INTERNATIONAL STANDARD

ISO 16061

Redline version
compares Third edition to
Second edition

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

Instrumentation à utiliser en association avec les implants chirurgicaux non actifs — Exigences générales

Reference number
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1.x ...	— Heading numbers containg modifications are highlighted in yellow in the Table of Contents

All changes in this document have yet to reach concensus by vote and as such should only be used internally for review purposes.

DISCLAIMER

This Redline version provides you with a quick and easy way to compare the main changes between this edition of the standard and its previous edition. It doesn't capture all single changes such as punctuation but highlights the modifications providing customers with the most valuable information. Therefore it is important to note that this Redline version is not the official ISO standard and that the users must consult with the clean version of the standard, which is the official standard, for implementation purposes.

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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~~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 ~~rules given in~~editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

~~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. 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 on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT), see the following URL: Foreword — Supplementary information.

~~ISO 16061 was prepared by Technical Committee~~The committee responsible for this document is ISO/TC 150, *Implants for surgery*.

This ~~second~~third edition cancels and replaces the ~~first~~second edition (ISO 16061:~~2000~~2008), which has been technically revised.

~~In this corrected version of ISO 16061:2008 the normative reference to EN 1041 has been altered:~~

- ~~in Clause 2 (date deleted);~~
- ~~in subclause 11.1 (date and reference to 4.3 deleted).~~

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

1 Scope

This International Standard specifies 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 resupplied after refurbishment.

This International Standard also applies to instruments which may be connected to power-driven systems, but does not apply to the power-driven systems themselves.

With regard to safety, this International Standard gives requirements for intended performance, design attributes, ~~selection of~~ materials, design evaluation, manufacture, sterilization, packaging, and information ~~to be~~ supplied by the manufacturer.

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

2 Normative references

The following ~~referenced documents~~ documents, in whole or in part, are normatively referenced in this document and are indispensable for ~~the application of this document~~ its application. 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 11135~~-1~~, *Sterilization of health~~-~~ care products — Ethylene oxide ~~— Part 1: Requirements for~~ — 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*

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~~-1~~, *Clinical investigation of medical devices for human subjects — ~~Part 1: General requirements~~ Good clinical practice*

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

ISO 14971, *Medical devices — Application of risk management to medical devices*

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

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*

~~EN 556~~ISO 80000-1, ~~*Sterilization of medical devices — Requirements for medical devices to be designated "STERILE"*~~ *Quantities and units — Part 1: ~~Requirements for terminally sterilized medical devices~~General*

~~EN 556-2, *Sterilization of medical devices — Requirements for medical devices to be designated "STERILE" Part 2: Requirements for aseptically processed medical devices*~~

~~EN 1041, *Information supplied by the manufacturer of medical devices*~~

3 Terms and definitions

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

3.1
associated implant
specific non-active surgical implant in association with which a specific surgical instrument is intended to be used during a surgical procedure

~~3.1~~3.2
~~associated~~ instrument
~~instrument~~
non-active medical device intended for use during surgical procedures related to a specific non-active surgical implant

~~3.2~~3.3
resupplied instrument
instrument or set of instruments that has been returned to the manufacturer and has been re-issued

4 Intended performance

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

a) functional characteristics; and

b) intended conditions of use.

Account should be taken of:

— published standards;

— published clinical and scientific literature;

— validated test results.

~~NOTE Account should be taken of~~

~~— published standards;~~

~~— published clinical and scientific literature;~~

~~— validated test results.~~

The extent to which the intended performance of an instrument has been achieved shall be determined (see Clause 7).

