INTERNATIONAL STANDARD

ISO 6877

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Dental root-canal obturating points

Cônes d'obturation dentaires pour canaux radiculaires

Reference number
ISO 6877:1995(E)

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.

Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

International Standard ISO 6877 was prepared by Technical Committee ISO/TC 106, *Dentistry*, Subcommittee SC 1, *Filling and restorative materials*.

Annexes A and B of this International Standard are for information only.

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Introduction

The sizes of the obturating points (cones) specified in this International Standard have been aligned with the corresponding sizes for root-canal instruments specified in ISO 3630-1[1].

Specific qualitative and quantitative requirements for freedom from biological hazard are not included in this International Standard but it is recommended that, in assessing possible biological or toxicological hazards, reference should be made to ISO/TR 7405:1984[2] or any more recent edition.

Manufacturers wishing to declare conformity with this International Standard should refer to ISO/IEC Guide 22[3].

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Dental root-canal obturating points

1 Scope

This International Standard specifies the dimensions and compositional requirements for prefabricated metallic or polymeric-based points or cones suitable for use in the obturation of the dental root-canal, but not for support of a coronal restoration. It also specifies numerical systems and a colour coding system for designating the sizes.

In addition to the requirements for the product itself, this International Standard also contains information about packaging the product. Although this information is important, it is not included as part of the requirements because no test methods are available (see annex A).

Dental root-canal obturating points are marketed sterilized or unsterilized. This International Standard covers the physical attributes expected of such products as supplied. Requirements for sterility are not included, and any claim that the product is sterile is the responsibility of the manufacturer (see clause A.2).

2 Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this International Standard. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent editions of the standards indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

ISO 209-1:1989, *Wrought aluminium and aluminium alloys — Chemical composition and form of products — Part 1: Chemical composition.*

ISO 3665:1976, *Photography — Intra-oral dental radiographic film — Specification.*

3 Definitions

For the purposes of this International Standard, the following definitions apply.

3.1 point: Complete prefabricated metallic or polymeric dental root-canal obturating point.

3.2 end: Broad end of the point.

3.3 tip: Narrow end of the point.

3.4 unit pack: Smallest pack of points distributed, containing one or more sizes of point.

3.5 standardized points: Points having uniform standardized tapers throughout all the ranges of sizes available.

3.6 taper-sized points: Points whose sizes are determined by the tip sizes and the tapers.

4 Requirements

4.1 Materials

4.1.1 Metal points

Throughout their tapered length, the points shall be smooth, uniform in composition, without surface pitting and free from inclusions or extraneous matter.

Testing shall be carried out in accordance with 6.2.

4.1.2 Polymeric-based points

Throughout their tapered length, the points shall appear uniform in composition and colour, smooth, with an uncracked surface and free from inclusions and extraneous matter.

Testing shall be carried out in accordance with 6.2.

4.2 Biocompatibility

See the Introduction for guidance on biocompatibility.

4.3 Length

Unless otherwise stated by the manufacturer, the overall length shall be not less than 28 mm. If some other length is stated, the points shall be within ± 2 mm of the stated length.

To check this, choose ten samples at random. If all ten samples pass the requirement, the product passes. If eight or fewer samples pass, the product fails. If nine samples pass, test five additional samples. When the five additional samples are tested all five shall comply for the product to pass.

Testing shall be carried out in accordance with 6.3.

4.4 Size designation and taper

The designation is a numerical indication of the projected tip diameter, measured in millimetres.

4.4.1 Standardized points

The size designation of standardized points shall be in accordance with the numbering system shown in table 1.

Samples tested shall meet the requirements of table 1.
Choose ten samples at random. If all ten samples pass the requirement, the product passes. If eight or fewer samples pass, the product fails. If nine samples pass, test five additional samples. When five additional samples are tested all five shall comply for the product to pass.

