BS EN ISO 6874:2015

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Dentistry — Polymer-based pit and fissure sealants

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National foreword

This British Standard is the UK implementation of EN ISO 6874:2015. It supersedes BS EN ISO 6874:2005 which is withdrawn.

The UK participation in its preparation was entrusted to Technical Committee CH/106/1, Dental restorative and orthodontic materials.

A list of organizations represented on this committee can be obtained on request to its secretary.

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Dentistry - Polymer-based pit and fissure sealants (ISO 6874:2015)

Médecine bucco-dentaire - Produits dentaires à base de polymères pour comblement des puits et fissures (ISO 6874:2015)

Zahnheilkunde - Versiegelungskunststoffe für Grübchen und Fissuren (ISO 6874:2015)

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European foreword

This document (EN ISO 6874:2015) has been prepared by Technical Committee ISO/TC 106 "Dentistry" in collaboration with Technical Committee CEN/TC 55 “Dentistry” the secretariat of which is held by DIN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by March 2016, and conflicting national standards shall be withdrawn at the latest by March 2016.

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Endorsement notice

The text of ISO 6874:2015 has been approved by CEN as EN ISO 6874:2015 without any modification.

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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).

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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.

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 ± 2) °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 ± 2) °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

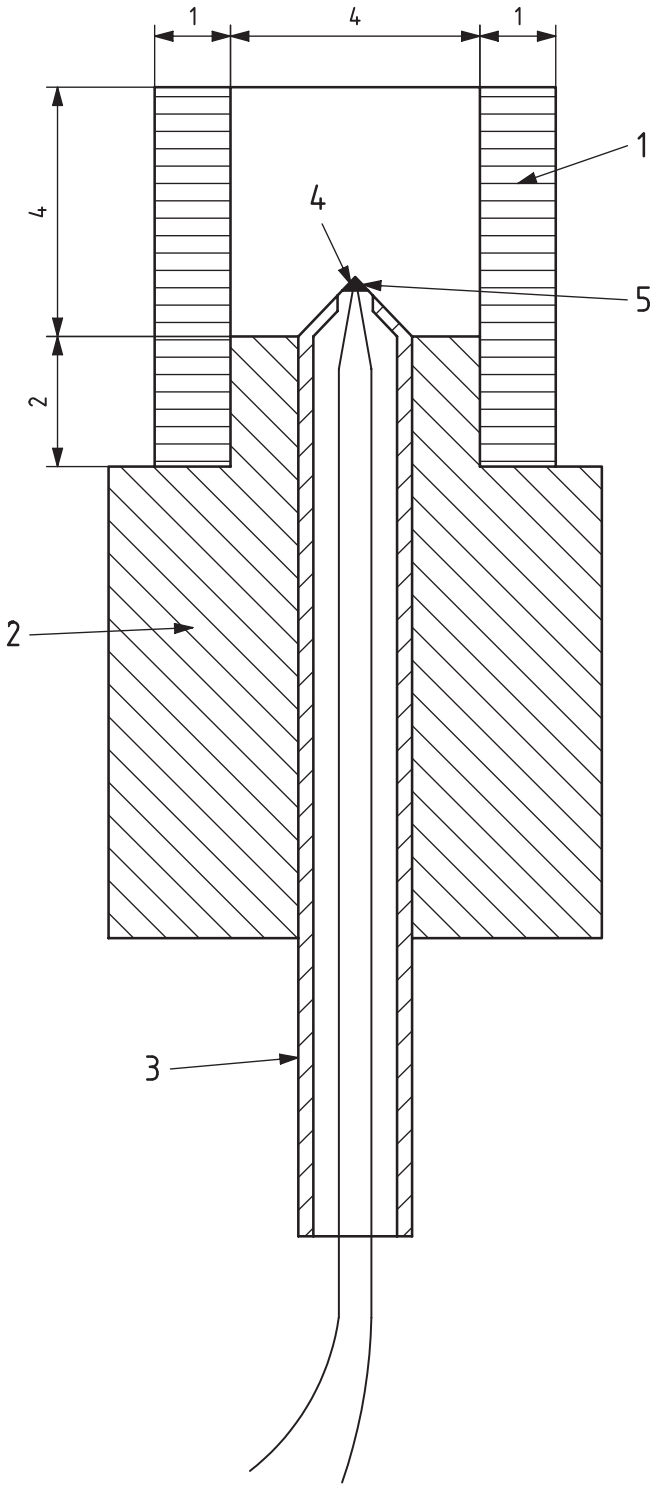
6.4.1.1 **Thermometry apparatus**, as shown in Figure 1.

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 × 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 ± 0,1 mm.

