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Dentistry — Endodontic obturating materials

Médecine bucco-dentaire — Matériaux d'obturation endodontique

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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 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~~_i
- ~~removal of inappropriate requirements for carrier-based obturation devices~~_i
- ~~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.

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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.

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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~~-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~~Clause 7 specifies ~~the~~marking, labelling and packaging~~needed~~, 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 ~~may~~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 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 13116:2014, *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*

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

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><https://www.iso.org/obp>
- —IEC Electropedia: available at <http://www.electropedia.org><http://www.electropedia.org>

3.1 ~~3.1~~

endodontic sealing material

material intended to permanently seal the root canal system usually in combination with endodontic obturating cones during “orthograde obturation” and used for other endodontic sealing procedures including apexification, perforation filling, resorption or retrograde root-end filling

Note 1 to entry: ~~endodontic~~ **Endodontic** sealing material is within the scope of ISO 6876.

3.2 ~~3.2~~

endodontic obturating material

radiopaque dental material used in the form of a *point*, ~~(3.3)~~, carrier-based obturating device, or injection material used in combination with an *endodontic sealing material* ~~(3.1)~~ **(3.1)** to fill voids and seal root canals during orthograde obturation

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3.4.3.3

point

preformed polymeric cone 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 smaller end of the point (cone) inserted towards the apex.~~

~~3.5~~ **3.4.3.4**

nominal size

D

general designation of a *point* ~~(3.2)~~, **(3.3)**, 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: ~~The nominal size is designated as *D* and described by “###” representing the size of *D* in hundredths of a millimetre.~~

Note 2 to entry: ~~See **Figure 1** for standard and greater taper points, where the determination of the nominal size is shown. For variable taper points, the extended diameter of the initial taper is used to determine *D*.~~

Note 3 to entry: ~~For a carrier-based obturating device, *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, *D*, of the device.~~

3.63.53.5**taper**

percentage increase in diameter from the tip to the proximal end of the *point* ~~(3.2)~~, ~~(3.3)~~, indicated by two numbers

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: The manufacturer designates the taper for a carrier-based obturating device.

3.73.63.6**standard point**

point ~~(3.2)~~, ~~(3.3)~~ that has a uniform 02 *taper* ~~(3.4)~~, ~~(3.5)~~ over the first 16 mm from the tip to the proximal end of the point

3.83.73.7**greater taper point**

point ~~(3.2)~~, ~~(3.3)~~ that has a uniform *taper* ~~(3.4)~~, ~~(3.5)~~ greater than 02 over the first 16 mm from the tip to the proximal end of the point

3.93.83.8**variable taper point**

point ~~(3.2)~~, *point* ~~(3.3)~~ that has multiple tapers that decrease over the first 16 mm from the tip to the proximal end of the point

Note 1-~~to~~-entry: The first taper, nearest the tip, is considered the initial taper.

3.103.93.9**auxiliary point**

point ~~(3.2)~~, ~~(3.3)~~, excepting *standard point* ~~(3.5)~~, ~~(3.6)~~, *greater taper point* ~~(3.6)~~, ~~(3.7)~~, and *variable taper point* ~~(3.7)~~, ~~(3.8)~~

Note-1-~~to~~-entry: Auxiliary points are not subject to *nominal size* ~~(3.4)~~ requirements.

3.113.103.10**carrier-based obturating device**

device designed that has thermoplastic polymeric material coated on a core or carrier material, usually in an imprecise shape of a cone or cylinder with a taper, used to obturate a root canal

Note 1 to entry: The core material can remain in the canal or can be removed after carrying the thermoplastic material into the root canal.

Note-2-~~to~~ entry: *Nominal size* ~~(3.4)~~ and *taper* ~~(3.5)~~ of a carrier-based obturating device corresponds to the final instrument taper of the root canal preparation that the manufacturer deems suitable for the nominal size of the device.

Note 3 to entry: Carrier-based obturating devices require a heating system, which is different from an *injection system* ~~(3.11)~~, ~~(3.12)~~, and neither system is included in this document.

3.123.113.11**injection material**

endodontic obturating material ~~(3.1)~~, ~~(3.1)~~ supplied in non-point form, such as pellets, which become plastic after being warmed, for injection in a root canal system