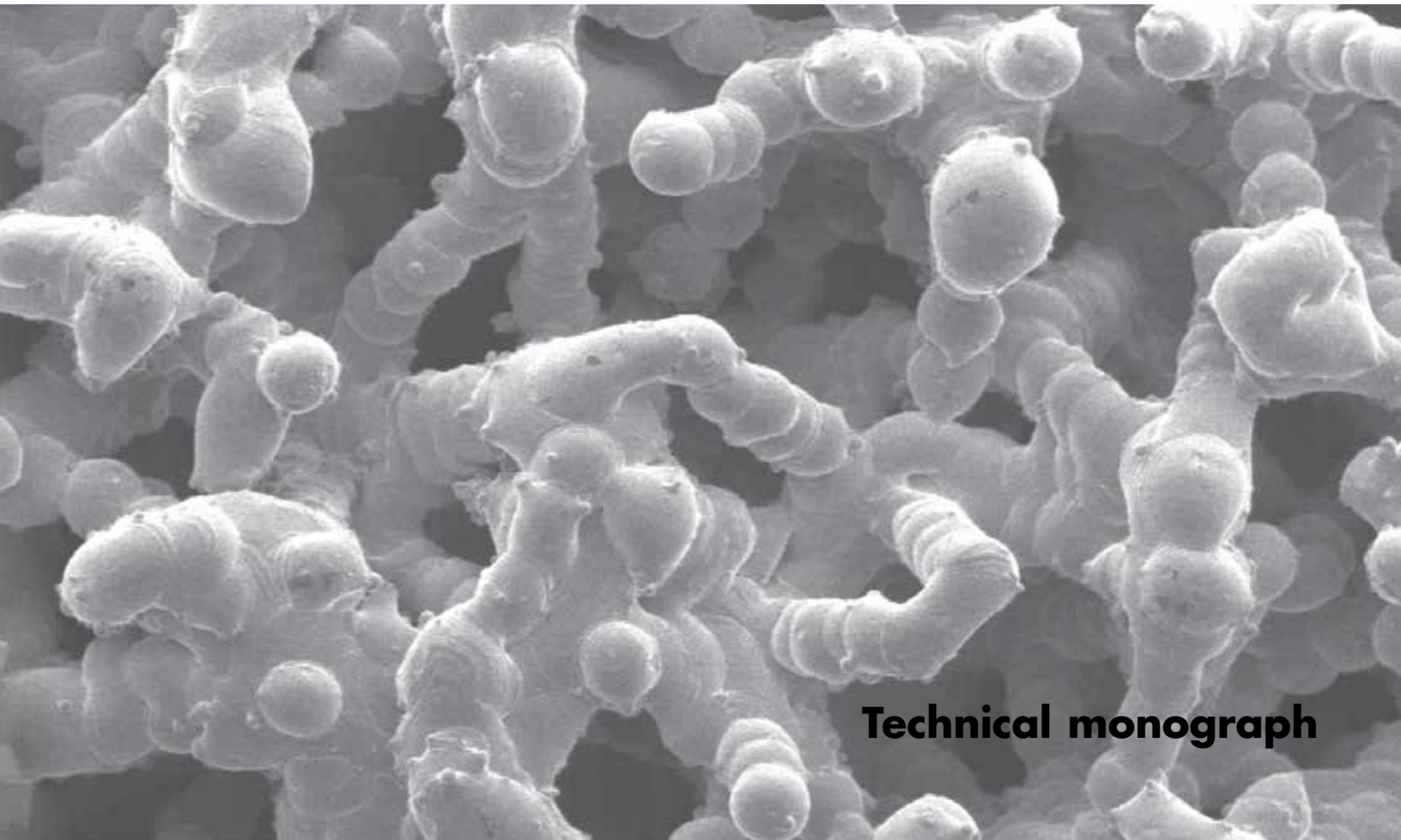


**stryker**

Tritanium®  
**manufacturing  
overview**



**Technical monograph**

# Introduction

There is a correlation between the clinical outcomes of lumbar spinal fusion and the achievement of bone fusion.<sup>1</sup> The anterior column of the spine is the load-carrying portion and handles up to 80% of the axial load. Interbody fusion devices have been used to provide anterior stabilization, limiting motion and bearing load, in the immediate postoperative period after fusion procedures. Over time, the anterior column will fuse with bone, and the new fusion mass will carry the load.

New design and manufacturing technologies are being used to develop orthopaedic implants for spinal fusion procedures. A novel Additive Manufacturing process provides the ability to create unique porous and solid structures. This technology creates new opportunities for device manufacturers to innovate for the potential benefit of surgeons and patients.

