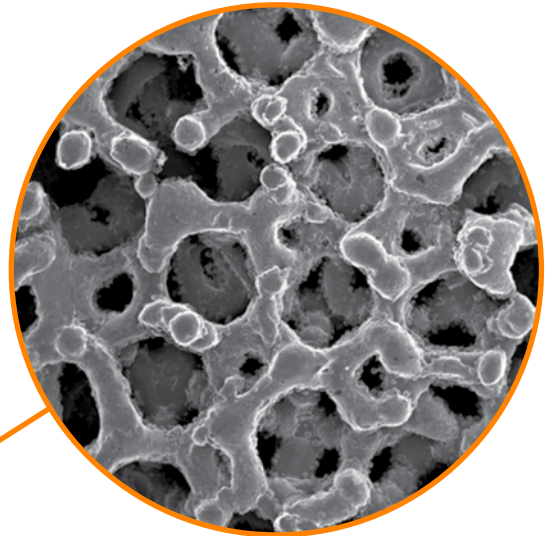
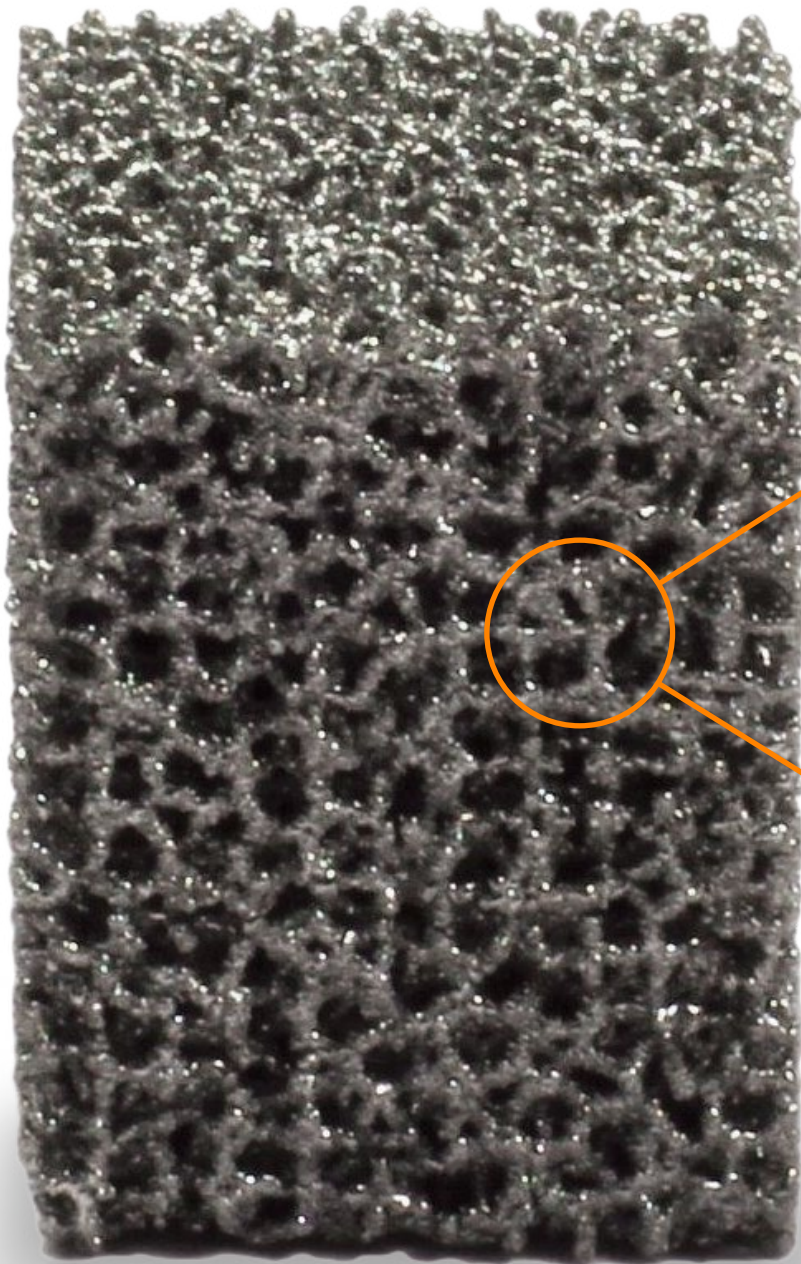
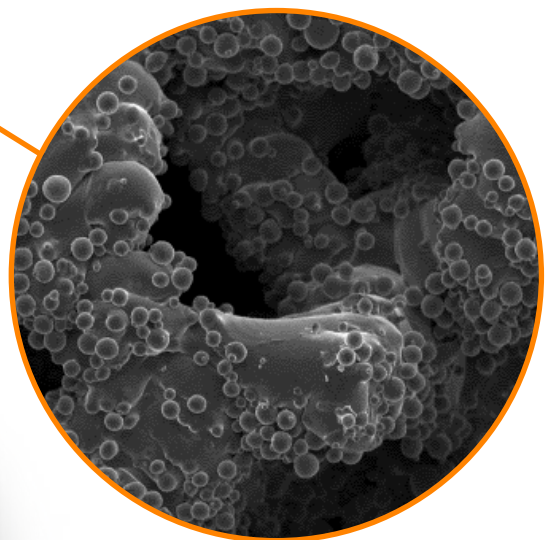


