INTERNATIONAL STANDARD



First edition 2006-11-15

Dentistry — Metallic materials for fixed and removable restorations and appliances

Art dentaire — Matériaux métalliques pour les restaurations fixes et amovibles et les appareillages

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ISO 22674:2006 https://standards.iteh.ai/catalog/standards/sist/4f46acbc-c123-45dc-bd3ec87fed260a39/iso-22674-2006



Reference number ISO 22674:2006(E)

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Contents

Forewo	ord	. iv			
Introductionv					
1	Scope	1			
2	Normative references	1			
3	Terms and definitions	1			
4	Classification	3			
5 5.1 5.2 5.3 5.4 5.5 5.6 5.7	Requirements Chemical composition Hazardous elements Biocompatibility Mechanical properties Density Corrosion resistance for material integrity	3 4 4 4 7 7			
5.8 5.9 5.10	Solidus and liquidus temperatures (for alloy) or melting point (for commercially pure metal) Thermal expansion coefficient	8 8 8			
6	Sampling	8			
7 7.1 7.2 7.3	ISO 22674:2006 Preparation of test specimens catabg/standards/sist/4f46acbc-cf23-45dc-bd3c- General	9 9 9			
8 8.1 8.2 8.3 8.4 8.5 8.6 8.7 8.8	Test methods Information, instructions and marking Chemical composition Mechanical properties Density Corrosion resistance Tarnish resistance (sodium sulfide test) Solidus and liquidus temperatures (alloys) or melting point (commercially pure metals) Linear thermal expansion	11 11 12 13 14 15 16 16			
9 9.1 9.2	Information and instructions for use Information Processing instructions	16 16 17			
10 10.1 10.2	Marking and labelling Marking Labelling on the package	17 17 18			
Annex	A (informative) Tensile testing of a non-cast Type 0 metallic material that is intended for use in a thickness between 0.1 mm and 0.5 mm	19			
Bibliog	raphy	22			

Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO 22674 was prepared by Technical Committee ISO/TC 106, *Dentistry*, Subcommittee SC 2, *Prosthodontic materials*.

This first edition cancels and replaces the following composition-derived International Standards: ISO 1562, ISO 6871-1, ISO 6871-2, ISO 8891 and ISO 16744 dards.iteh.ai)

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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 should 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.

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 Subcommittee 2.

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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 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 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., wire, bracket, band and screw).

Normative references 2

iTeh STANDARD PREVIEW

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 22674:2006

ISO 1942, Dentistry Vocabulary intensi/catalog/standards/sist/4f46acbc-c123-45dc-bd3e-

ISO 3696:1987, Water for analytical laboratory use — Specification 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 extensioneters 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

Terms and definitions 3

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

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

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

3.7

ISO 22674:2006 metallic base https://standards.iteh.ai/catalog/standards/sist/4f46acbc-c123-45dc-bd3enoble metal or base metal with highest concentration by mass fraction in the alloy

The name of this element shall precede the words "-based metallic material for dental restoration" or "-based NOTE 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 International 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 onesurface inlays, veneered crowns. NOTE Metallic materials for metal-ceramic crowns produced by electroforming or sintering belong

NOTE Metallic materials for metal-ceramic crowns produced by electroforming or sintering belong to Type 0. (standards.iteh.ai)

- Type 1: intended for low stress bearing single-tooth fixed restorations, e.g. veneered or unveneered one-surface inlays, veneered crownst 2006
- 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 International 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)].

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

ISO 22674:2006

5.3 Biocompatibility https://standards.iteh.ai/catalog/standards/sist/4f46acbc-c123-45dc-bd3e-

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See the introduction 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.

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

Table 1 — Mechanical properties

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

5.4.2.1 **Determination of compliance**

Refer to the classification Type stated in 9.1 b). iTeh STANDARD PREVIEW If four, five or six of the results for the set of six specimens in the first test series meet the requirement for proof strength 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 strength of 0,2 % non-proportional extension, the metallic material fails to comply with the requirement.

NOTE 1 Two sets of six specimens are produced (see 7.3.1). One of these sets 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 set of six specimens are rejected on the basis of 8.3.2 and replaced with specimens from the second set, all twelve specimens shall be tested. If at least eight results meet the requirement for proof strength 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 strength 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 strength of 0,2 % non-proportional extension, the metallic material complies with the requirement.

Under this compliance criterion, if one specimen from the first set has been rejected on the basis of inspection NOTE 3 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. N.B. Only one replacement is possible for a borderline metallic material.

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

5.4.2.2 Mean value

The mean value for the proof strength of 0,2 % non-proportional extension 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, which meet the requirement for proof strength 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 sets of six specimens are produced (see 7.3.1). One of these sets is tested in the first test series. If required, replacement specimens are drawn from the second set and used in the first test series. The remaining specimens in the second set 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 set of six specimens are rejected on the basis of 8.3.2 and replaced with specimens from the second set, all twelve specimens shall be tested. If at least eight results of the specimens that meet the requirement for proof strength of 0,2 % non-proportional extension also meet the requirement for elongation to fracture, the metallic material complies with the requirement for elongation after fracture.

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If three of the results for the first set of six specimens in the first test series, which meet the requirement for proof strength 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 strength 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 strength of 0,2 % non-proportional extension, the metallic material fails to comply with requirement for elongation after fracture.

NOTE 3 Under this compliance criterion, if one specimen in the first set has been rejected on the basis of inspection after fracture (8.3.2) during the first test series and a specimen from the second set of six used as its replacement, then all five remaining specimens in the second series shall meet the requirement. N.B. Only one replacement is possible for a borderline metallic material.

If three of the results for the 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 requirements for elongation after fracture, the metallic material fails to comply with the requirement for elongation after fracture.

5.4.3.2 Mean reported value

The mean value of percentage elongation after fracture shall 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)]