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Dentistry — Polymer-based restorative materials

Médecine bucco-dentaire — Produits de restauration à base de polymères

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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.

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).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

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 fifth edition cancels and replaces the fourth edition (ISO 4049:2009), which has been technically revised. The main changes compared to the previous edition are as follows:

— the test for sensitivity to ambient light has been changed because a filter used in the current test was not available;

— the test for radio-opacity has been updated to refer to ISO 13116;

— luting materials no longer have to conform to the requirement for depth of cure;

— the manufacturer is now required to publish details of material composition, see Clause 8;

— several minor changes have been made to clarify content together with editorial changes.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

Specific qualitative and quantitative requirements for freedom from biological hazard are not included in this document. It is recommended, however, that reference should be made to ISO 10993-1 and ISO 7405 when assessing possible biological or toxicological hazards.

Dentistry — Polymer-based restorative materials

1 Scope

This document specifies requirements for dental polymer-based restorative materials supplied in a form suitable for mechanical mixing, hand-mixing, or intra-oral and extra-oral external energy activation, and intended for use primarily for the direct or indirect restoration of the teeth and for luting.

The polymer-based luting materials covered by this document are intended for use in the cementation or fixation of restorations and appliances such as inlays, onlays, veneers, crowns and bridges. This document does not cover those polymer-based luting materials that have an adhesive component within the structure of the material (see ISO/TS 16506).

The document does not cover polymer-based materials intended to prevent caries (see ISO 6874), core materials or those used for veneering metal sub-frames (see ISO 10477).

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

ISO 7491:2000, *Dental materials — Determination of colour stability*

ISO 8601-1:2019, *Date and time —Representations for information interchange Part — 1: Basic rules*

ISO 8601-2:2019, *Date and time —Representations for information interchange Part — 2: Extensions*

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

ISO 17304:2013, *Dentistry — Polymerization shrinkage: Method for determination of polymerization shrinkage of polymer-based 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 https://www.iso.org/obp

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

3.1
opaque
shade of an intensely pigmented polymer-based restorative material of low translucency

3.2
outer pack
form of packaging used to combine a number of single dose containers or capsules

3.3
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

3.4
container
capsule
primary packaging of the material

4 Classification

4.1 Type

For the purposes of this document, dental polymer-based restorative materials are classified into the following types.

— **Type 1**: Polymer-based restorative materials claimed by the manufacturer as suitable for restorations involving occlusal surfaces;

— **Type 2**: All other polymer-based restorative materials, and luting materials.

4.2 Class

The three classes of dental polymer-based restorative materials are as follows:

— **Class 1**: Materials whose setting is effected by mixing an initiator and activator ("Self-curing" materials).

— **Class 2**: Materials whose setting is effected by the application of energy from an external source, such as blue light or heat, ("external-energy-activated" materials, see also Table 4, items 9 and 20). They are subdivided as follows:

1) **Group 1**: Materials whose use requires the energy to be applied intra-orally;

2) **Group 2**: Materials whose use requires the energy to be applied extra-orally. When fabricated, these materials will be luted into place.

Certain materials may be claimed by manufacturers to be both Group 1 and Group 2. In this event the material shall fulfil the requirements for both groups.

NOTE Class 2 luting materials fall into Group 1 only.

— **Class 3**: Materials that are cured by the application of external energy, and also have a self-curing mechanism present ("dual-cure" materials).

5 Requirements

5.1 Biocompatibility

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

5.2 Physical and chemical properties

5.2.1 General

If a restorative material is supplied by the manufacturer in various shades, each shade, including opaque shades, shall be capable of satisfying all the requirements for sensitivity to the dental operating light

(5.2.7), depth of cure (5.2.8), shade (5.3) and colour stability (5.4) appropriate to the material type and class. If the material is supplied such that it can be "tinted" or "blended" to the user's prescription, the material shall conform to the requirements both when used alone and when used with the maximum recommended proportion of tint or blender (see Table 4, item 19). Depth of cure (5.2.8) of luting materials shall not be tested.

Colour stability (5.4) of luting materials shall not be tested unless the manufacturer claims such a property.

In respect of the other requirements of 5.2 and those of 5.5, only one representative shade of restorative materials shall be tested. This representative shade shall be either that classified by the manufacturer as "Universal" or, in the event that no shade is so classified, that shade corresponding to "A3" in the Vita®[1)] classification of shade. However, if the manufacturer claims a higher value for radio-opacity (see 5.5 and Table 4, item 28) for any other shade, this claim shall be tested.

The requirements are summarized in Tables 1, 2 and 3.

5.2.2 Film thickness, luting materials

The film thickness of luting materials when determined in accordance with 7.5 shall be no more than 10 µm above any value claimed by the manufacturer and in any event shall be no greater than 50 µm.

5.2.3 Working time, Class 1 and Class 3 restorative materials, excluding luting materials

The working time for Class 1 and Class 3 restorative materials, excluding luting materials, determined in accordance with 7.6, shall be no less than 90 s.

5.2.4 Working time, Class 1 and Class 3 luting materials

When tested in accordance with 7.7, the material shall be capable of forming a thin layer; during its formation there shall be no detectable change in its homogeneity.

