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Implants for surgery — Cleanliness of orthopedic implants — General requirements

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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).

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).

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.

This document was prepared by Technical Committee ISO/TC 150, *Implants for surgery.*

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.

Implants for surgery — Cleanliness of orthopedic implants — General requirements

1 Scope

This document specifies requirements for the cleanliness of orthopaedic implants, hereafter referred to as implants, and test methods for the cleaning process validation and controls, which are based on a risk management process.

This document does not specify requirements for packaging or sterilization which are covered by other International Standards.

This document applies to in-process cleaning and final cleaning.

This document does not apply to liquid or gaseous implants.

This document does not apply to cleaning processes performed by the user or under the responsibility of the user.

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 9377-2, *Water quality — Determination of hydrocarbon oil index — Part 2: Method using solvent extraction and gas chromatography*

ISO 10993-1, *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management system*

ISO 10993-5, *Biological evaluation of medical devices — Part 5: Tests for in vitro cytotoxicity*

ISO 11737-1, *Sterilization of medical devices — Microbiological methods — Part 1: Determination of a population of microorganisms on products*

ASTM D7066-04, *Standard Test Method for dimer/trimer of chlorotrifluoroethylene (S-316) Recoverable Oil and Grease and Nonpolar Material by Infrared Determination*

3 Terms and definitions

For the purposes of this document, the following terms and definitions 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