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Non-active surgical implants — Implant coating —

Part 1: General requirements

Implants chirurgicaux non actifs — Revêtement de l'implant —

Partie 1: Exigences générales

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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).

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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.

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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.

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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.

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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.

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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.

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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.

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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.

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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.

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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.

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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

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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

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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

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

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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

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they are deemed not pertinent. The decision whether a generic coating property is considered pertinent shall be done within a risk assessment process.

This document describes a set of coating properties to be considered for their potential to impact the safety and performance of the implant when used in the intended application. It is ultimately the responsibility of the device manufacturer to identify, control, and assess critical performance properties of the coating as applied to a particular implant. Identification and evaluation can be facilitated by potentially pertinent general, material, and application-specific implant standards (see Annex C for a partial listing). Available standards, alone or in combination, can be sufficiently comprehensive to assess a device's safety and performance. It is within this broader and combined general, material, and application-specific context that pertinent coating properties shall be risk-assessed for their potential impact on implant performance. The generic coating properties provided here are not meant to be an exhaustive list, and other properties specific to a particular coating or intended function also shall be considered. The properties for evaluation or characterization shall be selected based on the intended function of the implant coating. The test method to be used for coating evaluation or characterization shall be selected to appropriately evaluate or characterize the coating according to its intended function.

The test methods and sample preparation procedures used shall be documented in detail. Justification shall be given for the adequacy of the method and the sample size chosen. The sample geometry shall be in accordance with the requirements of the test method and consideration shall be given to the substrate geometry. The substrate material of the test specimen shall be the same as the base material of the coated implant under evaluation. The production methods of the coating shall be representative of those used for the coating on the final implant. The test specimen shall be described including any post-coating processes performed on it, such as cleaning, sterilization and ageing representative of the shelf-life.

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4.2.2 Chemical composition

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The chemical composition and the measurable impurities of the coating shall be specified.

The chemical composition of the coating shall be characterized and documented using a methodology most appropriate for the specific coating.

NOTE 1 The chemical compositions of different coatings can typically be characterized and documented in e.g. elemental, molecular or oxide basis.

While deciding on the preparation technique and analysis method, the impact of the substrate material shall be taken into account. It might be required to remove the coating appropriately before performing the chemical analysis.

NOTE 2 ISO 10993-18 provides tests methods for chemical characterization of materials. These methods can be used to assess the chemical composition of coatings.

4.2.3 Phase composition

Properties of coatings with specific chemical or elemental compositions can vary due to the formation of different phases (i.e. physical states, such as crystallographic forms, amorphous states) and their relative proportions.

The phase composition of the material is limited by but not completely defined by the chemical composition of the coating. Phase composition of coatings is often used as a readily measured property for specification or quality control in contrast to some of the performance related properties. In case of crystalline solids, phase composition is ordinarily determined using X-ray diffraction analysis on a coating separated from the substrate.

The phase composition of the coating shall be taken under consideration and it shall be decided whether or not phase composition is a pertinent property for this specific coating.

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