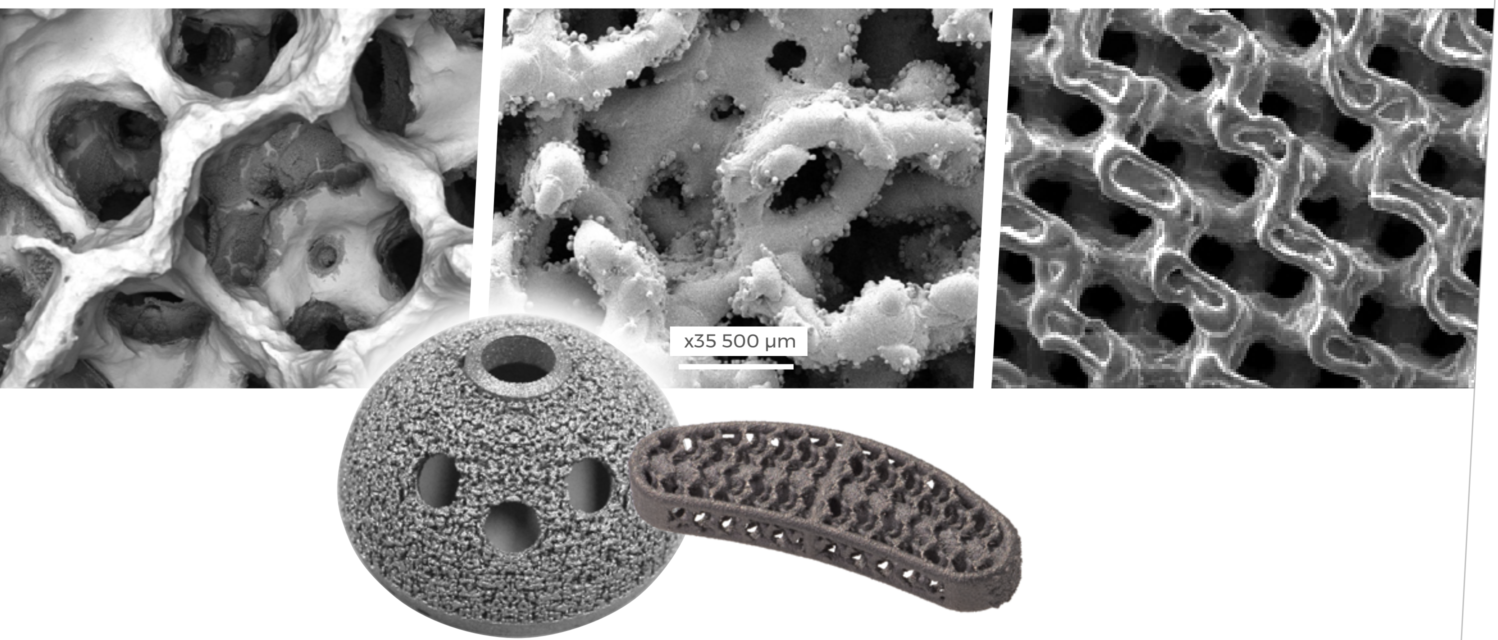
Lincotek

Medical

Additive Manufacturing

Long-term specialist expertise in manufacturing implantable devices



Using two of the most intriguing Additive Manufacturing (AM) processes available on the market: Electron Beam Melting (EBM) and Direct Metal Laser Sintering (DMLS).

Maximum design freedom.

Complex geometry and intricately shaped devices become an invaluable alternative for designers and end users. The design is extended to surface porous network details. The elastic modulus of devices can be tailor-made by engineering specific porous structures.

One-step manufacturing.

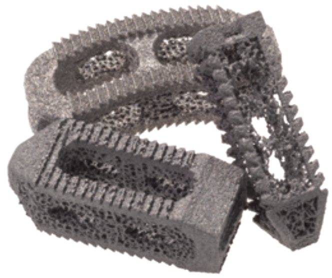
Porous structures are built up together with devices' solid parts. Parts delivered may be ready-to-use for implantation or require additional finishing steps such as post-machining, lapping etc, according to final requirements.

Development acceleration.

In R&D phases, AM technology allows for testing of real pieces as well as serial production cost evaluation. Design changes can be made simply by re-engineering CAD files.

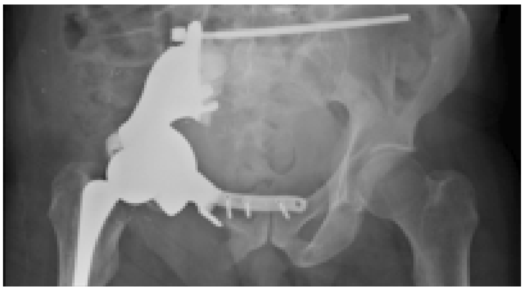
Maximum manufacturing flexibility.

