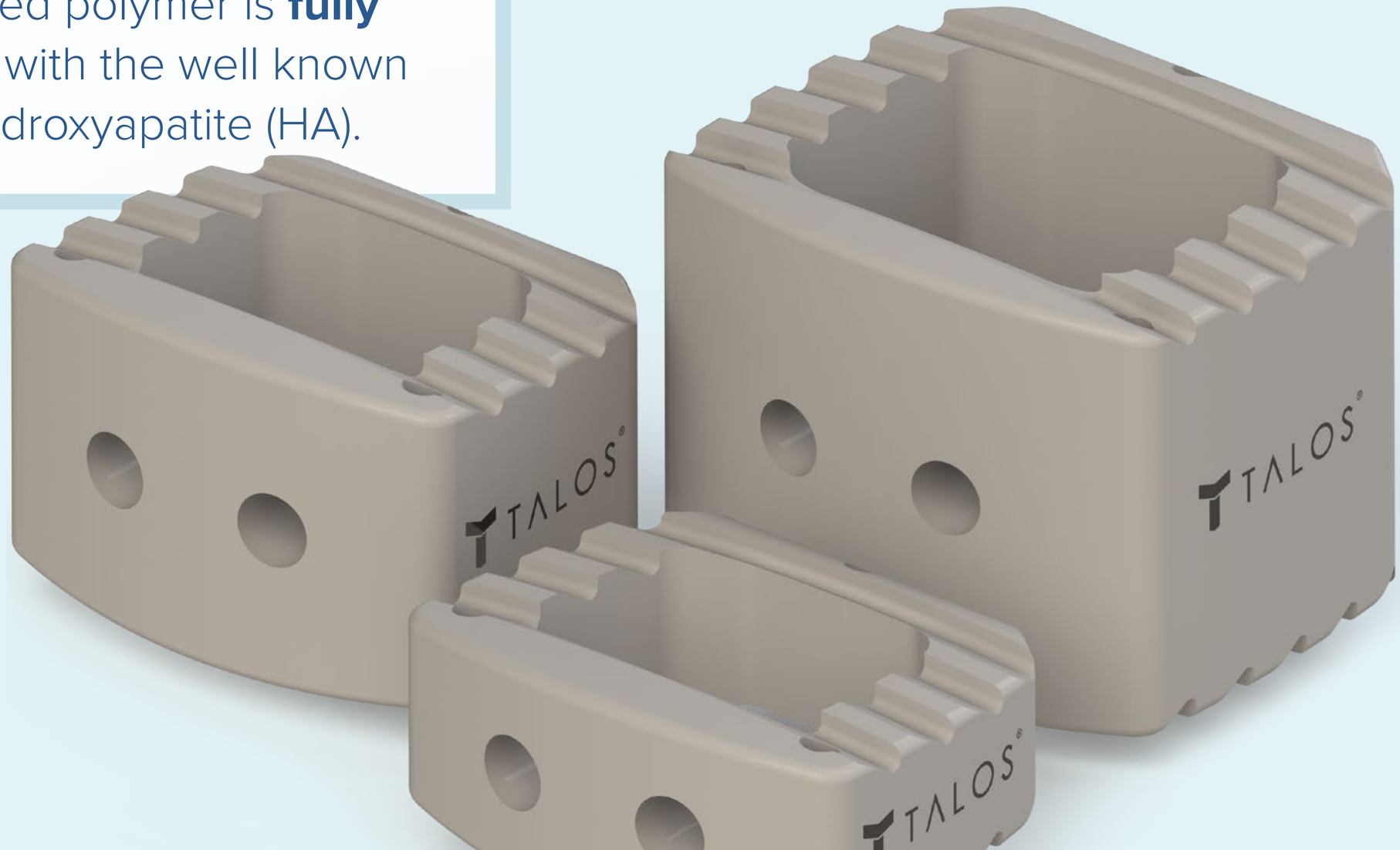
Talos®-C (HA) and the PEEK-OPTIMA® HA **Enhanced Technology**

TALOS®

meditech spine

The innovative Talos®-C (HA) IBF Implant made with PEEK-OPTIMA® HA Enhanced polymer is **fully integrated** with the well known material Hydroxyapatite (HA).



The Talos®-C (HA) IBF Implant for anterior cervical fusion is **one of the first medical devices manufactured with PEEK-OPTIMA® HA Enhanced** to be 510(k) cleared by the US FDA.

