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Non-active surgical implants — General requirements

Implants chirurgicaux non actifs — Exigences générales

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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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

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.

ISO 14630 was prepared by Technical Committee ISO/TC 150, *Implants for surgery*.

This third edition cancels and replaces the second edition (ISO 14630:2005), which has been technically revised.

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Introduction

This International Standard provides a method of addressing the fundamental principles outlined in ISO/TR 14283, as they apply to non-active surgical implants. It also provides a method to demonstrate compliance with the relevant essential requirements as outlined in general terms in Annex 1 of the European Council Directive 93/42/EEC of 14 June 1993 concerning medical devices, as they apply to non-active surgical implants, hereafter referred to as implants. It might also assist manufacturers to comply with the requirements of other regulatory bodies.

There are three levels of standards dealing with non-active surgical implants and related instrumentation. For the implants themselves these 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, such as this International Standard and reference [4] in the Bibliography, contain requirements that apply to all non-active surgical implants. They also anticipate that there are additional requirements in the level 2 and level 3 standards.

Level 2 standards (e.g. references [5] – [9] in the Bibliography) 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.

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Level 3 standards (e.g. references [10] – [13] in the Bibliography) apply to specific types of implants within a family of non-active surgical implants, such as hip joints or arterial stents.

To address all requirements for a specific implant, it is advisable that the standard of the lowest available level be consulted first.

NOTE The requirements in this International Standard correspond to international consensus. Individual or national standards or regulatory bodies can prescribe other requirements.

Non-active surgical implants — General requirements

1 Scope

This International Standard specifies general requirements for non-active surgical implants, hereafter referred to as implants. This International Standard is not applicable to dental implants, dental restorative materials, transendodontic and transradicular implants, intra-ocular lenses and implants utilizing viable animal tissue.

With regard to safety, this International Standard gives 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 tests are given or referred to in level 2 and level 3 standards.

NOTE This International Standard does not require that the manufacturer have a quality management system in place. However, the application of a quality management system, such as that described in ISO 13485, could be appropriate to help ensure the implant achieves its intended performance.

2 Normative references

The following referenced documents are indispensable for the application 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 31 (all parts), *Quantities and units*

ISO 8601, *Data elements and interchange formats — Information interchange — Representation of dates and times*
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ISO 10993-1, *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management system*

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

ISO 11135-1, *Sterilization of health care products — Ethylene oxide — Part 1: Requirements for 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 11607-1, *Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems*

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

ISO 14155-1, *Clinical investigation of medical devices for human subjects — Part 1: General requirements*

ISO 14155-2, *Clinical investigation of medical devices for human subjects — Part 2: Clinical investigation plans*

ISO 14160, *Sterilization of single-use medical devices incorporating materials of animal origin — Validation and routine control of sterilization by liquid chemical sterilants*

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, *Sterilization of medical devices — Information to be provided by the manufacturer for the processing of resterilizable medical devices*

ISO 17665-1, *Sterilization of health care products — Moist heat — Part 1: 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*

3 Terms and definitions

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

3.1 coating

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

3.2

implantable state

condition of an implant prepared for implantation into a human subject

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3.3

leakage

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

NOTE An unintended diffusion phenomenon is an example of leakage for the purposes of this International Standard.

3.4

magnetic resonance environment

MR environment

volume within the 0,50 mT [5 gauss (G)] line of a magnetic resonance imaging (MRI) system, which includes the entire three-dimensional volume surrounding the magnetic resonance imaging scanner

[ASTM F2503-05¹⁾, definition 3.1.7]

NOTE For cases where the 0,50 mT line is contained within the Faraday shielded volume, the entire room is considered the MR environment. For cases where the 0,50 mT line is outside the Faraday shielded volume (e.g. in the adjacent room or area), it is advisable that the entire adjacent room or area be considered part of the MR environment.

1) Definitions for magnetic resonance environment and magnetic resonance imaging are reproduced from ASTM F2503-05 and ASTM F2119-01 respectively, copyright ASTM. Reproduced with permission of ASTM International, <http://www.astm.org/>.

3.5**magnetic resonance imaging****MRI**

diagnostic imaging technique that uses static and time varying magnetic fields to provide images of tissue by the magnetic resonance of nuclei

[ASTM F2119-01¹⁾, definition 2.1.4]

3.6**non-active surgical implant**

surgical implant, the operation of which does not depend on a source of electrical energy or any source of power other than that directly generated by the human body or gravity

3.7**safety**

freedom from unacceptable risk

[ISO/IEC Guide 51:1999, definition 3.1]

3.8**surgical implant**

device that is intended to be totally introduced into the human body, or to replace an epithelial surface or the surface of the eye, by means of surgical intervention and that is intended to remain in place after the procedure, or any medical device that is intended to be partially introduced into the human body by means of surgical intervention and that is intended to remain in place after the procedure for at least 30 days

4 Intended performance (<https://standards.iteh.ai>)

The intended performance of an implant shall be described and documented by addressing the following, with particular regard to safety:

a) intended purpose(s); [ISO 14630:2008](#)

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b) functional characteristics;

c) intended conditions of use;

d) intended lifetime.

NOTE For this purpose, it is advisable that particular account be taken of

- published standards,
- published clinical and scientific literature, and
- validated test results.

5 Design attributes

The design attributes to meet the intended performance shall take into account at least the following:

- a) materials and their biocompatibility (see Clause 6);
- b) physical, mechanical and chemical properties of materials, including endurance properties and ageing (see Clauses 6 and 7);
- c) wear characteristics of materials and the effects of wear and wear products on the implant and the body (see Clauses 6 and 7);
- d) degradation characteristics of materials, and the effects of degradation, degradation products and leachables on the implant and the body (see Clauses 6 and 7);
- e) the extent and effect of leakage (see Clauses 6 and 7);
- f) safety with respect to viruses and other transmissible agents (unclassified pathogenic entities, prions and similar entities), of animal tissues or derivatives of animal tissue utilized in the implant or during its manufacture (see Clause 6);
- g) the effect of manufacturing processes (including sterilization) on material characteristics and performance (see Clauses 6, 7, 8 and 9);
- h) possible effects on the implant and its function due to interactions between its constituent materials and between its constituent materials and other materials and substances (see Clauses 6 and 7);
- i) interconnections and their effects on the intended performance (see Clause 7);
- j) interface(s) between the implant and body tissue(s), particularly relative to fixation and connection, and surface conditions (see Clause 7);
- k) shape and dimensions, including their possible effects on tissues and body fluids (see Clause 7);
- l) biocompatibility of the implant in its implantable state (see Clauses 6 and 7);
- m) physical and chemical effects of the body and external environment on the implant (see Clause 7);
- n) effects of radiation, electromagnetic and magnetic fields on the implant and its function, and any consequential effects on the body (see Clauses 6 and 7);

NOTE Particular attention is drawn to the fields used for magnetic resonance imaging (MRI) in respect of patient safety. The test methods in ASTM F2052, ASTM F2119, ASTM F2182 and ASTM F2213 can be used to evaluate the safety of an implant in the MR environment.

- o) the ability to implant and, when applicable, to remove or replace the implant (see Clause 7);
- p) the ability to visualize the position and orientation of the implant by radiological or other imaging procedures;
- q) microbiological and particulate contamination levels (see Clauses 8, 9 and 10);
- r) the suitability and effectiveness of packaging (see Clause 10).

Implant design attributes shall be documented. Where any of the above are not considered to be relevant, the reason shall be documented and justified.