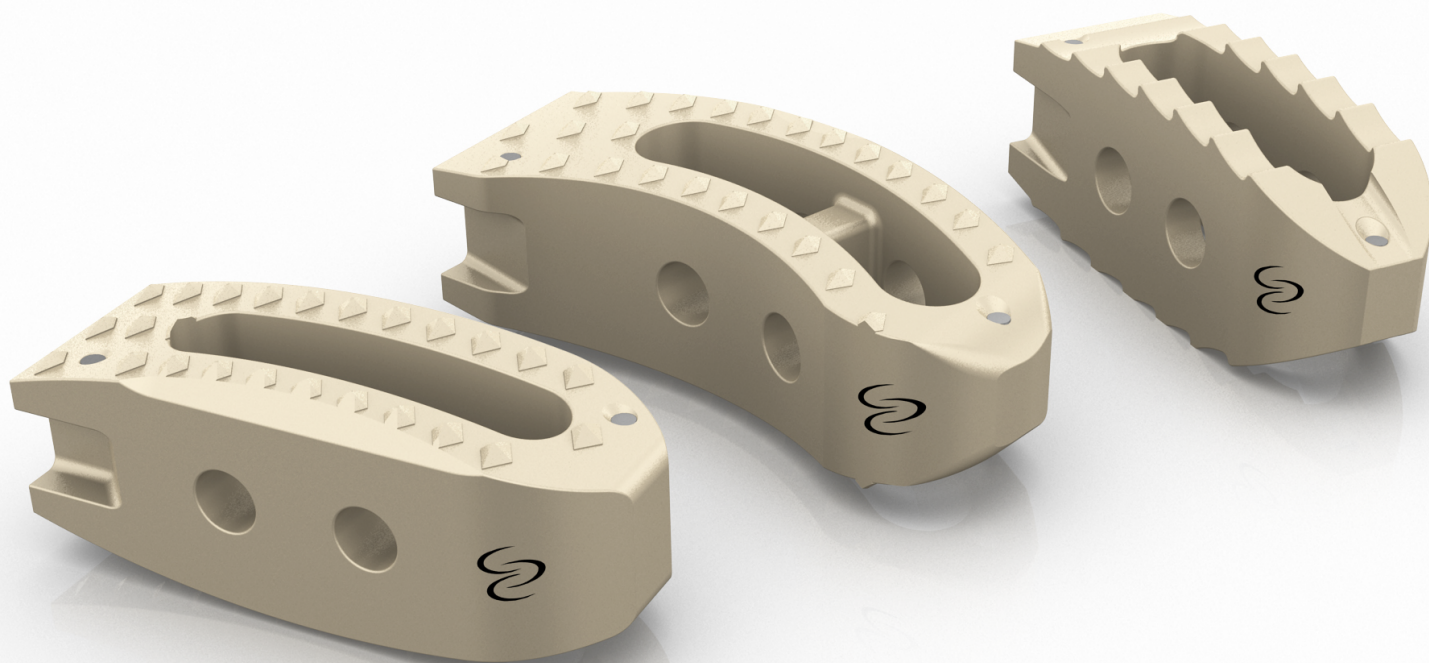




CEES[®]

CUTTING EDGE SPINE



EVO S HA

The First PEEK-OPTIMA[®] HA Enhanced Lumbar Interbodies in the US

HYDROXYAPATITE IMPREGNATED PEEK-OPTIMA Natural

PEEK-OPTIMA® HA ENHANCED

TWO PROVEN BIOMATERIALS. ONE SUPERIOR COMBINATION.

Invibio Biomaterial Solutions' PEEK-OPTIMA® HA Enhanced is a material enhancement in spinal device technology. Hydroxyapatite (HA), a well-known osteo-conductive material, is fully integrated with PEEK-OPTIMA Natural. This innovative compound encourages bone-on growth while providing the strength, versatility, and performance advantages of its proven and popular predecessor. PEEK-OPTIMA HA Enhanced offers a truly superior solution for bone apposition.

