Smith+Nephew

LEGION◊ CONCELOC◊

Cementless Total Knee System

Design Rationale

Known throughout the industry for our trusted innovation,

Smith+Nephew now offers an advanced porous option paired with clinically proven implant designs

LEGION◊ Cementless Total Knee System offers the benefits of CONCELOC◊ technology paired with the confidence of using clinically successful implant designs. CONCELOC Advanced Porous Titanium is a 3D printed technology designed to mimic cancellous bone. LEGION implant designs have over 20 years of successful clinical history.[1-3] Together this combination offers a biologic knee solution unique to the industry.

Cementless knees - A resurgence in philosophy

The first generation of cementless implants were introduced in the 1970's in the pursuit for a more durable implant. Patients placed stress on the conventional cemented implant to bone interface which led to failure.[4] Removing cement from the equation was seen as a possible biologic solution. Osseointegration of the bone to the implant could reduce aseptic loosening offering an advantage over traditional cemented fixation.[4] However, not all industry cementless implant designs were successful[4], especially with the tibia.[4] Smith+Nephew has continued its legacy as the leader in trusted innovation to learn from and build on past designs, offering surgeons our latest in modern cementless knee technology for their patients.

Potential advantages of cementless implants

- Shorter operating room time[5]
- Potential for life-long fixation through biologic interface[6]
- Eliminate cement and accessories cost
- Preservation of bone stock in a revision scenario
- No possibility of cement fragments which can lead to 3rd body wear
- Reduced risk of fat embolism and other issues related to pressurization of cement[7]

The perfect blend between modern and proven technology

Smith+Nephew introduces an advanced porous knee solution that incorporates our clinically successful implant designs with CONCELOC◊ Advanced Porous Titanium. The end result is a device that surgeons can use to increase efficiency in the OR[5] while having the confidence they are using an implant design that provides the benefits of long-term survivorship and reproducible patient reported outcomes.[8-20]

CONCELOC◊ Advanced Porous Titanium

A patented, proprietary, 3D printed porous structure technology

Through our trusted innovation approach to design, Smith+Nephew has developed 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: 80%[21]

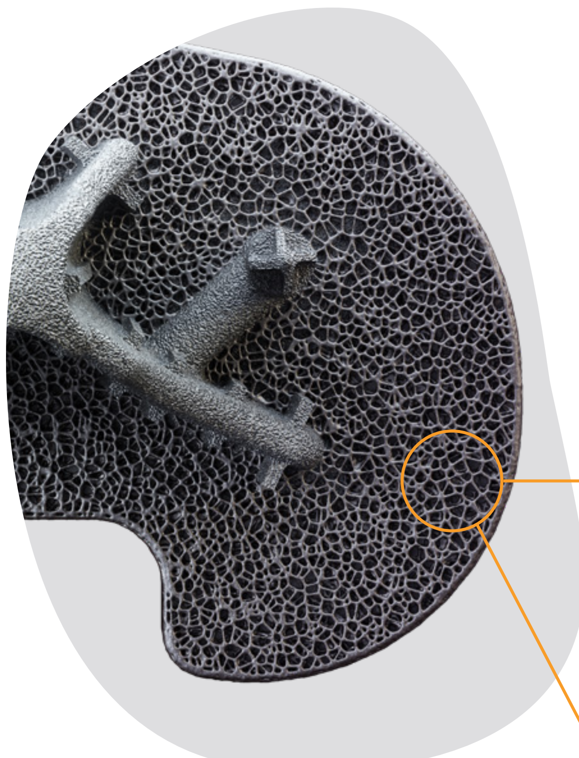
CONCELOC Advanced Porous Titanium has an interconnected network of pores with an average porosity of 80% in the near-surface regions, where the initial fixation will occur.

Pore size: 228µm to 633µm[22]

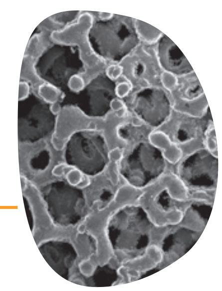
The literature suggests that pore sizes greater than 100µm benefit biological fixation.[23,24]

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

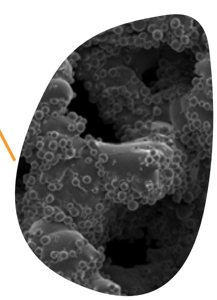
CONCELOC is made from Ti-6Al-4V which has a good clinical history with over 40 years of use in medical devices.[25]



Cancellous bone at 25x magnification



CONCELOC at 25x magnification



CONCELOC at 80x magnification

How It's Made

Scan here to see the LEGION◊ CONCELOC Manufacturing video

CONCELOC◊ Advanced Porous Titanium

Material properties*

	CONCELOC (S+N)	STIKTITE™ (S+N)	Trabecular Metal™ (ZB)	Tritanium™ (Stryker)	Regenerex™ (ZB)	Affixium™ (DePuy)
Material	**Titanium Alloy**	**CP Titanium**	**Tantalum**	**CP Titanium**	**Titanium Alloy**	**Titanium Alloy**
Porosity	80%[21]	62%[26]	80%[27]	72%[28]	67%[29]	56-67%[30]
Pore size (Ave)	228-633μm[22]	194μm[26]	430μm[27]	311-546μm[28]	100-600μm[30]	204-303μm[30]
Coefficient of friction	0.95[31]	0.93[31]	0.88[32]	1.01[28]	*Not available*	*Not available*

* 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.

