



May 1, 2019

R&D Update Q2 2019

Dear Colleague:

I am attaching an updated bibliography of our published science, confirming the advantages of silicon nitride in bone healing, radiographic imaging, and antibacterial properties.

Silicon nitride is a bioactive, non-oxide ceramic. Our formulation is made by bonding silicon with nitrogen, with trace amounts of added yttria and alumina ceramic.

Rapid bone healing is related, at least in part, to the surface expression of a bioactive glass phase during sintering, and the bioavailability of trace amounts of silicon, nitrogen, and other ions that are preferentially incorporated into newly-forming bone.

Implant retrievals, and animal data show the presence of an ion-substituted hydroxyapatite adjacent to silicon nitride interbody spacers. To our knowledge, silicon nitride is the only material that can favorably modulate the basic biology of bone healing.

In addition to the above mechanisms, silicon nitride also induces stem cell differentiation into osteoblasts that express hydroxyapatite. Data, including animal and clinical studies confirm bone healing into porous silicon nitride as early as 4 weeks.

SINTX has a 10-year safety history of >35,000 spinal implantations of silicon nitride. Beyond monolithic silicon nitride, we have developed coatings, composites, and other formulations of silicon nitride for exciting, new applications in spine, and beyond.

Others are taking notice. *Mobbs et al* reported a 30-year follow-up of patients who underwent lumbar fusion with silicon nitride, the earliest such study. *Wu et al* reported antibacterial and enhanced osteogenesis with a silicon nitride coating on a polymer. Other independent papers have also corroborated the antibacterial and osteogenic properties of silicon nitride.

We are working with commercial partners toward applying silicon nitride in the dental and arthroplasty fields. We are also investigating industrial applications for our material, in defense, agriculture, and other fields.

Thank you for your support.

Sincerely,

B. Sonny Bal, MD MBA JD PhD
President and CEO SINTX Technologies

Silicon Nitride Publications

Introduction to Silicon Nitride, General Processing and Properties

- B. J. McEntire and B. S. Bal, "The Story of Silicon Nitride, Product Brochure, Amedica Corporation (2017).
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- B.J. McEntire, "Bioceramics: From Clinic to Concept," *Bioceram. Dev. Appl.*, **07** [01] 1–2 (2017).
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Antibiotic Characteristics of Silicon Nitride

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- D.J. Gorth, S. Puckett, B. Ercan, T.J. Webster, M. Rahaman, and B.S. Bal, "Decreased Bacteria Activity on Si_3N_4 Surfaces Compared with PEEK or Titanium," *Int. J. Nanomedicine*, **7** 4829–4840 (2012).
- R.M. Bock, E.N. Jones, D.A. Ray, B.S. Bal, G. Pezzotti, and B.J. McEntire, "Bacteriostatic Behavior of Surface-Modulated Silicon Nitride in Comparison to Polyetheretherketone and Titanium," *J. Biomed. Mater. Res. Part A*, **105** [5] 1521–1534 (2017).
- G. Pezzotti, "A Spontaneous Solid-State NO Donor to Fight Antibiotic Resistant Bacteria," *Mater. Today Chem.*, **9** 80–90 (2018).
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Clinical Studies of Silicon Nitride

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- G. Pezzotti, N. Oba, W. Zhu, E. Marin, A. Rondinella, F. Boschetto, B.J. McEntire, K. Yamamoto, *et al.*, “Human Osteoblasts Grow Transitional Si/N Apatite in Quickly Osteointegrated Si₃N₄ Cervical Insert,” *Acta Biomater.*, **64** 411–420 (2017).
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Osteoconductivity, Osseointegration, and Osteoinductivity of Silicon Nitride

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Wear Characteristics of Silicon Nitride

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Imaging Characteristics of Silicon Nitride

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