



American National Standard/
American Dental Association
Specification No. 15

Synthetic Polymer Teeth

Identical to ISO 3336:1993



American Dental Association
Council on Scientific Affairs 1999

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**AMERICAN NATIONAL STANDARD/AMERICAN DENTAL ASSOCIATION
SPECIFICATION NO. 15 FOR SYNTHETIC POLYMER TEETH**

American Dental Association Specification No. 15 for Synthetic Polymer Teeth 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 working groups 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, and has forwarded them to the American National Standards Institute with a recommendation that the specifications be approved as American National Standards. The American National Standards Institute granted approval of ADA Specification No. 15 as an American National Standard on October 20, 1999. This standard becomes effective October 20, 2000.

The Council thanks the working group members and the organizations with which they were affiliated at the time the specification was developed: P.L. Fan (chairman), American Dental Association, Chicago, IL; Robert McConnell (secretary), University of Texas Health Science Center, San Antonio; Steve Duke, Indiana University, Indianapolis; Lawrence Gettleman, University of Louisville, Louisville, KY; Clyde Ingersoll, Ivoclar/Ardent, Tonawanda, NY; and Soren Sorenson, University of New York, Buffalo.

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FOR SYNTHETIC POLYMER TEETH**

FOREWORD

(This foreword is not a part of the ANSI/ADA Specification No. 15 for Synthetic Polymer Teeth.)

This revision is an adoption of the International Organization for Standardization International Standard 3336: 1993 for Dentistry—Synthetic Polymer Teeth with minor editorial changes. The Accredited Standards Committee MD156 Working Group examined the standard and found it acceptable for adoption as ANSI/ADA Specification No. 15.

INTRODUCTION

Specific qualitative and quantitative requirements of freedom from biological hazard are not included in this standard, but it is recommended that in assessing possible biological or toxicological hazards, reference should be made to ISO 10993-1: 1992, Biological Evaluation of Medical Devices—Part I: Guidance on Selection of Tests and ISO/TR 7405: 1984, Biological Evaluation of Dental Materials, or any more recent editions.

AMERICAN NATIONAL STANDARD/AMERICAN DENTAL ASSOCIATION SPECIFICATION NO. 15 FOR SYNTHETIC POLYMER TEETH

1. SCOPE

This standard specifies a classification, requirements and test methods for teeth that are composed of synthetic polymers such as polymethyl methacrylate and its copolymers, and that are manufactured for use in prostheses used in dentistry.

Terms used are in accordance with the definitions in ISO 1942-1 and ISO 1942-2.

2. NORMATIVE REFERENCES

The following standards contain provisions that, through reference in this text, constitute provisions of this standard. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this standard are encouraged to investigate the possibility of applying the most recent editions of the standards indicated below.

ISO 483:1988, Plastics—Small Enclosures for Conditioning and Testing using Aqueous Solutions to Maintain Relative Humidity at Constant Value

ISO 1567:1988, Dentistry—Denture Base Polymers

ISO 1942-1:1989, Dental Vocabulary—Part 1: General and Clinical Terms

ISO 1942-2:1989, Dental Vocabulary—Part 2: Dental Materials

ISO 3950:1984, Dentistry—Designation System for Teeth and Areas of the Oral Cavity

ISO 6873:1983, Dental Gypsum Products

ISO 7491:1985, Dental Materials—Determination of Colour Stability of Dental Polymeric Materials

3. CLASSIFICATION

Synthetic polymer teeth are grouped in accordance with the following classification:

Type 1: anterior teeth

Type 2: posterior teeth

4. REQUIREMENTS

4.1 Dimensions of Teeth

When measured in accordance with Section 6.2, the dimensions shall be within 5% of those stated by the manufacturer (see Section 7.3).

4.2 Color and Blend

Sets of anterior and posterior teeth, representing each shade from the same manufacturer, shall exhibit no perceptible color difference between each other and the manufacturer's shade guide (see Section 7.2.1), when tested in accordance with Section 6.3.