

Triathlon® Tritanium

Design rationale



Triathon Tritanium | Design rationale

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Encouraging outcomes for challenging patient demographics

Patient demographics for TKA have become younger and heavier,^{1,2} and these patients have demonstrated higher risk of revision in TKAs.^{3,4,5} When biologic fixation is achieved, cementless TKA has the potential for a more durable boneimplant interface that can better withstand the added mechanical stress in obese patients.⁶ In a retrospective study with 193 patients with a minimum of five-year follow-up, morbidly obese (BMI \geq 40) patients receiving cementless primary Triathlon TKA with a PS design demonstrated improved survivorship compared to those who received a cemented Triathlon TKA.⁵ Furthermore, the American Joint Replacement Registry reported male patients younger than 65 years adjusted for age receiving a cementless TKA showed a better survivorship than those who received cemented TKA; however, the difference is small (<1%) and does not account for other potential confounders.⁷

Potential savings in time and cost

As the volume of TKA procedures continues to increase, the costs associated with this surgical procedure continue to be an important topic. Cementless TKA allows the potential to reduce operating room time^{8,9} and save expenses without the use of bone cement and cement accessories.¹⁰ A healthcare economic study in the U.S. concluded that the actual overall cost of cementless TKA could be offset by shortened operating room time and the lack of need for cement and

cementing accessories.¹⁰





Strong clinical evidence

Cementless TKA is growing in popularity.⁷ The 2020 National Joint Registry Report in the U.K. supports the long-term outcome of cementless femoral components,¹¹ and the AAOS evidence-based clinical practice guideline found strong evidence suggesting similar functional outcomes between cemented and cementless tibial baseplates.¹² Triathlon Tritanium cementless TKA demonstrated excellent clinical outcomes in multiple studies with five-year followup^{13,14,15} and achieved similar functional outcomes and pain reduction when compared to cemented Triathlon TKA in multiple short- to midterm studies.^{8,16}



Survivorship

Triathlon Tritanium TKA survivorship	Source
98.4% aseptic survivorship in 296 Triathlon Tritanium TKAs and 99.2% survivorship for Triathlon Tritanium Baseplate at minimum five-year follow-up. ¹	Restrepo et al. Orthopaedic Proceedings. 2020
99.5% implant survivorship in 228 Triathlon Tritanium Baseplates at five-year follow-up.²	Tarazi et al. Journal of Knee Surgery. 2020
100% aseptic survivorship in 28 Triathlon Tritanium Baseplates with CR PA beaded femur at five-year follow-up. ³	Silverstein et al. Orthopaedic Research Society 2020 Annual Meeting.
98% all-cause survivorship in 261 Triathlon Tritanium Metal-Backed Patellas at 4.5-year follow-up.4	Harwin et al. Journal of Knee Surgery. 2020
99.5% all-cause survivorship in 1024 Triathlon PS cementless TKAs at four-year follow-up. ⁵ Both Tritanium and PA beaded versions of the tibial baseplate and metal-backed patella were included. ⁵	Harwin et al. Journal of Arthroplasty. 2017
99% all-cause survivorship in 708 Triathlon Tritanium TKAs at two- to four-year follow-up. ⁶ Tritanium Baseplate, Tritanium Metal-Backed Patella and PS PA beaded femurs were used. ⁶	Bhowmik-Stoker et al. 2018 World Arthroplasty Congress.
100% all-cause survivorship in 72 Triathlon Tritanium TKAs at mean three-year follow-up. ⁷ Tritanium Baseplate, Tritanium Metal-Backed Patella and CR PA beaded femurs were used. ⁷	Cohen et al. Orthopedics. 2018
No revision due to aseptic or septic loosening of Triathlon Tritanium Baseplate at two-year follow-up. ⁸	Masini et al. American Academy of Orthopaedic Surgeons (AAOS) 2019 Annual Meeting poster. #2263

PA beaded femur survivorship with long-term follow-up

Source

Triathlon PA beaded femur showed all-cause
survivorship of 96.8% for CR and 94.9% for PS at 10-year
follow-up.9Australian Joint
Registry. 2020Triathlon PS PA beaded femur 98% all-cause
survivorship at eight-year follow-up.10Harwin et al.
The Journal of
Arthroplasty. 2018

REFERENCES DISCLAIMER



Radiostereometric analysis (RSA)

RSA of 27 Triathlon Tritanium TKAs at two-year follow-up suggested that the Triathlon Tritanium Baseplate and Metal-Back Patella achieve fixation through highly porous metal.¹¹ This pattern is consistent with other longer-term RSA studies showing that stabilization of uncemented tibial components can be achieved after high initial migration.^{11,12,13}

Plot of implant migration over time, measured by maximum total point motion¹¹



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Outcomes compared to **cemented** Triathlon

Nam et al. The Journal of Bone and Joint Surgery¹⁴

A prospective, randomized controlled study of 76 Triathlon Tritanium TKAs vs. 65 Triathlon cemented TKAs demonstrated no differences in clinical results with no aseptic loosening in either cohort at mean two-year follow-up. Both cohorts received cruciate-retaining femoral components.





