SLOVENSKI STANDARD
oSIST prEN ISO 6877:2024

01-maj-2024

Zobozdravstvo - Endodontski materiali za polnitev koreninskih kanalov (obturacijo) (ISO/DIS 6877:2024)

Dentistry - Endodontic obturating materials (ISO/DIS 6877:2024)

Zahnheilkunde - Endodontische Obturationswerkstoffe (ISO/DIS 6877:2024)

Médecine bucco-dentaire - Matériaux d'obturation endodontique (ISO/DIS 6877:2024)

Ta slovenski standard je istoveten z: **prEN ISO 6877**

ICS:

11.060.10	Zobotehnični materiali	Dental materials

oSIST prEN ISO 6877:2024 **en,fr,de**

DRAFT International Standard

ISO/DIS 6877

Dentistry — Endodontic obturating materials

Médecine bucco-dentaire — Matériaux d'obturation endodontique

ICS: 11.060.10

ISO/TC **106**/SC **1**

Secretariat: **AFNOR**

Voting begins on:
2024-03-21

Voting terminates on:
2024-06-13

This document is circulated as received from the committee secretariat.

ISO/CEN PARALLEL PROCESSING

Reference number
ISO/DIS 6877:2024(en)

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Published in Switzerland

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.

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).

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For an explanation of 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*, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 55, *Dentistry*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This fourth edition cancels and replaces the third edition (ISO 6877:2021) which has been technically revised.

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

— elimination of metallic points (cones),

— inclusion of tolerances d_3 and d_{16} for standard, greater taper and variable taper points,

— change of terminology from "numbering system" to "nominal size",

— modification of Table 1,

— addition of Table 2,

— modification of Figures 1 and 2,

— inclusion of requirements to state the initial taper, and its length for variable taper points,

— inclusion of requirements to state the taper, and tolerances for auxiliary points,

— addition of a new normative reference,

— removal of inappropriate requirements for carrier-based obturation devices, and

— modification of the carrier-based obturation device drawing.

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 information should be taken into account when using this document: specific qualitative and quantitative test methods for demonstrating freedom from unacceptable biological risks are not included in this document but it is recommended that, for the assessment of such biological risks, reference be made to ISO 7405 and ISO 10993-1. No performance limits are provided in this document for melt mass-flow rate, but they can be added in the future.

Dentistry — Endodontic obturating materials

1 Scope

This document specifies the requirements for the dimensions of various endodontic obturating materials, and the radiopacity for preformed polymeric-coated, polymeric points, preformed polymeric-coated, thermoplastic obturating materials, or combinations of the above used for obturation of a root canal system. It also specifies numerical and colour-coding systems for designating the sizes of a preformed endodontic obturating points, a method for determining the melt mass-flow rate for injection material, and the requirements for marking, labelling, packaging, and the instructions for use.

Dental endodontic obturating points are marketed as sterilized or non-sterilized. Sterility is not included in this document and any claim that the product is sterile is the responsibility of the manufacturer (see Table 2).

Clause 7 specifies the labelling and packaging needed, including the instructions for use. A claim by the manufacturer that the contents of the unopened pack are sterile is the responsibility of the manufacturer (see Table 3). This document does not specify requirements or test methods for sterility.

NOTE 1 Reference to applicable national regulations can be made.

Reference is made to internationally accepted pharmacopoeia.

NOTE 2 National requirements can apply.

Standards on methods of validating sterilization processes are also available: ISO 11137-1, ISO 11137-2 and ISO 11137-3.

This document does not apply to instruments or apparatus used in conjunction with thermoplastic obturating materials (obturating material that become plastic with heat). This document is not applicable to materials for support of a coronal restoration.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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 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 1942, *Dentistry — Vocabulary*

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

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

ISO 6876, *Dentistry — Root canal sealing materials*

ISO 8601-1, *Date and time — Representations for information interchange — Part 1: Basic rules*

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

ISO 15223-1, *Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements*

ISO/IEC 17025, *General requirements for the competence of testing and calibration laboratories*

ISO 20417, *Medical devices — Information to be supplied by the manufacturer*

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 as a definitive product to fill a prepared root canal system

Note 1 to entry: Endodontic sealing materials are radiopaque dental cements used in combination with an *endodontic obturating material* (3.1), to fill voids and to seal root canals during orthograde obturation. Endodontic sealing materials are not part of this document, but are the subject of ISO 6876.

3.2
point
preformed polymeric cones for use in the obturation of a root canal system, used with endodontic sealer

Note 1 to entry: For the purposes of this document, the term "endodontic obturating point (cone)" is abbreviated as "point".

Note 2 to entry: For the purposes of this document, the term tip refers to the small end of the point (cone).

3.3
nominal size
general designation of a *point* (3.2), based on the size of the calculated diameter at the end of the point with the extended taper of the point in hundredths of a millimetre

Note 1 to entry: See Figure 1 for standard and greater taper points, where the nominal size is shown. For variable taper points the extended diameter of the initial taper is used to determine *D*.

Note 2 to entry: The nominal size is designated as *D*, and described by "###" representing the size of *D* in hundredths of a millimetre.

Note 3 to entry: For a carrier-based obturating device, the nominal size – *D* is designated by the manufacturer. *D* corresponds to the final instrument size of the root canal preparation that the manufacturer deems suitable for the nominal size of the device.

3.4
taper
percentage increase in diameter from the tip to the proximal end of the *point* (3.2), indicated by two numbers "XX"

EXAMPLE An 02 taper represents a nominal 2 % increase in diameter from the tip to the proximal end of the *point* (3.2).

Note 1 to entry: For a carrier-based obturating device, the nominal size – *D* is designated by the manufacturer. *D* corresponds to the final instrument size of the root canal preparation that the manufacturer deems suitable for the nominal size of the device.