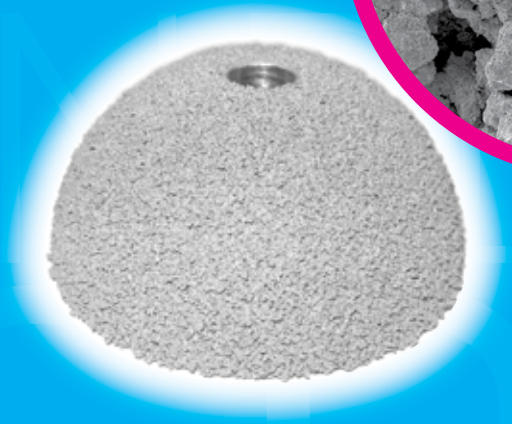
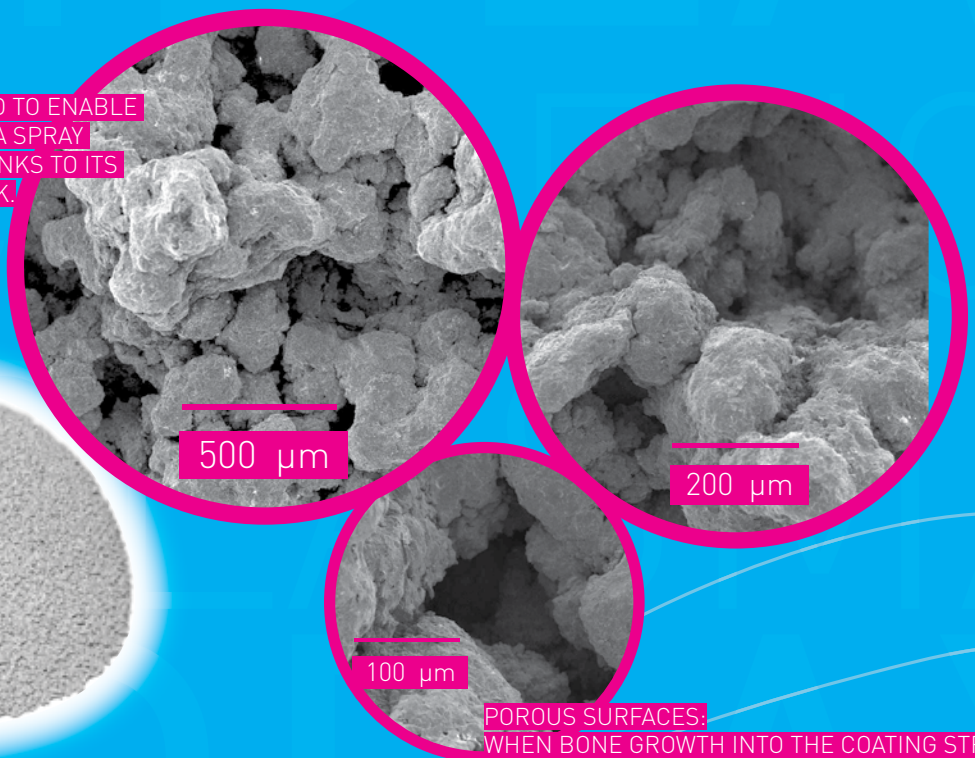
Ti-Growth®

Ti-Growth® THE FASTEST AND EASIEST PROCESS TO ACHIEVE LARGE PORE NETWORKS ON PROSTHESES.

Ti-Growth® WAS DESIGNED TO ENABLE POROUS TITANIUM PLASMA SPRAY FOR BONE INGROWTH THANKS TO ITS EXTENSIVE PORE NETWORK.





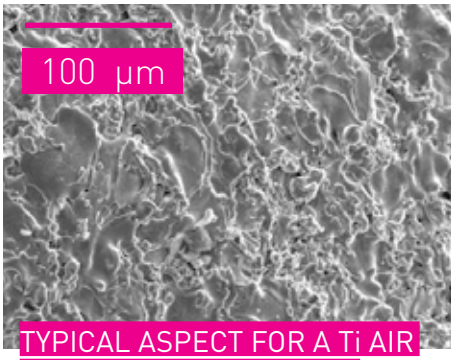
POROUS SURFACES:
WHEN BONE GROWTH INTO THE COATING STRUCTURE IS DESIRED (BONE INGROWTH) A LARGER SIZE INTERCONNECTED POROUS NETWORK IT IS NECESSARY.

