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STN	**Stomatológia** **Endodontické obturačné materiály (ISO 6877: 2021)**	**STN** **EN ISO 6877** 85 6346

Dentistry - Endodontic obturating materials (ISO 6877:2021)

Táto norma obsahuje anglickú verziu európskej normy.
This standard includes the English version of the European Standard.

Táto norma bola oznámená vo Vestníku ÚNMS SR č. 01/22

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Oznámením tejto normy sa ruší
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EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN ISO 6877

September 2021

ICS 11.060.10

Supersedes EN ISO 6877:2006

English Version

Dentistry - Endodontic obturating materials (ISO 6877:2021)

Médecine bucco-dentaire - Matériaux d'obturation endodontique(ISO 6877:2021)

Zahnheilkunde - Endodontische Obturationswerkstoffe (ISO 6877:2021)

This European Standard was approved by CEN on 7 August 2021.

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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

Ref. No. EN ISO 6877:2021 E

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European foreword

This document (EN ISO 6877:2021) 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of an identical text or by endorsement, at the latest by March 2022, and conflicting national standards shall be withdrawn at the latest by March 2022.

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 6877:2006.

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 websites.

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Endorsement notice

The text of ISO 6877:2021 has been approved by CEN as EN ISO 6877:2021 without any modification.

INTERNATIONAL STANDARD

ISO 6877

Third edition
2021-09

Dentistry — Endodontic obturating materials

Médecine bucco-dentaire — Matériaux d'obturation endodontique

Reference number
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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 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 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 having a non-uniform taper;

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

— standardization to the use of D, 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;

— harmonization of D, d_3 and d_{16} with the ISO 3630 series;

— reconsidering tests methods;

— addition of ISO 13116 for test method for determining radiopacity of material as a normative reference;

— 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.

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 might be added in the future.

INTERNATIONAL STANDARD **ISO 6877:2021(E)**

Dentistry — Endodontic obturating materials

1 Scope

This document establishes the specifications for the dimensions of 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 colour-coding system for designating the sizes of preformed endodontic obturating points.

Dental endodontic obturating points are marketed sterilized or non-sterilized. This document covers the physical attributes expected of such products as supplied.

Sterility is not included in this document, and any claim that the product is sterile is the responsibility of the manufacturer (see Table 3). Clause 7 specifies the labelling needed, including the instructions for use.

This document does not apply to instruments or apparatus used in conjunction with thermoplastic obturating materials (obturating material that deform 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 1942, *Dentistry — Vocabulary*

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

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*

