Dentistry - Endodontic obturating materials (ISO 6877:2025)

EESTI STANDARDIMIS- JA AKREDITEERIMISKESKUS
ESTONIAN CENTRE FOR STANDARDISATION AND ACCREDITATION

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

See Eesti standard EVS-EN ISO 6877:2025 sisaldab Euroopa standardi EN ISO 6877:2025 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 6877:2025 consists of the English text of the European standard EN ISO 6877:2025.
Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas.	This standard has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation and Accreditation.
Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 13.08.2025.	Date of Availability of the European standard is 13.08.2025.
Standard on kättesaadav Eesti Standardimis-ja Akrediteerimiskeskusest.	The standard is available from the Estonian Centre for Standardisation and Accreditation.

Tagasisidet standardi sisu kohta on võimalik edastada, kasutades EVS-i veebilehel asuvat tagasiside vormi või saates e-kirja meiliaadressile standardiosakond@evs.ee.

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

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English Version

Dentistry - Endodontic obturating materials (ISO 6877:2025)

Médecine bucco-dentaire - Matériaux d'obturation endodontique (ISO 6877:2025)

Zahnheilkunde - Endodontische Obturationswerkstoffe (ISO 6877:2025)

This European Standard was approved by CEN on 25 May 2025.

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This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

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European foreword

This document (EN ISO 6877:2025) has been prepared by Technical Committee ISO/TC 106 "Dentistry" in collaboration with 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 February 2026, and conflicting national standards shall be withdrawn at the latest by February 2026.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN shall not be held responsible for identifying any or all such patent rights.

This document supersedes EN ISO 6877:2021.

Any feedback and questions on this document should be directed to the users’ national standards body/national committee. A complete listing of these bodies can be found on the CEN website.

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

Endorsement notice

The text of ISO 6877:2025 has been approved by CEN as EN ISO 6877:2025 without any modification.

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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).

ISO draws attention to the possibility that the implementation of this document may involve the use of (a) patent(s). ISO takes no position concerning the evidence, validity, or applicability of any claimed patent rights in respect thereof. As of the date of publication of this document, ISO had not received notice of (a) patent(s), which may be required to implement this document. However, implementers are cautioned that this may not represent the latest information, which may be obtained from the patent database available at www.iso.org/patents. ISO shall not be held responsible for identifying any or all such patent rights.

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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 Figure 1 and Figure 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;

— 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 considered 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 polymeric points, polymeric-coated thermoplastic obturating carriers, non-point-shaped thermoplastic obturating material, 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 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. Any claim that the product is sterile is the manufacturer's responsibility (see Table 3). This document does not apply to instruments or apparatus used with obturating materials that become plastic with heat or materials supporting a coronal restoration.

Clause 7 specifies marking, labelling and packaging, including the instructions for use. This document does not specify requirements or test methods for sterility. Reference to applicable national regulations, internationally accepted pharmacopoeia and standards for validating sterilization processes can apply.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes the requirements of this document. For dated references, only the edition cited applies. The latest edition of the referenced document (including any amendments) applies for undated references.

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

ISO 13116:2014, *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