
Dentistry — Root canal sealing materials

*Médecine bucco-dentaire — Matériaux de 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 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 6876 was prepared by Technical Committee ISO/TC 106, *Dentistry*, Subcommittee SC 1, *Filling and restorative materials*.

This third edition cancels and replaces the second edition (ISO 6876:2001), which has been technically revised. The main modifications are the following:

- the test procedures for flow, working time and solubility have been revised and a new limit value has been set;
- the test to determine dimensional change following setting has been removed.

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Introduction

Following the publication of the second edition of this International Standard (ISO 6876:2001), test houses reported difficulties with some of the test procedures. In an attempt to improve the test procedures, a planned programme of revision began in 2006. The following should be taken into account when using this International Standard.

- 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 are expected to 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.
- Specific qualitative and quantitative test methods for demonstrating freedom from unacceptable biological risks are not included in this International Standard but it is recommended that, for the assessment of such biological risks, reference be made to ISO 10993-1 and ISO 7405.

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Dentistry — Root canal sealing materials

1 Scope

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

Specific qualitative and quantitative test methods for demonstrating freedom from unacceptable biological risks are not included in this International Standard but it is recommended that, for the assessment of such biological risks, reference be made to ISO 10993-1 and ISO 7405.

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 1942, *Dentistry — Vocabulary*

ISO 3665, *Photography — Intra-oral dental radiographic film and film packets — Manufacturer specifications*

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

ISO 6873, *Dentistry — Gypsum products* [ISO 6876:2012](#)

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

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 1942 and the following apply.

3.1

root canal sealing material

endodontic material intended to permanently seal the root canal filling material into the cavities previously occupied by the removed pulp

3.2

root canal filling material

endodontic material intended to permanently obturate the cavities previously occupied by the pulp

3.3

mixing time

that part of the working time required in order to obtain a satisfactory mix of the components

3.4

working time

period of time, measured from the start of mixing, during which it is possible to manipulate the root canal sealer without any adverse effect on its properties

3.5 setting time
period of time measured from the end of mixing until the sealer has set, according to the criteria and conditions described in 5.4

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 free from extraneous matter when tested according to 5.1.

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 the determination of microbiological growth are not included in this International Standard.

4.3 Physical and mechanical properties

4.3.1 Flow

When determined in accordance with 5.2, each disc shall have a diameter of not less than 17 mm.

4.3.2 Working time

For sealers that are claimed by the manufacturer to have a stated working time of up to 30 min, the diameter of the flow test, determined in accordance with 5.2, shall be not less than 17 mm 15 s before the end of the stated working time.

4.3.3 Setting time

For sealers that are claimed by the manufacturer to have a setting time of up to 30 min, the setting time shall be no more than 10 % longer than that claimed by the manufacturer, when determined in accordance with 5.4.

For sealers that are claimed by the manufacturer to have a setting time of more than 30 min and up to 72 h, and for which the manufacturer quotes a time range, the setting time measured shall be within the range stated by the manufacturer, when determined in accordance with 5.4.

4.3.4 Film thickness

Sealers shall have a film thickness of not more than 50 µm when tested in accordance with 5.5.

4.3.5 Solubility and disintegration

The solubility of the set sealer, when determined in accordance with 5.6, shall not exceed 3,0 % by mass.

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

4.3.6 Radio-opacity

The sealer, when tested in accordance with 5.7, shall have a radio-opacity equivalent to not less than 3 mm of aluminium.

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4.4 Sampling

Use 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.

4.5 Test conditions

Unless otherwise stated by the manufacturer, carry out all tests at (23 ± 2) °C and at (50 ± 5) % RH. Condition all components at this temperature and relative humidity for at least 24 h prior to testing.

4.6 Preparation of material for testing

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

5 Test methods

5.1 Extraneous matter

Examine under normal visual acuity.

5.2 Flow

5.2.1 Apparatus

5.2.1.1 Two glass plates, at least 40 mm x 40 mm and approximately 5 mm thick, and with a mass of approximately 20 g.

5.2.1.2 A weight with a mass of approximately 100 g.

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

5.2.2 Procedure

Place $(0,05 \pm 0,005)$ ml of sealer on the centre of one of the glass plates using the graduated syringe.

NOTE An alternative method is to use the mass of the sample, having first determined the density, and use the formula:

$$m = V \times d$$

where

m is mass;

d is density;

V is volume.

At (180 ± 5) s after the commencement of mixing, place the second glass plate centrally on top of the sealer and an additional mass on the plate to total (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 are within 1 mm of each other, record the mean of the two diameters. If the two diameters are not within 1 mm of each other, repeat the test.

5.2.3 Calculation and expression of results

Carry out three determinations and calculate the mean value. Round the result to the nearest integer in millimetres and record it as the flow value.

5.3 Working time

In order to determine the working time for sealers whose claimed working time is up to 30 min, use the procedure set out in 5.2 with the exception that the load is applied 15 s before the end of the manufacturer's stated working time.

