INTERNATIONAL STANDARD

ISO 6877

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Dentistry — Root-canal obturating points

Art dentaire — Cônes d'obturation dentaires pour canaux radiculaires

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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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. 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.

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.

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

This second edition cancels and replaces the first edition (ISO 6877:1995), which has been technically revised and a typographical error relating to the size of the specimen required to measure the radio-opacity has been corrected.

Introduction

The working group, who have prepared this International Standard have addressed the question of cadmium in polytransisoprene (gutta-percha) points and on the data obtained have concluded that the amount of cadmium in polytransisoprene (gutta-percha) points is most likely not intentionally added either as an aesthetic (colour) agent for the enhancement of the chemical or physical integrity of the points. It has likely resulted from the contamination of the chemical components in the manufacturing process. Based on the data obtained this trace amount of cadmium has no health implications.

Dentistry — Root-canal obturating points

1 Scope

This International Standard specifies the dimensions and compositional requirements for prefabricated metal or polymeric 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.

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 8 f)].

2 Normative references

The following referenced documents are indispensable for the application 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 3665, *Photography — Intra-oral dental radiographic film — Specification*

ISO 15223, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1
point
prefabricated metal or polymeric material for use in the obturation of the root-canal

NOTE For the purposes of this International Standard the term “root-canal obturating point” is abbreviated as “point”.

3.2
unit pack
smallest pack of points distributed, containing one or more sizes of point

3.3
standard taper point
point having uniform 2 % taper throughout all the ranges of sizes available

3.4
greater taper point
point having a taper greater than 2 %

3.5
size designation
numerical indication, “000”, of the projected tip diameter, measured in hundredths of a millimetre

4 Requirements

4.1 Points

Throughout their tapered length, the points shall be smooth and uniform in appearance.

Testing shall be carried out in accordance with 6.2.

4.2 Biocompatibility

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 10993-1 and ISO 7405.

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 not be less than the stated length.

Testing shall be carried out in accordance with 6.3.

4.4 Size designation and taper

4.4.1 General

4.4.1.1 The designation shall be in the form of a five-digit numerical set, having two parts:

000 XX

where

000 corresponds to the size designation;

XX corresponds to the 2 significant figures of the taper.

4.4.1.2 For all types of points a diameter 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.

4.4.2 Standard taper points

The size designation of standardized points shall be in accordance with the numbering system shown in Table 1. The taper of the points shall be uniform for a minimum of 16 mm from the tip as illustrated in Figure 1.

Testing shall be carried out in accordance with 6.4.2.1 and the taper calculated as shown in 6.4.3.

4.4.3 Greater taper points

Testing shall be in accordance with 6.4.2.2.The taper of the points shall be uniform up to 1 mm from the end of the taper. The calculated taper shall be within ± 10 % of the stated tapers. This is calculated as shown in 6.4.3.

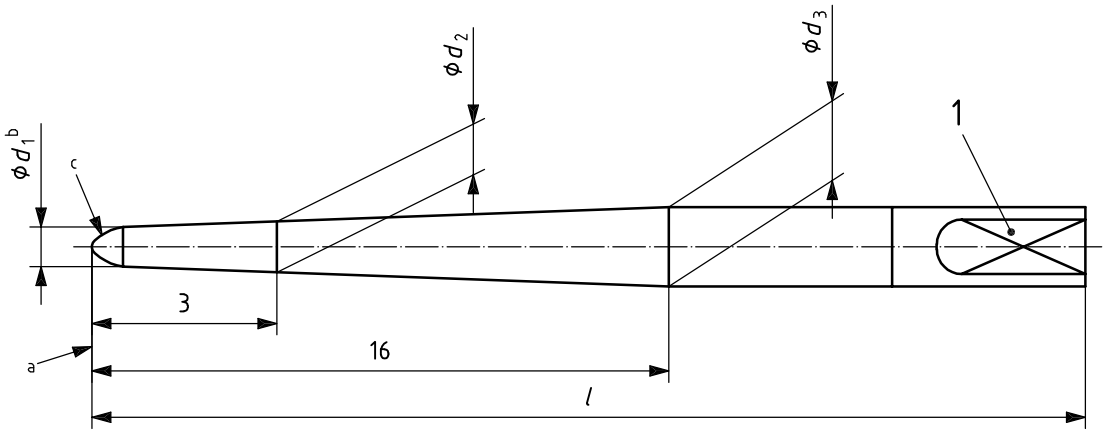
The tip diameter and the taper or tapers of the points shall be designated by the manufacturer (8.c).