Cervical Fusion Study¹ in Sheep compared outcomes between implants composed of PEEK-OPTIMA HA Enhanced, PEEK-OPTIMA Natural and allograft bone. Results indicate that PEEK-OPTIMA HA Enhanced may provide advantages.

Superior Mechanical Performance

PEEK-OPTIMA HA Enhanced devices outperformed allograft, with fracture of allograft devices in 6/13 (46%) instances.¹

Despite the ability of the allograft spacers to support direct bone-implant contact, fracture of the implants was frequently observed, even at early points.

Superior New Bone Formation

PEEK-OPTIMA HA Enhanced resulted in greater new bone formation at 6 weeks compared with PEEK-OPTIMA Natural.¹

New bone formation at an early time point with PEEK-OPTIMA HA Enhanced (based on uCT grading.)

■ 4 weeks ■ 12 weeks ■ 26 weeks

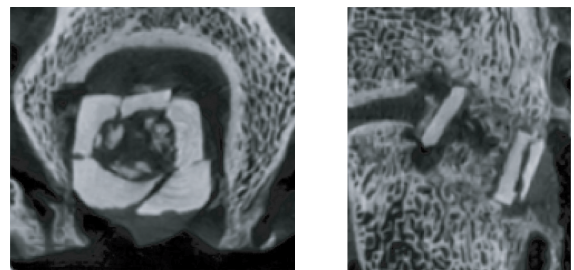
Superior Graft Quality

PEEK-OPTIMA HA Enhanced devices provided a more favorable environment, with higher quality local bone at 6 and 12 weeks compared with PEEK-OPTIMA Natural.¹

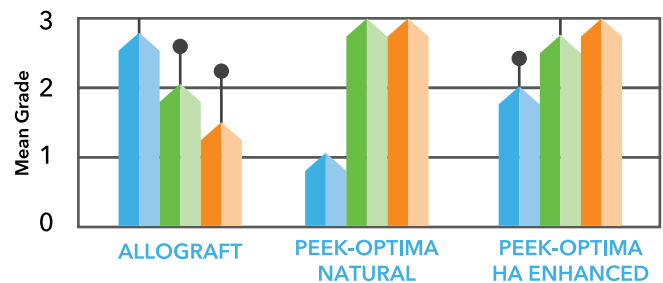
PEEK-OPTIMA HA Enhanced provides a more favorable environment for new bone formation (based on uCT grading.)