This evolutionary process has involved many technical efforts and continues to build upon the Talos® interbody platform first introduced by Meditech Spine in 2010.

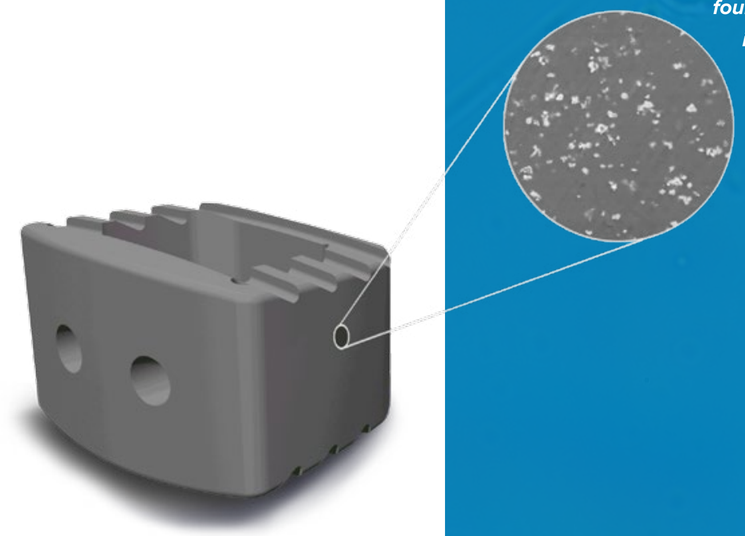


fig 1

Surface Coverage With The Integrated Compound

Applying HA coating to only the superior and inferior surfaces of an implant in order to improve bone apposition produces limited effectiveness. Improvement in the osseointegration process occurs exclusively on the coated surfaces. With the PEEK-OPTIMA® HA Enhanced material, there is no secondary application or additional coating process to validate. ***The hydroxyapatite is found on all surfaces and is fully integrated throughout the implant.***

ABOUT THE PEEK-OPTIMA® HA ENHANCED POLYMER

Hydroxyapatite (HA) is a naturally occurring mineral and the main inorganic component of bone. It is well-known for its osteoconductive properties and enhancing bone apposition with a variety of implants. Due to its well documented success for use in the cervical spine, PEEK-OPTIMA® Natural is currently the most common material used for interbody spinal devices. Surgeons are continually looking for ways to increase bone apposition with the existing armamentarium of spinal implants and one attempt has been to apply an exterior coating like Ti plasma or HA to IBF devices. This approach has yielded marginal improvement in bone fusion velocity and quality, the main draw-back being the limitation of coating only the exposed surfaces of the implant. However, by combining two clinically proven biomaterials (PEEK-OPTIMA® Natural and HA) together into one homogenous compounded polymer—Meditech Spine is able to offer a superior solution, the Talos®-C (HA) interbody system.