Similar pain reduction





Intraoperative outcome	Cemented	Cementless	p-value
Mean operative time (min)	93.7	82.1	0.001
Change in hemoglobin (g/dL)	-2.5	-2.6	0.5
All patients were permitted to fully we tolerated and ambulate on the day of s	eight bear, star surgery.	t range of moti	ion as
Four- to six-week postoperative	Cemented	Cementless	p-value
% of patients who reported "no pain"	31	34	0.7
Mean visual analog scale	3.5	3.2	0.3
Mean change in OKS	0.9	2.1	0.4
Mean change in KSS	-1.3	1.8	0.3
Two-year postoperative	Cemented	Cementless	p-value
Aseptic loosening	0	0	
Change in OKS	17.3	19.7	0.2
Change in KSS	33.5	39.2	0.2





Miller et al. Journal of Arthroplasty 15

A matched comparison of 200 Triathlon Tritanium TKAs vs. 200 Triathlon cemented TKAs showed similar functional and survivorship outcomes between the two cohorts at mean 2.4-year follow-up. Both groups received the same postoperative physical therapy protocol, which consisted of immediate weight bearing with passive and active motion exercises.

Intraoperative outcome	Cemented	Cementless	p-value
Total no. of revisions	8	7	.069
Aseptic loosening	5	1	0.2
Change in KSS function score	26.0	35.6	.0014
Change in KSS knee score	52.4	53.8	.385

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Patient selection data

Survivorship	Source
Male patients < 65 years of age Male patients younger than 65 years adjusted for age receiving a cementless TKA showed better survivorship than those who received cemented TKA; however, the difference is small (<1%) and does not account for other potential confounders. ¹⁶	American Joint Replacement Registry. 2020 Annual Report.
Patients <50 years of age Excellent survivorship and functional and radiographic outcomes at mean follow-up of four years with no component failure were observed in a study of 29 patients (31 knees). ¹⁷	Mont et al. The Annals of Translational Medicine. 2017
Patients >75 years of age Excellent aseptic and overall midterm survivorship and improvements in functional outcomes with 99.3% aseptic implant survivorship at mean follow-up of four years were observed in a study of 134 patients. ¹⁸	Newman et al. The Journal of Knee Surgery. 2017
Patients with BMI >40 In a retrospective study with 193 patients, survivorship in the cementless group remained at the steady state of 99.1% at eight years, whereas survivorship in the cemented group gradually decreased over time to 83.5% at 12 years. ¹⁹	Sinicrope et al. The Journal of Arthroplasty. 2019
Patients with rheumatoid arthritis Excellent survivorship outcomes were reported in a study of 126 TKAs in 122 patients with rheumatoid arthritis, with 99.2% survivorship at mean follow-up of four years. ²⁰	Patel et al. Orthopedics. 2018

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Triathlon design

Stable primary fixation of the implant is a prerequisite for biologic fixation.¹ The less constrained the design, the less potential for stresses generated at the articulating surface to be transferred to the bone-implant interface.² Triathlon is designed to minimize dynamic stress transfer to the tibial fixation interface by providing minimal resistance to internal and external motion and by locating the bearing sulcus directly over the tibial keel to help reduce sagittal rocking during ambulation.³

+/- 20° of internal/external freedom





Single radius design allows the bearing sulcus to sit directly over the tibial keel







Additionally, Triathlon's locking mechanism is designed to help minimize micromotion.⁴



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Peg design

Given the importance of stable primary fixation,¹ the underside of the Triathlon Tritanium Baseplate was designed to reduce micromotion and liftoff.⁵ Additive manufacturing technology provided our engineers the ability to think of a design, 3D print it and then test it. Many designs were tested, but none provided greater stability than the Triathlon peg design.⁶









Coupled with the Triathlon tibial keel design, the underside design of the Triathlon Tritanium Baseplate showed reduced liftoff compared to the dual hex pegs design of NexGen in a benchtop study.⁵



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Tritanium

Tritanium is a highly porous metal biologic fixation technology. The porous structure of the Triathlon Tritanium Baseplate and Metal-Backed Patella is made of commercially pure titanium.

