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Dentistry — Endodontic absorbent points

Médecine bucco-dentaire — Cônes absorbants utilisés en endodontie

Reference number
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ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Email: copyright@iso.org
Website: www.iso.org

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Contents

Page

Foreword

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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 document 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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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 second edition cancels and replaces the first edition (ISO 7551:1996), which has been technically revised.

The main changes are as follows:

— the format has been updated;

— absorbent points other than standard taper absorbent points have been added;

— Table 2 has been added for the dimensions of greater taper absorbent points;

— the sizes of the absorbent points specified in this document have been aligned with the sizes for obturating points specified in ISO 6877 and for instruments from the ISO 6360 series;

— the nomenclature of “numbering system” has been changed to “nominal size designation” of the tip;

— Figure 2 has been removed.

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.

Dentistry — Endodontic absorbent points

1 Scope

This document specifies the requirements and test methods for sterilized absorbent points used in endodontic procedures. Absorbent points are marketed sterilized or non-sterilized. The requirements apply to absorbent points which have been sterilized once in a manner approved by the manufacturer. This document specifies numerical systems and a colour-coding system for designating the sizes of absorbent points.

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 2). 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.

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 6360-1, *Dentistry — Number coding system for rotary instruments — Part 1: General characteristics*

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

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

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 terminology databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at https://www.electropedia.org/

3.1
absorbent point
elongated preformed cone or cylinder of a material suitable for absorption of liquids from a root canal, having a rounded, conical or blunt tip, and a neck that is tapered or cylindrical, or a combination of both

Note 1 to entry: The absorbent points may be used to apply a small quantity of a liquid disinfectant into the root canal for a short period.

3.2
nominal size designation
size of the tip, designated as *D*, measured in hundredths of a millimetre, indicated as "000"

3.3
taper
percentage increase in diameter along the length of the *absorbent point* (3.1) from the tip

EXAMPLE 02 taper represents a 2 % increase in diameter along the length of the absorbent point.

3.4
standard absorbent point
absorbent point (3.1) having a uniform 02 *taper* (3.3) over the first 16 mm from the tip

3.5
greater taper absorbent point
absorbent point (3.1) having a uniform *taper* (3.3) greater than 02 over the first 16 mm from the tip

3.6
variable taper absorbent point
absorbent point (3.1) having a *taper* (3.3) that varies over the first 16 mm from the tip

3.7
auxiliary absorbent point
absorbent point (3.1) excepting *standard absorbent point* (3.4), *greater taper absorbent point* (3.5) and *variable taper absorbent point* (3.6), not subject to *nominal size designation* (3.2) requirements

3.8
tip
distal end of an *absorbent point* (3.1) that is first inserted into a root canal

3.9
neck
portion of an *absorbent point* (3.1) for grasping while inserting the distal end in the root canal

3.10
unit pack
smallest pack of *absorbent points* (3.1) distributed, containing one or more sizes of absorbent points

4 Requirements

4.1 Appearance

An absorbent point shall be smooth and uniform in appearance throughout its length, free from extraneous matter and fibres projecting from the absorbent point. Test in accordance with 6.2.

4.2 Length

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

4.3 General

The designation for standard absorbent point, greater taper absorbent point, and variable taper absorbent point shall be in the form of a five-digit numerical set, having two parts: 000 XX, where 000 corresponds to the nominal size designation and XX corresponds to the two significant figures of the taper per cent. For example, a 2 % taper is designated as 02. The nominal size designation shall include the specified colour or its abbreviation.

4.4 Nominal size designation tolerances

The diameter tolerances of D, d_3 and d_{16} for standard absorbent points and greater taper absorbent points (see Figure 1) shall be:

— ±0,05 mm for absorbent point of sizes 008 to 060;

— ±0,07 mm for absorbent point of sizes 070 to 140.

For a variable taper absorbent point, two reference locations shall be used for the calculation of D within the first taper section of the absorbent point. The diameter tolerance shall be:

— ±0,05 mm for absorbent point of sizes 008 to 060;

— ±0,07 mm for absorbent point of sizes 070 to 140.

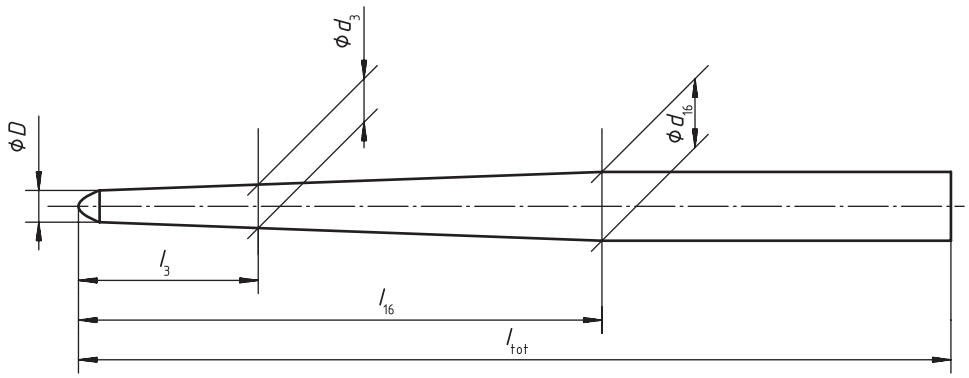
The diameter tolerance for an auxiliary absorbent point shall be ±0,05 mm for all auxiliary absorbent point sizes.