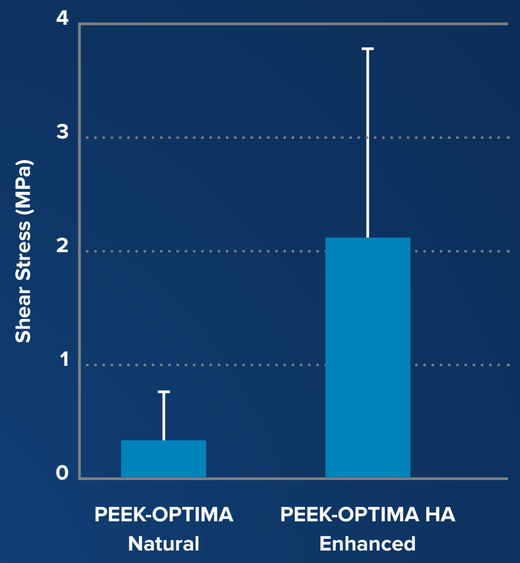


fig. 2

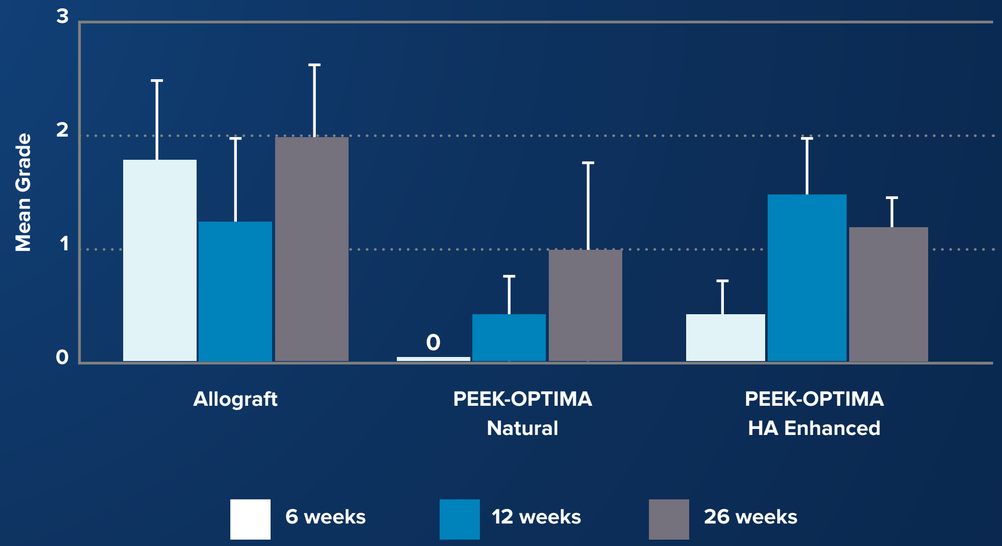
Push-out Shear

Four weeks after implantation, push-out testing showed that PEEK-OPTIMA® HA Enhanced had an increased interfacial shear strength compared to PEEK-OPTIMA® Natural.

fig. 3

Bone Contact Comparison

Micro CT analysis of direct bone-implant contact. PEEK-OPTIMA® HA Enhanced resulted in greater direct bone-implant contact at 6 and 12 weeks compared with PEEK-OPTIMA® Natural.



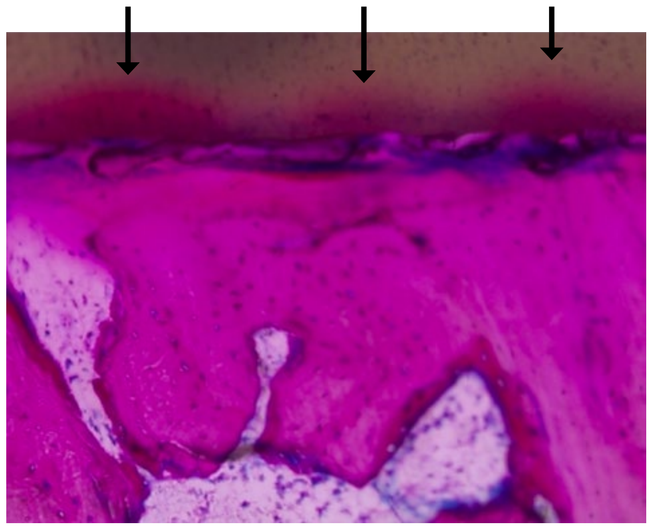
PERFORMANCE ADVANTAGE OF PEEK-OPTIMA® HA ENHANCED

To demonstrate early bone apposition, Invibio® Biomaterial Solutions commissioned a study designed to evaluate the in vivo response of PEEK-OPTIMA® HA Enhanced compared with PEEK-OPTIMA® Natural in a large animal model. The study was carried out at the Surgical & Orthopedic Research Laboratories at the University of New South Wales, following the approval of the UNSW Animal Care and Ethics Committee. Cylindrical dowels of PEEK-OPTIMA® HA Enhanced and PEEK-OPTIMA® Natural were placed in the anteromedial aspect of the tibia and the medial distal femoral condyle. The push out strength observed for the PEEK-OPTIMA® HA Enhanced at a 4 week interval demonstrated increased shear strength by at least four times when compared to PEEK-OPTIMA® Natural (see Figures 2 and 4). Also, a cervical fusion study was conducted comparing PEEK-OPTIMA® HA Enhanced, PEEK-OPTIMA® Natural and Allograft spacers. Each one of the implants was packed with autograft bone material. The data compiled during the pre-clinical animal study demonstrated direct bone contact to PEEK-OPTIMA® HA Enhanced at early time intervals (Figure 3).

fig. 4

Early Bone Apposition

At both 4 and 12 weeks, PEEK-OPTIMA® HA Enhanced demonstrated greater bone apposition than PEEK-OPTIMA® Natural. 75% direct bone apposition was observed as early as four weeks following implantation.[1]



