
Dentistry — Polymer-based pit and fissure sealants

Médecine bucco-dentaire — Produits dentaires à base de polymères pour comblement des puits et fissures

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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).

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For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: [Foreword - Supplementary information](#)

The committee responsible for this document is ISO/TC 106, *Dentistry*, Subcommittee SC1, *Filling and restorative materials*.

This third edition cancels and replaces the second edition (ISO 6874:2005), of which it constitutes a minor revision.

Introduction

The efficacy of pit and fissure sealants for the prevention of dental caries is widely accepted. The polymer-based materials intended for this purpose and covered by this International Standard harden by a free-radical polymerisation reaction that is either initiated by mixing components or by external energy, e.g. visible light.

Specific qualitative and quantitative requirements for freedom from biological hazard are not included in this International Standard but, when assessing possible biological hazards, reference can be made to ISO 10993 (all parts) and ISO 7405.

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Dentistry — Polymer-based pit and fissure sealants

1 Scope

This International Standard specifies requirements and test methods for polymer-based materials intended for sealing pits and fissures in teeth.

This International Standard covers both self-curing and external-energy-activated materials.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. 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 8601, *Data elements and interchange formats — Information interchange — Representation of dates and times*

3 Classification

For the purposes of this International Standard, polymer-based pit and fissure sealants are classified, according to the method of curing, 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 visible light (“external-energy-activated” materials).

4 Requirements

4.1 Biocompatibility

See the Introduction for guidance on biocompatibility, ISO 7405 and ISO 10993-1.

4.2 Physical properties

4.2.1 Working time, Class 1 sealant

The working time for Class 1 sealants, determined in accordance with 6.4, shall not be less than 40 s.

4.2.2 Setting time, Class 1 sealant

The setting time for Class 1 sealants, determined in accordance with 6.5, shall not be greater than 5 min.

4.2.3 Depth of cure, Class 2 sealant

The depth of cure for Class 2 sealants, determined in accordance with 6.6, shall be not less than 1,5 mm. If the material is supplied in more than one shade, each shade shall comply with this requirement.

5 Sampling

The test sample shall consist of a retail package, or packages, from the same batch containing sufficient material (a minimum of 20 g) to carry out the specified tests and repeat tests, if necessary.

6 Test methods

6.1 Inspection

Inspect visually to check that requirements specified in [Clause 7](#) have been met.

6.2 Test conditions

Unless specified otherwise by the manufacturer, prepare and test all specimens at $(23 \pm 2) ^\circ\text{C}$. Control the relative humidity to ensure that it remains greater than 30 % at all times. If the material was refrigerated for storage, allow it to attain $(23 \pm 2) ^\circ\text{C}$ before use.

For the preparation of class 2 materials, reference shall be made to the manufacturer's instructions [see [7.3 e\)](#) and [g\)](#)] that state the external energy source or sources recommended for the materials to be tested. Care shall be taken to ensure that the source is in a satisfactory operating condition.

NOTE See also ISO 10650 (all parts).

6.3 Preparation of test specimens

Mix or otherwise prepare the material in accordance with the manufacturer's instructions and the test conditions specified in [6.2](#).

