3D-Printed Tritanium®—Advancing Spinal Surgery

Advances in 3D printing pioneered by Stryker have led to the development of Tritanium, a novel, highly porous titanium alloy material designed for bone in-growth and biological fixation. This technology allows Stryker to create a material with precise porous structures that resemble cancellous bone, a type of spongy bone tissue.

The first spine implant based on this advanced technology is the Tritanium Posterior Lumbar (PL) Cage, introduced by Stryker’s Spine division in May 2016. The Tritanium PL Cage is an interbody fusion device that aids in lumbar spinal fixation for patients with low back pain resulting from degenerative disc disease. (See below for additional indications.) The Tritanium technology platform and Tritanium PL Cage were designed to help achieve vertebral fusion, and illustrate the ongoing commitment and leadership of Stryker’s Spine division to advancing spine health.

3D Additive Manufacturing Leadership is “Biologically Inspired”

Stryker is a pioneer in additive manufacturing, also known as 3D printing. In 2001, the company began collaborations in the university setting to develop 3D additive manufacturing technology and porous metal structures for Stryker’s medical applications. Tritanium is the culmination of nearly 15 years of extensive research, development, and validation in material science and manufacturing, and it has been utilized clinically for more than 10 years—with more than 300,000 knee and hip devices implanted.

In contrast to traditional manufacturing methods, 3D additive manufacturing is a process that creates three-dimensional objects by adding material in extremely thin layers. Guided by special computer-aided design software, a focused laser beam melts layers of titanium alloy particles in a process that is repeated hundreds of times, essentially “growing” the device from the bottom up and giving Stryker the ability to consistently produce precisely engineered porous structures that would be difficult or impossible to create using traditional manufacturing processes. Tritanium products are produced at Stryker’s state-of-the-art additive manufacturing facility.

Spinal Fusion for Degenerative Disc Disease

Patients with degenerative disc disease often experience back pain, which typically is treated with medication, heat or ice, physical therapy, and exercise. However, if conservative treatment for back pain does not provide relief, spinal fusion surgery may be recommended. This includes posterior lumbar interbody fusion (PLIF) and transforaminal lumbar interbody fusion (TLIF),
surgical procedures performed to help reduce pain by fusing two adjacent vertebrae so that there is very little movement between them.

In lumbar interbody fusion procedures, the disc space is cleaned of disc material, and an intervertebral fusion device, or “cage,” is inserted into the disc space. The cage, along with bone graft and the required supplemental fixation, is designed to help restore and maintain adequate spacing between the vertebrae in order to stabilize the spine while that section of the lumbar spine is fusing. Traditionally, cages used in interbody fusion procedures have been made of allograft bone (from a bone bank) or materials such as carbon-fiber-reinforced polymer, PEEK (polyetheretherketone polymer), or titanium alloy.

**Tritanium Posterior Lumbar Cage**
The new Tritanium PL Cage received 510(k) clearance from the U.S. Food & Drug Administration in November 2015. The Tritanium PL Cage is a hollow rectangular implant that is inserted into the disc space, packed with bone graft and supplemented by spinal fixation systems cleared for use in the lumbosacral spine.

The Tritanium PL Cage is:
- Created with fully interconnected pores that span endplate to endplate with a mean porosity of 60 percent and a mean pore size of roughly 450μm.
- Intelligently designed to closely fit the anatomy of the disc space.
- Created to allow imaging. The large lateral windows and open architecture of the Tritanium PL Cage allow visualization on CT and X-ray.
- Designed to resemble cancellous bone, with solid-tipped, precisely angled serrations on the superior and inferior surfaces that are designed to allow bidirectional fixation and to maximize surface area for endplate contact with the cage.
- Designed with a large central opening spanning endplate to endplate for bone graft containment and to permit fusion through the interbody cage.
- Offered in a variety of widths, lengths, heights, and lordotic angles designed to adapt to a variety of patient anatomies.

**Tritanium Technology**
In lumbar spinal fusion procedures, advancement of bony fusion at the target levels is at the cornerstone of a successful clinical outcome. In an effort to enhance the bony in-growth potential of implants, the scientific community has focused on porous metal implants in the hope of establishing a material similar in structure and mechanical properties to bone. Studies also have sought to understand which geometry and pore size would provide an optimal environment for cells to attach and multiply within this structure.²⁻⁴

Stryker’s Spine division conducted a pre-clinical animal study to investigate the biomechanical performance and bone in-growth potential of various lumbar interbody fusion implants utilizing different materials (including the Tritanium PL Cage). The study has been accepted as a podium presentation at the NASS Annual Meeting being held Oct. 26-29, 2016, in Boston.
Commitment to Collaboration
Stryker has spent more than 15 years developing 3D additive manufacturing capabilities, bringing together a team of talented scientists and engineers and collaborating with academic institutions, with the goal of creating innovative products that meet Stryker's standards, as well as the needs of surgeons and patients. In addition, surgeons have the opportunity to visit Stryker’s additive manufacturing facilities to get a first-hand look at the process and understand the "elegant complexity” of Tritanium products. Additional Tritanium spinal implants are anticipated.

Indications for Use
The Tritanium PL Cage is an intervertebral body fusion device indicated for use with autograft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft when used as an adjunct to fusion in patients with degenerative disc disease at one level or two contiguous levels from L2 to S1. Degenerative disc disease is back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The degenerative disc disease patients may also have up to Grade I spondylolisthesis at the involved level(s). These patients should be skeletally mature and have six months of nonoperative therapy. Additionally, the Tritanium PL cage may be used as an adjunct to fusion in patients diagnosed with degenerative scoliosis. It is to be implanted via a posterior approach and is intended to be used with supplemental spinal fixation systems that have been cleared for use in the lumbosacral spine.

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, which help improve patient and hospital outcomes. Stryker is active in over 100 countries around the world. For more information, visit www.stryker.com.

Editor’s note: For images, video footage, or animation of Tritanium products and Stryker's 3D additive manufacturing process, contact Barbara Sullivan at 714/374-6174 or bsullivan@sullivanpr.com.

References
1. PROJ*43909: Tritanium Technology Claim Support.