The thermocouple consists of wires (0,25 ± 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 °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

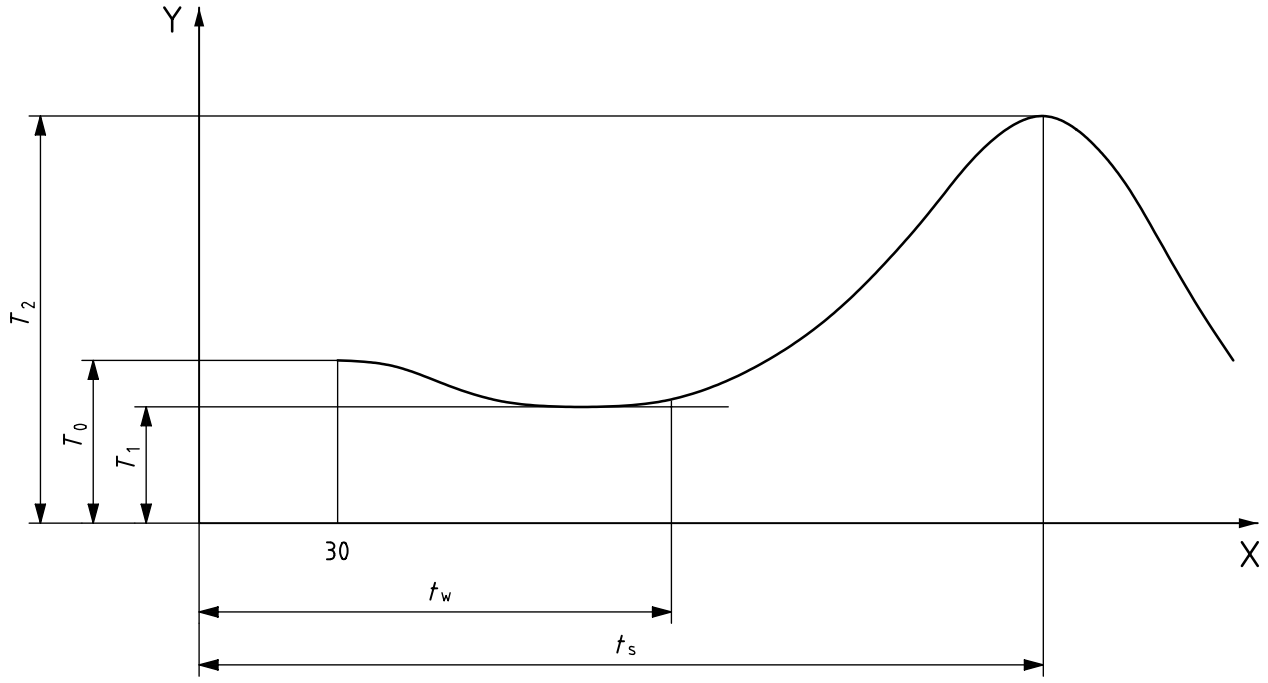
6.4.2 Procedure

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 ± 1) °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 ± 1) °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 T1, 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:

a) 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 ± 1) °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.

7.1 Packaging

The materials shall be supplied in containers or capsules (for the purposes of this International Standard, the container or capsule shall be considered to be the immediate wrapping of the material) that afford adequate protection and have no adverse effect on the quality of the contents.

An outer pack may also be used to present the containers or capsules as a single unit that provides protection for them.

7.2 Marking

7.2.1 Capsule or single dose container

NOTE The single dose container is a small syringe containing no more than 0,5 ml of material.

a) if the material is supplied in different shades, then the capsule or single dose container shall be marked to indicate the shade of the contained material;

b) the capsule or single dose container shall also be marked so that the product can be identified clearly;

c) the capsules or single dose containers shall be presented as a single unit in an outer pack;

d) the expiry date, expressed in accordance with ISO 8601, for the material if stored under the manufacturer's recommended conditions [see 7.3 h)].

7.2.2 Outer pack

The outer pack shall be marked with the following information:

a) the trade- or brand-name of the material;

b) the manufacturer's name and address and/or authorized representative in the country of sale;

c) the Class of sealant (see Clause 3) and its application given in clear language;

In addition, the following information shall be clearly visible either on the outer pack or in the manufacturer's instructions (see 7.3) or both:

d) the manufacturer's lot number;

e) the expiry date, expressed in accordance with ISO 8601, for the material if stored under the manufacturer's recommended conditions [see 7.3 k)];

f) recommended storage conditions [see 7.3 k)];

g) the mass and/or volume or number of dose units, etc.

7.3 Manufacturer's instructions and information for the user

Instructions and information shall accompany each individual outer pack of components and shall include the following details:

a) the principal component of the polymer base;

b) special indications or warnings when necessary;

c) any pharmaceutically active ingredients when present and referred to in the manufacturer's instructions for use of the material;

d) a description of the appearance of the components and the set sealant;

e) instructions for the pre-preparation of the sealant and information about those ambient conditions, such as temperature, humidity or light, that are likely to affect the sealant adversely;

f) instructions for manipulating the sealant;

g) the working and setting times of the sealant, determined in accordance with Clause 6;

h) the external energy source(s) suitable for curing Class 2 sealants and the irradiation time to be used;

i) detailed procedures for conditioning the tooth surfaces;

j) any limitation on the time of use of the sealant after preparation, particularly stating the effects of ambient light on external energy cured materials;

k) recommended storage conditions (e.g. need for refrigeration) making reference to the expiry date [see 7.2.2 e)];

l) any precautions for use and information on any adverse reactions that may be associated with the components or set sealant, particularly with regard to any uncured layer on the surface of the set sealant;

m) a description of the shade or shades of the material.

Bibliography

[1] ISO 4049, *Dentistry — Polymer-based restorative materials*

[2] ISO 7405, *Dentistry — Evaluation of biocompatibility of medical devices used in dentistry*

[3] ISO 10650-1, *Dentistry - Powered polymerisation activators - Part 1:Quartz tungsten halogen lamps*

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