



Standard Specification for High-Purity Dense Yttria Tetragonal Zirconium Oxide Polycrystal (Y-TZP) for Surgical Implant Applications¹

This standard is issued under the fixed designation F 1873; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon (ε) indicates an editorial change since the last revision or reapproval.

1. Scope

1.1 This specification covers material requirements for high-purity dense yttria tetragonal zirconium oxide polycrystal (Y-TZP) for surgical implant applications.

1.2 The values stated in SI units are to be regarded as the standard.

2. Referenced Documents

2.1 ASTM Standards:

C 373 Test Method for Water Absorption, Bulk Density, Apparent Porosity, and Apparent Specific Gravity of Fired Whiteware Products²

C 1161 Test Method for Flexural Strength of Advanced Ceramics at Ambient Temperature³

C 1198 Test Method for Dynamic Young's Modulus, Shear Modulus, and Poisson's Ratio for Advanced Ceramics by Sonic Resonance³

C 1239 Practice for Reporting Uniaxial Strength Data and Estimating Weibull Distribution Parameters for Advanced Ceramics³

C 1259 Test Method for Dynamic Young's Modulus, Shear Modulus, and Poisson's Ratio for Advanced Ceramic by Impulse Excitation of Vibration³

C 1327 Test Method for Vickers Indentation Hardness of Advanced Ceramics⁴

E 112 Test Method for Determining Average Grain Size⁴

F 748 Practice for Selecting Generic Biological Test Methods for Materials and Devices⁵

F 981 Practice for Assessment of Compatibility of Biomaterials for Surgical Implants with respect to Effects of Materials on Muscle and Bone⁵

2.2 American Society for Quality Control Document:

C 1 Specification of General Requirements for a Quality Program⁶

3. Chemical Composition

3.1 The chemical composition shall be as follows, measured by X-ray fluorescence (XRF) or mass spectroscopy:

ZrO ₂ HfO ₂ + Y ₂ O ₃	Weight %
Y ₂ O ₃	≥ 99
HfO ₂	4.5 to 5.4
Al ₂ O ₃	≤ 5
	≤ 0.5
Other Total Oxides	≤ 0.5
TiO ₂	
SiO ₂	
CaO	
Fe ₂ O ₃	
Na ₂ O	
K ₂ O	

NOTE 1—The radioactivity, defined as the sum of the massic activity of U²³⁸, Ra²²⁶, Th²³² and determined by γ-spectroscopy on the ready to use powder, should be less than 200 Bq/kg. This value will be reviewed at the next revision of this standard and will be based upon the radioactivity data from ceramic implant manufacturers.

4. Physical Properties

4.1 The minimum bulk density of yttrium oxide stabilized zirconium oxide shall be 6.00 g/cm³ or greater as determined by Test Method C 373 as applied with the following modifications:

4.1.1 Weight determination in 3.1 and 5.1 of Test Method C 373 shall be made to the nearest 0.5 mg.

4.1.2 The calculation of bulk density in 12.1 of Test Method C 373 shall be calculated as follows:

$$B=(D \cdot d)/(M-S) \quad (1)$$

where:

B = bulk density, g/cm³,

D = dry weight, g,

M = saturated weight, g,

S = suspended weight, g, and

d = density of water at the temperature when measurement is taken.

4.2 The total porosity shall be no greater than 1.0 vol % and open porosity shall be no greater than 0.1 vol % as determined by Test Method C 373.

4.3 Grain Size—The mean linear intercept distance shall be 0.6 μm or less, in accordance with Section 10 of Test Method E 112.

¹ This specification is under the jurisdiction of ASTM Committee F-4 on Medical and Surgical Materials and Devices and is the direct responsibility of Subcommittee F04.13 on Ceramic Materials.

Current edition approved June 10, 1998. Published August 1998.

² Annual Book of ASTM Standards, Vol 15.02.

³ Annual Book of ASTM Standards, Vol 15.01.

⁴ Annual Book of ASTM Standards, Vol 03.01.

⁵ Annual Book of ASTM Standards, Vol 13.01.

⁶ Available from the American National Standards Institute, 11 W. 42nd St., 13th Floor, New York, NY 10036.