

Smith+Nephew

ENGAGE[◇]

Cementless Partial Knee System

Design Rationale



Smith+Nephew partial knee history

• 1974



• First commercially produced UNI knee replacement – The Marmor

• 80's



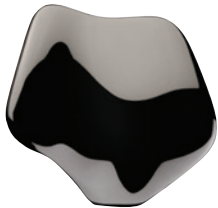
• Experience continued with the MOD I, II and III

• Early 90's



• GENESIS[®] UNI Knee System (ACCURIS)

• 2006



• JOURNEY[®] PFJ Patellofemoral Joint System

• 2008



• JOURNEY UNI Unicompartmental Knee System

• 2016



• Acquired Blue Belt/STRIDE[®] Unicompartmental Knee System in January

• 2019



• JOURNEY II UK Unicompartmental Knee System

• 2022



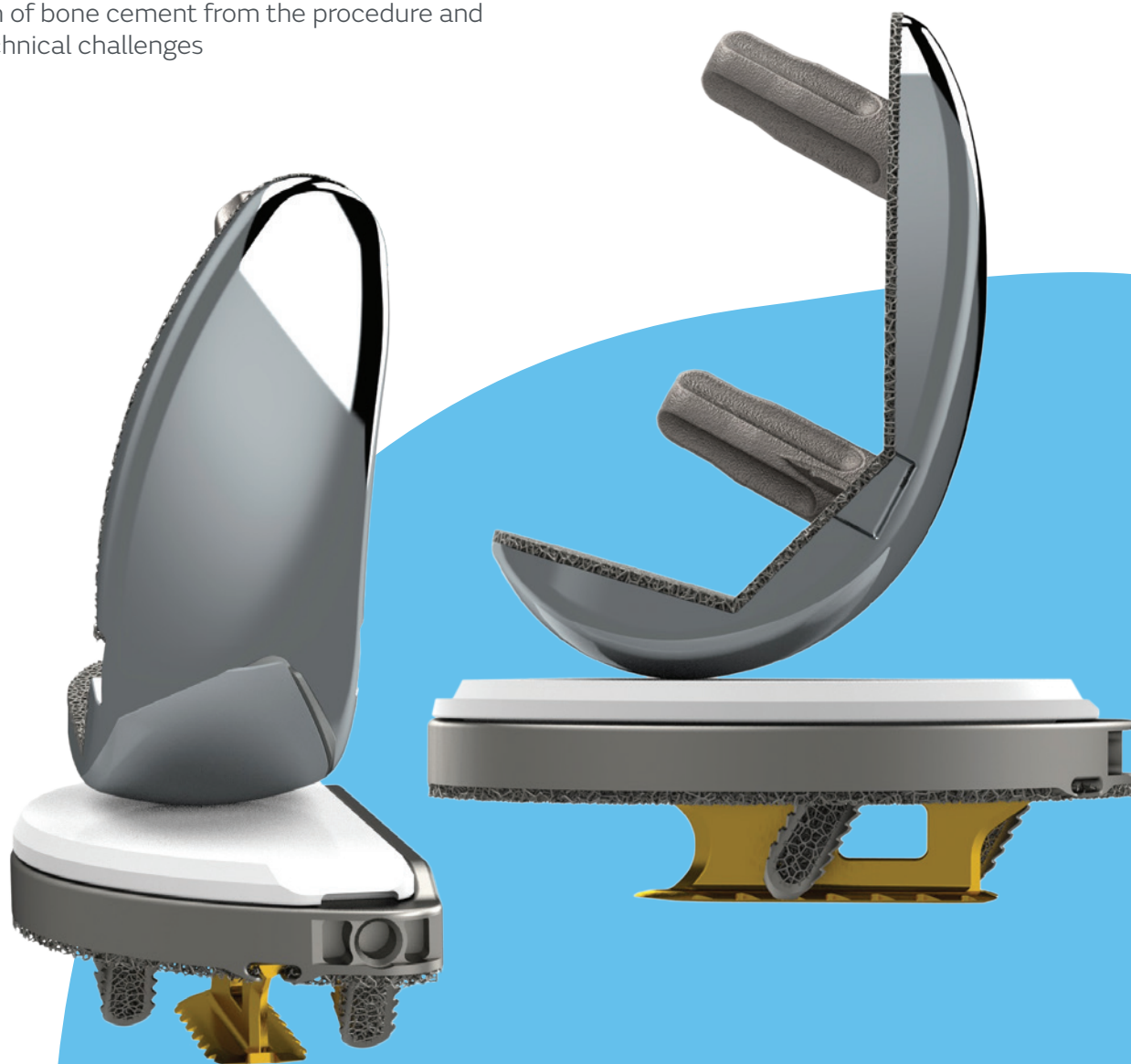
• Acquired ENGAGE[®] Cementless Partial Knee

