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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

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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.

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.