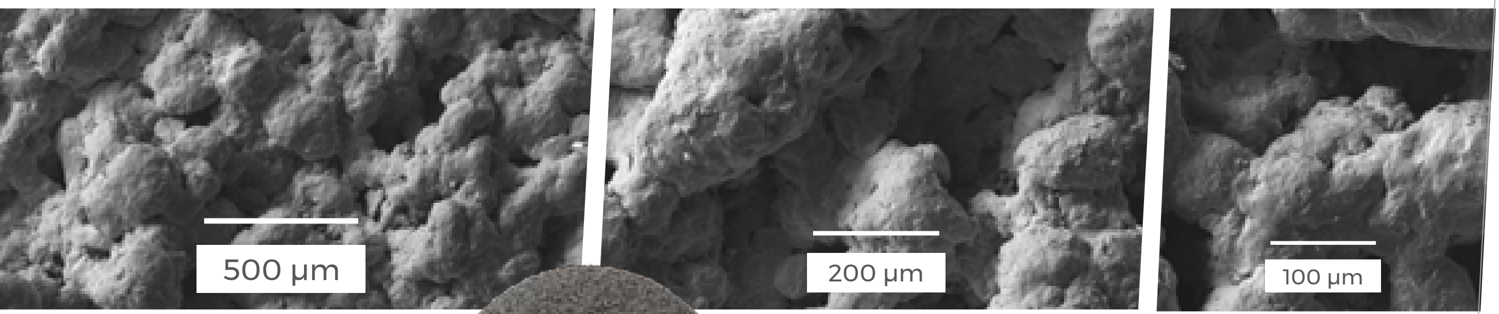
Lincotek Medical

TiGrowth®

TiGrowth® the fastest and easiest process to achieve large pore networks on prostheses.



TiGrowth®

was designed to enable porous titanium plasma spray for bone ingrowth thanks to its extensive pore network.

Porous surface:

when bone growth into the coating structure is desired (bone ingrowth), a larger size interconnected porous network is necessary.

TiGrowth® is the first titanium sponge applicable to prostheses made with thermal spray technology.

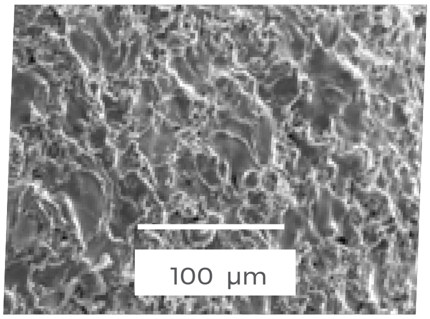
It consists of a series of open and interconnected large size pores arranged in a titanium matrix. The pore and interconnection channel size range is between 100 and 600 microns.

State of the art

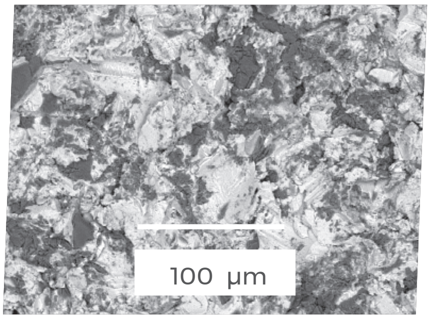
Rough Titanium Surfaces

Conventional cement-less endosseous prostheses are generally made of titanium alloys and are supplied with a surface roughened by sandblasting, plasma spray coating, etching etc. These surfaces, while fully biocompatible, allow prosthesis fixation by bone apposition (ongrowth) only.

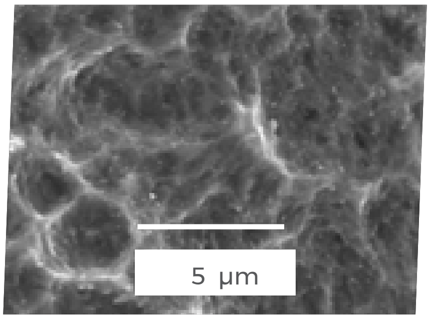
TYPICAL ASPECT FOR A Ti AIR PLASMA SPRAY COATING



