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Dentistry — Dental amalgam reusable mixing-capsules

Médecine bucco-dentaire — Capsules de mélange réutilisables pour amalgame dentaire

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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 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 6, *Dental equipment*.

This second edition cancels and replaces the first edition (ISO 13897:2003) including Technical Corrigendum 1 (ISO 13897:2003/Cor.1:2003), which has been technically revised.

The main changes compared to the previous edition are as follows:

— the scope has been revised and is now restricted to dental amalgam reusable mixing-capsules;

— classification into two types has been deleted;

— labelling requirements have been updated.

— requirements for single-use capsules are now within the scope of ISO 20749:2017, these being:

  — the requirement for surface contamination of the package and the capsule for pre-capsulated dental amalgam alloy products;

  — loss of mass during mixing from single-use capsules;

  — the requirement for containers in which single-use capsules are supplied to prevent spillage of dental mercury leaking from faulty or damaged single-use capsules;

  — labelling requirements for pre-capsulated dental amalgam products;

  — manufacturer's instructions regarding conditions of storage and the disposal of single-use capsules in pre-capsulated dental amalgam products.

Introduction

In order to produce dental amalgam, an electrically-powered mixing machine, as described in ISO 7488 is used for mixing dental amalgam alloy powder with dental mercury. In addition, a removable mixing-capsule is used to contain the dental amalgam alloy and the dental mercury during the mixing process.

NOTE Traditionally, the mixing machine for dental amalgam has been called an amalgamator. The latter is now a deprecated term.

Dentistry — Dental amalgam reusable mixing-capsules

1 Scope

This document specifies the requirements for reusable mixing-capsules intended to contain dental amalgam alloy powder and dental mercury when these are mixed to produce dental amalgam, and the test methods used to determine conformity to these requirements.

NOTE ISO 7488 specifies requirements for mixing machines. The requirements for mixing-capsule are not dealt with in ISO 7488, although the mixing-capsule is an essential part of the mixing machine.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitute 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 7488, *Dentistry — Mixing machines for dental amalgam*

ISO 24234:2015, *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 https://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

[SOURCE: ISO 20749:2017, 3.1]

3.2
dental mercury
mercury supplied for use in the preparation of dental amalgam

[SOURCE: ISO 20749:2017, 3.2]

4 Requirements

4.1 Dimensions

4.1.1 Length tolerance

The overall length of the mixing-capsule shall be within ±1 mm of the length specified by the manufacturer.

Testing shall be carried out in accordance with 6.1.

All 10 capsules in the sample under test shall meet the requirement for length tolerance.

4.1.2 Diameter tolerance

The maximum external diameter of the mixing-capsule shall be within ±0,5 mm of the diameter specified by the manufacturer.

Testing shall be carried out in accordance with 6.1.

All 10 capsules in the sample under test shall meet the requirement for diameter tolerance.

4.2 Loss of mass from the mixing-capsule during mixing

The loss in mass from the mixing-capsule during mixing shall not exceed 0,5 mg. Testing shall be carried out in accordance with 6.2.

Five out of five, or nine out of 10, mixing-capsules in the sample under test shall meet the requirement for loss of mass from the mixing-capsule during mixing.

4.3 Retention of dental amalgam in the mixing-capsule

The retention of dental amalgam in the mixing-capsule after the dental amalgam pellet has been removed shall not exceed 1 % of the combined masses of dental amalgam alloy and dental mercury inserted before mixing.

Testing shall be carried out in accordance with 6.3.

Five out of five, or nine out of 10, mixing-capsules in the sample under test shall meet the requirement for retention of dental amalgam in the mixing capsule.

5 Sampling

A number of mixing-capsules sufficient to perform all tests shall be obtained from a single lot produced for retail.

6 Measurements and test methods

6.1 Dimensions

6.1.1 Apparatus

6.1.1.1 Micrometer or an optical comparator, having an accuracy and resolution of 0,05 mm.

6.1.2 Test sample

10 mixing-capsules.

6.1.3 Procedure

Measurements shall be made to an accuracy of 0,05 mm.

Measure the overall length of each mixing-capsule.

Determine the location of the largest diameter and measure the diameter at this position for each mixing-capsule.

Record these values.

6.1.4 Report

6.1.4.1 General

Report the overall length and maximum diameter of all 10 mixing-capsules.

6.1.4.2 Conformity

Report whether the product does, or does not, conform to the requirements for dimensional tolerances given in 4.1.1 and 4.1.2.

