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Dentistry — Metallic materials for fixed and removable restorations and appliances

Médecine bucco-dentaire — Matériaux métalliques pour les restaurations fixes et amovibles et les appareillages

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ISO copyright office
Ch. de Blandonnet 8 • CP 401
CH-1214 Vernier, Geneva, Switzerland
Tel. +41 22 749 01 11
Fax +41 22 749 09 47
copyright@iso.org
www.iso.org

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Foreword

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The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: Foreword - Supplementary information

The committee responsible for this document is ISO/TC 106, *Dentistry*, Subcommittee SC 2, *Prosthodontic materials*.

This second edition cancels and replaces the first edition (ISO 22674:2006), which has been technically revised with the following changes:

— Corrosion resistance measurement was referred to the recent standard ISO 10271:2011.

— A second tarnish test was included, referring to provisions in ISO 10271:2011.

— Clarification of the term "free of" was added to the requirements of composition and labelling;

— Lead was added as a hazardous element.

— Measurement of elasticity was revised. Beside the method of calculation of elastic modulus using an extensometer, other alternative methods were added, namely, the flexure method in three- and four-point bending and the acoustic resonance method.

— Informative Annex A was added, dealing with tensile testing of non-cast Type 0 metallic materials intended for use in a thickness between 0,1 and 0,5 mm.

— Normative Annex B was added, giving information on calculation of uncertainty for elastic measurement.

— Informative Annex C was added, giving information for measurement of Poisson ratio.

Introduction

Specific qualitative and quantitative requirements for freedom from biological hazard are not included in this International Standard, but it is recommended that, in assessing possible biological hazards, reference has to be made to ISO 10993-1 and ISO 7405.

Requirements for the performance of metals and alloys used for the metallic component of a metal-ceramic restoration contained in this International Standard supersede such requirements formerly contained in ISO 9693. The requirements for the performance of ceramic material and the metal-ceramic bond in metal-ceramic restorative systems continue to be specified in ISO 9693-1.

Requirements for the proof stress and minimum elongation after fracture for Type 0 metallic materials are not included in this International Standard, but it is recommended to adopt the test procedure given in Annex A when measuring these properties. Requirements will be included in a revision of this International Standard when information becomes available to Technical Committee ISO/TC 106/SC 2.

Dentistry — Metallic materials for fixed and removable restorations and appliances

1 Scope

This International Standard classifies metallic materials that are suitable for the fabrication of dental restorations and appliances, including metallic materials recommended for use either with or without a ceramic veneer, or recommended for both uses, and specifies their requirements. Furthermore, it specifies requirements with respect to packaging and marking the products and to the instructions to be supplied for the use of these materials, including products delivered for sale to a third party.

This International Standard does not apply to alloys for dental amalgam (ISO 24234), dental brazing materials (ISO 9333), or metallic materials for orthodontic appliances (ISO 15841) (e.g. wires, brackets, bands and screws).

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. 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, *Water for analytical laboratory use — Specification and test methods*

ISO 5832-2, *Implants for surgery — Metallic materials — Part 2: Unalloyed titanium*

ISO 5832-3[1], *Implants for surgery — Metallic materials — Part 3: Wrought titanium 6-aluminium 4-vanadium alloy*

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

ISO 6892-1[2], *Metallic materials — Tensile testing — Part 1: Method of test at room temperature*

ISO 9513, *Metallic materials — Calibration of extensometer systems used in uniaxial testing*

ISO 9693-1, *Dentistry — Compatibility testing — Part 1: Metal-ceramic systems*

ISO 10271:2011, *Dentistry — Corrosion test methods for metallic materials*

ISO 15223-1:2012, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements*

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 (i. e. gold and metals of the platinum group) and silver

1) To be published.

2) To be published.

3.2
noble metal
gold and metals of the platinum group

[SOURCE: ISO 1942:2009, 2.187]

3.3
hazardous element
element that is known for its potential to produce an adverse biological effect

Note 1 to entry: 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 hazardous.

3.4
metallic material
material having the properties that are associated with an alloy, noble metal or base metal

Note 1 to entry: This may be a pure element, commercially pure metal or an alloy.

3.5
casting alloy
metallic material designed for casting into an investment mould

3.6
ceramic veneer
thin ceramic surface layer present on a metallic material restoration to provide an aesthetic effect

3.7
metal-ceramic restoration
dental restoration in which a ceramic veneer is bonded to a metallic material substructure by firing

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

Note 2 to entry: If recommended, such a metallic material may be used without a ceramic veneer.

3.8
metallic base
metal with highest concentration by mass fraction in the alloy

Note 1 to entry: 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.

3.9
base-metal alloy
alloy having a base metal as the principal element

3.10
as-cast condition
metallurgical condition of the metallic material in its solid state when removed from the casting machine

Note 1 to entry: This condition is dependent upon the manufacturer's recommended cooling procedure (e.g. bench cooling).

