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Dental base metal casting alloys —

Part 1:
Cobalt-based alloys

Alliages dentaires non précieux à couler —
Partie 1: Alliages à base de cobalt

Reference number
ISO 6871-1:1994(E)

Contents

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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.

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.

International Standard ISO 6871-1 was prepared by Technical Committee ISO/TC 106, *Dentistry*, Subcommittee SC 2, *Prosthodontic materials*.

This first edition of ISO 6871-1, together with ISO 6871-2, cancel and replace the first edition of ISO 6871 published in 1987, of which they constitute a technical revision.

ISO 6871 consists of the following parts, under the general title *Dental base metal casting alloys*:

— *Part 1: Cobalt-based alloys*

— *Part 2: Nickel-based alloys*

Annex A forms an integral part of this part of ISO 6871. Annex B is for information only.

Introduction

Dental base metal casting alloys are suitable for use in fabrication of removable dental appliances.

Specific qualitative and quantitative requirements of freedom from biological hazard are not included in this part of ISO 6871 but it is recommended that, in assessing possible biological or toxicological hazards, reference should be made to ISO/TR 7405[2] and ISO 10993-1[4].

For other compositions the manufacturer has to present adequate evidence of biological investigations in accordance with ISO/TR 7405 or ISO 10993-1, and/or clinical investigations in order to assess the biological response of the material.

Specific quantitative requirements for corrosion resistance are not included in this part of ISO 6871. In order to get information of the kind and amount of metal ions leached from the alloy, reference should be made to ISO/TR 10271[3], reference number 14, Static immersion test, described in annex A.

Dental base metal casting alloys —

Part 1:
Cobalt-based alloys

1 Scope

This part of ISO 6871 specifies requirements and test methods for cobalt-based dental casting alloys suitable for use in fabrication of removable dental appliances. It does not apply to alloys intended for use in fabrication of metal-ceramic dental restorations.

2 Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this part of ISO 6871. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this part of ISO 6871 are encouraged to investigate the possibility of applying the most recent editions of the standards indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

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

ISO 6892:1984, *Metallic materials — Tensile testing.*

ASTM-B 600-74, *Recommended practice for descaling and cleaning titanium and titanium alloy surfaces.*

3 Definitions

For the purposes of this part of ISO 6871, the following definitions apply.

3.1 alloy: Metallic substance consisting of a mixture of the basic metallic element (the element predominating by mass) and other elements such as alloying elements and impurities.

3.2 alloying element: Metallic or non-metallic elements added to or retained by a basic metal for the purpose of giving that metal certain special properties.

3.3 impurity: Metallic or non-metallic elements present but which are not intentionally added to or retained by a metal.

3.4 casting alloy: Alloy primarily intended for the production of castings.

3.5 base metal casting alloy: Casting alloy in which cobalt or nickel is the basic metallic element.

3.6 cobalt-based dental casting alloy: Dental casting alloy in which cobalt is the constituent present in the highest percentage by mass (main constituent).

4 Requirements

4.1 Composition

The chemical composition of the casting alloy shall meet the following requirements:

Cobalt	main constituent
Chromium	not less than 25 % (*m/m*)
Molybdenum	not less than 4 % (*m/m*)
Cobalt + Nickel + Chromium	not less than 85 % (*m/m*)

Constituents of the alloy in excess of 20 % (*m/m*) shall be within 2 % (*m/m*) of the value stated [see clause 8 b) and 9.2 d)]. Constituents in excess of

2 % (*m/m*) but not in excess of 20 % (*m/m*) shall be within 1 % (*m/m*) of the value stated [see clause 8b) and 9.2 d)]. The percentage of nickel shall not be greater than the percentage indicated on the package label or insert (see clause 8).

Other compositions with cobalt as the basic metallic element may be permissible subject to approval by regulatory authorities (see the Introduction). For such alloys, all alloying elements with more than 0,1 % (*m/m*) shall be given on the package or in the accompanying literature.

4.2 Biocompatibility

See the Introduction for guidance on biocompatibility.

4.3 Corrosion resistance

See the Introduction for guidance on corrosion resistance.

Testing shall be in accordance with annex A. The total of the mean aggregate quantity of ions released shall be reported as specified in A.3.

4.4 Mechanical properties

When tested in accordance with 7.3 and 7.4, the mechanical properties of the alloy shall comply with table 1.

Table 1 — Mechanical properties

Proof stress of non-proportional elongation, $R_{p0,2}$ MPa min.	Percentage elongation after fracture % min.
500	3,0

5 Sampling

The sample shall be adequate to prepare the specimens required for 6.2 and A.1, and shall be from one batch.

Further sample and packaging shall be made available for visual inspection and analytical procedures in accordance with 7.1 and 7.2.

6 Preparation of test specimens

6.1 General

Prepare the test specimens by the lost wax process of investment casting generally used in a dental laboratory, following the manufacturer's instructions for use.

Cleanly separate the test specimens from sprues, freed of casting beads, parting lines and surface impurities and then grit blast the specimens.

Replace any test specimens with visible defects.

6.2 Specimens for mechanical properties

Prepare six test specimens in accordance with figure 1 or 2.

