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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

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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 16061 was prepared by Technical Committee ISO/TC 150, *Implants for surgery*.

This second edition cancels and replaces the first edition (ISO 16061:2000), 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 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 11135-1, *Sterilization of health care products — Ethylene oxide — Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices*

ISO 11137-1, *Sterilization of health care products — Radiation — Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices*

ISO 11137-2, *Sterilization of health care products — Radiation — Part 2: Establishing the sterilization dose*

ISO 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*

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 556-1, *Sterilization of medical devices — Requirements for medical devices to be designated “STERILE” — Part 1: Requirements for terminally sterilized medical devices*

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

3.2
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:

a) functional characteristics;

b) intended conditions of use.

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).

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 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

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 (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 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 “STERILE” shall comply with EN 556-1 and EN 556-2.

Sterilization processes shall be validated and routinely controlled.

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

If instruments are to be sterilized by irradiation, ISO 11137-1, ISO 11137-2 and ISO 11137-3 apply.

If instruments are to be sterilized by steam, ISO 17665-1 applies.

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 against damage and deterioration and 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 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 ISO 11607-1 and ISO 11607-2.

11 Information to be supplied by the manufacturer

11.1 General

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 package, a contents list shall be enclosed. If symbols are to be used, they shall be in accordance with ISO 15223-1.

The manufacturer's address shall be included in the information supplied by the manufacturer.

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

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.

11.2 Instruments with measuring function

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

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

11.3 Restrictions in combinations

If the instrument is intended to be used in combination with other instruments, devices or equipment, restrictions in the use of the combination shall be indicated on the label or in the instruction leaflet or the manual.

11.4 Marking on instruments

Instruments shall be marked with the following:

— manufacturer's name or trademark;

— batch code or serial number, where appropriate;

— catalogue/article number, 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.

11.5 Instructions for use

If the instrument cannot be used safely without instructions for use, these shall be provided. It shall be indicated whether the instrument or any fragment thereof can be located by means of an external imaging device, and with what kind of such device.

11.6 Instruments intended for single use

Instruments intended for single use only shall be labelled either “For single use only” or by a symbol in accordance with ISO 15223-1.

If the instrument bears an indication that it is for single use only, the instructions for use shall contain information on known characteristics and technical factors known to the manufacturer that could pose a risk if the instrument was to be re-used.

Annex A
(informative)

Examples of typical instrument applications, together with materials found acceptable for instrument manufacture

A.1 Invasive applications

A.1.1 Instruments with cutting edges

— scissors;

— needles;

— knives;

— cannulae;

— chisels;

— drill bits;

— gouges;

— broaches;

— curettes;

— sawblades;

— burrs;

— reamers;

— trepans.

A.1.2 Instruments used as guides

— cannulae;

— saw guides;

— drill guides;

— aiming devices.

A.1.3 Instruments having implant contact

— punches;

— extractors;