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Implants for surgery — Cleanliness of orthopedic implants — General requirements

Implants chirurgicaux — Propreté des implants orthopédiques — Exigences générales

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Contents

Page

Foreword

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Introduction

Cleaning of orthopaedic implants is an essential step for achieving their biocompatibility as well as controlling the microbiological load required for their sterilization process.

Safe application of orthopaedic implants is related to their constitutive materials but also the contaminants that can be released from or reside on their surface. Cleanliness is a key factor to ensure the biocompatibility of an implant. When applicable, cleaning is an essential step to remove contaminations coming from the previous manufacturing steps. However, cleaning methods should not interact with materials and impair their biocompatibility or impair the performance of the implant. Moreover cleaning agents should be effectively removed unless it has been proven that they do not impair both the biocompatibility and the performance of the implant. As a consequence, the cleaning process validation is interconnected to the biological evaluation of the implant according to ISO 10993-1.

Orthopaedic implants can be delivered sterile or non-sterile. In both cases, it is the responsibility of the manufacturer to provide implants cleaned to remove manufacturing contaminants.

The objective of the cleaning validation is to verify the effectiveness of the cleaning process for reducing physical, chemical and microbial contaminants below a defined level. Evaluation and validation of cleaning methods is a difficult task that requires an exhaustive knowledge of the manufacturing process of the orthopaedic implants in order to identify potential contaminants and potential interactions between the cleaning process, the implant materials and the environment (e.g. the environment and handling of an implant following cleaning and subsequent packaging can influence the cleanliness of the implant).

As an alternative to final cleaning, the cleanliness of implants can be controlled by manufacturing in a clean environment and with clean processes. In this case, the cleaning of the implant before packaging might not be required but the cleanliness requirements defined in this document might apply.