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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.