Ti-Growth® is the first titanium sponge applicable to prostheses made with thermal spray technology. It consists in 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 800 microns.

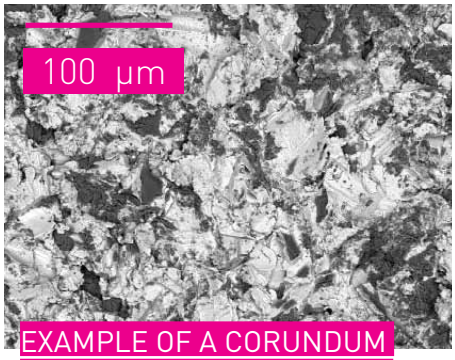
STATE OF THE ART

ROUGH TITANIUM SURFACES

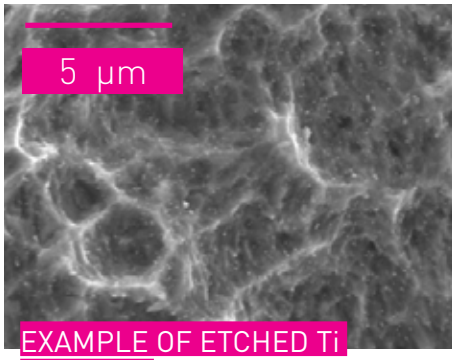
Conventional cement-less endosseous prostheses are generally made of titanium alloys and are supplied with a surface roughened by sandblasting, plasma spray coating, etching etc. These surfaces, while fully biocompatible, allow prosthesis fixation by bone apposition (ongrowth) only.



TYPICAL ASPECT FOR A Ti AIR PLASMA SPRAY COATING.



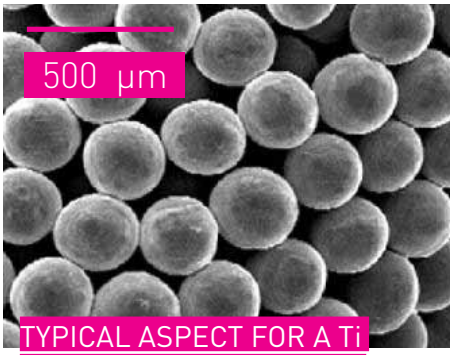
EXAMPLE OF A CORUNDUM SANDBLASTED Ti SURFACE.



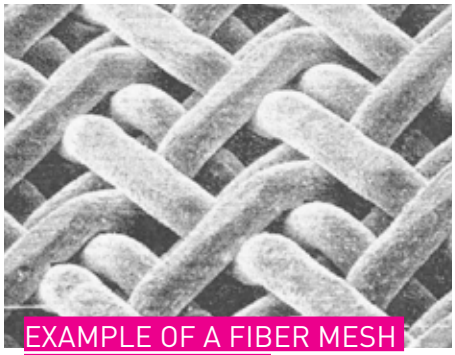
EXAMPLE OF ETCHED Ti SURFACE.

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]

