



American National Standard/
American Dental Association
Standard No. 27

Polymer-based Restorative Materials

Modified adoption of *ISO 4049:2009, Dentistry — Polymer-based restorative materials*

ADA American
Dental
Association®

Standards Committee on Dental Products

2016

These materials are subject to copyright claims of ISO and ADA. No part of this publication may be reproduced in any form, including electronic retrieval system, without the prior permission of ADA. All requests pertaining to ANSI/ADA Standard No. 27 should be submitted to ADA.

AMERICAN NATIONAL STANDARD/AMERICAN DENTAL ASSOCIATION STANDARD NO. 27 FOR POLYMER-BASED RESTORATIVE MATERIALS

The ADA Standards Committee on Dental Products (SCDP) has approved ANSI/ADA Standard No. 27 for Polymer-Based Restorative Materials. This and other standards for dental materials, instruments and equipment are being formulated by working groups of the ADA SCDP. The Committee has representation from all interests in the United States in the standardization of materials, instruments and equipment in dentistry. The Committee has adopted the standards, showing professional recognition of their usefulness in dentistry, and has forwarded them to the American National Standards Institute with a recommendation that the standards be approved as American National Standards. The American National Standards Institute granted approval of ADA Standard No. 27 as an American National Standard on June 22, 2016.

The ADA Standards Committee on Dental Products thanks the members of Working Group 1.3 and the organizations with which they were affiliated at the time the specification was developed:

Spiro Megremis (chairman), American Dental Association, Chicago, IL;
Frederick Eichmiller, Delta Dental of Wisconsin, Stevens Point, WI;
Scott Erickson, 3M ESPE, St. Paul, MN;
Bernard Koltisko, Dentsply Caulk, Milford, DE;
Sheng Lin-Gibson, NIST Polymers Division, Gaithersburg, MD; and
Sheldon Newman, University of Colorado Health Sciences Center, Centennial, CO.

AMERICAN NATIONAL STANDARD/AMERICAN DENTAL ASSOCIATION STANDARD NO. 27 FOR POLYMER-BASED RESTORATIVE MATERIALS

FOREWORD

(This Foreword does not form a part of ANSI/ADA Standard No. 27 for Polymer-based Restorative Materials).

The previous edition of this standard, ADA Standard No. 27-1993, Direct Filling Resins, was an adoption of ISO 4049:1988, Direct filling resins. This standard is a modified adoption of ISO 4049:2009, Dentistry – Polymer-based Restorative Materials, which is a revision of ISO 4049:1988. ADA SCDP Working Group No. 1.3 on Composite Resins examined the international standard and found it acceptable for adoption as revised ANSI/ADA Specification No. 27. It replaces ADA Standard No. 27-1993.

The language of this standard is very close to ISO 4049:2009, Dentistry – Polymer-based Restorative Materials with the exception of the instructions and information to be supplied by the manufacturer with respect to the requirements for claiming radiopacity.

AMERICAN NATIONAL STANDARD/AMERICAN DENTAL ASSOCIATION STANDARD NO. 27 FOR POLYMER-BASED RESTORATIVE MATERIALS

1 Scope

This Standard specifies requirements for dental polymer-based restorative materials supplied in a form suitable for mechanical mixing, hand-mixing, or intra-oral and extra-oral external energy activation, and intended for use primarily for the direct or indirect restoration of cavities in the teeth and for luting.

The polymer-based luting materials covered by this Standard are intended for use in the cementation or fixation of restorations and appliances such as inlays, onlays, veneers, crowns and fixed partial prostheses. This Standard does not cover those polymer-based luting materials that have an adhesive component within the structure of the material.

This Standard does not cover materials intended to prevent caries (see ISO 6874) or those used for veneering metal sub-frames (see ISO 10477).

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 1942, *Dentistry — Vocabulary*

ISO 3665, *Photography — Intra-oral dental radiographic film and film packets — Manufacturer specifications*

ISO 3696, *Water for analytical laboratory use — Specification and test methods*

ISO 7491, *Dental materials — Determination of colour stability*

ISO 8601, *Data elements and interchange formats — Information interchange — Representation of dates and times*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 1942 and the following apply.

3.1

opaque luting material

intensely pigmented polymer-based luting material intended to mask underlying materials and tooth structure

3.2

opaque

shade of an intensely pigmented polymer-based restorative material