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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 fourth edition cancels and replaces the third edition (ISO 14630:2008), which has been technically revised.

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 for demonstrating compliance with the relevant essential requirements as outlined in the 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 help manufacturers 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, 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, such as this International Standard and Reference [4], 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 (see References [5], [6], [7], [8] and [9]) 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 [10], [11], [12] and [13]) 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 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 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, might be appropriate to help ensure that 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 8601, *Data elements and interchange formats — Information interchange — Representation of dates and times*

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 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, *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, *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*

ISO 80000 (all parts), *Quantities and units*

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

3.3
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 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

NOTE 1 to entry: 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.

[SOURCE: ASTM F2503-05, 3.1.7, modified — the second sentence has been converted into a note.]

3.5
magnetic resonance imaging
MRI
imaging technique that uses static and time varying magnetic fields to provide images of tissue by the magnetic resonance of nuclei

[SOURCE: ASTM F2119-07, 2.1.4]

3.6
non-active surgical implant
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

[SOURCE: ISO/IEC Guide 51:1999, 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

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

a) intended purpose(s);

b) functional characteristics;

c) intended conditions of use;

d) intended lifetime.

NOTE To describe the intended performance, it is advisable that particular account be taken of the following, among other things:

— 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);

NOTE It is advisable that the shape, dimensions and tolerances of the interconnections, as well as the potential wear, degradation, corrosion and electrolytic effects, be taken into account.

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, where 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);

s) where appropriate, the anthropometric and anatomical features of the population for whom the implant is intended;

t) the condition and pathology of the host tissue;

u) required operative techniques and the appropriate care and handling of the implant to reduce the risk of use error while not impairing the intended use and performance of the implant;

v) where applicable, the nature and type of any radioactive substances incorporated in or used with the implant to achieve the intended performance while reducing or eliminating the risk of exposure of patients, users and other persons to unintended radiation.

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

6 Materials

Implant materials shall be selected with regard to the properties required for the intended purpose, also taking into account the effects of manufacture, handling, sterilization and storage, as well as any treatment (chemical, electro-chemical, thermal, mechanical, etc.) applied to the surface or a part of the surface of the implant material in order to modify its properties. Possible reactions of implant materials with human tissues and body fluids, other materials, other implants, substances and gases shall be considered. Possible effects of radiation and of magnetic and electromagnetic fields on the material shall also be considered.

When a medicinal product is an integral part of an implant, the medicinal product shall be assessed according to pharmaceutical principles. The performance of the medicinal product used in combination with the implant shall not be affected by the implant and/or vice versa.

NOTE 1 For the assessment of the safety, quality and usefulness of the medicinal product incorporated as an integral part of an implant, appropriate methods might be specified in national or regional regulations (e.g. European Directive 2001/83/EC).

Materials, including biological materials, used for implants and coatings shall be compatible to an acceptable degree with the biological tissues, cells and body fluids with which they are in contact in their implantable state. The compatibility of possible wear and degradation products shall also be acceptable. The biological acceptability in the particular application shall be demonstrated either:

a) by documented assessment in accordance with ISO 10993-1, or

b) by selection from the materials found suitable by proven clinical use in similar applications.

NOTE 2 Some of the level 2 standards include lists of materials which have been found acceptable in certain applications.

For implants utilizing materials of animal origin that are non-viable or have been rendered non-viable either in the implant or in its manufacture, these materials shall be evaluated and their safety with respect to viruses and other transmissible agents shall be in accordance with the requirements of ISO 22442-1, ISO 22442-2 and ISO 22442-3.

NOTE 3 See ISO 22442-1 for the definition of the terms “animal” and “tissue”.

7 Design evaluation

7.1 General

Implants shall be evaluated to demonstrate that the intended performance (see Clause 4) is achieved. The extent to which the intended performance has been achieved shall be determined and documented. Safety and intended performance shall be demonstrated by pre-clinical evaluation, clinical evaluation and post-market surveillance, including appropriate risk management at all stages of the life cycle of the implant, in accordance with the requirements of ISO 14971.

7.2 Pre-clinical evaluation

Implants shall undergo pre-clinical evaluation based on

a) the relevant scientific literature relating to the safety, performance, design characteristics, and intended use of the implant,

b) analysis of available predictive and outcome data from sources such as national and other registries, and

c) analysis of data obtained from testing, including bench-testing and, when available, data from validated techniques for evaluating implant safety and intended performance.

The extent of pre-clinical evaluation shall take account of existing data in relation to similar implants or design features.

Pre-clinical testing of implants should simulate conditions of intended use. Test methods and related limits for specific types of implants shall be defined and justified by the manufacturer and shall include, as appropriate, *in vitro* handling tests to verify the intended interaction between the implant and the instrumentation and, if applicable, between interconnecting implants.

In instances when implantation and, where appropriate, removal cannot be evaluated by direct comparison with existing devices, cadaveric evaluation should be performed where possible.

If static and/or dynamic loading tests are relevant for the evaluation of the implant, either accepted test standards, when available, or customized test models taking into account the characteristics of the implant shall be applied. Because of the wide variance of implants and their features, testing standards might not exist or may be modified as needed.

Where appropriate, biophysical or modelling research may be used to demonstrate that the intended performance of the implant is achieved.

Tests should take into account anticipated loading and/or environmental conditions. Where appropriate, test specimens should represent as closely as possible the implants to be implanted.

Test methods and limits for particular implants can be described in related standards, such as those listed in the bibliography.