Once the design has been agreed on, the manufacturing of implantable parts can begin. From custom-made to small size batches or even serial mass production: a miscellaneous range of items can be ready in just a few working days by using AM technology.



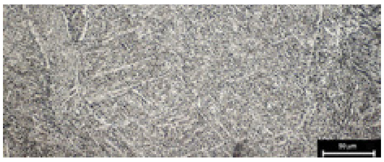
Real production.

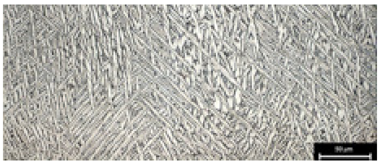
AM technology is currently used for manufacturing both standard and custom-made medical devices to be clinically implanted.



Bulk material properties.

Implantable-grade Titanium and Titanium alloy (Ti6Al4V). Chemical and Mechanical properties comply with ISO and ASTM Standards.
Mechanical Properties of the Bulk Materials are comparable to those resulting from standard manufacturing process i.e. forging and casting.



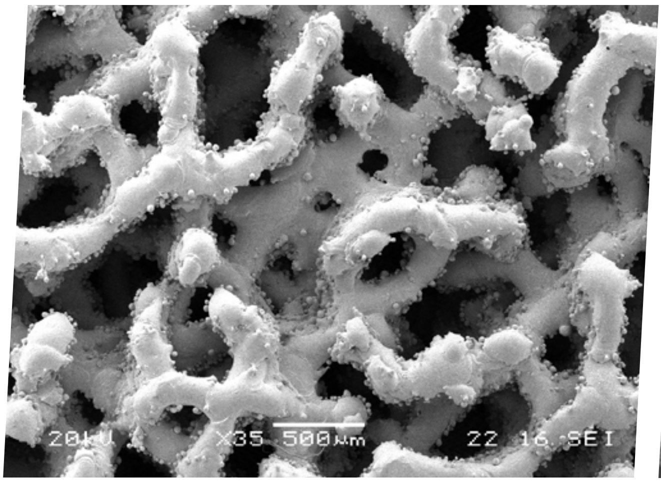


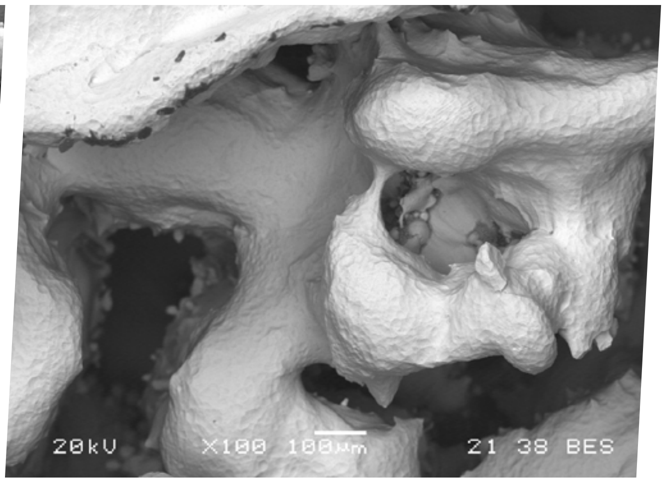
	Ti6Al4V EBM	Ti6Al4V Laser	ASTM F136
E (MPa)	118 ± 5	111 ± 1	N.Ap. (104 ± 2*)
UTS (MPa)	914 ± 10	1073 ± 4	> 860
ΔL (%)	13,1 ± 0,4	12,0 ± 0,2	> 10
Alternate Bending Fatigue limit @2*10^6 cycles (MPa)	441 ± 42	440 ± 53	N.Ap. (445 ± 7*)

[1] Reference: specimens from bar wrought and annealed

Component and Porous structure design

From geometrically complex components to lattice structures, with the specific porosity you have in mind. Alternatively you can choose one of our ready-to-use porous structures (FDA or CE cleared)