Material specifications



CONCELOC at 25x magnification



CONCELOC at 80x magnification

CONCELOC[◇]

Advanced Porous Titanium

Customized, patent pending porous structure technology

Through our pioneering approach to design, Smith & Nephew engineers have developed a patented method for creating a fully randomized porous structure with predictable porosity, pore size and node interconnectivity. Devices incorporating the patented CONCELOC Advanced Porous Titanium are created in a virtual environment and then fabricated at Smith & Nephew via additive manufacturing.



Design flexibility

Additive manufacturing (AM), commonly referred to as 3D printing, is a novel manufacturing method that involves the use of a laser or electron beam, for example, to sinter polymer or metal powders into a solid part that is built layer-by-layer. This unique fabrication method provides greater design flexibility compared to standard, subtractive manufacturing, i.e., machining. AM has also enabled Smith & Nephew to develop this custom porous structure for biological fixation combined with complex device geometries that would be difficult, expensive or impossible to attain through conventional fabrication methods. This design flexibility was leveraged to produce a roughened texture that is mapped onto the bone-interfacing surfaces of the virtual models to provide friction for enhanced initial stability. Furthermore, solid reinforcements can be added as an integral part of the porous structure where desired since both solid and porous features are fabricated layer-by-layer at the same time.

Material composition: Titanium Alloy (Ti-6Al-4V)

CONCELOC is made from Ti-6Al-4V and meets the ASTM and ISO standards for that alloy, which has been shown to be biocompatible¹ and has a good clinical history with over 40 years of use in medical devices.¹

Porosity: Up to 80%

CONCELOC Advanced Porous Titanium has an interconnected network of pores with a porosity of up to 80% in the near-surface regions, where the initial fixation will occur, and an overall porosity up to about 67%.²

Pore size: 202 μ m to 934 μ m

The literature suggests that pore sizes greater than about 100 μ m benefit biological fixation.^{3,4} CONCELOC Advanced Porous Titanium has an average pore size that ranges from 202 to 342 μ m overall and from 484 to 934 μ m at the surfaces of the porous structure.^{2,5}

Mechanical properties*

Compressive modulus (GPa)

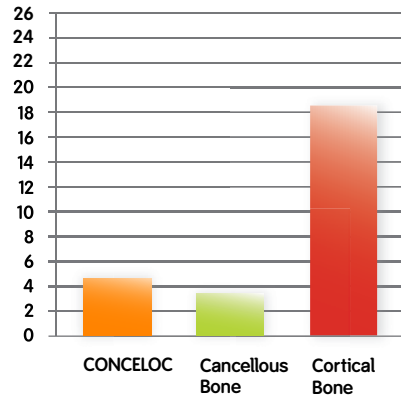


Figure 1: Plot illustrating the compressive modulus measured for the CONCELOEC⁶ Advanced Porous Technology⁶ compared to values reported for cancellous⁷ and cortical^{4,8} bone.

