INTERNATIONAL STANDARD

ISO 13504

First edition
2012-07-15

Dentistry — General requirements for instruments and related accessories used in dental implant placement and treatment

Médecine bucco-dentaire — Exigences générales relatives aux instruments et aux accessoires connexes utilisés en implantologie dentaire

Reference number
ISO 13504:2012(E)

ISO copyright office
Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
E-mail copyright@iso.org
Web www.iso.org

Published in Switzerland

Contents

Page

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 13504 was prepared by Technical Committee ISO/TC 106, *Dentistry*, Subcommittee SC 4, *Dental instruments*.

Introduction

The use of dental implants is increasing throughout the world. Due to improved and new applications of dental implants, the need for better instruments and related accessories to be used in the placement of dental implants and the further manipulation of connecting parts in the craniofacial area is also growing. Dental implants need to be approved by local authorities.

However, instruments used in the placement of dental implants are different and need a different approval procedure. This International Standard is intended to harmonize the approval procedures and to reduce the costs caused by repeated approval and test procedures in different countries.

Materials present in instruments used in dental implant procedures have proven to be well tolerated. Potential adverse reactions cannot be totally ruled out but such reactions are to be mitigated.

However, long-term clinical experience of the use of the materials referred to in this International Standard has shown that an acceptable level of biological response can be expected when they are used in appropriate applications and when instruments are manufactured under appropriate design considerations and processes.

Due to different stainless steel standards, Annex B has been added. This gives cross-references to designations of stainless steels which are listed in other international, regional or national standards designation systems.

Dentistry — General requirements for instruments and related accessories used in dental implant placement and treatment

1 Scope

This International Standard specifies general requirements for the manufacture of instruments and related accessories used in the placement of dental implants and further manipulations of connecting parts in the craniofacial area.

It is applicable to single-use and reusable instruments, regardless of whether they are manually driven or connected to a power-driven system.

It is not applicable to the power-driven system itself, nor to the dental implant or to parts intended to be connected to the dental implant.

With regard to safety, this International Standard gives requirements for classification, intended performance, performance attributes, material selection, performance evaluation, manufacture, sterilization and information to be supplied by the manufacturer.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 1043-1, *Plastics — Symbols and abbreviated terms — Part 1: Basic polymers and their special characteristics*

ISO 1942, *Dentistry — Vocabulary*

ISO 2768-1, *General tolerances — Part 1: Tolerances for linear and angular dimensions without individual tolerance indications*

ISO 5832-2, *Implants for surgery — Metallic materials — Part 2: Unalloyed titanium*

ISO 5832-3, *Implants for surgery — Metallic materials — Part 3: Wrought titanium 6-aluminium 4-vanadium alloy*

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

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

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 14155, *Clinical investigation of medical devices for human subjects — Good clinical practice*

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*

3 Terms and definitions

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

3.1
transient usage
usage for less than 60 min in any one clinical procedure

3.2 Instruments

3.2.1
surgically invasive device
device which penetrates into the human body through the surface of the body, with the aid or in the context of a surgical operation

3.2.2
instrument used in dental implant placement and treatment
surgically invasive device, used with a transient usage for the preparation of bone and tissue in the craniofacial region, to be used in the placement of dental implants and the further manipulation of connecting parts

3.2.3
accessory used in dental implant placement and treatment
non-surgically invasive device, used with a transient usage in direct or indirect contact with the human body, to be used in the placement of dental implants and the further manipulation of connecting parts

3.3 Stainless steel

3.3.1
stainless steel
steel, the main alloying element of which is chromium, of at least 10,5 % (mass fraction) Cr and maximum 1,2 % (mass fraction) C, and the primary importance of which is its resistance to corrosion

3.3.2
austenitic stainless steel
corrosion-resistant steel, typically with composition of less than 0,2 % (mass fraction) C, at least 16% (mass fraction) Cr, typically about 18 % (mass fraction) Cr and over 8 % (mass fraction) Ni, which cannot be hardened by heat treatment

3.3.3
martensitic stainless steel
corrosion-resistant steel with low to medium carbon, with at least 0,1 % (mass fraction) C and between 12 % (mass fraction) and 19 % (mass fraction) Cr, which can be hardened by quenching and tempering

3.3.4
precipitation-hardening stainless steel
corrosion-resistant steel with a high strength resulting from the precipitation of intermetallic compounds (the formation of very fine intermetallic phases, carbides and Laves phases in the structure) by a final heat treatment at relatively low temperature

4 Classification

4.1 Intended usage (application)

For the purposes of this International Standard, instruments used in dental implant placement and treatment are classified as follows, according to their intended usage (application), as stated by the manufacturer.

