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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 has been added as a requirement 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 the 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

Note 1 to entry: Derived from the definition of "final product" in ISO 10993-1:2018, 3.8 to reinforce that the instrument to be evaluated is the final product referred to in ISO 10993-1.

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, modified — 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 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 (i.e. instruments with similar functionality and intended use) 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.

8 Manufacture

Instruments shall be manufactured to specifications in accordance with the required design attributes (see Clause 5).

Instruments can be supplied sterile or non-sterile. In both cases, the manufacturer shall provide instruments that have been cleaned to remove manufacturing contaminants.

9 Sterilization

9.1 Instruments supplied sterile

For terminally sterilized instruments labelled "STERILE", the theoretical probability of there being a viable microorganism present on or in the instrument shall be equal to or less than 1×10^{-6}.

If instruments are to be sterilized by ethylene oxide, it shall be done according to ISO 11135.

If instruments are to be sterilized by irradiation, it shall be done according to ISO 11137-1, ISO 11137-2, and ISO 11137-3. If applicable, ISO/TS 13004 may be used to meet the requirements of ISO 11137-2.

If instruments are to be sterilized by moist heat, it shall be done according to ISO 17665-1.

If instruments are to be sterilized using low-temperature steam and formaldehyde, it shall be done according to ISO 25424.

NOTE In some regulatory jurisdictions, low-temperature steam and formaldehyde sterilization is not an accepted sterilization method.

If instruments are to be sterilized by any other terminal sterilization method, ISO 14937 shall apply.

9.2 Instruments supplied non-sterile

For instruments that are supplied non-sterile, the manufacturer shall provide information on the processing of these instruments in accordance with ISO 17664.

9.3 Instruments that are resterilizable

For instruments that are claimed to be resterilizable, the manufacturer shall provide information on the processing of these instruments in accordance with ISO 17664.

10 Packaging

10.1 Protection from damage in transport, storage and handling

For each instrument, the packaging shall be designed so that, under conditions specified by the manufacturer for transport, storage and handling (e.g. temperature, humidity, and, if applicable, UV environment, pressure), the instrument is protected against damage and deterioration and the packaging does not adversely affect the intended performance of the instrument.

NOTE 1 Possible test methods are specified in IEC 60068-2-27, IEC 60068-2-31, and/or IEC 60068-2-47. Possible methods for performance testing of packaging and shipping containers can be found in ASTM D4169, ASTM D7386 and ISTA 3A.

NOTE 2 Before any packaging is adopted, it is advisable to evaluate it to establish its suitability for the intended purpose. This can be done by hazard journey trials designed to simulate the conditions the package could encounter.

10.2 Maintenance of sterility in transport, storage and handling

Instruments labelled “STERILE” shall be packaged such that they remain sterile under the transport, storage and handling conditions specified by the manufacturer, unless the protective package is damaged or opened.

The packaging and packaging processes shall comply with ISO 11607-1 and ISO 11607-2.

NOTE See ISO 11607-1:2019, Table B.1 for a list of performance testing standards and test methods for sterile barrier systems.

11 Information supplied by the manufacturer

11.1 General

Each instrument shall be accompanied by the information needed to identify the instrument and its manufacturer, and by any safety and performance information relevant to the user, or any other person, as appropriate.

Such information may appear on the instrument itself, on the packaging for each unit, and/or on the packaging of multiple instruments or in the instructions for use.

The information that shall be marked on the instrument is provided in 11.2. The information that shall be placed on the label is provided in 11.3. The information that shall be included in the instructions for use is provided in 11.4.

Where appropriate, instructions for use shall be provided together with the instrument(s) or in a non-paper format (e.g. electronic).

Information supplied by the manufacturer and intended for direct visual recognition shall be legible when viewed under illumination of 215 lux using normal vision, corrected if necessary, at a distance of 1 m.

When appropriate, symbols, abbreviations, and identification colour may be used in the markings and accompanying documents of an instrument. Any symbols, abbreviations, and identification colours used shall conform to published international standards (e.g. ISO 15223-1). Where no such standards exist, the manufacturer shall describe the symbols, abbreviations, or identification colours used in the documentation supplied with the instrument.

NOTE 1 In some regulatory jurisdictions, there are additional requirements for the use of symbols in labelling (e.g. in the US, publicly available information on the use of symbols in labelling is available in the FDA final rule on the *Use of symbols in labeling*[41]).

