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Dentistry — Implantable materials for bone filling and augmentation in oral and maxillofacial surgery — Contents of a technical file

Art dentaire — Matériaux implantables de comblement et de reconstruction osseuse en chirurgie orale et maxillofaciale — Contenu d'un dossier technique

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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 22794 was prepared by Technical Committee ISO/TC 106, *Dentistry*, Subcommittee SC 8, *Dental implants*.

In this corrected version of ISO 22794:2007 changes have been made to the list of Normative references (Clause 2) and to the Bibliography. Consequently cross-references in subclauses 5.2, 5.5.5, 5.7, 5.8 and 5.9.2 have been altered.

Further, new subclauses 5.5.3 and 5.5.4 have been designated with the former 5.5.3 becoming 5.5.5.

Introduction

Different materials used for the preservation of masticatory function, such as dental restorative materials and dental implants are subject to standards and regulations, either in existence or in preparation, designed to evaluate the performance of these products.

Implantable materials for bone filling and augmentation in oral and maxillofacial surgery are not covered by the procedures for evaluating and testing dental restorative materials and dental implants; it is necessary to develop a new standard for these materials.

The aim of this International Standard is to define the content of a technical file that demonstrates safety and effectiveness of bone filling and augmentation materials used in oral and maxillofacial surgery.

Dentistry — Implantable materials for bone filling and augmentation in oral and maxillofacial surgery — Contents of a technical file

1 Scope

This International Standard applies to implantable materials, whether resorbable or non-resorbable, used as dental devices for filling and augmenting bones in oral and maxillofacial surgery. Products that are essentially pure (> 90 %) hydroxyapatite are not covered by this International Standard.

Evaluation includes the physico-chemical, mechanical, biological and clinical aspects and behaviour of these implantable dental materials.

Materials such as autografts, allografts and membranes, and products for which the primary intended use is to deliver a medicinal product, are not covered by this International Standard.

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 1942 [1], *Dentistry — Vocabulary*

ISO 10993-1 [2], *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management system*

ISO 10993-17, *Biological evaluation of medical devices — Part 17: Establishment of allowable limits for leachable substances*

ISO 11135-1 [3], *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 [4], *Sterilization of health care products — Radiation — Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices*

ISO 11607-2 [5], *Packaging for terminally sterilized medical devices — Part 2: Validation requirements for forming, sealing and assembly processes*

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1) To be published. (Revises and replaces ISO 1942 parts 1 to 5:1989)

2) To be published. (Revision of ISO 10993-1:2003)

3) Cancels and replaces ISO 11135:1994 and ISO 11135:1994/Cor.1:1994.

4) Cancels and replaces ISO 11137:1995, ISO 11137:1995/Cor.1:1997 and ISO 11137:1995/Amd.1:2001.

5) Cancels and replaces ISO 11607:2003.

ISO 13408-1, *Aseptic processing of health care products — Part 1: General requirements*

ISO 14155-1 [6], *Clinical investigation of medical devices for human subjects — Part 1: General requirements*

ISO 14155-2 [6], *Clinical investigation of medical devices for human subjects — Part 2: Clinical investigation plans*

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 15223, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied*

ISO 17665-1 [7], *Sterilization of health care products — Moist heat — Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices*

EN 1041, *Information supplied by the manufacturer of 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
biocompatibility

a) capability of a material to fulfil its function with an appropriate response for a specific application from the receiving host;

b) quality of being accepted in a specific living environment without adverse or unwanted side effects

3.2
biomaterial

a) material intended to interface with the biological system to evaluate, treat, augment or replace tissue, organ or function of the organism;

b) material specially prepared and/or presented to exhibit bioacceptability, biocompatibility or positive biocompatiblity

NOTE The implantable materials referred to in this document are all biomaterials.

3.3
filling
surgical placement of a biomaterial, resorbable or non-resorbable, into an intrabony cavity during oral and maxillofacial surgery

NOTE Intrabony cavity includes extraction socket.

3.4
augmentation
surgical placement of a biomaterial, resorbable or non-resorbable, to increase the volume of bone, usually on the sinus floor or the alveolar ridges

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6) Cancels and replaces ISO 14155:1996.

7) Cancels and replaces ISO 11134:1994 and ISO 13683:1997.

3.5
resorption
progressive elimination by cellular activity and/or dissolution of a material in a biological environment

3.6
medicinal product
substance that produces its intended effect by pharmaceutical means

4 Implantable materials

The development of implantable materials shall be considered with regard to the properties required for the intended purpose, taking into account the effects of manufacture, handling, sterilization and storage. Possible reactions (intended or not) of implantable materials with human tissues and body fluids, other materials, other implants, substances, gases, radiation and electromagnetic fields shall be considered.

Implantable materials for bone reconstruction in oral and maxillofacial surgery are used either for filling or augmentation.

5 Technical file

5.1 Contents

The contents of a technical file shall include at least the following:

— details of the chemical composition and physical properties of the implantable material;

— its intended performance;

— its preclinical and clinical evaluation;

— details of its manufacture, sterilization and packaging;

— all information necessary for the user (as detailed later).

New materials, for which the following characterization methods may not be adequate, shall be characterized using techniques appropriate to the materials and the choice of technique shall be justified.

5.2 Chemical composition

As appropriate, the following shall apply.

The complete chemical composition, summing to 100 % by mass, including all additives, shall be described.

The crystalline and non-crystalline phases, phase purity, and the mass fractions of phases, using X-ray diffraction (XRD), Fourier transform infrared spectroscopy (FTIR) and/or differential scanning calorimetry (DSC), as appropriate, shall be described.

The composition description shall also include elemental analysis, identifying the cation to anion ratio (e.g., Ca/P, Ca/S) and/or the carbon/oxygen/nitrogen ratios (e.g., C/O/N), as appropriate, and all trace impurities relevant to the application.

Diffraction patterns, along with superimposed patterns of each phase as given for the relevant calcium salt and available from the International Center for Diffraction Data/Joint Committee on Powder Diffraction Standards (ICDD/JCPDS), shall be described.

NOTE Several standards that address the specifics of different materials are available and can be useful references for other bone-filling materials. See references [11], [19], [20], [21], [22].