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Dentistry — Ceramic materials

Médecine bucco-dentaire — Matériaux céramiques

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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 document 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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This document was prepared by Technical Committee ISO/TC 106, *Dentistry,* Subcommittee SC 2, *Prosthodontic materials,* in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 55, *Dentistry,* in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This fifth edition cancels and replaces the fourth edition (ISO 6872:2015), which has been technically revised. It also incorporates the Amendment ISO 6872:2015/Amd 1:2018.

The main changes are as follows:

— Annex C on protocol to assess the hydrothermal stability of yttria-stabilized tetragonal zirconia (Y-TZP) has been added.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

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

Dentistry — Ceramic materials

1 Scope

This document 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 documents are referred to in the text in such a way that some or all of their content constitutes requirements 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*

ISO 13078, *Dentistry — Dental furnace — Test method for temperature measurement with separate thermocouple*

ISO 13078-2, *Dentistry — Dental furnace — Part 2: Test method for evaluation of furnace programme via firing glaze*

ISO 13078-3, *Dentistry — Dental furnace — Part 3: Test method for the evaluation of high temperature sintering furnace measurement with a separate thermocouple*

3 Terms and definitions

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

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at https://www.electropedia.org/

3.1 Material

3.1.1
chromatic dentine ceramic
dentine ceramic having a high strength or saturation of the hue (colour)

3.1.2
dental ceramic
ceramic material prepared for use in the fabrication of dental prostheses and restorations

3.1.3
dentine ceramic
slightly translucent, pigmented *dental ceramic* (3.1.2) used to simulate the natural appearance of dentine in a dental ceramic restoration or dental prosthesis

3.1.4
enamel ceramic
slightly translucent, pigmented *dental ceramic* (3.1.2) used to simulate the natural enamel in a dental ceramic restoration or dental prosthesis

3.1.5
fluorescent ceramic
dental ceramic (3.1.2) material that absorbs radiant energy and emits it in the form of radiant energy of a different wavelength band all or most of whose wavelengths exceed that of the absorbed energy

EXAMPLE Absorption of ultraviolet light with emission of blue light.

3.1.6
glass-ceramic
dental ceramic (3.1.2) 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

3.1.7
modelling fluid
liquid with which a *dental ceramic* (3.1.2) powder is mixed in order to shape or model it into its required form prior to firing

3.1.8
modifying enamel ceramic
enamel ceramic (3.1.4) used to modify the surface contour of a restoration, for example, add a contact, often fired at a lower temperature than the enamel ceramic or *dentine ceramic* (3.1.3)

3.1.9
monolithic ceramic
dental ceramic (3.1.2) that is substantially made of a single uniform material

Note 1 to entry: A thin layer of glaze ceramic (staining technique) can be applied.

3.1.10
opalescent enamel ceramic
enamel ceramic (3.1.4) containing microfine particulates, with a refractive index significantly different from the ceramic matrix in which they are incorporated

Note 1 to entry: This material scatters shorter wavelengths of light (e.g. blue) and transmits longer wavelengths of light (e.g. red)

3.1.11
pressable ingot
dental ceramic (3.1.2), in the form of a pellet or ingot, designed for use in a specialised furnace which enables the ingot to be injected, cast or pressed into a mould prepared through the lost wax technique

3.2 Processing

3.2.1
condensation
process for *dental ceramic* (3.1.2) whereby a slurry of dental ceramic powder is vibrated to compact the powder prior to sintering

3.2.2
firing
process whereby heat and potentially other process parameters (e.g. mechanical or gas pressure) are applied to a ceramic powder or powder compact in order to densify the ceramic into its required form.

3.2.3
sintering
process of densification and consolidation of a green body by the application of heat with resulting joining of ceramic particles and increasing contact interfaces due to atom movement within and between the ceramic grains of the developing polycrystalline microstructure

Note 1 to entry: Sintering may take place either directly or through the agency of a secondary phase (e.g. reaction sintering and liquid-phase sintering).

