
Dentistry — Ceramic materials

Art dentaire — Produits céramiques

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ISO copyright office
Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
E-mail copyright@iso.org
Web www.iso.org

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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.

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 6872 was prepared by Technical Committee ISO/TC 106, *Dentistry*, Subcommittee SC 2, *Prosthetic materials*.

This third edition cancels and replaces the second edition (ISO 6872:1995) and Amendment 1:1997 which have been technically revised.

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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 or toxicological hazards, reference be made to ISO 10993-1 and ISO 7405.

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Dentistry — Ceramic materials

1 Scope

This International Standard specifies the requirements and the corresponding test methods for dental ceramic materials for fixed all-ceramic and metal-ceramic restorations and prostheses.

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, *Water for analytical laboratory use — Specification and test methods*

3 Terms and definitions

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

3.1 Material

3.1.1

addition ceramic

dental ceramic material that is fired at a reduced temperature and is normally applied to restore contact points on a dental restoration or prosthesis

3.1.2

dental ceramic

inorganic, non-metallic material that is specifically formulated for use, when processed according to manufacturer's instructions, to form the whole or part of a dental restoration or prosthesis

3.1.3

dental porcelain

predominantly glassy dental ceramic material used mainly for aesthetics in a dental restoration or prosthesis

3.1.4

dentine ceramic

dental ceramic material used to form the overall shape and basic colour of a dental restoration or prosthesis, simulating the natural tooth dentine

3.1.5

enamel ceramic

dental ceramic material used to overlay either partially or wholly the dentine ceramic and also to form the more translucent incisal third of a dental restoration or prosthesis, simulating the natural tooth enamel

3.1.6

flame-sprayed dental ceramic

dental ceramic core or substructure layer formed via the technique of flame spraying

3.1.7

glass-ceramic (dental)

dental ceramic material formed by the action of heat treatment on a glass, in order to cause initiation and growth of a wholly or predominantly crystalline microstructure

3.1.8

glass-infiltrated dental ceramic

dental ceramic core or substructure layer, which is porous and is subsequently densified by the infiltration of specialized glass at elevated temperature

3.1.9

glaze ceramic

dental ceramic material that is overlaid and fired at a reduced temperature compared to dentine or enamel ceramic, to produce a thin coherent sealed surface, the level of gloss being determined by the firing conditions

3.1.10

liner

dental ceramic material used on all-ceramic substructure forming a layer that provides a background colour upon which dentine or opaceous dentine ceramic can be applied to achieve overall aesthetics

3.1.11

modelling fluid

liquid with which a dental ceramic powder is mixed, in order to shape or model it into its required form prior to firing

3.1.12

opaceous dentine ceramic

dental ceramic material having a higher opacity than a dentine ceramic material, but which can still be used to contribute to the overall shape and basic colour of a dental restoration or prosthesis, simulating the natural tooth dentine

3.1.13

opaque dental ceramic

dental ceramic material that, when applied to a metallic substructure in accordance with manufacturer's instructions, acts to bond to the metal surface forming a layer that provides a background colour and interface upon which other dental ceramic materials can be applied to achieve overall aesthetics

3.1.14

shoulder ceramic

dental ceramic material used to form shape and colour at the marginal area of the dental restoration or prosthesis, simulating natural tooth dentine in this area

3.1.15

stain ceramic

dental ceramic powder or paste that is normally intensely coloured and that is formulated to be used either internally or externally, during the build up of a dental restoration or prosthesis, to simulate details within or on the surface as are respectively found in natural teeth

3.1.16

substructure (core) dental ceramic

predominantly polycrystalline dental ceramic material that forms a supporting substructure upon which one or more layers of dental ceramic or dental polymer material are applied, either partially or totally, to form a dental restoration or prosthesis

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3.2 Processing

3.2.1

air firing dental ceramic

firing of dental ceramics under ambient atmospheric pressure

3.2.2

CAD/CAM dental ceramic

computer aided design/computer aided manufacture (CAD/CAM) procedures to manufacture a dental restoration or prosthesis normally including the following stages:

- 1) a digital scanning procedure of the model or wax-up to produce a 3D data set
- 2) software manipulation of the 3D data set to design the prosthesis
- 3) a computer directed machine tool that performs the manufacturing process

3.2.3

condensation of dental ceramic

powder process whereby a slurry of dental ceramic powder is vibrated to compact the powder prior to sintering

3.2.4

injectable, castable or pressable dental ceramic

dental ceramic material, normally in the form of a pellet or ingot (often pre-sintered), designed for use in a specialized furnace, which enables the pellet or ingot to be injected/cast/pressed into a mould, prepared via the lost wax technique

3.2.5

sintering of a dental ceramic

process whereby heat and potentially other process parameters (e.g. pressure and atmosphere) are applied to a ceramic powder or powder compact, in order to densify the ceramic into its required form

NOTE "Firing" and "sintering" are used interchangeably in this document ("firing" connotating the application of heat to drive sintering).

3.2.6

vacuum firing dental ceramic

firing of dental ceramics at reduced pressure (i.e. under vacuum) to yield the required density and associated aesthetics, especially the degree of translucency

NOTE Dental ceramics for vacuum firing have a specific particle size distribution to reduce the entrapment of porosity.

3.3 Properties

3.3.1

class of dental ceramic

classification of a dental ceramic material according to its intended function

3.3.2

fracture toughness

conventional fracture mechanics parameter indicating the resistance of a material to crack extension (propagation)

3.3.3

glass transition temperature

approximate mid-point of the temperature range over which a glass transforms between elastic and viscoelastic behaviour, characterized by the onset of a rapid change in its coefficient of thermal expansion

3.3.4

glaze (medium)

surface appearance obtained when the gloss is clinically and aesthetically acceptable

4 Types, classes and their identification

For the purposes of this International Standard, dental ceramics are designated into two types:

- Type I: ceramic products that are provided as powders, pastes or aerosols;
- Type II: all other forms of ceramic products.