EXAMPLE OF A CORUNDUM SANDBLASTED Ti SURFACE



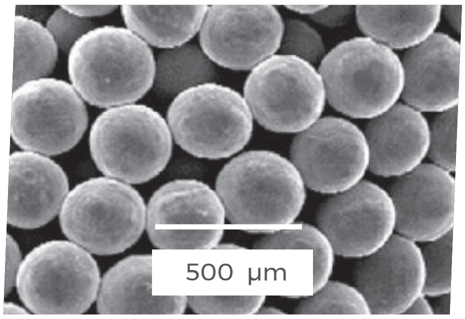
EXAMPLE OF ETCHED Ti SURFACE



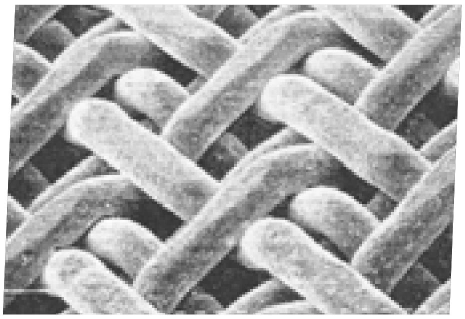
Porous surfaces

Large-size porous networks are created and applied to prostheses using complex post processes. In many cases these processes have a dramatic effect on bulk material performance or are difficult to apply to complex-shaped pieces.

TYPICAL ASPECT FOR A TI BEADS POROUS COATING[3]



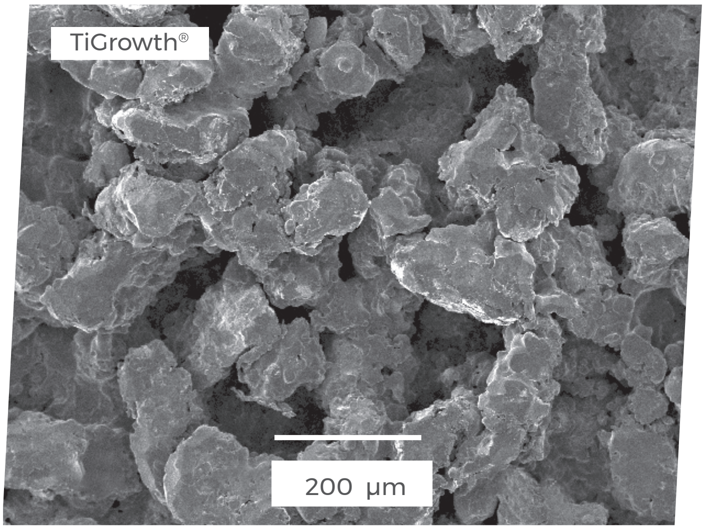
EXAMPLE OF A FIBER MESH POROUS COATING[5]



The innovation

TiGrowth® is a coating that eliminates the pore-size advantage of sintered beads.

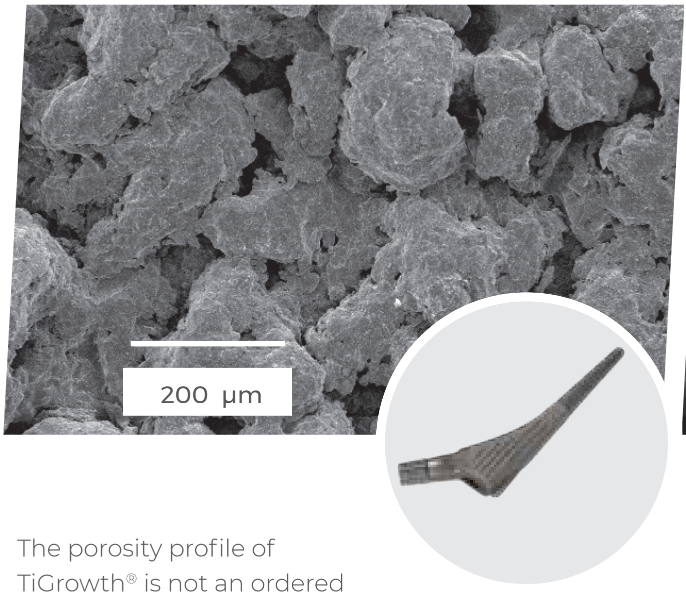
TiGrowth® consists of a series of open and interconnected large-size pores arranged in a titanium matrix, a type of titanium sponge applied on the pieces by Plasma Spray.
TiGrowth® can be applied to substrates at low temperatures, which reflects in a clear benefit for the mechanical performances of the system and enables polymer masking to protect the parts from the coating process.