6.4 Working time, Class 1 sealant

6.4.1 Apparatus

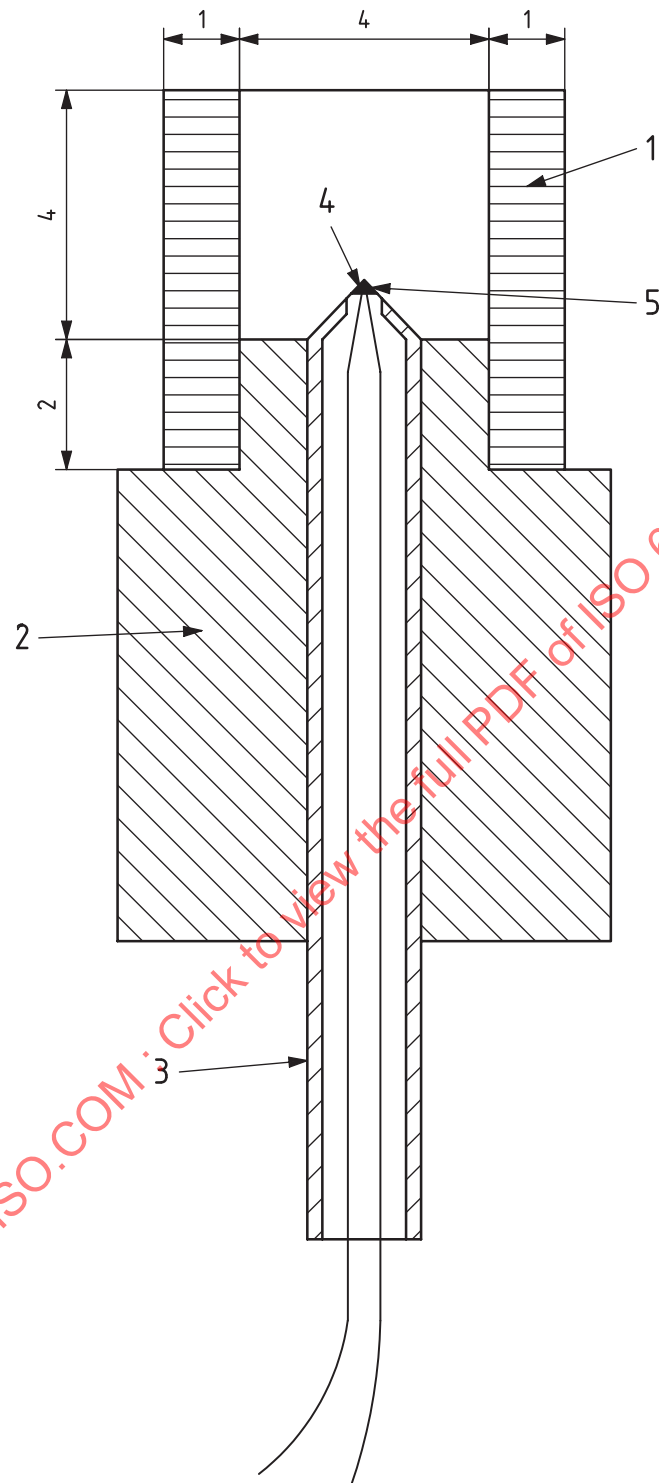
6.4.1.1 Thermometry apparatus, as shown in [Figure 1](#).

The apparatus consists of a piece of polyethylene (or similar material) tubing, A, located on a block of polyamide or similar material B, which has a hole into which is inserted a stainless steel tube, C, containing a stabilized thermocouple D.

The polyethylene tube A is 6 mm long, 4 mm in internal diameter and has a wall thickness of 1 mm. The locating part of block B is 4 mm in diameter and 2 mm high. When assembled, the two components form a specimen well 4 mm high $\times$ 4 mm in diameter. In order to facilitate removal of the specimen after testing, the thermocouple D has a conical tip that protrudes 1 mm into the base of the specimen well. The tolerances on the above-mentioned dimensions are $\pm 0,1$ mm.

The thermocouple consists of wires $(0,25 \pm 0,05)$ mm in diameter, made of a material (e.g. copper/constantan) capable of registering rapid temperature changes in a specimen of setting material to an accuracy of $0,1 ^\circ\text{C}$. The thermocouple is connected to an instrument (e.g. voltmeter or chart recorder) capable of recording the temperature to that accuracy.

NOTE A prefabricated thermocouple of similar size and performance can be substituted.

