INTERNATIONAL STANDARD

ISO 10451

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Dental implant systems — Contents of technical file

Systèmes d'implants dentaires — Contenu du dossier technique

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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 3.

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 International Standard 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 first edition cancels and replaces ISO/TR 10451:1991, 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.

Dental implant systems — Contents of technical file

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 which 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 normative documents contain provisions which, through reference in this text, constitute provisions of this International Standard. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent editions of the normative documents indicated below. For undated references, the latest edition of the normative document referred to applies. Members of ISO and IEC maintain registers of currently valid International Standards.

ISO 1942-1, *Dental vocabulary — Part 1: General and clinical terms*

ISO 7405, *Dentistry — Preclinical evaluation of biocompatibility of medical devices used in dentistry — Test methods for dental materials*

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*

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

3 Terms and definitions

For the purposes of this International Standard, the terms and definitions given in ISO 1942-1 and the following apply.

3.1
safety
freedom from unacceptable risk of harm

3.2
coating
layer of material used to cover or partially cover a surface of an implant

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

3.4
dental implant system
dental implant components that are designed to mate together

NOTE An implant system can represent a specific concept, invention or patent. It consists of the necessary parts and instruments to complete the implant body placement and abutment components.

3.5
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 4.13.

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 contraindications 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 406.

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;

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 of a coating (pore size and distribution);

4) crystallographic characteristics.

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) percentage total elongation at fracture;

v) elastic modulus.

NOTE Methods for tensile testing are given for information in ISO 6892.

2) ceramic materials (excluding coatings):

i) flexural strength and test method;

ii) flexure toughness.

3) polymeric materials:

i) flexural strength;

ii) elastic modulus.

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

d) Biological properties

Results of biological tests of the material(s) in use shall be provided.

ISO 10993-1 and ISO 7405 shall be consulted for guidance on biological evaluation and testing.

Additional biological testing may 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 and ISO 6474).

4.5 Properties of the final product

For any property which cannot be deduced from the constituent material, 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, if applicable in combination with a recommended interconnecting part to a suprastructure, and test method

NOTE A method for fatigue testing is given for information in ISO 14801.

b) Adhesive strength of a coating

For a coated implant, results of testing of the strength of adhesion of the coating to the underlying 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 4.4 d).

4.6 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.

4.7 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.

4.8 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 sterilization by the user is necessary, a detailed description of at least one validated sterilization method shall be provided. If resterilization is not allowed, this shall be noted.

4.9 Risk assessment

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

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.

4.11 Packaging

4.11.1 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.

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 storage and transport conditions until the protective package is opened.

4.11.2 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.

4.12 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;

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

c) where applicable, the symbol for "Sterile" and the method of sterilization; 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 should 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 take;

If the implant 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.