INTERNATIONAL STANDARD

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Dentistry — Membrane materials for guided tissue regeneration in oral and maxillofacial surgery — Contents of a technical file

Art dentaire — Membranes pour régénération de tissus en chirurgie buccale et maxillo-faciale — Contenu du dossier technique

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Foreword

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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 22803 was prepared by Technical Committee ISO/TC 106, *Dentistry*, Subcommittee SC 8, *Dental implants*.

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.

Membrane materials for periodontal tissue reconstruction in oral and maxillofacial surgery are not covered by the procedures for evaluating and testing dental restorative materials and dental implants, thus it is necessary to develop a new International 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 membrane materials used in oral and maxillofacial surgery.

Dentistry — Membrane materials for guided tissue regeneration in oral and maxillofacial surgery — Contents of a technical file

1 Scope

This International Standard gives the requirements for a technical file on the evaluation of the chemical, physical, mechanical, biological and clinical aspects and behaviour of membrane materials, whether resorbable, partially resorbable or non-resorbable, which are used

— for guided tissue regeneration in oral and maxillofacial surgery to correct a morphological defect or abnormality,

— in contact with teeth and/or dental implants,

— for prevention of epithelial migration in periodontal surgery,

— for the augmentation of bone prior to the planned insertion of dental implants,

— and/or for augmentation of bone for stabilization of dental prostheses.

This International Standard is not applicable to materials whose primary intended use is to deliver a medicinal product, autografts and allografts, or materials intended to act through pharmacological, immunological or metabolic means.

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, *Dentistry — Vocabulary*[1)]

ISO 10993-1, *Biological evaluation of medical devices — Part 1: Evaluation and testing*

ISO 10993-7, *Biological evaluation of medical devices — Part 7: Ethylene oxide sterilization residuals*

ISO 11134, *Sterilization of health care products — Requirements for validation and routine control — Industrial moist heat sterilization*

ISO 11135, *Sterilization of health care products — Ethylene oxide — Requirements for development, validation and routine control of a sterilization process for medical devices*

ISO 11137, *Sterilization of health care products — Requirements for validation and routine control — Radiation sterilization*

ISO 11607, *Packaging for terminally sterilized medical devices*

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

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*

1) Revision of ISO 1942-1:1989, ISO 1942-2:1989, ISO 1942-3:1989, ISO 1942-4:1989 and ISO 1942-5:1989.

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*

EN 1041, *Information supplied by the manufacturer with 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
periodontal tissue
all tissues constituting the dental periodontium, i.e. alveolar bone, gingival tissue, periodontal ligament and cementum

3.2
biocompatibility
⟨material action⟩ capacity of a material to fulfill its function with an appropriate response for a specific application in the recipient

3.3
biocompatibility
⟨material reaction⟩ quality of being accepted in a specific living environment without adverse or unwanted side effects

[ISO 1942-1:1989/Amd.5:1993, definition 1.200]

3.4
biomaterial
⟨general purpose⟩ material intended to interface with the biological system to evaluate, treat, augment or replace tissue, organ or function of the organism

3.5
biomaterial
⟨tailored preparation⟩ material specially prepared and/or presented to exhibit biacceptability, biocompatibility or positive biocompatiblity

[ISO 1942-1:1989/Amd.5:1993, definition 1.204]

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

3.6
membrane material
medical device specifically prepared as a material which, when placed into tissue, carries out a barrier function

NOTE The sheet may be occlusive or selectively permeable to cells, macromolecules and/or fluid.

3.7
barrier
structure which, when placed into tissue, prevents the intermixing of the cell population on each side of the structure and/or prevents the prolapse of tissue

3.8
packing
surgical placement of a biomaterial to fill an intrabony cavity or defect