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Instruments for use in association with non-active surgical implants — General requirements

Instruments à utiliser en association avec les 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.

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 documents 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).

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. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

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 fourth edition cancels and replaces the third edition (ISO 16061:2015), which has been technically revised. The main changes compared to the previous edition are as follows:

— A requirement to include intended purpose has been added in the list of items to be included when establishing the intended performance of the instrument.

— The list of design attributes in Clause 5 has been reorganized and several new attributes have added to the list.

— The selection of materials to be used in the instrument has been based on a risk analysis and the clause now includes a list of the minimum factors to be considered in the risk analysis.

— The requirement for pre-clinical evaluation has been expanded and includes the requirement for testing and biological evaluation of the final instrument.

— A clinical evaluation of the instrument is required in all cases. However, if the pre-clinical evaluation demonstrates the safety and intended performance of the instrument in the conditions of intended use, the results of the pre-clinical evaluation will satisfy the requirement for the clinical evaluation.

— A new requirement for post-market surveillance has been added to Clause 7.

— The requirements in Clause 11 have been reorganized and clarified to reflect current practice and to reference ISO 17664:2017, Clause 6 for instructions for applicable processing step (i.e. cleaning, disinfection, drying, packaging, and sterilization) that need to be carried out by someone other than the manufacturer.

— Annex A has been simplified to provide more consistent guidance on selection of material using a risk-based approach. The stainless-steel grade material characteristic tables have been removed.

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

This document provides a method of addressing the fundamental principles outlined in ISO/TR 14283 as they apply to instruments to be used in association with non-active surgical implants. It also provides a method that can be used to demonstrate compliance with applicable regulatory requirements relevant to the general safety and performance of medical devices as they apply to instruments used in association with non-active surgical implants.

There are three levels of standards dealing with instruments to be used in association with non-active surgical implants. They are as follows, with level 1 being the highest.

— Level 1: general requirements for instruments to be used in association with non-active surgical implants.

— Level 2: particular requirements for families of instruments to be used in association with non-active surgical implants.

— Level 3: specific requirements for types of instruments to be used in association with non-active surgical implants.

Level 1 standards include this document which contains requirements that apply to all instruments to be used in association with non-active surgical implants, ISO 14630, which contains requirement for non-active surgical implants and ISO 14708-1, which contains requirements for active implants. They also anticipate that there are additional requirements in the level 2 and level 3 standards.

Level 2 standards apply to a more restricted set or family of instruments, such as those designed for use with non-active surgical implants used in neurosurgery, cardiovascular surgery, or joint replacement.

Level 3 standards apply to specific types of instruments within a family of instruments used in association with non-active surgical implants, such as hip joints or arterial stents.

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

Compliance with a level 3 standard is intended to imply compliance with the applicable level 2 standards, if available, and with the applicable level 1 standard.

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

Instruments for use in association with non-active surgical implants — General requirements

1 Scope

This document specifies the general requirements for instruments to be used in association with non-active surgical implants. These requirements apply to instruments when they are manufactured and when they are supplied after refurbishment.

NOTE In this document, unless otherwise specified, the term "instrument" refers to an instrument for use in association with non-active surgical implants.

This document also applies to instruments which can be connected to power-driven systems, but it does not apply to the power-driven systems themselves.

With regard to safety, this document gives the requirements for intended performance, design attributes, materials, design evaluation, manufacture, sterilization, packaging, and information supplied by the instrument manufacturer, hereafter referred to as the manufacturer.

This document is not applicable to instruments associated with dental implants, transendodontic and transradicular implants and ophthalmic implants.

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 8601-1, *Date and time — Representations for information interchange — Part 1: Basic rules*

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

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

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, *Processing of health care products — Information to be provided by the medical device manufacturer for the processing of 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 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 terms and definitions apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— IEC Electropedia: available at http://www.electropedia.org/

— ISO Online browsing platform: available at https://www.iso.org/obp

3.1
associated implant
specific *non-active surgical implant* (3.4) associated with a specific *instrument* (3.3) intended to be used during a surgical procedure

3.2
final instrument
instrument (3.3) that has been subjected to all manufacturing processes for the “to be marketed” *instrument* including packaging and if applicable, sterilization

3.3
instrument
non-active medical device intended for use during surgical procedures related to specific *non-active surgical implants* (3.4)

Note 1 to entry: Examples of typical applications of instruments to be used in association with non-active surgical implants are presented in A.1.

3.4
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[SOURCE: ISO 14630:2012, 3.6]— the second term "implant" has been deleted.]

4 Intended performance

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

a) intended purpose;

b) functional characteristics;

c) intended conditions of use.

Instruments shall be evaluated to demonstrate that the intended performance is achieved (see Clause 7).

NOTE Information to support the description of the intended performance can be found in sources such as:

— published standards;

— published clinical and scientific literature;

— validated test results.

