INTERNATIONAL STANDARD

ISO 3107

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

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

Reference number
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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 fourth edition cancels and replaces the third edition (ISO 3107:2004), which has been technically revised. It also incorporates the Technical Corrigendum ISO 3107:2004/Cor.1:2006.

The main changes are that the

a) classification types have been consolidated into two,

b) compressive strength limit has been reduced to reflect materials in current use,

c) text on interpretation of compressive test results has been modified, and

d) lower setting time limit has been lowered to reflect materials in current use.

Introduction

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

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

1 Scope

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

This International Standard also specifies requirements for 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.

ISO 1942, *Dentistry — Vocabulary*

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

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

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 apply.

4 Classification

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

a) type I: for temporary cementation;

b) type II: for bases and temporary restorations.

5 Requirements

5.1 Performance requirements

When tested in accordance with the appropriate test methods specified in Clause 7, type I and type II cements shall comply with the performance requirements specified in Table 1.

Table 1 — Requirements

Type	Setting time at 37 °C		Compressive strength at 24 h		Film thickness	Acid-soluble arsenic mass fraction
	min		MPa		µm	mg/kg[a]
	min.	max.	min.	max.	max.	max.
Type I	1,5	10		35	25	2
Type II	1,5	10	5		N/A	2

N/A: not applicable

[a] mg/kg is the equivalent of ppm; ppm is a deprecated unit.

5.2 Biocompatibility

For guidance on biocompatibility, see ISO 10993-1 and ISO 7405.

6 Sampling

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. 50 g should be sufficient.

7 Test methods

7.1 Preparation of test specimens

Prepare the test material in accordance with the manufacturer's instructions (see 8.2).

7.1.1 Ambient conditions

Prepare and test all specimens at (23 ± 2) °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.

7.1.2 Procedure for mixing

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

7.2 Determination of setting time

7.2.1 Apparatus

7.2.1.1 **Cabinet**, capable of being maintained at a temperature of (37 ± 1) °C and a relative humidity of (95 ± 5) %.

7.2.1.2 **Indenter needle**

7.2.1.2.1 For type I materials, an indenter needle of mass (100 ± 0,5) g with a tip which is cylindrical for a distance of approximately 5 mm and has a flat end of diameter (2,0 ± 0,1) mm.

7.2.1.2.2 For type II materials, a similar indenter needle of mass (400 ± 5) g with a tip which is cylindrical for a distance of approximately 5 mm, and which has a flat end of diameter (1,0 ± 0,1) mm.

7.2.1.3 **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

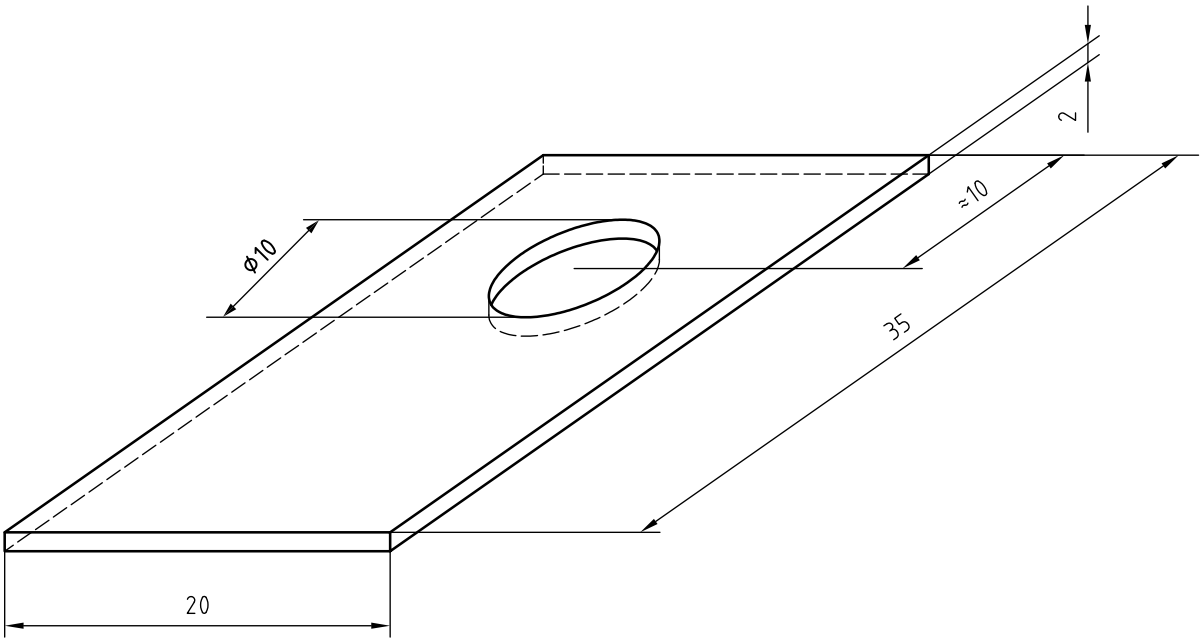

Figure 1 — Mould for use in determination of setting time

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

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

7.2.2 Procedure

Condition the metal block (7.2.1.4) and indenter needle (7.2.1.2) in the cabinet (7.2.1.1) at (37 ± 1) °C.

Place the metal mould (7.2.1.3), conditioned at (23 ± 1) °C, on the flat glass plate (7.2.1.5) and fill to a level surface with the cement.

After (60 ± 10) s from the start of mixing for all cements, place the specimen, mould and glass plate on to the metal block.

30 s before the setting time given by the manufacturer, carefully lower the indenter needle vertically on to the surface of the cement. Make indentations at 15 s intervals with no superimposition of indentations until the setting time 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.

7.2.3 Treatment of results

The result shall either be one of the limit values or lie between the limits given in Table 1.

7.3 Determination of compressive strength

7.3.1 Apparatus

7.3.1.1 **Split moulds and plates**, for example as shown in Figure 2, suitable for the preparation of a cylindrical specimen with a height of 6 mm and a diameter of 4 mm, and made of a material that is neither attacked nor corroded by the cement, such as stainless steel.