Silicon Nitride Demonstrates Statistical Superior Osteointegration and Anti-Infective Biomaterial Properties

Amedica Corporation

Results from Brown University Studies Show Significant Advantages when Compared to PEEK and Titanium

Amedica Corporation [1], a spinal and reconstructive implant manufacturer, announced today the publication of two peer-reviewed studies conducted at Brown University that demonstrate the superior osteointegration and bacterial-resistant properties of its proprietary Silicon Nitride (Si3N4) biomaterial when compared to poly-ether-ether-ketone (PEEK) or titanium (Ti). In related news, the company also announced the expansion of biomaterial property claims for its line of FDA 510(k) cleared interbody fusion devices. [2]

Spine and orthopedic surgeons have historically relied on allograft bone, metal and plastic implants to aid in spine fusions and joint replacements. Implants have traditionally been comprised of materials that are resistant to host immune mechanisms and systemic antibiotics, creating an environment for significant bacterial growth. As a result, functional implants can become colonized with bacteria, which may reduce fusion rates or cause serious infection. Treating implant-related infection is costly and generally requires extensive repeat surgery that may extend suffering and disability for patients.

The in-vitro data from the journal article titled, “Decreased Bacteria Activity on Si3N4 Surfaces Compared with PEEK or Titanium,” which appears in the International Journal of Nanomedicine 2012:7 1-12 [3] reports that Silicon Nitride is far less vulnerable to bacterial colonization (S. epidermidis, S. aureus, P. aeruginosa, E. coli and Enterococcus) than PEEK and titanium. Additionally, because of the positive surface charge, nanostructure and hydrophilic nature of Silicon Nitride, there was also rapid adherence of fibronectin, vitronectin and laminin proteins which can decrease susceptibility to bacteria and increase osteointegration.

An in-vivo study titled, “Anti-infective and Osteointegration Properties of Silicon Nitride, Poly (Ether Ether Ketone), and Titanium Implants,” which appears in the July 31 online edition of Acta Biomaterialia (2012) [4], reports that Silicon Nitride demonstrates superior new bone formation and resistance to bacterial infection when compared to PEEK and titanium. Specifically, the amount of regenerated bone associated with Silicon Nitride implants was essentially two- to three- times that of the other two implant materials at three months post-surgery. In as little as 14 days, Silicon Nitride demonstrated significantly greater new bone formation at both the surgical site and the implant interface.

“Bacterial infection is a serious risk that can lead to non-healing fusions, implant loosening, device failure and, in extreme cases, death,” said Dr. Thomas J. Webster, lead investigator, and Chair and Professor of the Department of Chemical Engineering at Northeastern University. “Selectively engineering the biomaterial or surface structure of the implant can decrease bacterial adhesion, lessening the potential for infection. Our study examined the innate biomaterial characteristics of Silicon Nitride, PEEK and titanium, and it was evident that Silicon Nitride holds the greatest potential for decreased risk of bacterial infection.”

“Silicon Nitride has been used in spine applications for more than four years with a proven record of safety and effectiveness, and a vast patient population has benefited from this innovative technology,” said Eric K. Olson, President and Chief Executive Officer, Amedica. “The increasing body of evidence supporting the benefits of Silicon Nitride for spine and orthopedic surgery indicates that material matters, and that Silicon Nitride interbody fusion devices may achieve faster fusion than PEEK and titanium spacers while reducing the incidents of infection. We are incredibly optimistic about the capabilities of the technology, its future applications and the ability to rapidly increase sales by demonstrating a clear advantage over PEEK and titanium.”

Additional information about the Company's complete line of products may be found at www.amedica.com [1].

About Amedica Corporation:
Amedica is an innovative spine and orthopaedic implant and device manufacturing and distribution company that provides advanced surgical applications including silicon nitride ceramic technologies. The company’s platform technologies represent a new standard for implants and biologics based on superior performance, safety and efficacy. Amedica is a privately held, private equity backed company founded in 1996 by internationally recognized orthopaedic surgeons and ceramicists. The company is ISO 13485 certified, its spine products are FDA cleared, CE marked, and sold in ten countries. Amedica Corporation is based in Salt Lake City, UT.

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