



American National Standard/
American Dental Association
Standard No. 134

Metallic Materials for Fixed and Removable Restorations and Appliances

Identical adoption of ISO 22674:2006, *Dentistry — Metallic materials for fixed and removable restorations and appliances*

ADA American
Dental
Association®
Council on
Scientific Affairs

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**AMERICAN NATIONAL STANDARD/AMERICAN DENTAL ASSOCIATION STANDARD NO. 134
FOR METALLIC MATERIALS FOR FIXED AND REMOVABLE RESTORATIONS AND
APPLIANCES**

The Council on Scientific Affairs of the American Dental Association has approved revised American Dental Association Standard No. 134 for Metallic Materials for Fixed and Removable Restorations and Appliances. This and other standards for dental materials, instruments and equipment are being formulated by working groups of the ADA Standards Committee on Dental Products (formerly Accredited Standards Committee MD156 for Dental Materials, Instruments and Equipment). The Committee has representation from all interests in the United States in the standardization of materials, instruments and equipment in dentistry. The Council 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. 134 as an American National Standard on February 19, 2013.

The ADA Standards Committee on Dental Products thanks the members of Working Group 2.13 and the organizations with which they were affiliated at the time the standard was developed:

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AMERICAN NATIONAL STANDARD/AMERICAN DENTAL ASSOCIATION STANDARD NO. 134 FOR METALLIC MATERIALS FOR FIXED AND REMOVABLE RESTORATIONS AND APPLIANCES

FOREWORD

(This Foreword does not form a part of ANSI/ADA Standard No. 134 for Metallic Materials for Fixed and Removable Restorations and Appliances).

This first edition of ANSI/ADA Standard No. 134 is an identical adoption of ISO 22674:2006, Dentistry-Metallic materials for fixed and removable restorations and appliances. ADA SCDP Working Group No. 2.13 on Casting Alloys examined the international standard and found it acceptable as an identical adoption.

ANSI/ADA Standard No. 134 provides one performance-based standard having the same requirements for all types of metallic materials for dental restorations and appliances. It replaces the following materials-based ANSI/ADA standards, which have been withdrawn:

- ANSI/ADA Standard No. 5 for Dental Casting Alloys;
- ANSI/ADA Standard No. 14 for Dental Base Metal Casting Alloys.

Requirements for the performance of metals and alloys used for the metallic component of a metal-ceramic restoration contained in this standard supersede such requirements contained in ANSI/ADA Standard No. 38-2000, Metal Ceramic Systems (reaffirmed 2010). The requirements for the performance of ceramic material and the metal-ceramic bond in metal-ceramic restorative systems continue to be specified in ANSI/ADA Standard No. 38.

Specific qualitative and quantitative requirements for freedom from biological hazards are not included in this standard, but it is recommended that, in assessing possible biological hazards, reference be made to ANSI/ADA Standard No. 41, ISO 10993-1 and ISO 7405.

AMERICAN NATIONAL STANDARD/AMERICAN DENTAL ASSOCIATION STANDARD NO. 134 FOR METALLIC MATERIALS FOR FIXED AND REMOVABLE RESTORATIONS AND APPLIANCES

1 SCOPE

This standard classifies metallic materials that are suitable for the fabrication of dental appliances and restorations, including metallic materials recommended for use either with or without a ceramic veneer, or recommended for both uses, and specifies their requirements. It further specifies requirements with respect to packaging and marking the products and to the instructions to be supplied for the use of these materials.

This standard does not apply to alloys for dental amalgam, dental brazing materials or metallic materials for orthodontic appliances, e.g., wire, bracket, band and screw.

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 3696:1987, *Water for analytical laboratory use — Standard and test methods*

ISO 6892, *Metallic materials — Tensile testing at ambient temperature*

ISO 7500-1:2004, *Metallic materials — Verification of static uniaxial testing machines — Part 1: Tension/compression testing machines — Verification and calibration of the force-measuring system*

ISO 9513:1999, *Metallic materials — Calibration of extensometers used in uniaxial testing*

ISO 9693, *Metal-ceramic dental restorative systems*

ISO 10271:2001, *Dental metallic materials — Corrosion test methods*

ISO 15223:2000, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied*

(ISO Standards are available from the American National Standards Institute, 25 W. 43rd St., New York, NY 10036 or www.ansi.org).

3 TERMS AND DEFINITIONS

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

3.1

base metal

any metallic element with the exception of noble metals and silver

3.2

hazardous element

element that is known for its potential to produce an adverse biological effect

NOTE The presence of such an element (as an alloying addition or as an impurity) in a dental alloy does not imply that the alloy, in itself, is harmful.

3.3

metallic material

material having the properties that are associated with an alloy, noble metal or base metal

NOTE This may be a pure element, commercially pure metal or an alloy.

3.4

casting alloy

metallic material designed for casting into a dental investment mould

3.5

ceramic veneer

thin ceramic surface layer present on a metallic material restoration to provide an aesthetic effect

3.6

metal-ceramic

dental restoration in which a ceramic veneer is bonded to a metallic material substructure by firing

NOTE 1 This can apply also to the metallic material used for such a restoration. In this context metal-ceramic alloy is a synonym.

NOTE 2 If recommended, such a metallic material may be used without a ceramic veneer.

