ANSI/ADA Specification No. 53:1999/ISO 10477:1992
Approval date: October 20, 1999

American National Standard/
American Dental Association
Specification No. 53

Polymer–Based Crowns and Bridge Resins

Identical adoption of ISO 10477:1992 and 10477 Amendment 1, 1998.

American Dental Association
Council on Scientific Affairs 1999

AMERICAN NATIONAL STANDARD/AMERICAN DENTAL ASSOCIATION SPECIFICATION NO. 53 FOR POLYMER-BASED CROWNS AND BRIDGE RESINS

American Dental Association Specification No. 53 for Polymer-Based Crowns and Bridge Resins 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. 53 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.

AMERICAN NATIONAL STANDARD/AMERICAN DENTAL ASSOCIATION SPECIFICATION NO. 53 FOR POLYMER-BASED CROWNS AND BRIDGE RESINS

FOREWORD

(This foreword does not form a part of the ANSI/ADA Specification 53 for Polymer-Based Crowns and Bridge Resins)

This specification is an adoption of the ISO 10477:1992, and 10477 Amendment 1:1998. The Accredited Standards Committee MD156 Working Group examined the standards and found them acceptable for adoption as ANSI/ADA Specification No. 53. The ISO standards have been combined into ANSI/ADA Specification No. 53.

INTRODUCTION

Specific qualitative and quantitative requirements for freedom from biological hazards are not included in this standard but it is recommended that, in assessing possible biological or toxicological hazards, reference should be made to ISO/TR 7405:1984, Biological Evaluation of Dental Materials, or any more recent edition.

Although this standard does not require manufacturers to declare details of the composition, attention is drawn to the fact that some national or international authorities require details to be provided to them.

AMERICAN NATIONAL STANDARD/AMERICAN DENTAL ASSOCIATION SPECIFICATION NO. 53 FOR POLYMER-BASED CROWNS AND BRIDGE RESINS

1. SCOPE

This standard covers polymer-based crown and bridge materials for laboratory-fabricated permanent facings or anterior crowns which may or may not be attached to a metal substructure. It excludes polymer-based materials that are used by the dentist to make crowns or veneers, or for repairs at the operatory. Nor does it cover the application of those materials for stress-bearing areas of posterior teeth.

This standard also applies to polymer-based crown and bridge materials for which the manufacturer claims adhesion to the metal sub-frame without macromechanical retention, such as beads or wires. It does not apply to denture base polymer and its adhesion to metal alloys, or to ceramic and its bonding to alloys.

This standard classifies polymer-based crown and bridge materials and specifies the requirements; it also specifies the test methods to be used to determine compliance with these requirements.

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. Members of IEC and ISO maintain registers of currently valid standards.

ISO 3696:1987, Water for Analytical Laboratory Use—Specification and Test Methods

ISO 6507-2:1983, Metallic Materials—Hardness Test—Vickers Test - Part 2. HV 0.2 to less than HV 5

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

ISO 8601:1988, Data Elements and Interchange Formats—Information Interchange—Representation of Dates and Times

ISO 1562:1993, Dental Casting Gold Alloys

ISO 8891:1998, Dental Casting Alloys with Noble Metal Content of 25% up to but Not Including 75%

3. DEFINITIONS

For the purposes of this standard, the following definitions apply:

3.1 Polymer-based Crown and Bridge Material: Composition of powders and liquids or pastes that may contain monomer, polymeric and/or inorganic fillers. The crown and bridge materials polymerize by heat, chemical activation or photoactivation to be suitable for the intended use as permanent facings or anterior crowns.

3.2 Dentine Resin: Pigmented and slightly translucent polymer-based crown and bridge material with a color suitable to imitate the natural color of dentine.

3.3 Enamel Resin: Translucent and slightly pigmented polymer-based crown and bridge material suitable to imitate the natural color of the tooth enamel packed in a layer over the dentine resin.