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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 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

3.9

augmentation

surgical placement of autogenous bone and/or of a biomaterial, resorbable or non-resorbable, to increase the volume of a bone or bridging of a defect

3.10

resorbable

ability of a membrane material to undergo progressive elimination by cellular activity and/or dissolution in a biological environment

3.11

tissue regeneration

reproduction or reconstruction of a lost or injured tissue by induction, conduction or healing process

3.12

guided tissue regeneration

GTR

formation of tissue among which the orientation, the function, the volume and the place are pre-modelled by an exogenous mean

3.13

guided bone regeneration

GBR

bone formation specifically obtained by GTR principles

4 General description

Membrane materials are widely used in periodontology and oral and maxillofacial surgery, and have characteristics which are unique to these applications, for example:

a) placement in contact with teeth and their supporting tissues;

b) prevention of oral mucosal epithelial migration into surgically treated defects;

c) predictable loss of structural integrity and mechanical properties over time in oral sites into which dental implants are to be subsequently placed;

d) known behaviour of the material should it become inadvertently exposed to the oral or paranasal cavities subsequent to placement;

e) augmentation of the volume or dimension of bone for enhanced stabilization of dentures or for placement of dental implants.

The development of membrane 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 membrane materials with human tissues and body fluids, other materials, other implants, substances, gases, radiation and electromagnetic fields shall be considered.

Membrane materials for periodontal tissue reconstruction in oral and maxillofacial surgery are used as either a barrier or a covering of packing materials.

During their use, these materials can induce an acute inflammatory reaction, which must be evaluated by specific tests.

5 Contents of a technical file

5.1 General

The contents of a technical file shall include the following information about the membrane material:

a) details of its chemical composition;

b) its intended performance;

c) its preclinical and clinical evaluations;

d) details of its manufacture, sterilization and packaging;

e) certain other items of information necessary for the user.

5.2 Chemical composition

Refer to ISO 10993-13, ISO 10993-14, ISO 10993-15 and ISO 10993-18 for guidance. All polymer characterization shall be completed after recommended sterilization procedures have been applied.

5.3 Intended performance

The intended performance of a membrane material shall be described and documented by addressing the following:

— general description of the product;

— functional characteristics: resorbable, partially resorbable or non-resorbable;

— typical intended applications: simple barrier (in this case give physical and mechanical characteristics, including deformability);

— completely submersed or not during use;

— intended conditions of use;

— whether the device is intended to be used with fixation;

— included physical additives (e.g. titanium);

— included chemical additives (e.g. mineral salts);

— included material degradation when undergoing multiple cycles of reprocessing;

— reference to published standards to which the device conforms, with particular regard to safety.

Account should be taken of

— published standards,

— published clinical and scientific literature,

— validated test results.

5.4 Preclinical and clinical evaluation

5.4.1 General

Following an appropriate risk analysis as part of a risk management programme in accordance with ISO 14971, membrane materials shall be evaluated to demonstrate that their intended performance is achieved in GTR and/or GBR. The extent to which the intended performance has been achieved shall be determined and documented. Safety shall be demonstrated by preclinical and clinical evaluations and testing, as appropriate.

5.4.2 Preclinical evaluation

All details of the preclinical evaluation shall be provided. Preclinical evaluation shall include both the physical and biological properties of the membrane materials.

Among its physical properties, the physical strength of the membrane in an artificial medium over a period of time, including its tear resistance, shall be determined, using appropriate methods.

The preclinical biological evaluation shall be carried out in accordance with ISO 10993-1 by

— a compilation and critical analysis of the relevant scientific literature; and

— if necessary, analysis of data obtained from tests performed.

Laboratory and, if necessary, animal tests should be designed to establish that the materials meet the requirements for their use in periodontal, oral and maxillofacial surgery. Such tests should include *in vitro* and *in vivo* studies aimed at establishing the biocompatibility of the membranes with the periodontal tissues and bone, their ability to inhibit or guide the migration of oral epithelial cells, their biodegradability by the host tissues and their behaviour when exposed to the oral environment, including the ability of oral and/or nasal micro-organisms to colonise them. Evidence to show that the membrane is compatible with devices and substances that would be encountered during intended uses shall be included.

5.4.3 Clinical evaluation

Details of the clinical evaluation shall be provided.

Membrane materials shall undergo clinical evaluation by

a) a compilation and critical analysis of the relevant literature covering the intended clinical use of the materials, and/or

b) an analysis of data obtained from clinical investigations of the specific membrane material, especially with regard to evidence of new bone formation, bone resorption and/or periodontal tissue regeneration.

If a clinical investigation is carried out, it shall be managed in accordance with the requirements of ISO 14155-1.

