

SPECIFICATIONS

SYSTEM IMPLANT CONFIGURATIONS

Lengths	25mm and 29mm
Insertion Profiles (HxW)	7x9mm and 9x9mm
Maximum Expanded Profiles (HxW)	12x14mm and 14x14mm
Lordosis options	0°, 6°, 9°, and 15°
0° Heights (in 1mm increments)	8 to 14mm
6° Heights (in 1mm increments)	10 to 14mm
9° Heights (in 1mm increments)	11 to 14mm
15° Heights (in 1mm increments)	12 to 14mm

SYSTEM FEATURES

Minimal Insertion Profile	✓
Multi-Directional Expansion	✓
Post-Packing Ability	✓
Endplate Conforming	✓

INDICATIONS FOR USE/INTENDED USE

The FlareHawk Interbody Fusion System is indicated for spinal intervertebral body fusion with autogenous bone graft and/or allogeneic bone graft composed of cancellous and/or corticocancellous bone in skeletally mature individuals with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1, following discectomy. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should have at least six (6) months of non-operative treatment. Additionally, these patients may have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). FlareHawk system spacers are intended to be used with supplemental fixation instrumentation, which has been cleared for use in the lumbar spine.

Refer to the FlareHawk Interbody Fusion System IFU for full prescribing information.

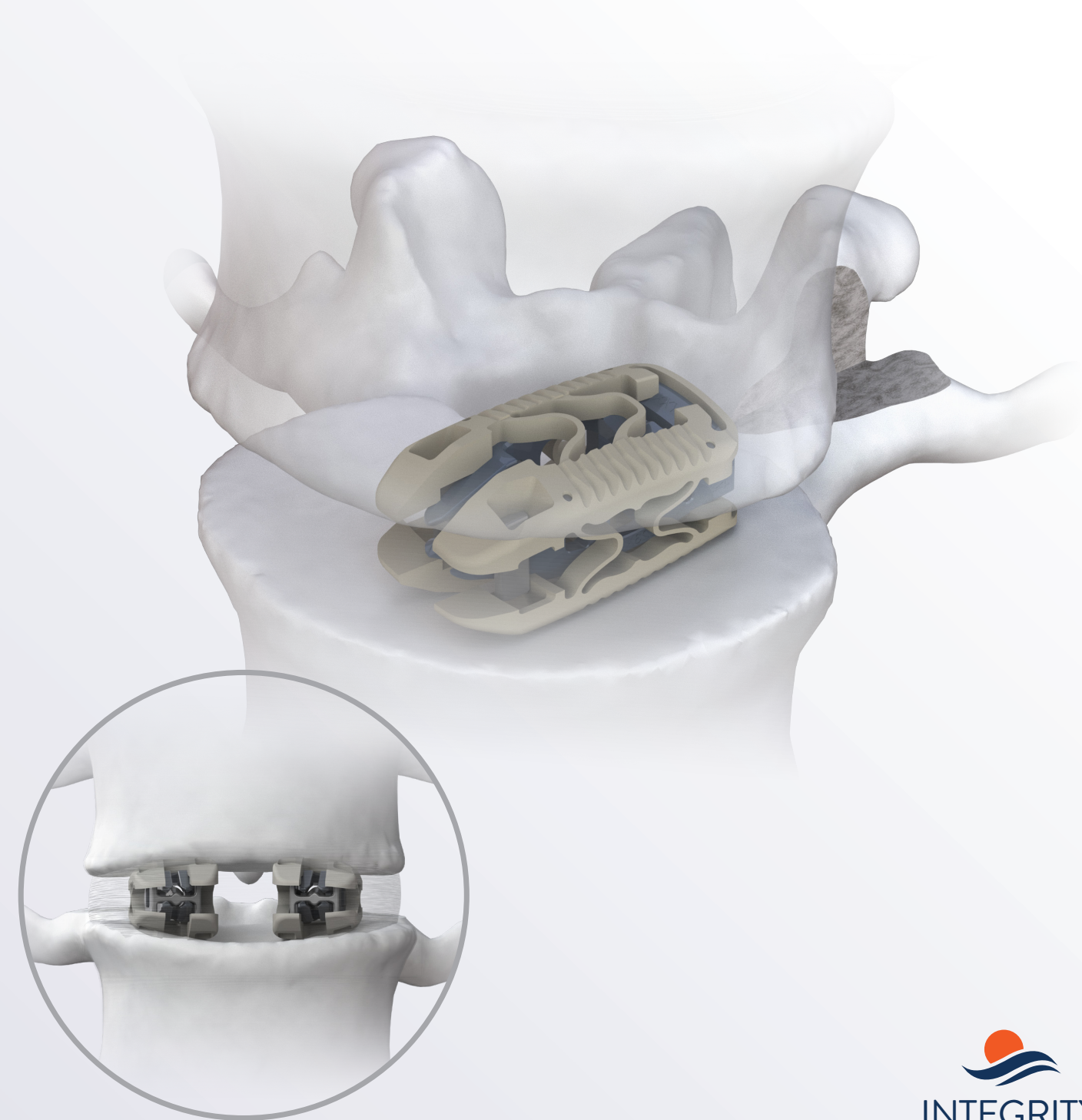
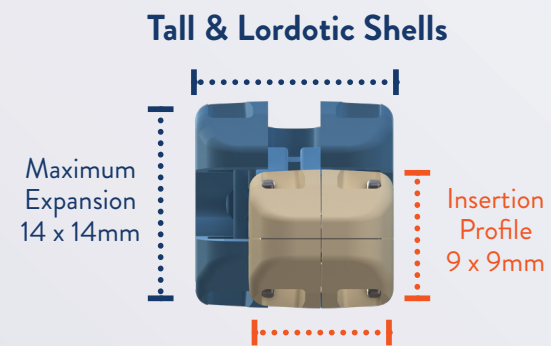
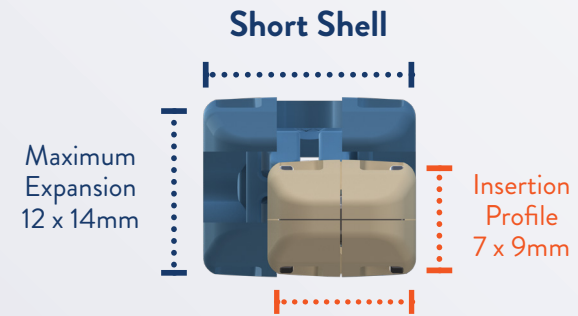
1 Cheng BC, Swink I, Yusufbekov R, Birgelen M, Ferrara L, Coric D. Current Concepts of Contemporary Expandable Lumbar Interbody Fusion Cage Designs, Part 2: Feasibility Assessment of an Endplate Conforming Bidirectional Expandable Interbody Cage. *Int J Spine Surg.* 2020 Dec;14(s3):S68-S74. doi: 10.14444/7129. Epub 2020 Oct 29. PMID: 33122178; PMCID: PMC7735472.

