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Dentistry — Zinc oxide/eugenol and zinc oxide/non-eugenol cements

Art dentaire — Ciments dentaires à base d'oxyde de zinc-eugénol et à base d'oxyde de zinc sans eugénol

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Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
E-mail copyright@iso.org
Web www.iso.org

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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 3107 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 3107:1988), which has been technically revised, including extensive revision and simplification of the classification system, and removal of the disintegration limit as a requirement for temporary cements.

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Introduction

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 be made to ISO 10993-1 and ISO 7405.

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Dentistry — Zinc oxide/eugenol and zinc oxide/non-eugenol cements

1 Scope

This International Standard specifies the requirements and performance test methods for non-water-based zinc oxide/eugenol cements suitable for use in restorative dentistry for temporary cementation, for permanent cementation, for cavity liners and bases and as temporary restorations.

This International Standard is also applicable to non-eugenol cements containing zinc oxide and aromatic oils suitable for temporary cementation.

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.

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ISO 2590, *General method for the determination of arsenic — Silver diethyldithiocarbamate photometric method*

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

ISO 3107:2004

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

3 Classification

For the purposes of this document, the following classification for cements is used, based on their intended use:

a) Type I: for temporary cementation;

   1) Class 1: setting cement;

   2) Class 2: non-setting cement.

b) Type II: for permanent cementation;

c) Type III: for bases and temporary restorations;

d) Type IV: for cavity liners.

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4 Requirements

4.1 Performance requirements

When tested in accordance with the appropriate test methods specified in Clause 6, cements shall comply with the performance requirements specified in Table 1.

Table 1 — Requirements

Type and Class	Setting time at 37 °C min		Compressive strength at 24 h MPa		Disintegration after 24 h % (mass fraction)	Film thickness µm	Acid-soluble arsenic content mg/kg
	min.	max.	min.	max.	max.	max.	max.
Type I, Class 1	4	10		35	N/A*	25	2
Type I, Class 2	Penetration at 1 h		N/A*	N/A*	N/A*	25	2
Type II	4	10	35		1,5	25	2
Type III	3	10	25		1,5	N/A*	2
Type IV	4	10	5		1,5	N/A*	2
N/A* not applicable.							

4.2 Biocompatibility

Guidance on biocompatibility is given in ISO 10993-1 and ISO 7405 (see Bibliography).

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5 Sampling

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The test sample shall consist of packages prepared for retail sale from the same batch containing enough material to carry out the specified tasks plus an allowance for repeats.

6 Test methods

6.1 Preparation of test specimens

Prepare the test material in accordance with the manufacturer's instructions (7.2)

Prepare all specimens at (23 ± 1) °C and a relative humidity of (50 ± 5) %. Before the start of mixing, condition the test samples and apparatus in these conditions for at least 1 h.

Prepare the cement according to the manufacturer's instructions. Mix sufficient cement to ensure that the preparation of each specimen is completed from one mix. Prepare a fresh mix for each specimen.