# 3D printing

....also known as Additive Manufacturing

Additive Manufacturing (AM) is a novel manufacturing technique that takes a computer model of a component and grows parts layer by layer.

Although Additive Manufacturing (AM) is the official industry standard term according to ASTM and ISO, 3D printing has been used routinely to describe the family of AM technologies.

The specific type of AM used to build the Tritanium PL Cage is Laser Rapid Manufacturing (LRM) which uses a focused laser beam to melt layers of metal powder in a fusion bed. LRM has been given many proprietary pseudonyms by machine manufacturers, such as SLM, DMLS and Cusing, and the first machines began to appear in the late 1980s and early 1990s. The development of metal based powder bed fusion systems was driven by European vendors.

Stryker began investigating laser powder bed fusion technologies in 2001 with academic research institutions. Stryker's research goal

was to investigate the feasibility of the technology for controlling porosity during manufacturing. During the next eight years Stryker developed an innovative approach to modeling and manufacturing porous structures using LRM and worked with hardware and software companies to develop production capable systems. In 2009 a pilot plant was established in Stryker's facility in Cork, Ireland to validate the production capability of the process, which ultimately led to the 510(k) clearance for Stryker's first LRM manufactured product in 2013, the Triathlon Tritanium Knee line.<sup>6</sup>

Metal powder bed fusion technologies are still developing with pace. Stryker continues to invest in research and development of the software and hardware that support these technologies as well as the expansion of production capabilities and product applications. Expanding the applications for the technology, Stryker is bringing LRM manufactured implants to Spine in 2016.

## Process description

The process begins by creating a computational model of a part, and then slicing the model into the layers that are to be manufactured as shown in **Figure 1**. A scanning strategy is then applied to each slice which controls where the laser will be scanned. For solid components, this strategy is analogous to coloring in each slice, where the inside and outside boundaries are scanned first and then area between is hatched, as shown in **Figure 2**. As each vector is scanned by the laser it creates a laser weld, which will coalesce with the neighboring welds to form a fully melted cross section.

The manufacturing process starts with a thin layer of metal powder spread across a metal substrate or

plate. A schematic of the process chamber is shown in **Figure 3**. The list of metal powders that can be used in the process includes Steels, Cobalt Chrome, Aluminum alloys and Titanium alloys. A scanning galvanometer is used to scan the laser over the powder bed, selectively melting only those regions that are required to be melted. The powder is prevented from oxidizing by processing in an inert gas environment. After the first scan is complete, the elevator platform is lowered by a layer thickness, the powder is recoated using a wiper mechanism, and the next layer is scanned. This sequence of events repeats as the part is grown from the bottom up as seen in **Figure 4** (next page).

The process parameters are controlled so that following heat treatment, the solid structural elements within the final part have been shown to possess equivalent mechanical properties to wrought product.<sup>7,8</sup>

As there are no process agents or material transfer during the process, the composition of the manufactured parts is the same as the input powder. Only the powder required for the part is melted during the process, and the completed build has final parts embedded in a non-melted powder. All non-fused powder is recovered from the machine and reused, so there is no metal powder wasted.

