

Camber Spine Announces FDA Clearance Of Spira™-C Open Matrix Cervical Interbody

WAYNE, Pa., Dec. 7, 2017 /PRNewswire/ --



Camber Spine announced today that it has received 510(k) clearance from the U.S. Food and Drug Administration (FDA) to market its SPIRA™-C Open Matrix Cervical Interbody device, an innovative interbody fusion implant, second in the SPIRA™ family to employ a novel arched design as well as Surface by Design™ technology. This clearance marks Camber's second implant clearance in the SPIRA™ family of implant systems to be released in the U.S. market.

The SPIRA™ family of interbody implants represents the next generation of open architecture; 3-D printed, titanium implants designed to enhance fusion. The combination of smart science and smart surfaces merged with SPIRA™ Arch Technology creates an optimal environment for cell proliferation and bone growth. According to Daniel Pontecorvo, CEO at Camber Spine, "The engineers and designing surgeons leveraged the latest in 3-D printing technology to incorporate the needs at each step of the fusion process with the SPIRA™ family. To enable immediate stability, significant friction was achieved with the unique surface design. For short-term stability, other features were added to the surface design. This includes both a roughened titanium surface designed to promote bone cell proliferation, and a pore size optimized for bone ingrowth. In a way, robust ingrowth achieves a "mechanical fusion", where we expect patients to feel better quicker. Lastly, long-term stability is achieved with the ultimate endplate-to-endplate fusion. The newly forming bone follows the multiple arches incorporated with the Surface By Design™ to encourage ongrowth and ingrowth throughout the cage. Also, using a key bone-growth principal called "Wolff's Law", the arched design structure enables the distribution of load and strain, helping to enhance the fusion. We are very excited about this great implant design."

The SPIRA™ Open Matrix ALIF implant, the first product released in the SPIRA™ family, also with an open architecture and arched design, was launched only three months ago, and has already been received with great surgeon enthusiasm for the treatment of their patients. Together, with the ENZA™ ALIF implant providing simple and stable, zero-profile integrated fixation, Camber Spine is poised to be a leader in the interbody implant arena.

The Camber Spine SPIRA™-C Open Matrix Cervical Interbody device is indicated for use at one or two contiguous levels in the cervical spine, from C3-C7, in skeletally mature patients who have had six weeks of non-operative treatment for the degenerative disk disease (DDD) with up to Grade 1 spondylolisthesis. DDD is defined as neck pain of discogenic origin with the degeneration of the disc confirmed by history and radiographic studies. The Camber Spine Technologies SPIRA-C™ Open Matrix Cervical Interbody is intended to be used with additional FDA-cleared supplemental fixation systems.

About Camber Spine

Camber Spine Technologies, LLP, is a fast-growing musculoskeletal implant company founded in 2010 bringing innovative, best-in-class products to the market, providing surgeons and their patients with better treatment options. The company is committed to delivering surgeon inspired new technologies to the spine market. Camber is an ISO 13485 certified medical device company. Camber Spine Technologies, located in Wayne, Pennsylvania, markets a line of proprietary musculoskeletal products nationwide through its exclusive distributor, S1 Spine. For further information please visit www.cambermedtech.com. For inquiries about SPIRA™-C or distribution opportunities please call 484.427.7060.

All of Camber Spine Technologies' products are proudly *MADE IN THE USA*.

SOURCE Camber Spine Technologies

[Online Version](#)