6.2 Loss of mass from the mixing-capsule during mixing

6.2.1 Principle

The loss of content from the mixing-capsule during mixing is determined by weighing the mixing-capsule initially and again after mixing. Repeating the measurement of loss of mass from the mixing-capsule and testing a number of mixing-capsules are required because the amount lost could vary from mix to mix and from capsule to capsule.

6.2.2 Test sample

Select five mixing-capsules at random. If the use of a pestle is recommended, select five of a type recommended for use with the mixing-capsule.

If one of these mixing-capsules does not satisfy the requirement for the loss of mass from the mixing-capsule during mixing, a further five mixing-capsules from the same lot will be required.

6.2.3 Apparatus

6.2.3.1 Laboratory balance, with an accuracy and resolution of 0,1 mg.

6.2.3.2 Periodontal probe, WHO type, ball ended (0,5 mm diameter).

6.2.3.3 Brush having soft bristles.

6.2.3.4 Mixing machine for dental amalgam, in accordance with ISO 7488.

6.2.3.5 Dental amalgam alloy and dental mercury in sachets, in accordance with ISO 24234.

6.2.3.6 Surgical gloves, latex or similar.

6.2.3.7 Stereomicroscope, ×10.

6.2.3.8 Tweezers, stainless steel with pointed ends.

6.2.3.9 Weighing boats (25).

6.2.4 Test procedure

6.2.4.1 First measurement

At all times wear the surgical gloves when handling the mixing-capsule, to avoid contaminating the surface.

Take the mixing-capsule and blow oil-free compressed air over the surface to remove any adhering dust. Use the stereomicroscope to inspect the surface of the mixing-capsule for any remaining contaminant. If any is present, remove it with the brush.

Using the stereomicroscope, inspect the surface of the mixing-capsule for scratches and blemishes. If any are present, make a note of these.

Select the appropriate number of dental mercury sachets to obtain the mass of dental mercury that is recommended for mixing with approximately 600 mg of the dental amalgam alloy according to the instructions of the manufacturer of the dental amalgam alloy that is to be used. For the mass of dental mercury in these sachets, calculate and weigh out the exact mass of dental amalgam alloy that is required. Place both sachets and dental amalgam alloy in the capsule. Add a pestle (if one is required). Close the capsule.

Place the filled mixing-capsule on a weighing boat and record the mass (m_I). This and all subsequent weighings are to be accurate to 0,1 mg.

NOTE 1 It is not necessary to subtract the mass of the weighing boat from the combined mass of filled mixing-capsule and boat. This will be removed during subtraction of the weighing recorded after mixing. It follows that the same weighing boat is to be used for both determinations.

Taking care not to score the surface of the plastic mixing-capsule, place the weighed mixing-capsule in the mixing machine.

NOTE 2 Sharp edges on the metal fork (or similar device) that holds the capsule in the mixing machine can cut small amounts of plastic from the mixing-capsule when the necessary force is applied to seat the capsule. Such a loss can affect the result.

Mix, using the setting on the mixing machine and mixing time that are recommended by the manufacturer for the mass of dental amalgam alloy that is being mixed.

Once again, taking care not to score its surface, remove the mixing-capsule from the mixing machine. Use the stereomicroscope to inspect the surface for any marks that may have been produced when the mixing-capsule was placed in, or removed from the mixing machine. If any are seen, note these.

Then, place the mixing-capsule in the weighing boat and leave at ambient temperature for 20 min.

NOTE 3 The mixing process generates heat which affects weighing at the accuracy required if the temperature of the mixing-capsule is above ambient temperature. It is necessary to let the temperature of the mixing-capsule equilibrate with the ambient temperature before it is reweighed.

Reweigh the mixing-capsule and weighing boat and record this mass (m_F).

6.2.4.2 Cleaning the mixing-capsule

Open the mixing-capsule and remove the dental amalgam pellet, together with the pestle (if one is present) and all remnants of the dental mercury sachets. Remove all pieces of dental amalgam that are retained on the internal surface of the mixing-capsule (using a combination of periodontal probe, tweezers, brush and compressed air). Take care to ensure that the removal process does not cause scratching on the internal surface of the plastic mixing-capsule. Similarly, remove any dental amalgam adhering to the pestle. Use the stereomicroscope to determine whether the cleaning process has been thorough.

6.2.4.3 Second and subsequent measurements

Repeat the measurement of the mass loss during mixing (6.2.4.1) four more times with the cleaning procedure (6.2.4.2) between each measurement. This will produce five determinations of mass loss during mixing for the first mixing-capsule.