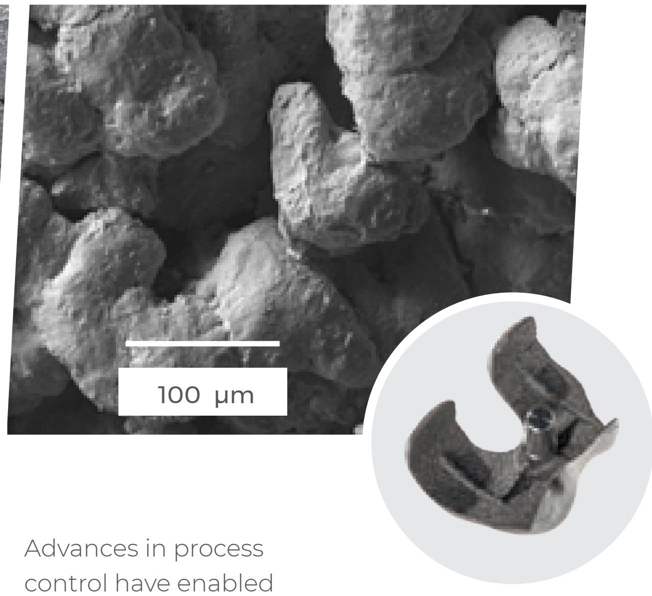
TiGrowth®: a new type of Titanium Plasma Spray coating

Plasma Spray is considered a pretty flexible technology, with the ability to generate an osteointegrating surface at the rate of a minute per piece. If properly handled in a modern lean organized production flow, plasma spray can be a tremendous competitor in term of cost-benefit ratio. The peculiarity of TiGrowth® is that, while designed to bring about bone ingrowth thanks to its large size pores, it can also be easily and quickly applied to all prosthetic surfaces lying along a line of sight.

Example of TiGrowth® porous coating



The porosity profile of TiGrowth® is not an ordered structure, like porous beads, but instead it is a completely random structure that is rough and porous at the same time.



Advances in process control have enabled the application of thick coatings (up to 900 µm), which allows for high and interconnecting porosity that are suitable for joint replacement components.

- **TiGrowth®** shows increased grip at the interface with host bone.
- **TiGrowth®** can be supplied in thicker layers than conventional coatings with cohesion and adhesion strength within applicable norms. The thickness of the coating determines the predictable amount of pore size, volume, and overall porosity that can be achieved.
- **TiGrowth®** is the easiest option for manufacturing macroporous structures. Applied through a Plasma Spray process it allows for greater overall output, which in turn gives a prostheses manufacturers more flexibility on delivery times and overall cost.
- **TiGrowth®** coating is commercially available in Europe, US and China. It is currently in clinical application associated to femor al stems and acetabular cups; CoCr Knee components; PEEK based spine; and in parts for shoulder joint or other reconstruction of extremities.

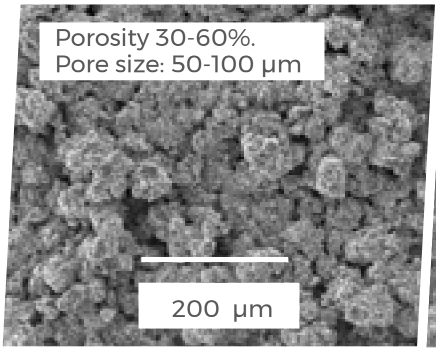
TiGrowth® topography description is performed through several different methods:

Comparative sem images of standard APS and VPS titanium coatin-gs vs. TiGrowth® coatings

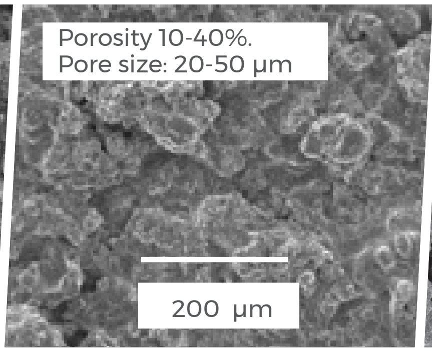
At SEM analysis, TiGrowth® appears highly porous, with large, deep pores.