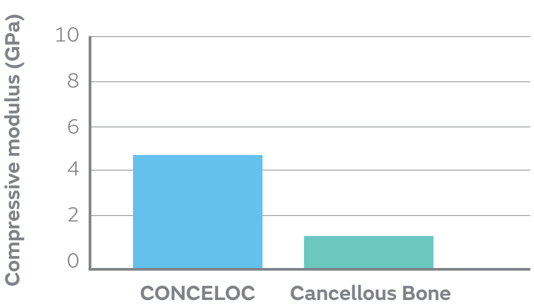


Figure 1: Compressive modulus measured for the CONCELOC Advanced Porous Technology[33] compared to values reported for cancellous[34] bone.

CONCELOC has flexibility similar to cancellous bone which will prevent stress shielding and aid in bone growth.

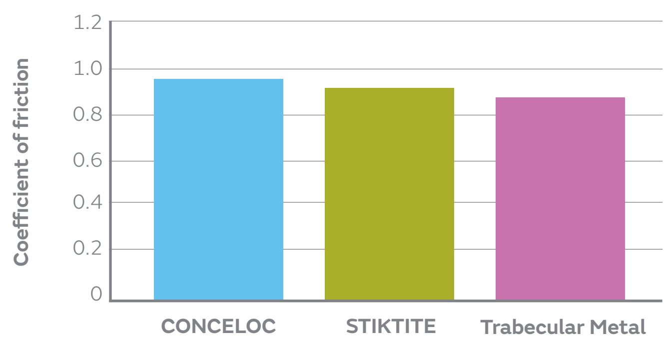


Figure 2: Coefficient of friction of CONCELOC Advanced Porous Technology compared to that reported for STIKTITE[31] porous coating and Trabecular Metal.[32]

The CONCELOC and STIKTITE porous structures were tested against 10 lb/ft (0.16 g/cm) foam.[31] The test method for these porous structures differed from that used for Trabecular Metal that was tested against cancellous bone.

CONCELOC has similar coefficient of friction as STIKTITE and Trabecular Metal leading to early fixation and stability of the construct.

Tested for strength

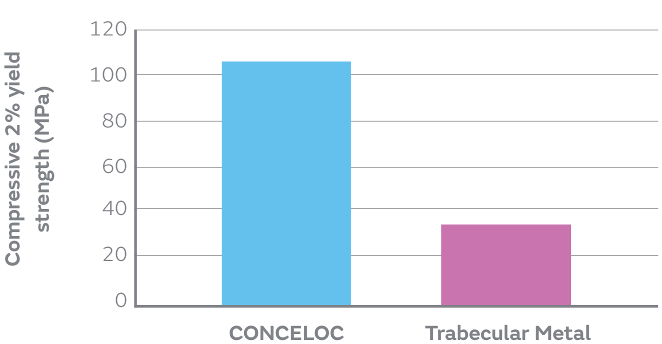


Figure 3: Compressive yield strength of the CONCELOC Advanced Porous Technology[35] compared to that reported for Trabecular Metal.[36]

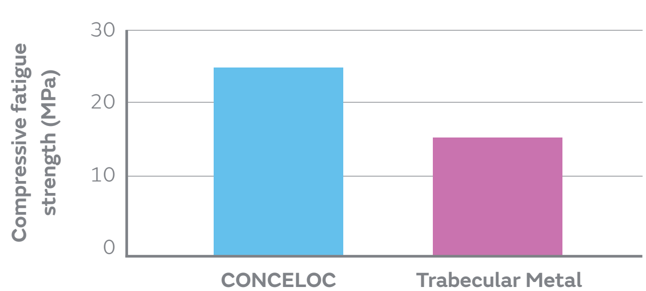


Figure 4: Compressive fatigue strength of the CONCELOC Advanced Porous Technology[37] compared to that reported for Trabecular Metal.[36]

CONCELOC Advanced porous has 3 and 1.7 times static and fatigue strength compared to clinically successful Trabecular metal which may reduce the risk of fracture.

Tested for biologic fixation and osseointegration

Method

Osseointegration of the CONCELOC◊ Advanced Porous Titanium was assessed using a previously validated, load-bearing ovine model.[38] Semi-circular implants were made with either the CONCELOC porous structure (Figure 1a) or CP-Ti (Figure 1b) on the top and bottom surfaces. Bilateral defects were created in the cancellous bone of the proximal tibias of adult sheep. Eight of each type of implant was randomly assigned to the left or right limb and press-fit into each bilateral defect (Figure 2). After 12 weeks, the tibias were harvested and subjected to testing.