The information supplied by the manufacturer shall be presented in a clear manner that cannot be confused with other essential information and shall be understandable by the intended user and/or, where appropriate, other persons.

Any units of measurement shall be expressed in SI units complying with ISO 80000-1. Equivalent values in non-SI units may be stated in parentheses.

NOTE 2 Attention is drawn to ISO 80000-1, which gives further guidance on the application of SI units.

When applicable, instruments with user adjustable controls shall have their function clearly described.

Any detachable components, intended by the manufacturer to be used separately from the original instrument, shall be identified by their batch code or by other appropriate means.

Any date shall be expressed in the format YYYY-MM-DD, or YYYY-MM, or YYYY, in accordance with ISO 8601-1.

11.2 Marking on instruments

Instruments shall be marked with the following:

a) manufacturer's name or trademark;

b) batch code or serial number, where appropriate;

c) catalogue/model designation, where appropriate, and/or size indication, if needed for safe selection or use.

If the marking would affect the intended performance or the instrument is too small to be legibly marked, the information required shall be given on the label.

NOTE In some regulatory jurisdictions, there are requirements to include a unique device identifier (UDI) in human- and/or machine-readable form permanently marked upon the instrument itself.

11.3 Label

The label shall bear the following information:

a) name and address of the manufacturer, including at least the city and the country;

b) type (name) of the instrument, the model designation of the instrument, and, if applicable:

— the batch code or the serial number of the instrument preceded by an appropriate identification;

— size or compatibility information;

EXAMPLE 1 "LOT", "SN", or the lot, or serial number symbols ISO 7000-2492 and ISO 7000-2498, respectively. See ISO 15223-1:2021[1)], 5.1.5 and 5.1.7.

c) if multiple instruments are provided in the package, the quantity in the package;

d) if the intended purpose of the instrument is not obvious to the user, a clear statement of the intended purpose;

e) if the instrument is terminally-sterilized, an indication that the contents of the package are sterile and the method of sterilization (see 9.1);

EXAMPLE 2 The word "STERILE" or the sterile symbol ISO 7000-2499, or one of the "sterilized using..." symbols ISO 7000-2500, ISO 7000-2501, ISO 7000-2502, or ISO 7000-2503. See ISO 15223-1:2021, 5.2.1 or 5.2.2, 5.2.3, 5.2.4, and 5.2.5.

f) if identical or similar instruments are sold in both sterile and non-sterile condition, a clear indication that the contents of the particular package are non-sterile, when applicable;

EXAMPLE 3 The "non-sterile" symbol ISO 7000-2609. See ISO 15223-1:2021, 5.2.7.

g) if applicable, the "use by date", expressed as year and month, and, if appropriate, day;

EXAMPLE 4 The "use by date" symbol ISO 7000-2607. See ISO 15223-1:2021, 5.1.4.

h) if the instrument is intended for single use, an appropriate indication;

EXAMPLE 5 The "do not re-use" symbol ISO 7000-1051. See ISO 15223-1:2021, 5.4.2.

i) any special storage (e.g. temperature, humidity, UV environment, pressure) and/or handling conditions;

1) Under preparation. Stage at the time of publication: ISO/FDIS 15223-1:2021.

j) any warnings or precautions relating to use;

k) if instructions for use is provided, an indication to check the instructions for use;

EXAMPLE 6 The "Consult instructions for use" symbol ISO 7000-1641. See ISO 15223-1:2021, 5.4.3.

l) if the instrument is not to be used in case the package is damaged or unintentionally opened, an appropriate indication.

EXAMPLE 7 The "Do not use if package is damaged" symbol ISO 7000-2606. See ISO 15223-1:2021, 5.2.8.

NOTE In some regulatory jurisdictions, there are requirements to include a UDI.

11.4 Instructions for use

If applicable, the instructions for use shall contain the following information:

a) name and contact details of the manufacturer, including at least the postal address and the country;

NOTE 1 Contact details can include telephone number, email address, website URL.