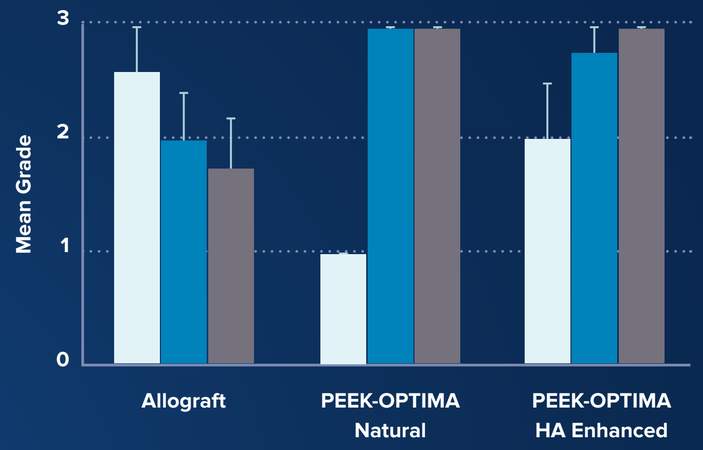


fig. 5

New Bone Formation

Micro CT analysis of new bone formation in the fusion as well as the device surface. PEEK-OPTIMA® HA Enhanced resulted in greater new bone formation at 6 weeks compared with PEEK-OPTIMA® Natural.

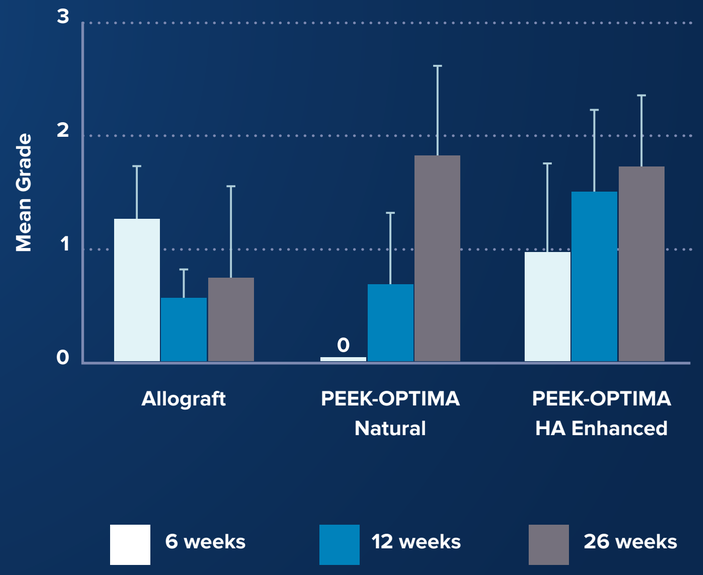


fig. 6

Quality of new bone bridging

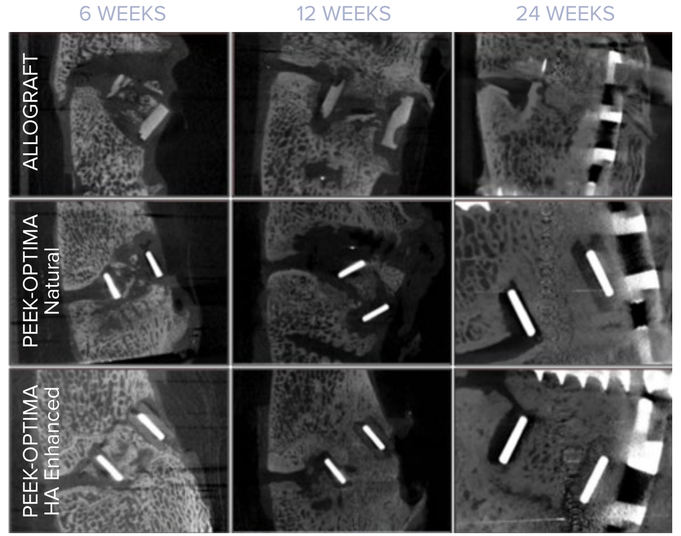
Micro CT analysis of the quality of new bone formation bridging in the fusion, as well as the device surfaces. PEEK-OPTIMA® HA Enhanced resulted in a higher quality of new bone bridging at 6 and 12 weeks compared with PEEK-OPTIMA® Natural.