2 Warburton, A., Girdler, S. J., Mikhail, C. M., Ahn, A., & Cho, S. K. (2020). Biomaterials in Spinal Implants: A Review. *Neurospine*, 17(1), 101–110. <https://doi.org/10.14245/ns.1938296.148>.

3 Ong, Y. (2015). New biomaterials for orthopedic implants. *Orthopedic Research and Reviews*, 7, 107–129. <https://doi.org/10.2147/ORR.S63437>.



MINIMAL INSERTION PROFILE | MULTIDIRECTIONAL EXPANSION | SUBSTANTIAL GRAFT DELIVERY | ENDPLATE CONFORMITY

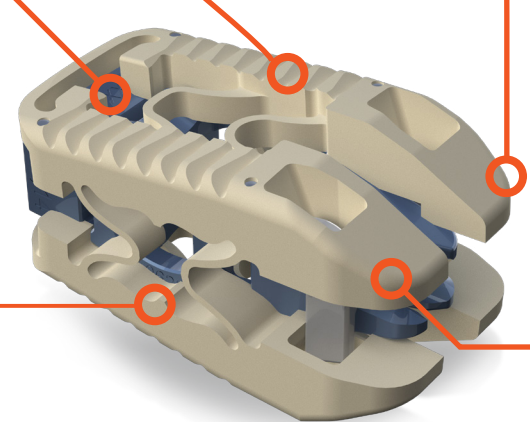
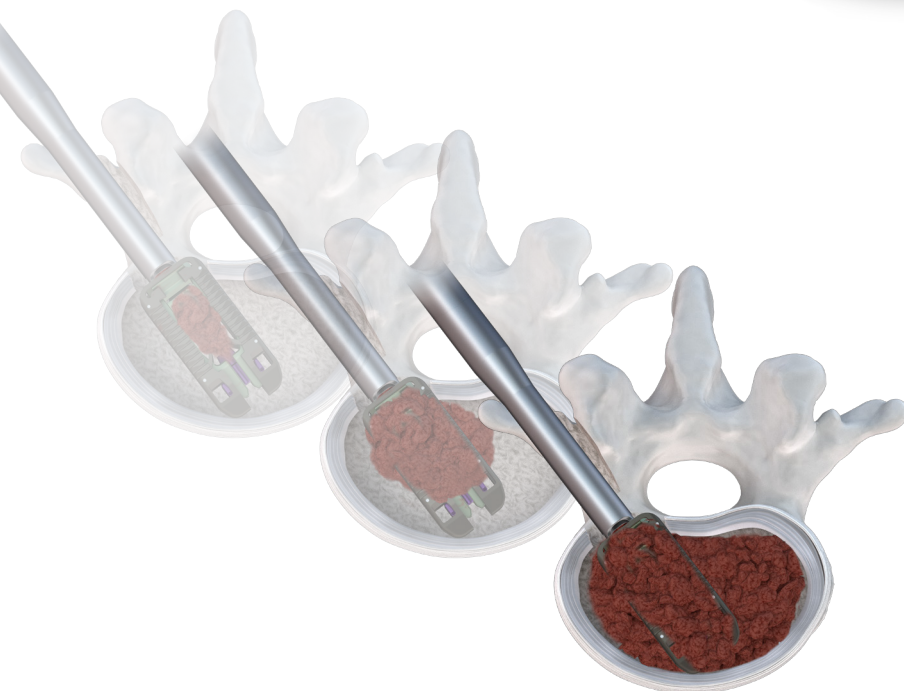


