



Technical Report

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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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Foreword

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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.