ANSI/ADA Specification No. 38 Approved by ANSI: March 23, 2000



American National Standard/ American Dental Association Specification No. 38

Metal-Ceramic Dental Restorative Systems

Modified adoption of ISO 9693:1999, Metal-ceramic dental restorative systems



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AMERICAN NATIONAL STANDARD/AMERICAN DENTAL ASSOCIATION SPECIFICATION NO. 38 FOR METAL-CERAMIC DENTAL RESTORATIVE SYSTEMS

The Council on Scientific Affairs of the American Dental Association has approved the American Dental Association Specification No. 38 for Metal-Ceramic Dental Restorative Systems. 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. 38 as an American National Standard on March 23, 2000. This standard becomes effective March 23, 2001.

The Council thanks the working group members and the organizations with which they were affiliated at the time the specification was developed: J. Robert Kelly (Chairman), NIST, Gaithersburg, MD; Ramon Baez, University of Texas Health Science Center at San Antonio, TX; Michael Bagby, West Virginia University, Morgantown, WV; Tom Cameron, Ney Dental, Inc., Bloomingfield, CT; Ronald Dudek, Austenal, Inc., Chicago, IL; Lawrence Gettleman, University of Louisville, KY; Steven Hondrum, Martinez, GA; Clyde Ingersoll, Tonawanda, NY; Abdul Khan, CMP Industries, Albany, NY; J. Rodway Mackert Jr., Medical College of Georgia, Augusta, GA; Carl Panzera, American Thermocraft Corp., Somerset, NJ; Arun Prasad, Jeneric Pentron, Inc., Wallingford, CT; Carolyn Primus, Ceramco, Inc., Burlington, NJ; Monty Reiger, University of Texas Health Science Center at Houston, TX; and Nikhil Sarkar, Louisiana State University, New Orleans, LA.

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FOREWORD

(This foreword does not form a part of the ANSI/ADA Specification 38 for Metal-Ceramic Restorative Systems)

This revision is essentially an adoption of the ISO International Standard 9693 for Metal-Ceramic Dental Restorative Systems with minor editorial changes. The ASC MD156 Working Group examined the standard and found it acceptable for adoption as ANSI/ADA Specification No.38. A number of editorial changes were made to make it suitable to the US dental profession. Based upon discussions held at the 1998 meeting of ISO TC106, the following changes have been made:

Figure 3 — Test Specimen Configuration

Change the porcelain thickness from (1.0 ± 0.1) mm to (1.1 ± 0.1) mm.

8.2.2 Metallic material

Under clause E change "white" to "gray":

The color of the metallic material (gray or yellow);

Under clause F add, "...the Young's modulus expressed in GPa...":

The proof stress (0.2% offset) expressed in MPa, the Young's modulus expressed in GPa, and the elongation expressed as a percentage.

Further changes were also made to the referencing of the "debonding/crack initiation strength" test. Editorial changes were made to reinforce the fact that this is not a bond strength test. It is a good screening test for metal-ceramic compatibility. This change is in the spirit of the equivalent ISO document, which also has language to clarify this issue. The changes from the ISO standards are as follows:

- 4.3.3. Substitute "bond compatibility index" for "debonding/crack initiation strength" in lines 1 and 4.
- 6.3.3. In the heading, substitute "compatibility" for "characterization."
- **6.3.3.4** Substitute "bond compatibility index" for "debonding/crack initiation strength" in the last line of that section.
- 6.3.3.5 Substitute "bond compatibility index" for "debonding/crack initiation strength" in the first line.
- **Figure 5** Substitute "compatibility index" for "bond strength" in the fifth box from the top.

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INTRODUCTION

Dental metallic materials and ceramics are suitable for use in fabrication of metal-ceramic dental restorations.

Specific qualitative and quantitative requirements for freedom from biological hazards are not included in this regional/national standard, but it is recommended that, in assessing possible biological hazards, reference be made to ISO 10993-1 and ISO 7405.

Requirements and test methods for tarnish and corrosion resistance for the components and for the metal-ceramic system will be included in the future when they are available.

AMERICAN NATIONAL STANDARD/AMERICAN DENTAL ASSOCIATION SPECIFICATION NO. 38 FOR METAL-CERAMIC DENTAL RESTORATIVE SYSTEMS

1 SCOPE

This regional/national standard specifies requirements and test methods for dental metallic materials processed by casting or machining, and for ceramics suitable for use in the fabrication of metal-ceramic dental restorations, together with requirements and test methods for the composite structure.

The requirements of this regional/national standard apply to the metallic materials and ceramics when used in combination, and compliance may not be claimed for either metallic materials or for ceramics alone.

2 NORMATIVE REFERENCES

The following normative documents contain provisions which, through reference in this text, constitute provisions of this regional/national standard. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this regional/national 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 3696:1987, Water for Analytical Laboratory Use—Specification and Test Methods

ISO 6872:1995, Dental Ceramic

ISO 6892:1998, Metallic Materials—Tensile Testing at Ambient Temperature

ASTM B265-95, Standard Specification for Titanium and Titanium Alloy Strip, Sheet and Plate

ASTM B348-93, Standard Specification for Titanium and Titanium Alloy Bars and Billets

(Copies of ISO Specifications may be obtained from the American National Standards Institute, 11 West 42nd St., New York, NY 10036).

3 TERMS AND DEFINITIONS

For the purposes of this specification, the following terms and definitions apply.

3.1 Alloy/Metal Conditioning

Process of treating the metal substructure to enhance the bonding of ceramic to metal

3.2 Coating Agent/Bonding Agent

Substance which, when applied to the metal substructure and fired under appropriate time-temperature conditions, improves aesthetics and may enhance the adherence of ceramic to the coated metal surface

Note 1: Examples of such substances are electroplated layers, or agents containing ceramic and/or alloy particles.

3.3 Dental Dentine Ceramic

Slightly translucent, pigmented dental ceramic used to impart the overall shape and basic color of the ceramic part of a metal-ceramic restoration or prosthesis