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) physical, mechanical, and chemical properties of the instrument materials (see Clauses 6 and 7);

b) microbiological and particulate contamination levels (see Clauses 7, 9, and 10);

c) ease of use, cleaning, and maintenance (see Clause 7);

d) potential deterioration of the material characteristics due to sterilization and storage (see Clauses 6, 7, and 8);

e) effects of contact between the instrument and body, the implant, and other instruments (see Clause 7);

f) shape and dimensions of the instrument, including their possible effects on the body (see Clause 7);

g) wear characteristics of materials and the effect of wear and wear products on the instrument and the body (see Clauses 6 and 7);

h) insertion, removal, and interconnection of parts (see Clause 7);

i) extent of fluid leakage and/or diffusion of substances into or out of instruments (see Clauses 6 and 7);

j) accuracy and stability of instruments with a measuring function (see Clauses 7 and 8);

k) ability of the instrument or fragment of instrument to be located by means of an external imaging device (see ~~11.5~~11.3~~).~~ p); and

l) compatibility with any medicinal substances incorporated into or used with the instrument.

6 Selection of materials

Materials for the manufacture of instruments shall be selected with regard to the properties required for the intended purpose, taking into account the effects of manufacture, handling, sterilization, and storage ~~(see~~, as well as any treatment (chemical, electro-chemical, thermal, mechanical, etc.) applied to the surface or a part of the surface of the instrument in order to modify its properties. Possible reactions of instrument materials with human tissues and body fluids shall be considered (see Clause 7).

The suitability of a given material for a particular application shall be demonstrated by either~~:~~

~~a) evaluating in accordance with Clause 7~~

~~or~~

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

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

NOTE Annex A lists some of the materials that have been found acceptable in certain applications.

7 Design evaluation

7.1 General

Instruments shall be evaluated in association with the implant they are designed for, in order to demonstrate that the intended performance is achieved (see Clause 4) ~~is achieved~~. Safety shall be demonstrated by pre-clinical evaluation and by carrying out a risk analysis in accordance with ISO 14971.

~~NOTE In certain circumstances, a clinical evaluation can also be required.~~

7.2 Pre-clinical evaluation

If pre-clinical testing of instruments is required, the testing shall simulate conditions of intended use.

7.3 Clinical evaluation

If a clinical evaluation is required, it shall be based on the following:

a) critical evaluation of the relevant scientific and clinical literature relating to the safety, performance, design characteristics, and intended use of the instrument or demonstrably similar instruments; or

b) critical evaluation of the results of all clinical investigations conducted using the associated implant under the intended conditions of use; or

c) combination of the clinical data provided in a) and b) above.

~~If a clinical evaluation is required, it shall be conducted using the associated implant under the intended conditions of use.~~ Where a clinical investigation is carried out, it shall be managed in accordance with ISO 14155 ~~-1 and ISO 14155-2~~.

8 Manufacture

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

~~NOTE 1 The application of quality systems as described in ISO 13485 might be appropriate.~~

~~NOTE 2 The design specification for re-supplied instruments need not necessarily be the same as the original, provided that the requirements of this International Standard are met.~~

9 Sterilization

9.1 Products supplied sterile

~~Instruments which are labelled~~For terminally sterilized instruments to be designated "STERILE" ~~shall comply with EN 556-1 and EN 556~~, the theoretical probability of there being a viable microorganism present on or in the instrument shall be equal to or less than $1 \times 10^{-2-6}$.

~~Sterilization processes shall be validated and routinely controlled~~Manufacturers may use other sterility assurance levels, provided that this is justified by a documented risk assessment.

If instruments are to be sterilized by ethylene oxide, ~~ISO 11135-1 applies~~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 ~~apply~~.

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

9.2 Products provided non-sterile

For instruments that are supplied non-sterile, the manufacturer shall specify at least one appropriate sterilization method such that the functional safety of the product is not adversely affected. If multiple sterilizations are not allowed, this shall be stated ~~(see 11.6)~~.

For instruments that are supplied non-sterile or 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 storage and transport

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

NOTE Possible test methods are specified in IEC 60068–2-27, IEC 60068–2-31, and/or IEC 60068–2-47.

10.2 Maintenance of sterility in transit

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

The packaging shall ~~conform to~~comply with ISO 11607-1 and ISO 11607-2.

11 Information ~~to be~~ supplied by the manufacturer

11.1 General

Information supplied by the manufacturer and intended for direct visual recognition shall be legible when viewed under illumination of 215 lx using normal vision, corrected if necessary, at a distance that takes into account the form and size of the individual instrument.

