

INTERNATIONAL STANDARD

**ISO
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Dentistry — Reversible-irreversible hydrocolloid impression material systems

*Art dentaire — Systèmes de produits pour empreintes à base
d'hydrocolloïdes réversibles-irréversibles*



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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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 3.

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 13716 was prepared by Technical Committee ISO/TC 106, *Dentistry*, Subcommittee SC 2, *Prosthetic materials*.

Introduction

Specific qualitative and quantitative requirements for freedom from biological hazards are not included in this ISO Standard. But it is recommended that, in assessing possible biological or toxicological hazards, reference be made to ISO 7405 and ISO 10993-1.

Dentistry — Reversible-irreversible hydrocolloid impression material systems

1 Scope

This international Standard specifies requirements and test methods for tensile bond strength and linear dimensional change of reversible-irreversible hydrocolloid impression materials used in dentistry, as well as requirements for their labelling and manufacturer's instructions.

This International Standard is applicable to those alginate and syringeable agar dental impression materials which have been formulated such that they will bond to each other, when used in combination, to provide elastic impressions of oral tissues.

NOTE Requirements for other characteristics and properties of these impression materials are given in ISO 1563 and ISO 1564.

2 Normative references

The following normative documents contain provisions which, through reference in this text, constitute provisions of this International Standard. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent editions of the normative documents indicated below. For undated references, the latest edition of the normative document referred to applies. Members of ISO and IEC maintain registers of currently valid International Standards.

ISO 1563:1990, *Dental alginate impression material*.

ISO 1564:1995, *Dental aqueous impression materials based on agar*.

ISO 1942 (all parts), *Dental vocabulary*.

3 Terms and definitions

For purposes of this International Standard, the terms and definitions given in ISO 1942 and the following apply.

3.1 bond

(between dental reversible and irreversible impression materials) adherence of the materials to each other after both materials have set

3.2 storing

(of agar impression material) conditioning of the material, immediately after liquefaction, to reduce and maintain the temperature required for use in a succeeding step

3.3 tensile bond strength

(of reversible-irreversible impression material specimen) force per unit area required to create a rupture in a specimen tested in the tensile mode

4 Requirements

4.1 Biocompatibility

See Introduction.

4.2 Requirements given in ISO 1563 and ISO 1564 for characteristics and properties

When a manufacturer identifies any alginate material as being acceptable for use in combination with a particular agar material, each alginate material so identified shall be subject to all applicable requirements and tests stated in this International Standard and in ISO 1563 for alginate materials. Likewise, any agar material identified for use with a particular alginate material shall be subject to all applicable requirements and tests stated in this International Standard and to those in ISO 1564, except for the gelation temperature requirement (see clause 2).

4.3 Requirements given in this International Standard for characteristics and properties

4.3.1 Tensile bond strength

When tested in accordance with clause 7, the tensile bond strength between the agar and alginate shall not be less than 50 kPa.

4.3.2 Linear dimensional change

When tested in accordance with clause 8, the negative dimensional change of the combined impression material system specimens shall not be more than 1,0 % when measured at 20 min after commencement of mixing of the alginate component.

4.4 Requirements for instructions for use, packaging and labelling

The materials shall be subject to applicable requirements specified in clauses 9 and 10 of this International Standard and to requirements specified for instructions, packaging and labelling in pertinent clauses of ISO 1563 and ISO 1564.

5 Sampling

Samples shall be procured from a single manufacturing batch as packaged for retail marketing, to include the manufacturer's instructions.

6 Test methods — General

6.1 Laboratory conditions

Unless otherwise specified in this International Standard, conduct all specimen preparation and testing under ambient laboratory conditions of $(23 \pm 2) ^\circ\text{C}$ and $(50 \pm 10) \%$ relative humidity. Unless otherwise specified in this International Standard, bring all equipment and materials used in the tests to ambient temperature before beginning specimen preparation and testing.

6.2 Apparatus function verification

Before using any accessories, instruments or other items of equipment, calibrate or otherwise determine whether they comply with specifications given in this International Standard or in a related supporting standard.

6.3 Material manipulation and specimen preparation

Unless otherwise specified in this International Standard, prepare and manipulate the materials used for forming the test specimens using the equipment and procedures recommended in the manufacturer's instructions (see clause 9 of this International Standard and corresponding pertinent clauses in ISO 1563 and ISO 1564).