INTERNATIONAL STANDARD

ISO 1563

Second edition
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Dental alginate impression material

Produits pour empreintes dentaires à base d'alginate

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Contents

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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.

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.

International Standard ISO 1563 was prepared by Technical Committee ISO/TC 106, *Dentistry*.

This second edition cancels and replaces the first edition (ISO 1563:1978), of which it constitutes a technical revision.

This revision of ISO 1563 differs from the first edition in the following respects:

a) The system of classification into classes A, B and C based on clinical application has been deleted because it has been recognized that class A alginate materials should not be used to obtain models for making fixed restorations and that all class C alginates can be used for normal impression procedures. As a consequence the "viscosity" requirement has also been deleted.

   The system of classification into types I and II, based on the speed of setting, has also been deleted because it has been recognized that the best indication of the speed of setting is given by the setting time itself.

b) The test for setting time given in the first edition of ISO 1563 has been omitted because it proved to be too laborious and because no other test has been introduced due to lack of knowledge about the clinical significance. As a result this revision does not contain a requirement for the setting time as such but requires the manufacturer's stated setting time to be checked by the requirement on recovery after deformation.

c) The water-bath testing temperature is now defined as 35 °C ± 1 °C, the temperature which offers a heating rate of the test specimen comparable to the heating rate of impression material under oral conditions.

d) The requirement as to the proportioning devices has been deleted because of the opinion that a moderate deviation in the powder-to-water ratio will not affect clinical results.

Introduction

While it was recognized by the committee that prepared this International Standard that the mixed paste, when used in accordance with the manufacturer's instructions, should have no unpleasant odour or flavour, the committee was unable to specify any requirements in this respect.

The material should neither cause irritation of the normal oral mucosa nor contain poisonous ingredients of sufficient quantity to harm human beings.

Specific qualitative and quantitative requirements for freedom from biological hazard are not included in this International Standard, but it is recommended that reference should be made ISO/TR 7405, *Biological evaluation of dental materials*, when assessing possible biological or toxicological hazards.

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Dental alginate impression material

1 Scope

This International Standard applies to dental alginate impression materials used in dentistry to take impressions of teeth and tissues of the oral cavity. It specifies requirements for dental materials containing an alginate as essential gel-forming ingredient, which, after mixing with water in accordance with the manufacturer's instructions, is capable of reacting to form a material suitable for taking impressions.

2 Normative reference

The following standard contains provisions which, through reference in this text, constitute provisions of this International Standard. At the time of publication, the edition indicated was valid. All standards are subject to revision, and parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent edition of the standard indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

ISO 6873:1983, *Dental gypsum products*.

3 Definitions

For the purposes of this International Standard, the following definitions apply.

3.1 mixing time: That part of the total working time specified or required in order to obtain a satisfactory mix.

3.2 total working time: That period of time between the start of mixing and the commencement of setting.

3.3 setting time: That period of time between the start of mixing and the achievement of the necessary elasticity to remove the impression.

4 Requirements

4.1 Powder

The powder shall be uniform and free from foreign materials (matter).

Compliance with this requirement shall be determined in accordance with 6.2.

4.2 Biocompatibility

See the introduction (p. v) for guidance on biocompatibility.

4.3 Mixed material

The material, mixed in accordance with the manufacturer's instructions, shall be homogeneous and free from lumps and granules and shall have a smooth surface; it shall form a smooth plastic mass.

Compliance with this requirement shall be determined in accordance with 6.2.

4.4 Mixing time

The mixing time, stated by the manufacturer, shall not be more than 60 s (1 min).

4.5 Total working time

When determined in accordance with 6.3, the average penetration value achieved shall not exceed 0,25 mm at the end of the total working time stated by the manufacturer.

4.6 Compatibility with gypsum and reproduction of detail

The impression material shall impart a smooth surface to, and separate cleanly from, a gypsum cast made from a recommended brand of gypsum product; this cast poured against the impression shall reproduce the 50 µm-line [see figure 3a)] without

interruption when the test specified in 6.4 is carried out.

4.7 Recovery from deformation

When determined in accordance with 6.5, the recovery from deformation shall be at least 95 %.

4.8 Strain in compression

When determined in accordance with 6.6, the strain in compression shall be neither less than 5 % nor more than 20 %.

4.9 Compressive strength

When determined in accordance with 6.7, the compressive strength shall be at least 0,35 MPa.

5 Sampling

Representative samples from a single manufacturing batch, including all necessary manufacturer's instructions and devices, shall be obtained.

The amount of material and deionized or distilled water to be obtained shall be sufficient to produce approximately 750 g of impression material to complete all the tests.

6 Test methods

6.1 General

The alginate powder in the closed original container and the test equipment (except for the smaller items used for mixing and specimen formation) shall be conditioned for not less than 10 h at 23 °C ± 2 °C and (50 ± 10) % relative humidity. The smaller items may be used after 30 min storage in the prescribed environment.

Unless otherwise stated, all tests shall be carried out under these conditions. Distilled or deionized mixing water shall be used at the temperature as stated by the manufacturer or otherwise at 23 °C ± 1 °C.

The proportions of powder and water shall be in accordance with the manufacturer's instructions and shall be achieved by weighing the components.

The specimen shall be prepared by mixing the alginate powder with water using the ratio and the method of mixing specified in the manufacturer's instructions.

6.2 Visual inspection

Compliance with the requirements laid down in 4.1, 4.3, clause 7 and, as far as applicable, clause 8 shall be determined by visual inspection.