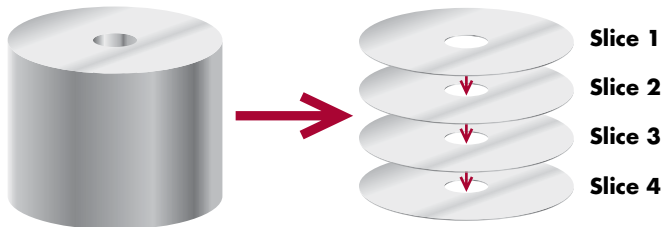


Figure 1: Preparing part for manufacture by slicing into layers

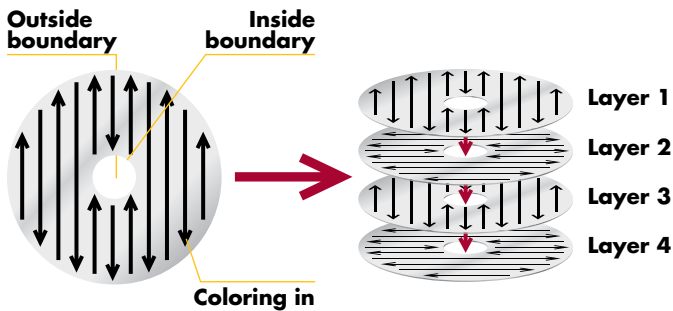


Figure 2: Creating laser scan strategy per layer

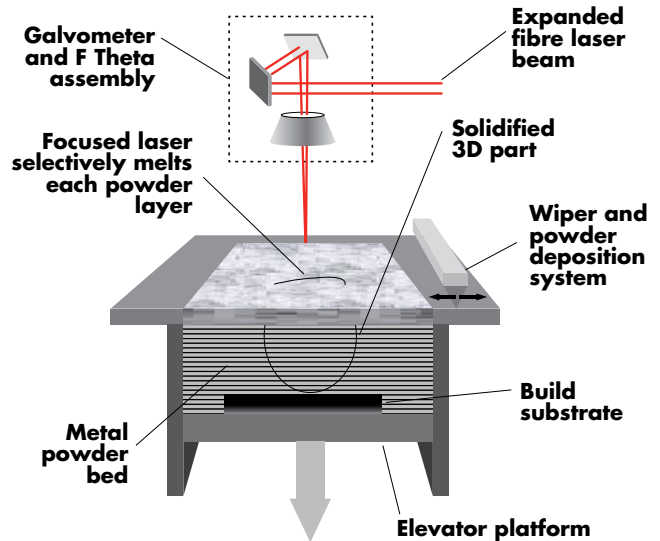


Figure 3: Schematic showing the mechanics of the laser metal powder bed system.

## Process capabilities

The traditional benefits of Additive Manufacturing are that it can be used to manufacture previously unmanufacturable geometries, produces minimal material waste, and potentially offers unrivaled product development speed. The Tritanium products utilize these capabilities to combine highly porous structures with solid structural elements in designs that cannot be manufactured using other traditional manufacturing techniques. Additionally it is the ability to create unique porous structures that really differentiates these products. Unlike traditional metal foam techniques, every element of

Stryker's AM metal porous matrix is created in a computer model before manufacturing, which allows the porous matrix to be specifically engineered for its intended use.

### Tritanium PL Cage

- Strategic smooth metal placement to aid in insertion and protect neural elements (**Figure 5**).
- The porous structure that contacts bone surfaces (**Figure 6**) is designed with fully interconnected porosity, mean pore diameters of 400-500 microns and a mean porosity of 55-65%.<sup>14</sup> Although this structure has an organic and random appearance, as shown in **Figure 7**, this effect is in fact

entirely controlled through the computer model. The properties of the porous matrix are therefore engineered to be consistent throughout the structure.

In addition, Stryker's method for modeling and creating the metal porous matrix allows for unique features such as integrated surface roughness and part-specific marking. Finally, because each implant is generated from a single master computer model, the metal porous matrix that is created for a given model and size of a particular product is virtually identical to that which was originally tested and validated.



Figure 4: Laser Rapid Manufacturing Process



Figure 6: Different bone-facing architectures made possible with Additive Manufacturing.



Figure 5: Smooth wedge nose and sides. Porous and roughened superior and inferior surfaces where the cage contacts the vertebral endplates.



Figure 7: Cancellous bone (left) and the porous matrix of Tritanium technology (right)

# Potential future applications

Stryker plans to continue developing Additive Manufacturing and exploring additional opportunities in which this technology can help surgeons and patients. There are great opportunities for reducing product development lead times while simultaneously incorporating more innovative design features that can be included as standard. It is also now possible to design porous matrices such that the density, pore diameter and mechanical properties can differ in various regions of that implant.





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### U.S.A and Canada Indications for Use:

The Stryker Spine 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 (DDD) at one level or two contiguous levels from L2 to S1. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The DDD 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 non-operative therapy. Additionally, the Tritanium PL Cage can be used as an adjunct to fusion in patients diagnosed with degenerative scoliosis. The Tritanium PL Cage is to be implanted via a posterior approach. The Tritanium PL Cage is intended to be used with supplemental spinal fixation systems that have been cleared for use in the lumbosacral spine.

### Outside U.S.A and Canada Indications for Use:

The Tritanium PL cage is an intervertebral body fusion device indicated for the treatment of spondylolisthesis, degenerative spine disorders and discal and vertebral instability, and may also be used in cases of spine revision surgery. Packing bone graft material within the implant is recommended. The Tritanium PL cage is to be implanted via a posterior approach. The Tritanium PL cage is intended for use with supplemental fixation.

A surgeon must always rely on his or her own professional clinical judgment when deciding whether to use a particular product when treating a particular patient. Stryker does not dispense medical advice and recommends that surgeons be trained in the use of any particular product before using it in surgery.

The information presented is intended to demonstrate the breadth of Stryker product offerings. A surgeon must always refer to the package insert, product label and/or instructions for use before using any Stryker product. Products may not be available in all markets because product availability is subject to the regulatory and/or medical practices in individual markets. Please contact your Stryker representative if you have questions about the availability of Stryker products in your area.

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