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Dentistry — Amalgam capsules

Art dentaire — Capsules pour amalgame

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Foreword

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The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

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ISO 13897 was prepared by Technical Committee ISO/TC 106, *Dentistry*, Subcommittee SC 6, *Dental equipment*.

Introduction

In order to produce dental amalgam, electrically powered amalgamators as described in ISO 7488 are primarily used for mixing (trituration) of amalgam alloys with mercury. In many amalgamators, a removable capsule is used to contain the alloy and mercury. Although the capsule must be considered as part of the amalgamator when in use or under test, the requirements for capsules are not dealt with in ISO 7488. These requirements are the subject of this International Standard.

Dentistry — Amalgam capsules

1 Scope

This International Standard specifies requirements and test methods for predosed capsules and for reusable capsules used for mixing dental amalgam alloys and mercury.

2 Normative references

The following referenced documents are indispensable for the application 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 1559:1995, *Dental materials — Alloys for dental amalgam*

ISO 1560, *Dental mercury*

ISO 1942-2, *Dental vocabulary — Part 2: Dental materials*

ISO 7488:1991, *Dental amalgamators*

ISO 8601, *Data elements and interchange formats — Information interchange — Representation of dates and times*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 1559, ISO 1942-2, ISO 7488 and the following apply.

3.1
predosed capsule
single-use capsule supplied containing separated measured amounts of alloy powder and mercury in such a way that premature contact is prevented

3.2
self-activating capsule
predosed capsule in which contact between the alloy powder and mercury occurs automatically during amalgamation

3.3
activation
action that renders the contained alloy powder and mercury mixable

4 Classification

Amalgam capsules covered by this International Standard shall be classified as follows, according to the reusability of the mixing capsule:

— Type 1: predosed mixing capsule

— Type 2: reusable mixing capsule

5 Requirements

5.1 Package and capsule contamination

The packaging container and the outer surface of Type 1 capsules shall be free of mercury and/or alloy powder contamination when tested in accordance with 7.1.

5.2 Dimensions

5.2.1 Length tolerance

The overall length of activated Type 1 capsules and of Type 2 capsules shall be within ± 1 mm of the length specified by the manufacturer.

Testing shall be carried out in accordance with 7.2.

5.2.2 Diameter tolerance

The maximum external diameter of Type 1 and Type 2 capsules shall be within ± 0,5 mm of the diameter specified by the manufacturer.

Testing shall be carried out in accordance with 7.2.

5.3 Loss of mass

5.3.1 General

The loss in mass for Type 1 and Type 2 capsules during amalgamation shall not exceed 0,5 mg.

Testing shall be carried out in accordance with 7.3.

5.3.2 Type 1 capsules

Type 1 capsules shall contain dental amalgam alloy and dental mercury which meet the following requirements:

— the dental amalgam alloy shall conform to ISO 1559;

— the dental mercury shall conform to ISO 1560.

5.3.3 Type 2 capsules

Type 2 capsules shall be tested using dental amalgam alloy and dental mercury which meet the following requirements:

— the dental amalgam alloy shall conform to ISO 1559;

— the dental mercury shall conform to ISO 1560.

5.4 Mercury and alloy retention

The mass of the retained material found within Type 1 and Type 2 capsules after amalgamation shall not exceed 1 % of the mass of alloy and mercury.

Testing shall be carried out in accordance with 7.4.

6 Sampling

A sufficient number of capsules to perform all tests shall be obtained from a single manufactured batch.

7 Test methods

7.1 Package and capsule contamination (Type 1 capsules only)

7.1.1 Apparatus

7.1.1.1 **Stereomicroscope** with 8x magnification.

7.1.2 Procedure

Visually examine both the primary package or container and 25 randomly selected capsules under a magnification of 8×.

7.2 Dimensions

7.2.1 Apparatus

7.2.1.1 **Micrometer** or an **optical comparator**, having an accuracy of ± 0,05 mm.

7.2.2 Procedure

Test 10 samples of the capsules. For Type 1 capsules, other than self-activating units, activate each sample but do not amalgamate before the test. Measure and record the overall length of each capsule. Determine the location of the largest diameter, measure and record each result.

7.2.3 Pass/fail determination

The length and diameter of all 10 capsules shall meet the requirements specified in 5.2.1 and 5.2.2.

7.3 Loss of mass

7.3.1 Apparatus

7.3.1.1 **Amalgamator** in accordance with ISO 7488 and tested using a strobe light as specified in ISO 7488:1991, 7.3, to ensure that the stated oscillation frequency is obtained.

7.3.1.2 **Laboratory balance** with an accuracy of ± 0,05 mg.

7.3.1.3 **Pliers**, needle-nosed type.

7.3.1.4 **Brush** having soft bristles.

7.3.2 Procedure for Type 1 capsules

Select five capsules at random and test each as follows. Before amalgamation, remove any loose material from the surface of each capsule and weigh each capsule to the nearest 0,1 mg. Amalgamate in accordance with ISO 1559:1995, 6.1.2. After amalgamation, allow each capsule to cool to room temperature for 1 h and then reweigh it to the nearest 0,1 mg.

7.3.3 Procedure for Type 2 capsules

Fill each of five randomly selected capsules with 600 mg alloy powder and add the mass of mercury specified by the manufacturer for this mass of alloy. Close the capsule, remove any loose material from the surface, and weigh to the nearest 0,1 mg. Amalgamate in accordance with ISO 1559:1995, 6.1.2. After amalgamation,

allow the capsule to cool to room temperature for 1 h and then reweigh it to the nearest 0,1 mg. Using the same capsules, repeat the test for each capsule four more times.

