INTERNATIONAL STANDARD

ISO 16744

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Dentistry — Base metal materials for fixed dental restorations

Art dentaire — Matériaux métalliques pour les restaurations fixes

Reference number
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Foreword

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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 16744 was prepared by Technical Committee ISO/TC 106, *Dentistry*, Subcommittee SC 2, *Prosthodontic materials*.

This corrected version of ISO 16744:2003 incorporates the following corrections.

— The French title has been aligned with the English title.

— In Table 1, under the second column heading the symbol has been corrected to read "$R_{p0,2}$".

— In Table 2, the last line under the first column has been corrected to read "$> 100\ \mu g/cm^2$ to $\leqslant 1\ 000\ \mu g/cm^2$".

Introduction

Dental base metal materials are suitable for use in fabrication of fixed dental restorations.

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 be made to ISO 10993-1 and ISO 7405.

For base metal materials that are also intended as the substructure of a metal-ceramic dental restorative system, ISO 9693 also applies.

Dentistry — Base metal materials for fixed dental restorations

1 Scope

This International Standard gives the classification of, and specifies requirements and test methods for, metallic materials with a base metal as the main constituent. It applies to base metal materials suitable for use in the fabrication of fixed dental restorations.

This International Standard is not applicable to base metal materials intended for use in the fabrication of removable appliances, for which ISO 6871-1 and ISO 6871-2 apply.

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 3585, *Borosilicate glass 3.3 — Properties*

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

ISO 6507-1, *Metallic materials — Vickers hardness test — Part 1: Test method*

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

3 Terms and definitions

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

3.1
alloy
substance with metallic properties and composed of two or more elements, of which at least one is a metal

3.2
alloying element
element added to or retained by a metal or alloy for the purpose of giving the resulting alloy particular properties

3.3
impurity
element present but which is not intentionally added to or retained by a metal

3.4
base metal
any metallic element with the exception of gold, silver, platinum, palladium, ruthenium, iridium, rhodium and osmium

3.5
base metal material
base metal or an alloy with a base metal as main constituent

4 Classification

For the purposes of this International Standard, dental base metal materials are classified, according to their mechanical properties and the application for which they are recommended, as follows:

Type 1: Low strength: for applications subject to very slight stress, e.g. inlays.

Type 2: Medium strength: for applications subject to moderate stress, e.g. inlays, onlays and full crowns.

Type 3: High strength: for applications subject to high stress, e.g. onlays and overlays, crowns, thin cast backings, pontics, and implant-retained suprastructures.

Type 4: Extra high strength: for applications subject to very high stress, e.g. veneered single crowns, long-span bridges or bridges with small cross-sections, bars, attachments, and implant-retained suprastructures.

5 Requirements

5.1 Chemical composition

5.1.1 General

All alloying elements which are present in more than 20 % mass fraction shall not deviate from the composition value stated on the package or label or insert by more than 2 % mass fraction. Those present in excess of 1 % mass fraction but not in excess of 20 % mass fraction shall not deviate from the value stated on the package or label or insert by more than 1 % mass fraction.

5.1.2 Hazardous elements

For the purpose of this International Standard, the elements nickel, cadmium and beryllium are defined to be hazardous elements.

The alloy shall not contain more than 0,02 % mass fraction of cadmium and/or beryllium. If the alloy contains more than 0,1 % mass fraction of nickel, the percentage shall not exceed the amount indicated on the package [see 10.2 g)] or label or insert [see 9 b)].

5.2 Biocompatibility

See the Introduction for guidance on biocompatibility.

5.3 Mechanical properties

The mechanical properties of the different types of dental base metal material shall comply with the requirements specified in Table 1.

Table 1 — Mechanical properties

Type	Proof strength of non-proportional elongation $R_{p0,2}$ MPa min.	Percentage elongation after fracture % min.
1	80	18
2	180	10
3	240	6
4	400	3

Testing shall be carried out in accordance with 7.1 and 8.3.

5.4 Density

The mass density shall not deviate by more than 0,5 g/cm^3 from the value stated by the manufacturer in the instructions [see 9 h)].

5.5 Melting range

The solidus and liquidus temperatures shall not deviate by more than 25 °C from the values stated in the instructions [see 9 i)].

5.6 Corrosion resistance

The total amount of ions per surface area leached in seven days shall not exceed 1 000 μg/cm^2.

Testing shall be carried out in accordance with 7.2 and 8.4.

The corrosion resistance found by testing in accordance with 7.2 and 8.4 shall be classified according to Table 2.

Table 2 — Classification of corrosion resistance

Total amount of ions leached in 7 days	Level of corrosion resistance
less than 10 μg/cm^2	excellent
10 μg/cm^2 to 100 μg/cm^2	good
> 100 μg/cm^2 to ⩽ 1 000 μg/cm^2	acceptable

6 Sampling

The sample shall be an adequate amount to prepare the specimens required in 7.1 and 7.2, including provision for a second set for tensile testing, and shall be from one lot. Further samples and packaging materials shall be made available for inspection in accordance with 8.1.