Continuing Smith+Nephew's legacy with partial knees

The ENGAGE[®] Cementless Partial Knee continues the heritage of Smith+Nephew's long history with unicompartmental knees while also leveraging the latest advances in materials, manufacturing, and technology innovation.

ENGAGE Cementless adopts the most clinically successful features of previous designs to present a next-generation unicompartmental knee platform:

- Advanced 3D Printed porous in-growth surfaces for osseointegration
- ENGAGE Anchor Technology that provides stability and promotes compression¹
- Ligament-balancing technique
- Elimination of bone cement from the procedure and related technical challenges





These features combine to create a next generation joint preservation solution using disruptive technology in the treatment of medial compartment disease.

A cementless solution

The first generation of cementless implants were introduced in the 1970s in the pursuit for a more durable implant. Historically, greater patient activity level and/or heavier patients resulted in higher stresses being placed on conventional cemented implants that led to fixation failure and loosening.²

This issue was even more prevalent in partial knee replacement where the small relative surface area led to challenges achieving reliable fixation with traditional bone cement.^{3,4}

Removing cement from the procedure in favor of a more biologic fixation strategy was found to be the clinical solution. Osseointegration of the bone to the implant could reduce aseptic loosening offering an advantage over traditional cemented fixation.⁵ Building on the legacy of clinically successful fixed-bearing designs and introducing the latest technology in porous materials and tibial fixation, the ENGAGE^o Cementless was born.

Clinical advantages of cementless implants

- Shorter operating room time⁵
- Potential for life-long fixation through biologic interface⁶
- Eliminate loose cement fragments which can lead to 3rd body wear or need for re-operation to remove loose bodies⁷
- Eliminate tibial loosening due to cement failure
- Eliminate cement and accessories cost
- Reduced risk of fat embolism and other issues related to pressurization of cement⁸

A modernized implant leveraging a proven design philosophy

- Round-on-flat fixed bearing articulation
- Twin-peg femoral design
- Divergent posterior lug for posterior femoral compression and stability
- Ligament balancing in flexion/extension with 1mm increments on poly thicknesses



ENGAGE[◇] CONCELOC[◇] Advanced Porous Titanium

A patented, proprietary, 3D printed porous structure technology

Through our trusted innovation approach to design, Smith+Nephew's Advanced Porous Titanium involves a patented process to create a fully randomized porous structure with predictable porosity, pore size and node interconnectivity. Knee systems that incorporate CONCELOC[®] Advanced Porous Titanium are created in a virtual environment and then made via additive manufacturing. This technique allows design flexibility capable of producing a porous structure similar to cancellous bone.

Porosity: 74%⁹

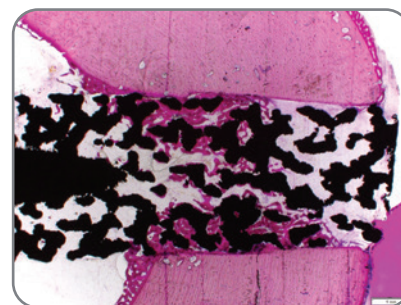
ENGAGE CONCELOC[®] Advanced Porous Titanium has an interconnected network of pores with an average porosity of 74% in the near-surface regions, where the initial fixation will occur.

