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American National Standard/
American Dental Association
Specification No. 75

Resilient Lining Materials for Removable Dentures—

Part 1: Short-Term Materials

Modified adoption of ISO 10139-1:1991 Dentistry — Short term resilient lining materials for removable dentures

American Dental Association
Council on Scientific Affairs 1997

AMERICAN NATIONAL STANDARD/AMERICAN DENTAL ASSOCIATION SPECIFICATION NO. 75 FOR RESILIENT LINING MATERIALS FOR REMOVABLE DENTURES—PART 1: SHORT-TERM MATERIALS

American Dental Association Specification No. 75 for Resilient Lining Materials for Removable Dentures—Part 1: Short-Term 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 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. Approval of ADA Specification No. 75 as an American National Standard was granted by the American National Standards Institute on October 31, 1997. This standard becomes effective October 31, 1998.

The Council thanks the working group members and the organizations with which they were affiliated at the time the specification was developed: Glen Johnson (Chairman), University of Washington, Seattle; Kenneth Rudd (Secretary), San Antonio, TX; Sam Ancheril, San Antonio, TX; John F. Bowley, Ohio State University, Columbus; Ronald Dudek, Austenal, Inc., Chicago, IL; Lawrence Gettleman, University of Louisville, KY; David Hoover, Omaha, NE; John D. Jones, University of Texas, San Antonio; Andrew Koran, III, University of Michigan, Ann Arbor; Tren Meyer, Stow, OH; Glen Nederhouser, Harry J. Bosworth Co., Skokie, IL; Brahma Sharma, Confi-Dental Products Co., Louisville, CO; W. Stephen Stemm, New Albany, NY; Ronald Zentz, Dentsply International, York, PA; Henry J. Vogelstein, Coltene/Whaledent International, Mahwah, NJ; Wayne Wozniak, American Dental Association, Chicago; and John Yearn, GC International, Chicago.

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FOREWORD

(This Foreword does not form a part of the ANSI/ADA Specification No. 75 for Resilient Lining Materials for Removable Dentures—Part 1: Short-Term Materials)

Short-term resilient denture liners are used only provisionally (days, weeks) until a denture reline is performed or a new denture is made and are typically placed at chair-side. They are not intended for long-term use (years). One clinical purpose of a short-term liner is to stabilize an ill-fitting denture. Products specifically formulated for this purpose are often called *temporary denture liners.* Another category of short-term liners are *tissue conditioners.* These products are capable of greater flow (creep) than temporary denture liners, thereby readily accommodating a reduction in inflammation of denture bearing tissues. Short-term liner products may serve one or both purposes, but they do not serve as permanent or long-term resilient denture liners. Long-term resilient denture liners are processed into the denture base, most often in a dental laboratory, and are intended to last several years. This class of products is addressed in ISO Specification 10139—Part 2.

This specification is essentially an adoption of ISO 10139-1:1991 with a minor exception. An additional Figure 3 has been included to facilitate understanding of the penetration test (5.2.2). The drawing supplied shows the location of the areas where the penetrator is to be placed. Locate the three penetration points on the perimeter of a 20 mm diameter circle, 118° to 122° apart. Also note that the outer and inner diameters of the ring are 40 mm and 30 mm, respectively.

INTRODUCTION

0.1 This part of ANSI/ADA Specification No. 75 applies to denture lining materials commonly referred to as "tissue conditioners" and temporary lining materials. These materials are intended to be inserted into a denture at the chairside, to be used for a limited period, or "short-term," of approximately seven days with the aim of assisting the tissues in contact with the prosthesis to return to a healthy condition, or to improve the fit of a denture for several weeks.

0.2 Specific qualitative and quantitative requirements for 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/TR 7405:1984, *Biological Evaluation of Dental Materials*.

0.3 Although this Standard does not specify requirements for the composition of the lining materials, some national and international authorities do require details of composition to be provided by the manufacturer.

DENTISTRY—RESILIENT LINING MATERIALS FOR REMOVABLE DENTURES

PART 1: SHORT-TERM MATERIALS

1 SCOPE

This part of ANSI/ADA Specification No. 75 specifies requirements for the physical properties, test methods, packaging, marking and manufacturer's instructions for denture lining materials suitable for short-term use.

2 NORMATIVE REFERENCES

The following standards contain provisions which, through reference in this text, constitute provisions of this specification. At the time of publication, the editions indicated were 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 editions of the standards indicated below.

ISO 1563:1990, *Dental alginate impression material*

ISO 4823:1992, *Dental elastomeric impression materials*

3 REQUIREMENTS

3.1 Consistency

3.1.1 When determined according to 5.1, the consistency shall be between 25 mm and 75 mm. The higher the consistency the greater the initial flow.

3.1.2 The consistency measured shall be within ± 15% of the value stated by the manufacturer [see clause 8f] and shall not exceed limits stated in 3.1.1.

3.2 **Penetration** (behavior in water)

3.2.1 When tested according to 5.2, the material shall satisfy the following requirements:

- **A** the 2 h penetration shall be not greater than 1.8 mm;
- **B** the seven-day penetration shall be not less than 0.18 mm;
- **C** the ratio *A*/*B* shall be not greater than 5.

3.2.2 When according to 5.2, the value obtained for the penetration ratio (ratio *A*/*B*) shall not vary from the value stated by the manufacturer [see clause 8g] by more than 0.5 and shall not exceed the limit stated in 3.2.1.