New bone formation was greater with the PEEK-OPTIMA® HA Enhanced spacers after 6 weeks compared with PEEK-OPTIMA® Natural devices at the same time point. Additionally, the quality of new bone bridging was superior in the PEEK-OPTIMA® HA Enhanced group compared with PEEK-OPTIMA® Natural at both the 6 and 12 weeks time points. (see Figures 5 and 6.[2]) Micro CT analysis was also used to assess the fusion progression over time for the study group at 6, 12 and 26 weeks (see Figure 7). As stated earlier, the quality and quantity of new bone formation improved over time with both PEEK-OPTIMA® HA Enhanced and PEEK-OPTIMA® Natural.[2] It was observed that at 6 weeks the allograft implants had significant bone formation; however, 6 of the 13 allograft implants fractured during the fusion process and there was significant resorption detected as early as the 6 week mark. Using histology to compare the results of bone formation, there appears to be more robust formation in the PEEK-OPTIMA® HA Enhanced samples than the PEEK-OPTIMA® Natural samples at the 6 and 12 week time intervals. Fewer differences were evident at the 26 week interval, but there were still suggestions of superior graft formation with the PEEK-OPTIMA® HA Enhanced polymer when comparing the two samples.[2]

fig. 7

Graft Material Over Time

Micro CT comparison between Allograft, natural PEEK and Enhanced PEEK.



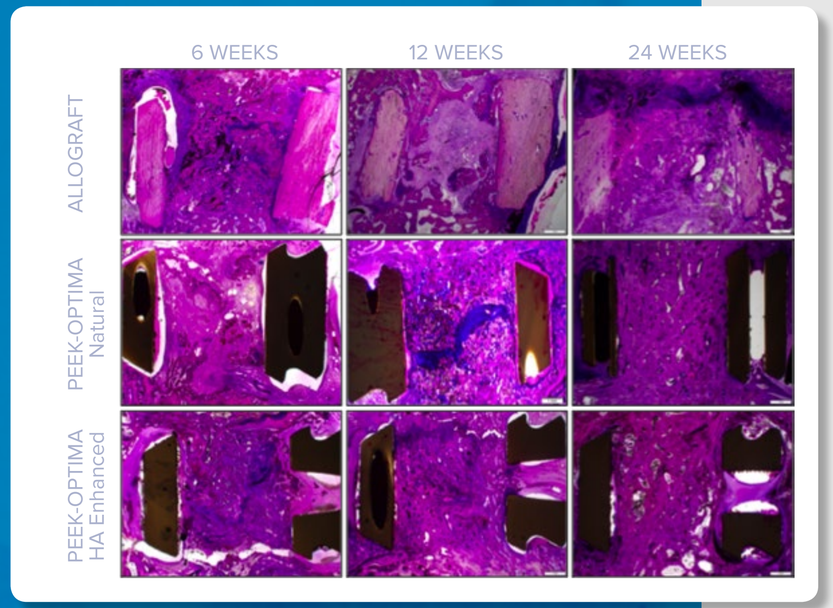


fig 8

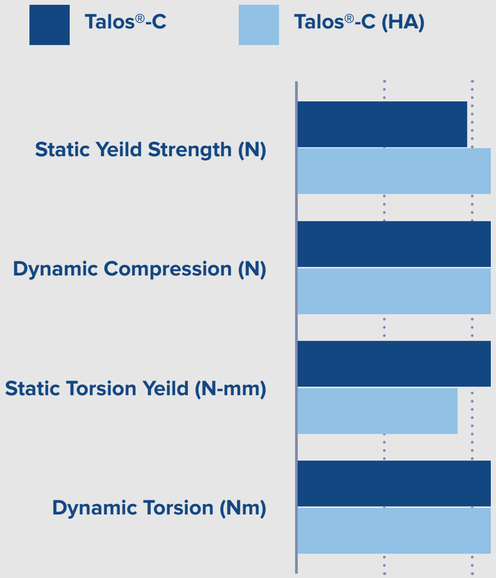
Histological Comparison

PEEK-OPTIMA® Natural and PEEK-OPTIMA® HA Enhanced demonstrates the status of the graft material inside the devices over time. Local bone inside PEEK-OPTIMA® HA Enhanced devices was more robust at 6 and 12 weeks compared to local bone inside the PEEK-OPTIMA® Natural devices at the same time points.

fig 9

Mechanical Strength Comparison

*ASTM F2077 Conducted on Talos®-C and Talos®-C (HA) Implants. *Data on file at Meditech Spine*



DISCUSSION

When Meditech Spine evaluated the need for an enhanced osteoconductive additive for interbody devices, the evidence was clear that a completely homogenous compound was a better solution. PEEK-OPTIMA® HA Enhanced offers a versatile, strong and superior solution for bone apposition. With the introduction of the Talos®-C (HA) interbody device and building on the proven track record of the Talos®-C product line, Meditech now offers a more robust platform of spinal interbodies to meet the challenging demands of surgeons and their patients.