Pore size: 537 +/- 65 μm ⁹

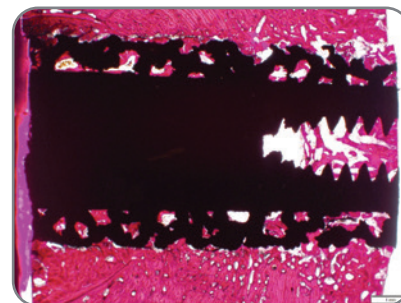
The literature suggests that pore sizes greater than 100 μm benefit biological fixation.¹⁰⁻¹²

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

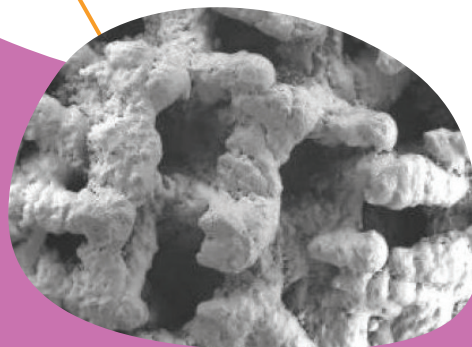
ENGAGE CONCELOC[®] Advanced Porous Titanium is made from Ti-6Al-4V which has a strong clinical history with over 40 years of use in medical devices.¹³



Histology image from 4-week sheep study of ENGAGE CONCELOC^{®14} Advanced Porous Titanium



Histology image from 12-week sheep study of ENGAGE CONCELOC^{®14} Advanced Porous Titanium



ENGAGE CONCELOC[®] Advanced Porous Titanium at 50x magnification

ENGAGE[◇] Anchor Technology

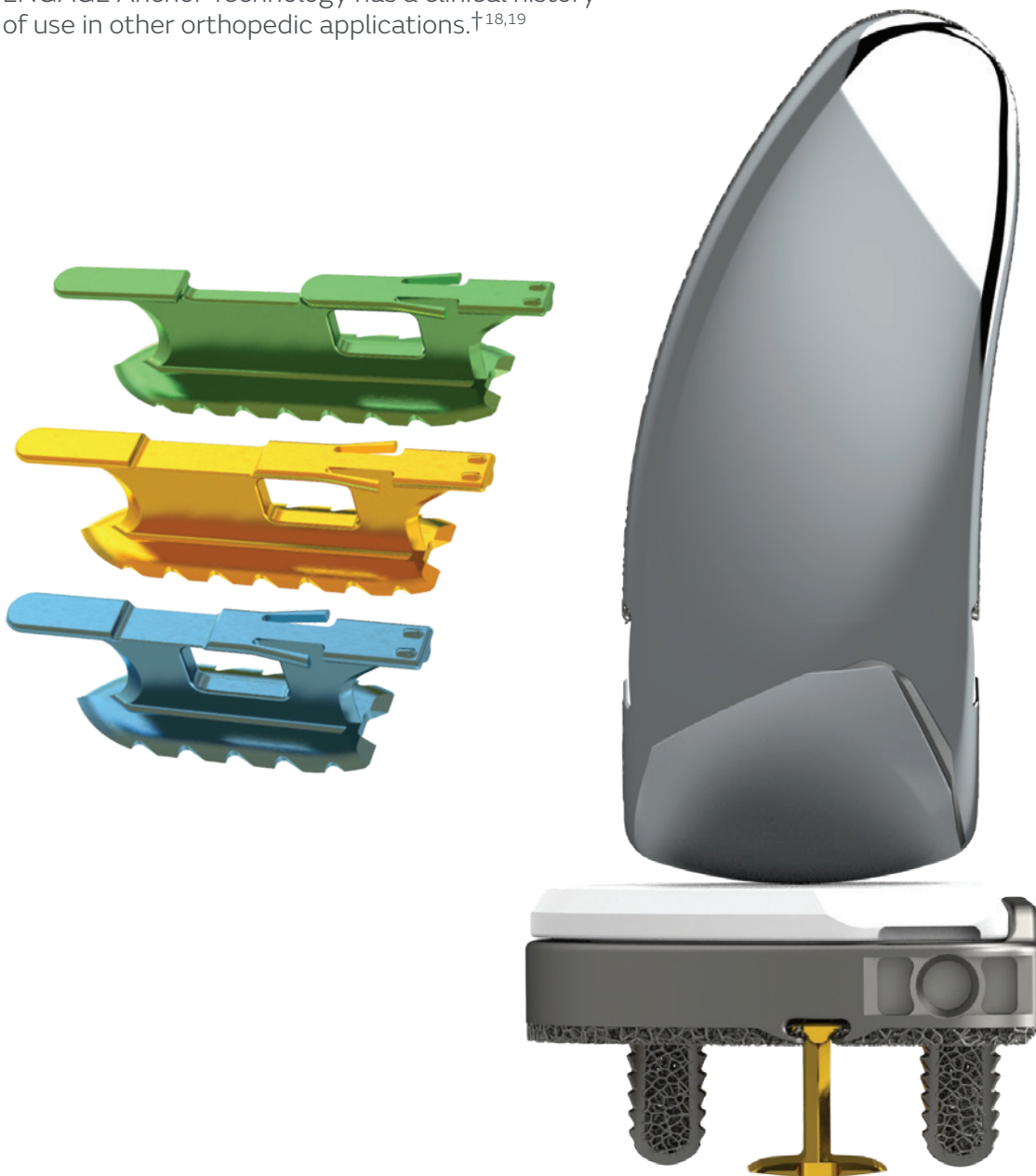
First and only system that uses a blade-based anchoring mechanism that creates a compressive force pulling the tray toward the tibia to promote stability¹

