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

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EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

Käesolev Eesti standard EVS-EN ISO 22803:2005 sisaldab Euroopa standardi EN ISO 22803:2005 ingliskeelset teksti. Käesolev dokument on jõustatud 28.12.2005 ja selle kohta on avaldatud teade Eesti standardiorganisatsiooni ametlikus väljaandes. Standard on kättesaadav Eesti standardiorganisatsioonist.	This Estonian standard EVS-EN ISO 22803:2005 consists of the English text of the European standard EN ISO 22803:2005. This document is endorsed on 28.12.2005 with the notification being published in the official publication of the Estonian national standardisation organisation. The standard is available from Estonian standardisation organisation.

Käsitlusala: 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.	**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.

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English Version

Dentistry - Membrane materials for guided tissue regeneration in oral and maxillofacial surgery - Contents of a technical file (ISO 22803:2004)

Art dentaire - Membranes pour régénération de tissus en chirurgie buccale et maxillo-faciale - Contenu du dossier technique (ISO 22803:2004)

Zahnheilkunde - Membranmaterialien für die gesteuerte Geweberegeneration bei oralen und maxillofazialen Eingriffen - Inhalt der Technischen Dokumentation (ISO 22803:2004)

This European Standard was approved by CEN on 7 October 2005.

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Ref. No. EN ISO 22803:2005: E

Foreword

The text of ISO 22803:2004 has been prepared by Technical Committee ISO/TC 106 "Dentistry" of the International Organization for Standardization (ISO) and has been taken over as EN ISO 22803:2005 by Technical Committee CEN/TC 55 "Dentistry", the secretariat of which is held by DIN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by May 2006, and conflicting national standards shall be withdrawn at the latest by May 2006.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Slovakia, Slovenia, Spain, Sweden, Switzerland and United Kingdom.

Endorsement notice

The text of ISO 22803:2004 has been approved by CEN as EN ISO 22803:2005 without any modifications.

INTERNATIONAL STANDARD

ISO 22803

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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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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 bioacceptability, 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