Table 1 — Size designation for standardized points

Dimensions in millimetres

Size designation	Diameter d_1	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



Key

1 optional flattened end

l overall length

NOTE 1 The diameters d_1, d_2 and d_3 are expressed in hundredths of a millimetre.

NOTE 2 Table 1 gives values of d_1, d_2 and d_3 for each size.

NOTE 3 The taper is 0,02 mm per 1 mm length, therefore $d_3 = d_1 + 0{,}32$ mm.

a Datum line.

b Projected diameter d_1 at tip.

c The exact shape of the tip is left to the option of the manufacturer.

Figure 1 — Diagrammatic representation of standard points

4.5 Physical integrity

None of the five samples tested shall show any sign of fracture when tested in accordance with 6.5.2.

4.6 Radio-opacity

The material from which polymeric points are made shall have a radio-opacity equivalent to at least 6 mm aluminium when tested in accordance with 6.6.2.

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 to Table 2. With regard to taper identification the colour scheme shall be light to dark to indicate the increasing taper of the various points, e.g. a brand may have tapers of 2 %, 4 %, 6 %, 8 %, and 10 % and the colours would be consecutively white, yellow, red, blue and green.

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 ± 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

Choose ten points at random. Visual examination without magnification shall be used to determine the characteristics of the points as specified in 4.1 and Clause 7. The observer shall be of normal visual acuity.

6.3 Length

Choose ten points of any size and taper 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. If all ten points pass the requirement, the product passes. If eight or fewer points pass, the product fails. If nine points pass, test five additional points. When the five additional points are tested all five shall comply for the product to pass.

6.4 Size designation

6.4.1 Equipment

An optical comparator calibrated to an accuracy of 0,005 mm to measure polymeric points. Metallic points can be measured with any type of techniques unless the precision of the equipment reaches 0,001 mm.

6.4.2 Method

6.4.2.1 Standard taper points

Choose ten points at random.

Visually examine the shadow cast by the point and confirm that the stated diameter size meets the calculated d_1 dimension using the T value as shown in 6.4.3 and Equation (1):

$$d_1 = a - L_a T \tag{1}$$

where L_a is the distance, in millimetres, from the tip to the measured diameter a.

Confirm that there is an evenly tapered portion for a minimum of 16 mm from the tip. Measure and record the diameter of the ten points at distances of 3 mm (d_2) and 16 mm (d_3) from the tip.

If all ten points pass the requirement, the product passes. If eight or fewer points pass, the product fails. If nine points pass, test five additional points. When five additional points are tested all five shall comply for the product to pass.

6.4.2.2 Greater taper points

Choose ten points at random.

Visually examine the shadow cast by the point and confirm that the stated diameter size meets the calculated d_1 dimension using the T value as shown in 6.4.3 and Equation (1). Confirm that there is an evenly tapered portion up to 1 mm from the end of the taper. Measure and record the diameter of the ten points at two distances L_a mm (a) and L_b mm (b) from the tip.

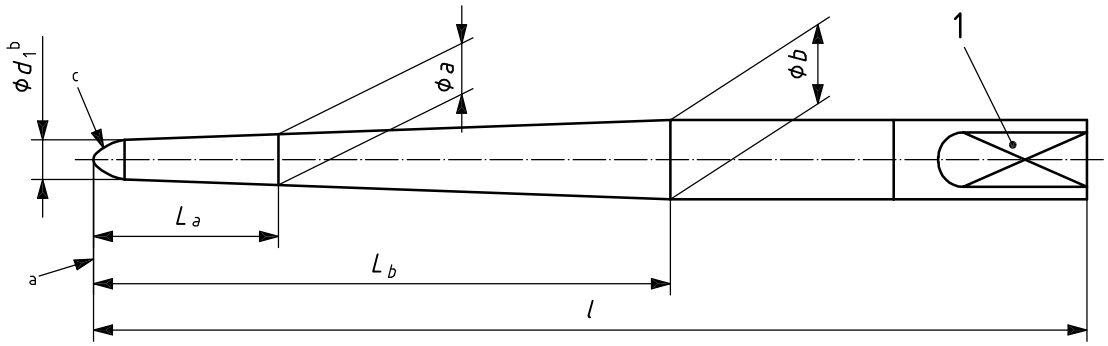
If all ten points pass the requirement, the product passes. If eight or fewer points pass, the product fails. If nine points pass, test five additional points. When five additional points are tested all five shall comply for the product to pass.