6.2 Determination of setting time

6.2.1 Apparatus

6.2.1.1 Cabinet, capable of being maintained at a temperature of (37 ± 1) °C and a relative humidity not less than 95 %.

6.2.1.2 Indenter needle.

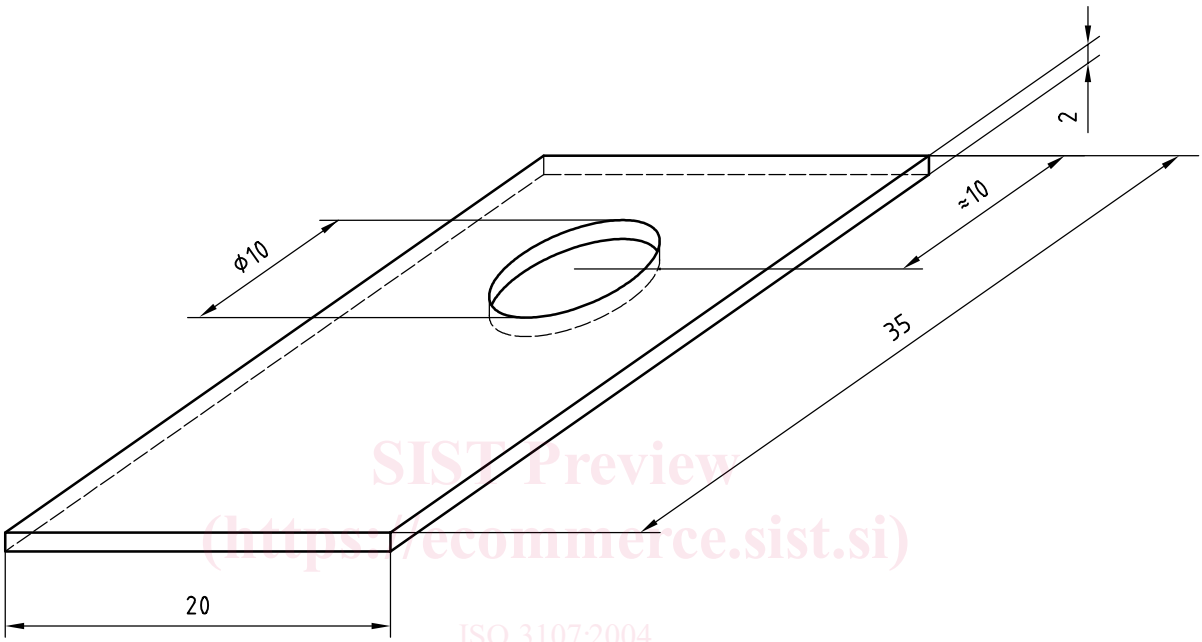
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6.2.1.2.1 For Type I Class 1, Type II and Type III materials, an **indenter needle** of mass (400 ± 2) g with a tip which is cylindrical for a distance of approximately 5 mm, which has a flat end of diameter (1,0 ± 0,1) mm.

6.2.1.2.2 For Type I Class 2 and Type IV materials, an **indenter needle** similar to that of 6.2.1.2.1 but of mass (100,0 ± 0,5) g and having a flat end of diameter (2,0 ± 0,1) mm.

6.2.1.3 **Mould**, made of non-corrodible metal, consisting of a rectangular plate with a circular hole conforming to the dimensions given in Figure 1.

Dimensions in millimetres



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Figure 1 — Mould for use in determination of setting time

6.2.1.4 **Metal block**, of minimum dimensions 8 mm × 20 mm × 10 mm.

6.2.1.5 **Flat glass plate**, approximately 1 mm thick (for example, a microscope slide).

6.2.2 Procedure

Condition the metal block (6.2.1.4) and indenter needle (6.2.1.2) in the cabinet (6.2.1.1) at (37 ± 1) °C.

Place the metal mould (6.2.1.3), conditioned at (23 ± 1) °C, on a flat glass plate (6.2.1.5) and fill with the cement to give a level top surface.

At (120 ± 10) s after the start of mixing for Type III cements, or (180 ± 10) s from the start of mixing for other cements, place the specimen on the metal block in the cabinet.

As soon as possible after placing the specimens in the cabinet, carefully lower the indenter needle vertically onto the surface of the cement. Make indentations at 15 s intervals with no superimposition of indentations until the time of setting has been reached. Maintain the needle tip in a clean condition between indentations.

Record the setting time, to the nearest 15 s, as the period of time which elapses from the start of mixing to the time when the needle fails to penetrate completely the 2 mm depth of cement.

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Type I Class 2 materials are non-setting. To verify this property, use the (100,0 ± 0,5) g indenter needle and test every 15 min for 1 h. Penetration can be confirmed by holding the specimen up to the light and examining visually. For Type I Class 2 cements, record presence or absence of penetration at 1 h.

