International Standard

ISO 14630

Non-active surgical implants — General requirements

Implants chirurgicaux non actifs — Exigences générales

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Contents

Page

Foreword ... **iv**
Introduction ... **vi**
1 Scope ... **1**
2 Normative references ... **1**
3 Terms and definitions ... **2**
4 Intended performance ... **6**
5 Design attributes ... **6**
6 Selection of materials ... **7**
7 Design evaluation ... **8**
7.1 General ... 8
7.2 Pre-clinical evaluation ... 8
7.3 Clinical evaluation and clinical investigation ... 10
7.4 Post-market surveillance ... 11
8 Manufacture ... **11**
9 Sterilization ... **11**
9.1 Implants supplied sterile ... 11
9.2 Implants supplied non-sterile ... 12
9.3 Re-sterilizable implants ... 12
9.4 Sterilization residuals ... 12
10 Packaging ... **12**
10.1 Protection from damage in transport, storage and handling ... 12
10.2 Maintenance of sterility in transport, storage and handling ... 13
10.3 Use by date ... 13
11 Information supplied by the manufacturer ... **13**
11.1 General ... 13
11.2 Marking on implants ... 14
11.3 Label ... 14
11.4 Instructions for use ... 16
11.5 Patient record label(s) ... 17
11.6 Implant card ... 18
11.7 Implants for special purposes ... 18
Bibliography ... **19**

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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 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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For an explanation of 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 www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 150, *Implants for surgery,* in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 285, *Non-active surgical implants,* in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This fifth edition cancels and replaces the fourth edition (ISO 14630:2012), which has been technically revised.

The main changes are as follows:

— the scope has been revised to clarify that this document does not apply to implants utilizing viable animal or human tissue;

— definitions have been added for clinical evaluation and clinical investigation based on the International Medical Device Regulators Forum (IMDRF) guidance on clinical evaluation;

— definitions have been added for demonstrably similar implant and reference implant to clarify when data for other implants can be used during pre-clinical and clinical evaluation of the implant under investigation;

— indications, contraindications and target patient population have been added in Clause 4 to the list of factors to consider when establishing the intended performance of an implant;

— reorganized list of design attributes in Clause 5 to put then in a more logical sequence;

— revised Clause 6 on selection of material to use a risk analysis as the basis for selection of implant materials and to list factors to be taken into account when performing the risk analysis;

— Clause 7 has been significantly expanded on design evaluation to address pre-clinical evaluation, clinical evaluation and investigation, and post-market surveillance in more detail;

— Clause 8 has been expanded on manufacturing to address cleanliness of the implant;

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— subclause 9.1 has been revised to list the methods of sterilizing the implant in a tabular form rather than as running text;

— a new subclause 10.3 has been added to address the determination of the use by date;

— Clause 11 has been revised on information supplied by the manufacturer to include new subclauses addressing patient record labels (11.5) and implant card (11.6);

— the subclause on restrictions on combinations (formerly 11.4) has been deleted because the safety of combinations is addressed in Clause 5 l).

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.

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Introduction

There are three levels of standards dealing with non-active surgical implants and related instrumentation. For the implants themselves, they are as follows, with Level 1 being the highest:

— Level 1: general requirements for non-active surgical implants;

— Level 2: particular requirements for families of non-active surgical implants;

— Level 3: specific requirements for types of non-active surgical implants.

Level 1 standards include this document which contains requirements that apply to all non-active surgical implants, and ISO 16061, which contains requirement for instruments associated with non-active surgical implants. They also anticipate that there are additional requirements in the Level 2 and Level 3 standards.

Level 2 standards (see References [2], [12], [23], [27] and [42]) apply to a more restricted set or family of non-active surgical implants, such as those designed for use in neurosurgery, cardiovascular surgery or joint replacement.

Level 3 standards (see References [3], [13], [24] and [25]) apply to specific types of implants within a family of non-active surgical implants, such as hip joints or arterial stents.

To address the requirements for a specific implant, all related Level 1, 2 and 3 standards should be applied.

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Non-active surgical implants — General requirements

1 Scope

This document specifies general requirements for non-active surgical implants, hereafter referred to as implants.

