

PROTI 360°™ Titanium Integrated Technology

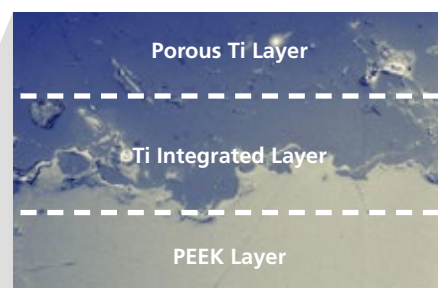
The Benefits of Both Worlds: Combining a PEEK Core + Titanium Integrated Surface

STIMULATE, CREATE, INTEGRATE

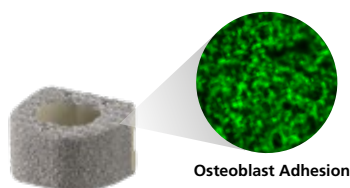
STIMULATE – Bone matrix formation directly on the implants' titanium surfaces through contact osteogenesis¹

CREATE – Interbody cages that are designed to prevent surface delamination while combining the benefits of PEEK and Titanium osteoconductive properties^{1,2,3,4,5}

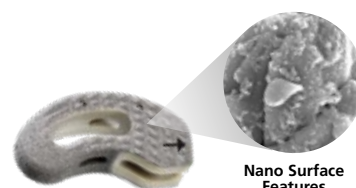
INTEGRATE – 360° external surface titanium integration designed to promote bony on-growth at the endplates and within the disc space¹



Cage Cross Section



Osteoblast Adhesion

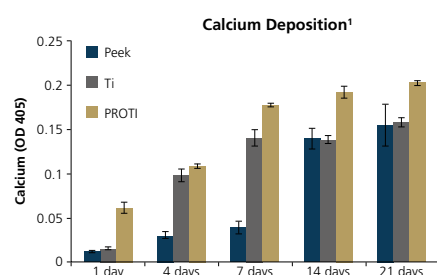


Nano Surface Features

STIMULATE

Accelerated osteoconduction and bone matrix formation on the titanium integrated cage surfaces¹

- The detection of calcium is the ultimate measure of bone matrix formation¹
- Osteoblast functions, including bone matrix production, are enhanced on surfaces that are most similar to bone¹
- At day 1, the calcium deposition on PROTI 360°™ Technology is 470.4% higher than PEEK, and 305.1% higher than bare Titanium



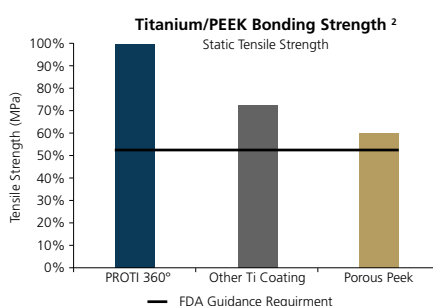
CREATE

Designed to prevent delamination

- Enhanced Titanium/PEEK Bonding Strength.²
- Bonding strength approximately twice that of regulatory coating requirement and 30% more compared to other Ti coated PEEK devices.²
- Uniform proprietary process allows approximately 10% of the titanium thickness to penetrate into the PEEK.¹

Fortified Titanium Edges

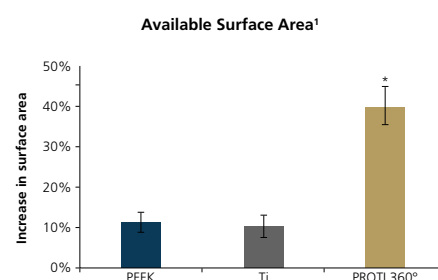
- No external, leading edge exposed PEEK corners



INTEGRATE

Greater surface area for osteoblast integration¹

- 30% more surface area per sq. micron¹
- Additional osteoconductive surfaces with 360° design
- More favorable environment for bone growth³



PROTI 360° = PROTI 360° Integrated Technology
PEEK = Poly-ether-ether-ketone
Ti = Titanium