The major difference between TiGrowth® and conventional Plasma Spray coatings is its porosity, pore depth and pore size. Top view SEM analysis makes this clear.

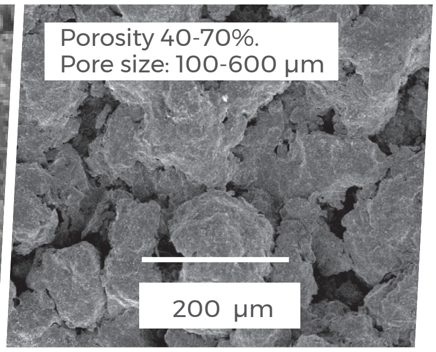
TiVPS



TiAPS



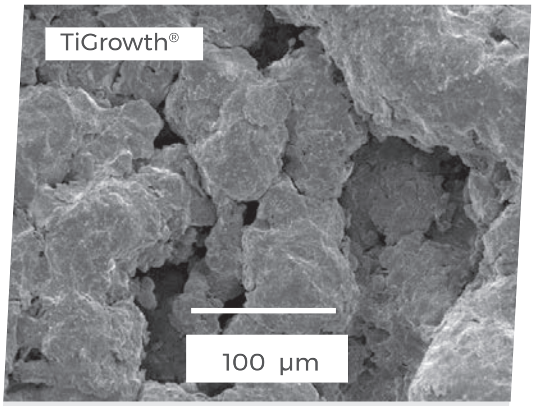
TiGROWTH®

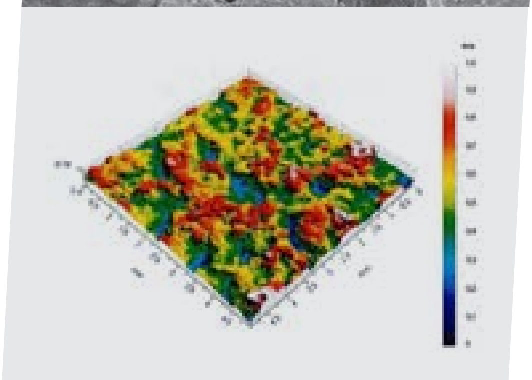


Morphological characterization of the TiGrowth® Coating Surface and section

Tridimensional maps obtained by optical laser profilometry can be useful to quantitative to describe TiGrowth® surfaces quantitatively.

Bars with different colors highlight peak-to-valley distances. They are greatly superior when compared with conventional rough titanium surfaces.





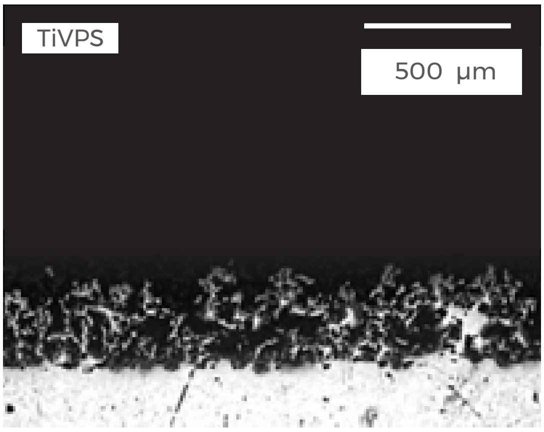
Peculiar topographic features of TiGrowth® guarantee high friction levels at bone to implant interface.

Metallographic sections

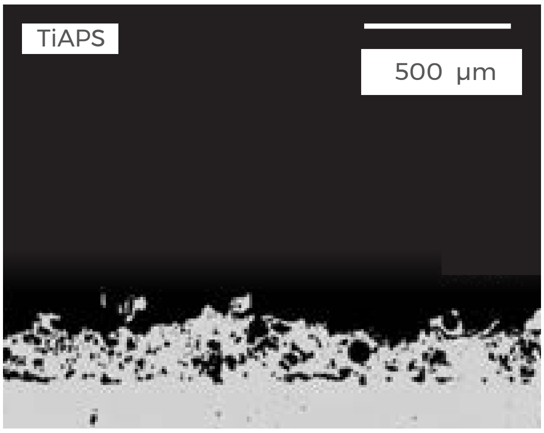
Comparison of standard APS and VPS Ti-coatings vs. TiGrowth® coating

Micrography at same magnification highlights differences in thickness and porous size for **TiGrowth®** coating.

