INTERNATIONAL STANDARD

ISO 6876

Second edition
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Dental root canal sealing materials

Produits dentaires pour le scellement des 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 3.

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 International Standard may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

International Standard ISO 6876 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 6876:1986), which has been technically revised.

Introduction

This International Standard was first published in 1986 (ISO 6876:1986). There were significant differences between ISO 6876 and the United States specification ANSI/ADA Specification No 57 (1983). In addition test houses had reported difficulties with some of the test procedures in the International Standard. In an attempt to harmonize the ISO and ANSI/ADA Standards and improve the test procedures, a planned programme of revision was commenced in 1991. The changes in this second edition are as follows:

The classification has been removed.

Non-setting materials are no longer covered by this International Standard.

The test procedures for flow, working time and setting time have been altered.

A new test to determine dimensional change following setting has been added.

For dental root canal sealers which require moisture to facilitate setting, a new test procedure to simulate the setting mode of the sealers in the root canal system has been included.

Dental root canal sealing materials

1 Scope

This International Standard specifies requirements and test methods for root canal sealing materials which set with and without the assistance of moisture and are used for permanent obturation of the root canal, with or without the aid of obturating points. It is applicable only to sealers intended for orthograde use, i.e. a root filling placed from the coronal aspect of a tooth.

2 Normative references

The following normative documents contain provisions which, through reference in this text, constitute provisions of this International Standard. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent editions of the normative documents indicated below. For undated references, the latest edition of the normative document referred to applies. Members of ISO and IEC maintain registers of currently valid International Standards.

ISO 3665:1996, *Photography — Intra-oral dental radiographic film — Specification*.

ISO 3696:1987, *Water for analytical laboratory use — Specification and test methods*.

3 Terms and definitions

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

3.1
mixing time
that part of the working time specified or required in order to obtain a satisfactory mix of the components

3.2
working time
period of time, measured from the start of mixing, during which it is possible to manipulate the dental sealer without an adverse effect on its properties

3.3
setting time
period of time measured from the end of mixing until the sealer has set according to the criteria and conditions described in 7.4

NOTE For the purposes of this International Standard, the setting time is determined from the end of mixing because of the wide variation in mixing times.

4 Requirements

4.1 Components

The components of the sealer shall be visually free from extraneous matter when tested according to 7.1.

The components shall, when used in accordance with the manufacturer's instructions, form a sealer which complies with the requirements of this International Standard.

4.2 Microbiological hazard

Specific qualitative and quantitative requirements for freedom from biological hazards are not included in this International Standard but it is recommended that in assessing possible biological or toxicological hazards reference be made to ISO 10993-1 and ISO 7405.

Verification for a claim of sterility is the responsibility of the manufacturer. This International Standard does not specify requirements or test methods for sterility and it is recommended that reference be made to any national requirements that may exist. When no national requirements exist, reference should be made to the United States, European or Japanese Pharmacopoeia.

If a therapeutic effect is claimed, the purity and sterility of the constituents shall comply with the relevant pharmacopoeia applicable in the country in which the sealer is marketed, or with such national regulations as are applicable to purity and sterility of pharmaceutical products.

4.3 Physical and mechanical properties

4.3.1 Flow

When determined in accordance with 7.2, each disc shall have a diameter not less than 20 mm.

4.3.2 Working time

The minimum working time of a sealer, when determined by the method described in 7.3, shall be not less than 90 % of the working time stated by the manufacturer.

This test applies only to sealers having a working time claimed by the manufacturer to be less than 30 min.

4.3.3 Setting time

For sealers having a setting time of less than 30 min, the setting time of a sealer, when determined by the method described in 7.4, shall be no greater than 110 % of that stated by the manufacturer.

For sealers having a setting time greater than 30 min, and up to 72 h, for which the manufacturer quotes a time range, the setting time measured shall be within the range stated by the manufacturer.

4.3.4 Film thickness

Sealers shall have a film thickness of not more than 50 μm when tested in accordance with 7.5.

4.3.5 Dimensional change following setting

The mean dimensional change in length of the sealer, measured in accordance with the method set out in 7.6, shall not exceed 1,0 % in shrinkage or 0,1 % in expansion.

4.3.6 Solubility

The solubility of the set sealer, when determined in accordance with 7.7, shall not exceed 3 % mass fraction.

The specimens shall show no evidence of disintegration when examined visually.

4.3.7 Radiopacity

The sealer, when tested in accordance with 7.8, shall have a radiopacity equivalent to not less than 3 mm of aluminium.

5 Sampling

The sample shall consist of one or more retail packages from the same batch, containing sufficient sealer to carry out the specified tests, plus an allowance for repeats, if necessary.

6 Test conditions

Unless otherwise stated by the manufacturer, all tests shall be carried out at (23 ± 2) °C and at a relative humidity of (50 ± 5) %. The components shall be conditioned at this temperature and relative humidity for at least 24 h prior to testing.

7 Test methods

7.1 Extraneous matter

When examined under normal visual acuity, the components of the sealer shall show no evidence of any extraneous matter.

7.2 Flow

7.2.1 Apparatus

7.2.1.1 Two glass plates, at least 40 mm × 40 mm and approximately 5 mm thick.

NOTE The mass of one glass plate is approximately 20 g.

7.2.1.2 Weight, of mass approximately 100 g.

7.2.1.3 Graduated syringe, designed to deliver $(0{,}05 \pm 0{,}005)$ ml of mixed sealer.

7.2.2 Procedure

Manipulate the components of the sealer in accordance with the manufacturer's instructions.

Place $(0{,}05 \pm 0{,}005)$ ml of sealer on the centre of one of the glass plates (7.2.1.1) using the graduated syringe (7.2.1.3). At (180 ± 5) s after the commencement of mixing, place the second glass plate centrally on top of the sealer, followed by the weight (7.2.1.2) to make a total mass on the plate of (120 ± 2) g. Ten minutes after the commencement of mixing remove the weight and measure the maximum and minimum diameters of the compressed disc of sealer. If the diameters agree to within 1 mm, record the mean of the two diameters. If the two diameters are not within 1 mm, repeat the test.

7.2.3 Treatment of results

7.2.3.1 Carry out three determinations. The result of each determination shall comply with the requirement in 4.3.1.

7.2.3.2 In addition for the purposes of 7.3.3, calculate the mean value of the three specimens to the nearest millimetre.