Conclusions

After 12 weeks *in-vivo*, the push-out strength of the CONCELOC implants was significantly higher at 23% ($p=0.013$) than that of clinically successful Ti beads.[39] This difference is likely due to the combination of higher friction and the greater porosity of the CONCELOC porous structure. As a result it may be reasonable to hypothesize that the CONCELOC structure may provide excellent fixation and osseointegration.

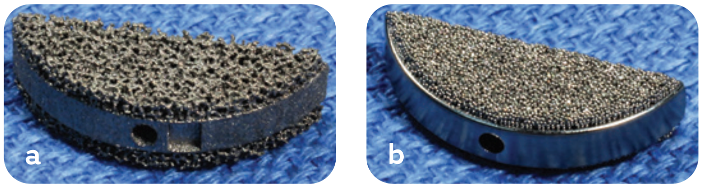


Figure 1. Images of the (a) additive-manufactured CONCELOC and (b) CP-Ti bead sub-articular implants.

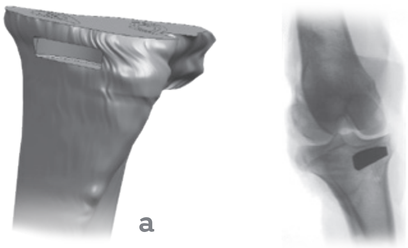


Figure 2. (a) A schematic illustration of the defect created in the proximal tibia below the tibial plateau and (b) an X-Ray of one of the CONCELOC implants in the tibia.

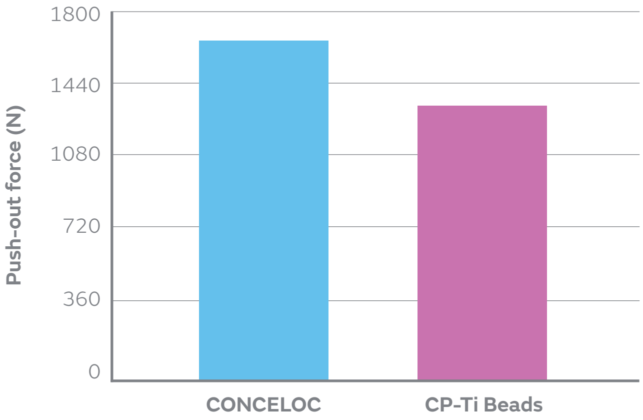


Figure 3: Mean push-out forces for the CP-Ti beads and CONCELOC Advanced Porous Titanium after 12 weeks *in vivo*.

CONCELOC◊ Tibia Baseplate

The proximal tibia bone can be divided up into four quadrants comprised of bone with different densities.[40] This porous tibia implant has been designed to maximize surface area to take advantage of the different types of bone. The goal of the design is to optimize press fit while reducing risk of cortical impingement. This optimization was done through strategically placed design features while incorporating aspects of a proven tibial baseplate design with over 20 years of clinical success.[8-20]

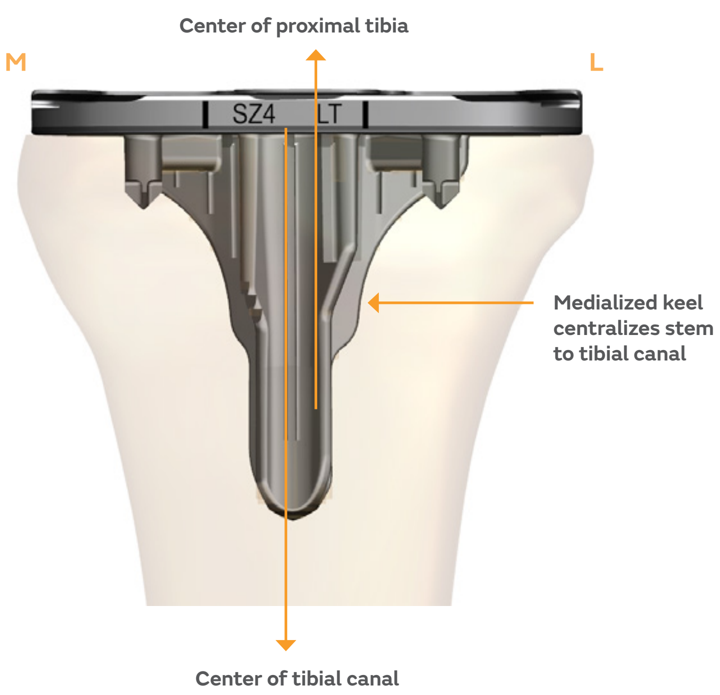
- CONCELOC Porous Structure
- Anatomic footprint
- Asymmetric anterior fins
- Proven locking mechanism[41-44]
- Indicated for cemented and cementless applications
- Posterior fin location and geometry same as clinically proven cemented baseplate

