

Nanovis Announces FDA Clearance of FortiCore® PLIF and TLIF Spinal Interbodies with Nanosurface Features.

Spinal Implants Cleared with the Most Advanced Nanosurface and Best Imaging.

Carmel, Ind. (March 28, 2018) – Nanovis, today announced the successful FDA clearance of its FortiCore® TLIF and PLIF interbodies featuring a Nanosurface-enhanced deeply porous titanium scaffold intermolded with a PEEK core.

"Implant nano surface science has advanced from the early days when we simply created nanoroughness for implants because tissues have nanoroughness. Now we understand the mechanisms by which nanotopographies can interact with cellular signaling pathways. I'm delighted that with Nanovis' implants, patients can now benefit from a carefully designed and controlled nanotopography that harnesses this groundbreaking research," said Thomas Webster, PhD, Chemical Engineering Department Chair, Northeastern University, who with Chang Yao, PhD, were early pioneers in the use of nanosurfaces to enhance bone growth.

Nanovis' foundational FortiCore interbody fusion platform is well proven with over 4,250 implanted to date. FortiCore interbodies have deeply porous interconnected titanium scaffolds intermolded with a PEEK core, giving surgeons important fixation and imaging advantages. Data comparing the osseointegration strength of the FortiCore scaffold, PEEK, and allograft to the strength of trabecular host bone was published in Spine in late 2016. Now the titanium scaffolds on the FortiCore TLIF and PLIF interbodies are enhanced with a carefully designed and controlled nanosurface.

"The timing for this clearance is very good because surgeons are searching for the best surface technologies. I've watched Nanovis methodically develop technology platforms in a surface on a surface bone fixation strategy. Now they offer the most advanced interbody fixation technology with the best imaging profile on the market," said Dr. Alan McGee, Orthopedics Northeast, a participant in the alpha launch of FortiCore. "My partners and I have implanted over 300 FortiCore interbodies. I can tell my patients I'm giving them the most advanced technology available today, and they have recovered quickly and have been very satisfied. It's easy for me to assess bone growth through and around the FortiCore implants with plain X-ray. It's a struggle to assess bone growth through 3D printed titanium interbodies with plain X-ray and I'm hesitant to expose my patients to the extra radiation from an unnecessary CT scan. I'm encouraged by Nanovis' pre-clinical data for this nanotechnology enhanced surface and look forward to upgrading my use."

"The science behind this nano technology is very exciting and clearance of the surface provides Nanovis another highly differentiated platform designed to reduce fixation related complications across a wide range of implant systems. In the short term, this nanopatterned surface targets fixation related complications and in the intermediate term this nanopatterned surface is the foundation of a bactericidal program targeting infection related complications," said Matt Hedrick, CEO, Nanovis.

About Nanovis

Nanovis' clinical and scientific goals are to reduce fixation and infection related complications. The Company's patented and proprietary regenerative technology platforms provide differentiated surface advantages enabling the potential for existing medical devices to achieve new outcomes. Nanovis is commercializing science-driven platforms: the deeply porous scaffold and nanopatterned surface on select FortiCore interbody fusion devices and developmental bactericidal technology.

For more information about Nanovis, FortiCore or other proprietary Nanovis science-enhanced technologies, please visit www.nanovisinc.com or call 1-317-507-1058.

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For Reference:



Caption: Surface Structure: Nanovis' FortiCore TLIF interbody fusion devices.

Caption: Radiolucency: Nanovis' FortiCore TLIF interbody fusion device.

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