Suggested thickness	150 - 500 µm
Adhesion Strength	≥ 40 MPa
Porosity	30 - 60 %
Roughness (Rt)	90 - 170 µm

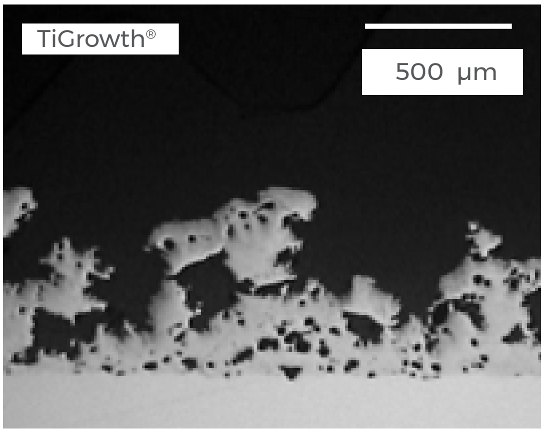


Thickness Advised	150 - 350 µm
Adhesion Strength	≥ 30 MPa
Porosity	20 - 40 %
Roughness (Rt)	90 - 170 µm



In addition to well-established applications, TiGrowth® can now be used to realise highly macroporous titanium surfaces, coat thermally sensitive materials and realise unexpected couplings of different biomaterials.

Thickness Advised	350 - 700 µm
Adhesion Strength	35 MPa
Porosity	40 -70 %
Roughness (Rt)	200 - 400 µm

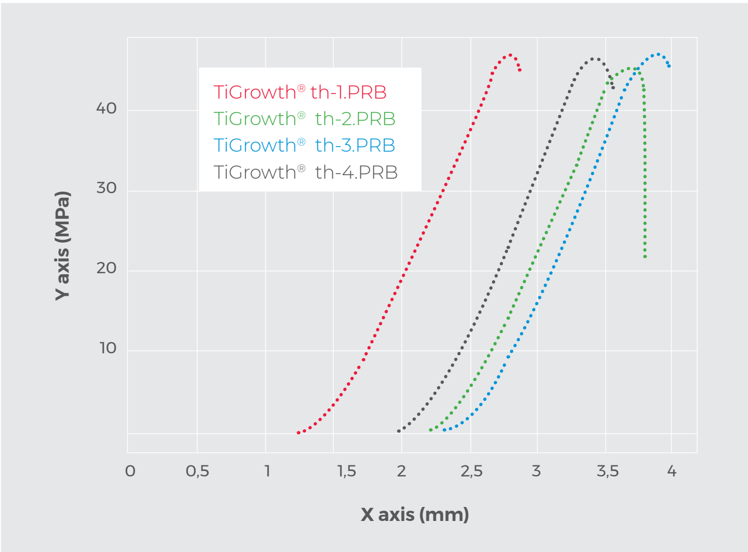


Physical and mechanical properties

Mechanical adhesion and debris release, measured under a Taber abrasion test, are within FDA-required limits.

Property	Fda acceptance	Conformity	
		Yes	No
Shear Fatigue Strength at 1-10 MPa	> 10^7 cycles	X	
Shear Static Strength (MPa)	> 20	X	
Static Tensile Strength (MPa)	> 22	X	
Abrasion resistance (mg)	< 65	X	

TIGROWTH® ADHESION



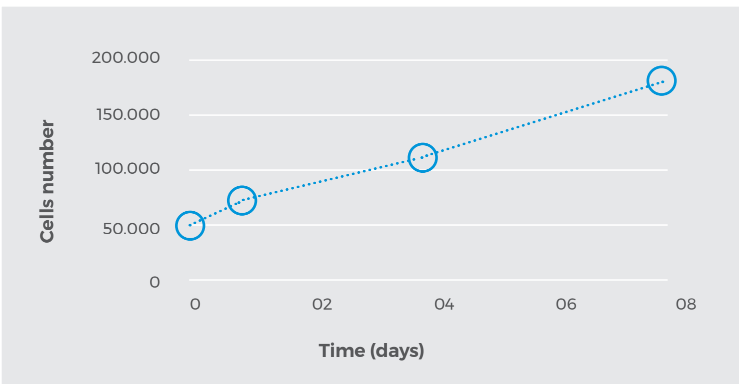
Examples of adhesion strength detected on coupons coated with TiGrowth® V and tested according to ASTM F 1147.