■ 6 weeks ■ 12 weeks ■ 26 weeks

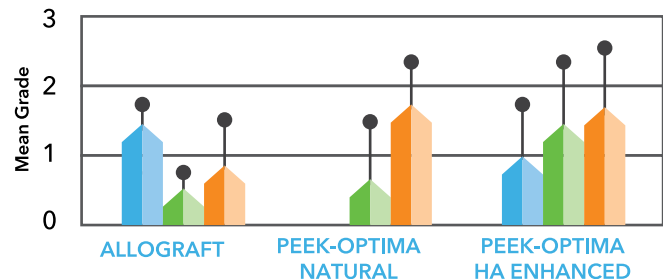
MICRO CT ANALYSIS ²



NEW BONE FORMATION ²



QUALITY OF NEW BONE BRIDGING ²



Invibio
BIOMATERIAL SOLUTIONS

REFERENCES

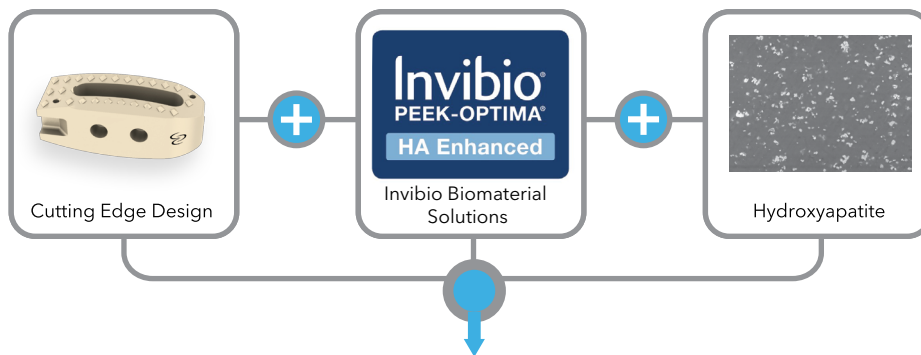
1. Study evaluated the in vivo response to PEEK-OPTIMA Natural, PEEK-OPTIMA HA Enhanced and allograft in a cervical spine fusion model in sheep. Data on file at Invibio. This has not been correlated with human clinical experience.
2. Study did not use Cutting Edge Spine products.

PEEK-OPTIMA HA Enhanced images provided courtesy of Invibio Biomaterial Solutions. All rights are reserved.
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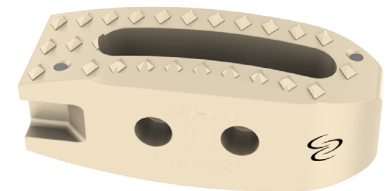
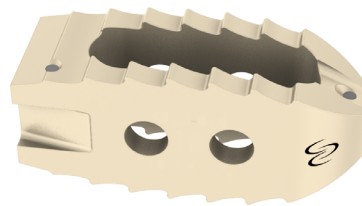
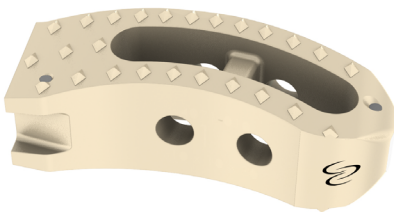
A GAME CHANGER

HA INTEGRATED INTO PEEK-OPTIMA® Natural



EVOS^{HA}

1,857 FOOTPRINTS



CURVED

- ▶ Chamfered leading edge
- ▶ Biconvex or flat endplates
- ▶ 0 or 6 degrees lordosis

STRAIGHT

- ▶ 3 Nose styles
- ▶ Multiple sizes & forms, including true oblique lordotic design
- ▶ Unilateral, bilateral, or oblique placement

ROTATE

- ▶ In situ distraction up to 4mm with ¼ turn
- ▶ Multiple sizes & forms, including true oblique lordotic design
- ▶ Unilateral, bilateral, or oblique placement

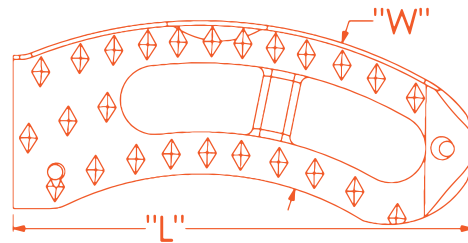
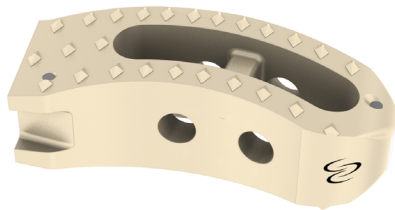
STERILE PACKAGING

Increased Safety & Traceability

All EVOS implants are single-use, barcoded, and pre-sterilized.



EVOS-HA CURVED



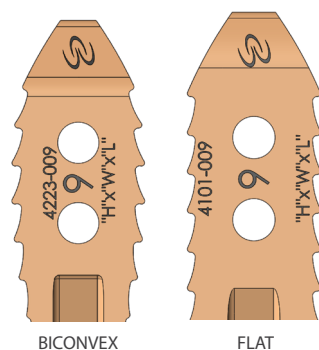
Specifications

- ▶ Biconvex & flat endplates (available in 0° & 6° lordosis)
- ▶ 26 & 30mm lengths
- ▶ 9, 10, & 11mm widths
- ▶ 6 to 16mm heights (1mm increments)

