Stryker Receives FDA Clearance for Tritanium® PL Posterior Lumbar Cage

Advanced 3D Additive Manufacturing Technology Used to Create Proprietary Tritanium Material, for Stryker’s Spine Division, Designed for Bone In-Growth and Biological Fixation

ALLENDALE, NJ – March 3, 2016 – Stryker’s Spine division today announced that its Tritanium PL Posterior Lumbar Cage, an intervertebral body fusion device that aids in lumbar spinal fixation for patients with degenerative disc disease, has received 510(k) clearance from the U.S. Food and Drug Administration.

The Tritanium PL posterior lumbar cages are constructed out of propriety Tritanium technology used by Stryker’s Spine division and are manufactured via a 3D additive manufacturing process. Tritanium is a novel highly porous titanium material designed for bone in-growth and biologic fixation in spine applications.

Tritanium PL Cages are offered in a variety of widths, lengths, heights and lordotic angles designed to adapt to a variety of patient anatomies and are designed to be implanted via a posterior approach. The cage is intended for use in patients with degenerative disc disease, grade I spondylolisthesis, and degenerative scoliosis. Degenerative disc disease is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies.

The large lateral windows and open architecture of the Tritanium PL Cage allow visualization of fusion on CT and X-ray. Its solid-tipped, precisely angled serrations are designed for bidirectional fixation and to maximize surface area for endplate contact with the implant. The Tritanium PL Cage is also designed to address the potential for subsidence into the endplates.

“This is an exciting time for Stryker.” said Brad Paddock, President, Spine Division, Stryker. “We are committed to offering a full range of innovative spinal products that allow surgeons to help their patients return to a more active lifestyle. Our advanced 3D additive manufacturing
capabilities allow us to precisely manufacture the porous structures of Tritanium and specific implant geometries. We are pleased to bring this technology to our spine surgeon community and their patients.”

The Tritanium PL Cage is intended for use with autograft and/or allogenic bone graft, comprised of cancellous and/or corticocancellous bone graft inside the device, and with supplemental spinal fixation systems that have been cleared by the FDA for use in the lumbosacral spine (i.e., pedicle screws, rods, or plates). The implants will be available to orthopaedic and neurosurgeons in the second quarter of 2016.

About Stryker
Stryker is one of the world’s leading medical technology companies and together with our customers, we are driven to make healthcare better. The Company offers a diverse array of innovative products and services in Orthopaedics, Medical and Surgical, and Neurotechnology and Spine that help improve patient and hospital outcomes. Stryker is active in over 100 countries around the world. For more information, visit www.stryker.com.

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Content ID TRIT-PR-1_REV-2