International Standard

ISO 14630

Non-active surgical implants — General requirements

Implants chirurgicaux non actifs — Exigences générales

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Foreword

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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;

— 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.

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.

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*

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.

[SOURCE: ISO 16054:2019, 3.5, modified — “implantable device” has been replaced by “implant”.]

3.3
B_0 hazard area
space around the magnetic resonance equipment where the static magnetic field can cause harm

Note 1 to entry: The B_0 hazard area is not identical to the special environment as defined in IEC 60601-1-2.

Note 2 to entry: The B_0 hazard area is not identical to the *magnetic resonance environment* (3.10) as defined in IEC 62570.

[SOURCE: IEC 60601-2-33:2022, 201.3.202, modified — the abbreviation "MR" in the definition and Note 2 to entry has been replaced by "magnetic resonance".]

3.4
clinical evaluation
set of ongoing activities that use scientifically sound methods for the assessment and analysis of clinical data to verify the safety, clinical performance and/or effectiveness of the device when used as intended by the manufacturer

[SOURCE: IMDRF MDCE WG/N56FINAL:2019, 4.0]

3.5
clinical investigation
systematic investigation or study in or on one or more human subjects, undertaken to assess the safety, clinical performance and/or effectiveness of a medical device

[SOURCE: IMDRF MDCE WG/N56FINAL:2019, 4.0]

3.6
coating
layer of material covering or partially covering a surface of an implant

3.7
final implant
implant that has been subjected to all manufacturing processes including packaging, and if applicable, sterilization, and that is ready to be marketed

Note 1 to entry: The final implant (i.e. implant to be evaluated) is the final product referred to in ISO 10993-1:2018, 3.8.

3.8
demonstrably similar implant
legally-marketed implant with the same intended use to the *implant* under evaluation for which similarity can be demonstrated in technical, biological and clinical characteristics based on proper scientific justification and to the extent that there is no clinically significant difference in the safety and clinical performance of the implants under evaluation

Note 1 to entry: Manufacturers shall have sufficient levels of access to the data relating to implants with which they are claiming similarity in order to justify their claims of similarity.

Note 2 to entry: In a demonstrably similar implant, most of the performance parameters (technical, biological and clinical) under consideration are similar to the implant under evaluation whereas in a *reference implant* (3.15) as few as one performance parameter may be considered.

Note 3 to entry: A demonstrably similar implant is one which can be used to avoid some technical or biological tests or a clinical investigation of the implant under evaluation.

Note 4 to entry: Some regulatory authorities can require that a demonstrably similar implant is one that is legally marketed in their own country or jurisdiction.

Note 5 to entry: For a demonstrably similar implant, there shall be evidence of successful clinical use in sufficient numbers, for a sufficient period of time, and, at a minimum, without known or reasonably known evidence of design or performance-related recalls.

Note 6 to entry: The manufacturer is responsible for identifying the demonstrably similar implant according to the regulatory requirements in the jurisdictions where the implant under evaluation will be marketed.

3.9
leakage
unintended movement of fluid, including body fluids, into or out of an implant

Note 1 to entry: An unintended diffusion phenomenon is an example of leakage for the purposes of this document.

3.10
magnetic resonance environment
MR environment
three-dimensional volume surrounding the magnetic resonance magnet that contains both the special environment (Faraday shielded volume) and the B_0 *hazard area* (3.3)

Note 1 to entry: This volume is the region in which an item can pose a hazard from exposure to the electromagnetic fields produced by the magnetic resonance equipment and accessories, and for which access control is part of the risk mitigation.

Note 2 to entry: The entrance to the magnetic resonance environment is controlled by the responsible organization. The area to which entry is controlled is sometimes referred to as the magnetic resonance controlled access area.

[SOURCE: IEC 60601-2-33:2022, 201.3.224]

3.11
magnetic resonance imaging
MRI
imaging technique that uses a static magnetic field, time-varying gradient magnetic fields and radio frequency fields to provide images of tissue by the magnetic resonance of nuclei

[SOURCE: ASTM F2182-19e2, 3.1.6]

3.12
manufacturer
natural or legal person with responsibility for design and/or manufacture of an implant with the intention of making the implant available for use, under their name, whether or not such an implant is designed and/or manufactured by that person or on their behalf by another person(s)

Note 1 to entry: This natural or legal person has the ultimate legal responsibility for ensuring compliance with all applicable regulatory requirements for the implant in the countries or jurisdictions where it is intended to be made available or sold, unless this responsibility is specifically imposed on another person by the regulatory authority (RA) within that jurisdiction.

Note 2 to entry: The manufacturer's responsibilities are described in other Global Harmonization Task Force (GHTF) guidance documents. These responsibilities include meeting both pre-market requirements and post-market requirements, such as adverse event reporting and notification of corrective actions.

Note 3 to entry: "Design and/or manufacture" can include specification development, production, fabrication, assembly, processing, packaging, repackaging, labelling, relabelling, sterilization, installation or remanufacturing of an implant; or putting a collection of devices, and possibly other products, together for a medical purpose.

Note 4 to entry: Any person who assembles or adapts an implant that has already been supplied by another person for an individual patient, according to the instructions for use, is not the manufacturer, provided the assembly or adaptation does not change the intended use of the implant.

Note 5 to entry: Any person who changes the intended use of or modifies an *implant* without acting on behalf of the original manufacturer and who makes it available for use under their own name, should be considered the manufacturer of the modified implant.

Note 6 to entry: An authorised representative, distributor or importer who only adds its own address and contact details to the implant or the packaging, without covering or changing the existing labelling, is not considered a manufacturer.