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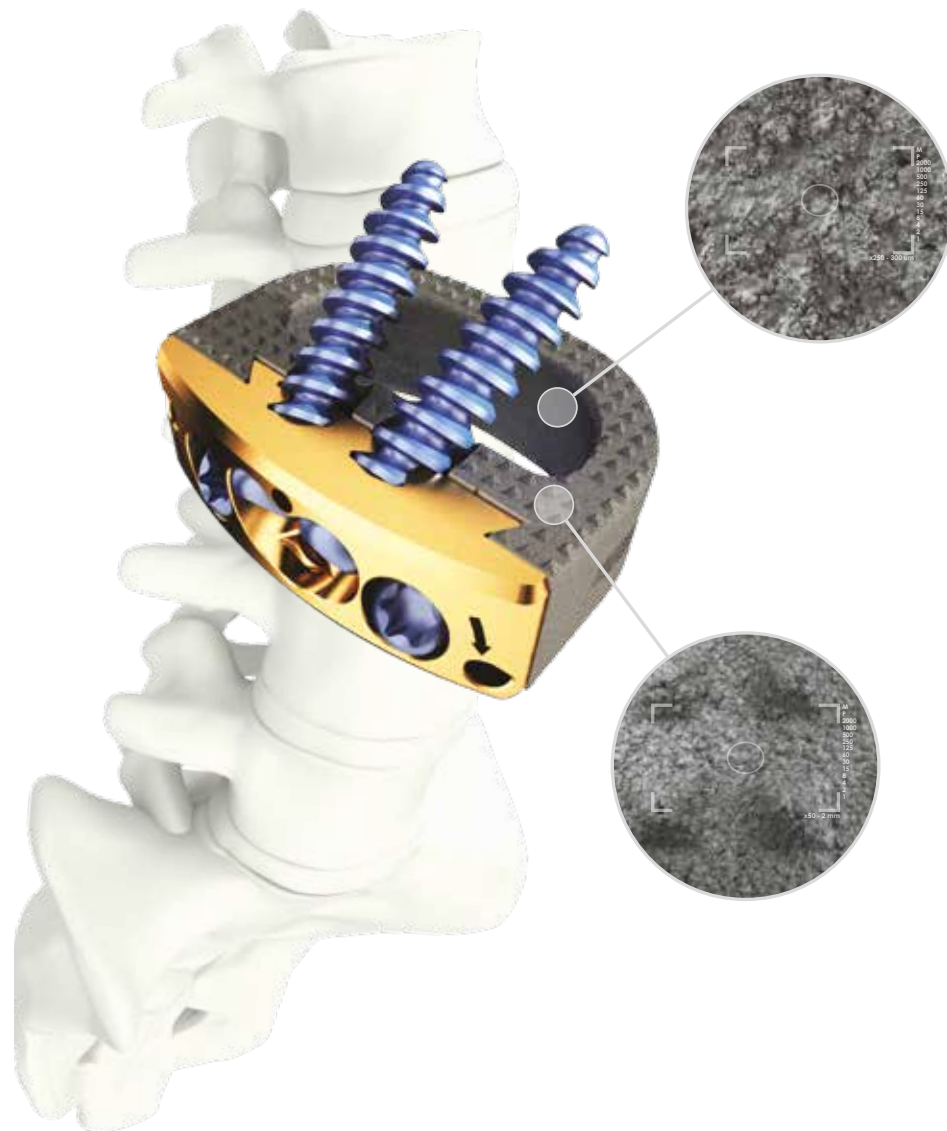
MEDACTA ORTHOPAEDIC  
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Titanium coated cage enhances  
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GEERT MAHIEU, MD. AZ MONICA

# MedactaLIF TIPEEK

TI-COATED INTERBODY FUSION DEVICE



## Titanium Coated PEEK Enhanced Bone Contact

# Titanium coated cage enhances fusion rates in posterior lumbar interbody fusion

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## ABSTRACT

Titanium coated PEEK cages incorporate the advantages of both PEEK, which offers a native-like elastic modulus and a radiolucent behaviour, and Titanium which provides improved biocompatibility and promotes osseointegration. In this study, we evaluated the response of Titanium plasma sprayed PEEK cages to provide safe support of the lumbar spine and promote bony fusion.

