INTERNATIONAL STANDARD

ISO 6877

Second edition
2006-04-01

Dentistry — Root-canal obturating points

Art dentaire — Cônes d'obturation dentaires pour canaux radiculaires

Reference number
ISO 6877:2006(E)

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Published in Switzerland

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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