6.4.3 Taper calculation

The taper (T) is determined by calculation using actual measurements from 6.4.2.1 and 6.4.2.2 Taper is the difference between measured diameters divided by the distance between them. Taper tolerance is controlled solely by the tolerance of the specified diameters and it varies with size. From the dimensions indicated in Figure 2 calculate the taper using Equation (2):

$$T = \frac{b - a}{L_b - L_a} \tag{2}$$

where a and b are the diameters in millimetres at distances L_a and L_b, respectively (see Figure 2).



Key

1 optional flattened end

l overall length

a Datum line passing through tip.

b Projected diameter d_1 at tip.

Figure 2 — Taper calculation

6.5 Physical integrity

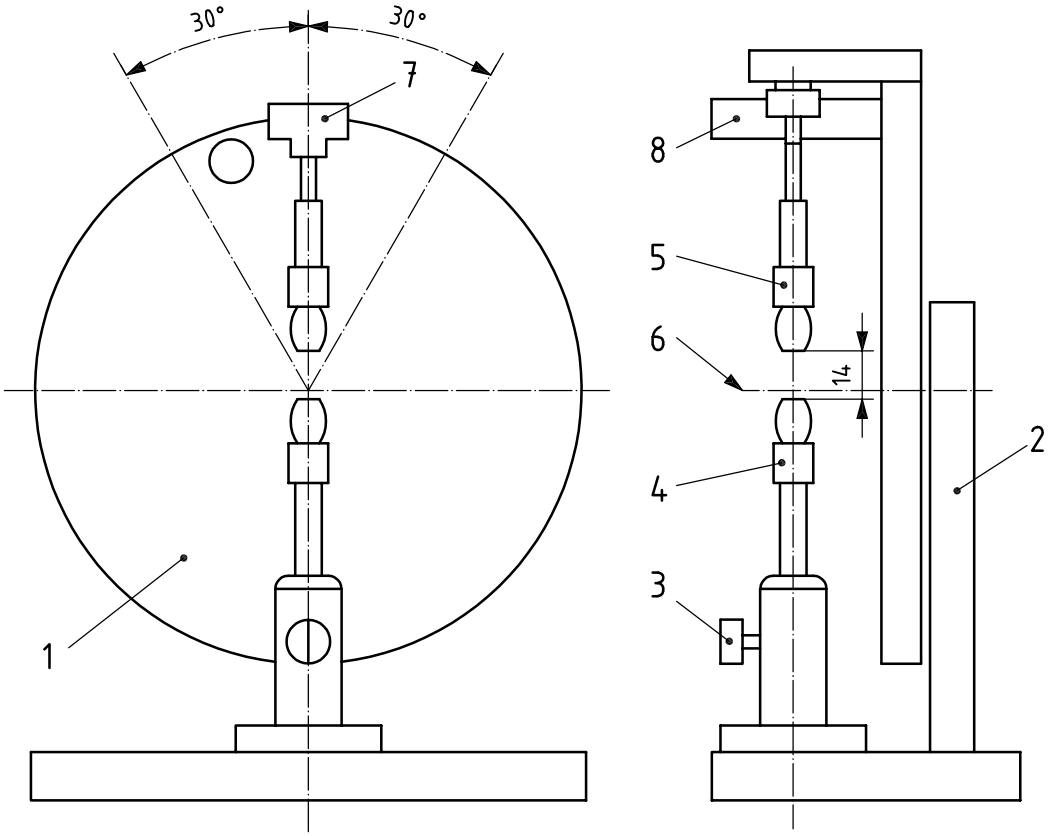
6.5.1 Apparatus

See Figure 3.

6.5.2 Procedure

Test five samples using the apparatus in Figure 3 or equivalent apparatus. Grip the first 5 mm of the tip of a point in the stationary pin vice (4 in Figure 3) taking care to minimize damage to the point. Adjust the point so that the junction of the point and the pin vice (4) is at the starting point of the test. Clamp the free end of the point in the moveable pin vice (5) so that the distance between the junctions of the point pin vices (4) and (5) is 14 mm. Rotate the disc (1) anticlockwise through 30°, then clockwise through 60° and finally return anticlockwise to the starting point of the test. Complete the bending cycle in approximately 2 s. Repeat the bending cycle four times for metallic points and 20 times for polymeric points. Report whether any of the five points fractured.