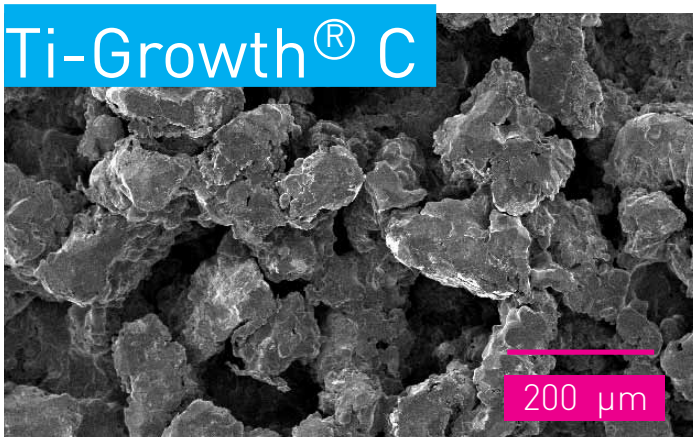
THE INNOVATION

Ti-Growth® COATINGS

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

Ti-Growth® V

Ti-Growth® C

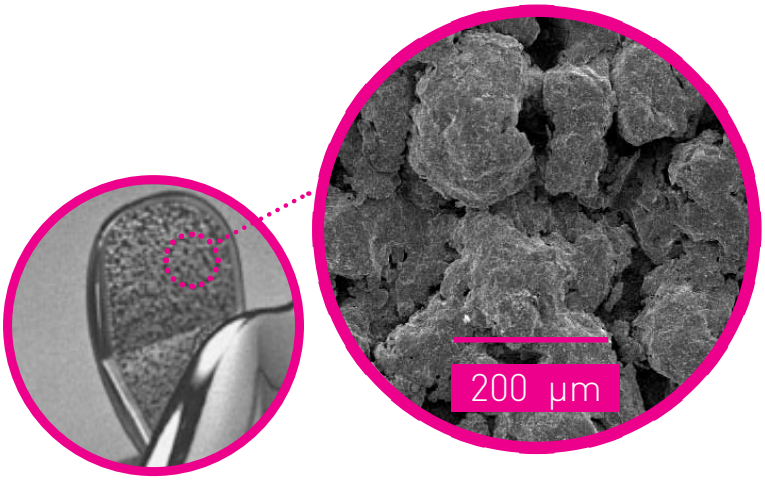


Ti-Growth® consists in a series of open and interconnected large size pores arranged in a titanium matrix, a sort of titanium sponge applied on the pieces by Plasma Spray.

Ti-Growth® can be applied to substrate at low temperature, this reflects in a clear benefit for the mechanical performances of the system and enables polymer masking to protect the parts from the coating process.

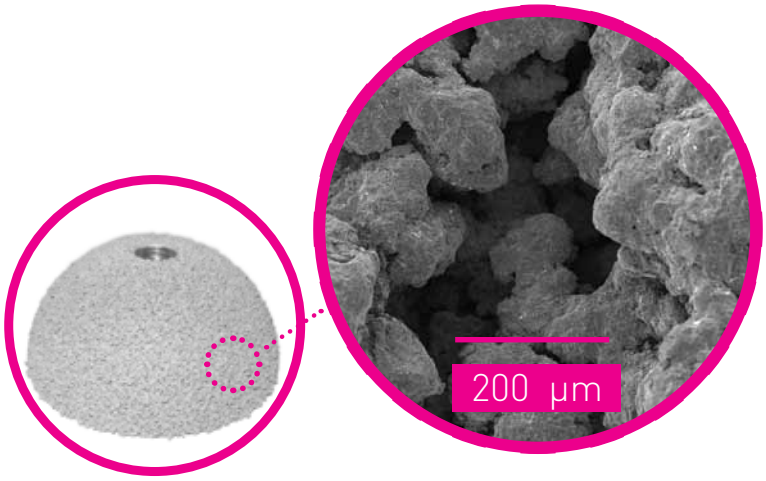
Ti-Growth®: A NEW TYPE OF TITANIUM PLASMA SPRAY COATING

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 costs benefits ratio. The peculiarity of Ti-Growth® 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 Ti-Growth® C POROUS COATING.

The porosity profile of Ti-Growth® 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.



EXAMPLE OF Ti-Growth® V POROUS COATING.

Advances in process control have enabled the application of thick coatings (up to 1000 µm), which allows for high and interconnecting porosity that are suitable for joint replacement components.

- Ti-Growth® shows increased grip at the interface with host bone.
- Ti-Growth® can be supplied in thicker layers than conventional coatings with cohesion and adhesion strength within applicable norms requirements. The thickness of the coating determines the predictable amount of pore size, volume, and overall porosity that can be achieved.
- Ti-Growth® is the easiest way for manufacturing macroporous structures.
  Applied through a Plasma Spray process it allows for greater overall output, which in turn gives a prostheses manufacturer more flexibility on delivery times and overall cost.
- Ti-Growth® coating is commercially available both in Europe and US. It is currently in clinical application associated to femoral stems and acetabular cups.

