Published Data Enables Significant Expansion of Biomaterial Claims for Amedica's FDA 510(K)-Cleared Devices

Amedica Corporation

Amedica's Proprietary Silicon Nitride Interbody Fusion Devices Become the New Standard of Care

Amedica Corporation [1], a spinal and reconstructive implant manufacturer, announced today the expansion of biomaterial claims for its FDA 510(k)-cleared Valeo® Interbody Fusion Devices. The expansion of these claims focus on the innate properties of the Company's proprietary Silicon Nitride (Si3N4) biomaterial, which has been proven to provide superior osteointegration and anti-infective capabilities when compared to products comprised of poly-ether-ether-ketone (PEEK) or titanium (Ti). The expanded labeling for Amedica's Silicon Nitride technology will drive the evolution of the standard of care for patients suffering from back pain requiring spinal fusion.

The expansion of the biomaterial claims is based on data published in peer-reviewed journal articles in Acta Biomaterialia and the International Journal of Nanomedicine, demonstrating superior new bone formation, and osteointegration, as well as anti-infective properties of Silicon Nitride in comparison to PEEK and titanium. Additional details can be found in a related announcement also released today. [2]

With mounting pressure on physicians and hospitals to provide the highest possible quality of care, spine surgeons have become increasingly aware of the material characteristics of PEEK and titanium, the most commonly used biomaterials for spinal devices. In both studies, PEEK and titanium developed a biofilm around the implant that appears to dramatically reduce bone formation, indicating the potential for less than optimal patient outcomes in clinical applications.

Additionally, due to recent changes in federal reimbursement for Medicare and Medicaid patients, the United States Congress has begun to focus on quality outcome measures. In fact, future payments will be provided only for those services and procedures that meet quality of care standards. Because of these changes, there is a significant need to further incorporate biomaterials into orthopedic and spinal implants that can improve overall patient outcomes. The use of Silicon Nitride products should allow hospitals and surgeons to benefit from higher reimbursements for spinal fusion procedures that reduce the risk for infection and increase the potential for improved fusion rates.

"The expansion of these biomaterial claims to our Silicon Nitride Interbody Fusion Devices demonstrates the clear superiority of our technology in comparison to PEEK and titanium," said Eric K. Olson, President and Chief Executive Officer, Amedica.

“The company is prepared to take advantage of these enhanced claims, to dramatically increase sale of our Silicon Nitride products, grow company revenue and ultimately, we believe this technology will become the new standard of care.”

Silicon Nitride has been used in interbody fusion devices for more than four years with a proven record of safety and effectiveness. Surgeons at leading hospitals are utilizing Silicon Nitride interbody fusion devices to help minimize patient exposure to infection risk while increasing the potential for fusion.

“Patients undergoing spinal fusion surgery typically experience pain and decreased range of motion, which can vastly diminish their quality of life. My goal is to treat these patients and get them back to activities of daily living as soon as possible,” said Dr. Grant Skidmore of Neurosurgical Specialists, Inc., in Norfolk, Virginia. “In my experience, Silicon Nitride interbody fusion devices exceed the capabilities of PEEK and titanium, resulting in less risk of infection and faster fusion rates. This means better results for my patients.”

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

Links:
[1] http://www.amedica.com
[2] http://amedica.com/company/news/silicon-nitride-superior-osteointegration.html