6.2.3 Compliance

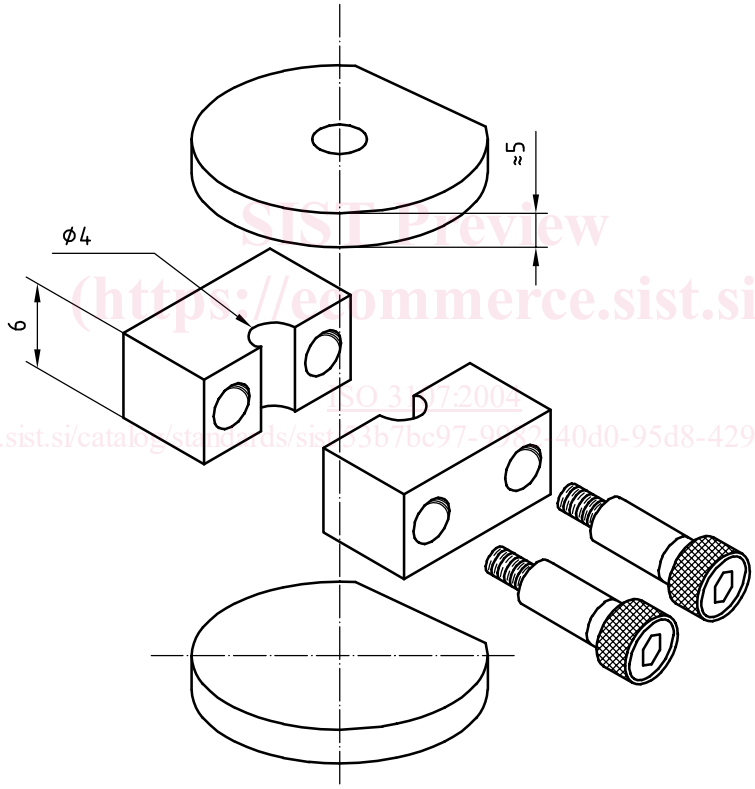
Results are required to pass the limits given in Table 1.

6.3 Determination of compressive strength

6.3.1 Apparatus

6.3.1.1 Split moulds and plates, such as shown in Figure 2, 6 mm high and with an internal diameter of 4 mm, made of stainless steel or other material that is not attacked or corroded by the cement.

Dimensions in millimetres



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Figure 2 — Mould for preparation of compressive strength test specimens

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6.3.1.2 Five individual screw clamps, such as those shown in Figure 3.

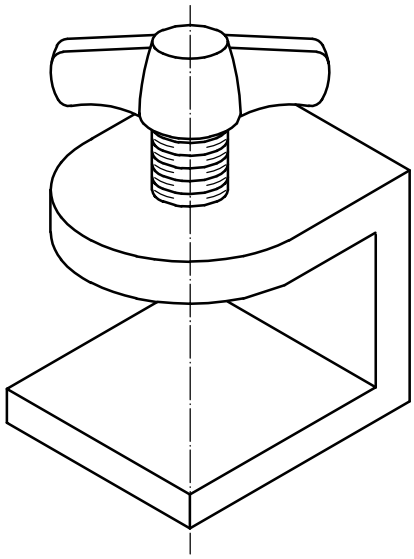


Figure 3 — Clamp for preparation of compressive strength test specimens

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6.3.1.3 Cabinet, as specified in 6.2.1.1.

6.3.1.4 Micrometer or similar measuring device, accurate to 1 µm.

6.3.1.5 Mechanical tester, capable of being operated at a cross-head speed of (0,75 ± 0,30) mm/min or at a loading rate of (50 ± 16) N/min.

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6.3.2 Preparation of test specimens

Condition the moulds (6.3.1.1), screw clamps (6.3.1.2) and top and bottom plates (6.3.1.1) at (23 ± 1) °C.

Five satisfactory specimens are required for this test.

After mixing in accordance with the manufacturer's instructions, pack the cement, to a slight excess, into the split moulds within 1 min after the completion of mixing. In order to consolidate the cement and to avoid trapping air, it is advisable to convey the largest convenient portions of mixed cement to the mould and apply to one side with a suitable instrument. Fill the mould to excess in this manner and then place the mould on the bottom plate and pack the cement, such that the excess is expressed.

To facilitate the removal of the hardened cement specimen, the internal surface of the mould may be evenly coated, prior to filling, with a 3 % solution of microcrystalline or paraffin wax in pure toluene. Alternatively, a thin film of silicone grease or polytetrafluoroethylene (PTFE) dry film lubricant may be used.

Remove any extruded cement, place the top metal plate in position and squeeze together. Put the mould and plates in the clamp (6.3.1.2) and screw tightly together. Not later than 2 min after completion of mixing, transfer the whole assembly to the cabinet (6.3.1.3) maintained at (37 ± 1) °C.

At 1 h after completion of mixing, remove the plates, and prepare the surface of the ends of the specimen plane, at right angles to its long axis, using a small amount of 45-µm silicon carbide powder or similar abrasive, mixed with water (ISO 3696 grade 2) on a flat glass plate. Keep the specimen wet during preparation.

Alternatively, use an equivalent grade of abrasive-coated paper and water (ISO 3696 grade 2). Keep the ends of the specimen flat by rotating the specimen one-quarter turn after every few strokes of the paper.

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