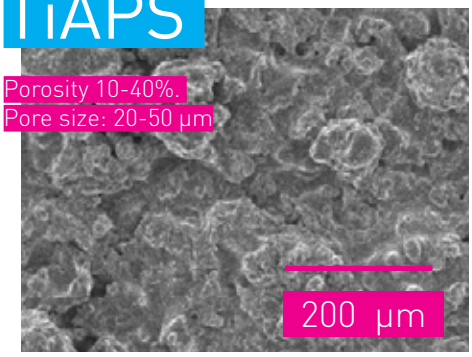
Ti-Growth® topography description is performed through several different methods:

COMPARATIVE SEM IMAGES OF STANDARD APS AND VPS TITANIUM COATINGS vs. Ti-Growth® COATINGS

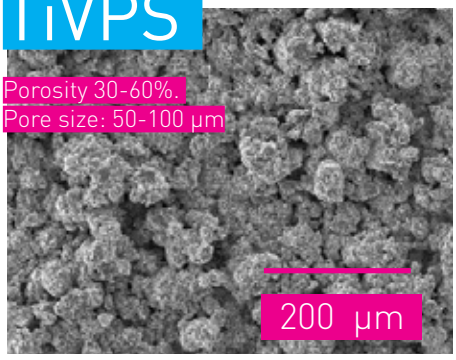
At SEM analysis, Ti-Growth® appears highly porous, with large, deep pores.

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

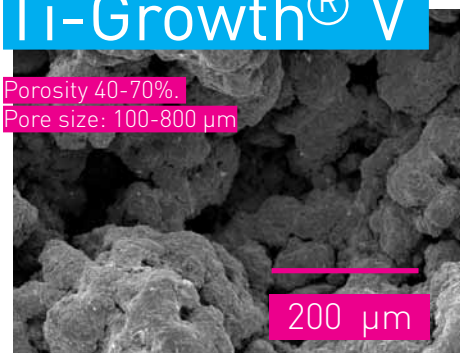
TiAPS



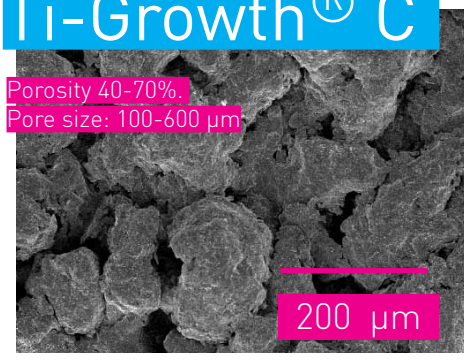
TiVPS



Ti-Growth® V



Ti-Growth® C



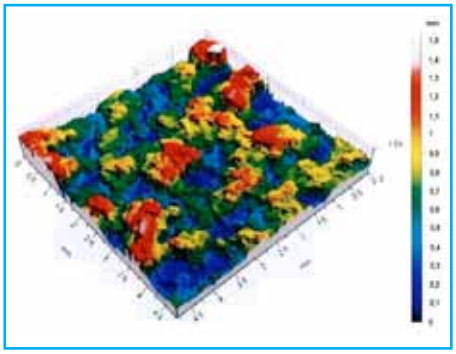
MORPHOLOGICAL CHARACTERIZATION OF THE Ti-Growth® COATINGS SURFACE AND SECTION

Tridimensional maps obtained by optical laser profilometry can be useful to quantitative describe Ti-Growth® surfaces.

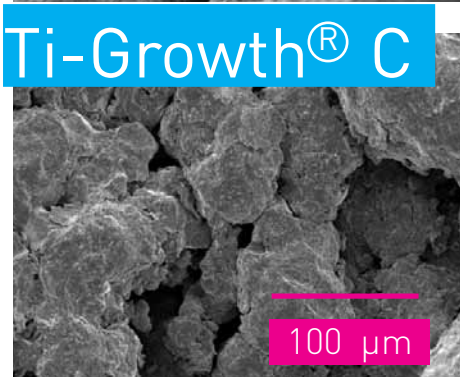
Bars with different colors highlight peaks to valleys distances. They are greatly superior when compared with conventional rough titanium surfaces.

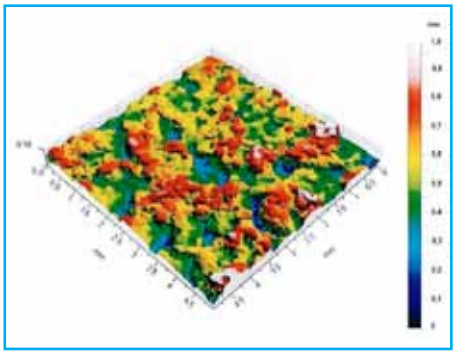
Peculiar topographic features of Ti-Growth® guarantee high friction levels at bone to implant interface.

