SLOVENSKI STANDARD
oSIST prEN ISO 6877:2020

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Zobozdravstvo - Endodontski materiali za polnitev koreninskih kanalov (obturacijo) (ISO/DIS 6877:2020)

Dentistry - Endodontic obturating materials (ISO/DIS 6877:2020)

Zahnheilkunde - Endodontische Obturationsmaterialien (ISO/DIS 6877:2020)

Art dentaire - Cônes d'obturation dentaires pour canaux radiculaires

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Dentistry — Endodontic obturating materials

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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.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation on the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see the following URL: www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 106, *Dentistry,* Subcommittee SC 1, *Filling and Restorative Materials*.

This third edition cancels and replaces the second edition (ISO 6877:2006), which has been technically revised.

The main changes compared to the previous edition are as follows:

— Use of “endodontic” rather than “root canal” for the terminology;

— Inclusion of points have non-uniform taper;

— Inclusion of thermoplastic materials not in the form of a point;

— Standardization to the use of d_0, d_3 and d_{16} for measurements of endodontic points at the projection of the tip, 3 mm or 16 mm from the tip of a point;

— Addition of ISO 13116 for digital radiopacity as a normative reference;

— Change in the radiopacity sample thickness to 1 mm from 2 mm with concomitant reduction of the radiopacity requirement from 6 mm to 3 mm of equivalent Al;

— Augmenting the packaging requirements for providing information;

— Addition of an annex for measuring the melt-flow rate of thermoplastic materials that are not supplied in point form. No performance limits are provided in this document but they may beadded in the future.

Any feedback or questions on this document should be directed to the user’s national standards body. A complete listing of these bodies can be found at www .iso .org/members .html.

Introduction

The following should be taken into account when using this International Standard:

— Specific qualitative and quantitative test methods for demonstrating freedom from unacceptable biological risks are not included in this International Standard but it is recommended that, for the assessment of such biological risks, reference be made to ISO 7405 and ISO 10993-1.

Dentistry — Endodontic obturating materials

1 Scope

In this document are the specifications for the dimensional and compositional requirements for various endodontic obturating materials including preformed metal, preformed polymeric-coated metal, polymeric points, thermoplastic obturating material or combinations of the above suitable for use in the obturation of the root canal system. This document also specifies numerical systems and a color-coding system for designating the sizes.

This document does not include materials for support of a coronal restoration. Dental endodontic obturating points are marketed sterilized or non-sterilized. This

International Standard covers the physical attributes expected of such products as supplied. Requirements for sterility are not included, and any claim that the product is sterile is the

— responsibility of the manufacturer (see Table 3). Article 7 specifies the requirements for

— packaging and labelling, including the instructions for use.

This International Standard does not apply to instruments or equipment used in conjunction with thermoplastic obturating materials (obturating material that deform with heat).

2 Normatives 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.

ASTM D1238, *Standard Test Method for Melt Flow Rates of Thermoplastics by Extrusion Plastometer*

ISO 1942, *Dentistry —Vocabulary*

ISO 1133-1, *Plastics — Determination of the melt mass-flow rate (MFR) and melt volume-flow rate (MVR) of thermoplastics — Part 1: Standard method*

ISO 1133-2, *Plastics — Determination of the melt mass-flow rate (MFR) and melt volume-flow rate (MVR) of thermoplastics — Part 2: Method for materials sensitive to time-temperature history and/or moisture*

ISO 3630-1, *Dentistry — Endodontic instruments — Part 1: General requirements*

ISO 3665, *Photography — Intra-oral dental radiographic film and film packets — Manufacturer specifications*

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

ISO 11607-1, *Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems*

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

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

ISO 11137, *Sterilization of health care products — Radiation*

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 11737-2, *Sterilization of health care products — Microbiological methods — Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process*

ISO 11138-1, *Sterilization of health care products — Biological indicators — Part 1: General requirements*

ISO 11138-2, *Sterilization of health care products — Biological indicators — Part 2: Biological indicators for ethylene oxide sterilization processes*

ISO 11138-3, *Sterilization of health care products — Biological indicators — Part 3: Biological indicators for moist heat sterilization processes*

ISO 11139, *Sterilization of health care products — Vocabulary of terms used in sterilization and related equipment and process standards*

ISO 13116, *Dentistry — Test method for determining radio-opacity of materials*

ISO 14160, *Sterilization of health care products — Liquid chemical sterilizing agents for single-use medical devices utilizing animal tissues and their derivatives — Requirements for characterization, development, validation and routine control of a sterilization process for medical devices*

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 15223-1, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements*

ISO 15223-2, *Medical devices — Symbols to be used with medical device labels, labelling, and information to be supplied — Part 2: Symbol development, selection and validation*

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, ISO 3630-1 and the following apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at http: //www.electropedia.org

3.1
endodontic obturating material
substance intended to permanently obturate the cavities previously occupied by the pulp, and may be augmented by a sealing material

3.2
point
preformed metal, preformed polymeric-coated metal, and polymeric cones for use in the obturation of a root canal

Note 1 to entry: For the purposes of this International Standard the term “endodontic obturating point (cone)” is abbreviated as “point”.

3.3
size designation
numerical indication, “000”, of the projected tip diameter, measured in hundredths of a millimetre