MEDICAL GRADE SILICON NITRIDE

AMEDICA®

Amedica's proprietary composition of silicon nitride provides the right combination of strength, toughness, wear resistance, biocompatibility, bioactivity, bone integration, structural stability, corrosion resistance, and easier imaging, all of which are desirable in medical implants.

THE IDEAL BIOMATERIAL

Strength and fracture toughness: Interlocking anisotropic grains deflect and bridge cracks.

Wear resistance: High hardness, strength, and fracture toughness prevent wear.

Material phase stability: No spontaneous phase transformation or associated weakening.

Hydrophilicity: Tunable through modification of surface topography and chemistry, from <10° up to ~70°.

Osseointegration: Nanostructured topography combined with complex surface chemistry optimal for cell adhesion and bone growth.

Favorable imaging: Semi-radiolucent density appears bone-like in X-rays and low magnetic susceptibility eliminates distortion in CT and MRI scans.

Bacterial resistance: Surface chemistry, nanotexture, and charge inhibit biofilm formation.

CALL **855.839.3500** OR VISIT US AT **AMEDICA.COM** TO DISCOVER WHY MATERIAL MATTERS.

AMEDICA'S SILICON NITRIDE

TYPICAL PROPERTIES

Property	Units	Test Method	Typical	Specification
Density	g/cc	ASTM C 373	3.26	≥ 3.23
Grain Size	microns	BS EN 623-3	0.5 x 5.0	≤ 25
Flexural Strength	MPa	ASTM C 1161	1,000	≥ 900
Compressive Strength	MPa	*	>4,000*	-
Elastic Modulus	GPa	ASTM C 1161	296	≥ 290
Poisson's Ratio	-	*	0.27*	-
Weibull Modulus	-	ASTM C 1239	10	≥6
Fracture Toughness	MPa·m1/2	ASTM E 399	10.5	≥ 9.0
Biocompatibility	-	ISO 10993	Pass	Pass
Hardness	GPa	ASTM C 1327	15.0	≥ 14.3
Coefficient of Thermal Expansion (RT – 200°C)	1 x 10-6/°C	*	2.2*	-
Thermal Conductivity	W/m·°K	*	15-30*	-
Si3N4 Phase Composition	%	X-ray Diffraction JCPDS# 82-0697	100% ß-Si3N4	≥95% ß-Si3N4
Specific Heat	J/Kg·°K	*	170*	-
Volume Resistivity	ohm-cm	*	>1012*	-

*Reported data are typical of silicon nitride. These values have not been specifically measured for Amedica's silicon nitride.

BIOCOMPATIBILITY TESTING

Test	Method
Cytotoxicity	ISO 10993-05
Sensitization	ISO 10993-10
Intracutaneous Toxicity	ISO 10993-10
Acute Systemic Toxicity	ISO 10993-11
Subchronic Toxicity	ISO 10993-11
Genotoxicity	ISO 10993-3
Muscle Implant tests	ISO 10993-6
Physicochemical Testing	USP

COMPATIBILITY WITH STERILIZATION METHODS

	Gamma Irradiation, E-Beam, X-Ray	Steam	Ethylene Oxide Gas
Silicon Nitride	Yes	Yes	Yes

ASTM OR ISO SPECIFICATIONS FOR BIOMATERIALS TABLE[1]