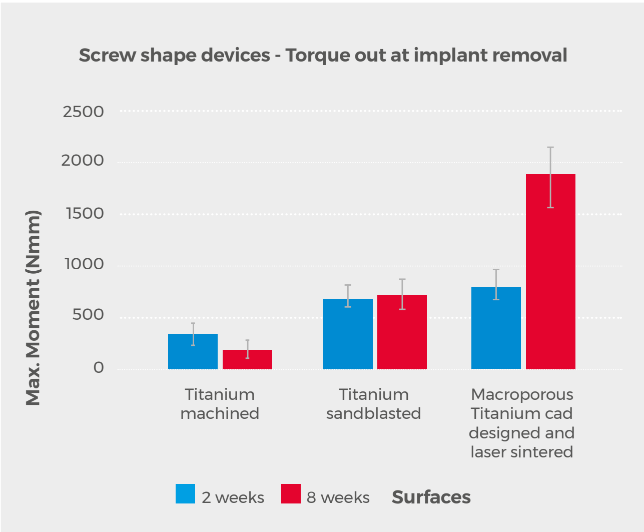
Biological porous structures characterization.

For properly designed and manufactured porous structures, in vivo tests have shown:

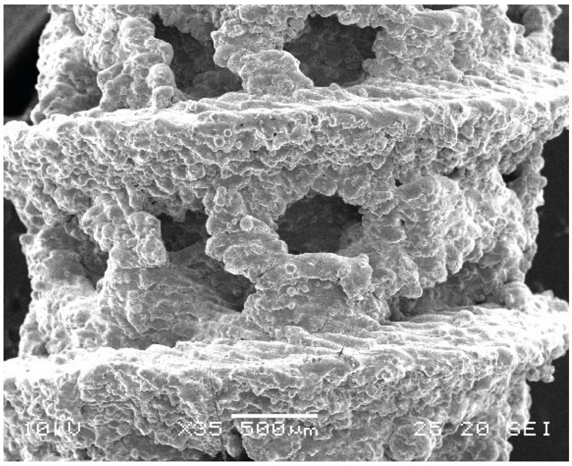
- bone ingrowth into AM lattice structures
- healthy bone near the implants
- improved implant fixation strength

Implantation study performed in sheep pelvis with Ti alloy Laser sintered samples

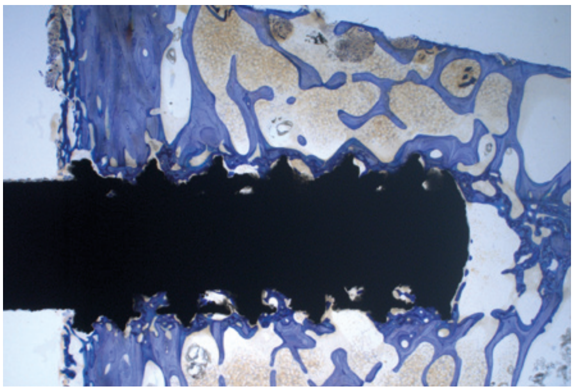
Fixation strength significantly increased 8 weeks after implantation



SEM PICTURE OF A LASER SINTERED TITANIUM POROUS STRUCTURE TESTED

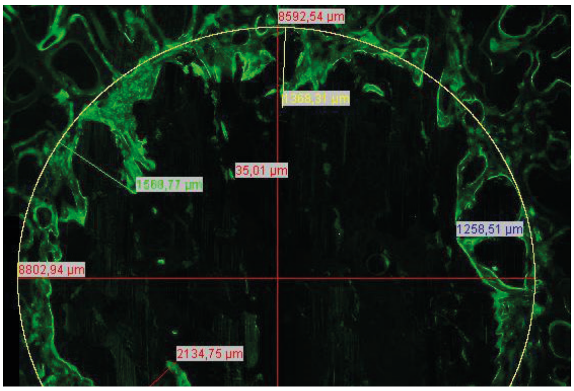


IMPLANTATION STUDY PERFORMED IN SHEEP PELVIS WITH TI ALLOY LASER SINTERED SAMPLES



Histological evaluation after 8 weeks of implantation showed the ingrowth of the new bone into the laser sintered titanium porous structure.

