



SLOVENSKI STANDARD
oSIST prEN ISO 23325:2019
01-julij-2019

Zobozdravstvo - Odpornost zobnega amalgama proti koroziji (ISO/DIS 23325:2019)

Dentistry - Corrosion resistance of dental amalgam (ISO/DIS 23325:2019)

Zahnheilkunde - Korrosionsbeständigkeit von Dentalamalgam (ISO/DIS 23325:2019)

Médecine bucco-dentaire - Résistance à la corrosion des amalgames dentaire (ISO/DIS 23325:2019)

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en

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Dentistry — Corrosion resistance of dental amalgam

Médecine bucco-dentaire — Résistance à la corrosion des amalgames dentaire

ICS: 11.060.10

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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).

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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.

ISO 23325, of which this is the first edition, was prepared by Technical Committee ISO/TC 106, *Dentistry*, Subcommittee SC 1, *Filling and Restorative Materials*. It uses one of the three corrosion test procedures present in ISO/TS 17988, *Dentistry – Corrosion test methods for dental amalgam* for which a requirement is given in this International Standard.

Introduction

This International Standard sets a requirement, being the acceptable limit, for the reduction in strength of dental amalgam that is a consequence of crevice corrosion when the test is conducted using the procedure specified in this standard. The testing protocol is designed to accelerate the effect, such that results will be obtained in a time suited to an *in vitro* test. Its purpose is to differentiate acceptable products from those that are not (by using a benchmark value) and not to rank products. It is not intended for use in product comparison claims.

This International Standard gives the first requirement for corrosion resistance of dental amalgam that conforms to ISO 24234, *Dentistry – Dental amalgam* or ISO 20749 *Dentistry – Pre-capsulated dental amalgam*.

The results of this test procedure should not be used for any biocompatibility claims, for which its use is inappropriate.

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Dentistry — Corrosion resistance of dental amalgam

1 Scope

This document gives the requirement for the permissible reduction in strength resulting from crevice corrosion of dental amalgam products that are within the scope of ISO 24234: *Dentistry – Dental amalgam* and ISO 20749: *Dentistry – Pre-capsulated dental amalgam*. It provides details of the test procedure for determining this.

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 4289, *Geometrical Product Specifications (GPS) — Surface texture: Profile method — Terms, definitions and surface texture parameters*

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

ISO 7488, *Dentistry — Mixing machines for dental amalgam*

ISO 13897, *Dentistry — Dental amalgam reusable mixing-capsules*

ISO/TS 17988, *Dentistry — Corrosion test methods for dental amalgam*

ISO/TS 20746, *Dentistry — Determination of the strength of dental amalgam by the Hertzian indentation strength (HIT) method*

ISO 20749, *Dentistry — Pre-capsulated dental amalgam*

ISO 24234, *Dentistry — Dental amalgam*

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

dental amalgam alloy

alloy in fine particles, composed mainly of silver, tin and copper, which when mixed with dental mercury produces a dental amalgam for dental restoration

[SOURCE: ISO 20749:2017, 3.1]

ISO/DIS 23325:2019(E)**3.2****dental mercury**

mercury supplied for use in the preparation of dental amalgam

[SOURCE: ISO 20749:2017, 3.2]

3.3**pre-capsulated product**

product supplied in a sealed capsule that contains measured amounts of dental amalgam alloy powder and dental mercury with masses that are appropriate for the production of a mass of dental amalgam that is considered to be suitable for a single small or medium size restoration in a single tooth

Note 1 to entry: The dental amalgam alloy powder and dental mercury are separated by a barrier that is broken immediately prior to mixing, allowing their contact. The capsule remains sealed until mixing has been completed.

[SOURCE: ISO 20749:2017, 3.3]

3.4**dental amalgam alloy tablet**

quantity of dental amalgam alloy powder that has been compressed to form a single entity for the purpose of providing a pre-dosed quantity of the alloy that, when mixed with an appropriate mass of dental mercury, produces a mass of dental amalgam that is considered to be suitable for a single small or medium size restoration in a single tooth

Note 1 to entry: During mixing the tablet is intended to break apart, forming a fine powder.