Histological image of Tritanium plug implanted in a rabbit after 10 weeks^{1*}



*Animal studies are not necessarily indicative of clinical performance. Correlation to human clinical outcomes has not been demonstrated or established.

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TECHNOLOGY

The Tritanium porous matrix closely resembles that of cancellous bone.



Material properties ²⁻⁴	Tritanium Baseplate	Tritanium Metal- Backed Patella
Mean pore diameter (µm)	527	497
Coefficient of friction	1.02	.80
Mean porosity	68%	65%

The Triathlon Tritanium Baseplate and Metal-Backed Patella are also indicated for cemented applications, providing surgeons intraoperative flexibility to decide on the fixation method with the actual component once bone quality is assessed.



Additive manufacturing

Triathlon Tritanium Baseplate and Metal-Backed Patella components are additive manufactured using a focused laser beam to sinter numerous layers of titanium powder to grow the implant structure layer by layer.

Triathlon Tritanium Tibial Baseplate

With additive manufacturing technology, we can manufacture implants that were previously difficult – or even impossible – to manufacture using conventional techniques, making it possible to selectively position porous structures in desired zones of the Triathlon Tibial Baseplate. Avoiding porous metal in the distal areas may reduce the risk of stress shielding. Additionally, avoiding distal biologic fixation is also

a consideration in the event of a revision.



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TECHNOLOGY

Triathlon Tritanium Metal-Backed Patella



The Triathlon Tritanium Metal-Backed Patella addresses the past clinical issue of dissociation of the metalpolyethylene interface⁵ by enhancing the bond between the two components.⁶ The architecture on the back side of the Triathlon Tritanium Metal-Backed Patella, combined with a direct compression molding process, is designed to minimize the potential for dissociation.⁶ Additive manufacturing makes it possible to build a solid barrier layer between the porous surfaces, which allows for a smaller metal backing and greater polyethylene thickness.



Triathlon Tritanium



Triathlon Peri-Apatite (PA)





SOMA

Stryker Orthopaedic Modeling and Analytics (SOMA) is a global database of bone morphology – including size, shape, density, stiffness, and inner and outer cortical diameters – drawn from diverse populations. SOMA was used to optimize the depth and placement of the Tritanium pegs. The Triathlon Tritanium Baseplate's size-specific peg design allows for purchase into denser regions of bone without perforating the cortex.⁷

Placement of pegs for baseplate sizes 1, 4, and 8.7 The green line represents the cortex and the spheres represent the distal-most point on the pegs.



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Peri-Apatite (PA)

Peri-Apatite (PA) was developed to coat hydroxyapatite (HA) onto porous-coated fixation surfaces. Triathlon cementless femoral components are manufactured with PA-beaded technology. As opposed to plasma-sprayed HA coatings, the PA coating wraps itself around the circumference of the porous surface, which is designed to increase the HA surface available for fixation.⁸



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Fexibility with fixation techniques Triathlon Tritanium Baseplate and Metal-Backed Patella are indicated for both cemented and cementless applications, providing surgeons intraoperative flexibility to decide the fixation method with the actual component after assessing bone quality.

Triathon Tritanium Baseplate

The Triathlon Tritanium Baseplate can be implanted with minimal additional preparation compared to a cemented Triathlon implant. The only additional step is to prepare the tibia for the pegs, which are designed to aid in initial stability.¹ The four peg prep holes on the Tibial Peg Drill Template correspond to the pegs on the implant.

- Use Cementless Keel Punch



Cementless Keel Punch		
6541- 6 -013	Size 1-3	
6541- 6 -046	Size 4-6	
6541- 6 -078	Size 7-8	

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• Use Cemented Keel Punch



Cemented Keel Punch		
6541- 2 -013	Size 1-3	
6541- 2 -046	Size 4-6	
	$C_{-2}^{i} = 7$ O	

6541-**2**-078

Size 7-8

- Place size-specific tibial drill template on the prepared keel slot
- Prepare peg holes with 1/8 Tibial Peg Drill (6541-2-625)



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PROCEDURAL HIGHLIGHTS



• The optional 7/32 Peg Drill (6541-2-626) may be used to increase the size of the peg holes in dense, sclerotic bone



Triathlon Tritanium

Tibial baseplate







Triathlon Tritanium Metal-Backed Patella

Drill selection guide

- For Triathlon Tritanium Metal-Backed Patella: Use the standard Metal-Backed Patella Drill (6541-3-522); 5.7mm (0.225in) drill diameter = 0.4mm (0.016in) pressfit.
- If the bone is sclerotic in any of the peg locations, the surgeon may elect to use the Tritanium Dense Bone Patella Drill (6541-3-526), which will create slightly less pressfit; 6.0mm (0.235in) drill diameter = 0.15mm (0.006in) pressfit.
- If the surgeon chooses to cement the Triathlon Tritanium Metal-Backed Patella or prefers to use a cemented All Poly-Patella, then the All-Poly Patella Drill (6541-3-524) must be used.
- Drill three fixation holes with the appropriate drill.