This document is not applicable to dental implants, dental restorative materials, transendodontic and transradicular implants, intra-ocular lenses and implants utilizing viable animal or human tissue.

With regard to safety, this document specifies requirements for intended performance, design attributes, materials, design evaluation, manufacture, sterilization, packaging and information supplied by the manufacturer, and tests to demonstrate compliance with these requirements.

Additional requirements applicable to specific implants or implant families are given or referred to in Level 2 and Level 3 standards.

NOTE 1 This document does not require that the manufacturer have a quality management system in place. However, many regulatory authorities require the application of a quality management system, such as that described in ISO 13485, to ensure that the implant achieves its intended performance and safety.

NOTE 2 In this document, when not otherwise specified, the term "implant" refers to each individual component of a system or a modular implant, provided separately or as a set of components, as well as to all ancillary implants or associated implants designed for improving the intended performance.

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

ISO 10993-7, *Biological evaluation of medical devices — Part 7: Ethylene oxide sterilization residuals*

ISO 10993-17, *Biological evaluation of medical devices — Part 17: Toxicological risk assessment of medical device constituents*

ISO 11135, *Sterilization of health-care products — Ethylene oxide — Requirements for the development, validation and routine control of a sterilization process for medical devices*

ISO 11137-1, *Sterilization of health care products — Radiation — Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices*

ISO 11137-2, *Sterilization of health care products — Radiation — Part 2: Establishing the sterilization dose*

ISO 11137-3, *Sterilization of health care products — Radiation — Part 3: Guidance on dosimetric aspects of development, validation and routine control*

ISO 11607-1, *Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems*

ISO 11607-2, *Packaging for terminally sterilized medical devices — Part 2: Validation requirements for forming, sealing and assembly processes*

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ISO 13408-1, *Aseptic processing of health care products — Part 1: General requirements*

ISO 14155, *Clinical investigation of medical devices for human subjects — Good clinical practice*

ISO 14160, *Sterilization of health care products — Liquid chemical sterilizing agents for single-use medical devices utilizing animal tissues and their derivatives — Requirements for characterization, development, validation and routine control of a sterilization process for medical devices*

ISO 14937, *Sterilization of health care products — General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices*

ISO 14971, *Medical devices — Application of risk management to medical devices*

ISO 17664-1, *Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices — Part 1: Critical and semi-critical medical devices*

ISO 17665, *Sterilization of health care products — Moist heat — Requirements for the development, validation and routine control of a sterilization process for medical devices*

ISO 20857, *Sterilization of health care products — Dry heat — Requirements for the development, validation and routine control of a sterilization process for medical devices*

ISO 22442-1, *Medical devices utilizing animal tissues and their derivatives — Part 1: Application of risk management*

ISO 22442-2, *Medical devices utilizing animal tissues and their derivatives — Part 2: Controls on sourcing, collection and handling*

ISO 22442-3, *Medical devices utilizing animal tissues and their derivatives — Part 3: Validation of the elimination and/or inactivation of viruses and transmissible spongiform encephalopathy (TSE) agents*

ISO 25424, *Sterilization of health care products — Low temperature steam and formaldehyde — Requirements for development, validation and routine control of a sterilization process for medical devices*

ISO 80000-1, *Quantities and units — Part 1: General*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 14971 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
ancillary implant
implant, not included as a component of an implant system, but without which the system cannot be surgically inserted

EXAMPLE Cement for cemented stem of a hip joint replacement or screws for orthopaedic plates.

[SOURCE: ISO 16054:2019, 3.4, modified — “implantable device” has been replaced by “implant”.]

3.2
associated implant
implant, included as a component of a *modular implant* (3.13) or supplied separately, that is surgically inserted for the specific clinical condition to facilitate the use of the primary implant

EXAMPLE An augmentation device used to stabilise the tibial tray of a knee joint replacement or the acetabular cup of a hip joint replacement; sleeves applied to the stem of a hip or knee joint prosthesis to fill canal defects and prevent rotation; a cement restrictor used in hip joint replacement to occlude the intramedullary canal.

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