ACIS PROTI 360 LORDOTIC SMALL	
108843605	ACIS PROTI LOR/S 5 mm H
108843606	ACIS PROTI LOR/S 6 mm H
108843607	ACIS PROTI LOR/S 7 mm H
108843608	ACIS PROTI LOR/S 8 mm H
108843609	ACIS PROTI LOR/S 9 mm H
108843610	ACIS PROTI LOR/S 10 mm H

ACIS PROTI360 LORDOTIC STND	
108843005	ACIS PROTI LOR/M 5 mm H
108843006	ACIS PROTI LOR/M 6 mm H
108843007	ACIS PROTI LOR/M 7 mm H
108843008	ACIS PROTI LOR/M 8 mm H
108843009	ACIS PROTI LOR/M 9 mm H
108843010	ACIS PROTI LOR/M 10 mm H

ACIS PROTI 360 LORDOTIC LARGE	
108843305	ACIS PROTI LOR/L 5 mm H
108843306	ACIS PROTI LOR/L 6 mm H
108843307	ACIS PROTI LOR/L 7 mm H
108843308	ACIS PROTI LOR/L 8 mm H
108843309	ACIS PROTI LOR/L 9 mm H
108843310	ACIS PROTI LOR/L 10 mm H

ACIS PROTI 360 PARALLEL STND	
108843105	ACIS PROTI PAR/M 5 mm H
108843106	ACIS PROTI PAR/M 6 mm H
108843107	ACIS PROTI PAR/M 7 mm H
108843108	ACIS PROTI PAR/M 8 mm H
108843109	ACIS PROTI PAR/M 9mm H
108843110	ACIS PROTI PAR/M 10 mm H

ACIS PROTI 360 CONVEX STND	
108843205	ACIS PROTI CON/M 5 mm H
108843206	ACIS PROTI CON/M 6 mm H
108843207	ACIS PROTI CON/M 7 mm H
108843208	ACIS PROTI CON/M 8 mm H
108843209	ACIS PROTI CON/M 9 mm H
108843210	ACIS PROTI CON/M 10 mm H

ACIS PROTI 360 CONVEX LARGE	
108843505	ACIS PROTI CON/L 5 mm H
108843506	ACIS PROTI CON/L 6 mm H
108843507	ACIS PROTI CON/L 7 mm H
108843508	ACIS PROTI CON/L 8 mm H
108843509	ACIS PROTI CON/L 9 mm H
108843510	ACIS PROTI CON/L 10 mm H

T-PAL PROTI 360 - HIGH CURVE	
10 mm wide	
108812007	T-PAL PROTI 10x7x28 mm
108812008	T-PAL PROTI 10x8x28 mm
108812009	T-PAL PROTI 10x9x28 mm
108812010	T-PAL PROTI 10x10x28 mm
108812011	T-PAL PROTI 10x11x28 mm
108812012	T-PAL PROTI 10x12x28 mm
108812013	T-PAL PROTI 10x13x28 mm
108812014	T-PAL PROTI 10x14x28 mm
108812015	T-PAL PROTI 10x15x28 mm

12 mm wide	
108812207	T-PAL PROTI 12x7x32 mm
108812208	T-PAL PROTI 12x8x32 mm
108812209	T-PAL PROTI 12x9x32 mm
108812210	T-PAL PROTI 12x10x32 mm
108812211	T-PAL PROTI 12x11x32 mm
108812212	T-PAL PROTI 12x12x32 mm
108812213	T-PAL PROTI 12x13x32 mm
108812214	T-PAL PROTI 12x14x32 mm
108812215	T-PAL PROTI 12x15x32 mm

CONCORDE PROTI 360 PARALLEL	
Short 9 mm x 23 mm	
188823107	CONCORDE PROTI P, 9x7x23 mm
188823108	CONCORDE PROTI P, 9x8x23 mm
188823109	CONCORDE PROTI P, 9x9x23 mm
188823110	CONCORDE PROTI P, 9x10x23 mm
188823111	CONCORDE PROTI P, 9x11x23 mm
188823112	CONCORDE PROTI P, 9x12x23 mm
188823113	CONCORDE PROTI P, 9x13x23 mm
188823114	CONCORDE PROTI P, 9x14x23 mm
188823115	CONCORDE PROTI P, 9x15x23 mm

