CES®

CUTTING EDGE SPINE

EVOSHA

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

HYDROXYAPATITE IMPREGNATED PEEK-OPTIMA Natural

LBL-10025 R.A

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 Study[1] 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

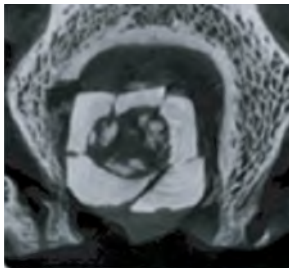
Superior Graft Quality

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]

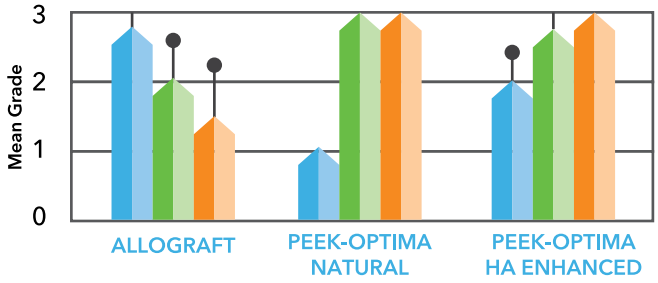
PEEK-OPTIMA HA Enhanced provides a more favorable environment for new bone formation (based on uCT grading.)

6 weeks 12 weeks 26 weeks

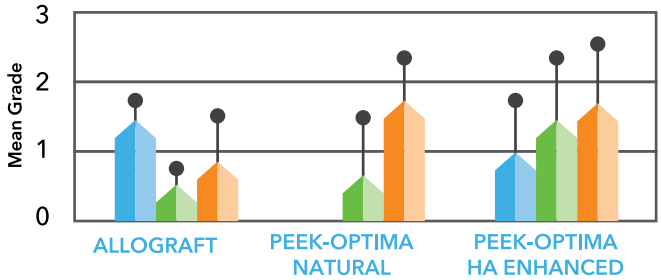
MICRO CT ANALYSIS [2]



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.

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A GAME CHANGER

HA INTEGRATED INTO PEEK-OPTIMA® Natural

1,857 FOOTPRINTS

CURVED	STRAIGHT	ROTATE
Chamfered leading edge	3 Nose styles	In situ distraction up to 4mm with ¼ turn
Biconvex or flat endplates	Multiple sizes & forms, including true oblique lordotic design	Multiple sizes & forms, including true oblique lordotic design
0 or 6 degrees lordosis	Unilateral, bilateral, or oblique placement	Unilateral, bilateral, or oblique placement

STERILE PACKAGING

Increased Safety & Traceability

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

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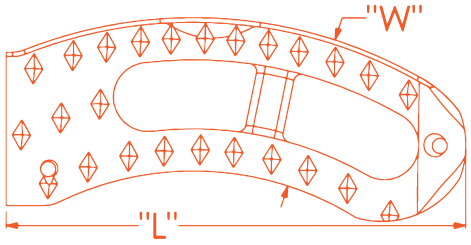
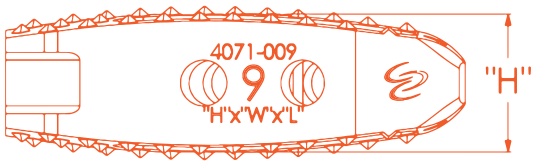
EVOS-HA CURVED





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

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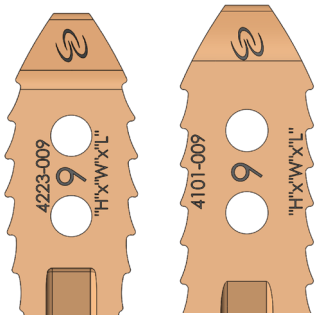
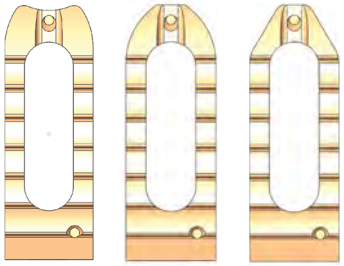
EVOS-HA STRAIGHT

TWO ENDPLATE DESIGNS

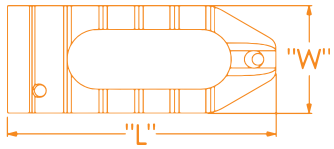


BICONVEX FLAT

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
		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
		11, 12, 13, 14, 15, 16	9, 10	30
Flat endplates, 17°		11, 12, 13, 14, 15, 16	9, 10	22
		12, 13, 14, 15, 16	9, 10	26
		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

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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 Transforamanial (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)
Flat endplates, 5°	9, 10, 11	8	22, 26, 30
	10, 11, 12	9	22, 26, 30
	11, 12, 13	10	22, 26, 30
	12, 13, 14	11	22, 26, 30
	13, 14, 15, 16	12	22, 26, 30
Flat endplates, 8°	9, 10, 11	8	22, 26, 30
	10, 11, 12	9	22, 26, 30
	11, 12, 13	10	22, 26, 30
	12, 13, 14	11	22, 26, 30
	13, 14, 15, 16	12	22, 26, 30
Flat endplates, 13°	12, 13	10	26, 30
	12, 13, 14	11	22, 26, 30
	13, 14, 15, 16	12	22, 26, 30
Flat endplates, 17°	13	10	26
	12, 13, 14	11	22
	13, 14	11	26
	14	11	30
	13, 14, 15, 16	12	22, 26
	14, 15, 16	12	30
Biconvex endplates, 0°	9, 10, 11	8	22, 26
	11	8	30
	10, 11, 12	9	22, 26, 30
	11, 12, 13	10	22, 26, 30
	12, 13, 14	11	22, 26, 30
	13, 14, 15, 16	12	22, 26, 30

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

**True Oblique Lordotic*

LBL-10025 R.A

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

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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.

Value

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

Market

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

HA-PEEK

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

FDA

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

CES®
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