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Standard Specification for High-Purity Dense Magnesia Partially Stabilized Zirconia (Mg-PSZ) for Surgical Implant Applications¹

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1. Scope

1.1 This specification covers material requirements for high-purity, dense zirconium oxide partially stabilized by magnesium oxide (magnesia partially stabilized zirconia (Mg-PSZ)) for surgical implant applications.

1.2

1.2 The values stated in SI units are to be regarded as standard. No other units of measurement are included in this standard.

1.3 This standard does not purport to address all of the safety concerns, if any, associated with its use. It is the responsibility of the user of this standard to establish appropriate safety and health practices and determine the applicability of regulatory requirements prior to use.

2. Referenced Documents

2.1 ASTM Standards:²

C373 Test Method for Water Absorption, Bulk Density, Apparent Porosity, and Apparent Specific Gravity of Fired Whiteware Products

~~C1145 Terminology of Advanced Ceramics~~

C1161 Test Method for Flexural Strength of Advanced Ceramics at Ambient Temperature

C1198 Test Method for Dynamic Young's Modulus, Shear Modulus, and Poisson's Ratio for Advanced Ceramics by Sonic Resonance

C1239 Practice for Reporting Uniaxial Strength Data and Estimating Weibull Distribution Parameters for Advanced Ceramics

C1259 Test Method for Dynamic Young's Modulus, Shear Modulus, and Poisson's Ratio for Advanced Ceramics by Impulse Excitation of Vibration

C1327 Test Method for Vickers Indentation Hardness of Advanced Ceramics

~~E112 Test Methods for Determining Average Grain Size~~

~~F748 Practice for Selecting Generic Biological Test Methods for Materials and Devices~~

~~F981 Practice for Assessment of Compatibility of Biomaterials for Surgical Implants with Respect to Effect of Materials on Muscle and Bone~~ Test Methods for Determining Average Grain Size

2.2 American Society for Quality Standard (ASQ):

C1 Specification of General Requirements for a Quality Program³

2.3 ISO Standard:

ISO 18754 Fine Ceramics (Advanced Ceramics, Advanced Technical Ceramics)—Determination of Density and Apparent Porosity⁴

3. Chemical Requirements

3.1 The chemical composition shall be as follows, measured by ICP-AAS, ICP-ES, XRF, or mass spectroscopy:

Oxides	Weight percent
	Weight percent

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

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² For referenced ASTM standards, visit the ASTM website, www.astm.org, or contact ASTM Customer Service at service@astm.org. For Annual Book of ASTM Standards volume information, refer to the standard's Document Summary page on the ASTM website.

³ Available from American Society for Quality (ASQ), 600 N. Plankinton Ave., Milwaukee, WI 53203.

⁴ Garvie, Ronald C., and Nicholson, Patrick F., "Phase Analysis in Zirconia Systems," *Journal of the American Ceramic Society*, 55, [6], 1972, pp. 303-305.

⁴ Available from American National Standards Institute (ANSI), 25 W. 43rd St., 4th Floor, New York, NY 10036, http://www.ansi.org.

ZrO ₂ +	≧99.9
HfO ₂ +	
MgO	
ZrO ₂ +	≧99.8
HfO ₂ +	
MgO	
MgO	3.1-3.4
HfO ₂	≦2.0
Other	
Oxides	
Total	<0.20
Other	
Oxides	
Total	<0.1
	<0.1
Al	
Other	
Oxides	
Fe ₂ O ₃ <0.05	<0.01
Fe ₂ O ₃	<0.01
SiO ₂	<0.05
CaO	<0.02
Fe ₂ O ₃	<0.002
Al ₂ O ₃	<0.05

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.

4. Physical Requirements

4.1 The minimum bulk density of magnesia partially stabilized zirconia shall be ~~5.82~~5.800 g/cm³ ~~or greater as determined by Test Method C373 as supplied with the following modifications:~~

~~4.1.1 Weight determination in sections 3.1 and 5.1 of Test Method as supplied, with the following modifications or by ISO 18754.~~

4.1.1 Weight determination per sections 3.1 and 5.1 of Test Method C373 and section 7.1 of ISO 18754 shall be made such that it can be calculated and reported to four significant figures.

ASTM F2393-10

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