Biological Performances

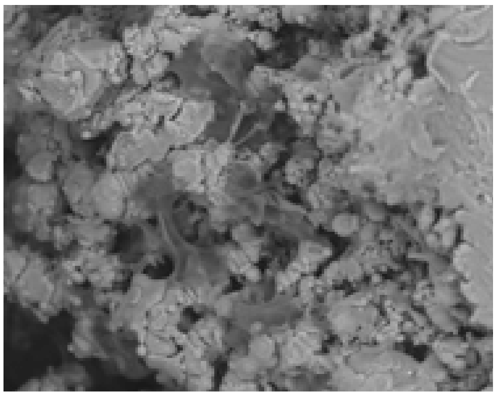
TiGrowth® was biologically tested and showed excellent biocompatibility performances.

MTT test SAOS-2 on TiGrowth®

Osteoblast cells growing proliferation trend.[1]



OSTEOBLAST CELLS ADHERING TO TiGrowth® SURFACE.

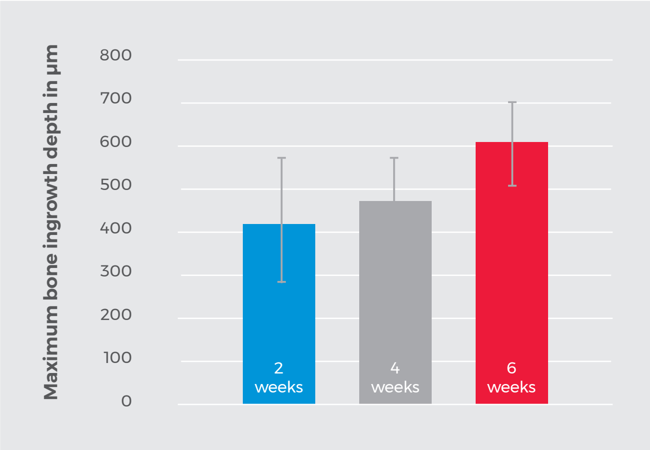


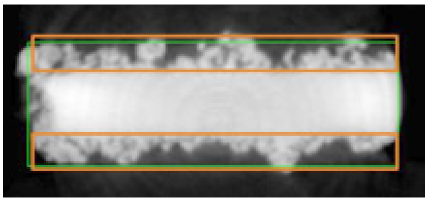
In proliferative medium, SAOS-2 cells maintain similar growth rates in both short and medium term. By SEM image analyses, performed at 24 h and 8 days, cells appeared flattened and adherent to the surface.[1]

In vivo assays were performed during the research activity.[2,7,8]
In large animal models TiGrowth® was shown as being able to promote deep bone ingrowth, whereas conventional small pore size Ti coatings permit bone ongrowth only.

TiGROWTH®

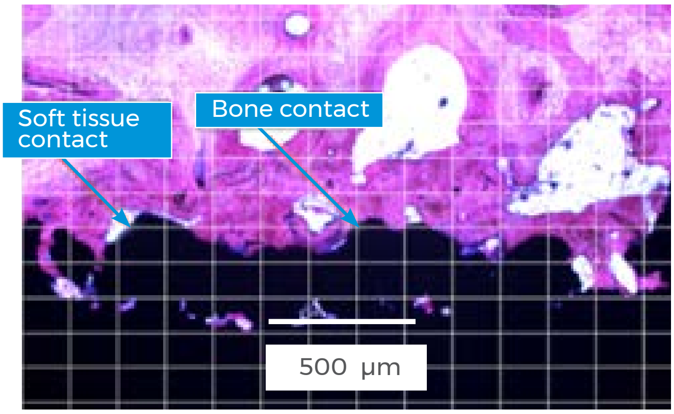
Bone ingrowth during implantation[2]