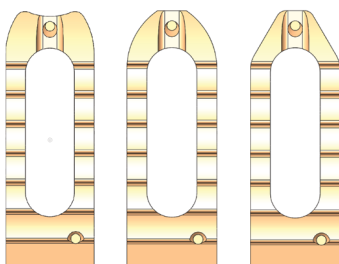
Curved Interbodies	Heights (mm)	Widths (mm)	Lengths (mm)
Flat endplates, 0°	6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16	9, 10, 11	26, 30
Biconvex endplates, 0°	8, 9, 10, 11, 12, 13, 14, 15, 16	9, 10, 11	26, 30
Flat endplates, 6°	7, 8, 9, 10, 11, 12, 13, 14, 15, 16	9, 10, 11	26, 30
Biconvex endplates, 6°	9, 10, 11, 12, 13, 14, 15, 16	9, 10, 11	26, 30

EVOS-HA STRAIGHT

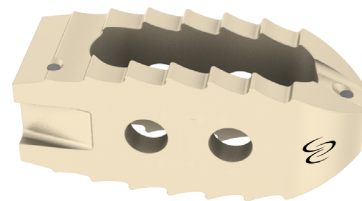
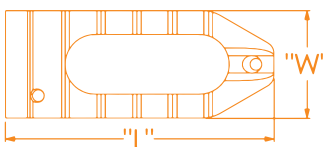
TWO ENDPLATE DESIGNS



THREE NOSE DESIGNS



WIDE STANDARD NARROW



Specifications

- ▶ Biconvex & Flat endplates (available in 0°, 5°, 13° & 17° lordosis)
- ▶ True Oblique Lordotic (TOL) design has accurate lordosis at 30° degrees oblique placement
- ▶ 22, 26, & 30mm lengths
- ▶ 8, 9, 10, & 11mm widths
- ▶ 6 to 16mm heights (1mm increments)
- ▶ Posterior (PLIF) or Transforaminal (TLIF) approach

Straight Interbodies	Nose Styles	Heights (mm)	Widths (mm)	Lengths (mm)
Flat endplates, 0°	Standard, Wide, Narrow	6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16	8, 9, 10, 11	22, 26, 30
Biconvex endplates, 0°		8, 9, 10, 11, 12, 13, 14, 15, 16	8, 9, 10, 11	22, 26, 30
Flat endplates, 5°		7, 8, 9, 10, 11, 12, 13, 14, 15, 16	8, 9, 10, 11	22
Flat endplates, 13°		8, 9, 10, 11, 12, 13, 14, 15, 16	8, 9, 10, 11	26, 30
Flat endplates, 13°		10, 11, 12, 13, 14, 15, 16	9, 10	22, 26
Flat endplates, 13°		11, 12, 13, 14, 15, 16	9, 10	30
Flat endplates, 17°		11, 12, 13, 14, 15, 16	9, 10	22
Flat endplates, 17°		12, 13, 14, 15, 16	9, 10	26
Flat endplates, 17°		13, 14, 15, 16	9, 10	30
Flat endplates, 5° TOL*		8, 9, 10, 11, 12, 13, 14, 15, 16	8, 9, 10, 11	30

*True Oblique Lordotic

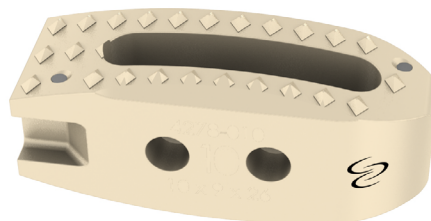
EVOS-HA ROTATE

SPECIFICATIONS

- ▶ Monolithic PEEK-OPTIMA® HA Enhanced interbody allows biologics to be packed prior to insertion
- ▶ Threaded connection to the T-handle implant inserter
- ▶ Chamfered edges on implant for easier ¼ clockwise rotation
- ▶ Unilateral, bilateral, or oblique placement
- ▶ Posterior (PLIF) or Transforaminal (TLIF) approach
- ▶ Biconvex & flat endplates (available in 0°, 5°, 8°, 13° & 17° lordosis)
- ▶ 9 to 16mm heights (1mm increments) provide 1 – 4mm in-situ distraction
- ▶ True Oblique Lordotic (TOL) design has accurate lordosis at 30° degrees oblique placement