5.5 Manufacture

Manufacturing processes shall be described and evidence of their validation shall be provided.

Membrane materials shall be manufactured in such a way that the intended performance is achieved.

5.6 Sterilization

5.6.1 Products supplied sterile

The sterility assurance level of terminally sterilized membrane materials shall be 10^{-6} or better. Sterilization processes shall be validated and routinely controlled.

If membrane materials are to be sterilized by ethylene oxide, ISO 11135 shall apply; by irradiation, ISO 11137; by steam, ISO 11134; by any other method, validation shall be carried out according to ISO 14937.

If the manufacturer states that resterilization is acceptable, the maximum permissible number of cycles shall be stated and at least one validated method shall be specified.

For membrane materials that are supplied non-sterile, the manufacturer shall specify at least one validated method of sterilization such that their functional safety is not adversely affected. If multiple sterilizations are not allowed, this shall be stated in the information provided by the manufacturer (see 5.8).

5.6.2 Sterilization residuals

Testing for residuals of sterilization shall be in accordance with the principles set out in ISO 10993-1. The levels of residuals shall not exceed the limits specified in ISO 10993-7.

5.7 Packaging

5.7.1 Protection from damage in storage and transport

Details of packaging methods and materials shall be given and a sample package shall be provided.

The packaging shall be designed so that, under conditions specified by the manufacturer for storage, transport and handling (including control of temperature, humidity and ambient pressure, if applicable), it protects against damage and deterioration and the material is not adversely affected. Validation of this capability shall be referenced in the technical file.

5.7.2 Maintenance of sterility in transit

Membrane materials supplied in sterile conditions shall be packaged so that they remain sterile under normal storage, transport and handling conditions unless the package is damaged or opened.

For terminally sterilized products, packaging shall conform to ISO 11607.

5.8 Additional information supplied by the manufacturer

5.8.1 General

Information supplied by the manufacturer shall be in accordance with EN 1041. If symbols are used, they shall be in accordance with ISO 15223.

A copy of the instructions for use and product label shall be included. If the instructions for use are revised, the technical file should also include date of revision and/or revision number.

Validation of the product capability shall be referenced in the technical file.

5.8.2 Restrictions on combinations

If the membrane material is intended to be used in combination with other devices, any restrictions in the use of the combination shall be stated on the label or in the instructions for use.

5.8.3 Identification of membrane materials

In order to provide traceability, the following information shall be included on the primary package label:

— name of product;

— manufacturer's name or trademark;

— address of the manufacturer;

— batch code (lot number) or serial number;

— date of manufacture;

— sterile (plus method of sterilization) or not sterile;

— storage recommendation; and

— expiry date of sterility (if sterilized by manufacturer).

Bibliography

[1] ISO 1942-1:1989/Amd.5:1993, *Dental vocabulary — Part 1: General and clinical terms — Amendment 5*

[2] ISO 10993-2, *Biological evaluation of medical devices — Part 2: Animal welfare requirements*

[3] ISO 10993-3, *Biological evaluation of medical devices — Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity*

[4] ISO 10993-4, *Biological evaluation of medical devices — Part 4: Selection of tests for interactions with blood*

[5] ISO 10993-5, *Biological evaluation of medical devices — Part 5: Tests for in vitro cytotoxicity*

[6] ISO 10993-6, *Biological evaluation of medical devices — Part 6: Tests for local effects after implantation*

[7] ISO 10993-9, *Biological evaluation of medical devices — Part 9: Framework for identification and quantification of potential degradation products*

[8] ISO 10993-10, *Biological evaluation of medical devices — Part 10: Tests for irritation and delayed-type hypersensitivity*

[9] ISO 10993-11, *Biological evaluation of medical devices — Part 11: Tests for systemic toxicity*

[10] ISO 10993-12, *Biological evaluation of medical devices — Part 12: Sample preparation and reference materials*

[11] ISO 10993-13, *Biological evaluation of medical devices — Part 13: Identification and quantification of degradation products from polymeric medical devices*

[12] ISO 10993-14, *Biological evaluation of medical devices — Part 14: Identification and quantification of degradation products from ceramics*

[13] ISO 10993-15, *Biological evaluation of medical devices — Part 15: Identification and quantification of degradation products from metals and alloys*

[14] ISO 10993-18, *Biological evaluation of medical devices — Part 18: Chemical characterization of materials*

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

[16] ISO 14160, *Sterilization of single-use medical devices incorporating materials of animal origin — Validation and routine control of sterilization by liquid chemical sterilants*

[17] ISO/TR 14283, *Implants for surgery — Fundamental principles*

[18] ISO 14630, *Non-active surgical implants — General requirements*

[19] EN 980, *Graphical symbols for use in the labelling of medical devices*

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