

American Dental Association
Specification No. 18

Alginate Impression Materials

Modified adoption of ISO 1563:1990, Alginate
impression materials



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ADA Specification No. 18 - 1992

**AMERICAN DENTAL ASSOCIATION
SPECIFICATION NO. 18 FOR ALGINATE IMPRESSION MATERIALS**

American Dental Association Specification No. 18 for Alginate Impression Materials has been approved by the Council on Scientific Affairs of the American Dental Association. This and other specifications for dental materials, instruments and equipment are being formulated by subcommittees of the Accredited Standards Committee MD156 for Dental Materials, Instruments and Equipment. The Council acts as administrative sponsor of that committee, which has representation from all interests in the United States in the standardization of materials, instruments and equipment in dentistry. The Council has adopted the specifications, showing professional recognition of their usefulness in dentistry. Approval of ADA Specification No. 18 was granted by the American Dental Association in 1992.

The Council thanks the subcommittee members and the organizations with which they were affiliated at the time the specification was developed: Kenneth Rudd (Chairman), University of Texas Health Science Center, San Antonio; Ramon Baez (Secretary), University of Texas Health Science Center, San Antonio; David Appleby, Temple University, Philadelphia, PA; Richard Bennett, L.D. Caulk Company, Milford, DE; Robert Craig, University of Michigan, Ann Arbor; Richard Demke, GC America, Inc., Chicago, IL; Jerold Horn, Unitek Corporation, Monrovia, CA; Robert McConnell, University of Texas Health Science Center, San Antonio; Brahma Sharma, Biotrol International, Louisville, CO; Duncan Waller, Kerr Manufacturing Company, Romulus, MI; and Ann Marie Wieveg, Gingi-Pak, Camarillo, CA.

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FOREWORD

This Foreword is not a part of ADA Specification No. 18.

1. GENERAL INFORMATION

This American Dental Association (ADA) Specification is identical to International Standard ISO 1563 for alginate impression materials with exceptions which are explained in this Foreword. The exceptions strengthen this specification with respect to applications in the United States and its territories.

ISO (The International Organization for Standardization) is a world wide federation of national standards bodies (ISO member bodies). The work of preparing international standards is carried out through ISO Technical Committees. Each member body interested in a subject for which a technical committee has been established has a right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work of ISO and collaborate closely with the International Electro-Technical Commission (IEC) on all matters of electro-technical standardization.

Draft International Standards (DIS) are circulated to the member bodies for approval before they are accepted as international standards by the ISO Council. They are approved in accordance with set procedures requiring at least 75% approval by the member bodies voting.

The International Standard ISO 1563 Dental Alginate Impression Materials was prepared by the Technical Committee ISO/TC 106, Dentistry, following ISO Directive Part 3, Drafting and Presentation of International Standards, second edition, 1989.

Interested parties in the United States contribute to the development of ISO Standards through the activities of the U.S. Technical Advisory Group which is accredited by the American National Standards Institute (ANSI). ANSI is the member body representing United States interests in the work of ISO.

Accredited Standards Committee (ASC) MD 156 is an independent committee accredited by the American National Standards Institute and sponsored by the American Dental Association. The ASC MD156 coordinates efforts toward drafting, review, and approval of dental product standards in the United States.

2. EXCEPTIONS TO ISO 1563

In addition to a few minor editorial changes, the following exceptions to ISO 1563 have been approved for inclusion in this specification to strengthen it with respect to applications in the United States and its territories.

- 2.1 The ISO Standard has never prescribed requirements for the "Initial setting time" and "deterioration" tests which have been integral parts of all previous editions of ADA Specification No. 18. Requirements associated with these tests are continued in this revised edition of the specification.
- 2.2 Annex A and Annex B are added to this specification to permit options in specimen preparation needed to provide for more reliable ways of making specimens.
- 2.3 The description of the Mould C in Figure 3 has been changed to read "Slit" mould instead of "Split" mould because (1) the term "Slit" better defines the character of the mould and (2) the change will help eliminate confusion possible because the mould shown in Figure 5 is also, but more properly, described as a split mould.
- 2.4 The requirements for labeling and marking of the outer wrapping of packages does not include requirement for the outer wrappings or containers to indicate batch numbers and the net mass of the content of packages. Requirements have been added to 8.2.1 of this specification to require these two essential markings.
- 2.5 Since some of the requirements in 8.2.2 of ISO 1563 for labeling and marking of immediate containers can be unrealistic in some instance. The corresponding subclause in this specification specifies certain instances when the requirement for such markings may be waived.