The taper of the points shall be uniform for a minimum of 16 mm from the tip as illustrated in figure 1 and as shown in table 1.

A tolerance of ± 0,02 mm for metallic points, ± 0,05 mm for polymeric points of sizes 010 to 025 and 0,07 mm for polymeric points of sizes 030 to 140 is permissible.

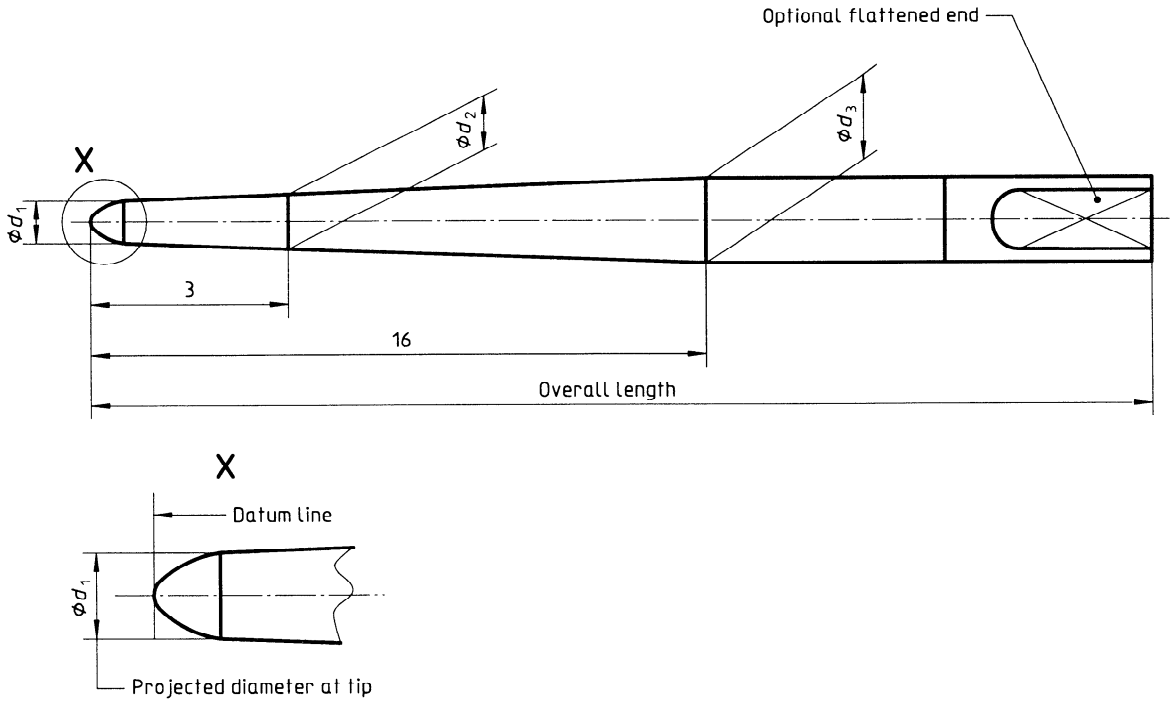
Testing shall be carried out in accordance with 6.4.

Table 1 — Size designation for standardized points

Dimensions in millimetres

Size designation	Diameter d_1 ref.	Diameter d_2	Diameter d_3
010	0,10	0,16	0,42
015	0,15	0,21	0,47
020	0,20	0,26	0,52
025	0,25	0,31	0,57
030	0,30	0,36	0,62
035	0,35	0,41	0,67
040	0,40	0,46	0,72
045	0,45	0,51	0,77
050	0,50	0,56	0,82
055	0,55	0,61	0,87
060	0,60	0,66	0,92
070	0,70	0,76	1,02
080	0,80	0,86	1,12
090	0,90	0,96	1,22
100	1,00	1,06	1,32
110	1,10	1,16	1,42
120	1,20	1,26	1,52
130	1,30	1,36	1,62
140	1,40	1,46	1,72

Dimensions in millimetres



NOTES

1 The diameters are expressed in hundredths of a millimetre. Table 1 gives the values of d_1, d_2 and d_3 for each size.

2 The taper is 0,02 mm per 1 mm, length, therefore, $d_3 = d_1 + 0{,}32$ mm.

3 In detail X, the exact shape of the tip is left to the option of the manufacturer.

Figure 1 — Diagrammatic representation of standardized points

4.4.2 Taper-sized points

The size designation of taper points shall be in accordance with the system shown in figure 2.