3.7

metallic base

noble metal or base metal with highest concentration by mass fraction in the alloy

NOTE The name of this element shall precede the words “-based metallic material for dental restoration” or “-based dental casting alloy” or “-based dental metal-ceramic material”, as is appropriate.

3.8

base-metal alloy

alloy having a base metal as the principal element

3.9

as-cast condition

metallurgical condition of the metallic material in its solid state after removal from the casting machine

NOTE This condition is dependent upon the manufacturer's recommended cooling procedure (e.g., bench cooling).

3.10

bench-cooling

process whereby a casting is retained in its investment with exposed metal uppermost and placed on a flat, insulating surface at ambient temperature in freely circulating air until its temperature falls to ambient

3.11

hardening

heat-treatment producing a condition which provides a higher 0.2 % proof strength than the “as-cast” state

NOTE If recommended by the manufacturer, explicit instructions should be given in the instructions for use.

3.12

softening

heat-treatment producing a condition which provides a lower 0.2 % proof strength than the “as-cast” state

NOTE If recommended by the manufacturer, explicit instructions should be given in the instructions for use.

3.13

one-surface inlay

an inlay restoration that is exposed to the oral environment on one and no more of the surfaces that are used to define the tooth for the purposes of charting

3.14

veneer

thin covering of surface material applied to a coarser base material

4 CLASSIFICATION

For the purposes of this Standard a metallic material is classified, according to its mechanical properties as a Type number, of which there are six.

Examples of the applications for which these Types are intended are as follows:

Type 0: intended for low stress bearing single-tooth fixed restorations, e.g. small veneered one-surface inlays, veneered crowns.

NOTE Metallic materials for metal-ceramic crowns produced by electroforming or sintering belong to Type 0.

Type 1: intended for low stress bearing single-tooth fixed restorations, e.g. veneered or unveneered one-surface inlays, veneered crowns.

Type 2: intended for single tooth fixed restorations, e.g. crowns or inlays without restriction on the number of surfaces.

Type 3: intended for multiple unit fixed restorations, e.g. bridges.

Type 4: intended for appliances with thin sections that are subject to very high forces, e.g. removable partial dentures, clasps, thin veneered crowns, wide-span bridges or bridges with small cross-sections, bars, attachments, implant retained superstructures.

Type 5: intended for appliances in which parts require the combination of high stiffness and strength, e.g. thin removable partial dentures, parts with thin cross-sections, clasps.

5 REQUIREMENTS

5.1 Chemical composition

5.1.1 Reported composition

For all elements that are present in excess of 1.0 % (mass fraction), each constituent element shall be declared by the manufacturer and shall be reported [see 9.1 a)] to a precision of 0.1 % (mass fraction).

Any element that is present in excess of 0.1 % (mass fraction), but not of 1.0 % (mass fraction), shall be identified [see 9.1 a)] either by name or symbol.

5.1.2 Permitted deviation from the reported composition for elements

For silver-based or noble-metal alloys, the percentage of each of the constituents of the alloy shall not deviate by more than 0.5 % (mass fraction) from the values stated on the package label or insert [see 9.1 a)].

For base-metal alloys, all elements present in excess of 20 % (mass fraction) shall not deviate by more than 2.0 % (mass fraction) from the value stated on the package or label or insert. Those present in excess of 1.0 % (mass fraction) but not in excess of 20 % (mass fraction) shall not deviate by more than 1.0 % (mass fraction) from the value stated on the package or

label or insert [see 9.1 a)].

5.2 Hazardous elements

5.2.1 Recognized hazardous elements

For the purposes of this standard the elements nickel, cadmium and beryllium are designated hazardous elements.

5.2.2 Permitted limits for the hazardous elements cadmium and beryllium

The metallic material shall not contain more than 0.02 % (mass fraction) cadmium or beryllium.

5.2.3 Manufacturer's reported nickel content and permitted deviation

If the metallic material contains more than 0.1 % (mass fraction) nickel, this content shall be given to an accuracy of 0.1 % (mass fraction) in the literature which accompanies the package [see 9.1 n)] and on the package, label or insert [see 10.2 f)].

The mass fraction shall not exceed the value stated in 9.1 n) and 10.2 f).

5.3 Biocompatibility

See the Foreword for guidance on biocompatibility.

5.4 Mechanical properties

5.4.1 General

Testing shall be done according to 8.3.2.

The requirements in Table 1 shall be met by the metallic material after the recommended processing techniques (e.g., casting, bench-cooling, machining) and after the ceramic firing schedule (if appropriate) have been applied. A metallic material recommended for use either with or without a ceramic veneer shall meet this requirement in both metallurgical conditions.

If heat-treatment is recommended by the manufacturer [see 9.2 c)] this requirement shall be met by the material in the heat-treated condition, applied in accordance with the manufacturer's instructions for use.

For a metallic material, the Type may be classified differently (according to Table 1) if it is recommended for use in more than one metallurgical condition (produced by alternative processing schedules). The highest applicable Type shall be specified for each condition.

Table 1 — Mechanical properties

Type	Proof strength of 0.2 % non-proportional extension $R_{p0.2}$ MPa minimum	Elongation after fracture % minimum	Young's modulus GPa minimum
0	—	—	—
1	80	18	—
2	180	10	—
3	270	5	—
4	360	2	—
5	500	2	150