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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).

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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;

— 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

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 sealing material is within the scope of ISO 6876.

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) to fill voids and seal root canals during orthograde obturation

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.

3.4
nominal size
D
general designation of a *point* (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.

3.5
taper
percentage increase in diameter from the tip to the proximal end of the *point* (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.

Note 1 to entry: The manufacturer designates the taper for a carrier-based obturating device.

3.6
standard point
point (3.3) that has a uniform 02 *taper* (3.5) over the first 16 mm from the tip to the proximal end of the point

3.7
greater taper point
point (3.3) that has a uniform *taper* (3.5) greater than 02 over the first 16 mm from the tip to the proximal end of the point

3.8
variable taper point
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.

3.9
auxiliary point
point (3.3), excepting *standard point* (3.6), *greater taper point* (3.7), and *variable taper point* (3.8)

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

3.10
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* (3.12), and neither system is included in this document.

3.11
injection material
endodontic obturating material (3.1) supplied in non-point form, such as pellets, which become plastic after being warmed, for injection in a root canal system

3.12
injection system
device designed to dispense thermoplastic *injection material* (3.11) that has been warmed for obturation of a root canal system

Note 1 to entry: Injection system device is not within the scope of this document.

3.13
melt mass-flow rate
MFR
measure of flow through a capillary of a thermoplastic *injection material* (3.11) at a particular temperature, measured in grams per unit of time under a given force

Note 1 to entry: Thermoplastic materials may be placed into a root canal system using an *injection system* (3.12).

3.14
unit pack
smallest pack of *points* (3.3) distributed, containing one or more sizes of point or *carrier-based obturating device* (3.10)

3.15
radiopacity
property of materials to obstruct the passage of X-rays through the material, appearing grey or white on an exposed film or sensor image

4 Requirements

4.1 General

Calibrate all critical apparatus in accordance with ISO/IEC 17025.

4.2 Appearance

A point shall be smooth, uniform, and free from extraneous matter throughout its length. Test in accordance with 6.2.

4.3 Length

The overall length, l_{tot}, shall be not less than 28 mm, unless otherwise stated by the manufacturer. If some other length is stated, the point shall not be less than the stated length. Test in accordance with 6.3.

4.4 Designation and nominal size

The designations for the standard point, the greater taper point, the initial taper of a variable taper point, and the carrier-based obturating device shall be in the form of a five-digit numerical set consisting of two parts: ### XX, where ### corresponds to the nominal size and XX corresponds to the two significant figures of the taper percent. The nominal size designation shall be accompanied by its specified colour or its abbreviation.

The nominal size of the tip, *D*, except for auxiliary points, shall be in accordance with the numbering system shown in Tables 1 and 2.

EXAMPLE A point of nominal size 040 and 2 % taper is designated as 040 02 and has black colour coding.

4.5 Tolerances

The tolerances of the diameters of a standard point and a greater taper point for d_3 and d_{16} (see Figure 1) shall be:

— ±0,05 mm for polymeric points or carrier-based obturating devices of sizes 008 to 025;

— ±0,07 mm for polymeric points of carrier-based obturating devices of sizes 030 to 140.

The dimensions of standard points and greater taper points shall conform to Table 1 and Figure 1.

For a variable taper point of a given nominal size, the manufacturer shall state the initial taper and its length, that is, the first taper of the point nearest the tip. Reference locations (distance from the tip) within the initial taper shall be designated as l_x and l_y ($l_x < l_y$), and the corresponding diameters shall be defined as d_x and d_y.

The tolerance of the diameters shall be ±0,05 mm for sizes 008 to 025 and ±0,07 mm for sizes 030 to 140, and they shall be verified to be within tolerance. The initial taper length shall be stated as ±0,1 mm.

The tolerance of the diameters of an auxiliary point for d_3 and d_{16} shall be ±0,05 mm. The diameters d_3 and d_{16} of auxiliary points at l_3 and l_{16} shall be verified to be within tolerance.

Test in accordance with 6.4 and ISO 3630-1.

4.6 Colour-coding

The unit pack shall have a colour corresponding to the nominal size, *D*, in Table 1 for a standard point, greater taper point, variable taper point or carrier-based obturating device.

Colour-coding is optional on the individual points or carrier-based obturators; if used, the colours shall conform to Table 1.

If a manufacturer chooses to colour-code an auxiliary point, the colour shall be other than those in Table 1.

NOTE A colour code system is not defined for taper.

4.7 Taper

a) The taper of a standard point, a greater taper point and an auxiliary point shall be uniform for a minimum of 16 mm from the tip (see Figure 1), increasing at the taper designated by the manufacturer along their length.

b) Table 1 lists the dimensions for d_3 and d_{16} for standard taper points of nominal sizes from 008 to 140.