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## INTRODUCTION

The ultimate lumbar intervertebral cage provides load sharing support, promotes fusion and enables fusion assessment. PEEK cages have a physiological-like stiffness<sup>[1,2]</sup> allowing for a proper load force transmission. PEEK is radiolucent<sup>[2]</sup>, thus not affecting the diagnostic assessment. On the other side, PEEK is relatively inert to bone, as studies have reported the possible deposition of a non- reactive tissue layer at the implant-cage interface<sup>[3-5]</sup>.

Titanium cages, on the other hand, have a high stiffness which may concentrate load bearing and stress shielding and retain limited radio opacity<sup>[5]</sup> which could produce artefacts under diagnostic assessment. However, Titanium is biocompatible and “positively” interacts with bone<sup>[6,7]</sup> eventually promoting osteoblastic differentiation and increased bone formation<sup>[9-10]</sup>.

Plasma-sprayed Titanium coated cages should therefore represent an optimal solution by merging the physiological-like mechanical properties of PEEK and the osteoconductive Titanium features<sup>[3, 8-10]</sup>.

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## OBJECTIVE

We evaluated the response of Titanium-coated PEEK cages (TiPEEK) for lumbar fusion in providing safe support of the lumbar spine and promotion of (assessable) fusion.

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## METHODS

146 Lumbar posterior TiPEEK plasma sprayed Titanium coated cages from Medacta International SA, were placed by one surgeon in 59 patients affected by degenerative discopathy (max 2 levels) or by degenerative/lytic listhesis: 46 patients had one level surgery, 13 patients had two level surgery. 94% of the cages were placed at L4-L5 and/or L5-S1 level. All cages were filled with autograft and no extra graft was placed in the intervertebral space outside the cages. Patient follow up was established up to 21 months after surgery. Post-operatively, X-rays were taken at 3 months while CT scans were taken at 6 months and 12 months (only in cases of non-fusion reported at 6 months).

## RESULTS

Evidence of bony fusion was achieved in 57/59 patients with a rate of ~97% successful fusion at 6 months. Two potential non-fusion cases could not be diagnosed with symptoms directly related to non fusion.

Radiological findings on CT scans suggested that bone formation had been established directly to the titanium layer in all treated patients (Figure 1).



Figure 1. Evidence of bony fusion in a post-op CT scan

In one patient, one of the cages at L5-S1 was placed with intra-operative destruction of the endplate. Nevertheless, fusion was achieved after one year. Another patient had subsidence of the cages at 6 weeks after surgery but suffered from Chronic Obstructive Pulmonary Disease (COPD) and was on corticosteroids for a long time. Revision surgery was performed with a longer construct, no cage revision was necessary.

Overall, no other complications directly related to the implant were seen in this study.

## DISCUSSION

For a long time PEEK cages were considered to be the gold standard implants to support the lumbar spine while promoting intervertebral fusion. Nonetheless, direct interaction between bone and PEEK could not be seen due to its lack of bioactivity and relative inertness<sup>[2,3]</sup>. A non-reactive fibrous tissue layer between PEEK and bone could be demonstrated on microscopic evaluation<sup>[4]</sup>; the fibrotic

encapsulation may potentially affect the fusion rate as well as the bony fusion speed and eventually affect the cage implantation success<sup>[10]</sup>. Therefore in these cases, fusion depends on the interaction of the bone graft inside the cage and the bony endplate of the vertebral body. Lee et al.<sup>[12]</sup> showed that the ratio of the fused area of local bone inside cages at regions exposed to endplates was less than 50%. In our opinion, minor quality of the graft, insufficient graft amount or scarce direct contact between graft and endplate are potential explanations for this finding. Therefore, Lee et al recommended that additional bone should be grafted into the disc space or new bone bonding interbody spacers should be considered<sup>[12]</sup>. The bone formation onto the TiPEEK surface may represent the evidence that the Titanium layer onto PEEK cage represents a solution to increase the graft surface and improve the bony fusion.

With the rationale to increase the biocompatibility<sup>[9, 10]</sup>, while retaining its native mechanical physiological-like response, PEEK cages are plasma sprayed with a rough and porous micrometric layer of Titanium, thus generating the TiPEEK interbody fusion devices (Medacta International SA).