NOTE 2 In some regulatory jurisdictions, there are requirements to include the name and address of the authorized representative or local agent.

b) description of the instrument and the model designation of the instrument;

c) if the intended purpose of the instrument is not obvious to the user, a clear statement of the intended purpose;

d) the intended performance described in Clause 4 and, if appropriate, any undesirable side-effects;

e) information allowing the user to select a suitable instrument (including a correct size), its accessories, and related devices, in order to obtain a safe combination;

f) if the instrument is intended to be used in combination with other instruments, devices, or equipment, then:

1) information to identify such instruments, devices or equipment, in order to obtain a safe combination, and

2) information on any known restrictions;

Further information may be provided in a brochure and/or manual.

g) if applicable, any information needed to verify that the instrument is functioning correctly and safely;

h) if the instrument is intended to be reused, any information needed to verify that the instrument's form and function has not deteriorated due to repeated use and reprocessing;

EXAMPLE 1 A screwdriver tip that becomes worn and round due to repeated use.

i) if the instrument is terminally sterilized, an indication that the contents of the package are sterile and the method of sterilization used;

EXAMPLE 2 The word "STERILE" or the sterile symbol ISO 7000-2499, or one of the "sterilized using…" symbols ISO 7000-2500, ISO 7000-2501, ISO 7000-2502, or ISO 7000-2503. See ISO 15223-1:2021, 5.2.1 or 5.2.2, 5.2.3, 5.2.4, and 5.2.5.

j) details of any treatment or handling needed before the instrument can be used including information for each applicable processing step (i.e. cleaning, disinfection, drying, packaging, and sterilization) as specified in ISO 17664:2017, Clause 6;

EXAMPLE 3 Final assembly.

EXAMPLE 4 Sterilization of an instrument provided non-sterile.

NOTE 3 ISO 17664:2017 requires at least one validated method be specified for each applicable processing step.

k) if the instrument is intended for single use:

   1) a statement that the instrument is intended for single use, and

   2) information on known characteristics and technical factors that could pose a risk if the instrument was to be re-used;

l) if the instrument is intended to be reused, instructions on each required processing step as specified in ISO 17664:2017, Clause 6, and any limitations and restrictions on processing (see ISO 17664:2017, 6.3);

   NOTE 4 ISO 17664:2017 requires the manufacturer to provide appropriate information including the number of processing cycles or some other end-of-life indicator if processing of the instrument in accordance with the manufacturer's instructions is known to lead to degradation that might limit the intended lifetime of the instrument (e.g. functionality, biocompatibility or suitability for effective processing).

m) if appropriate, a statement that the instrument can be reused only if it is refurbished under the responsibility of the manufacturer;

n) details for dealing with the unused contents of a sterile package, where the sterile barrier is no longer intact (e.g. due to damage, because the package has been opened), including, if applicable, instructions on each required processing step as specified in ISO 17664:2017, Clause 6;

o) either any special storage (e.g. temperature, humidity, UV environment) or handling conditions, or both;

p) warnings or precautions relating to use, including limitations on chemicals (e.g. alcohol) or other environmental conditions to which the instrument might reasonably be exposed in the clinical setting;

   NOTE 5 See IEC 62570 or ASTM F2503 for information on how to label for safety in the magnetic resonance environment.

q) if appropriate, an indication of whether the instrument or any fragment, thereof, can be located by means of an external imaging device, and with what kind of such device;

r) instructions for the proper disposal of the instrument, if there are special or unusual risks;

s) if applicable, information on any medicinal products incorporated into or used with the instrument (see Clause 5);

t) date of issue or the latest revision of the instructions for use, if applicable.

11.5 Additional information for instruments with a measuring function

The limit of error of instruments having a measuring function shall be indicated by either a marking on the instrument or label, or both, and in the instructions for use.

NOTE The limit of error is the extreme value of the measurement error with respect to a known reference quantity value.

This requirement does not apply to gauges used for component size selection and for the go/no-go gauges used to check a workpiece against its allowed tolerances via a go/no-go test.

Annex A
(informative)

Examples of typical applications of instruments to be used in association with non-active surgical implants and materials found acceptable for instrument manufacture

A.1 General

Instruments to be used in association with non-active surgical implants are those whose design is established by the requirements of the design of the associated implant. Instruments for general use are not a part of this family, although they can be included if they have special characteristics or special use requirements, which is dictated by the design of the associated non-active surgical implant.

Typical applications for instruments to be used in association with non-active surgical implants include both invasive and non-invasive applications and might or might not come into contact with the implant.

This can include instruments with functionality intended for implant contact, cutting tissue, defining implant size, position or alignment.