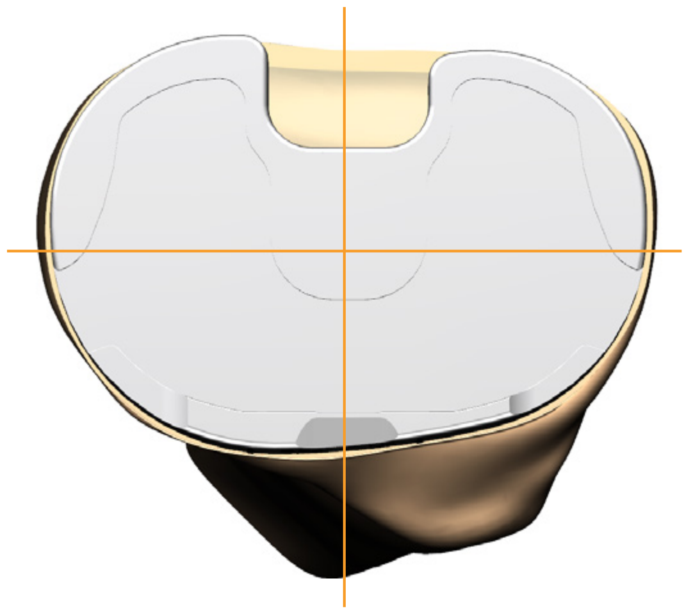
Anatomic keel

- Proportionally medialized on the proximal tibia to align with the intramedullary canal[45]

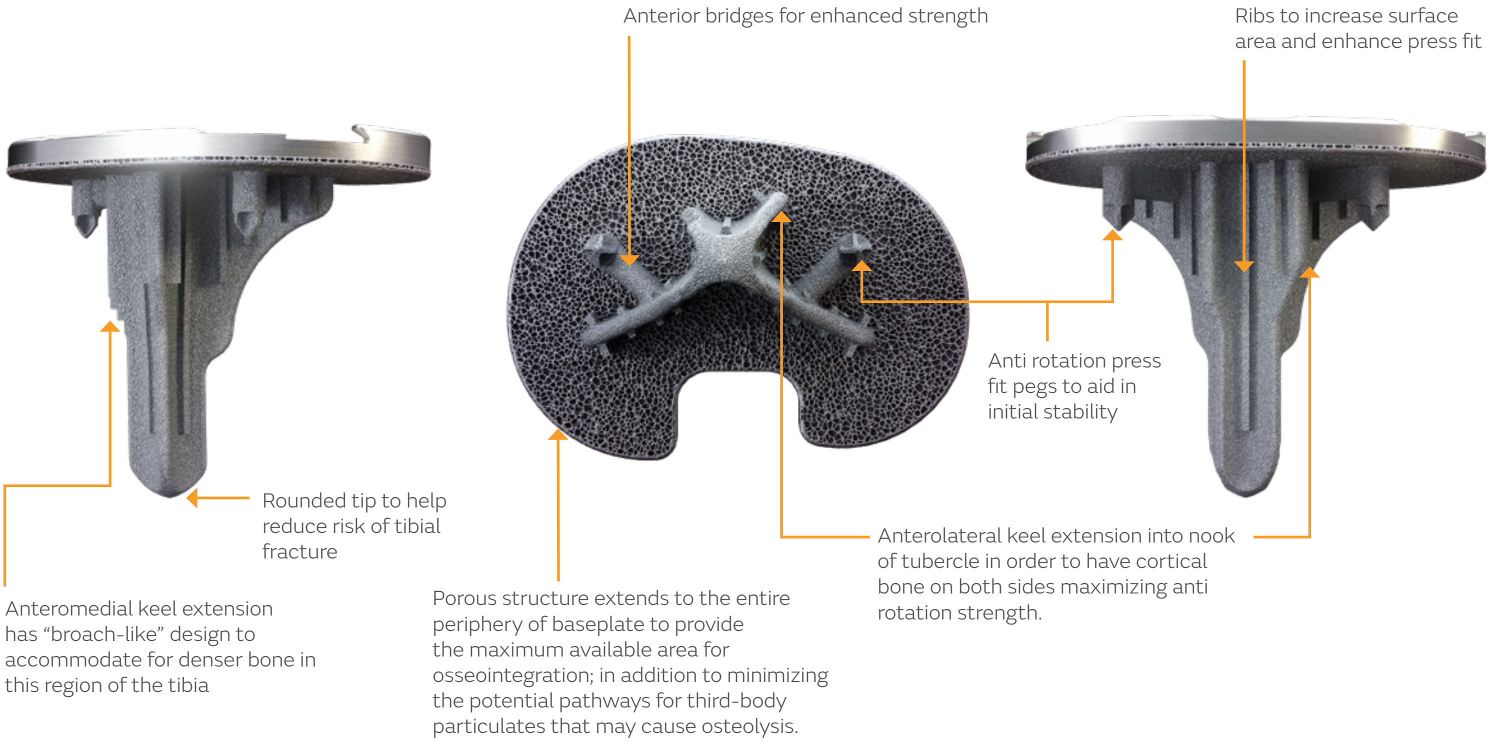
Anatomic footprint

- Designed to match anatomy of the tibia for optimal cortical rim coverage and even stress distribution[46,47]
- Designed to minimize tibia rotational errors and baseplate overhang[48-50]
- Achieves >90% bony coverage on average[51]
- Circumferential cortical support to potentially aid in initial fixation