7 Preparation of test specimens

7.1 Specimens for tensile testing

For tensile testing in accordance with 8.3, prepare six specimens which conform to either Figure 1 or Figure 2.

Test specimens shall be prepared in accordance with the manufacturer's procedure for processing fixed dental restorations. Discard and replace specimens with visible defects. Test the specimens as processed.

7.2 Specimens for corrosion testing

Prepare two specimens with dimensions of approx. 34 mm × 13 mm × 1,5 mm in accordance with the manufacturer's recommended procedure for processing fixed dental restorations.

Blast surfaces with pure alumina of particle size 125 μm.

If recommended in the instructions (see Clause 9), heat-treat the specimens in accordance with the manufacturer's instructions.

Dimensions in millimetres

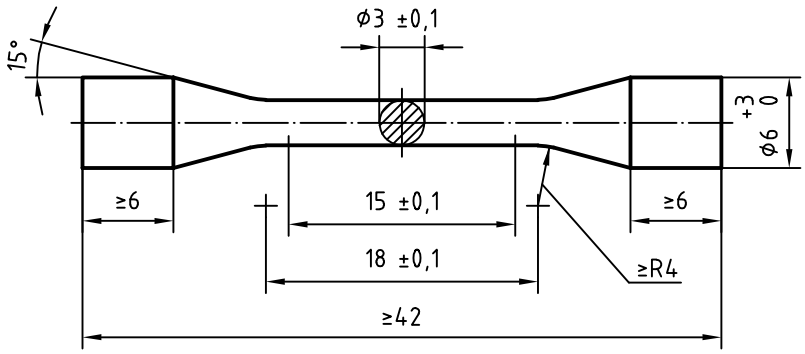

Figure 1 — Test specimen with conical shoulders

Dimensions in millimetres

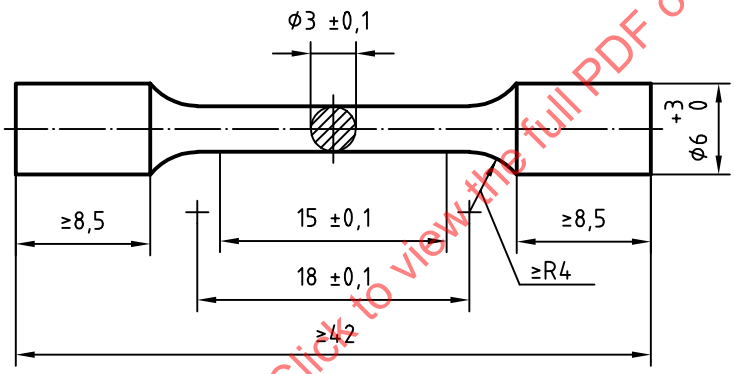

Figure 2 — Test specimen with radial shoulders

Remove at least 0,1 mm from all surfaces of the specimens using standard metallographic procedures, ending with ASTM 600 or FEPA P 1200 wet silicon carbide paper. Use fresh abrasive paper for each base metal material.

8 Testing

8.1 Visual inspection

Visually inspect to check that requirements specified in Clauses 9 and 10 have been met.

8.2 Chemical composition

Determine the composition using analytical procedures with sensitivities appropriate to the concentration of each element and its permitted deviation from the stated value or permitted limit.

8.3 Tensile testing

8.3.1 Procedure

Determine the proof stress of 0,2 % non-proportional elongation and the percentage elongation after fracture in accordance with ISO 6892 on six test specimens prepared in accordance with 7.1. Load the test specimens in tension in a mechanical testing instrument at a cross-head speed of $(1{,}5 \pm 0{,}5)$ mm·min^{-1} until the specimens fracture.

Calculate the proof stress on the basis of the original cross-sectional area, using the force for 0,2 % non-proportional elongation derived from the force/elongation diagram.

Determine the percentage elongation after fracture on the same specimens.

8.3.2 Evaluation of tensile testing results

If four, five or six test specimens are found to exceed the minimum requirements for a type, as given in 5.3, Table 1, the base metal material satisfies the tensile property requirements of this International Standard.

If two or fewer test specimens are found to comply with the minimum requirements for a type, as given in 5.3, Table 1, the base metal material fails the tensile property requirements of this International Standard.

If three test specimens are found to comply with the minimum requirements for a type, as given in 5.3, Table 1, repeat the test with a second set of six test specimens.

If, in the second test, five or six test specimens are found to exceed the minimum requirements for a type, given in 5.3, Table 1, then the base metal material satisfies the tensile property requirements of this International Standard.