Compressive 2% yield strength (MPa)

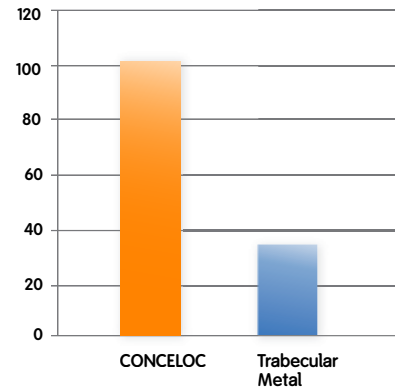


Figure 2: Plot illustrating the compressive yield strength of the CONCELOEC Advanced Porous Technology⁹ compared to that reported for Trabecular Metal.¹⁰

Compressive fatigue strength (MPa)

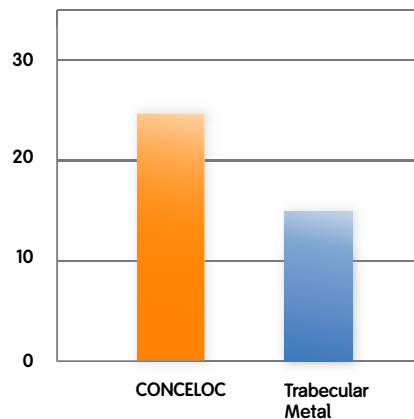


Figure 3: Plot illustrating the compressive fatigue strength of the CONCELOEC Advanced Porous Technology¹¹ compared to that reported for Trabecular Metal.¹⁰

Coefficient of friction

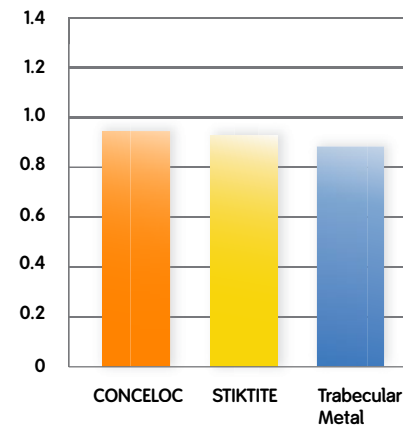


Figure 4: Plot illustrating the coefficient of friction of CONCELOEC Advanced Porous Technology¹² compared to that reported for STIKTITE¹² porous coating and Trabecular Metal.¹³

The CONCELOEC and STIKTITE porous structures were tested against 10 lb/ft³ (0.16 g/cm³) foam. The test method for these porous structures differed from that used for Trabecular Metal.

Material properties*

	CONCELOEC	STIKTITE	Trabecular Metal	Tritanium	Regenerex	Gription
Material	Titanium Alloy	Titanium Alloy	Tantalum ¹⁴	CP Titanium ¹⁵	Titanium Alloy ¹⁶	CP Titanium ¹⁷
Modulus of Elasticity	4.3 GPa ⁶	113 GPa ^{**18}	1.3-3.9 GPa ^{10,19}	113 GPa ^{**18}	1.9 GPa ¹⁶	113 GPa ^{**18}
Compressive 2% Yield Stress	101.2 MPa ⁹	N/A	36.9 MPa ¹⁰	N/A	N/A	N/A
Porosity	Up to 80% ²	62% ²⁰	80% ¹⁴	72% ²¹	67% ¹⁶	63% ²²
Pore Size (Ave)	202-934μm ^{2,5}	194μm ²⁰	430μm ¹³	311-546μm ²¹	100-600μm ¹⁶	300μm ²²
Coefficient of Friction	0.95 ¹²	0.93 ¹²	0.88 ¹³	1.01 ²¹	N/A	1.2 ¹⁷
Porous Matrix or Coating	Porous Matrix	Coating	Porous Matrix	Both	Both	Coating

* Data for competitive porous structures was obtained from the referenced literature with test methods that differ between porous structures. Data is tabulated for general comparisons only.