Ti-Growth® V



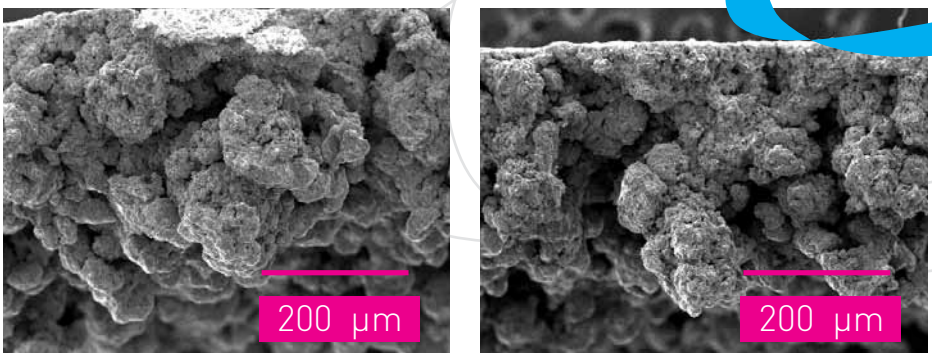
Ti-Growth® C





FRACTURE SECTION

The two images at the side were obtained using a specific procedure: substrate was eliminated and free-standing coating was fractured in order to analyze the structure in section. The substrate before its removal was on the top. Pores several hundreds of microns deep are visible.



METALLOGRAPHIC SECTIONS

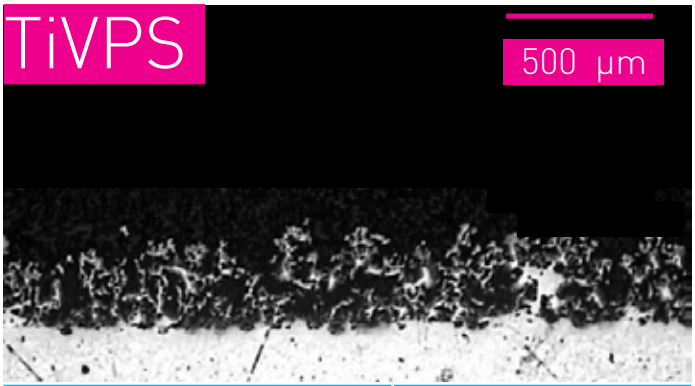
COMPARISON OF STANDARD APS AND VPS Ti-COATINGS vs. Ti-Growth® V AND Ti-Growth® C COATINGS

Micrography at same magnification highlight differences in thickness and porous size for Ti-Growth® coatings.

Ti-Growth® V

Thickness Advised	600 - 1100 µm
Adhesion Strength	35 MPa
Porosity	40 -70 %
Roughness (Rt)	700 µm

TiVPS



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

Ti-Growth® C

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

TiAPS

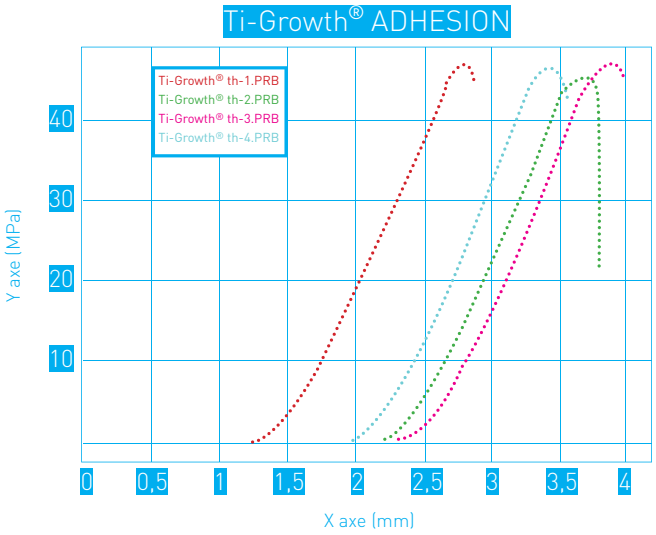
Thickness Advised	150 - 350 µm
Adhesion Strength	≥ 30 MPa
Porosity	20 - 40 %
Roughness (Rt)	90 - 170 µm