Property	Al_2O_3 ASTM F-603	Al_2O_3 ISO 6474-1	Mg-PSZ ASTM F-2393	Y-TZP ASTM F-1873	ZTA, AMC ISO 6474-2	Si_3N_4 ASTM F-2094[1]	Si_3N_4 ISO 266021	CoCr ASTM F799	Ti6Al4V ASTM F136	PEEK ASTM F2026
Chemical Purity (%)	≥ 99.5	≥ 99.7	≥ 99.8	≥ 99.0	≥ 99.8	≥ 97.0	NS	NA	≥ 99.3	NA
Density (g/cc and %)	≥ 3.93 ≥ 98.6	≥ 3.94 ≥ 98.8	≥ 5.80 ≥ 98.8	≥ 6.00 ≥ 98.4	≥4.31 ≥ 98.6	3.0 – 3.4 ≥ 99.8	3.0 – 3.6 NS	NA	NA	1.28 – 1.32
Grain Size (µm)	≤ 4.5	≤ 2.5	NS	≤ 0.6	Al_2O_3 ≤ 1.5 ZrO_2 ≤ 0.6	NS	NS	≤ 64	NA	NA
Flexural Strength (MPa)[1]	≥ 400	≥ 500	≥ 600	≥ 800	≥ 750	≥ 765	≥ 760	827 (YS) 1172 (TS)[2]	760 (YS) 825 (TS)	110
Weibull Modulus	≥ 8	≥ 8	≥ 10	NR	≥ 8	≥ 12	≥ 12	NA	NA	NA
Fracture Toughness (MPa·$m^{1/2}$)	NS	≥ 2.5	NS	NS	≥ 3.5	≥ 6.0	≥ 6.0	NA	NA	50[3]
Hardness (GPa)	≥ 18	≥ 18	≥ 10	≥ 12	≥ 15.5	≥ 15	≥ 14.2	≥ 3.3	NA	NA
Elastic Modulus (GPa)	≥ 380	≥ 380	≥ 180	≥ 200	≥ 320	270 – 330	270 – 330	NA	NA	3

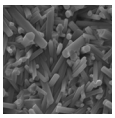
PHYSICAL & MECHANICAL PROPERTIES AND PERFORMANCE OF BIOMATERIALS[1]

