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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).