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

PHYSICAL AND MECHANICAL PROPERTIES

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

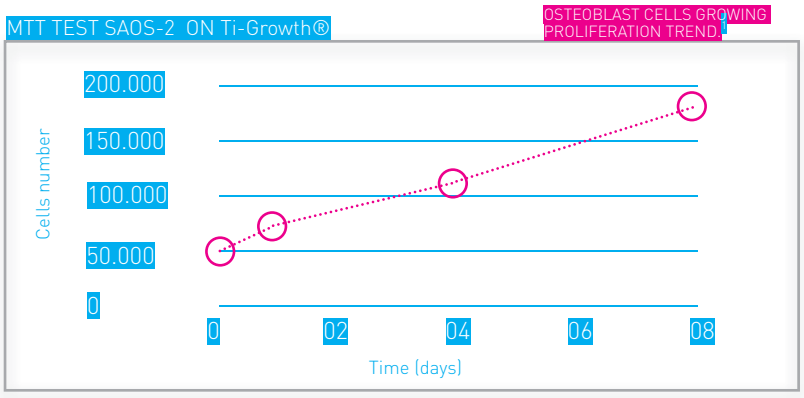
PROPERTY	FDA ACCEPTANCE	CONFORMITY	
		YES	NO
Shear Fatigue Strength at 1-10 MPa	> 10^7 cycles	X	
Shear Static Strength (MPa)	> 20	X	
Static Tensile Strength (MPa)	> 22	X	
Abrasion resistance (mg)	< 65	X	



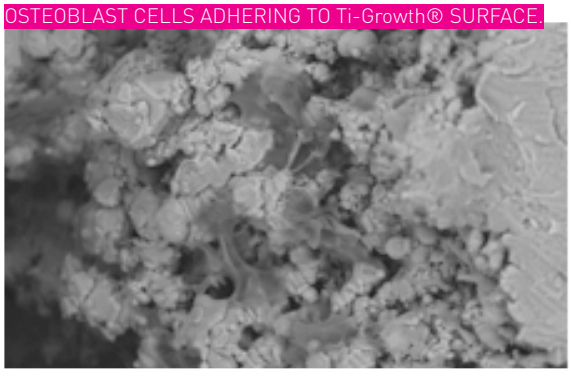
EXAMPLES OF ADHESION STRENGTH DETECTED ON COUPONS COATED WITH TI-GROWTH® V AND TESTED ACCORDING TO ASTM F 1147.

BIOLOGICAL PERFORMANCES

Ti-Growth® was biologically tested showing excellent biocompatibility performances.



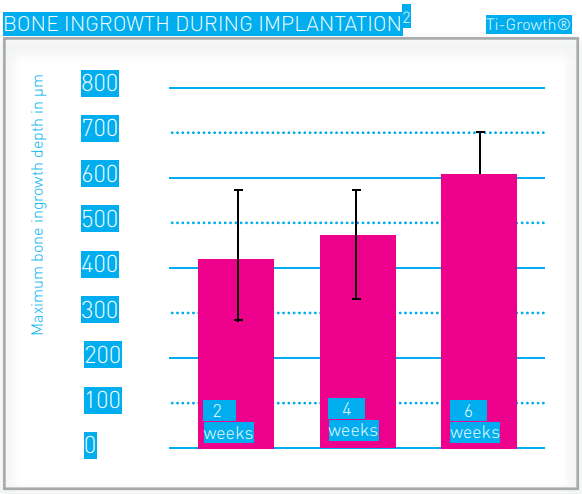
OSTEOBLAST CELLS ADHERING TO Ti-Growth® SURFACE.



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

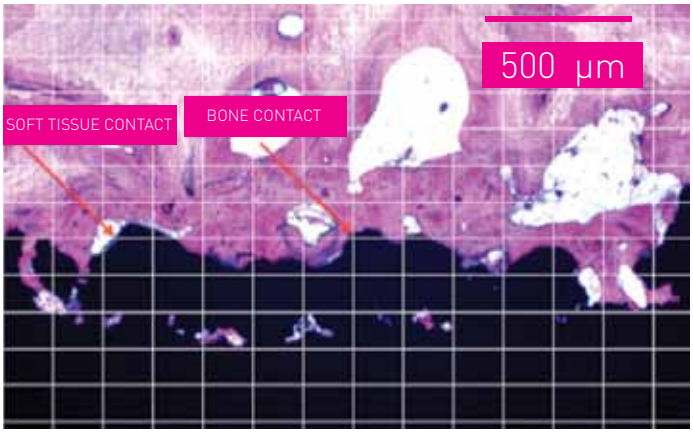
In vivo assays were performed during the research activity.[2,7,8]
In large animal models Ti-Growth® was shown as being able to promote deep bone ingrowth.
Whereas conventional small pore size Ti coatings permit bone ongrowth only.