[SOURCE: ISO/TS 20746:2016, 3.4]

3.5**dental mercury sachet**

measured quantity of dental mercury supplied in a sachet (for use in a reusable mixing capsule) in a mass that, when mixed with an appropriate mass of dental amalgam alloy, produces a mass of dental amalgam that is considered to be suitable for a single small or medium size restoration in a single tooth

Note 1 to entry: The sachet is intended to rupture during mixing to allow the dental mercury to come into contact with the dental amalgam alloy powder.

Note 2 to entry: A dental mercury sachets may be referred to as a dental mercury pillow.

[SOURCE: ISO/TS 20746:2016, 3.5]

3.6**hertzian-loading strength-reduction corrosion test**

test in which a test-piece is immersed for a defined period of time in a specified solution (at a specified temperature) in a way that creates crevice corrosion conditions on one surface, after which it is removed from the solution and fractured with the force to do this then compared with the force to fracture an identical test-piece subjected to ageing in air at the same temperature

Note 1 to entry: Fracture is initiated from the surface subjected to crevice corrosion conditions and proceeds by radial crack growth.

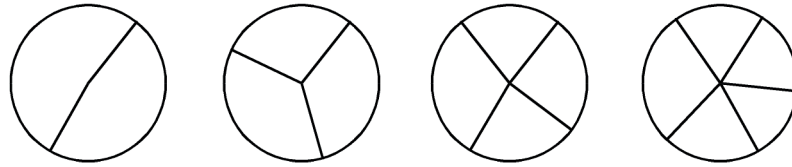
[SOURCE: ISO/TS 17988: 2019, 3.8]

3.7**radial cracking**

fracture pattern of a Hertzian-loaded test-piece in which (more or less) planar cracks form along radii, normal to the face of the disc shaped test-piece, thus dissecting it into two or more sectors

Note 1 to entry: Such radial cracks initiate on the test surface of the test-piece and propagate through the disc to produce approximately equiangular dissection in most cases.

EXAMPLE Some radial fracture patterns in disc shaped test-pieces are illustrated here



[SOURCE: ISO/TS 20746:2016, 3.8]

3.8

top surface of the Hertzian-loading test-piece

surface of the disc shaped test-piece that has been produced by carving back unset amalgam that is above the level of the mould until the surface of the test-piece is flat and level with that mould surface

[SOURCE: ISO/TS 20746:2016, 3.6]

3.9

test surface of the Hertzian-loading test-piece

surface of the disc shaped test-piece that has been produced by contact with the polished glass plate when the mixed amalgam is packed into the mould

[SOURCE: ISO/TS 20746:2016, 3.7]

3.10

mixing machine for dental amalgam

DEPRECATED: amalgamator

electrically-powered mixing machine that operates using an oscillating action for mixing dental amalgam alloy and dental mercury (in a capsule) to produce a dental amalgam

[SOURCE: ISO/TS 17988: 2019, 3.12] ^{ST EN ISO 23325:2020}

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4 Sampling

Products shall be procured in packages that have been produced for retail.

For pre-capsulated dental amalgam products, procure a sufficient number of capsules from a single lot.

For dental amalgam alloy in the form of a powder supplied in bulk or in tablets, procure sufficient dental amalgam alloy and a sufficient number of dental mercury sachets from single lots. The dental mercury sachets shall conform to ISO 24234.

NOTE In this context “sufficient” is deemed to be the quantity to make the required number of test-pieces and the maximum number of test-pieces allowed to replace any that are rejected.

At least 2,5 g of dental amalgam alloy is required per test-piece.

5 Requirement

When tested in accordance with 6, 7, 8 and 9 the mean value (in newtons) of ten valid results for corrosion test-pieces shall not be less than 80 % of the mean value (in newtons) of ten valid results for control test-pieces.