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Dentistry — Water-based cements —

Part 2: Resin-modified cements

Médecine bucco-dentaire — Ciments à base d'eau —

Partie 2: Ciments modifiés par addition de résine

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Foreword

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The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

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For an explanation on the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see the following URL: www.iso.org/iso/foreword.html.

This document 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 9917-2:2010), which has been technically revised.

The main changes compared to the previous edition are as follows:

— the adoption of ISO 13116 as the measuring procedure of the test method for radio-opacity;

— the inclusion of tooth core build-up as a restoration in the scope;

— the adoption of other minor technical revisions in the test methods.

A list of all parts of the ISO 9917 series can be found on the ISO website.

Introduction

This document has been prepared in order to present the requirements and test methods for cements in which setting is achieved by a combination of an acid-base reaction and polymerization. The polymerization component of the reaction may be activated by mixing different components or through application of energy from an external source. As far as possible, test methods employed within this document have been harmonized with those used in ISO 4049 and ISO 9917-1.

No specific qualitative and quantitative requirements for ensuring the absence of biological hazard are included in this document, but it is recommended that reference be made to ISO 10993-1 and ISO 7405 when assessing possible biological or toxicological hazards.

Dentistry — Water-based cements —

Part 2: Resin-modified cements

1 Scope

This document specifies requirements and test methods for water-based dental cements in which setting is achieved by a combination of an acid-base reaction and polymerization. The materials are intended for luting, base or lining, restoration and tooth core build up purposes.

EXAMPLE Conventional glass polyalkenoate cements are normally formed by reacting an ion-leachable aluminosilicate glass with a polyalkenoic acid in an aqueous environment. Materials that fall within the scope of this document will normally be able to effect setting by such an aqueous acid-base type reaction but in addition will be able to undergo setting by polymerization.

NOTE The attention of manufacturers and test laboratories is drawn to the closely-related International Standards ISO 4049 and ISO 9917-1 so that they can consider which is the most appropriate for evaluating any individual product.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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 3696, *Water for analytical laboratory use — Specification and test methods*

ISO 6344-1, *Coated abrasives — Grain size analysis — Part 1: Grain size distribution test*

ISO 7491, *Dental materials — Determination of colour stability*

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

ISO 13116:2014, *Dentistry — Test method for determining radio-opacity of materials*

3 Terms and definitions

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

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at http://www.iso.org/obp

— IEC Electropedia: available at http://www.electropedia.org/

3.1
mixing time
portion of the working time required in order to obtain a satisfactory mix of the components

Note 1 to entry: Materials that fall within the scope of this document include materials that require mixing and single component materials that do not require mixing.

[SOURCE: ISO 9917-1:2007, 3.1, modified — "that part of" has been replaced with "portion of" in the definition, and note 1 to entry has been added.]

3.2
working time
period of time, measured from the start of mixing (if required), during which it is possible to manipulate the material without an adverse effect on its properties

[SOURCE: ISO 9917-1:2007, 3.2 modified]

3.3
setting time
period of time, from the start of mixing, until the completion of setting, as defined by the ability of the material to support an indenter under a known load, when the material needs to be mixed to set

3.4
outer pack
packaging used for single dose container(s)/capsule(s)

3.5
outermost packaging
packaging used to combine material and additional items, including instructions for use and any proportioning or mixing devices that are supplied with the material

4 Classification and applications

4.1 Classification

For the purposes of this document, materials consist of water-based components which set by acid-base reaction and polymer-based component(s) are classified on the basis of their setting characteristics of polymer-based component(s) as follows:

— Class 1: materials setting of polymer-based components is activated following mixing of the components of the material;

— Class 2: materials setting of polymer-based component(s) is activated by irradiation of light to the mixed material;

— Class 3: materials setting of polymer-based components is activated following mixing of the components and which can also be activated by irradiation of light to the mixed material.

4.2 Applications

For the purposes of this document, the clinical application of these materials is signified as follows:

a) luting;

b) base or lining;

c) restoration, including for tooth core build-up.

5 Requirements

5.1 Materials

During the course of testing, there shall be no visible signs of extraneous matter in any component. Separately supplied liquid shall be free of any gelation.

NOTE Gelation is the transition of a material from a fluid consistency to a state in which the material has developed viscous or elastic properties. See ISO 14356:2003, 3.9.

5.2 Working time

When tested in accordance with Annex A, the working time shall comply with the requirements given in Table 1 and shall be at least as long as the value given by the manufacturer (see Table 2, item 22).

5.3 Setting time — Class 1 and Class 3 materials only

When tested in accordance with Annex A, the setting time of Class 1 and Class 3 materials shall comply with the requirements given in Table 1 and shall be no longer than the value given by the manufacturer (see Table 2, item 23).

5.4 Film thickness — Luting materials only (see 4.2)

The film thickness of luting materials when determined in accordance with Annex B, shall be no more than 5 µm above any value claimed by the manufacturer (i.e. the first requirement) and in any event shall comply with the requirements given in Table 1 (i.e. the second requirement).

5.5 Flexural strength

When tested in accordance with Annex C, the flexural strength shall comply with the requirements given in Table 1.