3. DIFFERENCES BETWEEN THIS REVISION AND THE PRECEDING EDITION OF ANSI/ADA SPECIFICATION 18.

- 3.1 The system of classification into Types I and II, based on the speed of setting, has been deleted because it has been recognized that the best indication of the speed of setting behavior is given by the setting time information which 8.2.1 and 8.2.2 require to be shown on the outer wrapping of the packages and the immediate container.
- 3.2 The requirement for odor and flavor has been removed due to lack of an appropriate test. However, it is recognized that the mixed paste, when used in accordance with the manufacturer's instructions, should have no unpleasant odor or flavor.
- 3.3 The requirement for "Irritation" was removed because no single specific test for irritation has been specified. This does not relieve the manufacturer of the responsibility to make sure that the material does not cause irritation of the normal mucosa and does not contain poisonous ingredients of sufficient quantity to harm human beings.

Specific qualitative and quantitative requirements for freedom from biological hazards are not included in this specification, but it is recommended that reference should be made to ANSI/ADA Document 41 for Recommended Standard Practices for the Biological Evaluation of Dental Materials (1979) and ISO/TR 7405, Biological Evaluation of Dental Materials, when assessing possible biological or toxicological hazards.

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- 3.4** The compatibility with gypsum requirement and test was changed to make it more clinically relevant. The use of unmodified alpha calcium sulfate hemihydrate was discontinued because it is not used in the dental office or laboratory for making casts. Compatibility must be established with one Type III and one Type IV or Type V brand name of dental gypsum of the manufacturer's choice.
- 3.5** The working time requirement has been changed to permit the manufacturer to state his own working time rather than restrict him to specific limits. Since the Type I and Type II Classifications have been eliminated, this seems most logical.
- 3.6** The term "Initial setting time" as defined and used in this edition is substituted for the term "Setting time" as that term was used in previous editions to indicate a condition of near gelation, or setting, that was measurable using a simple test.
- 3.7** The term "Setting time" as defined and used in this edition is associated with a condition of gelation, or setting, which, for all practical purposes, is complete or "final." This specification does not specify a test for determining this condition because no reliable method has been identified.
- 3.8** "Permanent deformation" has been redefined as "recovery from deformation." Clinically it is better to know the amount of recovery rather than the amount of deformity. The amount is written as a positive rather than a negative.
- The recovery from deformation test now requires the specimen to be deformed 20% for 5 seconds instead of 10% for 30 seconds as required by the preceding editions. Evidence has been presented to illustrate that the requirement for the 20% deformation is justified. The shorter deformation time is reflective of what occurs in clinical practice.
- 3.9** The water-bath testing temperature is now defined as $(35 \pm 1)^{\circ}\text{C}$, a temperature comparable to that which the impression material will be exposed under oral conditions.
- 3.10** Changes in the equipment designs illustrated in figures 1,2,3,4, 5 and 6 constitute improvements over the designs prescribed in previous editions for the same purposes. The new designs are in harmony with those prescribed for the other ISO elastic impression material standards 1564 and 4823.
- 4** There are two informative annexes to this standard. Annex A is added to permit options in specimen preparation that will provide for improved quality in specimens needed for reproduction of detail and compatibility testing. Annex B has been added to illustrate how the split mould depicted in Figure 5 can be modified to make it more effective for forming specimens made of the more viscous materials.

- 5** Suggestions for improvement of this standard will be welcomed. They should be sent to:
 Department of Standards Administration
 American Dental Association
 211 E. Chicago Avenue
 Chicago, IL 60611-2678

This revision cancels and replaces ANSI/ADA Specification No. 18 for Alginate Impression Material effective May, 1969.

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AMERICAN DENTAL ASSOCIATION SPECIFICATION NO. 18 FOR DENTAL ALGINATE IMPRESSION MATERIAL

1 SCOPE

This Specification applies to dental alginate impression materials used in dentistry to make impressions of teeth and tissues of the oral cavity. It specifies requirements for dental materials containing an alginate as an essential gel-forming ingredient. After mixing with water in accordance with the manufacturer's instructions, this ingredient is capable of reacting to form an elastic material suitable for making impressions.

2. NORMATIVE REFERENCE

The following specification contains provisions which, through reference in this text constitute provisions of this ANSI/ADA Specification. At the time of publication, the edition indicated was valid. All standards are subject to revision, and parties to agreements based on this specification are encouraged to investigate the possibility of applying the most recent edition of the standard indicated below.

ANSI/ADA Specification No. 25 for Dental gypsum products, 1989.

3. DEFINITIONS

For the purpose of this Specification 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 gelation (setting).
- 3.3 Initial Setting Time.** The time measured from the beginning of mixing, when the impression material, setting and tested outside the mouth at $(23 \pm 2)^{\circ}\text{C}$, exhibits a loss of tackiness.
- 3.4 Setting Time.** The time measured from the beginning of mixing, at which the impression material achieves the elastic properties necessary for optimum recovery of the material from the deformation it undergoes when the impression is removed from the mouth.

4. REQUIREMENTS

- 4.1 Powder.** The powder shall be uniform and free from foreign materials (matter).