Camber Spine
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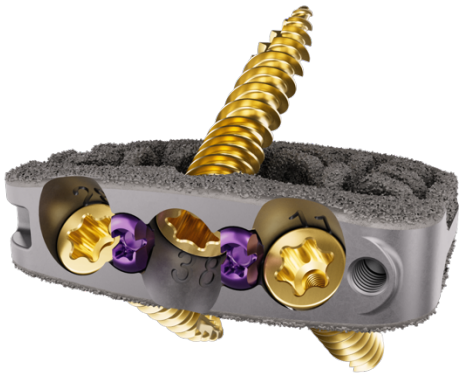
Press Release

Camber Spine Receives FDA Clearance for SPIRA®-A Integrated Fixation System



July 23, 2024

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 its SPIRA-A Integrated technology.

Part of the SPIRA product platform, the SPIRA-A Integrated Fixation System is an anterior lumbar interbody fusion device that has an open matrix design to permit packing with autogenous and/or allogenous graft material to facilitate fusion, as well as additional fixation options to secure the implant in the disc space.

“The FDA’s 510(k) clearance of our SPIRA-A Integrated technology ushers in the next evolution in our innovative SPIRA platform and marks another major step forward in our company’s development,” said Camber Spine CEO Brooks McAdam. “It also helps bring more innovation-based solutions and options to the surgical community and a solution for surgeons engaging or wanting to engage in the ALIF market. We believe SPIRA Technology, which encompasses the structure, surface, and science behind our 3D-printing process, is the archetypal design for modern spine implants and exemplifies the true benefits of additive manufacturing.”

SPIRA-A Integrated offers a complete solution to the ALIF procedure, with integrated fixation deployed in a traditional ALIF cage and approach, as well as a windswept cage geometry for accessing L5-S1 with difficult vascular anatomy, and each implant offers up to 40 points of endplate contact.

The superior and inferior surfaces of the SPIRA-A Integrated device have a rough surface to help prevent movement of the device while fusion takes place, and structural arches to help distribute load across the joint space. The device contains three holes to insert

bone screws or anchors for integrated fixation, as well as blocking screws to prevent fixation back-out.

SPIRA-A's screws and anchors have been designed to complement the performance of the cage, increase fixation in the cortical endplate, and provide first-of-their-kind 3D-printed anchors with a SPIRA Surface, designed to increase potential for osseointegration and resist pull-out.

The robust inserter attachment, multiple technique possibilities, and a wide variety of screw prep options are designed to facilitate clear visualization of, and easy access to, the surgical site once the approach is complete.

The FDA's action means that SPIRA-A Integrated is now indicated for use at one or more levels, from L1-S1 as an adjunct to fusion in skeletally mature patients with degenerative disc disease (DDD), disc herniation (with myelopathy and/or radiculopathy) spondylolisthesis, deformity (degenerative scoliosis or kyphosis), spinal stenosis and failed previous fusion (pseudarthrosis).

Camber's 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.

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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