

Z-BLANKS SPECIFICATION

Z-Blanks are porously presintered zirconium dioxide partially stabilized with yttrium oxide. Zirconium dioxide has been used for 30 years in the medical sector (like hip-joint prostheses) due to the excellent aesthetics and biocompatibility.

We produce and test the Z-Blanks under the International Standards:

1. ISO 6872 Second Edition 1995-09-01 Dental Ceramic
2. ISO 6872 Amendment 1 1997-12-01 Dental Ceramic Amendment 1
3. ISO 9693 Metal-ceramic dental restorative systems
4. ISO 13356 First Edition 1997-09-15 Implants for surgery – Ceramic materials based on yttria-stabilized tetragonal zirconia (Y-TZP)

1. Physical and chemical properties

1.1 Z-Blank vs. ISO:

Property	Unit	Z-Blank Value	Requiemnt for ISO 13356:1997
Bulk density	g/cm ³	6.045 ~6.070	≥ 6.00 (ISO 13356)
Chemical composition:			(ISO 13356)
ZrO ₂ + HfO ₂ + Y ₂ O ₃		99.6	> 99.0
ZrO ₂	percent mass fraction	91.6	N/A
Y ₂ O ₃		5.0	4.5 to 5.4
HfO ₂		3.0	≤ 5
Al ₂ O ₃		0.25	< 0.5
Other oxides*		0.15	< 0.5
Microstructure:			
Mean linear intercept distance	μm	0.52±0.05	≤ 0.6 (ISO 13356)
Strength:			
Biaxial flexure	Mpa	950 ± 50	≥ 500 (ISO 13356)
Radioactivity:	Bq/g	0.005	1.0 (ISO 6872)

* Other oxides: SiO₂ 0.135%; Fe₂O₃ 0.005%; Na₂O 0.005%; TiO₂ 0.005%

The data above shows the Z-Blanks have excellent technical properties.

2. Biocompatibility

2.1 Introduction

Z-Blank is a yttrium-stabilized zirconium oxide (Y-TZP). Y-TZP is considered to be a highly compatible material, which has already been used in medical applications such as artificial hip joints.

The biocompatibility results recorded for Y-TZP also apply to Z-Blank.

2.2 Chemical durability

Dental materials are exposed to a large variety of pH values and temperatures in the oral cavity. Chemical durability is therefore a highly important prerequisite for all dental materials. According to Anusavice¹, ceramics are among the most durable dental materials.

Chemical durability according to ISO 6872:

	Chem. Solubility [µg/cm ²]	Limit value according to standard [µg/cm ²]
Z-Blank	10	< 100

- The chemical solubility of Z-Blank is far below the limit value according to the relevant standard.

2.3 Biocompatibility of yttrium-stabilized zirconium oxide²

The following tests were conducted on Z-Blank.

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|-------------------|---|
| Tests into vitro: | Cytotoxicity (cell cultures)
Chromosome damage (mutagenicity test, Ames test)
Haemolysis |
| Test into vivo: | (with rabbits, mice, guinea pigs, and sheep)
Haemolysis
Acute toxicity (systemic)
Irritation (intracutaneous)
Sensitization
Pyrogenicity test
Short-term implantation (90 days)
Long-term implantation (24 months) |

None of these tests showed a potential of Z-Blank to cause adverse health effects.

2.4 *In vitro toxicity/in vitro genotoxicity*

Josset et al³ investigated the biocompatibility of two implant materials – zirconium oxide and aluminum oxide in osteoblast cell cultures. Both materials were reported to have neither a toxic nor a genotoxic

2.5 *Biological reaction on implant material in vivo*

Warashina et al.⁴ implanted different materials (Z-Blank among others) in the skullcap of mice and traced the biological reactions (inflammation parameters, bone resorption). The biological properties confirmed the biocompatibility of Z-Blank when used for artificial hip joints.

2.6 *Radioactivity*

The radioactivity of Z-Blank was measured at the research center in Jinan, China. The measured value of 0.005 Bq/g is much lower than the maximum value of 1.0 Bq/g permitted by ISO 6872.

2.7 *Conclusion*

In the view of the present data and today's level of knowledge, it can be stated that Z-Blank does not feature a toxic potential. If the material is used according to the Instructions for Use, it does not pose any risk to the health of patients, dental technicians, and dentists.

3. Bibliography

- 1 Anusavice KJ. Degradability of Dental Ceramics. Adv Dent Res 6 (1992) 82089
- 2 Rieger W. (1944), Studies of Biocompatibility of ZrO₂ and Al₂O₃ ceramics. Contribution 6th Biomaterial Symposium Göttingen.
3. Josset Y, Oum'Hamed Z, Zarrinpour A, Lorenzato M, Adnet JJ, Laurent-Maquin D.(1999) In vitro reactions of human osteoblasts in culture with zirconia and alumina ceramics. J Biomed Mater Res. Dec 15,47(4): 48-93
4. Warashina H, Sakano S, Kitamura S, Yamauchi KI, Yamaguchi J, Ishiguro N, Hasegawa Y.(2003). Biological reaction to alumina, zirconia, titanium, and polyethylene particles implanted onto murine calvaria. Biomaterials. Sep;24(21):3655-61

Dimensions of Z-Blank:

The material blanks are in rectangular parallelepiped (box) shape with eleven different dimensions, measured in length, width and height, and in cylinder shape with two different dimensions, measured in diameter and height.

Ref. Blocks	Length (mm)	Width (mm)	Height (mm)
Z-Blank 20-14-15	20	14	15
Z-Blank 20-15-15	20	15	15
Z-Blank 20-16-19	20	16	19
Z-Blank 40-16-19	40	16	19
Z-Blank 42-16-16	42	16	16
Z-Blank 42-20-16	42	20	16
Z-Blank 42-20-20	42	20	20
Z-Blank 55-16-19	55	16	19
Z-Blank 55-16-20	55	16	20
Z-Blank 60-20-20	60	20	20
Z-Blank 60-25-20	60	25	20
General tolerance: +/- 0.5mm			

Ref. Blocks	Diameter (mm)	Length (mm)
Z-Blank D16-16	16	16
Z-Blank D20-20	20	20
Z-Blank D98-10	98	10
Z-Blank D98-12	98	12
Z-Blank D98-14	98	14
Z-Blank D98-16	98	16
Z-Blank D98-18	98	18
Z-Blank D98-20	98	20
Z-Blank D98-25	98	25
General tolerance: +/- 0.5mm		

The final sintering temperature will be range from 1450 °C to 1530 °C.