5.4 Setting time

5.4.1 Apparatus

5.4.1.1 Cabinet, capable of being maintained at $(37 \pm 1) ^\circ\text{C}$ and not less than 95 % RH.

5.4.1.2 Gilmore-type metric indenter, having a mass of $(100,0 \pm 0,5)$ g and a flat end of diameter $(2,0 \pm 0,1)$ mm. The needle tip shall be cylindrical over a distance of at least 5 mm. The end of the needle shall be plane and at right angles to the longitudinal axis.

5.4.1.3 Moulds

- a) For materials that do not require moisture for setting, a stainless steel ring mould, having an internal diameter of 10 mm and a height of 2 mm.
- b) For materials that do require moisture for setting, a gypsum mould (complying with Type 2 of ISO 6873) incorporating a cavity with a diameter of 10 mm and a height of 1 mm.

NOTE This mould can be made by placing a plastics disc ($D = 10$ mm, $h = 1$ mm) on the bottom of a plastics cup (1 ml to 2 ml capacity) and filling the cup with freshly mixed gypsum. After the gypsum has set, the cup and disc are removed.

5.4.1.4 Metal block, with dimensions of at least 8 mm \times 20 mm \times 10 mm, conditioned at $(37 \pm 1) ^\circ\text{C}$ in the cabinet for at least 1 h.

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5.4.1.5 Flat glass plate, approximately 1 mm thick.

NOTE A microscope slide is suitable.

5.4.2 Sample preparation

- a) For materials not requiring moisture for setting, place the mould on the glass plate and fill it to a level surface with sealer. After (120 ± 10) s from the end of mixing, place this assembly on the metal block in the cabinet.
- b) For materials that do require moisture for setting, store the gypsum mould at $(37 \pm 1) ^\circ\text{C}$ and 95 % RH for 24 h. After this time, fill the cavity in the preconditioned gypsum mould with the mixed sealer and place this assembly in the cabinet.

5.4.3 Procedure

When the setting time stated by the manufacturer approaches, carefully lower the Gilmore-type indenter vertically on to the horizontal surface of the sealer. If an indentation is visible, raise the needle, clean the needle tip and lower the needle to a new position on the surface of the sealer. Repeat this operation until indentations cease to be visible. Record the time, from the end of mixing, at which this occurs.

5.4.4 Calculation and expression of results

Carry out three determinations and calculate the mean value. Record this as the setting time.

5.5 Film thickness

5.5.1 Apparatus

5.5.1.1 Two optically flat square or circular glass plates, having a minimum uniform thickness of 5 mm and a contact surface area of approximately (200 ± 25) mm².

5.5.1.2 Loading device, to apply a force of (150 ± 3) N.

5.5.1.3 Micrometer or similar measuring instrument, accurate to 1 μ m.

5.5.2 Procedure

Measure the combined thickness of the two glass plates in contact to an accuracy of 1 μ m. Deposit a portion of sealer onto the centre of one of the glass plates. Place the other glass plate centrally on the sealer. After (180 ± 10) s from the start of mixing, carefully apply, by means of the loading device, a load of 150 N vertically on the top plate. Ensure that the sealer completely fills the area between the glass plates. After 10 min from the start of mixing, measure the combined thicknesses of the two glass plates and the film of sealer using the micrometer.

5.5.3 Calculation and expression of results

Calculate the thickness of the film by determining the difference in the thickness of the plates with and without sealer.

Carry out three determinations, calculate the mean value and record it, to the nearest 5 μ m, as the film thickness.

5.6 Solubility

5.6.1 Apparatus and materials

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5.6.1.1 Two split ring moulds, having an internal diameter of (20 ± 1) mm and a height of $(1,5 \pm 0,1)$ mm, made of stainless steel or other materials compatible with the samples (such as polytetrafluoroethylene for resin-based sealers).

5.6.1.2 Four flat glass plates, having dimensions larger than the maximum dimensions of the split ring moulds.

5.6.1.3 Plastics sheets impervious to water, such as polyethylene plastic, (50 ± 30) μ m thick.

5.6.1.4 Two shallow dishes A and B, Petri or other suitable glass or porcelain, having a diameter of approximately 90 mm, with a minimum volume of 90 ml. The mass of dish B shall be known to the nearest 0,001 g.

5.6.1.5 Cabinet, capable of being maintained at (37 ± 1) °C and not less than 95 % RH.

5.6.1.6 Water, complying with grade 3 of ISO 3696.

5.6.1.7 Desiccator, containing phosphorus pentoxide or another suitable desiccant.

5.6.1.8 Heating oven, capable of being maintained at a temperature of (110 ± 2) °C.

5.6.2 Sample preparation

Prepare three specimens in accordance with one of the following methods.

a) For materials that do not require water for setting, place the mould (5.6.1.1) on a glass plate (5.6.1.2) and fill to slight excess with mixed sealer. Press another glass plate faced with a plastics sheet (5.6.1.3) on top