

FDA Approves Expanded 510k Classification for Titan Spine's ENDOSKELETON® TA Anterior Interbody Fusion Device

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MEQUON, Wis.--(BUSINESS WIRE)--The US Food and Drug Administration (FDA) has expanded Titan Spine's ENDOSKELETON® TA Vertebral Body Replacement Device (VBR) 510k to include an Interbody Fusion Device indication.

Under its expanded 510K indication, the ENDOSKELETON® TA Interbody Fusion Device is approved for use in skeletally mature patients with Degenerative Disc Disease (DDD) at one or two contiguous levels from L2-S1. Degenerative Disc Disease is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). Patients should have received six months of non-operative treatment prior to treatment with the devices. The device may be used with supplemental fixation.

While degenerative disc disease is most often treated by more conservative therapies, the condition can often lead to more severe disorders, such as lumbar spinal stenosis (narrowing of the spinal canal) or spondylolistheses (disc slips forward).

"This is an important step for Titan Spine as it gives the surgeon the ability to utilize the ENDOSKELETON® TA as an Interbody Device while taking off the VBR label, as well as the ability to feel comfortable knowing that they now have the option to use the device in a stand-alone setting," said Steve Cichy, Vice President of Sales of Titan Spine.

Titan Spine expects that this new product indication will increase product adoption among a group of surgeons that are focused both on technique proficiency and positive, predictable outcomes for their patients. Kevin Gemas, President of Titan Spine, underscored the importance of the expanded classification by adding "with an estimated 65 million people in the US with some type of degenerative disc condition, the ENDOSKELETON® TA continues to be accepted and better positioned to positively impact an even larger percentage of the patient population." Gemas went on to add "this is an exciting time for Titan Spine, as we take another step forward with our bioactive interbody-focused product portfolio."

The ENDOSKELETON® TA is a unique Titanium cage that sits on the strongest portion of the lumbar endplate, yielding excellent resistance to subsidence and expulsion. Coupled with a large open area for bone graft, the device's acid-etched Titanium surface serves to provide a strong press fit and boney ingrowth.

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