Ceramics are divided into six classes according to their intended clinical use according to descriptions in Table 1. If colour is added to a ceramic powder for identification purposes, the colour coding given in Table 2 is recommended.

Table 1 — Classification of ceramics for fixed prostheses by intended clinical use

Class	Recommended clinical indications	Mechanical and chemical properties	
		Flexural strength minimum (mean)	Chemical solubility maximum
		MPa	µg·cm ⁻²
1	a) Aesthetic ceramic for coverage of a metal or a ceramic substructure. b) Aesthetic-ceramic: single-unit anterior prostheses, veneers, inlays, or onlays.	50	100
2	a) Aesthetic-ceramic: adhesively cemented, single-unit, anterior or posterior prostheses.	100	a) 100
	b) Adhesively cemented, substructure ceramic for single-unit anterior or posterior prostheses.	100	b) 2 000
3	Aesthetic-ceramic: non-adhesively cemented, single-unit, anterior or posterior prostheses.	300	100
4	a) Substructure ceramic for non-adhesively cemented, single-unit, anterior or posterior prostheses.	300	2 000
	b) Substructure ceramic for three-unit prostheses not involving molar restoration.		
5	Substructure ceramic for three-unit prostheses involving molar restoration.	500	2 000
6	Substructure ceramic for prostheses involving four or more units.	800	100

Table 2 — Recommended colour coding for the identification of Type I dental ceramic powders

Material	Colour coding
Dentine	Pink
Enamel	Blue
Fluorescent	Yellow
Highly chromatic dentine	Orange
Opalescent enamel	Blue-green
Modifying enamel (e.g., translucent, clear)	Purple

5 Requirements

5.1 Uniformity

The inorganic pigment(s) used to produce the colour of a fired dental ceramic and any organic colorants (for colour coding) shall be uniformly dispersed throughout the dental ceramic material and, in powdered ceramic products, no segregation of the pigment(s) shall take place when the powder is mixed as described in 7.1.4. Check by visual inspection.

5.2 Freedom from extraneous materials

5.2.1 Dental ceramic materials shall be free from extraneous materials, when assessed by visual inspection.

5.2.2 Dental ceramic materials shall not have an activity concentration of more than $1,0 \text{ Bq}\cdot\text{g}^{-1}$ of uranium²³⁸. Test in accordance with 7.2.2.

5.2.3 Any colorants used to colour code the ceramic powder as listed in Table 2 are recommended to be food quality organic materials.

5.3 Mixing and condensation properties, type I ceramics

When mixed as described in 7.1.4, with water or the modelling fluid recommended by the manufacturer, a dental ceramic powder shall not form lumps or granules when assessed by visual inspection.

The paste so formed shall be suitable for making the indicated restorations and prostheses by condensation of successive layers. When the paste is condensed as in 7.1.5, it shall not crack or crumble during drying, as later assessed by visual inspection.

5.4 Physical and chemical properties

The physical and chemical properties of ceramic test specimens tested in accordance with the relevant methods, detailed for Type I and Type II ceramics in Clause 7, shall comply with the requirements specified in Table 1. The coefficient of thermal expansion of the ceramics shall not deviate by more than $0,5 \times 10^{-6} \text{ K}^{-1}$ from the value stated by the manufacturer [see 8.2.2 d)]. The glass transition temperature of the ceramics shall not deviate by more than 20 °C from the value stated by the manufacturer [see 8.2.2 d)].

5.5 Biocompatibility

See the Introduction for guidance on biocompatibility.

6 Sampling

6.1 Type I ceramics

Take a sufficient amount of ceramic to carry out the necessary tests. Where there is more than one shade in a class of dental ceramic, combine equal quantities of each shade.

Sufficient quantities of essential modelling fluids shall be obtained, if their use is recommended by the manufacturers. The quantities shall be those recommended by the manufacturer concerned.

6.2 Type II ceramics

All of a material procured for testing in accordance with this International Standard shall be of the same lot.

7 Test methods

7.1 Preparation of test specimens

7.1.1 General

For detailed instructions, see the individual test methods.

For Type I specimens (unless otherwise stated or inconsistent with the text) the apparatus detailed in 7.1.3 along with the conditions for mixing, condensation and firing (7.1.4 to 7.1.6) apply to all test methods.

7.1.2 Components of test specimens, Type I ceramics

The liquid used in the preparation of test specimens shall be water that complies with the requirements for grade 3 water (see ISO 3696) or, when applicable, the modelling fluid recommended by the manufacturer of the dental ceramic powder. The required amount of powder shall be taken from the appropriate pool of powder obtained in accordance with 6.1.

7.1.3 Apparatus for mixing

All apparatus for mixing shall be clean and dry.

7.1.3.1 Glass slab or mixing palette.

7.1.3.2 Spatula, made from a material that is not readily abraded by the dental ceramic powder (glass is recommended). Instruments used for the mixing procedure shall be made of materials that do not contaminate the ceramic material.

7.1.3.3 Open multipart mould, from which the condensed specimen can be removed without distortion.

7.1.3.4 Vibration system (vibration table or mechanical brush), capable of vibrating at a frequency of 50 Hz to 60 Hz or in accordance with the manufacturer's instructions.

7.1.4 Method of mixing

Combine the water or modelling liquid and the ceramic powder in the proportions recommended by the manufacturer. Avoid vigorous mixing which will tend to incorporate air bubbles with the paste and, both during and after mixing, examine for compliance with 5.1 and 5.2.1.