— Type 1: energized or motor driven instruments.

— Type 2: instruments for manual use (hand instruments).

4.2 Tissue contact

For the purposes of this International Standard, instruments used in dental implant placement and treatment are classified as follows, according to their intended main tissue contact within the working environment.

— Class 1: hard tissue.

— Class 2: soft tissue.

— Class 3: without tissue contact.

4.3 Reprocessing

For the purposes of this International Standard, instruments used in dental implant placement and treatment are classified as follows, according to their intended use determined by reprocessing requirements.

— Group 1: multiple use.

— Group 2: single use.

5 Intended performance

The intended performance of an instrument used in dental implant placement and treatment shall be described and documented by addressing the following:

a) functional characteristics;

b) intended conditions of use, according to Clause 4.

NOTE The following should be taken into account:

— 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 8).

6 Performance attributes

The development of the performance attributes of an instrument used in dental implant placement and treatment in order to meet the level intended by the manufacturer shall take into account at least the following:

a) physical, mechanical and metallurgical properties of the instrument materials (see Clauses 7 and 8);

b) microbiological and particulate contamination levels (see Clauses 8, 10 and 11);

c) usability, cleaning and maintenance (see Clause 8 and Clause 10);

d) potential deterioration of the material's characteristics due to sterilization and storage (see Clauses 7, 8 and 9);

e) effects of contact between the instrument and the human body, the implant and other instruments (see Clause 8);

f) shape and dimensions of the instrument, including their possible effects on the body (see Clause 8);

g) wear characteristics of materials and the effect of wear and wear products on the instrument and the human body (see Clauses 7 and 8);

h) insertion, removal and interconnection of parts (see Clause 8);

i) extent of fluid leakage and/or diffusion of substances into or out of instruments (see Clauses 7 and 8).

Tolerances for dimensions for an instrument used in dental implant placement and treatment shall be specified. If no specific tolerances are specified, the general tolerances for drawings shall be in accordance with ISO 2768-1.

7 Material selection

Materials for the manufacture of instruments used in dental implant placement and treatment 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 8).

The suitability of a given material for a particular application shall be demonstrated by either:

a) design evaluation in accordance with Clause 8; or

b) selection from the materials specified in Annex A, which are found suitable by proven clinical use in similar applications.

NOTE Refer to the Introduction for additional information.

If other materials are used, a biological evaluation for the final product or representative samples from the final product shall be made in accordance with ISO 7405 and ISO 10993-1.

8 Performance evaluation

8.1 General

Instruments shall be evaluated in association with the implant system they are designed for, in order to demonstrate that the intended performance (see Clause 5) is achieved. Safety shall be demonstrated by pre-clinical evaluation and by carrying out a risk analysis in accordance with ISO 14971.

If the instrument is intended for reuse, its suitability for reprocessing shall be evaluated.

NOTE In certain circumstances a clinical evaluation can also be required.

8.2 Pre-clinical evaluation

If pre-clinical testing of instruments is required, the testing shall simulate conditions of intended use.

8.3 Clinical evaluation

If a clinical evaluation is required, it shall be conducted using the associated implant system under the intended conditions of use. If a clinical investigation is carried out, it shall be managed in accordance with ISO 14155.

9 Manufacturing

9.1 General

Instruments shall be manufactured to specifications in accordance with the required performance attributes (see Clause 6).

NOTE The application of quality management systems as described in ISO 13485 might be appropriate.

9.2 Technical documentation

The technical documentation of the manufacturer shall include at least the information required in Clauses 4 to 8, 10 and 11.

10 Reprocessing

10.1 Products supplied sterile

Instruments which are labelled “STERILE” shall comply with the corresponding regional or national regulation.

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 radiation, ISO 11137-1 applies.

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

10.2 Products provided non-sterile

For instruments which 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 11.4. c)].

10.3 Reprocessing information

For instruments which 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.

11 Information to be supplied by the manufacturer

11.1 General

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.

11.2 Marking on instruments

Instruments and related accessories used in dental implant placement and treatment shall be marked with the following:

a) name or registered trademark of the manufacturer;

b) lot number (batch code) or serial number, where appropriate;

c) reference number (catalogue/article number), where appropriate;

d) size indication, if needed for safe selection or use;