The dimensions of standard absorbent points and greater taper absorbent points shall comply with Table 1 and Figure 1. Within the dimensions specified, variations in shape and design are permitted. Testing for compliance shall be carried out in accordance with ISO 3630-1, and in accordance with 6.2 and 6.3. The dimensions of the absorbent points shall be as shown in Table 1.

For variable taper absorbent point, the manufacturer shall designate two reference locations to describe the taper section nearest the tip. The reference locations (length from the tip) shall be designated as l_x and l_y ($l_x < l_y$), and the corresponding diameters, d_x and d_y shall be measured. The diameter tolerance of a variable taper absorbent points at l_y, shall be ±0,05 mm.

The diameters at l_{16} or l_y (d_{16} or d_y) shall be verified to be within tolerance for absorbent points.

The tip of absorbent points shall be rounded, conical or blunt. The neck may be continuously tapered or cylindrical, or a combination of both.



Key

D	nominal size designation, mm	l_{tot}	overall length, mm
d_3	diameter, mm	l_3	length, mm
d_{16}	diameter, mm	l_{16}	length, mm

NOTE 1 Table 1 gives values of d_3 and d_{16} for each size of standard absorbent points only.

NOTE 2 The manufacturer is responsible for the exact shape of the tip.

Figure 1 — Diagrammatic representation of a standard or greater taper absorbent point

Table 1 — Nominal size designation, tip diameters and colour-coding for standard absorbent points

Dimensions in millimetres

Nominal size designation	D	d_3	d_{16}	Colour	Abbreviation
Tolerance ±0,05 mm					
008	0,08	0,14	0,40	grey	gry
010	0,10	0,16	0,42	purple	pur
015	0,15	0,21	0,47	white	wht
020	0,20	0,26	0,52	yellow	yel
025	0,25	0,31	0,57	red	red
030	0,30	0,36	0,62	blue	blu
035	0,35	0,41	0,67	green	grn
040	0,40	0,46	0,72	black	blk
045	0,45	0,51	0,77	white	wht
050	0,50	0,56	0,82	yellow	yel
055	0,55	0,61	0,87	red	red
060	0,60	0,66	0,92	blue	blu
Tolerance ±0,07 mm					
070	0,70	0,76	1,02	green	grn
080	0,80	0,86	1,12	black	blk
090	0,90	0,96	1,22	white	wht
100	1,00	1,06	1,32	yellow	yel
110	1,10	1,16	1,42	red	red
120	1,20	1,26	1,52	blue	blu
130	1,30	1,36	1,62	green	grn
140	1,40	1,46	1,72	black	blk

4.5 Colour-coding

The unit pack shall show that the colour corresponding to the nominal size designation, *D*, in Table 1 for a standard absorbent point, greater taper absorbent point and variable taper point absorbent point. Colour-coding is optional on the individual absorbent points; if used, the colours shall conform to Table 1. Colour-coding is optional for auxiliary absorbent points.

NOTE 1 Colour-coding of individual points can be confined to the neck.

NOTE 2 No colour-code system has been designated for taper.

4.6 Taper

The taper of the absorbent points shall be verified using measurements of the diameters at two distances from the tip of the point.

a) The taper of a standard absorbent point, greater taper absorbent point and an auxiliary absorbent 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) The tapers of the variable taper absorbent point shall be designated by the manufacturer. The length and taper of the section closest to the tip shall be stated by the manufacturer by providing the dimensions of l_x, l_y and the taper.

c) Test in accordance with 6.4, to calculate the taper and confirm the nominal size designation.

d) The nominal size designation of the tip, except for auxiliary absorbent points shall be in accordance with the numbering system shown in Table 1.

NOTE The tip size, shape and taper or shape of the auxiliary absorbent points is left to the discretion of the manufacturer.

4.7 Absorption

The absorbent point shall absorb liquid to a height of 10 mm or more above the liquid level when tested in accordance with 6.5.

4.8 Disintegration

The absorbent point shall not visually disintegrate or change shape while immersed in water at (37 ± 2) °C for (10 ± 1) min or during removal from the water with forceps. Test in accordance with 6.2.

5 Procurement of samples

Use one or more retail packages from the same batch, containing sufficient material to carry out the specified tests, plus an allowance for repeats, if necessary. Procure at least 20 absorbent points of any size or taper to be tested.

6 Measurement and test methods

6.1 Test conditions

Conduct all tests at (23 ± 2) °C and a relative humidity of (50 ± 20) %. Condition the absorbent points at this temperature and humidity for 1 h prior to testing.

If non-sterile, sterilize the absorbent points once, as recommended by the manufacturer, then precondition for at least 1 h in the test atmosphere.