IMPLANTATION STUDY PERFORMED IN SHEEP CONDYLES WITH TI ALLOY EBM SINTERED SAMPLES

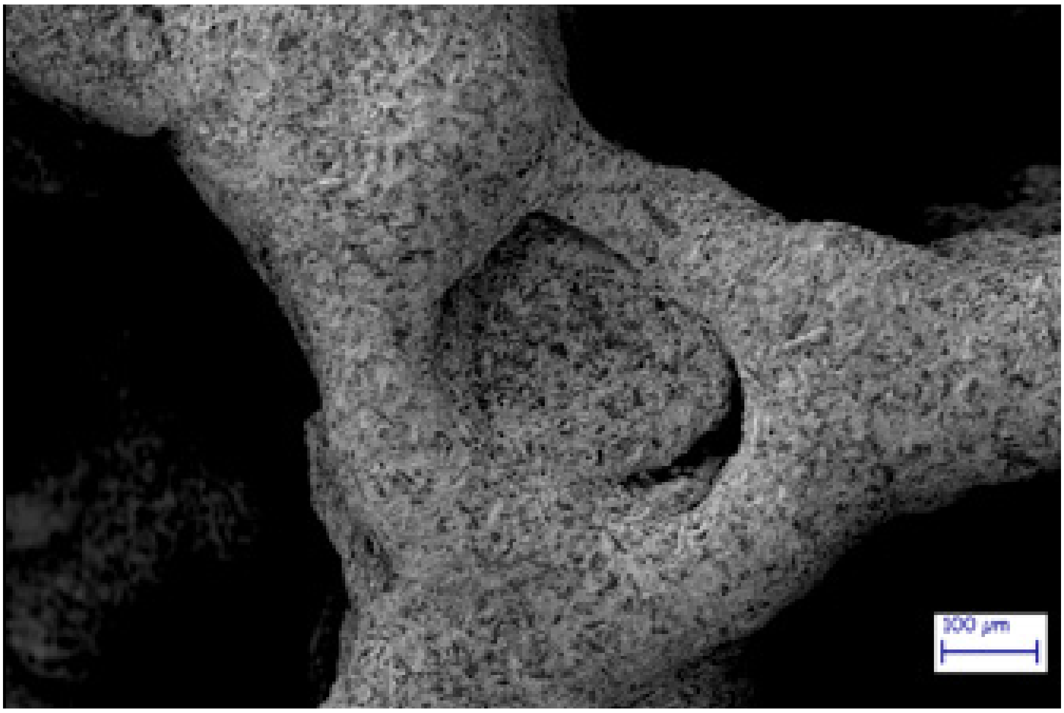


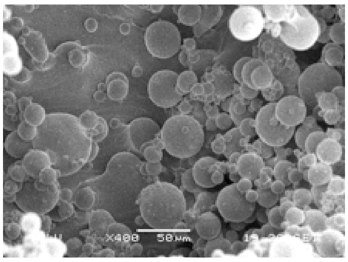
Fluorochrome picture after 6 weeks of implantation: white ring surgery cut; black titanium porous specimen; green new bone formed into specimen porous structure.

Additive Manufacturing complementary services.

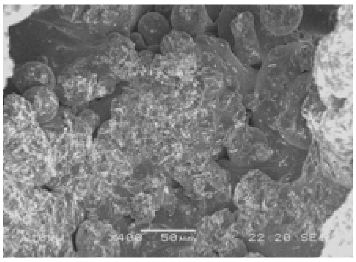
Cleaning

Post treatment processes may be further applied to manufactured 3D metal networks with the aim of modifying the native surface of struts. In porous structures, additional treatments can be used to change the metal surface morphology inside pores.

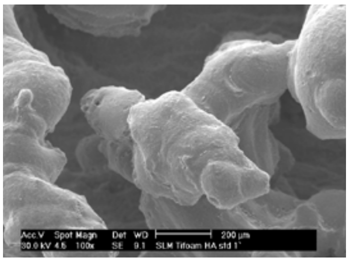




NATIVE ADDITIVE MANUFACTURED SURFACE



ADDITIVE MANUFACTURED SURFACE AFTER SANDBLASTING



ADDITIVE MANUFACTURED SURFACE AFTER ETCHING

Post-processing

Vacuum Thermal Treatment

Machining

Polishing

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Medical

Bibliography

1. **Microstructural and mechanical characterization of Ti-6Al-4V biomedical components produced by ebeam.** L. Facchini, E. Magalini, P. Robotti, A. Molinari; 21st European Conference on Biomaterials, 09-13th September, 2007, Brighton, UK.

2. **Possibility to use rapid manufacturing technology in the medical devices market: free geometry and intrinsic surface roughness.** E. Magalini, P. Robotti; Rapid Implant Manufacturing Forum; Leuven, Belgium, September 12, 2007.

3. **Mechanical and microstructural characterization of ASTM f75 alloy produced by Laser Melting.** L. Facchini et al.; 16th Congress European Society of Biomechanics, Lucerne (Switzerland), July 6th – 9th, 2008.

4. **Mechanical properties and microstructural features of biomedical components produced by ebeam melting of CoCrMo powder** L. Facchini, E. Magalini, P. Robotti, A. Molinari; World Congress on Powder Metallurgy & Particulate Materials – June 8-12, 2008 – Washington, D.C. (USA).