Dimensions in millimetres

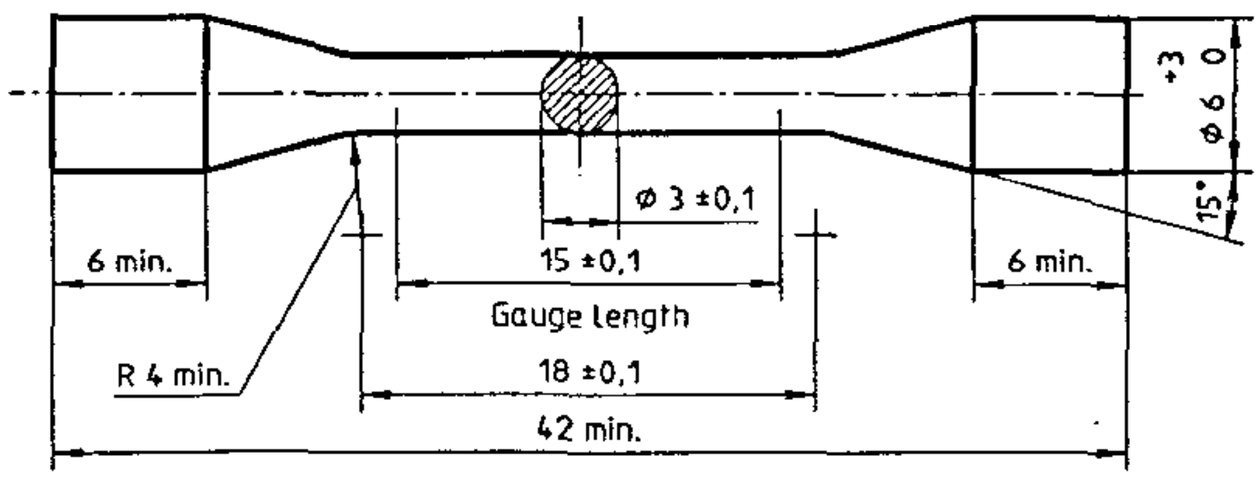

Figure 1 — Test specimen with conical shoulders

Dimensions in millimetres

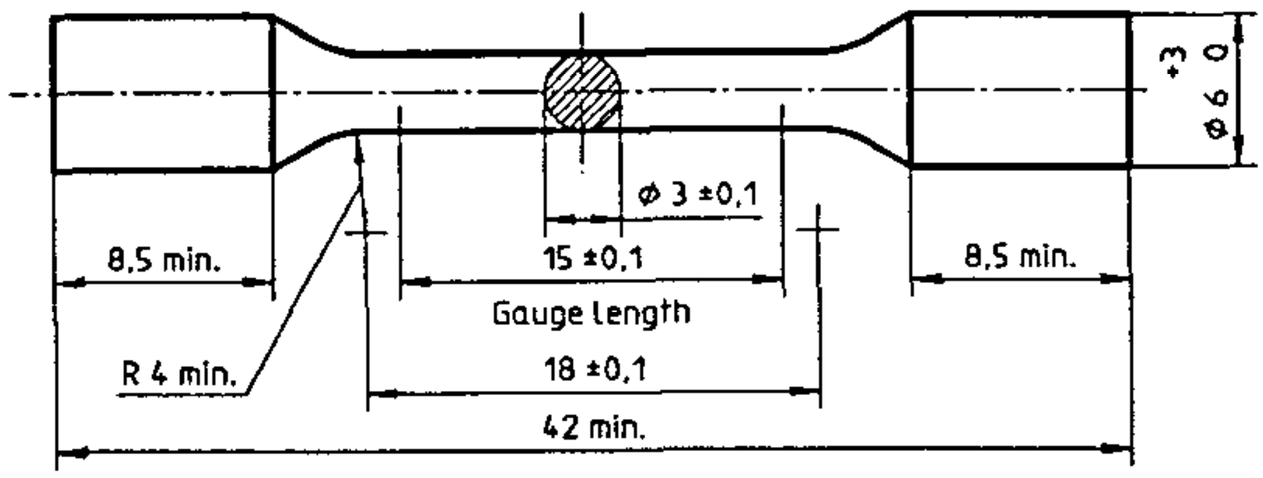

Figure 2 — Test specimen with radius shoulders

7 Testing

7.1 Visual inspection

Visually inspect the specimens to check that the requirements specified in clauses 8 and 9 have been met.

7.2 Analytical procedures

Recognized analytical procedures shall be used in determining the composition (ISO methods where these exist).

7.3 Proof stress of non-proportional elongation

Determine the 0,2 % proof stress of non-proportional elongation in accordance with ISO 6892 on test specimens (see 6.2), cast and conditioned in accordance with 6.1. Load the test specimens in a universal mechanical testing instrument at a cross-head speed of $(1,5 \pm 0,5)$ mm min^{-1} up to the fracture point of the specimens.

If less than four specimens comply with the requirements in table 1, take another full set of specimens and repeat the test. If less than four specimens of the new set comply, reject the alloy.

