

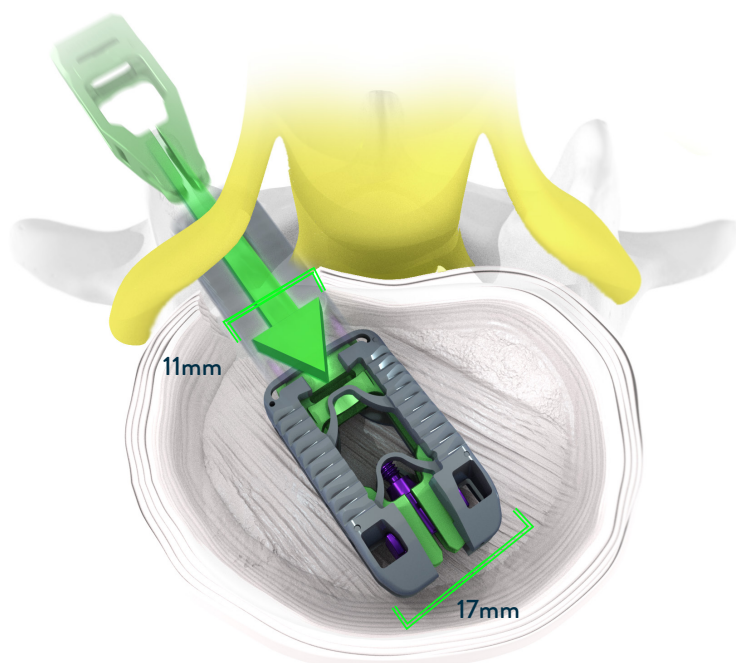
**FLAREHAWK® INTERBODY
FUSION SYSTEM**

Multiplanar Expansion | Minimal Insertion Profile | Maximum Graft Delivery | Titanium Surface

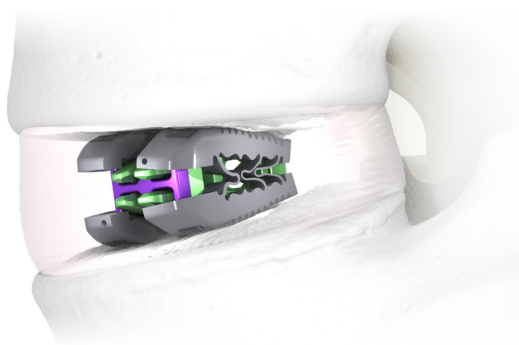
FOOTPRINT WITHOUT COMPROMISE



17mm wide TiHawk11 implant provides **70% more footprint** than a 10mm wide PLIF/TLIF cage.



TiHawk11 pictured with 55% width expansion.



Sagittal Conformity
(TiHawk11 pictured)

TiHawk utilizes Adaptive Geometry™ to expand simultaneously in width, height, and lordosis after traversing the neural corridor with a small profile.

Once expanded, the conformable footprint is designed to reduce subsidence, restore foraminal height, and re-establish sagittal balance.

MINIMAL NEURAL RETRACTION

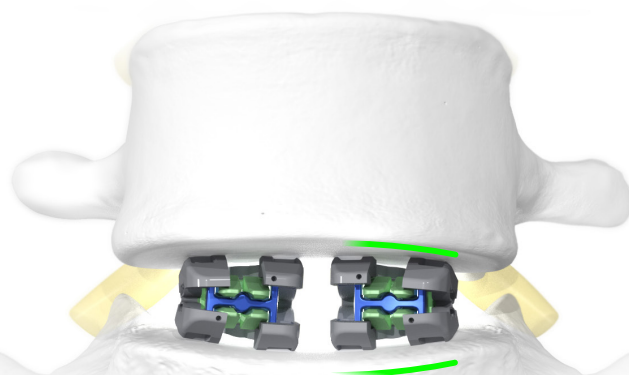
- Insertion profile as small as 7x9mm is designed to minimize neural retraction that could lead to nerve root injury.
- Multiple insertion profile options to help accommodate patient and level-specific neural corridors.

EXPANSIVE FOOTPRINT

- TiHawk9 expands from 9mm to 14mm wide. TiHawk11 expands from 11mm to 17mm wide.
- A single TiHawk11 cage provides 70% more footprint than a 10mm wide cage of equivalent length.
- TiHawk11 enables the delivery of a 34mm wide footprint from a single-position PLIF approach.