**Key**

- 1 polyethylene tubing
- 2 polyamide block
- 3 stainless steel tube
- 4 thermocouple
- 5 silver soldering

Figure 1 — Apparatus for determination of working and setting times

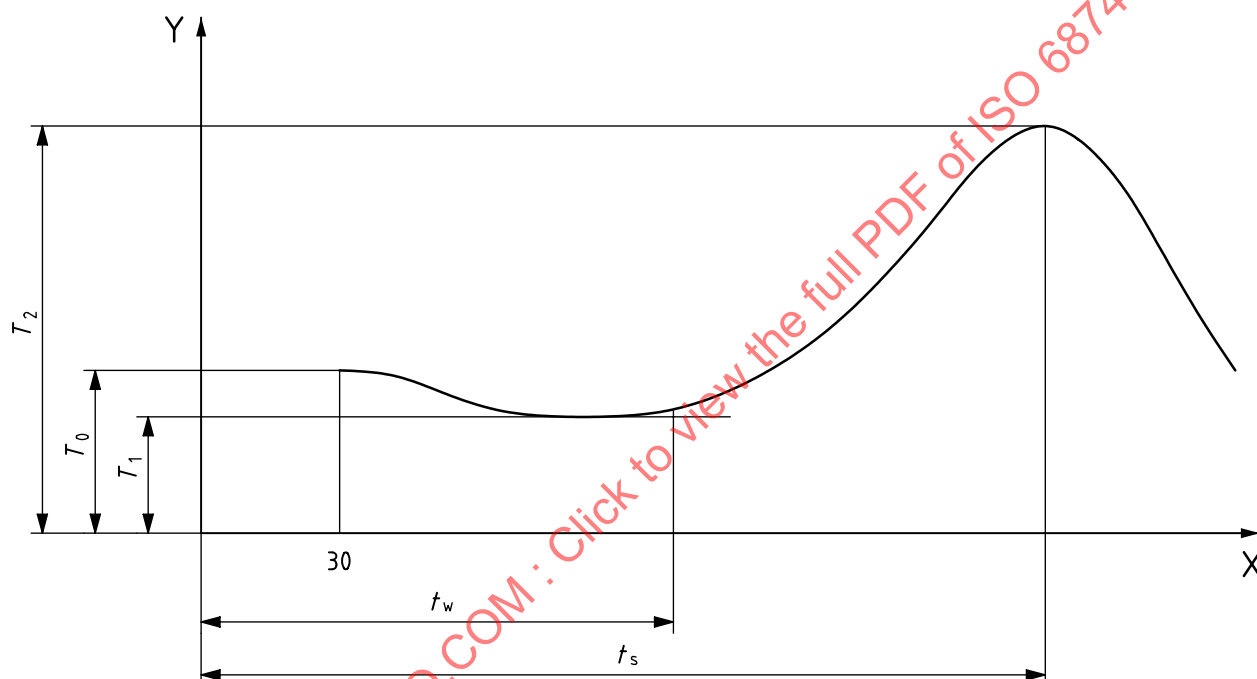
6.4.2 Procedure

Prepare the sealant in accordance with the manufacturer's instructions (see 7.3) and start timing from the moment mixing is begun. Maintain the mould at $(23 \pm 1) ^\circ\text{C}$. At 30 s after the start of mixing, place the mixed sealant in the mould and record the temperature, T_1 , of the sealant. Maintain the apparatus at $(23 \pm 1) ^\circ\text{C}$ and continuously record the temperature of the sealant until the peak temperature is reached.

NOTE A typical recording trace is shown in Figure 2. As soon as the sealant is inserted into the mould, the temperature can fall slightly until it becomes steady at T_0 and then starts to increase. The point at which the temperature begins to increase denotes the start of the setting reaction and, therefore, the end of the working time. The results are extremely temperature dependent and slight variations within the permitted temperature range will cause variations of several seconds.

Record the time, t_w , from the start of mixing until the temperature starts to increase.

Carry out five determinations.