Property or Performance	Units	Alumina	Zirconia		Zirconia-Alumina Composites			Industrial Silicon Nitride	Cobalt Chromium	Ti6Al4V	PEEK	Cortical Bone	Titanium Nitride	Diamond-Like Carbon	Zirconium Nitride	Titanium Niobium Nitride	Oxidized Zirconium	Hydroxyapatite
Composition	NA	Al2O3	Mg-PSZ	Ce- or Y-TZP	m-ZTA	AMC	ATZ	Si_3N_4	ASTM F799	ASTM F136	ASTM F2026	Collagen, Proteins, HAp	TiN	DLC	ZrN	TiNbN	Ox-Zr	ASTM F1609
Density	g/cc	3.98	5.65 – 5.77	6.00 – 6.05	4.25	4.37	5.51	3.22 – 3.35	8.29 – 8.50	4.43 - 4.50	1.29	1.5 – 2.0	4.87 – 5.22	0.90 – 3.20	7.09	~5.69	5.84	2.55 – 3.21
Grain Size	µm	<1.8 Equiaxed	50 Equiaxed	0.1 – 0.6 Equiaxed	0.4 – 0.7 Equiaxed	0.54 Equiaxed	0.4 Equiaxed	0.5 x 5.0 Non-Equiaxed	~62 Equiaxed	~10 x 60 Lamellar	NA	NA	30 – 300 nm Columnar	Amorphous 2 - 25 nm	10 – 30 nm Nanocrystals	10 – 30 nm Nanocrystals	40 x 200 nm	0.4 - 100 µm splats
Flexural or Tensile Strength	MPa	400 – 580 Flexural	450 – 700 Flexural	700 – 1500 Flexural	700 – 1248 Flexural	1250 – 1400 Flexural	755 – 1163 Flex./Biaxial	800 – 1100 Flexural	827 Tensile	860 – 970 Tensile	170 Flexural	90 – 228 Flexural	10 – 60 N LC Adhesion	35 – 160 N LC Adhesion	24 – 60 N LC Adhesion	83 N LC Adhesion	35 N LC Adhesion	39 – 189 Bond 25 – 60
Compressive Strength	MPa	4100 – 5000	2000 - 3000	2000 – 2200	4000 - 4500	4300	~2600	4000	600 – 1800	800 - 970	118	150 – 260 // 70 – 110 ⊥	400 – 5500	NA	NA	NA	~2000	102 – 1000
Elastic Modulus	GPa	380	200 – 250	210 – 223	340 – 390	358	240 - 250	296 – 313	197 – 210	105 – 120	4	7.5 – 25.8 // 5 – 20 ⊥	402 – 550	110 – 900	175 – 395	200 – 600	200	3.2 to 122 coat vs. bulk
Poisson's Ratio	NA	0.23	0.30	0.30 – 0.33	~0.24	0.24	~0.28	0.27	0.27 – 0.32	0.31 – 0.34	0.4	0.19 – 0.48	0.21	0.17 – 0.20	0.19	~0.20	0.34	0.11 – 0.27
Weibull Modulus	NA	5 – 29	22	7 – 87	NA	10 – 15	6 – 17	8 – 53	NA	NA	NA	NA	5 – 18	6 – 12	NA	NA	NA	2 – 19
Fracture Toughness	KIC, MPa·$m^{1/2}$	3.3 – 4.2	2.9 – 16.0	4.5 – 20.0	>4.1	6.4 – 8.5	8.0 – 12.0	4.4 – 15.0	50 – 100	46.3 – 93.3	7.6 kJ/m^2 Impact Test	1.0 – 5.0 // 3.0 – 20.0 ⊥	0.7 – 12.4	1.6 – 5.1	2.3 – 7.5	NA	2.2 – 2.8	0.5 – 1.2
Fatigue Resistance	K_{TH}/K_{IC}	0.52 – 0.84	0.45 – 0.90	0.37 – 0.92	NA	0.67	NA	0.50 – 0.97	0.14 – 0.36	0.10 – 0.40	0.53 – 0.62	0.30 – 0.83	NA	NA	NA	NA	NA	0.61
Biocompatibility	NA	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Marginal	Pass	Marginal	Pass	Pass	Pass	Pass	Pass	Pass	Pass
Surface Phase Composition	%	100% α-Al_2O_3	42% - 54% t-ZrO_2	65% - 95% t-ZrO_2	83% - 93% t-ZrO_2	58% - 90% t-ZrO_2	95% - 99% t-ZrO_2	100% ß-Si_3N_4	NA	Mixture of α & ß Ti	Amorphous & Crystalline	Collagen and HAp	TiN Nanocrystals	Amorphous	ZrN Nanocrystals	TiN, NbN Nanocrystals	95% m-ZrO_2 5% t-ZrO_2	ACP, TCP, HA
LTD Susceptibility	NA	Stable	Marginal	Metastable (Y-TZP; Marginal (Ce-TZP)	Stable	Marginal	Metastable	Stable	Stable	Stable	Stable	NA	Stable	Stable	Stable	Stable	Stable	Purposely Unstable
Hardness	GPa	18.0 – 23.0	10.0 – 12.0	11.0 – 12.5	15.7 – 20.8	19	13.7 – 15.0	15.0	3.0 - 4.0	2.8 – 3.3	99 Rockwell M	0.68 – 0.78 // 0.46 – 0.57 ⊥	33 – 56	14.5 – 80.0	14.0 – 31.0	14.0 - 24.5	12.0 – 14.0	3.0 – 9.0
Wear Rate PE HXLPE Hard-on-Hard	mm^3/MC	20 – 58 0.0 – 6.9 0.02 – 4.71	- 1.8 – 5.1 NA	11 – 63 5.0 – 6.0 Catastrophic	NA	1 – 20 0.1 – 4.4 0.00 – 0.45	17 - 32 5.6 – 6.1 0.02 – 0.06	17 - 25 3.7 – 6.3 0.18 – 0.98	14 – 201 0.0 – 11.7 0.18 – 25.00	NA	NA	NA	21 NA NA	28 – 67 2.8 NA	NA 3.5 NA	NA	- 0.2 – 1.7 NA	NA
Thermal Expansion Coefficient	10-6/°C	8	7 - 10	11	~8	8.1	~10	2.0 – 4.6	7.32	8.5 – 9.7	47	22.0 – 32.4	7.4 – 9.2	2.3	5.9 - 7.2	~7.4 – 9.2	7 – 10	11.6 – 14.2
Thermal Conductivity	W/m°K	30	2	2 – 3	~17	17	~6	30 - 50	12.7	6.7 - 7.0	0.29	0.41 – 0.63	11.9	0.2 – 30	20	~12 - 14	2 – 3	1.1 – 1.2
X-Ray Radiolucency	NA	Radiolucent	Opaque	Opaque	Opaque	Opaque	Opaque	Radiolucent	Opaque	Opaque	Transparent	Radiolucent	Opaque	Opaque	Opaque	Opaque	Opaque	Radiolucent
Sessile Water Contact Angle	Degree (°)	50 – 72	79	82	90	90	90	40 – 70	55 – 93	76	95	NA	31 - 69	55 – 71	89	73 - 75	71	34 – 39
Bacteriostatic Capabilities	⊕ = Excellent; + = Good; ∅ = Fair; ⊗ = Poor; × = Very Poor	∅	+	+	NA	+	NA	⊕	⊗	+	×	NA	+	+	⊕	NA	+	+
Osseointegration Ability		∅	+	+	NA	+	NA	⊕	⊗	+	×	⊕	+	+	⊕	NA	NA	⊕