6.2.4.4 Mass loss during mixing for the four other mixing-capsules

Repeat procedures 6.2.4.1, 6.2.4.2 and 6.2.4.3 for the four other mixing-capsules to produce five mass losses during mixing measurements for each of these mixing-capsules.

6.2.5 Expression of the results

Tabulate the results.

The loss of mass of dental mercury and dental amalgam alloy during mixing (m_L) is given by Formula (1):

$$m_L = (m_T - m_F) \quad (1)$$

where

m_T is the mass of filled mixing capsule before mixing, in mg;

m_F is the mass of filled mixing capsule after mixing, in mg;

m_L is the loss of mass from filled mixing capsule during mixing, in mg.

If the loss in mass from any particular mixing-capsule in any of the five determinations is 0,5 mg or more, examine the record to ascertain whether any scratches or other markings had been introduced onto the mixing-capsule surface when the mixing-capsule was put into or removed from the mixing machine. Reject the result if such scratching or other marking is present, and make an additional measurement for mass loss during mixing for that mixing-capsule, so that five valid results are available.

A loss in mass of 0,5 mg or more from any one of the five valid determinations to which a mixing-capsule is subjected constitutes a failure for that capsule.

If only four of the five mixing-capsules meet the requirement specified in 4.2, test a further five mixing-capsules following the procedures given in 6.2.4.

6.2.6 Report

6.2.6.1 General

Present the results for the loss of mass from all 5 or 10 mixing-capsules tested (to 0,1 mg) for all five valid determinations to which each was subjected. Present any rejected result and give the reason for rejection. Report any irregularity in the test procedure.

6.2.6.2 Conformity

Report whether the product does or does not conform to the requirement for loss of mass from the mixing-capsule during mixing, in accordance with 4.2.

6.3 Retention of dental amalgam in the mixing-capsule

6.3.1 Principle

The retention of dental amalgam on the walls of the mixing-capsule during mixing and after the dental amalgam pellet has been removed is determined by weighing the mixing-capsule empty then reweighing

it after mixing and the dental amalgam pellet has been removed. Repeating the measurement of the retention dental amalgam on a number of mixing-capsules is required because the amount retained may vary from mixing-capsule to mixing-capsule.

NOTE In ISO 20749, it is the yield of usable dental amalgam from the single use capsules that is determined. For reusable mixing-capsules the retention of dental amalgam on interior surfaces after the pellet of mixed dental amalgam has been removed is more relevant and is determined in this document. The retained dental amalgam = 100 – yield of dental amalgam, expressed as a percentage (mass fraction).

6.3.2 Test sample

Select five mixing-capsules at random from a single lot that has been made for retail. If the use of a pestle is recommended, select five of a type recommended for use with the mixing-capsule.

A further five mixing-capsules from the same lot will be required if one of the first set of five does not satisfy the requirement for the retention of dental amalgam in the mixing-capsule. (If required, five more pestles will be required as well.)

6.3.3 Apparatus

All items listed in 6.2.3.

6.3.4 Test procedure

6.3.4.1 First measurement

At all times wear the surgical gloves when handling the mixing-capsule, to avoid contaminating the surface.

Take the mixing-capsule and blow oil-free compressed air over the surface to remove any adhering dust. Use the stereomicroscope to inspect the surface of the mixing-capsule for any remaining contaminant. If any is present, remove it with the brush.

Place the mixing-capsule on a weighing boat and weigh. Record this as the mass of the empty capsule (m_N). This and all subsequent weighings are to be accurate to 0,1 mg.

(It is not necessary to subtract the mass of the weighing boat from the combined mass of mixing-capsule and weighing boat (m_N). The mass of the weighing boat is removed in Formula (3). It follows that the same weighing boat is to be used for both weighings of the mixing-capsule.)

After selecting the appropriate number (n) of dental mercury sachets to obtain the mass of dental mercury that is recommended for mixing with approximately 600 mg of the dental amalgam alloy, use the mass of mercury in one sachet (m_{Hg}), as declared by the manufacturer in accordance with ISO 24234:2015, 7.2.1 f), to calculate the total mass of dental mercury in the sachets that are to be placed in the mixing-capsule ($n \cdot m_{Hg}$). Record this value.

Weigh out the exact mass of dental amalgam alloy that is to be used with this mass of dental mercury. Record the mass of the dental amalgam alloy (m_A).

Calculate and record the charge (m_C) of dental mercury and dental amalgam alloy in the capsule:

$$m_C = (n \cdot m_{Hg} + m_A) \quad (2)$$

where