MECHANICAL STRENGTH AND ASSESSMENT OF TALOS®-C (HA) AND TALOS®-C

Meditech Spine received FDA clearance for its first cervical interbody device, the Talos®-C IBF in early 2013. Similar testing on the Talos®-C (HA) interbody devices were conducted at an independent facility. Mechanical testing was performed in accordance with ASTM F2077, “Test Methods for Intervertebral Body Fusion Devices” and ASTM 2267, “Standard Test Method for Measuring Load Induced Subsidence of Intervertebral Body Fusion Devices under Static Axial Compression.”

The ASTM F2077 standard is for testing intervertebral body fusion devices to assess the static and dynamic strength of the interbody fusion device in compression, compression-shear, and torsional loading paradigms. ASTM F2267 was performed to assess the interbody’s ability to resist subsiding into the endplates of the vertebral bodies. It was determined that there was no statistical difference between the two devices in mechanical testing and the information is summarized on Figure 9.

Talos®-C (HA) Lordotic Shape - 12x12mm, 14x12mm, 16x14mm

Part #	Height	Width	Depth	Lordosis	Part #	Height	Width	Depth	Lordosis	Part #	Height	Width	Depth	Lordosis
5-21105-07	5	12	12	7°	5-21205-07	5	14	12	7°	5-21305-07	5	16	14	7°
5-21106-07	6	12	12	7°	5-21206-07	6	14	12	7°	5-21306-07	6	16	14	7°
5-21107-07	7	12	12	7°	5-21207-07	7	14	12	7°	5-21307-07	7	16	14	7°
5-21108-07	8	12	12	7°	5-21208-07	8	14	12	7°	5-21308-07	8	16	14	7°
5-21109-07	9	12	12	7°	5-21209-07	9	14	12	7°	5-21309-07	9	16	14	7°
5-21110-07	10	12	12	7°	5-21210-07	10	14	12	7°	5-21310-07	10	16	14	7°
5-21111-07	11	12	12	7°	5-21211-07	11	14	12	7°	5-21311-07	11	16	14	7°
5-21112-07	12	12	12	7°	5-21212-07	12	14	12	7°	5-21312-07	12	16	14	7°

Talos®-C (HA) Convex Shape - 12x12mm, 14x12mm, 16x14mm

Part #	Height	Width	Depth	Lordosis	Part #	Height	Width	Depth	Lordosis	Part #	Height	Width	Depth	Lordosis
5-22105-00	5	12	12	0°	5-22205-00	5	14	12	0°	5-22305-00	5	16	14	0°
5-22106-00	6	12	12	0°	5-22206-00	6	14	12	0°	5-22306-00	6	16	14	0°
5-22107-00	7	12	12	0°	5-22207-00	7	14	12	0°	5-22307-00	7	16	14	0°
5-22108-00	8	12	12	0°	5-22208-00	8	14	12	0°	5-22308-00	8	16	14	0°
5-22109-00	9	12	12	0°	5-22209-00	9	14	12	0°	5-22309-00	9	16	14	0°
5-22110-00	10	12	12	0°	5-22210-00	10	14	12	0°	5-22310-00	10	16	14	0°
5-22111-00	11	12	12	0°	5-22211-00	11	14	12	0°	5-22311-00	11	16	14	0°
5-22112-00	12	12	12	0°	5-22212-00	12	14	12	0°	5-22312-00	12	16	14	0°

Additional sizes available upon request.

Talos®-C (HA)

PEEK-OPTIMA® HA Enhanced
biocompatible and radiolucent
fits lordotic anatomy

Angled Teeth
prevents implant migration

Lordotic Shape
fits lordotic anatomy

Large Graft Windows
permits bony ingrowth

Tantalum Markers
confirms radiographic placement

Convex Shape
fits concave endplate anatomy

REFERENCES

1. Study evaluated the bone on-growth of PEEK-OPTIMA® Natural and PEEK-OPTIMA® HA Enhanced in a bone defect model in sheep. Data on file at Invibio Biomaterial Solutions. This has not been correlated with human clinical experience and did not use Meditech Spine devices.
2. 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 and did not use Meditech Spine devices.

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