**Ti-6Al-4V substrate with coating.

References:

1. D.F. Williams, "Titanium and Titanium Alloys," in Biocompatibility of Clinical Implant Materials, D. F. Williams, Eds., Boca Raton, FL: CRC Press, Inc., 1981.
2. Smith & Nephew Research report. OR-14-091A.
3. J.D. Bobyn, R.M. Pilliar, H.U. Cameron and G.C. Weatherly, "The optimum pore size for the fixation of porous-surfaced metal implants by the ingrowth of bone," Clin Orthop Relat Res, 1980;150:263-270.
4. V. Karageorgiou and D. Kaplan, "Porosity of 3D biomaterial scaffolds and osteogenesis," Biomaterials, 2005;26(27):5474-5491.
5. Smith & Nephew Research report. OR-15-119.
6. Smith & Nephew Research report. OR-14-106.
7. E.F. Morgan and T.M. Keaveny, "Dependence of yield strain of human trabecular bone on anatomic site," J Biomech, 2001;34(5):569-577.
8. A.H. Burstein, D.T. Reilly and M. Martens, "Aging of bone tissue: mechanical properties," J Bone Joint Surg Am, 1976;58(1):82-86.
9. Smith & Nephew Research report. OR-15-114.
10. L.D. Zardiackas, D.E. Parsell, L.D. Dillon, D.W. Mitchell, L.A. Nunnery and R. Poggie, "Structure, metallurgy, and mechanical properties of a porous tantalum foam," J Biomed Mater Res B, 2001;58(2):180-187.
11. Smith & Nephew Research report. OR-15-022A.
12. Smith & Nephew Research report. OR-16-008.
13. J.D. Bobyn, S.A. Hacking, S.P. Chan, K.K. Toh, J.J. Krygier and M. Tanzer, "Characterization of a new porous tantalum biomaterial for reconstructive orthopaedics," AAOS, Anaheim, CA, Feb 4-7, 1999.
14. U.S. Food and Drug Administration, K032344, 2003.
15. Stryker website – <http://www.stryker.com/en-us/products/Orthopaedics/HipReplacement/Acetabular/TritaniumAcetabularShell/index.htm>. Last accessed: Aug 23, 2016
16. N. Bertollo, M. Matsubara, T. Shinoda, D. Chen, M. Kumar and W.R. Walsh, "Effect of surgical fit on integration of cancellous bone and implant cortical bone shear strength for a porous titanium," J Arthroplasty, 2011;26(7):1000-1007.
17. J.E. Minter, K. Rivard and B. Aboud, "Characterization of a new rougher porous coating for revision reconstructive surgery," Orthop Res Soc, San Francisco, CA, Mar 2-5, 2008, 1870.
18. R. Boyer, G. Welsch and E.W. Collings, Materials Properties Handbook: Titanium Alloys, Materials Park, OH: ASM International, 1994.
19. J.J. Krygier, J.D. Bobyn, R. Poggie and R. Cohen, "Mechanical characterization of a new porous tantalum biomaterial for orthopaedic reconstruction," SIROT, Sydney, Australia, 1999.
20. D.A. Heuer, "Structural comparison of advanced and conventional bone ingrowth technologies," Orthop Res Soc, Long Beach, CA, Jan 13-16, 2011, 1034.
21. "Tritanium primary acetabular shells," Stryker, 2008, SODTR-SS.
22. "Pinnacle Hip Solutions: Design Rationale," DePuy Orthopaedics, 2013, EO-129 (Rev 1).

Supporting healthcare professionals for over 150 years

Smith & Nephew, Inc.
1450 Brooks Road
Memphis, TN 38116
USA

www.smith-nephew.com

Telephone: 1-901-396-2121
Information: 1-800-821-5700
Orders and Inquiries: 1-800-238-7538