NOTE 1 The first three numbers of the system represent the projected tip diameter measured in hundredths of millimetres. The last two numbers indicate the taper.

Not less than eight out of ten measurements of each diameter of the ten samples tested shall meet the requirements of figure 2.

The taper of the points may vary with the size but the taper shall be uniform for at least the first 16 mm measured from the tip, or throughout its complete length if shorter than 16 mm.

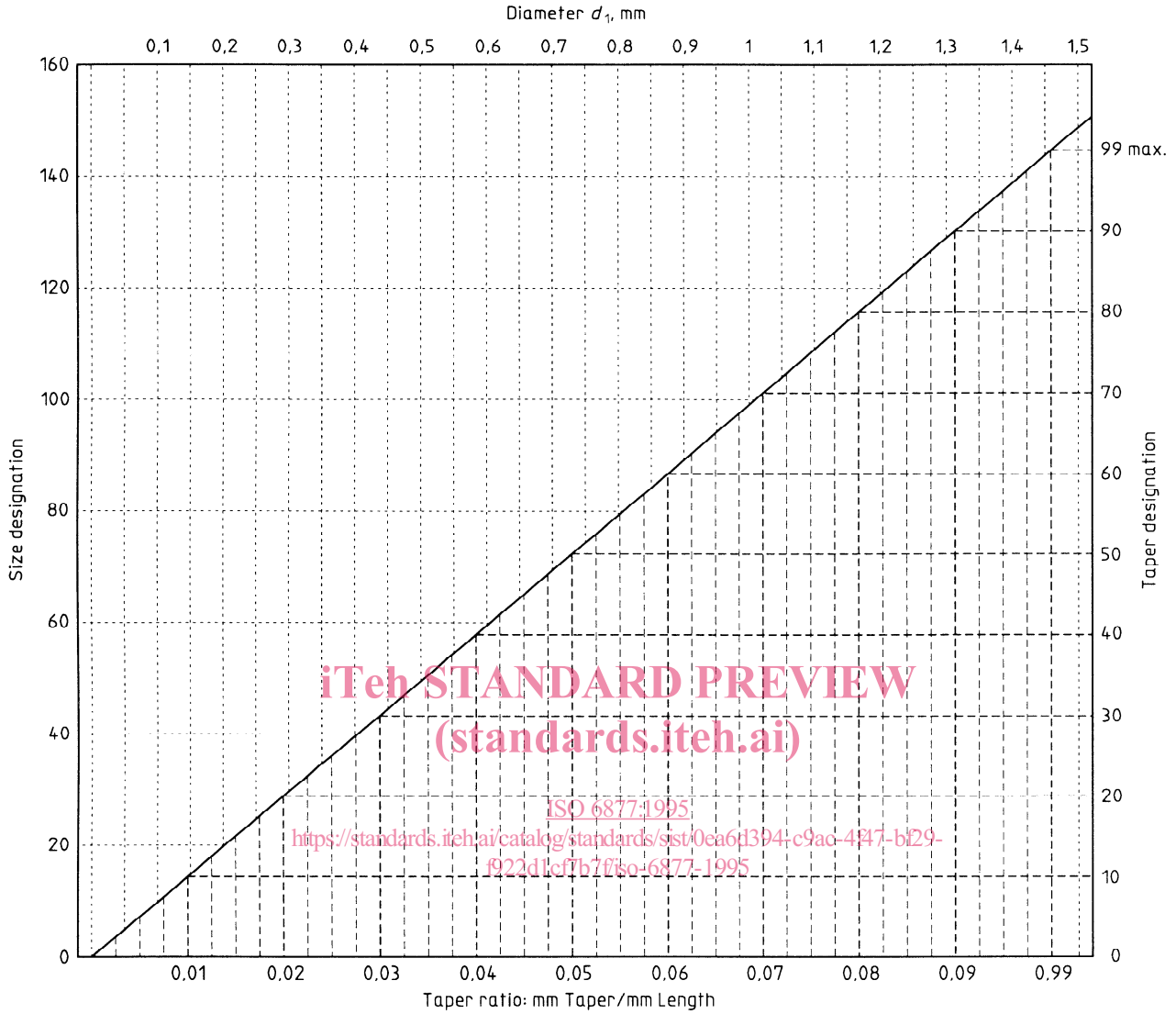
Testing shall be carried out in accordance with 6.4.