ENDPLATE CONFORMITY

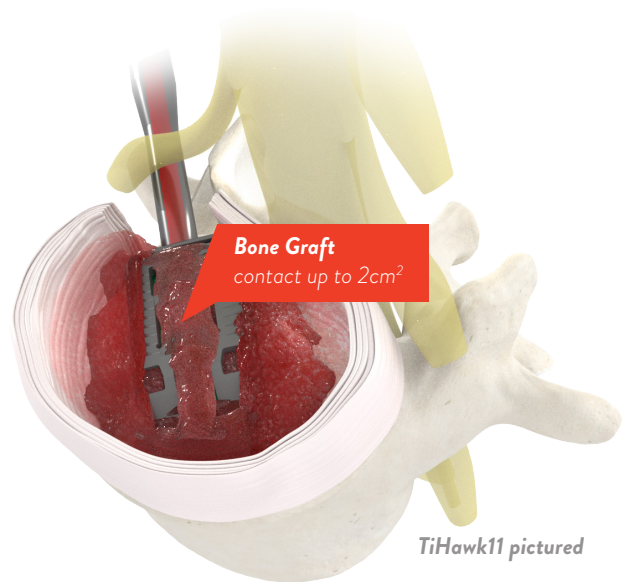
- The multi-material construct of the cage conforms to each patient's endplate topography when expanded.
- Naturally occurring deformation of a multi-material bidirectional cage may increase the bone-implant interface's surface area and better distribute the load across the endplate.



Coronal Conformity
(TiHawk11 pictured)

MAXIMUM GRAFT DELIVERY

- Open architecture allows for continuous graft delivery through the implant and into the disc space.
- Up to 2cm² of bone-graft-to-endplate contact area through the open architecture of the implant.



TiHawk11 pictured

FlareHawk9 Retrospective Data

Bidirectional Expandable Technology for Transforaminal or Posterior Lumbar Interbody Fusion: A Retrospective Analysis of Safety and Performance

Domagoj Coric, Raphael R. Roybal, Mark Grubb, Vincent Rossi, Alex K. Yu, Isaac R. Swink, Jason Long, Boyle C. Cheng and Jason A. Inzana in International Journal of Spine Surgery October 2020, 7123; DOI: <https://doi.org/10.14444/7123>

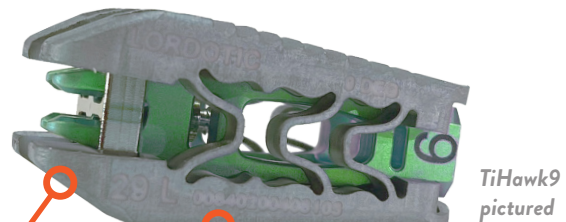
STUDY DESIGN

129	PATIENTS
3	STUDY SITES
100%	SURGERIES UTILIZING AUTOGRAFT, ALLOGRAFT (NO BMP USED)
88%	SURGERIES UTILIZING MINIMALLY INVASIVE APPROACH

RESULTS

97.4%	OF LEVELS ACHIEVED FUSION
	BASED ON BRIDWELL-LENKE GRADING
0	REPORTED DEVICE-RELATED ADVERSE EVENTS
	<ul style="list-style-type: none"> 0% NERVE INJURIES REPORTED 0% SUBSIDENCE* 0% END-PLATE FRACTURE REPORTED 1 CASE DEVICE MIGRATION**

*Cage subsidence defined as an overlap between the vertebral endplates and the device exceeding 25% of the device height. **Device migration was defined as displacement of the device relative to the position within intra-operative or immediate post-operative images.



TiHawk9 pictured

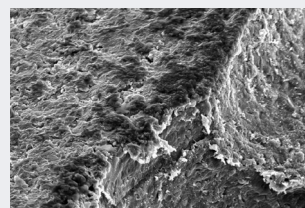
TITANIUM SURFACE TECHNOLOGY



a) Uninhibited radiographic visualization of TiHawk9



b) 0.5-micron-thick titanium layer



c) Pre-roughened PEEK increases surface area

Titanium intermixed with PEEK at the interface to help reduce risk of delamination.

Image of TiHawk surface coating on roughened PEEK at 20x (b) and 200x (c).

SPECIFICATIONS

SYSTEM IMPLANT CONFIGURATIONS	TIHAWK9
Lengths	25mm 29mm
Insertion Profiles (HxW)	7x9mm 9x9mm
Maximum Expanded Profiles (HxW)	12x14mm 14x14mm
Lordosis Options	0°, 6°, 9°, 15°
0° Heights	8 to 14mm
6° Heights	10 to 14mm
9° Heights	11 to 14mm
15° Heights	12 to 14mm



Short Shell

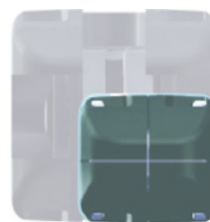
Insertion Profile
7 x 9mm



Maximum Expansion
12 x 14mm

Tall Shell

Insertion Profile
9 x 9mm



Maximum Expansion
14 x 14mm

SYSTEM IMPLANT CONFIGURATIONS	TIHAWK11
Lengths	23mm 25mm 29mm
Insertion Profiles (HxW)	7mm x 11mm 9mm x 11mm
Maximum Expanded Profiles (HxW)	12x17mm 14x17mm
Lordosis Options	0°, 6°, 9°, 15°
0° Heights	7 to 14mm
6° Heights	10 to 14mm
9° Heights	10 to 14mm
15° Heights	12 to 14mm



Short Shell

Insertion Profile
7 x 11mm



Maximum Expansion
12 x 17mm

Tall Shell

Insertion Profile
9 x 11mm



Maximum Expansion
14 x 17 mm

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 B idirectional 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.

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.