[1] B.J. McEntire, B.S. Bal, M.N. Rahaman, J. Chevalier, and G. Pezzotti, "Ceramics and Ceramic Coatings in Orthopaedics," J. Eur. Ceram. Soc., **35** [16] 4327–4369 (2015).

SILICON NITRIDE FORMS

As Fired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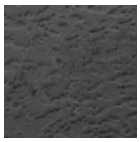
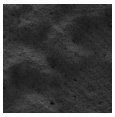
Nano-scale topography, increased surface area
Ideal for: Bone on growth

Textured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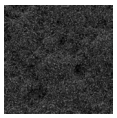
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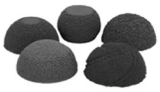
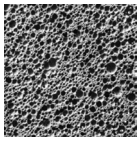
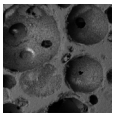


Customizable macro-scale topography
Ideal for: Grip, bone on growth

Porous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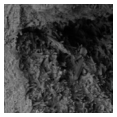
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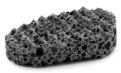
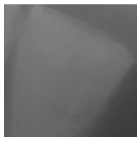
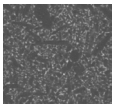


Up to 70% connective porosity with 100-700 µm pore size
Ideal for: Bone ingrowth

Polished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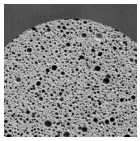
Ra ~ 5 nm, Hardness ~15 GPa
Ideal for: Bearing surfaces

Composite




Application-specific custom morphologies
Ideal for: Hybrid applications

SHARING OUR EXPERTISE

At Amedica, we have the scientific and manufacturing expertise to produce medical grade silicon nitride - a patented platform technology for use in a variety of medical applications. Silicon nitride is bioactive and compatible across all imaging modalities, offering surgeons and patients a preferable alternative to commonly used materials.

Let our leading R&D and manufacturing teams convert your existing medical devices into silicon nitride. With our unrivaled in-house capabilities, we are equipped to control complex geometries on a macro-, micro-, and nano-level, which allows for intricate designs and shapes that can be rapidly developed, prototyped, and tested in our FDA registered and ISO 13485 certified facility.

Contact us at **855.839.3500** or online at **amedica.com** to learn more.

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