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Additional instruments for Triathlon Tritanium Tibial Baseplate and Metal-Backed Patella

Part #	Description	Size	Tray location
6541-6-013	Triathlon Cementless Keel Punch	1-3	
6541-6-046	Triathlon Cementless Keel Punch	4-6	Triathlon Cementless Case
6541-6-078	Triathlon Cementless Keel Punch	7-8	_
6541-8-003	Triathlon Cementless Case		
6541-2-64X	Triathlon Tibial Peg Drill Template	X=1-8	
6541-2-625	Tritanium Tibial Peg Drill	1/8 inch	
6541-2-626	Tritanium Dense Bone Peg Drill Tibial	7/32 inch	
6541-3-530	Tritanium Patella Inserter		
6541-3-319	Symmetric Patella Capture	S31	
6541-3-339	Symmetric Patella Capture	S33	
6541-3-360	Symmetric Patella Capture	S36	Triathlon
6541-3-391	Symmetric Patella Capture	S39	Tray
6541-3-299	Asymmetric Patella Capture	A29	
6541-3-320	Asymmetric Patella Capture	A32	
6541-3-350	Asymmetric Patella Capture	A35	_
6541-3-391	Asymmetric Patella Capture	A38	_
6541-3-401	Asymmetric Patella Capture	A40	_
6541-3-526	Tritanium Dense Bone Patella Drill		
6541-8-100	Triathlon Tritanium Prep Tray		
1020-9000	Single Tray Case		

*6541-3-522 Metal-Backed Patella Drill is used to prepare both the Triathlon Metal-Backed Patella Beaded w/Peri-Apatite and the Tritanium Metal-Backed Patella

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DIMENSIONS

Triathlon Tritanium Baseplate dimensions

Size	M/L width	A/P width	Keel depth
1	61	40	28
2	64	42	28
3	67	44	28
4	70	46	34
5	74	49	34
6	77	52	34
7	80	56	39
8	85	60	39

Note: All dimensions are in millimeters

Pegs are cruciform in shape and the pressfit is not circumferential. The pressfit is on the flutes

Tritanium Baseplate								
Peg diameter	7							
Tritanium foam thickness	1.14							
Keel pressfit on each side	When prepared with Cementless Keel Punch (6541-2-013 for size 1-3, 6541-2-046 for size 4-6, or 6541-6-078 for size 7-8): AP: 0.36							
Peg pressfit	When prepared with 1/8" Peg Drill: 3.7 When prepared with the 7/32" Dense Peg Drill: 1.4							
Peg length	Size 1	Size 2	Size 3	Size 4	Size 5	Size 6	Size 7	Size 8
	7	8	9	9	10	11	11	12

Note: All dimensions are measured in millimeters

Tritanium Metal-Backed Patella

Asymmetric patella

		_	_			
Size	$A29 \times 9$	$A32 \times 10$	A35×10		$A38 \times$	11 A40×11
Superior/inferior width	29	32	35		38	40
M/L width	33	36	39		42	44
Thickness	9	10	10		11	11
Peg diameter	6.1					
Symmetric patella						
Size	S31 ×	9 S3	3×9	S36>	< 10	S39×11
Patella diameter	31		33	36	5	39

Thickness	9	9	10	11

Tritanium patella peg diameter is 0.03 mm larger than the pegs of PA Beaded Metal-Backed Patella

Patella sizes with the same colors have the same peg locations							
All-poly Asymmetric	A29 imes 9	$A32 \times 10$	A35 imes 10	$A38 \times 11$	A40 imes 11		
All-poly Symmetric	S27 imes 8	S29×8	$S31 \times 9$	$S33 \times 9$	S36 imes 10	S39 imes 11	
Tritanium Asymmetric	$A29 \times 9$	$A32 \times 10$	A35 x 10	$A38 \times 11$	A40 imes 11		
Tritanium Symmetric			S31×9	S33×9	$S36 \times 10$	S39×11	

Peg pressfit for Metal-Backed Patella					
When prepared with 5.7 mm Standard Metal-Back Patella Drill (6541-3-522)	0.4				
When prepared with 6 mm Dense Bone Patella Drill (6541-3-526)	0.15				

Note: All dimensions are measured in millimeters.