4.5 Brittleness

None of the five samples tested (see 6.5) shall show any sign of fracture.

Testing shall be carried out in accordance with 6.5.

Dimensions in millimetres



NOTES

1 d_1 is the projected diameter at the tip and the designation is a three-digit number in hundredths of millimetres.

2 The taper is given by the manufacturer and the designation is a two-digit number in thousands of millimetres.

3 A tolerance of ± 0,02 mm for metallic points and ± 0,05 mm for polymeric-based points applies to all calculated diameters.

4 The designation form is a five-digit number: "000XX" where "000" represents tip diameter (d_1) and "XX" represents taper.

5 To determine diameters to test taper

$d_2 = d_1 + 3 \times \text{taper}$

$d_3 = d_1 + 16 \times \text{taper}$

Example d_1 = 0,22

taper = 0,037

taper size = 02237

Figure 2 — Identification and dimensions of obturating point taper size

4.6 Radiopacity

The material from which polymeric points are made shall have a radiopacity equivalent to 6 mm thick aluminium.

Testing shall be carried out in accordance with 6.6.

4.7 Colour coding

The use of colour coding on the packaging or the individual points to indicate the nominal size designation is optional; if used the colours shall conform with table 2.

Table 2 — Colour code for size designation

Size designation	Colour code	Abbreviation
010	purple	pur
015	white	wh
020	yellow	yel
025	red	red
030	blue	blu
035	green	grn
040	black	blk
045	white	wh
050	yellow	yel
055	red	red
060	blue	blu
070	green	grn
080	black	blk
090	white	wh
100	yellow	yel
110	red	red
120	blue	blu
130	green	grn
140	black	blk

5 Procurement of samples

Samples for testing for compliance with this International Standard shall be procured on the open market. Sufficient numbers shall be obtained so that all tests can be carried out on at least five sizes of points from each manufacturer, or the maximum numbers of sizes manufactured if less than five.

6 Test methods

6.1 Test conditions

Conduct all tests at 23 °C ± 2 °C and a relative humidity of (50 ± 5) %. Condition the points at this temperature and humidity for 24 h prior to testing.

6.2 Visual examination

Examine under a bright light at normal visual acuity.

6.3 Length

Test ten specimens selected at random.

Place the point on a scale rule marked in 0,5 mm graduations and measure the overall length to the nearest 0,5 mm.

6.4 Size designation

6.4.1 Equipment

Use a shadowgraph or other suitable non-compression testing apparatus calibrated to an accuracy of 0,001 mm.

6.4.2 Method

Visually examine the shadow cast by the point and confirm that at least the first 16 mm is evenly tapered. Measure and record the diameter of the ten points at distances 3 mm (d_2) and 16 mm (d_3) from the tip.

6.4.3 Calculation

Calculate the taper of taper points using the system shown in figure 3. Determine the size designation using the system shown in figure 2.