

Architecturally Advancing Fusion in Lateral Surgery*

Advanced Surface Technologies. The need to improve postoperative patient outcomes after interbody fusion procedures has pushed the scientific community to develop additively manufactured (AM) architectures that play a more active role in the bone-healing process. Advancements in AM using titanium, a material shown to elicit direct bony apposition, have allowed for the creation of macro and micro surface architectures previously unascertainable with subtractive manufacturing. The 3D-printed wave-like structure that makes up WaveForm® Lateral (L) interbodies is only possible through AM, and it has been deliberately designed to modulate surface topography, structural stiffness, and macro architecture to meet the needs of an evolving surgeon community.



WaveForm's repeating wave-like structure unit cell.

Design Rationale. WaveForm L 3D-printed interbodies are thoughtfully designed with clinical needs of the end user in mind, prioritizing strength, surface, and stability. Made from a proprietary repeating wave-like structure, WaveForm L is made to withstand the highest compressive loads for a given porosity.¹ WaveForm L interbodies balance the desire to increase surface area and space for bone packing, decrease stiffness, and enhance imaging characteristics, all without compromising strength. Additionally, WaveForm L features an endplate and body architecture designed to partner with SeaSpine's best-in-class orthobiologics portfolio. When coupled with OsteoStrand™ or OsteoStrand™ Plus, an osteoinductive environment is created within the WaveForm interbody, where graft can flow from the inside out, filling all voids, and ultimately remain contained within the WaveForm structure.

Technology Overview. WaveForm's repeating wave-like structure has the highest strength-to-porosity ratio compared to other 3D-printed structures,¹ allowing WaveForm L to incorporate the following features:

- 80% body porosity to decrease interbody stiffness and improve imaging characteristics†
- Continuous channels for easy graft packing and retention, up to 15 cc
- A self-supporting sheet-based design to create the greatest internal surface area for bone to grow along and maximize endplate surface area¹



Additionally, WaveForm L interbodies incorporate 50 µm microtopography throughout to create a roughend surface for bone to grow onto† and 65% endplate porosity to facilitate early stability.²

Fusion Engineered® Deliberate Design. Driven by Science. WaveForm L is another example of SeaSpine's **Fusion Engineered** design philosophy, which is founded on three pillars: Complementary Technologies, Procedural Versatility, and Scientifically Driven. These pillars allow SeaSpine to provide a comprehensive portfolio of innovative, procedurally focused products strategically designed to work together to drive fusion. The latest advancements in bone biology and materials science guide the development of in-house manufactured advanced orthobiologics and proprietary spinal interbody technology engineered to address the many nuances of spinal pathology. SeaSpine products can be tailored to meet individual patient needs, delivering both clinical and economic value to patients, surgeons, and hospital systems.

Indications for use: The SeaSpine Waveform L System is indicated for use as an adjunct to fusion in skeletally mature patients with degenerative disc disease (DDD, defined as back pain of discogenic origin, with degeneration of the disc confirmed by history and radiographic studies). It is intended for use at either one level or two contiguous levels in the lumbar spine, from L1 to S1, for the treatment of DDD with up to Grade 1 spondylolisthesis at the involved level(s). The interior of the interbody spacer component may be packed with autogenous bone graft and/or allogeneic bone graft material composed of cortical, cancellous, and/or corticocancellous bone. Patients must have undergone a regimen of at least 6 months of nonoperative treatment prior to being treated with the device.

The SeaSpine Waveform L System is intended for use as an adjunct to fusion in the thoracolumbar spine from T1 to T12 and at the thoracolumbar junction (T12-L1), for the treatment of symptomatic disc degeneration (DDD) or degenerative spondylolisthesis at one or two adjacent levels, including thoracic disc herniation (with myelopathy and/or radiculopathy with or without axial pain). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The SeaSpine Waveform L System can also be used as an adjunct to fusion in patients diagnosed with multilevel degenerative scoliosis. The SeaSpine WaveForm L System is intended for use with supplemental Fixation.

*Pending 510(k) approval
†Data on file

¹Al-Ketan O, Rowshan R, Abu Al-Rub RK. Topology-mechanical property relationship of 3D printed strut, skeletal, and sheet based periodic metallic cellular materials. *Addit Manuf.* 2018;19:167–183.
²Kelly CN, et al. High-strength, porous additively manufactured implants with optimized mechanical osseointegration. *Acta Biomater.* 2021;279.