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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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## 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](http://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](http://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](http://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.

## 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.



# 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.

## 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.