6.3 Total working time

6.3.1 Apparatus

6.3.1.1 Penetrometer, equipped with a cylindrical penetrator ① and a dial indicator ②, graduated in 0,01 mm intervals, with a spindle ③ having a travel of at least 25 mm (see figure 1).

The penetrator shall have a total mass of 50 g ± 1 g and shall be positioned with its longitudinal axis perpendicular to the base of the instrument. The penetrometer shall have a mechanical or magnetic locking device ④ so that the penetrator can be fixed in any vertical position.

6.3.1.2 Rigid ring mould, made of brass or stainless steel, at the discretion of the manufacturer (see figure 2).

NOTE 1 If brass is used, the internal surface of the ring should be covered with a thin film of a non-reactive grease.

6.3.1.3 Smooth flat glass plate, large enough to support the ring mould (6.3.1.2).

6.3.2 Procedure

Place the glass plate (6.3.1.3) on the base of the penetrometer (6.3.1.1). Allow the penetrator to come into contact with the plate, take a fiducial reading (reading a) and then raise and fix the penetrator so that the tip is well above the upper end of the ring mould (6.3.1.2). Place the ring mould on the plate centrally under the penetrator and fill it with mixed material. Level the upper surface. Place the penetrator in contact with the upper surface of the material and fix it in that position. Five seconds (5 s) before the end of the total working time stated by the manufacturer, release the penetrator, with the spindle ③ held in the "up" position. Ten seconds (10 s) after release, fix the penetrator in the released (lowered) position. The lower the spindle until contact is made and take a second reading (reading b).

6.3.3 Expression of results

Calculate the difference between readings a and b in millimetres.

Record the average of three tests as the result.

6.4 Compatibility with gypsum and reproduction of detail

6.4.1 Apparatus

6.4.1.1 Ruled test block, made of cast or wrought austenitic stainless steel [see figure 3a)].

6.4.1.2 Ring mould [figure 3b)].

6.4.1.3 Split mould, such that gypsum cast can be removed without damage [see figure 3c)].

6.4.1.4 Smooth flat metal or glass plate, large enough to be a base for the ring mould (6.4.1.2).

6.4.1.5 Mass, 1 kg.

6.4.1.6 Water bath, capable of being maintained at 35 °C ± 1 °C.

6.4.2 Procedure

Place the ring mould (6.4.1.2) on the plate (6.4.1.4) and slightly overfill with mixed alginate material. Twenty seconds (20 s) before the end of the working time stated by the manufacturer, centre the clean test block (6.4.1.1) above the mould and press it down into the mass of alginate. Immediately place the assembly in the water bath (6.4.1.6), maintained at 35 °C ± 1 °C, and load with the 1 kg mass (6.4.1.5) conditioned at 35 °C ± 1 °C. Three minutes (3 min) after the stated setting time, remove the assembly from the water bath and separate the ring mould, together with the plate, from the test block.

Immediately prepare a gypsum mix, using a gypsum brand type 3 or 4 in accordance with ISO 6873, as recommended by the manufacturer [see (clause 7i)]. Rinse the alginate surface with water, or treat in any other way described in the manufacturer's instructions (e.g. with fixative solution), and shake off the excess fluid. Place the split mould (6.4.1.3) on the ring mould and gently fill with the gypsum product mix, using mechanical vibration in such a way that the gypsum product displaces any moisture adhering to the surface of the alginate. Allow the gypsum product mix to harden for 30 min in excess of the setting time. Separate the split mould containing the gypsum cast from the ring mould containing the alginate.

6.4.3 Test observation

Examine the gypsum cast under low-angle illumination, at a magnification of ×4 to ×12, and record whether the 50 µm-line [line a in figure 3a)] is completely reproduced over the full length of 25 mm between the intersection lines.

NOTES

2 If the alginate impression material tends to stick to the surface of the ruled test block, it is recommended that this surface be painted immediately before the alginate is mixed with a suitable separating agent.

3 To check that the gypsum product has not deteriorated, it is recommended that the setting time be determined in accordance with ISO 6873; the setting time should be within ± 20 % of the time stated by the manufacturer.

6.4.4 Expression of results

Record whether the 50 µm-line [line a in figure 3a)] is fully reproduced by at least two casts, resulting from three tests.

6.5 Recovery from deformation

6.5.1 Apparatus

6.5.1.1 Deformation apparatus, with sufficient force to deform the specimen height by 20 % and capable of measuring the height with an accuracy of 0,01 mm, without the specimen being displaced (see figure 4). The force exerted by the spindle of the dial indicator shall be 0,6 N ± 0,1 N.

The material of the apparatus in figure 4 shall be cast or wrought austenitic stainless steel.

Other apparatus with equal accuracy and performance may be used.

6.5.1.2 Split mould, with fixation ring, made of stainless steel or brass alloy (see figure 5).

6.5.1.3 Two flat glass plates, approximately 50 mm × 50 mm and at least 3 mm thick.

6.5.1.4 Flat glass plate, approximately 15 mm × 15 mm and 2 mm thick.

6.5.1.5 Water bath, capable of being maintained at 35 °C ± 1 °C.

6.5.1.6 C-clamps, having a throat capacity of at least 30 mm.

6.5.2 Preparation of the test specimen

Place the fixation ring (6.5.1.2) on one of the glass plates (6.5.1.3) and fill it slightly more than one-half full with alginate material, mixed in accordance with the manufacturer's instructions. Press the split mould in the ring until the bottom of the mould touches the plate and alginate extrudes above the top of the mould. Then press the second plate (6.5.1.3) over the mould to force away the excess alginate material and to form the upper surface of the specimen.