Due to its elastic modulus and a limited rigidity which is similar to the physiologic bone, PEEK and TiPEEK are capable of supporting the spine with little chance of subsidence. Conversely, reported rates of progressive subsidence of solid titanium core cages are over 30%<sup>[12, 13]</sup>. In our study, with a mean follow up of 21 months, no progressive subsidence was seen on X-rays, except for the above mentioned patient, affected by COPD, where anyway cage revision was not performed. Similarly, Rickert et al. have shown favourable results with both PEEK and TiPEEK cages for single- or two-level instrumented lumbar spine<sup>[11]</sup>. In the above mentioned study, TiPEEK showed a positive trend in the actual restoration of intervertebral disc height of the fused segments and no subsidence up to 12 months follow up.

Walsh et al<sup>[3]</sup> were able to prove the bioactivity of the Titanium coating onto the TiPEEK cages (Medacta International SA) as well as their osteoconductive trends. In fact they demonstrated that the Titanium coating is capable of supporting the formation of a calcium phosphate film, which eventually transforms into an apatite-like structure. This interface ultimately represents the bone-cage physical bonding structure that has the capability to boost bone formation, maturation and to increase bone integration. In light of the above mentioned results, increasing the graft surface by coating a PEEK substrate with a titanium layer could combine the advantages of the two materials.

CT scan images at 6 months suggest macroscopic bony formations between the Titanium coated cage and the endplates showing also that the graft inside the cage fuses with the vertebral body (Figure 2 & Figure 3).

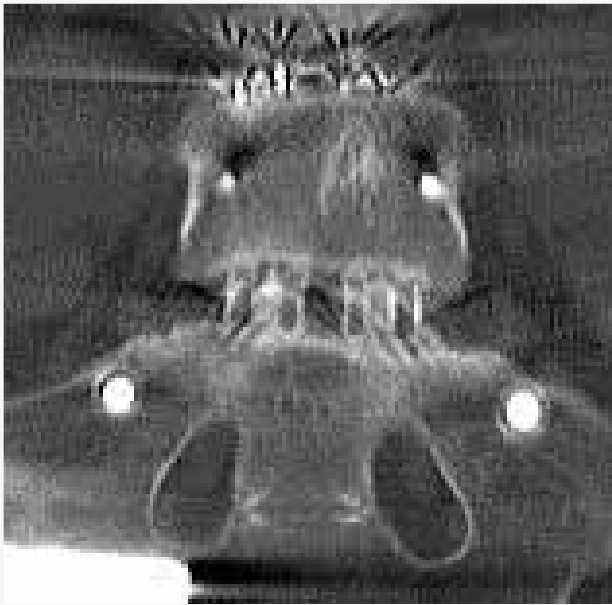


Figure 2. Frontal cut through the middle of the cage.  
Fusion masses formation through the cage



Figure 3. Frontal cut at the posterior border of the cage.  
Clear ingrowth of bone on the titanium layer of the cage.

According to the provided CT images, the TiPEEK cages retain a significant potential to increase fusion rates with enhanced bony fusion through the cage and also onto a Titanium film surface.

Due to the already high reported fusion rates of PEEK cages (especially when extra bone graft is placed in the intervertebral space outside the cages), a very large study population would be necessary to statistically prove differences with TiPEEK.

In patients at risk of for non-fusion (smokers, diabetes, osteoporosis or irregular endplate configuration etc...), the advantages of TiPEEK over PEEK cages might be more obvious. Rickert et al. have confirmed the high levels of fusion trend, demonstrating that TiPEEK cages can reach faster fusion than PEEK devices, with 88% fusion rate vs 70% confirmed at 3 months after surgery [12].

In our opinion CT is the gold standard with frontal and sagittal cuts in bone window. Customising the window settings is essential to evaluate bone formation in and on the cage.

## CONCLUSION

The Titanium coated MectaLIF TiPEEK cage is safe to use. It provides us with a high fusion rate in our patients as could be assessed with CT scans. Radiological, clinical and histological studies suggest significant bone ingrowth on the Titanium coating.

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Medacta International is a **Swiss company** developing, manufacturing and distributing orthopaedic and neurosurgical medical devices worldwide.

Medacta was founded in 1999 with a vision of redefining better through innovation for people needing joint and spine replacement.

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