If there is insufficient space on each instrument’s individual packaging, the relevant information may be given on an insert, accompanying document, or on the next layer of packaging, as applicable.

The recognition of certain markings on small or specialized instruments might require the use of methods other than visual, e.g. electronic methods.

~~Information supplied with instruments by manufacturers shall be in accordance with EN 1041. All packages shall bear a label which indicates the full contents. If the label does not list the full contents of the~~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~~ package, a contents list shall be enclosed. If symbols are to be used, they shall be in accordance with~~). Where no such standards exist, the manufacturer shall describe the symbols, abbreviations, or identification colours used in the documentation ~~ISO 15223-1~~supplied with the instrument.

The ~~manufacturer’s address shall be included in the information supplied by the manufacturer~~information supplied by the manufacturer shall not be presented in such a manner that it can be confused with other essential information and shall be understandable by the intended user and/or other persons, where appropriate.

~~NOTE 1 The European regulation requires the name and address of the authorized representative established in the European Community.~~

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

~~NOTE 2 The European regulation requires that the date of issue or the latest revision of the instructions for use is mentioned in the instructions for use.~~

As far as practicable and appropriate, the information needed to use the instrument safely shall be set out on the instrument itself and/or on the packaging for each unit or, where appropriate, on the sales packaging. If individual packaging of each unit is not practicable, the information shall be set out in the leaflet supplied with each instrument or package.

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

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.

11.2 Labelling

The label shall bear the following information:

a) if the packaging contains any radioactive substance, it shall have markings that state the type and activity of the radioactive substance;

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

c) description of the instrument, the model designation of the instrument, and, if applicable, the batch number or the serial number of the instrument preceded by an appropriate identification;

EXAMPLE “LOT”, “SN”, or the lot, or serial number symbols ISO 7000-2492 and ISO 7000-2498, respectively. See ISO 15223-1:2012, 5.14 and 5.16.

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 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 15223-1:2012, 5.20 or 5.21, 5.22, 5.23, and 5.24.

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 The “non-sterile” symbol ISO 7000-2609. See ISO 15223-1:2012, 5.26.

g) if applicable, the “use by date”, expressed as year and month;

EXAMPLE The “use by date” symbol ISO 7000-2607. See ISO 15223-1:2012, 5.12

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

EXAMPLE The “do not re-use” symbol ISO 7000-1051. See ISO 15223-1:2012, 5.2.

i) any special storage and/or handling conditions;

j) any special operating instructions;

k) any warnings or precautions relating to use.

11.3 Instructions for use

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

a) if the packaging contains any radioactive substance, the type and activity of the radioactive substance;

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

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

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

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

f) 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;

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

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

EXAMPLE 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 15223-1:2012, 5.20 or 5.21, 5.22, 5.23, and 5.24.

i) if identical or similar instruments are sold in both sterile and non-sterile condition, an instruction, when applicable, that the contents shall be sterilized;

j) instructions on the method of sterilization with its appropriate cycle parameters for an instrument that is delivered non-sterile, or for dealing with the contents of a sterile package that has been damaged or has been previously opened, and maximum number of re-sterilization cycles that may be performed;

k) if the instrument is intended to be reused, instructions on appropriate processing before reuse including cleaning, disinfection packaging, and, where appropriate, the method(s) of sterilization with its appropriate cycle parameters, and any restriction on the number of reuses;

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

EXAMPLE The “do not re-use” symbol ISO 7000-1051. See ISO 15223-1:2012, 5.2.

m) details of any treatment or handling needed before the instrument can be used;

EXAMPLE Final assembly, cleaning, sterilization, etc.

n) any special storage and/or handling conditions;

o) 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;

p) 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;

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

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

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

~~11.2~~11.4 Instruments with measuring function

The limits of accuracy of instruments having a measuring function shall be indicated by a marking on the ~~device~~instrument and/or label, ~~instruction leaflet or manual~~and in the instructions for use.

~~NOTE This requirement does not apply to gauges used for component size selection and GO/NO GO determination.~~

This requirement does not apply to gauges used for component size selection and GO/NO GO determination.