8.3.3 Calculation of proof stress for 0,2 % non-proportional elongation and percentage elongation after fracture

Calculate the proof stress for 0,2 % non-proportional elongation as the mean of the values of those four, five or six test specimens of the first test, or, if applicable, of those three test specimens of the first test plus those five or six test specimens of the second test, that are found to comply with 5.3, Table 1, and report the results to the nearest 5 MPa.

Calculate the percentage elongation after fracture as the mean of the values of those four, five or six test specimens of the first test or, if applicable, of those three test specimens of the first test plus those five or six test specimens of the second test, that are found to comply with 5.3, Table 1, and report the results to the nearest 1 %.

8.4 Corrosion testing, static immersion test

8.4.1 Reagents

8.4.1.1 Lactic acid ($C_3H_6O_3$), 90 %, chemically pure.

8.4.1.2 Sodium chloride (NaCl), analytical grade.

8.4.1.3 Water, conforming to grade 2 of ISO 3696:1987.

8.4.1.4 Ethanol or methanol (C_2H_5OH or CH_3OH), analytical grade.

8.4.1.5 Immersion solution

Prepare a fresh immersion solution for each test. Dissolve $(10{,}0 \pm 0{,}1)$ g of 90 % $C_3H_6O_3$ (8.4.1.1) and $(5{,}85 \pm 0{,}05)$ g of NaCl (8.4.1.2) in approximately 300 ml of water (8.4.1.3). Dilute to $(1\,000 \pm 10)$ ml with water. The pH value shall be 2,3 ± 0,1. If not, discard the solution and check the reagents.

8.4.2 Apparatus

8.4.2.1 Borosilicate glass container, conforming to ISO 3585.

8.4.2.2 pH-meter.

8.4.2.3 Analytical instrumentation.

8.4.2.4 Micrometer.

8.4.3 Procedure

8.4.3.1 Exposure of test specimens

Determine the surface area of each test specimen to the nearest 0,1 cm^2. Using an ultrasonic bath, clean the specimens in ethanol or methanol for 2 min. Rinse them in water (8.4.1.3).

Place each specimen in a separate glass container of approximately 16 mm × 160 mm.

Record the pH value of the solution. Add sufficient solution to each container to produce a ratio of 1 ml of solution per 1 cm^2 of specimen surface area. Record the volume of solution to an accuracy of 0,1 ml. Close the container to prevent evaporation of the solution. Maintain the container at (37 ± 1) °C for 7 d ± 1 h. Remove the samples and record the pH value of the residual solution.

8.4.3.2 Analysis

Using an analytical method of adequate sensitivity, e.g. atomic absorption spectrometry or inductively coupled plasma atomic emission spectrometry, analyse each residual solution quantitatively for constituents of the base metal material and for nickel, cadmium and beryllium.

8.4.3.3 Report

Describe the analytical method used, and give the detection limits for the elements under investigation. For all elements found in each test solution, record the values in micrograms per square centimetre ($\mu g/cm^2$) separately. Calculate the total amount of leached ions for each residual solution and report the mean.

9 Information and instructions

The manufacturer's or distributor's instructions shall contain at least the following information about applications and processing of the base metal material:

a) all alloying elements present in more than 1 % mass fraction shall be stated quantitatively, and all other alloying elements shall be mentioned by name;

b) if the base metal material contains more than 0,1 % mass fraction nickel, adequate detailed instructions regarding safety precautions shall be given in the package or in the accompanying literature;

c) a general warning regarding the potential health hazards associated with the inhalation of metallic dust;

d) 0,2 % proof stress of non-proportional elongation, expressed in megapascals (MPa);

e) percentage elongation after fracture;

f) Vickers hardness HV 5, determined in accordance with ISO 6507-1;

g) modulus of elasticity, expressed in gigapascals (GPa);

h) density, expressed in grams per cubic centimetre (g/cm^3);

i) solidus and liquidus temperatures, expressed in degrees Celsius (°C);

j) level of corrosion resistance (see 5.6);

k) instructions for fabrication and processing.

10 Marking and labelling

10.1 Marking

The ingots shall be clearly marked to identify the manufacturer or distributor and the base metal material. For base metal materials, supplied as small and/or irregular particles which cannot be marked, the direct packaging shall be clearly marked to identify the manufacturer or distributor and the base metal material.

10.2 Package

The label or package-insert shall be marked at least with the following information:

a) manufacturer's or distributor's name or trademark and address;

b) trade name or brand name of the base metal material;

c) type, in accordance with the classification given in Clause 4;

d) the three principal constituents of the base metal material and their percentages by mass fraction;

e) lot number;

f) minimum net mass, expressed in grams or kilograms;

g) a warning, if the base metal material contains nickel [see 9 b)], and the percentage by mass fraction in which it is present.