For reporting calculate the value for proof stress as the mean of the values from those four, five or six specimens of the one set which are found to comply with the requirements in table 1.

7.4 Percentage elongation after fracture

Determine the percentage elongation after fracture in accordance with ISO 6892.

If less than four specimens comply with the requirements in table 1, take another full set of specimens and repeat the test. If less than four specimens of the new set comply, reject the alloy.

For reporting calculate the value for elongation as the mean of the values from those four, five or six specimens of the one set which are found to comply with the requirements in table 1.

At least four of these specimens shall also comply with the proof stress requirement in table 1.

8 Information and instructions

The following information shall be in the package or be supplied with it:

a) the alloy's intended use given in unambiguous language;

b) a list of all the elements present and their percentage concentration (*m/m*) if present in concentrations equal to or greater than 2 %;

c) density in grams per cubic centimetre;

d) 0,2 % proof stress in megapascals;

e) modulus of elasticity in gigapascals;

f) percentage elongation after fracture;

g) Vickers hardness;

h) solidus and liquidus temperatures (melting range) in degrees Celsius;

i) processing instructions.

If the alloy contains more than 0,1 % (*m/m*) of nickel or other hazardous elements, this shall be clearly stated on the package, and adequately detailed instructions regarding precautions shall be given in the package or accompanying literature. Alloys with less

than 0,1 % (*m/m*) of nickel may be described as nickel-free.

9 Marking

9.1 Casting ingots

The casting ingots or other forms in which the alloys are supplied shall be clearly marked to identify the alloy. Dental casting alloys in accordance with this part of ISO 6871 shall be supplied in a form and size suitable for crucibles in a dental investment casting process and in a stable container.

9.2 Packaging

The packaging shall be clearly labelled with the following information:

a) the manufacturer's and/or distributor's name and address;

b) trade- or brand-name of the alloy;

c) the alloy's intended use given in unambiguous language;

d) the three principal constituents of the alloy and their percentage by mass;

e) batch number: each package shall be provided with a serial number or letter/number combination related to the manufacturer's records for the particular batch which shall permit positive identification;

f) net mass in grams;

g) a **WARNING** if the alloy contains more than 1 % (*m/m*) of nickel or any other hazardous elements. The warning shall also name the elements and state the percentage by mass in which they are present.

Annex A
(normative)

Static immersion test

In order to get information of the kind and amount of metal ions leached from the alloy, the following specimens, reagents and procedure shall be applied.

A.1 Specimens

Prepare two sets of three specimens, each with dimensions of 32 mm × 10 mm × 1,5 mm.

Prepare the test specimens by the lost wax process of investment casting generally used in a dental laboratory, following the manufacturer's instructions for use.

Cleanly separate the test specimens from sprues, freed of casting beads, parting lines and surface impurities.

Grit blast, then wet grind using standard metallographic procedure to ASTM-B 600 or FEPA P 1200 silicon carbide paper. Remove at least 0,1 mm from all sides. Clean away any residual abrasive.

Replace any test specimens with visible defects.

A.2 Reagents

Lactic acid	$C_3H_6O_3$ analytical grade
Sodium chloride	NaCl analytical grade
Water	Grade 2 of ISO 3696

A.3 Procedure

Prepare the surface of the test specimens as specified in A.1 and measure the surface area of the specimens to the nearest 0,1 cm^2.

Clean away any abrasive, oil or grease. Rinse the specimens in ethanol or methanol, and dry.

Divide the specimens in two sets of three, each set having a total surface of approximately 20 cm^2. Prepare an aqueous solution comprising 0,1 mol/l lactic acid and 0,1 mol/l sodium chloride.

Select containers so as to avoid adsorption of trace elements on the surface of the container and that the volume of solution will be approximately 1,3 ml cm^{-2} of the test specimen surface area.

Suspend each set of three test specimens hanging on nylon threads in a separate container for 7 days at (37 ± 1) °C in a manner such that all specimens are completely covered by the test solution and do not come into contact with each other or the wall or the bottom of the container. Most appropriate is a triangular arrangement of the samples in the container. Tightly seal the container to prevent evaporation.

Analyse each test solution separately for elements listed in clause 8 b) using an adequately sensitive, quantitative analytical method, e.g. AAS (atomic absorption spectrometry) or OES (optical emission spectrometry). For each of the two tests, report the values of each element present in micrograms per square centimetre in accordance with national regulations.

NOTE 1 When an International Standard for corrosion testing becomes available, the test solution and procedures given above will be revised in conformity with that International Standard.

Annex B
(informative)

Bibliography

[1] ISO 1942-2:1989, *Dental vocabulary — Part 2: Dental materials.*

[2] ISO/TR 7405:1984, *Biological evaluation of dental materials.*

[3] ISO/TR 10271:1993, *Dentistry — Determination of tarnish and corrosion of metals and alloys.*

[4] ISO 10993-1:1992, *Biological evaluation of medical devices — Part 1: Guidance on selection of tests.*

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Descriptors: dentistry, dental materials, casting, alloys, cobalt alloys, specifications, chemical composition, mechanical properties, tests, mechanical tests, marking, packaging, technical data sheets.

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