5.2.5 Setting time, Class 1 materials

The setting time for Class 1 restorative materials, excluding luting materials, determined in accordance with 7.8, shall be no more than 5 min. The setting time for Class 1 luting materials, determined in accordance with 7.8, shall be no more than 10 min.

5.2.6 Setting time, Class 3 materials

The setting time for Class 3 materials, determined in accordance with 7.8, shall be no more than 10 min.

5.2.7 Sensitivity to light, Class 2 materials

When tested in accordance with 7.9, the material shall remain physically homogeneous.

5.2.8 Depth of cure, Class 2 materials excluding luting materials

When determined in accordance with 7.10, the depth of cure of Class 2 restorative materials shall be no less than 1 mm if they are labelled by the manufacturer as opaque, or no less than 1,5 mm for other restorative materials.

In any event, the values for all materials shall not be more than 0,5 mm below the value stated by the manufacturer.

1) Vita® is a trade name of Vita Zahnfabrik, H Rauter GmbH & Co K G, Postfach 1338, D-79704 Bad Saeckingen, Germany. This information is given for the convenience of the users of this document and does not constitute an endorsement of this system by ISO.

5.2.9 Flexural strength

The flexural strength of polymer-based restorative materials determined in accordance with 7.11, shall be equal to or greater than the limits specified in Table 1.

Table 1 — Flexural strength

Restorative materials		Flexural strength MPa minimum
Type 1	Class 1	80
	Class 2, Group 1	80
	Class 2, Group 2	100
	Class 3	80
Type 2	Class 1	50
(including luting materials)	Class 2, Group 1	50
	Class 3	50

5.2.10 Water sorption and solubility

When determined in accordance with 7.12:

a) the water sorption of all materials shall be equal to or less than 40 µg/mm^3.

b) the solubility of all materials shall be equal to or less than 7,5 µg/mm^3.

5.3 Shade of restorative materials

When the material is assessed in accordance with 7.13 and ISO 7491, the shade of the set material shall closely match that of the manufacturer's shade guide. If a shade guide is not supplied by the manufacturer, then the manufacturer shall nominate a commercially available shade guide that shall be used in assessing conformance with this requirement (see Table 4, items 13 and 25). In addition, the set material shall be evenly pigmented when viewed without magnification.

5.4 Colour stability after irradiation and water sorption

When the material is tested in accordance with 7.13 and ISO 7491, no more than a slight change in colour shall be observed. In respect of luting materials, colour stability shall be tested only in the event of a manufacturer's claim for colour stability. In the event of such a claim, no more than a slight change in colour shall be observed when the material is tested in accordance with 7.13 and ISO 7491.

5.5 Radio-opacity

5.5.1 If the manufacturer claims that the material is radio-opaque (see Table 4, items 16 and 28), the radio-opacity, determined in accordance with 7.14, shall be equal to or greater than that of the same thickness of aluminium and no less than 0,5 mm below any value claimed by the manufacturer.

5.5.2 This test shall be performed on a "universal" shade (see 5.2.1) but if the manufacturer claims a value for another shade or shades that is at least twice the "universal" shade value, this other shade or shades shall be tested as described in 5.5.1 (see Table 4, item 28).

NOTE Aluminium has a radio-opacity equivalent to that of dentine. Thus 1 mm of material having a radio-opacity equivalent to 1 mm of aluminium has a radio-opacity equivalent to that of dentine.

Table 2 — Physical and chemical property requirements for restorative materials, excluding luting materials
(see Table 1 for minimum flexural strength)

Material Class	Requirement (subclause)				
	Working time (5.2.3) s minimum	Setting time (5.2.5, 5.2.6) min maximum	Depth of cure[a] (5.2.8) mm minimum	Water sorption (5.2.10) µg/mm³ maximum	Solubility (5.2.10) µg/mm³ maximum
Class 1	90	5 (5.2.5)	—	40	7,5
Class 2	—	—	1,0 (opaque shade) 1,5 (others)	40	7,5
Class 3	90	10 (5.2.6)	—	40	7,5

[a] The values for all materials shall be no more than 0,5 mm below the value stated by the manufacturer.

Table 3 — Physical and chemical property requirements for luting materials

Material Class	Requirement (subclause)				
	Film thickness[a] (5.2.2) µm maximum	Working time (5.2.4) s minimum	Setting time (5.2.5, 5.2.6) min maximum	Water sorption (5.2.10) µg/mm³ maximum	Solubility (5.2.10) µg/mm³ maximum
Class 1	50	60	10 (5.2.5)	40	7,5
Class 2	50	—	—	40	7,5
Class 3	50	60	10 (5.2.6)	40	7,5

[a] The determined value shall be no more than 10 µm above any value claimed by the manufacturer.

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 tests, plus an allowance for repeat tests, if necessary. 50 g should be sufficient.

7 Test methods

7.1 General reagent — Water

For the tests, use water prepared in accordance with ISO 3696:1987 Grade 2.

7.2 Test conditions

Unless otherwise specified by the manufacturer, prepare and test all specimens at (23 ± 2) °C. Control the relative humidity to ensure that it remains greater than 30 % and less than 70 % at all times. If the material was refrigerated for storage, allow it to attain (23 ± 2) °C before testing.