Long 9 mm x 27 mm	
188827107	CONCORDE PROTI P, 9x7x27 mm
188827108	CONCORDE PROTI P, 9x8x27 mm
188827109	CONCORDE PROTI P, 9x9x27 mm
188827110	CONCORDE PROTI P, 9x10x27mm
188827111	CONCORDE PROTI P, 9x11x27 mm
188827112	CONCORDE PROTI P, 9x12x27 mm
188827113	CONCORDE PROTI P, 9x13x27 mm
188827114	CONCORDE PROTI P, 9x14x27 mm
188827115	CONCORDE PROTI P, 9x15x27 mm

CONCORDE PROTI 360 LORDOTIC	
Short 9 mm x 23 mm	
188823408	CONCORDE PROTI 5°, 9x8x23 mm
188823409	CONCORDE PROTI 5°, 9x9x23 mm
188823410	CONCORDE PROTI 5°, 9x10x23 mm
188823411	CONCORDE PROTI 5°, 9x11x23 mm
188823412	CONCORDE PROTI 5°, 9x12x23 mm
188823413	CONCORDE PROTI 5°, 9x13x23 mm
188823414	CONCORDE PROTI 5°, 9x14x23 mm
188823415	CONCORDE PROTI 5°, 9x15x23 mm

Long 9 mm x 27 mm	
188827408	CONCORDE PROTI 5°, 9x8x27 mm
188827409	CONCORDE PROTI 5°, 9x9x27 mm
188827410	CONCORDE PROTI 5°, 9x10x27 mm
188827411	CONCORDE PROTI 5°, 9x11x27 mm
188827412	CONCORDE PROTI 5°, 9x12x27 mm
188827413	CONCORDE PROTI 5°, 9x13x27 mm
188827414	CONCORDE PROTI 5°, 9x14x27 mm
188827415	CONCORDE PROTI 5°, 9x15x27 mm

PROTI 360° Titanium Integrated Technology is engineered to provide immediate mechanical stability and to promote rapid and long-lasting biological fixation with supporting bone as demonstrated by in vitro testing. This is accomplished through a number of unique design considerations:

- PEEK core with mechanical properties similar to bone provides mechanical stability and effectively disperses dynamic loads to minimize stress shielding effects^{2, 3, 4, 5}
- Titanium integrated surface treatment creates a bioactive surface that promotes the attachment and growth of bone forming cells^{2, 3, 4, 5}
- The additional surface area created by more surface roughness increases in vitro osteoblast population by ~50% within 7 days compared to standard PEEK surfaces¹
- Osteoblast population is increased by 21% after 14 days compared to Ti 6Al 4V¹
- Incorporation of 3-dimensionally complex surface features increases the in vitro formation of mineralized bone matrix from osteoblasts by more than 350% within 7 days compared to PEEK¹
- Calcium deposition increases by 470% compared to PEEK, and 305% compared to Titanium after just one (1) day¹

Combined, the PROTI 360° Titanium Integrated Technology provides an enhanced structure for spinal fusion procedures by sustained mechanical and biological stability throughout the bone remodeling process.

References

1. Data on file TR-201-B (PROTI Test Report) 2. Data on file TR-201803-A (Integrated Titanium Bonding strength testing report) 3. Lincks, J.et al. Response of MG63 osteoblast-like cells to titanium and titanium alloy is dependent on surface roughness and composition. Biomaterials 19, 1998. Pages 2219-32 4. Kurtz, S. M. & Devine, J. N., PEEK biomaterials in trauma, orthopedic, and spinal implants. Biomaterials. 2007 Volume 28 Pages 4845-69 5. Rho, J. Y., Ashman, R. B. & Turner, C. H., Young's modulus of trabecular and cortical bone material: Ultrasonic and microtensile measurements. J., Biomech. 1993. Volume 26. Pages 111-119

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