ADA Specification No. 27
Date Approved: July 16, 1993

American Dental Association
Specification No. 27

Resin-Based Filling Materials

Modified adoption of ISO 4049:1998, Resin-based dental filling materials

American Dental Association
Council on Scientific Affairs 1993

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AMERICAN NATIONAL STANDARD/AMERICAN DENTAL ASSOCIATION SPECIFICATION NO. 27 FOR RESIN-BASED FILLING MATERIALS

Revised American Dental Association Specification No. 27 for Resin-Based Filling Materials has been approved by the Council on Dental Materials, Instruments and Equipment of the American Dental Association. This and other specifications for dental materials, instruments and equipment are being formulated by subcommittees 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. 27 as an American National Standards was granted by the American National Standards Institute on July 16, 1993. This standard becomes effective July 16, 1994.

The Council thanks the subcommittee members and the organizations with which they were affiliated at the time the specification was developed: Joseph Dennison (Chairman), University of Michigan, Ann Arbor; John Mitchem (Secretary), University of Oregon, Portland; Richard Bennett, L.D. Caulk Co., Milford, DE; Ray Bowen, Paffenbarger Research Center, Gaithersburg, MD; J. David Eick, University of Missouri, Kansas City; Don McKenzie, 3M Dental Products, St. Paul, MN; H. Ralph Rawls, University of Texas, San Antonio; Marjorie Swartz, Indiana University, Indianapolis; and Duncan Waller, Kerr Manufacturing Co., Romulus, MI.

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(This foreword does not form a part of Revised ANSI/ADA Specification No. 27 for Resin-based filling materials).

This revision is essential identical to ISO 4049-1988 which was approved by ISO on 1988-12-15. In accordance with the desire to have ISO and ANSI/ADA Specifications as similar as possible, this ISO Standard was circulated to the ASC MD156 Subcommittee on Direct Filling Resins for acceptance as a revision of ANSI/ADA Specification No. 27-1976.

The Subcommittee voted to accept the ISO 4049-1988 with a few exceptions. Sections that have been changed include scope, classification, depth of cure, and radio-opacity. An Appendix has also been included with additional test methods that may be used for testing of resin based filling materials. The test methods in the appendix do not, however, form a part of this specification and are included for information purposes only.

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INTRODUCTION

This second edition of ISO 4049 takes account of the considerable volume of technical information which has accumulated since the first edition was published in 1978. Some of the tests in the first edition have been omitted and other added for the reasons given below.

This Standard does not cover requirements for materials intended for the restoration of occlusal surfaces of those intended to prevent caries. In order to make this clear, a classification system has been introduced (see clause 3). This Standard, therefore, covers class B materials, i.e. materials other than those intended for occlusal surfaces, and manufacturers are now required to classify their materials accordingly. Furthermore, in order to assist the purchaser, manufacturers are now also required (see clause 8) to describe the filler particle size range and the principal component of the resin base.

The possibility was considered that materials might be classified by filler loading or its corollary, water uptake, and solubility of the resin phase. However, collaborative testing revealed considerable overlapping of these properties in "conventional" and "microfine" materials and such a classification was not adopted.

Resin-based restorative materials activated by external energy are now well established and requirements for these materials are, therefore, included. As the materials do not have an unlimited working time in the dental surgery, a test for sensitivity to ambient light has been included (see 7.6).

Working and setting times of chemically cured materials cannot be determined accurately because of their rapid setting and varying viscosities after mixing. The test in the first edition of this Standard, using an oscillating rheometer, had poor sensitivity and gave results that could not be correlated with "clinical" working time. In this second edition the test has been replaced by one which is simple and widely applicable.

A requirement relating to modulus-dependent flexural strength has been included with the limiting value set to reveal conventional composites with poor filler/resin bonding.

Requirements have been included for materials claimed to be radio-opaque (see 4.5).

Although tests are not included in this second edition for determining non-mandatory or optional properties, such as polymerization shrinkage, it is hoped to do so in a later edition. At present more than one test may be used to determine a single such property which makes true comparisons impossible and confuses the purchaser.

The test for depth of cure of external-energy-activated materials will be reviewed and revised, if necessary, when more data become available.

Specific qualitative and quantitative requirements for freedom from biological hazard are not included in this Standard, but it is recommended that reference should be made to ISO/TR 7405 when assessing possible biological or toxicological hazards.

REVISED AMERICAN NATIONAL STANDARD/AMERICAN DENTAL ASSOCIATION SPECIFICATION NO. 27 FOR RESIN-BASED FILLING MATERIALS

1 SCOPE

This Standard specifies requirements for dental resin-based restorative materials supplied in a form suitable for mechanical mixing, hand mixing, or external energy activation.

It now includes Class A materials which are required, as a minimum, to meet the same requirements as Class B materials. Different requirements for Class A materials, in spite of their different clinical application, are not considered possible. (See Addendum 2).

Dual cure materials are classified as Type 2 materials.

This Standard does not cover requirements for materials intended to prevent dental caries, or for materials which are cured outside the mouth.

2 NORMATIVE REFERENCES

The following standards contain provisions which, 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 listed below. Members of IEC and ISO maintain registers of currently valid International Standards.

ISO 3665: 1976, *Photography - Intra-oral dental radiographic film - Specification.*

ISO/TR 7405: 1984, *biological evaluation of dental materials.*

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.*

ANSI/ADA Specification No. 80 for Color Stability Test Methods.