



Revised American National Standard/
American Dental Association
Standard No. 19

Elastomeric Impression Materials

Modified adoption of ISO 4823:2015, *Dentistry-Elastomeric dental impression materials*

ADA American
Dental
Association®

Standards Committee on Dental Products

2018

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REVISED AMERICAN NATIONAL STANDARD/AMERICAN DENTAL ASSOCIATION STANDARD NO. 19 FOR ELASTOMERIC IMPRESSION MATERIALS

The ADA Standards Committee on Dental Products (SCDP) has approved Revised ANSI/ADA Standard No. 19 for Elastomeric Impression Materials. This and other standards for dental materials, instruments and equipment are being formulated by working groups of the ADA SCDP. The Committee has representation from all interests in the United States in the standardization of materials, instruments and equipment in dentistry. The Committee has adopted the standards, showing professional recognition of their usefulness in dentistry, and has forwarded them to the American National Standards Institute with a recommendation that the standards be approved as American National Standards. The American National Standards Institute granted approval of ADA Standard No. 19 as an American National Standard on August 4, 2017.

The ADA Standards Committee on Dental Products thanks the members of Working Group 2.10 and the organizations with which they were affiliated at the time the specification was developed:

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FOREWORD

(This Foreword does not form a part of Revised ANSI/ADA Standard No. 19 for Elastomeric Impression Materials).

This edition of ANSI/ADA Standard No. 19 cancels and replaces ANSI/ADA Standard No. 19: 2004, Dental Elastomeric Impression Materials. ANSI/ADA Standard No. 19:2004 was an identical adoption of ISO 4823:2000, Dentistry-Elastomeric impression materials. This edition of ANSI/ADA Standard No. 19 is a modified adoption of ISO 4823:2015.

Some of the clauses have been re-ordered and re-numbered. Additionally, the clauses that have been modified are: Definitions; Classifications; Requirements for characteristics and properties; Test methods-general; Test methods-specific; Requirements for information in manufacturer instructions; and Requirements for packaging and labeling.

Concerning the order in which some clauses are presented

Whereas in later years most dental product standards have been structured to have the Requirements and Test methods clauses appear before the Requirements for Labeling and Instructions for use clauses, this document gives first ordering to the Labeling and Instructions for use Requirements. This change was thought to be necessary because experience informs us that test operators will be better equipped to obtain success in testing if they first take into account the information available in the labeling and in the instructions for use (see Clause 5).

Concerning a new clause added: Pretest planning approaches

This clause has been added for reasons explained in the first paragraph of Clause 6.

Modifications

Terms and definitions

The following definitions that are not included in ISO 4823: 2015 have been added to assist users of this standard: application steps; cast; consumer packaging; effective setting time; end purpose function; extrusion packaging; homogeneous mixture; impression; intaglio surface; preparatory steps; performance standard; sample; secondary packaging (outer packaging); specimen; thixotropic material; Type.

4.1.1 Types

Classification has been assigned a sub clause number.

5.2.1 Secondary packaging labels

Use by is used in Standard 19 instead of USE BEFORE DATE

This is accepted and for clarification purposes, examples have been given to the provision stated in ISO 8601 for *Calendar date representations with reduced precision*^[6].

6.2.2 Examinations for effectiveness of the packaging

This sub clause has been added in Standard 19 to examine the package for possibilities that the quality of the content may have been compromised since its manufacture.

7.2.3 Specimen increment formation, delivery and positioning steps and 7.2.4 Test procedure steps

These subclauses have been separated, giving specific instructions to the user for forming test increments and to facilitate conducting the actual test procedure. Details for performing the test are given under 7.2.4.

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FOREWORD, continued

7.3.1 Apparatus and materials applicable to the Type 0, impression materials (putty) materials

More precise information on each element required for performing the test is given. The word "Nitrile gloves" has been substituted by "elastic gloves" since it is not imperative to use nitrile; the importance is that no latex gloves should be used since it has been demonstrated that this material interferes with the setting reaction of elastomerics.

