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Dental implants — Prefabricated parts connecting suprastructures to dental implants — Contents of technical file

Implants dentaires — Organes préfabriqués destinés à relier les suprastructures aux implants dentaires — Contenu du dossier technique

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.

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.

International Standard ISO 14727 was prepared by Technical Committee ISO/TC 106, *Dentistry*, Subcommittee SC 8, *Dental implants*.

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Introduction

The functions of the masticatory system can be restored with implant-retained prostheses. Such prosthetic suprastructures are joined to the dental implants by "connecting parts" that provide an appropriate means of fixation.

Quality system requirements as laid down in ISO 9001 and ISO 13485 call for a file containing documents defining the product specifications for each type/model of medical device.

This International Standard specifies particular technical information to be contained in such a file for prefabricated parts connecting dental suprastructures to dental implants, termed a technical file for this purpose.

Dental implants — Prefabricated parts connecting suprastructures to dental implants — Contents of technical file

1 Scope

This International Standard specifies requirements for the contents of a technical file for prefabricated parts connecting a dental suprastructure to a transgingival dental implant. It applies to all parts providing functional load transfer from a suprastructure to a dental implant, excluding custom-made devices for the same purpose.

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

ISO 10993-1, *Biological evaluation of medical devices — Part 1: Guidance on selection of tests.*

ISO 14155, *Clinical investigation of medical devices* .

3 Terms and definitions

For the purposes of this International Standard, the terms and definitions given in ISO 1942-1 and ISO 10993-1 together with the following apply.

3.1
dental implant
device specially designed to be placed surgically within or on the mandibular or maxillary bone as a means of providing support and retention to the displacement of a dental prosthesis

NOTE 1 A dental implant can be either transgingival (with part of the implant emerging from the gingiva for direct abutment), or fully embedded under the gingiva (intended only to support a removable prosthesis).

[ISO 1942-1]

NOTE 2 In the case where the implant itself consists of two parts according to the manufacturer's definition, the transmucosal part, which is inserted by a surgical procedure, is part of the implant and not covered by this International Standard.

3.2
suprastructure
custom-made device attached to a dental implant

3.3
prefabricated part:
part, other than custom-made parts, used to connect a suprastructure to a dental implant

3.4
technical file
documentation supplied by the manufacturer containing the available basic information on a device

4 Requirements

4.1 General

A technical file of a prefabricated part connecting an implant to a prosthesis shall contain at least the information described in 4.2 to 4.13.

4.2 Intended use

The intended use of the prefabricated part shall be stated. The intended-use statement shall comprise a specification of the implant(s) by brand name or generic description for use with which the connecting part is intended.

4.3 Biological properties

Results of biological tests of the materials in use shall be available.

Guidance for biological testing is given in ISO 7405 and ISO 10993-1.

Adequate bioresponse properties are assumed for any material complying with the compositional requirements given in an appropriate International Standard specification for a surgical implant material, where a biocompatibility statement appears in that standard (e.g. ISO 5832-2, ISO 5832-3 and ISO 6474).

In many cases biological data are available in the literature or in files available to the manufacturer. In all other cases the manufacturer is responsible for carrying out biological testing.

4.4 Chemical properties, including electrochemical properties of the connecting part and its interaction with the implant

The following information on the chemical properties shall be given:

a) chemical composition;

b) relevant impurities and their upper limits;

c) solubility and the test method used;

d) degradation and the test method used;

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

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

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

4.5 Physical properties

Information on the following physical properties shall be available where appropriate:

a) density;

b) thermal coefficient of expansion;

c) melting point/range;

d) degree of radiopacity;

e) magnetic properties.

4.6 Mechanical properties

The following information on the mechanical properties shall be available.

a) Properties of the materials as such

1) Metallic materials

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

ii) proof stress of nonproportional elongation;

iii) tensile strength;

iv) percentage total elongation at fracture;

NOTE Methods for tensile testing are given in ISO 6892.

v) elastic modulus and test method used;

vi) hardness.

NOTE Hardness testing is described in ISO 6507-1.

2) Ceramic materials

i) Flexural strength and test method used;

ii) elastic modulus and test method used;

3) Polymeric materials

i) Flexural strength.

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

b) Properties of the final product

Results of fatigue testing of the prefabricated parts in combination with the recommended implant system and test method used shall be provided.

4.7 Design characteristics

4.7.1 Dimensions of the prefabricated part and stability calculations

Mechanical calculations on the stability of the prefabricated part and technical drawings, showing the dimensions of the prefabricated part and their tolerances, shall be provided.

NOTE It is recommended that tolerances be stated in accordance with ISO 406.

4.7.2 Surface finish of the prefabricated part

A description of the required surface finish, together with roughness limits and their characterization, and a description of a suitable test method shall be provided.

4.7.3 Interchangeability of prefabricated parts

A description of the provisions to ensure interchangeability of prefabricated parts within the recommended implant system(s) shall be provided.

4.8 Manufacturing process

A detailed description of the manufacturing process shall be provided.

4.9 Control of infection and microbial contamination

A description shall be given of the provisions in the design of the connecting part and in the manufacturing process to minimize the risk of microbial or other contamination.

The condition of delivery (i.e. nonsterile or sterile) shall be stated.

If delivery is in a sterile state, provisions shall be described taken in the manufacturing process and packaging to ensure sterility when placed on the market and that sterility remains under storage and transport conditions until the protective package is opened.

If sterilization by the user is necessary, a description of the suitability of an appropriate sterilization method shall be available.

Provisions taken that packaging systems maintain the level of cleanliness of the contents shall be described.

4.10 Risk assessment

Documentation of the performed risk assessment shall be provided.

4.11 Clinical evaluation

Documented results of the clinical evaluations shall be provided.

If a clinical investigation is necessary for a proper risk assessment by the manufacturer, it shall be documented in accordance with ISO 14155.

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 trademark and address of the manufacturer;

b) a description of the connecting part, including name, intended use, size and material(s);

c) where appropriate, the word or symbol for "Sterile";

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

e) the expiry date where applicable, expressed in accordance with ISO 8601;

f) an indication that the part is for single use;

g) if the connecting part is intended for clinical investigation, the words "exclusively for clinical investigations";

h) any special storage and/or handling conditions;

i) any warnings and/or precautions to take;

j) if the connecting part is provided in both sterile and nonsterile conditions, its packaging and labelling shall clearly indicate which condition it is in.

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.

4.13 Instructions for use

A sample of the instructions for use shall be included in the technical file. These instructions shall contain at least the following information:

a) the details referred to in 4.12 with the exception of items d) and e);

b) the intended purpose of the connecting part and any undesirable side effects;

c) sufficient details of the type of implant with which the connecting part is intended to be used;

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

e) a detailed description of how to connect the part with the implant and with the suprastructure;

f) where appropriate, information on how to avoid risks in connection with fixation of the connecting part;

g) instructions to follow in the event of damage to the sterile packaging and, where appropriate, details of appropriate methods of resterilization;

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

i) contra-indications and known side effects;

j) details allowing the professional staff to brief the patient on any precautions to be taken during use;

k) information on possible hazards arising from interactions with medical imaging systems and other electro-magnetic systems;

l) where appropriate, melting point/range.