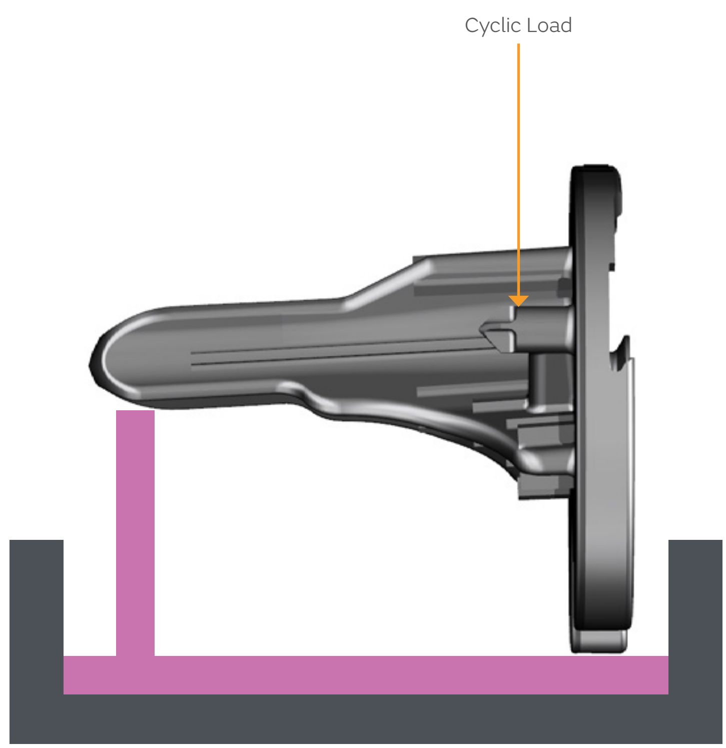
Design benefits



Tested for strength

Porous Tibia Baseplate static and shear fatigue

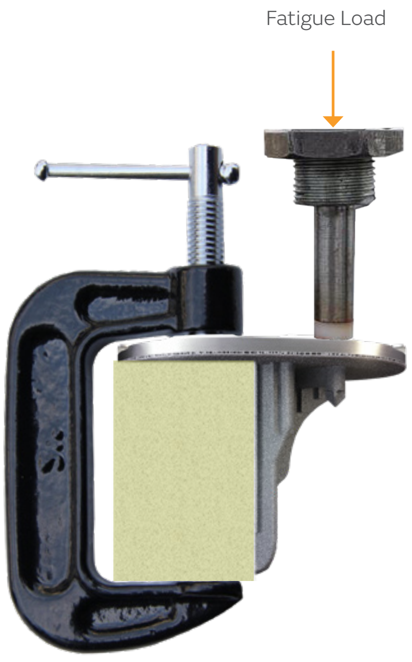
The shear attachment strength of the baseplate to the pegs and keel was examined using fatigue testing with 10 million cycles as an endpoint. The run-out shear fatigue strength of the porous tibia was 4 times greater than a clinically successful predicate porous tibia baseplate design.[52]



Tested for strength

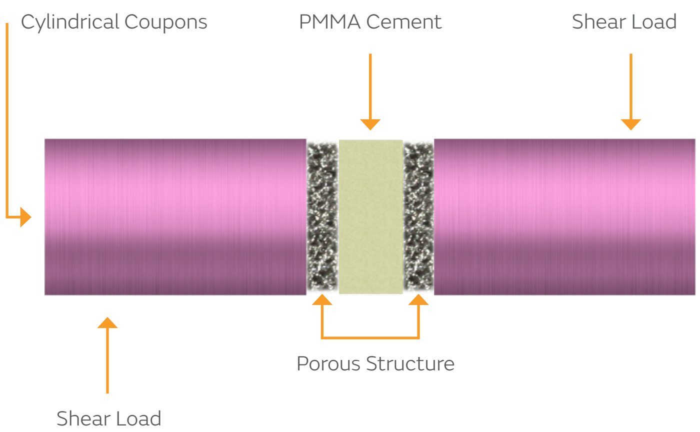
Unsupported fatigue according to ASTM F1800

To assess the Porous Tibia Baseplate fatigue strength under worst-case conditions (complete lack of support under one condyle), testing was conducted according to ASTM F1800-19.[53] Multiple sizes of the Porous Tibia Baseplate were tested to 10 million cycles of fatigue loading. The run-out load for tested sizes exceeded the run-out load of a clinically successful predicate porous tibia baseplate design.[54,55]

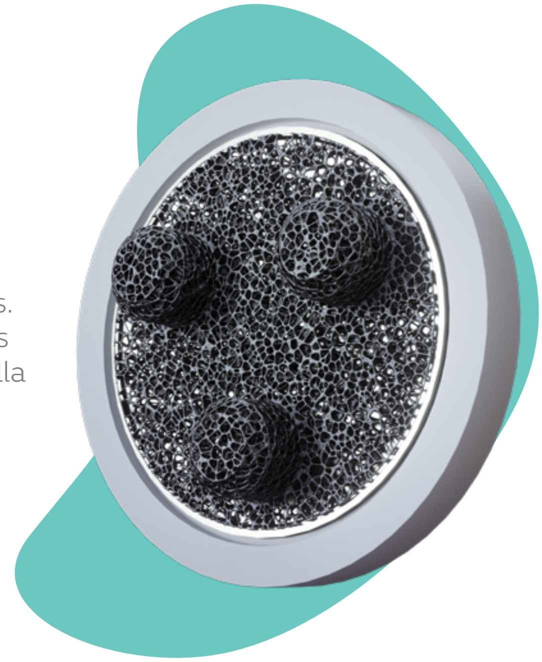


Cement attachment strength

The Porous Tibia Baseplate and Patella can be used in a cementless or cemented application. To examine the effect of the porous structure on a cemented baseplate and/or patella, the CONCELOC◊ porous ends of two coupons were fixed together with PMMA cement and tested in shear. The CONCELOC structure had a cement interface shear strength greater than that of porous coatings used on predicate porous designs.[56]



CONCELOC◊ Patella



A CONCELOC pad is manufactured and fused to Ultra High Molecular Weight Polyethylene (UHMWPE) through direct compression molding to create a monolithic patella component. Direct compression molding has been used for decades in the reconstructive industry to produce acetabular and tibial inserts. By applying heat and pressure the polyethylene resin permeates into the pores of the CONCELOC structure. Once cooled they are bonded together. The patella combines an advanced porous fixation option while incorporating a proven articulating surface design with over 20 years of clinical success.[8-20]

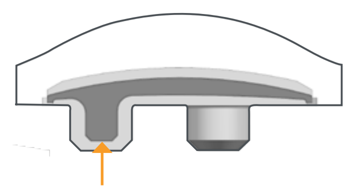
- CONCELOC Porous Structure
- Ultra High Molecular Weight Polyethylene
- Round and anatomic (oval) designs
- 3 pegs for initial fixation
- Articulating surface design with over 20 years of clinical success
- Indicated for both cemented and cementless applications

There has been renewed interest in uncemented patella implants due to the increased demand for OR efficiency and more crucial than ever[4] long-term biologic fixation. Initial industry designs were fraught with early failures and poor outcomes such as polyethylene fracture, osteolysis, and debonding of the polyethylene from the metal backed surface.[57] Over time structural and biomaterial changes like those incorporated into the new CONCELOC patella have led to successful outcomes.[57] Similar modern designs have shown excellent survivorship, clinical and radiographic outcomes.[57] These designs also show the ability to obtain biologic fixation and promise for excellent long-term durability.[57]

Design features

- >2.75mm UHMWPE thickness on periphery and >5mm centrally
- >1mm porous structure on all surfaces
- Pegs each have 0.4mm of press fit built in

CONCELOC pad designed flush with poly in order to sit flat on patella bone



Pegs and pad contain a solid titanium core for added strength

Tested for strength

Porous Patella shear static and fatigue

The porous patella pegs were tested for static shear and shear fatigue strength. The static load to failure was nearly ten times that of the predicate device.* The patella tested in shear had no failures when run at the same load as the predicate and ultimately failed at a load 3.5 times greater than the predicate.[58,59]

*compared to GENESIS II Total Knee System.

LEGION◊ Porous Femoral

Proven porous technology and implant design

Rich clinical history

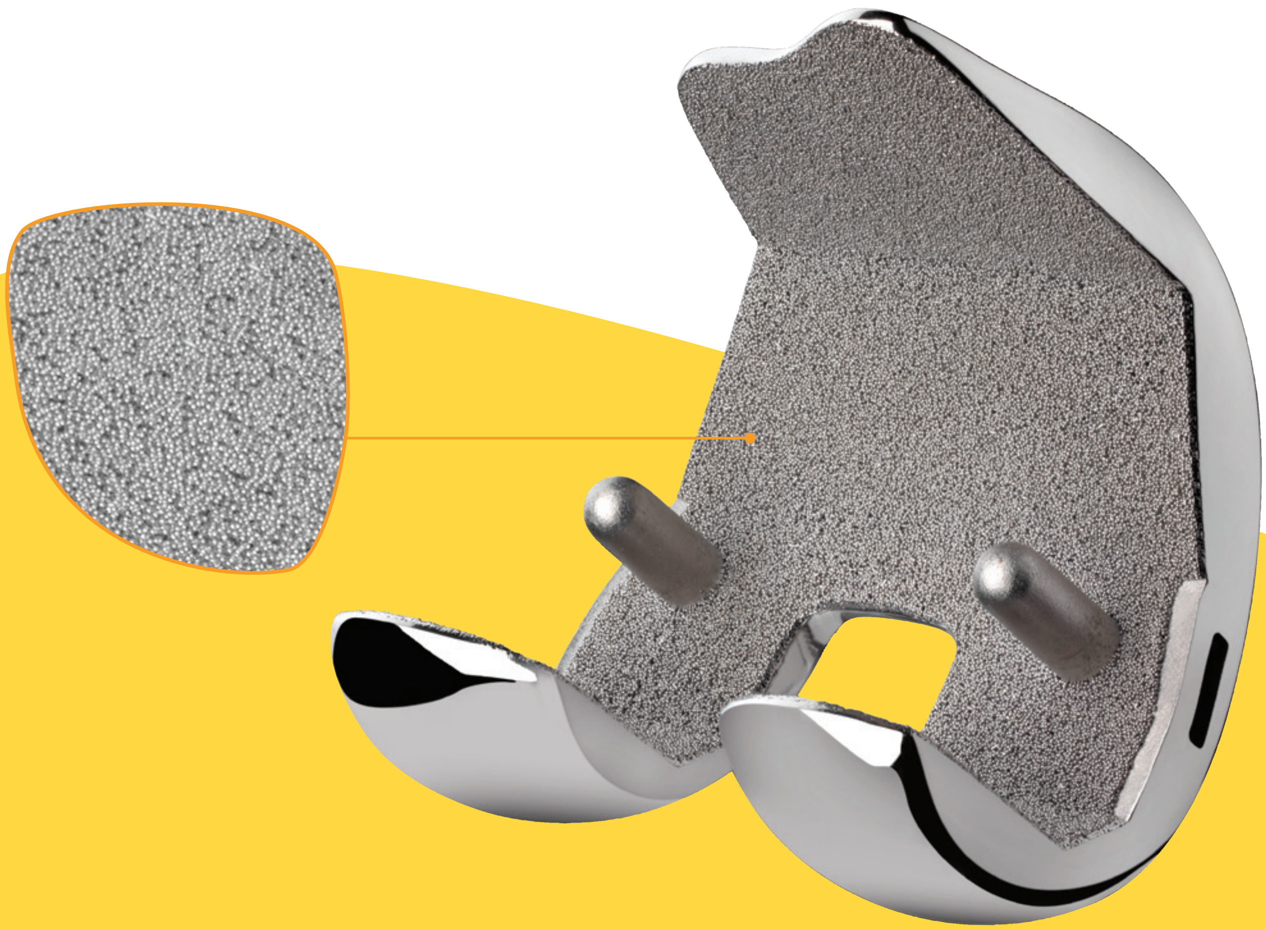
With over 20 years of proven clinical success LEGION provides confidence in reproducible outcomes.[1-3] LEGION has consistently high survivorship in international registries and clinical studies, with excellent ODEP ratings at 7 years.[10,11,14,15]

Complete porous surface coverage

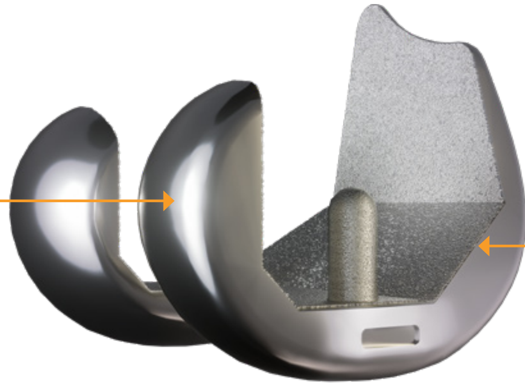
The CoCr beads extend from the far tip of the anterior flange to the edge of the posterior condyles to provide the maximum available area for osseointegration; in addition to minimizing the potential pathways for third-body particulates that may cause osteolysis.

Sintered porous beads

CoCr sintered porous coating has been used for decades in the orthopaedic community with substantial success.[60,61] Sintered beads provide an interconnected structure for bone in-growth thus providing stability for survivorship.[8-20] The LEGION Porous CR Femur is offered with and without hydroxyapatite (HA) coating.

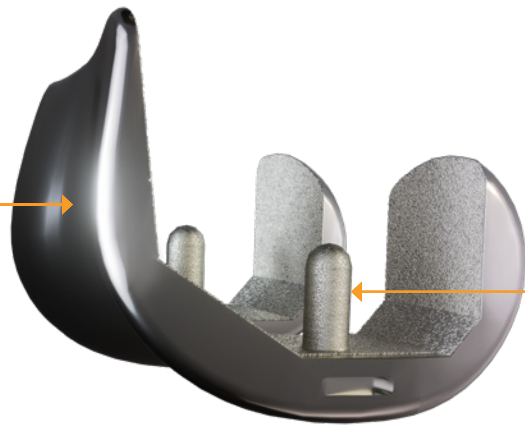


Design benefits



Flexion friendly
Tightly radiused posterior condyles designed to allow for deeper flexion without the risk of edge loading or excessive collateral ligament tension

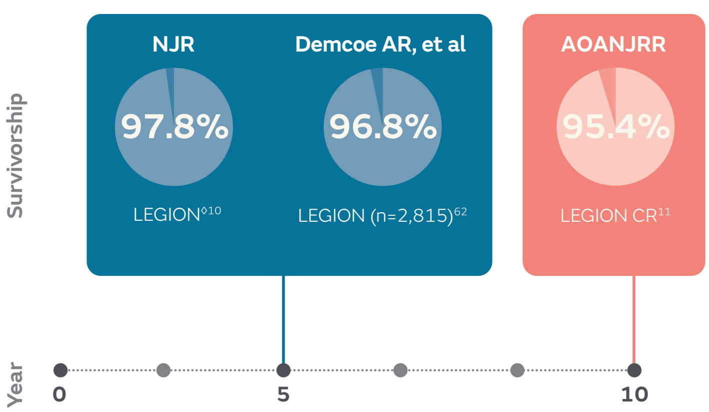
No notch preparation
Anterior chamfer design allows for deepened patellar groove without secondary preparation



Better patella tracking
Lateralized trochlear groove with S-curve at base funnels the patella toward the midline for better patella tracking in deep flexion. This has been shown to reduce lateral release rates.[61]

Fixed pegs
Fixed pegs offer initial medial/lateral stability upon implantation of the femoral component to the bone. The uncoated pegs also help to preserve bone stock in the event of component revision.

Design clinical history



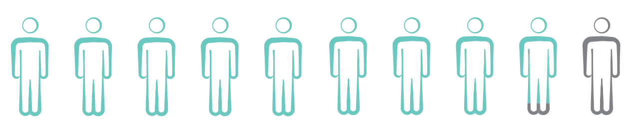
Registry and clinical study survivorship data for LEGION

LEGION Total Knee System
LEGION CR

ODEP[62] **7A***

Over 1 Million LEGION knees implanted since 2005

88% of patients reported being **satisfied or very satisfied** post-LEGION TKA[64]



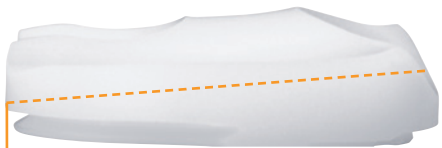
Percentage of LEGION TKA patients (n=133) who reported being satisfied or very satisfied at a mean follow-up of 55 months[64]

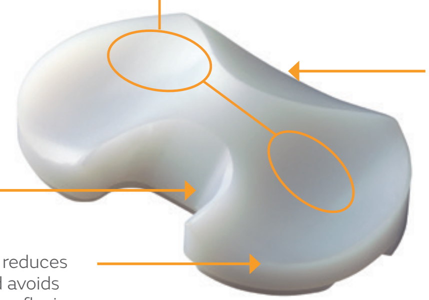
LEGION◊ CR Articular Inserts

Design benefits

- 1mm polyethylene thickness increments for more precise balancing
- XLPE (highly cross-linked polyethylene) to optimize wear performance

LEGION CR High Flex XLPE Insert w/JRNY Lock





LEGION Deep Dish XLPE Insert w/JRNY Lock

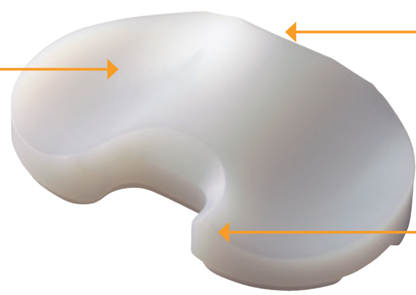


Figure 1 shows the position of the LEGION CR femoral component in relation to the Deep Dish insert through 90º of flexion in a LifeMod[65] computer simulation. Since the LEGION component has minimal anterior translation before rolling back, it does not come in contact with the anterior lip of the insert at any point during flexion. Therefore anterior stability is not dependent on a high anterior lipped feature on the insert as may be seen with other knee designs.

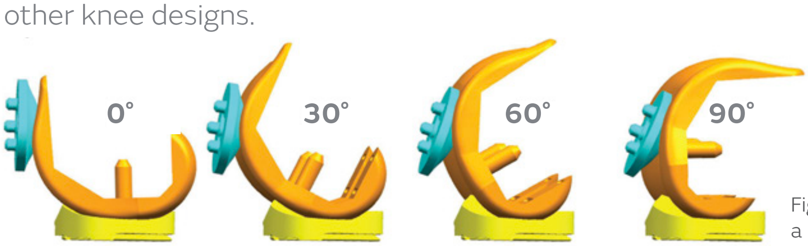


Figure 1: LEGION femoral on a Deep Dish insert

Smith+Nephew's XLPE Knee Specifications

Material	GUR Resin	Total Dose (Mrad)	Source	Thermal Treatment	Sterilization	Free Radicals?	Oxidation?
S+N 7.5-XLPE	1020	7.5	Gamma	Re-melt	EtO	No	No

Notes

Notes

Disclaimer: Pending 510K clearance and not available in all markets.

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