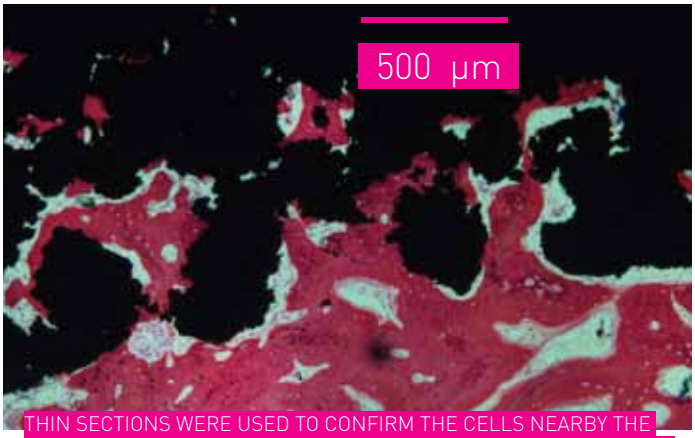
BONE INGROWTH DURING IMPLANTATION[2]



XRAY IMAGE OF SPECIMEN USED IN THE ANIMAL STUDY. Ti-GROWTH® COATING APPLIED TO TOP AND BOTTOM SURFACES.

Histology observations after 4, 6 and 8 weeks 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 debries around implanted specimens were detected.



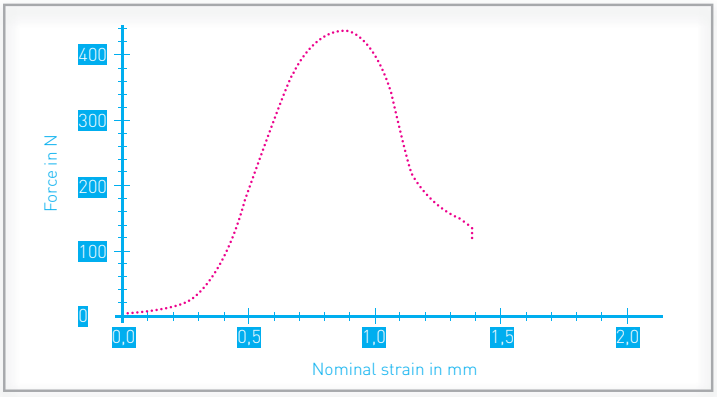


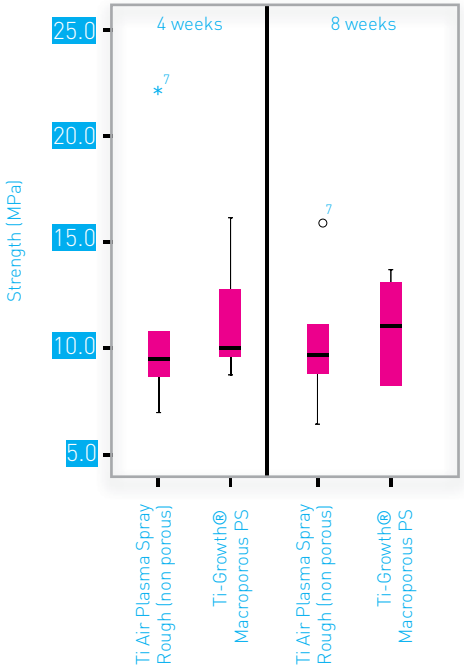
THIN SECTIONS WERE USED TO CONFIRM THE CELLS NEARBY THE SPECIMENS SURFACE WERE OSTEOCYTES AND THE HIGH DENSITY IS NORMAL IN RAPID GROWING NEW BONE.[7,8]

BIOMECHANICAL ASSAY

Bone ingrowth helps device fixation in the hosting site.

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





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8. **In-vivo assessment of the ingrowth potential of engineered surface topographies produced by innovative powder metallurgy;** A.Goodship[a], G.Blunn[a], E. Preve[b], L. Facchini[b], F. Bucciotti[b] and P. Robotti[b]; [a] *Institute of Orthopaedics and Musculoskeletal Science*, UCL, *Royal National Orthopaedic Hospital, Stanmore, UK;*[b] *Eurocoating S.p.A., Pergine Valsugana, Italy.* 9th World Biomaterials Congress, 1st – 5th June 2012, Chengdu, China.

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