INTERNATIONAL STANDARD

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Dentistry — Contents of technical file for dental implant systems

Médecine bucco-dentaire — Contenu du dossier technique pour les systèmes d'implants dentaires

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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 10451 was prepared by Technical Committee ISO/TC 106, *Dentistry*, Subcommittee SC 8, *Dental implants*.

This second edition cancels and replaces the first edition (ISO 10451:2002) which has been technically revised.

Introduction

Legal/regulatory requirements on the documentation of the design, manufacture and performance of dental implants are developing in various ways in different countries and international regions. As the dental implant industry is already active on a global basis, and is becoming more so, concern is growing as to the need for international and mutually recognized standards for documentation of the design and the performance of such devices.

Dentistry — Contents of technical file for dental implant systems

1 Scope

This International Standard specifies requirements for the contents of a technical file to demonstrate the fulfilment of regulatory requirements for a dental implant and any prefabricated part thereof that remains in the mouth after surgery.

This International Standard is not applicable to instruments and other parts specifically made for the dental implant system but which do not remain in the mouth. However, documentation relating to these components may be included in the technical file.

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 129-1, *Technical drawings — Indication of dimensions and tolerances — Part 1: General principles*

ISO 1942, *Dentistry — Vocabulary*

ISO 7405, *Dentistry — Evaluation of biocompatibility of medical devices used in dentistry*

ISO 8601, *Data elements and interchange formats — Information interchange — Representation of dates and times*

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

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

ISO 10993-9, *Biological evaluation of medical devices — Part 9: Framework for identification and quantification of potential degradation products*

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/TS 11135-2, *Sterilization of health care products — Ethylene oxide — Part 2: Guidance on the application of ISO 11135-1*

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 14405-2, *Geometrical product specifications (GPS) — Dimensional tolerancing — Part 2: Dimensions other than linear sizes*

ISO 14801, *Dentistry — Implants — Dynamic fatigue test for endosseous dental implants*

ISO 14937, *Sterilization of health care products — General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices*

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

ISO 17664, *Sterilization of medical devices — Information to be provided by the manufacturer for the processing of resterilizable medical devices*

ISO 17665-1, *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/TS 22911, *Dentistry — Preclinical evaluation of dental implant systems — Animal test methods*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 1942 and the following apply.

3.1
coating
layer of material used to cover or partially cover a surface of an implant or part of an implant system

3.2
dental implant system
device that consists of integrated components including the ancillary instruments and specific equipment necessary for the clinical and laboratory preparation and placement of the implant, and for the construction and insertion of the dependent prosthesis

3.3
technical file
documentation provided by the manufacturer containing the basic available information on a device or indicating its location

3.4
water sorption
gain in water content, per volume, of an initially dry specimen after immersion in water for a given time

4 Requirements

4.1 General

A technical file of a dental implant system shall include at least the contents described in 4.2 to 4.15.

Documentation may contain data from the scientific literature as well as from specifically performed tests. If information on more than one property can be obtained from a single test, it is not necessary to conduct separate tests for each property.

4.2 Intended use

The intended use shall be stated. Device specific indications and contra-indications shall be given.

4.3 Design characteristics

The following information on the design characteristics shall be provided:

a) Design justification: justification for the specific design shall be given.

b) Dimensions: technical drawings showing the dimensions and their tolerances shall be provided. It is recommended that tolerances be stated in accordance with ISO 129-1 and ISO 14405-2.

c) Surface finish: a description of the required surface finish, its characterization and the test method(s) used for characterization shall be given.

4.4 Properties of the constituent materials

The following information on the properties of the constituent materials and the test methods used to establish these properties shall be provided where appropriate:

a) Chemical properties, including electrochemical properties:

   1) chemical composition, to a sum of 100 % by mass, including all additives;

   2) relevant impurities and their upper limits;

   3) solubility and the test method used;

   4) degradation and the test method used;

   5) information on possible combinations of materials and their interactions;

   6) for polymeric materials: water sorption and the test method used;

   7) for metals: corrosion data and electrochemical properties, and the test methods used.

b) Physical properties:

   1) degree of radio-opacity;

   2) magnetic properties (ferromagnetic or non-ferromagnetic);

   3) surface porosity (pore size and distribution);

   4) crystallographic characteristics;

   5) melting range, where relevant for use.

c) Mechanical properties:

1) metallic materials:

i) condition of the material (cold worked, heat treated, etc.);

ii) proof stress of non-proportional elongation (yield strength);

iii) tensile strength;

iv) total elongation at fracture (%);

v) elastic modulus;

2) ceramic materials (excluding coatings):

i) flexural strength and test method;

ii) fracture toughness;

3) polymeric materials:

i) flexural strength;

ii) elastic modulus.

NOTE Methods for the determination of flexural properties are given in ISO 178.

4.5 Properties of the final product

For any property which cannot be deduced from the constituent material(s), results of the following tests and the test methods for the final product shall be provided where appropriate:

a) Fatigue testing: results of fatigue testing in accordance with ISO 14801, if applicable in combination with a recommended interconnecting part to a superstructure.

b) Adhesive strength of a coating: for a coated implant or part of an implant system, results of testing of the strength of adhesion of the coating to the substrate material(s) and a description of the test method.

c) Biological properties: results of the biological evaluation and testing of the final product and a justification for the selection of the tests. References for biological evaluation and testing are given in 4.9.

d) Degradation: results of degradation tests in accordance with ISO 10993-9.