Key

X	time, in seconds
Y	temperature
T_0	temperature at time of insertion
T_1	temperature after a slight drop immediately after time of insertion
T_2	peak temperature
t_w	time of insertion to the start of the setting reaction at T_1 , denoted as the working time
t_s	time of insertion to the time of the peak temperature, denoted as the setting time

Figure 2 — Typical recording trace showing temperature changes in time for determination of working and setting times

6.4.3 Treatment of results

Record the working times and report as follows:

- if at least four of the times obtained are equal to or longer than 40 s, the material is deemed to have complied with the requirement of 4.2.1;

- b) if three or more of the times are shorter than 40 s, the material is deemed to have failed;
- c) if only three of the times are equal to or longer than 40 s, repeat the whole test. All the specimens in the second series shall comply with the requirement otherwise the material is deemed to have failed the whole test.

6.5 Setting time, Class 1 sealant

6.5.1 Apparatus

6.5.1.1 Thermometry apparatus, as specified in [6.4.1.1](#).

6.5.2 Procedure

Repeat the procedure described in [6.4.2](#), but maintain the apparatus at $(37 \pm 1)^\circ\text{C}$ in air.

Record the time elapsed between the start of mixing and the peak temperature, T_2 , as the setting time, t_s .

Carry out five determinations.

6.5.3 Treatment of results

Record the setting times and report as follows:

- a) if at least four of the times obtained are equal to or shorter than 5 min, the material is deemed to have complied with the requirement of [4.2.2](#);
- b) if three or more of the times are longer than 5 min, the material is deemed to have failed;
- c) if only three of the times are equal to or shorter than 5 min, repeat the whole test. All the specimens in the second series shall comply with the requirement otherwise the material is deemed to have failed the whole test.

6.6 Depth of cure, Class 2 sealant

6.6.1 Apparatus

6.6.1.1 Stainless steel mould, for the preparation of a cylindrical specimen, 6 mm long and 4 mm in diameter.

NOTE A mould release agent that does not interfere with the setting reaction, for example a 3 % solution of polyvinyl ether wax in hexane, can be used to facilitate removal of the specimen.

6.6.1.2 Two glass slides/plates, each of sufficient area to cover one side of the mould.

NOTE Standard glass microscope slides can be used.

6.6.1.3 White filter paper.

6.6.1.4 Film, transparent to the activating radiation, (50 ± 30) μm thick, e.g. polyester.

6.6.1.5 External energy source, as recommended by the manufacturer for use with the test material [see 7.3 e)].

6.6.1.6 Micrometer, accurate to 0,01 mm.

6.6.1.7 Plastics spatula.

6.6.2 Procedure

Place the mould (6.6.1.1) onto a strip of the transparent film (6.6.1.4) on one of the glass slides (6.6.1.2). Fill the mould with the test material, prepared in accordance with the manufacturer's instructions, taking care to exclude air bubbles. Slightly overfill the mould and place a second strip of the transparent film on top followed by the second microscope slide. Press the mould and strips of film between the glass slides (6.6.1.2) to displace excess material. Place the mould onto the filter paper (6.6.1.3), remove the microscope slide covering the upper strip of film and gently place the exit window of the external energy source (6.6.1.5) against the strip of film. Irradiate the material for the time recommended by the manufacturer to achieve a depth of cure of at least 1,5 mm.

Immediately after completion of irradiation remove the specimen from the mould and remove the uncured material with the plastics spatula (6.6.1.7). Measure the height of the cylinder of cured material with the micrometer (6.6.1.6) to an accuracy of 0,1 mm.

Record this value as the depth of cure.

Carry out three determinations.

6.6.3 Treatment of results

If all three values are greater than 1,5 mm, the material has complied with the requirement of 4.2.3. If one or more values is less than 1,5 mm, the material has failed the requirement.

7 Packaging, marking and instructions and information to be supplied by the manufacturer

NOTE Additional information can be included at the discretion of the manufacturer or as required by legislation.