- The anchor is designed like an up-side-down airplane wing and instead of creating lift, it creates a downward force when driven into bone.
- Compressive force measured at 75lbs in benchtop testing¹

Improved initial fixation over porous keel competitor tray to minimize risk of post-operative loosening¹⁵

Greater construct strength due to more uniform loading in tibial bone compared to porous keel competitor^{16,17}

ENGAGE Anchor Technology has a clinical history of use in other orthopedic applications.^{†18,19}

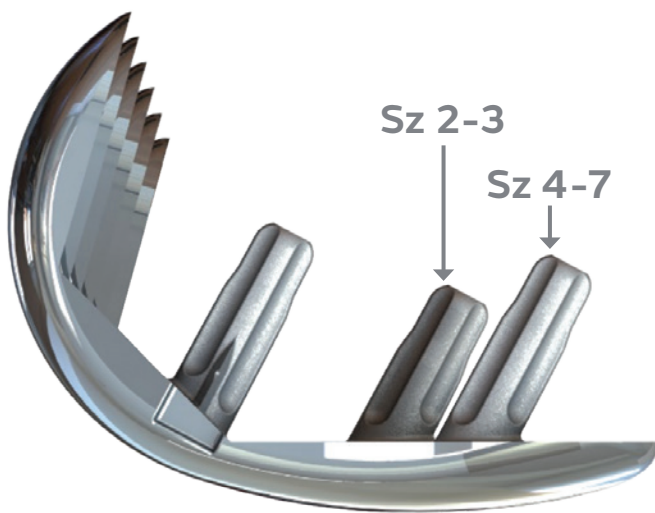


Scan here to see
ENGAGE product
animation

ENGAGE[◇] Porous Femoral

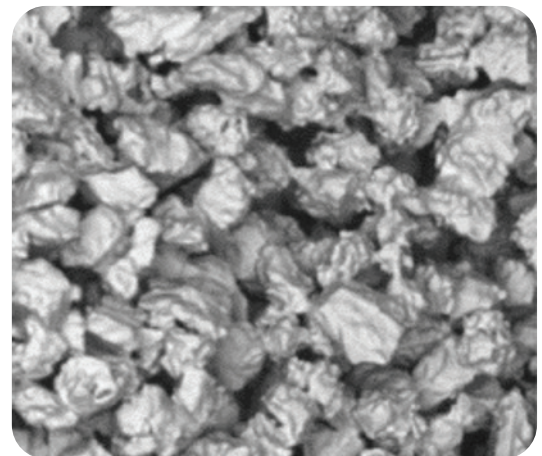
100% porous coated – coating all the way to the edge to maximize surface area for osseointegration to occur

- Coating – CoCr asymmetrical crushed bead
- Serrated fin for increased compression
- Stepped peg design for improved alignment and fixation
- Intraoperative down-sizing possible with common peg location.
- Condyle thickness is constant for all sizes : 7mm