For example, invasive applications can include specialized instruments:

— with cutting edges such as scissors, needles; knives; cannulae; chisels; drill bits; gouges; broaches; curettes; sawblades; burrs; reamers and trepans;

— used as guides such as cannulae, saw guides, drill guides, aiming devices and location guides;

— having non-active surgical implant contact such as punches, extractors, introducers, impactors, pullers and trial implants;

— having passive contact such as retractors, spreaders, sizers, forceps, measuring devices, holders, trial implants and locations pins.

The degree of contact with the non-active surgical implant also varies with intended function and material selection should take this into account. Examples can include:

— external alignment guides for intramedullary locking nails are instruments intended for non-invasive applications and for defining non-active surgical implant position and alignment;

— acetabular cup reamers are invasive instruments, but not intended to have contact with the non-active surgical implant;

— spinal cage positioners as well as neurosurgical clip applier might be also considered non-invasive instruments, when intended to not touch body tissues, but always contact the non-active surgical implant;

— instruments with more complex design include the invasive delivery systems for vascular and cardiac stents, which contact the non-active surgical implant and tissue and blood in the vascular system.

The selection of material for each instrument requires a thorough understanding of all associated applications in order to define the applicable material requirements. As stated in Clause 6, for each application the selection of an appropriate material is to be based on a risk analysis which takes into account the necessary requirements for the intended use.

The materials listed in A.2 are materials that have been found to be acceptable for certain applications. The list of materials given in A.2 is not all-inclusive and is intended only to give examples of materials

which can be acceptable. Other materials can be used and can be just as acceptable as those listed in A.2. Examples of standards for such materials are listed in the Bibliography.

However, for each application it remains the responsibility of the manufacturer to verify the suitability of the material chosen.

A.2 Materials

A.2.1 Stainless steels

ISO 7153-1, ISO 5832-1 and ISO 5832-9 provide information on stainless steels that have been found acceptable for the manufacture of certain types of instruments for use in association with non-active surgical implants.

A.2.2 Cobalt/chromium alloys

ISO 5832-4, ISO 5832-5, ISO 5832-6, ISO 5832-7 and ISO 5832-12 provide information on cobalt/chromium alloys that have been found acceptable for the manufacture of certain types of instruments for use in association with non-active surgical implants.

A.2.3 Titanium/titanium alloys

ISO 5832-2, ISO 5832-3, ISO 5832-11 and ISO 5832-14 provide information on unalloyed titanium as well as titanium alloys that have been found acceptable for the manufacture of certain types of instruments for use in association with non-active surgical implants.

A.2.4 Aluminium alloys

Certain aluminium alloys have been found acceptable for the manufacture of certain types of instruments for use in association with non-active surgical implants.

Aluminium alloy instruments should not be used in applications in direct contact with the implant. However, aluminium alloys may be considered for use in cases and trays, if they have been designed and validated for the storage and sterilization of implant systems. One example of such an application is the use of cases and trays for the storage and sterilization of screws and plates used in orthopaedic trauma systems.

Aluminium alloy instruments used in non-implant contacting applications should be anodized.

Aluminium alloy instruments intended for processing can show insufficient stability after treatment with many alkaline processing detergents. Application for intended uses requiring prion-inactivating processing is not recommended.

A.2.5 Polymers

Certain polymers have been used and found acceptable for the manufacture of certain types of instruments for use in association with non-active surgical implants.

It should be noted that some polymers can be susceptible to environmental conditions or other processes that can affect their performance. For example, some polymers exhibit cracking if exposed to lipids or can have their properties affected when subjected to re-sterilization processes.

Polymers can be particularly susceptible to minor variations in chemical composition, additives or processing. Such variations can change the desired properties of the polymer. Care should be taken in selecting the appropriate grade.

Bibliography

[1] ISO 4957, *Tool steels*

[2] ISO 5832-1, *Implants for surgery — Metallic materials — Part 1: Wrought stainless steel*

[3] ISO 5832-2, *Implants for surgery — Metallic materials — Part 2: Unalloyed titanium*

[4] ISO 5832-3, *Implants for surgery — Metallic materials — Part 3: Wrought titanium 6-aluminium 4-vanadium alloy*

[5] ISO 5832-4, *Implants for surgery — Metallic materials — Part 4: Cobalt-chromium-molybdenum casting alloy*

[6] ISO 5832-5, *Implants for surgery — Metallic materials — Part 5: Wrought cobalt-chromium-tungsten-nickel alloy*

