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Non-active surgical implants — Implant coating — Best practices for coating system assessment

Implants chirurgicaux non actifs — Revêtement de l'implant — Bonnes pratiques pour l'évaluation du système de revêtement

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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

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Foreword

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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 document 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*.

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

Coatings for surgical implants are widely used in the medical device industry. These coatings are sophisticated systems involving the coating, the coating interface and substrate(s) to the coating. Due to this increasing complexity and variability of coating systems, tools for the consistent assessment of their performance and suitability to their application (i.e. their service environment) are increasingly necessary. Specifically, herein the assessment of coating systems is described from design, functional and manufacturing perspectives.

As described in ISO 17327-1, an implant coating is a layer of material with any different property than the natural surface of the substrate that it is intentionally added [upon] and it is designed to have specific physical features such as dimension, phase and coverage as well as mechanical, physical, optical, electrical, bonding and perhaps other properties such as elution. A coating also can have specific interactions with the contacting tissues, that can lead to the tissue's biological reactions to the coating and the tissue's impact on the coating.

A coating has multiple intended functions, such as allowing easier delivery, achieving optimal tissue integration and supporting the proper functioning of the device. The functions of a coating are supported by a coating's characteristics and intended use conditions in the patient. This drives the coating evaluation work into two areas:

a) coating characterization per design; and

b) functional evaluation in context of the finished products for the patients.

Although these two areas can overlap, e.g. lubricity of the lubricious coating where both the designer and user see the same thing from the patient's function perspective, these two perspectives can also diverge significantly from a coating characteristic testing perspective.

A coating and the substrate upon which the coating is placed make up a system that is intimately connected through the interface such that the coating can have an effect on the substrate and the substrate can have an effect on the coating. Some coatings are multi-layered, and as such, they can have multiple coating-substrate and coating-coating interfaces to consider. The substrate and intermediate surface can require pre-treatment such as roughening and cleaning, the use of process and post coating finishing can be necessary. Due to this complexity, it is possible that some unintended chemicals, physical structures or properties can be present in the final product. Therefore, the process is not only considered for producing the coating but can also impart characteristics to the coating. For this reason, both the pre- and post-coating processes are evaluated when determining the necessary biological functions and safety of a coating system.

A coating is usually made with a validated manufacturing process, that can involve one or more steps or technologies. It is common that multiple parties are involved in designing and manufacturing finished devices for medical uses. All parties have to be aware of the intended use of the materials, components and product that they produce. Blind use of materials, components and processes to make finished products cannot only add risks to the quality control but also add burden to be compliant to regulations.

Non-active surgical implants — Implant coating — Best practices for coating system assessment

1 Scope

This document specifies a systematic approach for the development of an assessment plan for coating systems for potential use for implants. This document provides brief introductory guidance on the coating system and intended functions. This document describes the assessment process from the context of product design, manufacturing (including sterilization), product aging and clinical intended use. This assessment process is intended to help evaluate coating properties that are pertinent to the performance of the coated devices and uses relevant examples to illustrate the process.

NOTE ISO 17327-1 defines a set of coating properties that can be pertinent for any specific coating.

This document is intended to be a useful tool in the development of an assessment plan of coating systems and is meant to support communication, e.g. among coatings manufacturer, original equipment manufacturer and regulatory bodies (through direct interaction or master files).

This document does not address the clinical safety and performance of the surgical implant for which the coating system is a part.

This document also does not cover specific tests for coating systems, as it is intended to be a structure for determining important properties and tests that can be appropriate for any given coating system.

NOTE ISO/TR 17327-2 provides several tables listing standards related to coatings including some known test methods.

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*

ISO 17327-1, *Non-active surgical implants — Implant coating — Part 1: General requirements*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 14630, ISO 17327-1 and the following apply.

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

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

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

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.