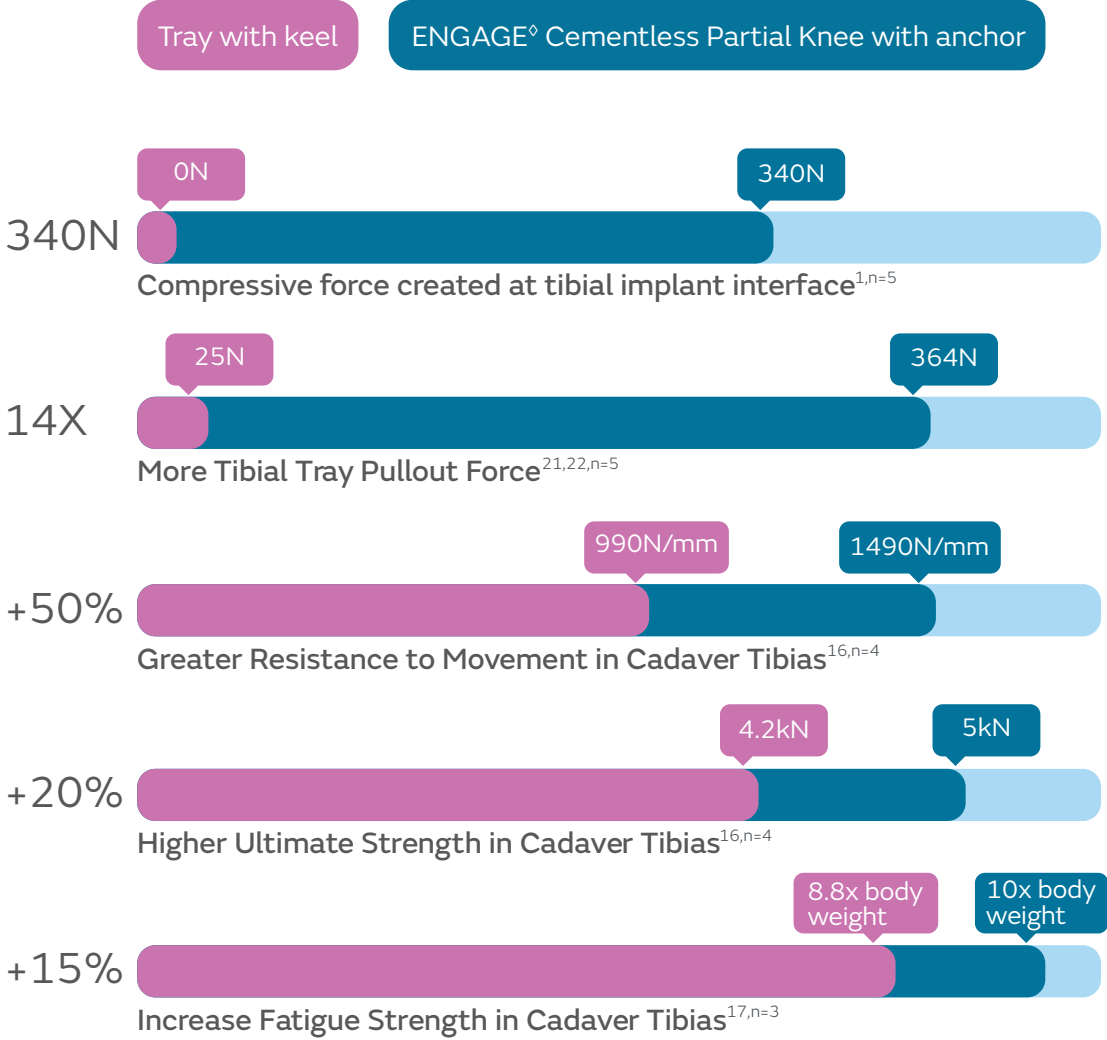


Porous Coating Geometry

- Coating thickness: 0.75mm
- 58% average porosity, 284+/-39 μm average pore size²⁰
- Peg Interference: 1.0mm



Performance data



Comparison of product performance of an ENGAGE tibial construct with tibial anchor to a traditional tibial tray utilizing keel fixation.

.....

Notes

*While the ENGAGE[®] CONCELOC[®] porous surface may be comparable in porosity and pore size range to the CONCELOC Advanced Porous Titanium surface in Smith+Nephew Cementless Total Knee and Revision Acetabular Systems, other technological and performance characteristics, including biomechanical properties, have not been evaluated for equivalence and may not be presumed comparable.

†The Anchor Technology of the ENGAGE Cementless Partial Knee System is contained within some spinal fixation devices. However, the clinical performance of the Anchor Technology in spinal implants is not predictive of its clinical performance in partial knee systems.