FLAREHAWK9 TECHNOLOGY

Multidirectional expandable lumbar fusion device that can be inserted at a low profile of 7mm or 9mm tall by 9mm wide before expanding up to 12mm or 14mm tall (respectively) and to 14mm wide.

IMPLANT DESIGN FEATURES

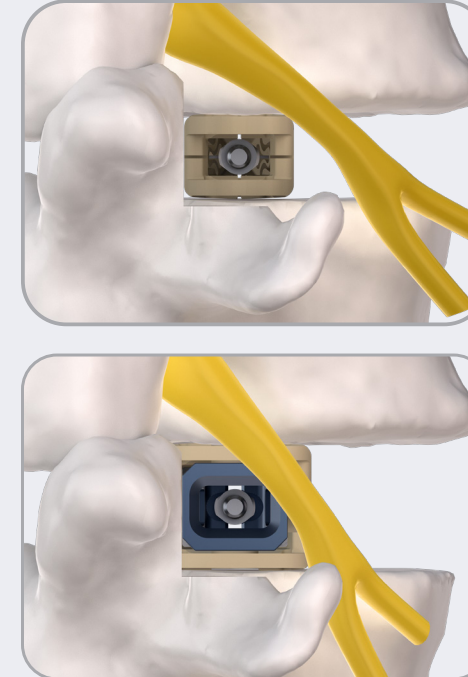
- Titanium shim allows stability and height restoration
- PEEK has been found to be appealing in orthopedic applications due to its stiffness properties comparable to bone, inertness, and biocompatibility.^{2,3}
- Open architecture allows for continuous graft delivery through the implant and out into the disc space for substantial graft delivery
- FlareHawk technology delivers an increase in width, height, and lordosis
- Tapered nose facilitates insertion

SUBSTANTIAL GRAFT DELIVERY

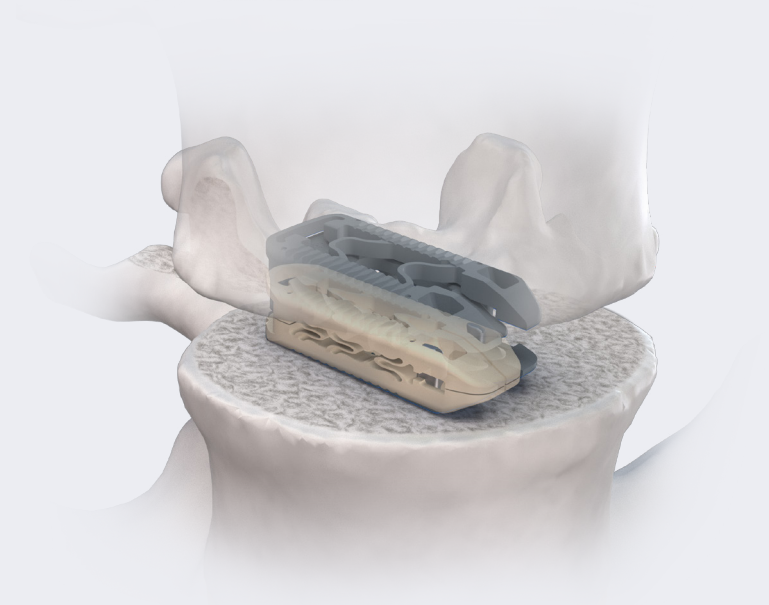
- Open architecture allows for continuous graft delivery through the implant and into the disc space
- Graft volume is only restricted by the volume of disc removed

MINIMAL INSERTION PROFILE



MULTIDIRECTIONAL EXPANSION

- Expansion in width, height, and lordosis



UP TO 71% HEIGHT INCREASE
56% WIDTH INCREASE

ENDPLATE CONFORMITY¹

- The open-architecture of the cages has shown the ability to conform to individual patients' endplate topography