Rotate Interbodies	Heights (mm)	Widths (mm)	Lengths (mm)	Rotate Interbodies	Heights (mm)	Widths (mm)	Lengths (mm)
Flat endplates, 5°	9, 10, 11	8	22, 26, 30	Biconvex endplates, 5°	10, 11	8	22
	10, 11, 12	9	22, 26, 30		11	8	26
	11, 12, 13	10	22, 26, 30		10, 11, 12	9	22
	12, 13, 14	11	22, 26, 30		11, 12	9	26
	13, 14, 15, 16	12	22, 26, 30		11, 12, 13	10	22, 26
Flat endplates, 8°	9, 10, 11	8	22, 26, 30	Biconvex endplates, 6°	13	10	30
	10, 11, 12	9	22, 26, 30		12, 13, 14	11	22, 26
	11, 12, 13	10	22, 26, 30		13, 14	11	30
	12, 13, 14	11	22, 26, 30		13, 14, 15, 16	12	22, 26, 30
	13, 14, 15, 16	12	22, 26, 30		13	10	22
Flat endplates, 13°	12, 13	10	26, 30	Biconvex endplates, 6°	12, 13, 14	11	22
	12, 13, 14	11	22, 26, 30		13, 14	11	26
	13, 14, 15, 16	12	22, 26, 30		14	11	30
Flat endplates, 17°	13	10	26		13, 14, 15, 16	12	22, 26
	12, 13, 14	11	22		14, 15, 16	12	30
	13, 14	11	26	Flat endplates, 5° TOL*	9, 10, 11	8	30
	14	11	30		10, 11, 12	9	30
	13, 14, 15, 16	12	22, 26		11, 12, 13	10	30
Biconvex endplates, 0°	14, 15, 16	12	30		12, 13, 14	11	30
	9, 10, 11	8	22, 26	Flat endplates, 8° TOL*	13, 14, 15, 16	12	30
	11	8	30		10, 11	8	30
	10, 11, 12	9	22, 26, 30		10, 11, 12	9	30
	11, 12, 13	10	22, 26, 30		11, 12, 13	10	30
	12, 13, 14	11	22, 26, 30		12, 13, 14	11	30
	13, 14, 15, 16	12	22, 26, 30		13, 14, 15, 16	12	30

*True Oblique Lordotic



STREAMLINED INSTRUMENTATION

INSTRUMENTS AT WORK FOR THE SURGEON



The EVOS-HA instruments are an all-encompassing intuitive system designed to make the surgical procedure simple and quick. Only one instrument set for the straight, curved, and rotate interbodies.



Streamlined tray configuration for reduced space requirements, easier portability and minimized autoclave burden.

KIT COMPOSITION *

Trial \ distractor	6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16 mm
Paddle shavers	6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16 mm
Straight and curved implant manipulator	
Mallet	
Slap hammer with adaptor	
Silicone T-Handle	
Bone funnel assembly	
Non-rotate & rotate inserters	
Inner inserter shaft	
EVOS instrument tray	

*Disc prep instruments in stock and available upon request



ABOUT CES



Founded in 2009, Cutting Edge Spine (CES) is a privately owned medical device organization, headquartered in Waxhaw, North Carolina, dedicated to developing and distributing new generation spinal technologies.



CES was built on the conviction that patients, payers and healthcare providers deserve more value from the technologies that they select.



CES is future ready, providing the market with highly differentiated implant systems that meet the clinical and economic demands of today's marketplace.



CES developed the EVOS-ha, the first PEEK-OPTIMA® HA Enhanced Lumbar Interbody system approved in the United States.



CES possesses a range of FDA cleared spinal technologies and a comprehensive R&D pipeline.



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