3.3 Properties

3.3.1
class of dental ceramic
classification of a *dental ceramic* (3.1.2) material in accordance with 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
T_g
approximate midpoint 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
surface appearance obtained when the gloss is clinically and aesthetically acceptable

4 Types, classes, and their identification

For the purposes of this document, 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 five classes in accordance with their intended clinical use and in accordance with the descriptions in Table 1. If colour is added to a ceramic powder for identification purposes, then the colour coding given in Table 2 is recommended.

Table 1 — Classification of ceramics for restorations and fixed prostheses by intended clinical use and required values of mechanical and chemical properties

Class	Recommended clinical indications	Mechanical and chemical properties	
		Flexural strength [MPa] minimum value for mean (see 7.3)	**Chemical solubility** [µg/cm²] (see 7.6)
1	a) Monolithic ceramic for single-unit anterior prostheses, veneers, inlays, or onlays adhesively cemented.	50	< 100
	b) Ceramic for coverage of a metal framework or a ceramic substructure.	50	< 100
2	a) Monolithic ceramic for single-unit anterior or posterior prostheses adhesively cemented.	100	< 100
	b) Fully covered substructure ceramic for single-unit anterior or posterior prostheses adhesively cemented.	100	< 2 000
3	a) Monolithic ceramic for single-unit anterior or posterior prostheses and for three-unit prostheses not involving molar restoration adhesively or non-adhesively cemented.	300	< 100
	b) Fully covered substructure for single-unit anterior or posterior prostheses and for three-unit prostheses not involving molar restoration adhesively or non-adhesively cemented.	300	< 2 000
4	a) Monolithic ceramic for three-unit prostheses involving molar restoration.	500	< 100
	b) Partially or fully covered substructure for three-unit prostheses involving molar restoration.	500	< 2 000
5	Monolithic ceramic for prostheses involving partially or fully covered substructure for four or more units.	800	< 100

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

Material	Colour coding
Dentine ceramic	Pink
Enamel ceramic	Blue
Fluorescent ceramic	Yellow
Highly chromatic dentine ceramic	Orange
Opalescent enamel ceramic	Blue-green
Modifying enamel ceramic (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 colourants (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 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 $Bq \cdot g^{-1}$ of ^{238}U. Test in accordance with 7.2.

5.2.3 Any colourants used to colour code the ceramic powder, as per Table 2, are recommended to be food-quality organic materials.

5.3 Mixing and condensation properties of type I ceramics

When mixed as in 7.1.4 with water or the modelling fluid recommended by the manufacturer, a dental ceramic powder shall neither form lumps, nor granules, when assessed by visual inspection.

The paste formed shall be suitable for making the indicated restorations and prostheses by condensation of successive layers. When the paste is condensed, as in 7.1.4, it shall neither crack, nor crumble, when assessed by visual inspection during drying.

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. In addition to the required physical and chemical properties, there are other important physical and chemical properties that can be reported, including fracture toughness (Annex A), strength distribution parameters (Annex B), and hydrothermal stability (Annex C). The coefficient of thermal expansion of the ceramics shall not deviate by more than $0{,}5 \times 10^{-6}\ K^{-1}$ from the value stated by the manufacturer (see 8.2.2). 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).

5.5 Shrinkage factor

The absolute uncertainty of measurement of the shrinkage factor by which the dimensions of the partially sintered material is to be divided (as provided under 9.2.2 c) shall be ±0,002.

6 Sampling

6.1 Type I ceramics

Use retail packages from the same batch containing enough material to carry out the specified tests plus an allowance for repeated tests, if necessary. Where there is more than one shade of a dental ceramic, perform test with a colour/shade most commonly used. All of the materials tested shall be of the same lot.

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 the materials procured for testing in accordance with this document shall be of the same lot. Where there is more than one shade of a dental ceramic, perform test with a colour/shade most commonly used.