INTERNATIONAL STANDARD

ISO 9917-2

Second edition
2010-04-15

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

Reference number
ISO 9917-2:2010(E)

ISO copyright office
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

Published in Switzerland

Contents

Page

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 9917-2 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 9917-2:1998), which has been technically revised by the inclusion of resin-modified cements which set by both chemically activated and light-activated polymerization.

ISO 9917 consists of the following parts, under the general title *Dentistry — Water-based cements*:

— *Part 1: Powder/liquid acid-base cements*

— *Part 2: Resin-modified cements*

Introduction

This part of ISO 9917 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 part of ISO 9917 have been harmonized with those used in ISO 4049 and ISO 9917-1.

Specific qualitative and quantitative requirements for freedom from biological hazard are not included in this part of ISO 9917, 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 part of ISO 9917 specifies requirements and test methods for dental cements that are intended for luting, base or lining and restoration purposes and for which the materials are water-based and set by multiple reactions in which setting is achieved by a combination of an acid-base reaction and polymerization.

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 part of ISO 9917 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 Attention of manufacturers and test laboratories is drawn to the closely-related International Standards ISO 4049 and ISO 9917-1. Consideration should be given as to which is the most appropriate International Standard by which to evaluate any individual product.

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

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

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

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

NOTE Materials that fall within the scope of this part of ISO 9917 include materials that require mixing and single component materials that do not require mixing.

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

NOTE Working time is determined in the absence of activating radiation, if required for activation for Class 3 materials (see Clause 4).

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

3.4
outer pack
form of packaging used to combine a number of single dose containers or capsules

3.5
outermost packaging
form of 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 part of ISO 9917, materials are classified on the basis of their setting characteristics as follows.

— Class 1: materials in which the setting reaction of the polymerizable component is activated chemically following mixing of components.

— Class 2: materials in which the setting reaction of the polymerizable component is light-activated.

— Class 3: materials in which the setting reaction of the polymerizable component is activated chemically following mixing of components and may also be light-activated.

4.2 Applications

For the purposes of this part of ISO 9917, the clinical application of these materials is signified as follows:

a) luting;

b) base or lining;

c) restoration.

5 Requirements

5.1 Materials

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

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 24).

5.3 Setting time — Classes 1 and 3 materials only

When tested in accordance with Annex A, the setting time of Classes 1 and 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 25).

5.4 Film thickness — Luting cements only (see 4.2)

When tested in accordance with Annex B, the film thickness of luting materials shall comply with the requirements given in Table 1.

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 16), the radio-opacity, determined in accordance with Annex D, shall be equal to or greater than that of the same thickness of aluminium. If greater radio-opacity is claimed, it shall not be less than 0,5 mm below the value claimed by the manufacturer (see Table 2, item 17).

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.

Table 1 — Requirements for dental cements

Application	Film thickness µm Max.	Working time min Min.	Setting time[a] 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] Class 1 and 3 materials only. Class 3 materials tested without activation by light.

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.

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. Test equipment should be maintained at the condition specified in individual tests.

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

Water used in all tests specified in this part of ISO 9917 shall be prepared in accordance with ISO 3696, grade 2.

For Classes 2 and 3 materials, reference shall be made according to the manufacturer's instructions (see Table 2, item 26), which state the external energy source to be used. Care shall be taken to 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 requirements

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.

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.

Information additional to that specified in Table 2 may be supplied at the discretion of the manufacturer.

NOTE Some information is indicated as mandatory and other as optional. The symbol "/ " indicates that this item is either irrelevant or optional for the product. 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

Requirement		Outermost packaging see 3.5	Outer pack of capsules see 3.4	Capsule (single-dose), syringes or bottles	Manufacturer's instruction leaflet
1	The name of the product.	M	M	/[a]	M[b]
2	The identification or name of the manufacturer.	M	M	/	M
3	The address of the manufacturer or the agent responsible for sale.	M	/	/	M
4	URL.	/	/	/	/
5	Information required by local/national legislation.	M	M	/	M
6	The recommended conditions of storage.	M	/	/	M
7	The manufacturer's batch number.	M	M	/	/
8	The expiry date, expressed in accordance with ISO 8601, for the cement when stored under the manufacturer's recommended conditions.	M	M	/	/
9	The shelf life under those conditions of storage.	/	/	/	/
10	The classification of the cement (see 4.1).	M	/	/	/
11	The clinical application (see 4.2).	/	/	/	M
12	The number of containers/capsules, for capsule or cartridge cements.	M	M	/	/
13	The net mass in each container/capsule.	/	M	/	M
14	Shade and/or colour of the cement according to the manufacturer's nominated shade guide (for multi-shade materials only).	/	M	M[c]	/
15	If the material is designated opaque, a clear statement to this effect[d].	M	/	/	M
16	If the cement is designated radio-opaque (see 5.6), a clear statement to this effect.	/	/	/	M
17	If a specific claim on the extent of radio-opacity is made, the equivalent thickness of aluminium for 1 mm thickness of the cement (see 5.6).	/	/	/	M
18	The recommended ratio of components (e.g. powder:liquid) and instructions for use of any proportioning aids (e.g. scoops, etc.) and the proportions on a mass/mass basis to a precision of 0,1 g (for hand mixed materials only).	/	/	/	M
19	The rate of incorporation of the powder into the liquid (for hand-mixed materials only).	/	/	/	M
20	The mixing time (see 3.1), if mixing required.	/	/	/	M
21	The mixing condition (if appropriate, the condition and type of the mixing slab and spatula). For hand-mixed materials only.	/	/	/	M
22	For encapsulated cements, the method of bringing about physical contact between the components, if required.	/	/	/	M
23	The method, timing and type of mechanical mixing, if required.	/	/	/	M