5 Design attributes

The development of the design attributes of an instrument to meet the performance intended by the manufacturer shall take into account at least the following:

a) role of the instrument in conjunction with the associated the non-active surgical implant (e.g. implantation, positioning, alignment, removal);

b) biocompatibility of materials for their intended use, including the influence of material by-products from manufacturing and chemical residuals;

c) physical, mechanical, biological and chemical properties of the instrument materials;

d) potential deterioration of the material characteristics;

e) usability;

f) compatibility with intended processing agent (e.g. cleaning agent, disinfectant, and sterilizing agent) and intended processing conditions (e.g. temperature, pressure, vacuum, humidity, time) for instruments requiring user processing (e.g. sterilization) or intended to be reused;

g) stability of instrument materials under intended manufacturing conditions (e.g. chemicals, temperature, pressure, vacuum, humidity, time);

h) potential deterioration of the form and/or function of the instrument due to repeated use and reprocessing;

i) ease of cleaning, disinfection (if intended by the manufacturer) and sterilization both by the manufacturer and the user;

j) ease of maintenance;

k) effects of contact between the instrument and the body;

l) effects of contact between the instrument and the non-active surgical implant, and other instruments;

m) shape and dimensions of the instrument, including their possible effects on the body or the non-active surgical implant;

n) wear characteristics of materials and the effect of wear and wear products on the instrument, the body or the non-active surgical implant;

o) insertion, removal, and interconnection of parts;

p) extent of fluid leakage and/or diffusion of substances into or out of instruments;

q) accuracy and stability of the measurement for instruments with a measuring function;

r) reciprocal interference with other devices in the specified use environment;

EXAMPLE Compatibility with diagnostic imaging systems such magnetic resonance imaging (MRI) equipment. See references [35], [37] and [38] for standards related to the hazards associated with the magnetic resonance environment.

s) ability of the instrument or fragment of instrument to be located by means of an external imaging device [see 11.4, q)];

t) compatibility with medicinal substances incorporated into or intended to be used with the instrument.

6 Selection of materials

The selection of materials to be used for the manufacture of instruments shall be based on a risk analysis, which shall take into account at least the following:

a) the properties required for the intended purpose considering factors such as mechanical/ functional requirements, anatomical location, dimensions, geometry, and conditions for use; and, duration and frequency of use over the intended lifetime of the instrument;

b) any intended treatment to the material or to the surface of the instrument (e.g. chemical, electro-chemical, thermal, mechanical, coating);

c) the effects of instrument manufacturing, handling, cleaning, packaging, sterilization, storage, and processing (if applicable);

NOTE 1 For information on processing of health care products, see ISO 17664.

d) possible adverse reactions by the human body and body fluids to the instrument materials;;

EXAMPLE 1 Adverse reaction to leachable chemicals, degradation products, additives (e.g. plasticisers and fillers) and impurities.

e) possible adverse reactions between the non-active surgical implant materials and instrument materials in the presence of body fluids.

EXAMPLE 2 Electrochemical corrosion.

NOTE 2 Annex A lists some of the materials that have been found acceptable in certain applications. Reference to Annex A does not eliminate the need to conduct a risk analysis taking into account the factors outlined above.

A biological evaluation of the final instrument shall be performed and shall form part of the pre-clinical evaluation (see 7.2).

7 Design evaluation

7.1 General

Instruments shall be evaluated in association with the non-active surgical implant they are designed for, in order to demonstrate that the safety and the intended performance is achieved (see Clause 4). 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 instrument.

NOTE Further information on risk management can be found in ISO 14971.

7.2 Pre-clinical evaluation

Instruments shall undergo pre-clinical evaluation based on a critical review of:

a) data obtained from testing of the instrument or demonstrably similar instruments and, when available, data from validated techniques for evaluating instrument safety and intended performance;

b) all available field data, safety reports, relevant complaint information, and adverse event data for the instrument or demonstrably similar instruments.

The pre-clinical evaluation can be supported by a critical review of:

c) applicable standards;

d) the relevant scientific literature relating to the safety, performance, design characteristics, and intended use of the instrument or of demonstrably similar instruments.

Testing of the instrument is required unless the critical review above demonstrates the safety and intended performance of the instrument. If testing of the instrument is required, the testing shall simulate conditions of intended use and, if applicable, re-use.

Testing to demonstrate the usability of the instruments is required unless the use of the instrument can be evaluated by direct comparison with existing devices.

NOTE 1 Testing to demonstrate usability can include cadaveric evaluation or simulated cadaveric evaluation.

NOTE 2 Further information on a process for demonstrating the usability of an instrument can be found in IEC 62366-1.

The biological evaluation of the final instrument shall be performed in accordance with ISO 10993-1. When determining the biocompatibility of the final instrument, residuals from the manufacturing processes (e.g. lubricants, cleaning agents, mould release agents) shall also be considered.

If the manufacturer specifies the instrument can be processed by the user, the effect of the specified processes on the intended lifetime of the instrument (e.g. maintaining functionality and biocompatibility) shall be considered.

NOTE 3 See also ISO 17664:2017, 6.2.

7.3 Clinical evaluation

Instruments shall undergo a clinical evaluation.

If the pre-clinical evaluation demonstrates the safety and intended performance of the instrument in the conditions of intended use, the results of the pre-clinical evaluation shall satisfy the requirement for the clinical evaluation and no further evaluation is required.

If the pre-clinical evaluation is not sufficient to demonstrate the safety and intended performance of the instrument in the conditions of intended use, the manufacturer may conduct a critical review of the results of all available clinical evaluations conducted using the instrument or demonstrably similar instruments under the intended conditions of use. If the results of the critical review demonstrate the safety and intended performance of the instrument in the conditions of intended use, the results of the critical review shall satisfy the requirement for the clinical evaluation and no further evaluation is required. Otherwise, the instrument shall undergo a clinical investigation.

If a clinical investigation is required, it shall be performed in accordance with ISO 14155.

7.4 Post-market surveillance

A systematic procedure to collect and review post-market data gained from use of the instrument shall be in place.

The design of the procedure to collect and review post-market data should be based on the risk that the instrument failure presents to the patient or end user.

Suitable methods for collection of post-market data on the instrument can include, but are not limited to, complaints analysis and user feedback.

NOTE Guidance on post-market surveillance for manufacturers can be found in ISO/TR 20416.