5.6 Radio-opacity

If the manufacturer claims that the material is radio-opaque (see Table 2, item 14), the radio-opacity, determined in accordance with Annex D and ISO 13116:2014, 7.3 or 7.4, shall be equal to or greater than that of the same thickness of aluminium. If greater radio-opacity is stated by the manufacturer, it shall not be less than the value stated by the manufacturer (see Table 2, item 15).

5.7 Shade and colour stability — Restorative materials only

When tested in accordance with Annex E, the set material shall closely match that of the shade guide specified by the manufacturer. When tested in accordance with Annex E and ISO 7491, there shall be no more than a slight change in colour after 7 d.

6 Sampling

A sample drawn from one batch shall provide sufficient material to complete all the prescribed tests plus an allowance for any repeat tests, should they become necessary. The test sample shall consist of packages prepared for retail sale.

Table 1 — Requirements for dental cements

Application	Film thickness[a] µm Max.	Working time[b] min Min.	Setting time[c] min Max.	Flexural strength MPa Min.
Luting	25	1,5	8	10
Base or lining	—	1,5	6	10
Restoration	—	1,5	6	25

[a] The determined value shall be no more than 5 µm above any value claimed by the manufacturer.

[b] Class 2 and Class 3 materials tested without activation by light.

[c] Class 1 and Class 3 materials only. Class 3 materials tested without activation by light.

7 Test conditions and preparation of test specimens

7.1 Test conditions

Prepare and test all specimens at an ambient temperature of (23 ± 2) °C. Control the relative humidity to ensure that it remains at (50 ± 20) % at all times. If the material was refrigerated for storage, allow it to reach (23 ± 2) °C before testing. Test equipment shall be maintained at the condition specified in individual tests.

For Class 2 and Class 3 materials, activating radiation shall be excluded during the determination of working time.

Water used in all tests specified in this document shall be prepared in accordance with ISO 3696, grade 2.

For Class 2 and Class 3 materials, refer to the manufacturer's instructions (see Table 2, item 24), which state the external energy source to be used. Ensure that the source is in a satisfactory working condition.

7.2 Method of mixing

The cement shall be prepared according to the manufacturer's instructions. Sufficient cement shall be mixed to ensure that the preparation of each specimen is completed from one mix. A fresh mix shall be prepared for each specimen.

NOTE For encapsulated materials, more than one capsule, simultaneously mixed, might be required for certain specimens. Likewise, for materials supplied in single dose containers, several containers might be required for each test specimen.

7.3 Inspection

Visual inspection shall be used in determining compliance with 5.1 and Clause 8.

8 Packaging, marking and information to be supplied by the manufacturer

8.1 Packaging

The components of the material shall be supplied in properly sealed containers which adequately protect their contents and have no adverse effect on the quality of the product.

An outer pack may be used to present the individual containers as a single unit or for marking of a single dose capsule, syringe or bottle.

NOTE Single paste and powder-liquid encapsulated products can be sold as a pack containing many unit doses of material.

8.2 Marking and instructions for use

Information shall be clearly marked on the outermost packaging or containers (for multi-dose packs or capsules), as appropriate, and as indicated in Table 2.

Instructions shall accompany each package of the material and shall include the information appropriate to the material (see Clause 4), as indicated in Table 2, where "M" means mandatory, "OPT" means optional, and "NA" not applicable.

Information additional to that specified in Table 2 may be supplied at the discretion of the manufacturer. Regulations might also require additional information to be supplied.

NOTE Table 2 contains several optional references and serves as a guide to the manufacturer as to the sort of information which might be useful to dentists.

Table 2 — Requirements for marking and instructions for use

	Items of marking and instructions for use	Outermost packaging see 3.5	Outer pack of capsule(s) see 3.4	Capsules, syringes or bottles (of single-dose)	Manufacturer's instruction leaflet
1	The name of the product	M	M	NA	M
2	The identification or name of the manufacturer	M	M	OPT	M
3	The address of the manufacturer or the agent responsible for sale	M	OPT	NA	M
4	URL	OPT	OPT	NA	OPT
5	The recommended conditions of storage	M	OPT	NA	M
6	The manufacturer's batch number	M	M	OPT	NA
7	The expiry date, expressed in accordance with ISO 8601, for the cement when stored under the manufacturer's recommended conditions	M	M	OPT	NA
8	The classification of the cement (see 4.1)	M	OPT	OPT	M
9	The clinical application (see 4.2)	OPT	OPT	NA	M
10	The number of containers/capsules, for capsule or cartridge cements	M	M	NA	NA
11	The net mass in each container/capsule	OPT	M	OPT	OPT
12	Shade and/or colour of the cement according to the manufacturer's nominated shade guide (for multi-shade materials only)	OPT	M	OPT	OPT
13	If the material is designated opaque, a clear statement to this effect[a]	M	OPT	OPT	M
14	If the cement is designated radio-opaque (see 5.6), a clear statement to this effect	OPT	OPT	OPT	M

"M" mandatory

"OPT" optional

"NA" not applicable

[a] Opaque designation can be included in the shade.