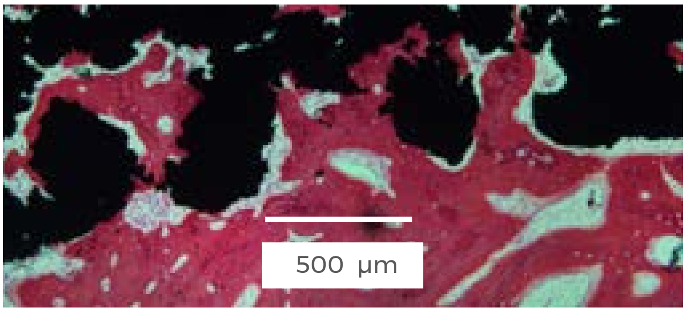


X-ray image of specimen used in the animal study. TiGrowth® coating applied to top and bottom surfaces.

Histology observations after 4, 6 and 8 weeks of implantation time confirmed bone ingrowth in the TiGrowth® plasma spray surface. No surgical or post-operative complications or lameness - and no indications of infection or abnormal tissue response at the time of retrieval - were noticed. This indicates good biocompatibility. No delamination for surfaces tested or metal debris around implanted specimens were detected.



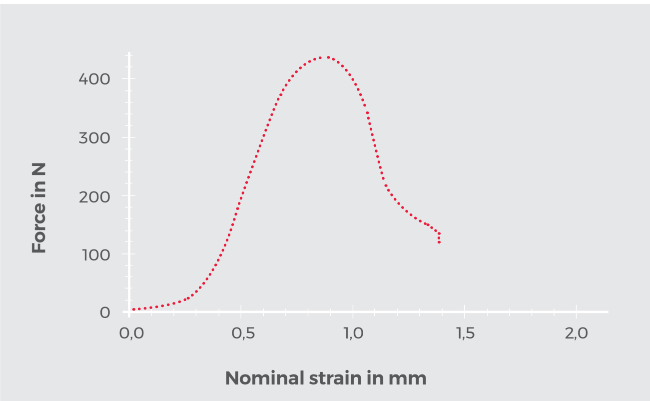
Thin sections were used to confirm that the cells near to the specimens' surface were osteocytes and the high density is normal in rapidly growing new bone.

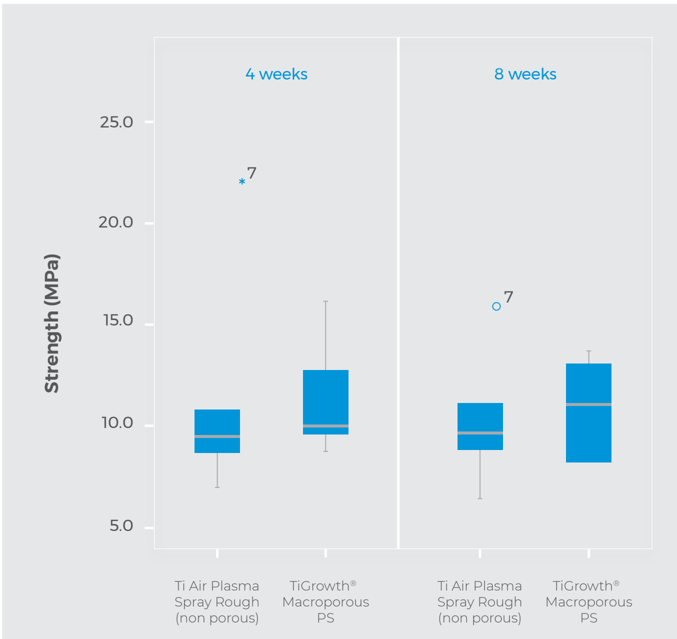


Biomechanical assay

Bone ingrowth helps device fixation in the hosting site.

Despite large-size pores dimension at the tissue interface, TiGrowth® rapidly reaches the maximum biomechanical fixation in trabecular bone. A push-out strength comparison is shown between a TiGrowth® and a Plasma Spray coating with decades of successful clinical history.





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