7.4 Detail reproduction before and after disinfection

Emphasis is made to the fact that detail reproduction test shall be conducted before and after disinfecting procedures.

7.4.2.3 Specimen formation steps

More precise description for forming specimens is given for each of the Types of materials including recommendations for thixotropic materials.

Concerning the Annexes

Annex A of this document was created due to the ISO Central Secretariat suggestion that all Figures, grouped together, instead of being presented individually, on related pages of the text, should be presented in a normative Annex and numbered according to existing rules. This is to make it easier for the Figures to be located by users of the document.

Normative Annex B provides for standardized hand mixing methods to be used by test operators so that specimen preparation mixing of the test specimens will be uniform and consistently fairer to the various products.

Bibliography

These reference are not included in ISO 4823 and have been added to this document to provide additional resources:

- [3] ANSI/ADA Standard No. 41, *Evaluation of Biocompatibility of Medical Devices Used in Dentistry*
- [5] ISO 1942, *Dentistry – Vocabulary*
- [6] ISO 8601, *Data elements and interchange formats – Information interchange –Representation of dates and times*
- [7] ISO 21531, *Dentistry – Graphical symbols for dental instruments*
- [8] ISO 4823, *Dentistry – Elastomeric impression materials*

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INTRODUCTION

Parties seeking clarification of any provisions of this document, or desiring to recommend improvements for the next edition, are encouraged to do so by contacting the American Dental Association (ADA) Department of Standards at standards@ADA.org.

REVISED AMERICAN NATIONAL STANDARD/AMERICAN DENTAL ASSOCIATION STANDARD NO. 19 FOR ELASTOMERIC IMPRESSION MATERIALS

1 SCOPE

This American National Standard specifies the requirements and tests that the state-of-the-art body of knowledge suggests for helping determine whether the elastomeric impression materials, as prepared for retail marketing, are of the quality needed for their intended purposes.

NOTE This standard does not address possible biological hazards associated with the materials; therefore, interested parties are encouraged to explore ISO 7405^[1], ISO 10993^[2] and ANSI/ADA Standard No. 41^[3] for assessment of such hazards.

2 NORMATIVE REFERENCES

The following reference documents are indispensable for application of this document. The latest edition of the referenced document applies. Member bodies of the ISO and IEC maintain registers of currently valid International Standards.

ANSI/ADA Standard 33 Dental Product Standards Development Vocabulary

ANSI/ADA Standard 25 Dental Gypsum Products

ISO 6873, *Dentistry – Gypsum products*

(ADA standards and ISO standards for dentistry may be purchased from the American Dental Association, Dept. of Standards, 211 E. Chicago Ave., Chicago, IL 60611, <https://ebusiness.ada.org>)

3 TERMS AND DEFINITIONS

For the purposes of this ANSI/ADA Standard, the terms and definitions given in ANSI/ADA Standard 33 and the following apply.

3.1

application steps

placement or shaping of a material in its end purpose form or functional position in operations such as those listed below, after all required proportioning, mixing or other preparatory steps have been completed:

- Formation of pattern, molds, custom trays, preformed restorations, etc.
- Seating of impressions and pouring of gypsum mixes
- Filling of molds and tooth cavities
- Treating surfaces such as with etchants or surfactants so as to better prepare it for a subsequent purpose.

NOTE Adapted from ISO TC106 Internal Document 11942

3.2

cast

positive copy of the intaglio surface of an impression, usually obtained by pouring a relatively fluid gypsum/water mixture into contact with the intaglio surface and allowing it to harden so as to provide a means of evaluating relationships existing between intra-oral or craniofacial tissues as may be necessary for purposes of diagnoses or treatment procedures in any of the specialties of dentistry

NOTE The term "model" is used for designating the same concept in English language speaking countries other than the US.