INTERNATIONAL STANDARD

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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 second edition cancels and replaces the first edition (ISO 14630:1997), which has been technically revised.

For the purposes of this International Standard, the CEN annex regarding fulfilment of European Council Directives has been removed.

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 Community 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 may 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.

This standard is a Level 1 standard and contains requirements that apply to all non-active surgical implants. It also anticipates that there are additional requirements in the Level 2 and Level 3 standards.

The Level 2 standards 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.

The Level 3 standards 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 the standard of the lowest available level should be consulted first.

References to other International Standards can also be found in the Bibliography.

The requirements in this International Standard correspond to international consensus. Individual or national standards or regulatory bodies may 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. It is not applicable to dental implants, dental restorative materials, transendodontic and transradicular implants and intra-ocular lenses.

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 required to demonstrate compliance with these requirements. Additional tests are given or referred to in Level 2 and Level 3 standards.

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*

ISO 10993-1, *Biological evaluation of medical devices — Part 1: Evaluation and testing*

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

ISO 11135:—[1)], *Sterilization of health care products — Ethylene oxide — Requirements for development, validation and routine control of a sterilization process for medical devices*

ISO 11137, *Sterilization of health care products — Requirements for validation and routine control — Radiation sterilization*[2)]

ISO 11607, *Packaging for terminally sterilized medical devices*

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

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1) To be published. (Revision of ISO 11135:1994). ISO 11135:1994 is not identical to EN 550, which was referenced in the last edition of ISO 14630. However, a revision of ISO 11135:1994 is under development and will be harmonized under the EU Medical Device Directive.

2) ISO 11137:1995 is not identical to EN 552 wich was referenced in the last edition of ISO 14630, however, a revision of this standard is under development and will be harmonized.

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:—[3)], *Sterilization of health care products — Moist heat — Development, validation and routine control of a sterilization process for medical devices*

EN 12442-1, *Animal tissues and their derivatives utilized in the manufacture of medical devices — Part 1: Analysis and management of risk*

EN 12442-2, *Animal tissues and their derivatives utilized in the manufacture of medical devices — Part 2: Controls on sourcing, collection and handling*

EN 12442-3, *Animal tissues and their derivatives utilized in the manufacture of medical devices — Part 3: Validation of the elimination and/or inactivation of viruses and transmissible agents*

3 Terms and definitions

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

3.1
surgical implant
device which is intended

— to be totally introduced into the human body, or

— to replace an epithelial surface or the surface of the eye,

by surgical intervention which is intended to remain in place after the procedure

NOTE Any medical device intended to be partially introduced into the human body by surgical intervention and which is intended to remain in place after the procedure for at least 30 d is also considered a surgical implant.

3.2
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

3.3
safety
freedom from unacceptable risk

3.4
implantable state
condition of an implant prepared for implantation into a human subject

3.5
leakage
unintended movement of fluid including body fluids into or out of implants through a defect in the structure of the containing wall

3) To be published.

3.6
coating
layer of material used to cover or partially cover a surface of an implant

4 Intended performance

The intended performance of an implant shall be described and documented by addressing the following:

— intended purpose(s);

— functional characteristics;

— intended conditions of use;

with particular regard to safety.

Account should also be taken of:

— published standards;

— published clinical and scientific literature;

— 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) extent and effect of leakage of substances (see Clauses 6 and 7);

f) effect of manufacturing processes (including sterilization) on material characteristics and performance (see Clauses 6, 7, 8 and 9);

g) 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);

h) interconnections and their effects on the intended performance (see Clause 7);

i) interface(s) between the implant and body tissue(s), particularly relative to fixation and connection, and surface conditions (see Clause 7);

j) shape and dimensions including their possible effects on tissues and body fluids (see Clause 7);

k) biocompatibility of the implant in its implantable state (see Clauses 6 and 7);

l) physical and chemical effects of the body and external environment on the implant (see Clause 7);

m) effects of radiation and electromagnetic fields on the implant and 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.

n) ability to implant, to remove and to replace the implant (see Clause 7);

o) ability to visualize the position and orientation of the implant by radiological procedures;

p) microbiological and particulate contamination levels (see Clauses 8, 9 and 10);

q) 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.

6 Materials

Implant materials shall be selected with regard to the properties required for the intended purpose, taking also into account the effects of manufacture, handling, sterilization and storage. 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 electro-magnetic 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.

When assessing the safety, quality and usefulness of the medicinal product incorporated as an integral part of an implant, appropriate methods, such as specified in European Directive 2001/83/EC should be employed.

Materials used for implants and coatings, including biological materials, shall be acceptably compatible in their implantable state. The compatibility of possible wear and degradation products shall also be acceptable. The acceptability in the particular application shall be demonstrated either:

a) by documented assessment in accordance with the principles of ISO 10993-1; or

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

NOTE 1 Some of the Level 2 standards include lists of materials which have been found acceptable in certain applications.

For implants that utilize animal tissues or derivatives of animal tissues, controls shall be applied in accordance with the requirements of EN 12442-1 (analysis and management of risk), EN 12442-2 (controls on sourcing, collection and handling) and EN 12442-3 (validation of the elimination and/or inactivation of viruses and transmissible agents).

NOTE 2 ISO/TC 194 is developing ISO Standards based on EN 12442-1, EN 12442-2 and EN 12442-3 as ISO 22442-1, ISO 22442-2 and ISO 22442-3, respectively.

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 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 by

a) a compilation and critical analysis of relevant scientific literature; and/or

b) an analysis of data obtained from testing.

Pre-clinical testing of implants shall simulate conditions of intended use. Test methods and related acceptance criteria for specific types of implants are referenced in other related International Standards.

7.3 Clinical evaluation

Implants shall undergo clinical evaluation by

a) a compilation and critical analysis of relevant scientific and clinical literature covering the intended use of the implant or similar implants; and/or

b) an analysis of data obtained from clinical investigation.

Where a clinical investigation is carried out it shall be performed in accordance with the requirements of ISO 14155-1. Requirements for clinical investigation of specific product types are included in other related International Standards.

7.4 Post market surveillance

A systematic procedure to review post market experience gained from implants shall be in place.

NOTE Suitable methodologies include survival analysis (with revision as the end point) and clinical assessment.

8 Manufacture

Implants shall be manufactured in such a way that the specified design attributes are achieved. Requirements are specified in other related International Standards.

The application of quality systems as described in ISO 13485 may be appropriate.

9 Sterilization

9.1 General

The effects of the sterilization method employed for surgical implants shall not impair the intended function.