This design rationale is for informational and educational purposes only. It is not intended to serve as medical advice. It is the responsibility of treating physicians to determine and utilize the appropriate products and techniques according to their own clinical judgment for each of their patients.

For detailed product information, including indications for use, contraindications, effects, precautions and warnings, please consult the product's Instructions for Use (IFU) prior to use.

Products may not be available in all markets because product availability is subject to the regulatory and/or medical practices in individual markets. Please contact your Smith+Nephew representative or distributor if you have questions about the availability of Smith+Nephew products in your area.

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

www.smith-nephew.com
T: 1-901-396-2121
Orders and Inquiries:
1-800-238-7538

[®]Trademark of Smith+Nephew
All Trademarks acknowledged
©2022 Smith & Nephew, Inc.
37037 V1 09/22

References

1. ENGAGE 2019. Anchor Compression Test Report. 101-09912-004-01. **2.** Christensen DD, Klement MR, Moschetti WE, Fillingham YA. Current Evidence-based Indications for Modern Noncemented Total Knee Arthroplasty. *J Am Acad Orthop Surg.* 2020;28(20):823-829. **3.** Van der List JP, Sheng DL, Kleeblad LJ, Chawla H, Pearle AD. Outcome of cementless unicompartmental and total knee arthroplasty: A systematic review. *Knee.* 2017;24(3):497-507. **4.** Dervin GF, Carruthers C, Feibel RJ, et al. Initial Experience With the Oxford Unicompartmental Knee Arthroplasty. *J Arthroplasty.* 2011;26(2):192-197. **5.** Pandit H, Liddle AD, Kendrick BJL, et al. Improved Fixation in Cementless Unicompartmental Knee Replacement. *J Bone Joint Surg.* 2013;95(15):1365-1372. **6.** Behery OA, Clair AJ, Long WJ, Deshmukh A, Schwarzkopf R. Cementless primary total knee arthroplasty will this be the future? *Bull Hosp Jt Dis.* 2013;79(1):6-10. **7.** Hauptmann SM, Weber P, Glaser P, et al. Free Bone cement fragments after minimally invasive unicompartmental knee arthroplasty: an underappreciated problem. *Knee Surg Sports Traumatol Arthrosc.* 2008;16(8):770-775. **8.** Donaldson AJ, Harper NJ, Kenny NW, Thomson HE. Bone cement implantation syndrome. *Br J Anaesth.* 2009;102:12-22. **9.** ENGAGE 2019. Evaluation of Additively Manufactured Porous Surfaces Report. 101-09030-01. **10.** Kienapfel H, Sprey C, Wilke A, Griss P. Implant fixation by bone ingrowth. *J Arthroplasty.* 1999;14(3):355-368. **11.** Bobyn JD, Pilliar RM, Cameron HU, Weatherly GC. 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. **12.** Taniguchi N, Fujibayashi S, Takemoto M, et al. Effect of pore size on bone ingrowth into porous titanium implants fabricated by additive manufacturing: An in vivo experiment. *Materials Science and Engineering.* 2016:690-701. **13.** Sidambe A. Biocompatibility of Advanced Manufactured Titanium Implants-A Review. *Materials.* 2014;7(12):8168-8188. **14.** ENGAGE 2017. Evaluation of implant fixation in an ovine bone ingrowth model Report. NAV2017-1 (study image). **15.** ENGAGE 2019. Tibial Press-fit Fixation Analysis. 101-09036-01. **16.** ENGAGE 2018. Static Tibial Cadaver Strength Report. 101-09912-009-01. **17.** ENGAGE 2019. ENGAGE Unicompartmental Knee System Biomechanical Testing. 1906527.000_0138. **18.** Stryker 2016. Aero[®]-C Brochure. CVAER-BR-1_11106. **19.** Stryker 2015. LiTe[®] ALIF Brochure. TLAER-BR-2 SC/GS 10/15. **20.** ENGAGE 2019. Cobalt Chrome Asymmetrical Sintered Coating Test Summary. 101-09027-02. **21.** ENGAGE 2018. Anchor Fixation Report. 101-09912-001-01. **22.** ENGAGE 2019. Tibia Tray Holding Power on ENGAGE's Unicompartmental Knee System, Pullout Testing. 10-3182.