3.11
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

3.12
hardening
heat-treatment of a metallic material producing a condition which provides a higher 0,2 % proof stress than the "as-cast" state

Note 1 to entry: If recommended by the manufacturer, explicit instructions shall be given in the instructions for use.

3.13
softening
heat-treatment of a metallic material producing a condition which provides a lower 0,2 % proof stress than the "as-cast" state

Note 1 to entry: If recommended by the manufacturer, explicit instructions shall be given in the instructions for use.

3.14
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

3.15
elastic modulus
E
the ratio of elastic stress to elastic strain, also termed tensile elastic modulus or Young's modulus, symbol *E*

4 Classification

For the purposes of this International Standard, a metallic material is classified according to its mechanical properties by 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 prostheses, 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:** for low stress bearing single-tooth fixed prostheses, e.g. veneered or unveneered one-surface inlays, veneered crowns;

— **Type 2:** for single tooth fixed prostheses, e.g. crowns or inlays without restriction on the number of surfaces;

— **Type 3:** for multiple unit fixed prostheses;

— **Type 4:** for appliances with thin sections that are subject to very high forces, e.g. removable partial dentures, clasps, thin veneered single crowns, full arch fixed dental prostheses or those with small cross-sections, bars, attachments, implant retained superstructures;

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

NOTE 1 The higher application type can include lower application types.

NOTE 2 Multiple-unit and full-arch, fixed dental prostheses are also referred to as bridges.

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 in [see 9.1 a)] either by name or symbol.

EXAMPLE If a constituent element is present with 0,6 % (mass fraction), it shall be identified [9.1 a)] either by name or symbol. If a constituent element is present with 22,06 % (mass fraction), it shall be reported [9.1 a)] as 22,1 % [precision of 0,1 % (mass fraction)].

If the metallic material contains less than 0,1 % (mass fraction) of a specified element (other than one named in 5.2), it may be named as "free of" this specified element [see 9.1 p) and 10.2 h)].

5.1.2 Permitted deviation from the reported composition for elements

The permitted deviation of the reported composition for elements from the value stated on the package or label or insert [see 9.1 a)] is given in Table 1.

Table 1 — Permitted deviation from the reported composition for elements

Alloy	Elemental content	
	1,0 % < mass fraction ≤ 20 %	mass fraction > 20 %
Base-metal alloy	max. 1,0 %	max. 2,0 %
Silver-based and noble metal alloy	max. 0,5 %	max. 0,5 %

5.2 Hazardous elements

5.2.1 Hazardous elements

For the purposes of this International Standard, the elements nickel, cadmium, beryllium and lead are designated to be hazardous elements.

5.2.2 Limits for the hazardous elements cadmium and beryllium

The metallic material shall not contain more than 0,02 % (mass fraction) cadmium or beryllium.

Cadmium and beryllium are neither alloying elements nor elements inherent to the manufacturing process of titanium metallic materials. For titanium metallic materials that comply with the requirements of chemical composition of ISO 5832-2 and ISO 5832-3, cadmium and beryllium do not need to be analysed.

5.2.3 Limit for lead

The metallic material shall not contain more than 0,02 % (mass fraction) lead.

Lead is neither an alloying elements nor an element inherent to the manufacturing process of titanium metallic materials. For titanium metallic materials that comply with the requirements of chemical composition of ISO 5832-2 and ISO 5832-3, lead does not need to be analysed.

5.2.4 Nickel

5.2.4.1 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).

5.2.4.2 Nickel-free products

For the purposes of this International Standard, alloys with a maximum of 0,1 % (mass fraction) nickel can be labelled "nickel free" [see 9.1 o) and 10.2 g)].

If nickel is not declared, it must be limited to a maximum of 0,1 %. This limit has to be adhered to when nickel is a natural impurity in a component of the alloy.

5.3 Biocompatibility

For guidance on biocompatibility, see Introduction.

5.4 Mechanical properties

5.4.1 General

This requirement (see Table 2) 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 a 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 can be classified differently (according to Table 2) 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 2 — Mechanical properties

Type	Proof stress of 0,2 % non-proportional extension $R_{p0,2}$ MPa minimum	Elongation after fracture % minimum	Elastic modulus GPa minimum
0	—	—	—
1	80	18	—
2	180	10	—
3	270	5	—
4	360	2	—
5	500	2	150

Testing shall be done according to 8.3.

5.4.2 Proof stress of 0,2 % non-proportional extension

5.4.2.1 Determination of compliance

Refer to the classification Type stated in 9.1 b).

If four, five or six of the results for the set of six specimens in the first test series meet the requirement for proof stress of 0,2 % non-proportional extension, the metallic material complies with the requirement.

If two or fewer of the results for the set of six specimens in the first test series meet the requirement for proof stress of 0,2 % non-proportional extension, the metallic material fails to comply with the requirement.