4.6 Reference to previous generation(s) or similar devices

Where development and/or evaluation of the implant system is based on one or more former generation(s) or similar device(s) that have already been marketed, a reference shall be given for information on these devices.

4.7 Risk assessment

Documentation of the risk analysis and risk assessment in accordance with ISO 14971 shall be provided.

4.8 Control of infection and microbial contamination

The following information shall be provided:

a) Disinfection

A description of the provisions in the design of the implant and in the manufacturing process to minimize the risk of microbial or other contamination shall be provided. In this context any necessary disinfection procedures shall be described.

b) Sterilization

The condition of delivery (non-sterile or sterile) shall be stated.

If the product is delivered sterile: the method of sterilization and its validation shall also be stated. If the product is to be sterilized by ethylene oxide, ISO 11135-1 and ISO/TS 11135-2 together with ISO 10993-7 shall apply. By radiation, ISO 11137-1, ISO 11137-2, and ISO 11137-3 shall apply and by any other method validation shall be carried out in accordance with ISO 14937.

If sterilization by the user is necessary, a detailed description in accordance with ISO 17664, of at least one validated sterilization method, shall be provided. If sterilization is done by moist heat, ISO 17665-1 shall apply. If resterilization is not allowed, this shall be noted.

4.9 Biological evaluation

Biological evaluation of the finished device shall be provided. ISO 7405, ISO 10993-1 and ISO/TS 22911 shall be consulted for guidance on biological evaluation and testing. Additional biological testing need not be required for any material complying with the compositional requirements of an appropriate International Standard for a surgical implant material, where a biocompatibility statement appears in the standard (e.g. ISO 5832-2, ISO 5832-3, ISO 6474-1 and ISO 13356).

4.10 Clinical evaluation

Documented results of the clinical evaluation shall be provided.

If a clinical investigation is necessary for a proper risk assessment by the manufacturer, it is recommended that it be documented in accordance with ISO 14155-1 and ISO 14155-2.

4.11 Manufacturing process

A detailed description of the manufacturing process shall be provided, including a description of the measures taken to assure that the specific design attributes are achieved. An analysis of manufacturing materials remaining on the final product shall be completed and reported. A justification for the acceptable level of manufacturing materials shall be provided.

4.12 Quality control of the implant manufacturing process

A detailed description of the quality control measures shall be provided, including process controls and finished device inspection procedures.

4.13 Packaging

4.13.1 Primary container

A description of the primary container together with a justification for the material in use, taking into account possible remnants of the container material on the implant surface, shall be provided. See ISO 11607-1 and ISO 11607-2.

If delivery is in a sterile state, the sterilization process together with its validation and provisions taken in the manufacturing process and packaging shall be described. Evidence shall be provided that sterility is retained under the storage and transport conditions recommended by the manufacturer until the protective package is opened.

4.13.2 Protection from damage in storage and transport

A description of the provisions taken by the manufacturer shall be provided such that, under conditions specified by the manufacturer for storage, transport and handling (including control of temperature, humidity and ambient pressure, if applicable), the packaging protects against damage and deterioration.

4.14 Label

A sample of the label shall be included in the technical file. The label shall bear the following information:

a) the name or registered trade mark and address of the manufacturer or its responsible distributor;

b) the details strictly necessary for the user to identify the implant or part of an implant system and the contents of the packaging;

c) where applicable, the symbol for “STERILE”, the method of sterilization and its expiry date, expressed in accordance with ISO 8601; if the implant is provided in both sterile and non-sterile conditions, its packaging and labelling shall clearly indicate which condition it is in;

d) the batch or lot number (related to the records of raw materials, manufacture, packaging and, where appropriate, sterilization);

e) where appropriate, an indication of the date by which the implant or part of an implant system shall be used, expressed in accordance with ISO 8601;

f) if applicable, an indication that the product is for single use;

g) any special storage and/or handling conditions;

h) any warnings and/or precautions to be taken;

i) If the implant or part of an implant system is intended for clinical investigation, it shall be marked in accordance with the specific legislation.

If it is not practicable for all the above to be included on the unit label, the relevant information shall be provided on any outer packaging or included in the instruction leaflet which shall be included within the outer packaging.

4.15 Instructions for use

A sample of the instructions for use shall be included in the technical file, containing at least the following information:

a) the details referred to in 4.14 with the exception of items c), d) and e);

b) the intended use;

c) sufficient details of any part connecting to a dental superstructure with which the implant is intended to be employed so as to enable its correct usage;

d) where appropriate, the recommended method of opening the pack to ensure sterile presentation at the time of use;

e) a detailed description of the surgical and insertion procedure and the use of the parts;

f) where appropriate, information on avoiding risks;

g) instructions for the procedures to be followed in the event of damage to the sterile packaging and, where suitable, details of appropriate methods of resterilization;

h) details of any further treatment or handling needed before the implant or part of an implant system can be used (for example, sterilization, final assembly, etc.);

i) contra-indications and known side-effects;

j) details allowing professional staff to advise the patient on the precautions to be taken;

k) information on possible hazards arising from interactions with medical imaging systems and/or other electromagnetic systems;

l) if resterilization is not permitted, the instruction: “Do not resterilize”.