Camber Spine
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Press Release

Camber Spine Receives FDA Clearance for SPIRA®-P and SPIRA®-T Technologies

August 03, 2021 03:14 PM Eastern Daylight Time

KING OF PRUSSIA, Pa.--(BUSINESS WIRE)--Camber Spine, a leading innovator in spine and medical technologies, announced today that it has received U.S. Food and Drug Administration (FDA) 510(k) clearance for both its SPIRA-P Posterior Lumbar Spacer technology and SPIRA-T Oblique Posterior Lumbar Spacer technologies.

"The FDA's approval of SPIRA-P and SPIRA-T not only marks a major step in our company's development."

Part of the SPIRA® product platform, the SPIRA-P Posterior Lumbar Spacer can be utilized to accommodate PLIF or TLIF procedures and features a patented open architecture design for optimal endplate load distribution. Plus, its uniquely designed surface allows for cell adhesion and bone cell proliferation while its interconnected porosity design mimics bone.

The SPIRA-T Oblique Posterior Lumbar Spacer features the same qualities but is designed specifically to accommodate traditional or "insert and rotate" TLIF procedures. Uniquely, its shape is angled for a 25° oblique insertion technique to optimize lordosis.

The FDA's action means that both of these lumbar interbody fusion devices are now indicated for use in skeletally mature patients with Degenerative Disc Disease (DDD) at one or two contiguous levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies.

"The FDA's approval of SPIRA-P and SPIRA-T not only marks a major step in our company's development," said Camber Co-Founder and CEO, Daniel Pontecorvo, "it also helps bring more innovation-based solutions and options to the surgical community. SPIRA technology provides structural stability following discectomy. SPIRA Posterior Lumbar Spacers have different shapes and designs to accommodate a broader array of posterior and transforaminal approaches and techniques. These new products are also significant in that they are our first SPIRA implants available for the TLIF market – the number one interbody market in the US today. To further expand upon this, we look forward to launching an articulating, arched TLIF SPIRA cage product in early 2022."

SPIRA implants are 3D printed. This specialized manufacturing technology allows Camber to create unique patented structures featuring open arched matrices and proprietary surfaces designed to enhance fusion and promote bone growth.

As with all products within Camber's SPIRA technology platform, SPIRA-P and SPIRA-T include strategically placed and optimal sized openings for graft packing. It also decreases the risk of subsidence due to the design's "snowshoe effect" and provides good visibility for fusion.

All of Camber Spine's products are developed and manufactured in the United States.

Innovative spine and medical technology company Camber Spine Technologies is dedicated to creating surgeon-designed solutions in MIS and minimally disruptive access for the treatment of complex spinal pathology. Incorporating state-of-the-art manufacturing, 3-D printing, and an acute sensitivity to patient anatomy, Camber Spine is making quantum leaps in the spinal fusion market. Learn more at CamberMedtech.com.

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