NOTE 1 Two lots of six specimens are produced (see Clause 7). One of these lots is tested in the first test series. If required, replacement specimens are drawn from the second lot and used in the first test series. The remaining specimens in the second lot form the second test series.

NOTE 2 In this context, the number six is reached to complete the set in the first test series when the number of specimens tested less those rejected after post fracture examination (8.3.2) is six, (i.e. replacement specimens are included in the total).

If three or four specimens in the first lot of six specimens are rejected on the basis of 8.3.2 and replaced with specimens from the second lot, all 12 specimens shall be tested. If at least eight results meet the requirement for proof stress of 0,2 % non-proportional extension, the metallic material complies with the requirement.

If three of the results for the set of six specimens in the first test series meet the requirement for proof stress of 0,2 % non-proportional extension, all remaining specimens shall be tested in a second test series. If five or six of the results for the specimens in the second test series meet the requirement for proof stress of 0,2 % non-proportional extension, the metallic material complies with the requirement.

Under this compliance criterion, if one specimen from the first lot has been rejected on the basis of inspection after fracture (8.3.2) during the first test series and a specimen from the second lot of six used as its replacement, then all five remaining specimens in the second series shall meet the requirement. Only one replacement is possible for a borderline metallic material.

If three of the results for the first set of six specimens in the first test series meet the requirement for proof stress of 0,2 % non-proportional extension and four or fewer of the results from the specimens in the second test series meet the requirement for proof stress of 0,2 % non-proportional extension, the metallic material fails to comply with the requirement.

Testing shall be done according to 8.3.2.

5.4.2.2 Mean value

The mean value for the proof stress of 0,2 % non-proportional extension, calculated according to 8.4.2 shall not differ by more than 10 % from the value given in the literature accompanying the package [see 9.1 c)].

5.4.3 Elongation after fracture

5.4.3.1 Determination of compliance with the requirement

Refer to the classification Type stated in 9.1 b).

If the four, five or six of the results for the set of six specimens in the first test series that meet the requirement for proof stress of 0,2 % non-proportional extension also meet the requirement for elongation after fracture, the metallic material complies with the requirement for elongation after fracture.

If two or fewer of the results for the set of six specimens in the first test series meet the requirement for elongation after fracture, the metallic material fails to comply with the requirement for elongation after fracture.

NOTE 1 Two lots of six specimens are produced (see Clause 7). One of these lots is tested in the first test series. If required, replacement specimens are drawn from the second lot and used in the first test series. The remaining specimens in the second lot form the second test series.

NOTE 2 In this context, the number six is reached to complete the set in the first test series when the number of specimens tested less those rejected after post fracture examination (8.3.2) is six, (i.e. replacement specimens are included in the total).

If three or four specimens in the first lot of six specimens are rejected on the basis of 8.3.2 and replaced with specimens from the second lot, all 12 specimens shall be tested. If at least eight results of the specimens that meet the requirement for proof stress of 0,2 % non-proportional extension also meet the requirement for elongation after fracture, the metallic material complies with the requirement.

If three of the results for the first set of six specimens in the first test series that meet the requirement for proof stress of 0,2 % non-proportional extension also have an elongation after fracture that meets the requirement for elongation after fracture, all remaining specimens shall be tested in a second test series. If five or six of the results for the specimens in the second test series have both an elongation after fracture and a proof stress of 0,2 % non-proportional extension that meet both requirements, the metallic material complies with the requirement for the percentage elongation after fracture. If the results for the five or six specimens in the second series meet the requirement for elongation after fracture, but not the requirement for proof stress of 0,2 % non-proportional extension, the metallic material fails to comply with requirement for elongation after fracture.

Under this compliance criterion, if one specimen in the first lot has been rejected on the basis of inspection after fracture (8.3.2) during the first test series and a specimen from the second lot of six used as its replacement, then all five remaining specimens in the second series must meet the requirement. Only one replacement is possible for a borderline metallic material.

If three of the results for the first set of six specimens in the first test series meet the requirement for the percentage elongation after fracture and four or fewer of the results from specimens in the second test series meet the requirement for elongation after fracture, the metallic material fails to comply with the requirement for elongation after fracture.

5.4.3.2 Mean value

The mean value of percentage elongation after fracture calculated according to 8.5.2 must exceed 70 % of the value stated in the literature accompanying the package and not be less than the minimum value for the type [see 9.1 d)].

5.5 Elastic modulus

5.5.1 Precision of measurement method

The measurement of elastic modulus shall be performed by a method (see 8.6) capable of a precision that gives a combined standard uncertainty less than 10 % of the measured value.

NOTE For guidance on the determination of combined standard uncertainty, see ISO/IEC Guide 98-3.

5.5.2 Determination of compliance with the requirements for Type 5 materials

Refer to classification Type stated in 9.1 b).

Where compliance with Type 5 is claimed, the mean value of the elastic modulus as determined according to 8.6 shall be at least 150 GPa.

