.

3.10
coverage integrity
<implant coating> absence of significant coverage defects

3.11
phase
<implant coating> homogeneous portion of an implant coating that has uniform physical and chemical properties

Note 1 to entry: Phases have distinct physical (e.g. according to their crystalline structure) or chemical (e.g. according to their chemical composition) properties and are separated from each other by definite phase boundaries.

[SOURCE: Callister Jr., W.D.; Rethwisch D.G. "Materials Science and Engineering: An Introduction"[37]. Chapter 9.3 "Phases", modified — replaced "system" with "implant coating" and "characteristics" with "properties", Note 1 to entry has been added.]

3.12
phase composition
description of the various phases and their proportions

3.13
pore size
dimensional measure of void space

Note 1 to entry: Depending upon the specific description, pore size can be described as a length, an area or a volume. Pore size can also describe either singular voids or aggregates of void spaces.

3.14
porosity
<implant coating> volume fraction of voids/pores in the total coating volume consisting of solid and void components

3.15
dissolvability
ability of a solid, liquid or gas to be dissolved in a solvent without any chemical reaction

© ISO 2018 – All rights reserved

3.16
solubility
maximum mass of a solute that can be dissolved in a unit volume of solution measured under equilibrium conditions

Note 1 to entry: The solubility depends on chemical composition, structure and *phase composition* (3.12) of the solute and the solvent as well as on temperature, pH and pressure of the solution.

3.17
dissolution rate
change of the dissolved mass of a solute with time

3.18
surface texture
property describing the non-smooth nature of a surface

Note 1 to entry: The surface texture can for example be characterized by:

a) The fabric as a directed or ordered, isotropic or non-isotropic arrangement of surface patterns (e.g. grooves or scratches);

b) The roughness as a measure of finely spaced surface irregularities with usually random distribution;

c) The waviness as a measure of surface irregularities with a spacing larger than that of the surface roughness (e.g. due to machining).

3.19
surface wettability
ability of a solid surface to influence the contacting liquid to spread over that surface

3.20
thickness
<implant coating> distance between the substrate and the outer surface of the coating in a direction orthogonal to the substrate

Note 1 to entry: For a multi-layer coating, the coating thickness is considered to be the total thickness of all individual layers.

4 General Requirements

4.1 General description of the coating

An implant coating shall be described by its materials, manufacture process (for examples see Annex A) and/or intended function (for examples see Annex B). Annex A and Annex B are only included as information to the user of this document and provide some practical examples for manufacture processes and intended functions respectively.

EXAMPLE PVD ceramic coating for wear reduction and as a diffusion barrier against allergenic substances.

EXAMPLE sprayed paclitaxel drug coating for restenosis reduction.

4.2 Generic coating properties

4.2.1 General

The coating and substrate constitute a system. The design and intended function of this system are both critical for the selection of appropriate properties to evaluate or characterize.

This subclause contains a set of generic coating properties that shall be considered for evaluation or characterization of the implant coating. Although all of the generic coating properties listed below need to be considered, it is not necessary to test or evaluate all of these properties for each type of coating, if

© ISO 2018 – All rights reserved