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Zimmer Biomet Persona¹

Trabecular Metal

Trabecular Metal is Zimmer Biomet's cementless technology. Note the underside geometry and peg designs of Zimmer Biomet's Trabecular Metal baseplates have changed over the years.^{1,2,3}

> NexGen Trabecular Metal Monoblock Tibia 2 hex pegs, symmetric design²

NexGen Trabecular Metal Tibial Tray³ 3 hex pegs, symmetric design

Persona Trabecular Metal Tibial Tray¹ 2 hex pegs, asymmetric design

Stress shielding

Bone tissue is sensitive to the mechanical loads or stresses applied to it, and changes in applied loads can trigger bone remodeling. If bone is not stressed, it can remodel to become less dense and weaker. Decreases in bone density may increase the risk of migration and loosening of the prosthesis.⁴ If biologic fixation occurs in a baseplate distally before it occurs proximally, the loads can be absorbed by the baseplate proximally and "shield" the proximal tibia from stress. This can lead to a decrease in bone density.

The cementless tibial pegs manufactured with Trabecular Metal technology feature pegs that are fully coated proximally and distally. In a study of 101 TKAs (93 patients) with NexGen Trabecular Metal baseplate, eight failures with stress shielding

were observed at a mean of 18 months.⁵

NexGen Trabecular Metal monoblock baseplate

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The additively manufactured Triathlon Tritanium Baseplate is designed to address the clinical challenges of stress shielding. The porous structures of the Triathlon Tritanium Baseplate are strategically positioned on the proximal pegs and keel to avoid porous metal in the distal areas, which may reduce the risks of stress shielding. Additionally, avoiding biologic fixation around distal pegs is a consideration in case of revision.

Triathlon Tritanium Baseplate

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Peg and keel designs

Given the importance of stable primary fixation,⁶ underside features of the Triathlon Tritanium Baseplate were designed to reduce micromotion and liftoff.^{7,8} A benchtop test analyzed the effect of peg geometry on fixation and showed increased pull-out force required for our bullet cruciform peg compared to Zimmer Biomet's hex peg.⁸ Coupled with our tibial keel design, Triathlon Tritanium Baseplate had less liftoff than Zimmer Biomet's dual pegs design.⁷

DePuy Attune Rotating Platform (RP) & Fixed Bearing (FB) Cementless Knee^{1,2,3}

Attune's cementless TKA system can be implanted with either Rotating Platform (RP) or fixed bearing (FB) tibial baseplates.^{1,2,3} The cementless

femoral components and RP tibial baseplate both feature POROCOAT porous-coating technology, which is composed of commercially pure titanium sintered metal beads.^{1,2} The FB cementless tibial baseplate is manufactured from 3D printed

Stress shielding

Bone tissue is sensitive to the mechanical loads or stresses applied to it, and changes in applied loads can trigger bone remodeling. If bone is not stressed, it can remodel to become less dense and weaker. Decreases in bone density may increase the risk of migration and loosening of the prosthesis.⁴ If biologic fixation occurs in a baseplate distally before it occurs proximally, the loads can be absorbed by the baseplate proximally and "shield" the proximal tibia from stress. This can lead to decrease in bone density.

The tibial pegs on Attune RP and FB cementless baseplates are fully coated with titanium sintered beads proximally and distally.^{1,2} In a study of 101 TKAs (93 patients) with NexGen Trabecular Metal baseplate, eight failures with stress shielding were observed at a mean of 18 months.⁵

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The additively manufactured Triathlon Tritanium Baseplate is designed to address the clinical challenges of stress shielding. The porous structures of the Tritanium Baseplate are strategically positioned on the proximal pegs and keel to avoid porous metal in the distal areas, which may reduce the risks of stress shielding. Additionally, avoiding biologic fixation around the distal pegs is a consideration in case of revision.

Peg designs

Given the importance of stable primary fixation,⁶ the underside feature of the Tritanium Baseplate was designed to reduce micromotion and liftoff.^{7,8} Attune's cementless tibia has four short rounded pegs.¹ A benchtop test analyzed the effect of peg geometry on fixation and showed increased pullout force required for our bullet cruciform peg compared to a 10 mm bullet design.⁸

WHY CEMENTLESS TKA

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