5. **In vitro and in vivo biological characterization on specimens made by SLM and EBM.** E. Magalini, P. Robotti, E. Biemond, P. Buma; Rapid Implant Manufacturing Forum; Schamburg- IL- USA; May 13, 2009.

6. **Complete coverage of Porous Substrate by Electrochemically Deposited Calcium Phosphate Coatings** D. Tonini et al.; 22nd European Conference on Biomaterials, 08-12th September, 2009, Lausanne, CH.

7. **Frictional and bone ingrowth properties of engineered surface topographies produced by E-beam technology.** J. E. Biemond, R. Aquarius, N. Verdonschot, P. Buma; Arch Orthop Trauma Surg (2011) 131:711–718.

8. **Ductility of a Ti-6Al-4V alloy produced by selective laser melting of prealloyed powders.** L. Facchini, S. Hoeges, E. Magalini, P. Robotti, K. Wissenbach, A. Molinari; Rapid Prototyping Journal, 16/6 (2010) 450–459.

9. **Assesment of bone ingrowth potential of biomimetic hydroxyapatite and brushite coated porous E-beam structures.** J.E. Biemond, T.S. Eufrasio, G. Hannink, N. Verdonschot, P. Buma; J Mater Sci: Mater Med (2011) 22:917–925.

10. **Metastable Austenite in 17-4 Precipitation-Hardening Stainless Steel Produced by Selective Laser Melting.** L. Facchini et al.; Advanced Engineering Materials, 2010, Volume 12, Issue 3, Pages 184 -188.

11. **Microstructure and mechanical properties of Ti-6Al-4V produced by electron beam melting of pre-alloyed powders.** L. Facchini et al; Rapid Prototyping Journal, 2009, Volume 15, Issue 3, Pages 171-178.

12. **The effect of E-beam engineered surface structures on proliferation and differentiation of hMSCs.** J.E. Biemond1, M. Giele, G. Hannink, N. Verdonschot, P. Buma; ORS 2010: Orthopaedic Research Society, 6-9 March, New Orleans - Louisiana, USA.

13. **In vivo assessment of bone ingrowth potential of 3-dimensional E-beam produced implant surfaces and the effect of additional treatment by acid-etching and hydroxyapatite coating.** JE Biemond, G Hannink, AMG Jurrius, N Verdonschot, P Buma; J Biomater Appl J Biomater Appl March 2012 vol. 26 no. 7 861-875.

14. **The effect of bone ingrowth depth on the tensile and shear strength of the implant bone interface.** M. Tarala, D. Waanders, J. E. Biemond, D. Janssen, N. Verdonschot; ORS 2011: Orthopaedic Research Society, 13-16 January, Long Beach-CAL-USA.

15. **Macromanagement: Surface Manufacturing for Implants.** L. Glass and P. Robotti, Orthotec on line, (http://www.orthotec.com/article/surface-anufacturing-implants), Sept/October 2(4), 2011.

16. **Cotile Fixa TiPor: prime impressioni.** M. Schiraldi and G. Bonzanini, SPHERA medical journal, 2008, 7(8), p 23-24.

17. **Orthopedic Implants with Integrated, Designed Network Structures for Improved Osseointegration.** P. Cremascoli and P. Oldhin, European Cells and Materials, 2009, 17(1), p 7.

18. **Series production of CE-certified orthopaedic implants with integrated network structures for improved bone ingrowth.** P. Ohldin and P. Cremascoli; Innovative Developments in Design and Manufacturing, Advanced Research in Virtual and Rapid Prototyping, Proceedings, Oct. 2009, Leiria, Portugal, Eds. Catarina Sofia Gaspar da Silva et al, CRC Press, 2009.

19. **Additive manufacturing technologies for implants production.** E. Magalini; Implants, 12-13 May, 2011, Lyon - France.

20. **Bone colonization evaluation for EBM Additive Manufactured Ti porous structures.** P. Robotti, E. Magalini, M. Tarala, L. Biemond, N. Verdonschot, P. Buma; ISTA - International Society for Technology in Arthroplasty; September 20-23, 2011; Bruges, Belgium.

21. **Laser Additive Manufactured Ti6Al4V hemi-pelvis custom implant.** E. Magalini, P. Robotti, C. Gerrand; ISTA - International Society for Technology in Arthroplasty; September 20-23, 2011; Bruges, Belgium.

22. **Histological and biomechanical characterization for Laser additive manufactured titanium porous screws.** P.Robotti, S.Stübinger, I.Mosch, S.Ferguson, B. von Rechenberg; MTE – Material and Surface Technology for Implants – April 23-24, 2012 - Interlaken, Switzerland.