7.3.4 Calculation of results

Calculate the loss of mass as capsule mass before amalgamation minus capsule mass after amalgamation.

7.3.5 Pass/fail determinations

7.3.5.1 Type 1 capsules

If one of five capsules fails the test, test 10 more capsules. Five out of five capsules or 14 out of the 15 capsules shall meet the requirements of 5.3.

7.3.5.2 Type 2 capsules

If one of five tests for each capsule fails the test, test 10 more capsules five times each. Five out of five capsules or 14 out of the 15 capsules shall meet the requirements of 5.3.

7.4 Mercury/alloy retention

7.4.1 Type 1 capsules

7.4.1.1 Procedure

Use the apparatus specified in 7.3.1. Select five capsules at random and test each as follows. Weigh each capsule to the nearest 1 mg as m_1. Amalgamate for the time and at the frequency recommended by the alloy's manufacturer. Remove the capsule from the amalgamator, open the capsule, and empty the amalgam into a receptacle. Weigh the capsule components to the nearest 1 mg as m_2. If necessary, use pliers to separate all capsule components and then brush out all retained material. Reweigh the capsule components to the nearest 1 mg as m_3.

7.4.1.2 Calculation of results

The difference $(m_2 - m_3)$ is the mass of alloy and mercury retained. Calculate the retained mass of alloy and mercury, Δm, as percentage of the initial mass of alloy and mercury for each capsule to the nearest 0,05 %, using the following equation

$$\Delta m = 100 \times \frac{(m_2 - m_3)}{(m_1 - m_3)}$$

where

m_1 is the capsule mass before amalgamation;

m_2 is the mass of the capsule components after amalgamation;

m_3 is the mass of the capsule components after amalgamation and after brushing out all retained material.

7.4.1.3 Pass/fail determinations

If one of five capsules fails the test, test 10 more capsules. Five out of five capsules or 14 out of the 15 capsules shall meet the requirements of 5.4.

7.4.1.4 Expression of results

Report the number of specimens tested, the number complying with the specified requirement and whether the capsule passes of fails.

7.4.2 Type 2 capsules

7.4.2.1 Procedure

Use the apparatus specified in 7.3.1. Select five capsules and test each as follows. Weigh and record each Type 2 capsule as m_1. Fill each Type 2 capsule with 600 mg of alloy powder and alloy manufacturer's recommended mercury mass for the test sample. Weigh each full capsule to the nearest 1 mg as m_2. Amalgamate the capsule for the time and frequency recommended by the alloy's manufacturer Remove the capsule from the amalgamator, open the capsule, and empty the amalgam into a receptacle. Weigh the capsule components to the nearest 1 mg as m_3.

7.4.2.2 Calculation of results

The difference $(m_3 - m_1)$ is the mass of alloy and mercury retained. Calculate the retained mass of alloy and mercury, Δm, as percentage of the initial mass of alloy and mercury for each capsule to the nearest 0,05 %, using the equation

$$\Delta m = 100 \times \frac{(m_3 - m_1)}{(m_2 - m_1)}$$

where

m_1 is the capsule mass without alloy powder and mercury;

m_2 is the mass of the capsule components including alloy powder and mercury;

m_3 is the mass of the capsule components after amalgamation and after brushing out all retained material.

7.4.2.3 Pass/fail determination

If one of five capsules fails the test, test 10 more capsules. Five out of five capsules or 14 out of the 15 capsules shall meet the requirements of 5.4.

7.4.2.4 Expression of results

Report the number of specimens tested, the number complying with the specified requirement and whether the capsule passes of fails.

8 Packaging

Type 1 capsules shall be packaged in containers that, under normal conditions of shipment, ensure that the capsules remain intact so as to prevent spillage or contamination with alloy or mercury or both.

9 Labelling

9.1 General

The following information shall be included on the package:

a) name and address of manufacturer and/or distributor;

b) lot number (batch code) and date of packaging expressed as a six-digit number in accordance with ISO 8601;

c) length and maximum exterior diameter of capsule;

d) quantity of units in each package.

9.2 Type 1 capsules

For Type 1 capsules, in addition to 9.1, the following information shall be included on the package:

a) brand or trade name of alloy powder;

b) nominal mass of alloy powder;

c) nominal powder/mercury ratio by mass in each capsule;

d) hazard warning symbol in accordance with the requirements of ISO 1560, and a reference to that International Standard;

e) recommendation to store at temperatures no higher than 25 °C.

9.3 Type 2 capsules

For Type 2 capsules, in addition to 9.1, the following information shall be included on the package:

a) nominal mass of each pestle, if applicable.

10 Manufacturer's instructions

Instructions for use shall include at least the following information:

a) conditions of use;

b) for Type 1 capsules: comment regarding conformity with the applicable information of ISO 1559:1995, 7.3;

c) conditions for storage;

d) recommendations for disposal, printed in bold type, and in addition the following statement, in bold type:

Dispose of used capsules in accordance with national regulations.

e) length and maximum exterior diameter of capsule;

f) for Type 2 capsules, recommendations for cleaning and the maximum number of uses.

ICS 11.060.10

Price based on 6 pages