



American National Standard/
American Dental Association
Standard No. 144

Alloy for Dental Amalgam

Identical adoption of ISO 20749:2017, *Dentistry — Pre-capsulated dental amalgam*

ADA American
Dental
Association®

Standards Committee on Dental Products

2018

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**AMERICAN NATIONAL STANDARD/AMERICAN DENTAL ASSOCIATION
STANDARD NO. 144 FOR ALLOY FOR DENTAL AMALGAM**

The ADA Standards Committee on Dental Products (SCDP) has approved ANSI/ADA Standard No. 144 for Alloy for Dental Amalgam. 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. 144 as an American National Standard on October 31, 2018.

The ADA Standards Committee on Dental Products thanks the members of Working Group 1.2 on Alloy for Amalgam and the organizations with which they were affiliated at the time the standard was developed:

Richard Mitchell (chairman), University of Kentucky, Lexington, KY;

Michael Adjodha, Food and Drug Administration, Rockville, MD;

J. Robert Kelly, University of Connecticut, Farmington, CT;

Bernard Koltisko, Dentsply Caulk, Milford, DE;

Spiro Megremis, American Dental Association, Chicago, IL; and

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AMERICAN NATIONAL STANDARD/AMERICAN DENTAL ASSOCIATION STANDARD NO. 144 FOR ALLOY FOR DENTAL AMALGAM

FOREWORD

(This Foreword does not form a part of ANSI/ADA Standard No. 144 for Alloy for Dental Amalgam).

This standard is an identical adoption of ISO 20749:2017, Dentistry – Pre-capsulated dental amalgam. ADA SCDP Working Group No. 1.2 on Alloy for Amalgam examined the international standard and found it acceptable for identical adoption as ANSI/ADA Standard No. 144.

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1 Scope

This document specifies the requirements and test methods for dental amalgam products supplied to the user in capsules, pre-dosed with dental amalgam alloy and dental mercury in quantities suitable for the creation of a single dental restoration.

This document specifies the requirements and test methods for dental amalgam alloys that are suitable for the preparation of dental amalgam and the capsule, together with the requirements and test methods for that dental amalgam and the requirements for packaging and marking.

This document is not applicable to dental amalgam alloys supplied as a free-flowing powder in bulk quantities or as powder compressed into tablets, or to dental mercury supplied in sachets or bulk quantities.

This document is not applicable to other metallic materials in which an alloy powder reacts with an alloy that is liquid at ambient temperature to produce a solid metallic material intended for dental restoration.

Specific qualitative and quantitative test methods for demonstrating freedom from unacceptable biological hazard are not included in this document. For the assessment of possible biological hazards, reference can be made to ISO 10993-1 and ISO 7405.

The scope of this document is restricted to dental amalgam products marketed in pre-capsulated form alone. Other products intended for use in the production of dental amalgam restorations (dental amalgam alloy as a free-flowing powder supplied in bulk masses, dental amalgam alloy powder supplied as compressed tablets and dental mercury sachets) are within the scope of ISO 24234.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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 286-2, *Geometrical product specifications (GPS) — ISO code system for tolerances on linear sizes — Part 2: Tables of standard tolerance classes and limit deviations for holes and shafts*

ISO 3310-1, *Test sieves — Technical requirements and testing — Part 1: Test sieves of metal wire cloth*

ISO 3864-2, *Graphical symbols — Safety colours and safety signs — Part 2: Design principles for product safety labels*

ISO 6344-1, *Coated abrasives — Grain size analysis — Part 1: Grain size distribution test*

ISO 7488, *Dental amalgamators*

ISO 13565-2, *Geometrical Product Specifications (GPS) — Surface texture: Profile method; Surfaces having stratified functional properties — Part 2: Height characterization using the linear material ratio curve*

ISO 15223-1, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements*