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Design Rationale

TRULIANT®

Porous Knee System

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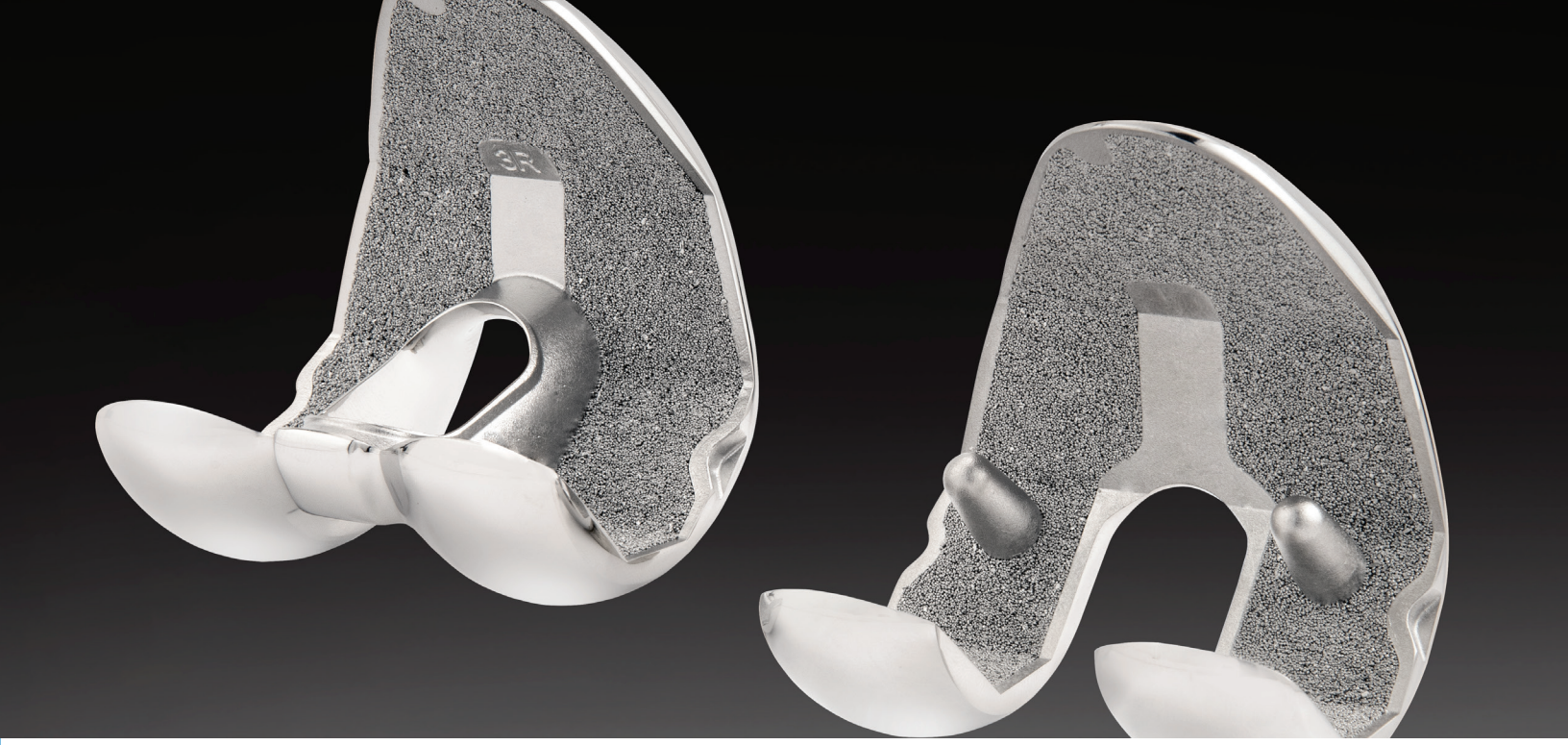


Introduction

With knee arthroplasty continuing to grow, orthopaedic surgeons are challenged to deliver superior clinical outcomes with ever greater efficiency.[1] The demographics of patients undergoing TKA are evolving to include younger and more active patients.[2] With patient demographics evolving into younger and heavier, there is a potential for greater risk of revision TKAs.[3]

Failure of early generation uncemented knees led to skepticism and limited adoption. In recent years, the orthopaedic industry has made large strides in improving both the implant designs, biomaterials, surgical techniques and patient indications to improve the longevity of porous implants.

The use of a cementless implant has been shown to be beneficial in providing long-term durable biologic fixation while delivering a reproducible and efficient experience for the surgeon.[1] Cementless TKA has the potential for biological fixation which may provide more durable long-term stability.[3]

Successful porous surfaces in total joint replacements need to strike a balance between porosity, pore size and mechanical strength. While increased porosity and pore size are favorable for biological fixation, there are also considerations to ensure sufficient mechanical strength of the porous lattice.

The objectives for the Truliant® Porous Knee System were focused on the following design and material parameters:

- Material is biocompatible and has proven orthopaedic use,
- Porous structure maintains sufficient mechanical strength,
- Porosity of the porous structure is greater than 60%,
- Mean pore size of the porous structure is greater than 300um, and
- Porous surface topology can provide good initial implantation stability.

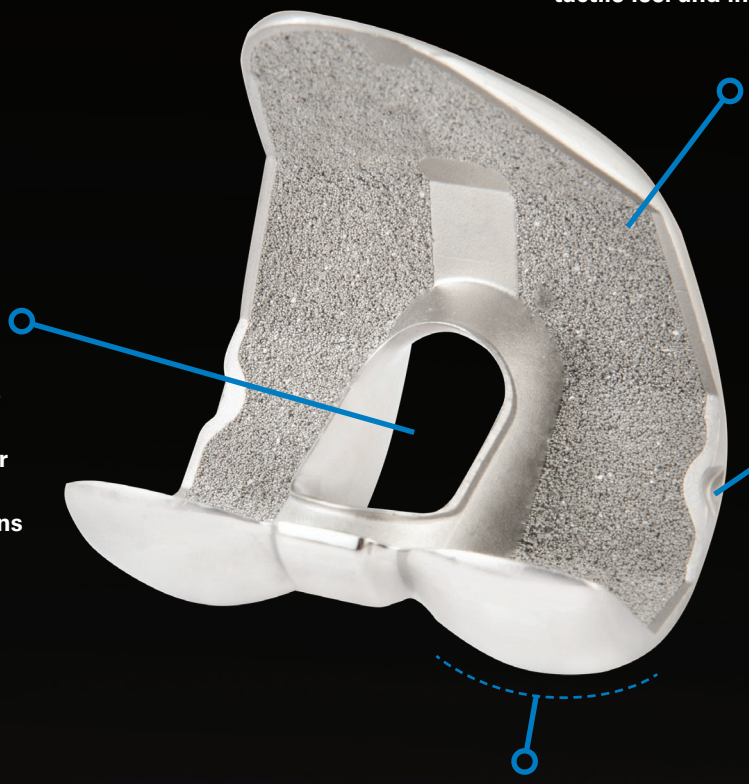
Truliant Porous Knee leverages today's advanced manufacturing technologies to mimic the trabecular nature of cancellous bone with optimal pore size and porosity. The porous structures integrated into the implant are designed to facilitate a durable bonding surface to allow for immediate and long-term biological fixation and facilitate potential bony in-growth.[1] Truliant Porous Knee is designed for strength and stability for the patient, and efficiency for surgeons and staff in the operating room.

DESIGN

Truliant is an evolution of the Optetrak® lineage which has demonstrated excellent long-term clinical outcomes including 98% or greater survivorship at 11.5 years.[4-5]

Scratch-Fit Porous Coating

Irregular, asymmetric shaped CoCr bead coating structure with a rough tactile feel and increased porosity.[6]



Bone-Sparing PS Notch Opening

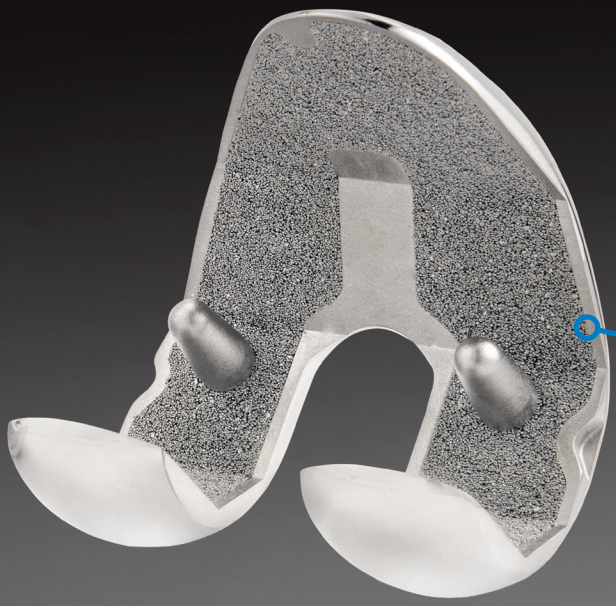
Cylindrical notch dimensions are proportional to the femoral size, minimizing the bone resection for smaller sizes, and removing 30% less bone than traditional resections across all sizes.[7]

Fixed Impaction/ Extraction Notches

Cylindrical notch dimensions aid in accurate femoral component placement.

Full Medial/Lateral Radius of Curvature

.96 M/L congruency results in an optimized conformity between femur and insert, providing stability, reducing contact stress and lowering the potential for surface damage and wear.[8]



CR and PS Femoral Options

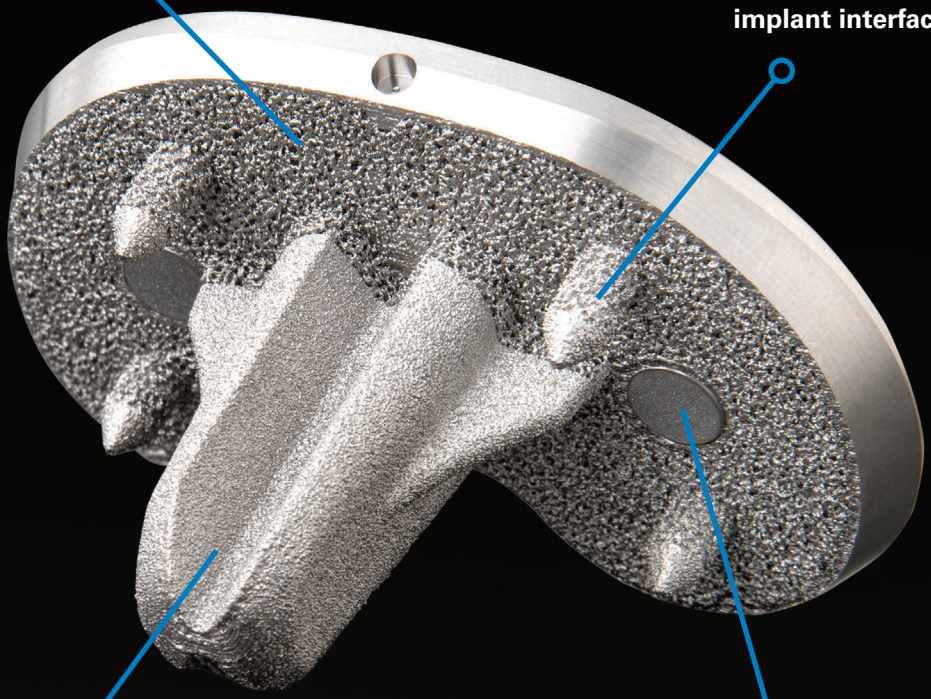
Cruciate-retaining and posterior-stabilized porous implant options to accommodate surgeon preference and patient anatomy

Additive Manufactured Porous Titanium

Replicates the trabecular nature of cancellous bone with optimized pore size and porosity characteristics for strong fixation.[1]

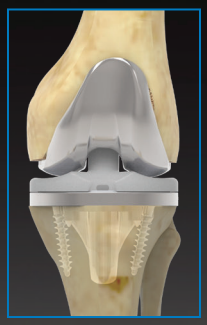
Coated, Peripheral Pegs

Peripherally placed porous tibial pegs allow for stable initial fixation and an increased bone-implant interface.[9]



Dual V-Channeled, Winged Keel

Two flutes, positioned anteriorly and posteriorly, along the length of the central keel are designed to increase early bone-implant engagement for increased rotational stability, resistance to micromotion and increased bone-implant interface.



Optional Screw Fixation

Designed to provide surgeons further intra-operative and long-term stability if desired

TRULIANT POROUS FEMUR

The Truliant Porous CR and PS femoral designs feature the same anatomical profile as their cemented counterparts, as well as the same anterior/posterior and chamfer dimensions. Truliant is built on the same design features as the Optetrak Logic® Knee System and is designed to minimize contact stresses at the articular surfaces between the femoral and tibial components, thus lowering the potential for surface damage and wear. Preparation is identical for the Truliant porous and cemented femoral implants, so there is no change to surgical flow or a need for additional instrumentation.[1]

The Truliant Porous PS femur features a proportional, cylindrical notch that removes 30% less bone, compared to traditional box resections.[1] Truliant PS is designed to maximize stability and range of motion while providing surgeons an easier, faster and more consistent notch preparation.[1]

TRULIANT POROUS TIBIA

The Truliant Porous tibial design features a size proportional, tapered, dual v-channeled keel intended to maximize stability.

The design of the keel was modified from a solid trapezoidal shape, to the v-channeled keel which incorporates flutes to increase the effective surface area. To provide more opportunity and location for bony in-growth, the porous structure of the tray extends down the proximal 2.5 mm of the keel.[1]

In addition, four peripherally placed porous pegs are incorporated to increase bony implant engagement, rotational stability and resistance to micromotion. The porous structure was carefully decided to mimic the trabecular nature of cancellous bone with optimal pore size and porosity characteristics.[1]

For surgeons who prefer further intra-operative stability, supplemental tibial bone screw fixation can be utilized. Two bone screws can be placed through the porous tibia after unthreading the two screw seals from the porous tibial component. The cone-shaped hole in the drill guide allows screws to be positioned at a maximum angle of 12° from normal in any direction.[1]

The Truliant Porous tibia was designed to minimize backside wear to extend the longevity of total knee replacements. Like its cemented counterpart, the porous tibia features a proven three-part locking mechanism made up of a peripheral rim, precision undercuts and a central mushroom.[1] Preparation for the Truliant Porous tibia requires only one additional half tray of instruments to complete the surgical steps.

Lastly, the Truliant Porous tibia is indicated for both cemented and cementless applications. It is important to assess the patient's bone density and quality prior to implantation to ensure sufficient mechanical support and biological fixation potential. Bone stock of insufficient quality may not provide the necessary stability for cementless implantation, and at that point the decision to use cement can be made.

Table 1. System Versatility Chart

	Femur				Tibia		Insert			
	Truliant CR Porous	Truliant PS Porous	Truliant CR Cemented	Truliant PS Cemented	Truliant Porous	Truliant Cemented	CR	CRC	PS	PSC
Cementless	X	X			X		X	X	X	X
Hybrid	X	X				X	X	X	X	X
Reverse Hybrid			X	X	X		X	X	X	X

Table 2. Porous Standards Comparison: Femur[10]

Specification	Exactech Porous	Standard
Chemical Composition	Porous Powder	ASTM F75
	Casting Substrate	
Tensile strength test	46.9 ± 10.0 MPa (n=5)	FDA Guidance: >20 MPa
Shear strength test	40.6 ± 5.2 MPa (n=10)	FDA Guidance: >20 MPa
Pore Characteristics	Porosity = 65.8% ± 2.9% Pore size = 339.9 ± 37.2µm	CoCr Porous spherical beads: Porosity = 30% to 50% Pore Size = 100 to 400µm

Materials

TRULIANT POROUS FEMUR

Truliant Porous femoral components are comprised of cobalt chrome and feature a porous crushed bead coating that has been proven to provide stable initial fixation. By utilizing a proprietary application process of layering and then sintering irregular shaped powder, a unique porous lattice with a strong, 3-dimensional interconnected porous structure[9] is created, providing increased average pore size and greater porosity than traditional spherical beads.[1] The combination of features is designed to provide consistent and reproducible results.[1] The powder geometry and size range have been carefully selected and optimized to achieve favorable pore characteristics which meet the design objective and facilitate bony ingrowth.

A porous surface of cobalt chrome crushed beads is coated onto the backside of the component. This coating provides an average porosity of 65% with a mean pore size of 339µm *(Table 1)*.[1]

TRULIANT POROUS TIBIA

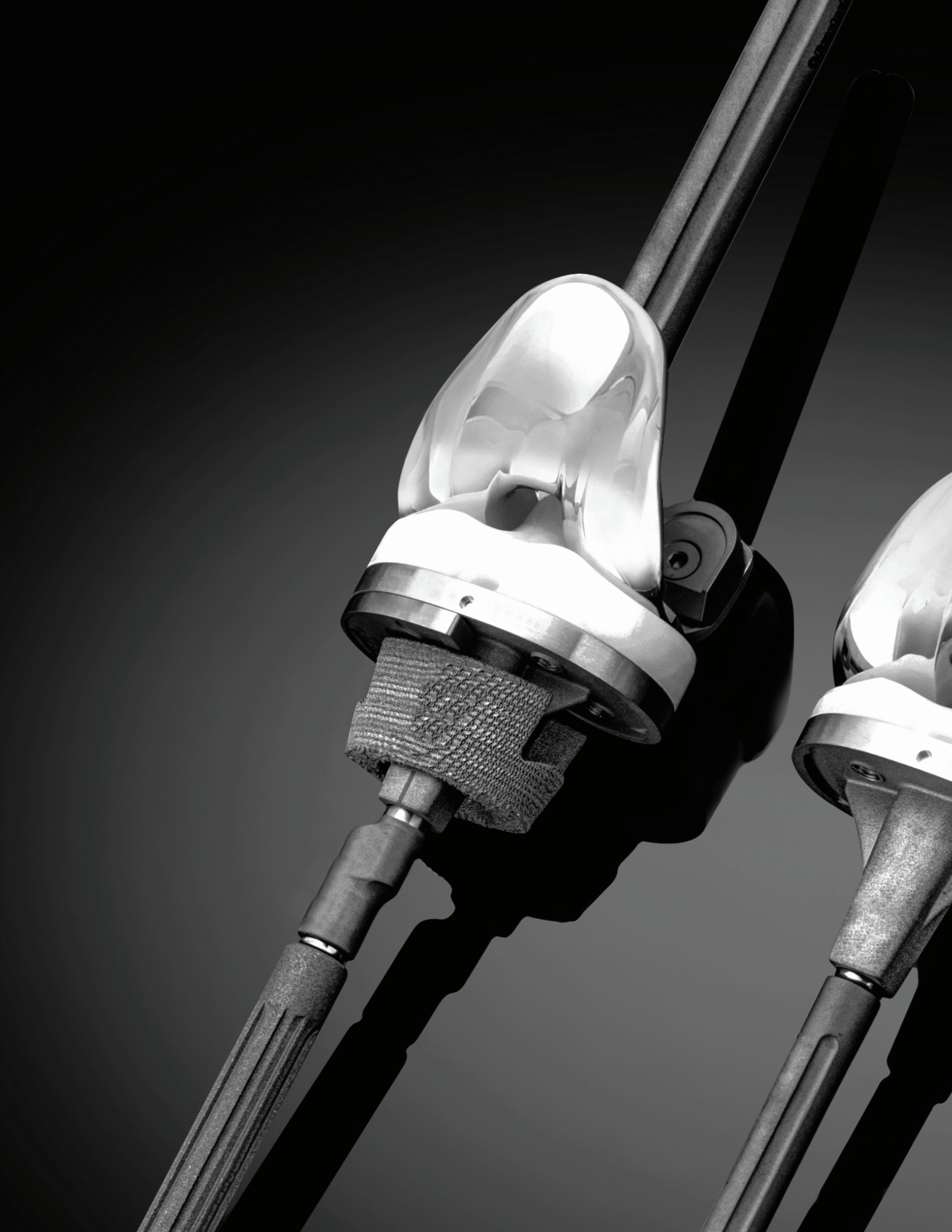
Truliant Porous tibial components feature an additive manufacturing technology. The tibial component is comprised of titanium, and the surface structure was designed to replicate the trabecular nature of cancellous bone with an optimized pore size of 425µm and an average porosity of 65% *(Table 3)*.[1]

The implant and porous structure is manufactured using electronic beam melting technology and fully melts titanium alloy metal powder layer by layer. The technology provides exceptional manufacturing flexibility to achieve attractive porous structure characteristics such as greater percent porosity, pore size and surface coefficient of friction.[1] The porous structure is an integral component to the tibial tray and is not a separately applied structure.

Preparation for the porous tibial component only requires one additional half instrument tray and is compatible with the Truliant Primary Knee System.[2]

Table 3. Porosity Chart

	Mean Pore Size	Porosity	Porous Structure
Truliant Porous Femur (CR & PS)	339 µm	65%	Asymmetric CoCr Beads
Truliant Porous Tibia	425 µm	65%	Printed Titanium Alloy



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**In vitro (bench) test results may not necessarily be indicative of clinical performance.*

For additional device information, refer to the Exactech Knee System–Instructions for Use for a device description, indications, contraindications, precautions and warnings. For further product information, please contact Customer Service, Exactech, Inc., 2320 NW 66th Court, Gainesville, Florida 32653-1630, USA. (352) 377-1140, (800) 392-2832 or FAX (352) 378-2617.

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