[7] ISO 5832-6, *Implants for surgery — Metallic materials — Part 6: Wrought cobalt-nickel-chromium-molybdenum alloy*

[8] ISO 5832-7, *Implants for surgery — Metallic materials — Part 7: Forgeable and cold-formed cobalt-chromium-nickel-molybdenum-iron alloy*

[9] ISO 5832-9, *Implants for surgery — Metallic materials — Part 9: Wrought high nitrogen stainless steel*

[10] ISO 5832-11, *Implants for surgery — Metallic materials — Part 11: Wrought titanium 6-aluminium 7-niobium alloy*

[11] ISO 5832-12, *Implants for surgery — Metallic materials — Part 12: Wrought cobalt-chromium-molybdenum alloy*

[12] ISO 5832-14, *Implants for surgery — Metallic materials — Part 14: Wrought titanium 15-molybdenum 5-zirconium 3-aluminium alloy*

[13] ISO 7000:2012, *Graphical symbols for use on equipment — Registered symbols*

[14] ISO 7153-1, *Surgical instruments — Materials — Part 1: Metals*

[15] ISO/TS 13004, *Sterilization of health care products — Radiation — Substantiation of selected sterilization dose: Method* VD_{max}^{SD}

[16] ISO/TR 14283, *Implants for surgery — Essential principles of safety and performance*

[17] ISO 14630, *Non-active surgical implants — General requirements*

[18] ISO 14708-1, *Implants for surgery — Active implantable medical devices — Part 1: General requirements for safety, marking and for information to be provided by the manufacturer*

[19] ISO 15223-1, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements*

[20] ISO/TR 20416, *Medical devices — Post-market surveillance for manufacturers*

[21] IEC 60068-2-27, *Environmental testing — Part 2-27: Tests — Test Ea and guidance: Shock*

[22] IEC 60068-2-31, *Environmental testing — Part 2-31: Tests — Test Ec: Rough handling shocks, primarily for equipment-type specimens*

[23] IEC 60068-2-47, *Environmental testing — Part 2-47: Test — Mounting of specimens for vibration, impact and similar dynamic tests*

[24] IEC 62366-1, *Medical devices — Part 1: Application of usability engineering to medical devices*

[25] IEC 62570, *Standard practice for marking medical devices and other items for safety in the magnetic resonance environment*

[26] ASTM A276/A276M, *Standard Specification for Stainless Steel Bars and Shapes*

[27] ASTM A314, *Standard Specification for Stainless Steel Billets and Bars for Forging*

[28] ASTM A564/A564M, *Standard specification for Hot-Rolled and Cold-Finished Age-Hardening Stainless Steel Bars and Shapes*

[29] ASTM B221, *Standard Specification for Aluminum and Aluminum-Alloy Extruded Bars, Rods, Wire, Profiles, and Tubes*

[30] ASTM D4169, *Standard Practice for Performance Testing of Shipping Containers and Systems*

[31] ASTM D7386, *Standard Practice for Performance Testing of Packages for Single Parcel Delivery Systems*

[32] ASTM F136, *Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications (UNS R56401)*

[33] ASTM F138, *Standard Specification for Wrought 18Chromium-14Nickel-2.5Molybdenum Stainless Steel Bar and Wire for Surgical Implants (UNS S31673)*

[34] ASTM F899, *Standard Specification for Wrought Stainless Steels for Surgical Instruments*

[35] ASTM F2052, *Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment*

[36] ASTM F2063, *Standard Specification for Wrought Nickel-Titanium Shape Memory Alloys for Medical Devices and Surgical Implants*

[37] ASTM F2213, *Standard Test Method for Measurement of Magnetically Induced Torque on Medical Devices in the Magnetic Resonance Environment*

[38] ASTM F2503, *Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment*

[39] ISTA 3A, *Packaged-products for parcel delivery system shipments 70kg (150 lbs) or less*

[40] MEDDEV 2.12-1, *Medical Devices: Guidance document, Guidelines on a medical devices vigilance system* Available at <https://ec.europa.eu/health/sites/health/files/md_sector/docs/md_guidance_meddevs.pdf>

[41] US Food and Drug Administration (FDA) final rule, *Use of Symbols in Labeling*, June 15, 2016 Available at: <https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/DeviceLabeling/ucm555598.htm)>

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