Dimensions in millimetres



Key

1 rotating disc
2 bearing support for rotating disc (1)
3 stationary pin vice support with lock
4 stationary pin vice
5 movable pin vice with vertical adjustment
6 centre of rotation
7 suspension point for pin vice (5)
8 handle for disc rotation

Figure 3 — Apparatus for physical integrity testing

6.6 Radio-opacity for polymeric points

6.6.1 Apparatus

6.6.1.1 Stainless steel ring mould, with an internal diameter of 10 mm and a height of 1 mm with covers made of plastics film or other radiolucent material.

6.6.1.2 Single phase dental X-ray unit, with total filtration of 1,5 mm of aluminium, capable of operation at (65 ± 5) kV with suitable accessories.

6.6.1.3 Dental X-ray occlusal film, complying with ISO 3665, developing solution and fixer.

6.6.1.4 Aluminium step wedge, purity of at least a mass fraction of 98 % with less than a mass fraction of 0,1 % copper and less than a mass fraction of 1,0 % iron present, 50 mm × 20 mm having a thickness range of 1 mm to 10 mm in steps of 1 mm or a small aluminium plate of 6 mm thickness.

NOTE Digital radiography can be used to produce equivalent results to the test method above.

6.6.1.5 Photographic densitometer.

6.6.2 Procedure

Take sufficient points of each size and soften, mix and compress them into the ring mould to make a disc of 1 mm uniform thickness. Position the specimen in the centre of the X-ray film adjacent to the aluminium step wedge or plate.

Irradiate the specimen, aluminium step wedge or plate and film with X-rays at a target film distance of 300 mm for such a time that, after processing, the region of the film beside the specimen and standard has a photographic density between 1,5 and 2,0.

After processing and drying the film, compare the density of the image of the specimen with that of the aluminium standard using the densitometer. Ensure that measurements with the densitometer are made in the lightest area of the image.

NOTE Voids or thin areas in the sample preparation are difficult to avoid and will be obvious in the developed radiographic film.

6.6.3 Interpretation of the results

Compare the density of the specimens with the density of the images of either the step wedge or the aluminium plate. In order to pass the test, the results of all three determinations shall meet the requirement in 4.6.

7 Packaging

Points shall be packaged in unit packs that protect the contents from damage and, where sterility is claimed [see 8.f)], maintain sterility during handling. Unit packs containing more than one size of point should not permit the various sizes to be readily or unknowingly mixed.

8 Marking and information to be supplied by manufacturer

The manufacturer shall provide at least the following information on, or with, each unit pack:

a) the identification of the material and the product, e.g. polytransisoprene (gutta-percha) root-canal obturating point;

b) the manufacturer's and/or supplier's name and address;

c) the size designation and taper (see 4.4);

d) the minimum number of points in the unit pack;

e) the nominal length of the points;

f) the word "STERILE", if the manufacturer claims that the contents of the unopened pack are sterile. In addition, on bulk packs of points marked "STERILE", a statement to the effect that sterility is not guaranteed after the pack is opened (A claim by the manufacturer that the contents of the unopened pack are sterile is the responsibility of the manufacturer. This International Standard does not specify requirements or test methods for sterility; reference should be made to any national requirements that may exist. When no national requirements exist, reference should be made to the United States Pharmacopoeia (USP) or the British Pharmacopoeia (BP). Standards on methods of validating sterilisation processes, produced by ISO/TC 198 *Sterilization of health care products*, are also available: ISO 11134, ISO 11135, ISO 11137, ISO 11737-2, ISO 13683, ISO 14160, ISO 14937);

g) the lot number;

h) if appropriate the “use by date” (expiry date) expressed in accordance with ISO 8601;

i) the recommended storage conditions;

j) an indication of the principal components;

k) if symbols are used on the package they shall be in accordance with ISO 15223.

NOTE Additional information may be included at the discretion of the manufacturer or as required by legislation.

Bibliography

[1] ISO 3630-1, *Dental root-canal instruments — Part 1: Files, reamers, barbed broaches, rasps, paste carriers, explorers and cotton broaches*

[2] ISO 7405, *Dentistry — Preclinical evaluation of biocompatibility of medical devices used in dentistry — Test methods for dental materials*

[3] ISO 8601, *Data elements and interchange formats — Information interchange — Representation of dates and times*

[4] ISO 10993-1, *Biological evaluation of medical devices — Part 1: Evaluation and testing*

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