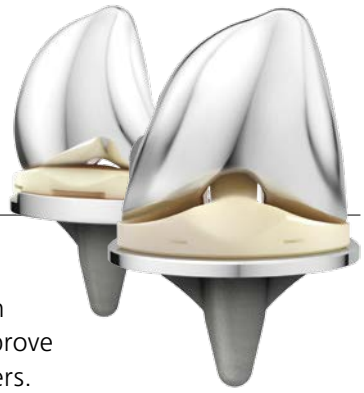
DePuy Synthes
PART OF THE Johnson & Johnson FAMILY OF COMPANIES

ATTUNE® KNEE SYSTEM

VALUE ANALYSIS BRIEF



VALUE SUMMARY

The ATTUNE® Knee System is designed to reduce pain and improve patient satisfaction around the world. Extensive research and science has gone into the design to help improve functional outcomes for patients, performance for surgeons, and efficiency for providers.

Since the commercial launch in 2013, the ATTUNE Knee System has shown statistically significant improvements in multiple Patient Reported Outcome Measures (PROMs) compared to certain leading knee brands.[1] Additional studies have demonstrated significant improvements in patellofemoral outcomes, including anterior knee pain, compared to another leading knee brand.[2,5,12,14] DePuy Synthes was granted over 60 patents based on proprietary ATTUNE Knee System technology.[3]

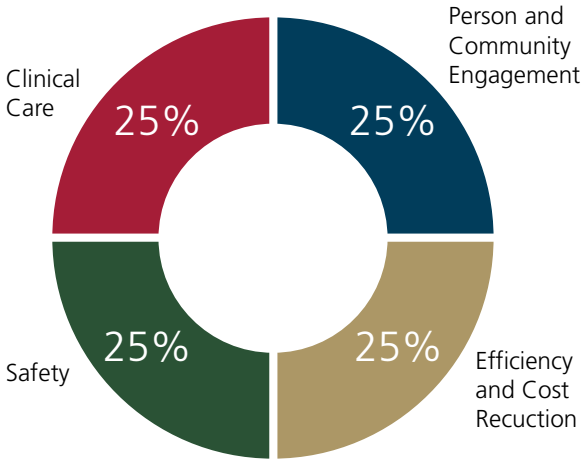
UNMET NEEDS IN TOTAL KNEE ARTHROPLASTY

Data shows that as recently as 2009, between 10% and 20% of total knee arthroplasty patients were dissatisfied with their results.[4]

What Impacts Patient Satisfaction:

- **Anterior Knee Pain:** One of the most common complaints after total knee replacement is anterior knee pain. Data has shown that up to 50% of patients experience anterior knee pain.[5,13]
- **Instability:** Data has shown that activities which cause a greater force on the knee after total knee arthroplasty lead to increased problems. This has been attributed to design factors, procedure related challenges, and inadequate soft tissue stability.[6] Patient dissatisfaction increases to 28% when patients perform high demand activities like going up or down stairs.[4]
- **Implant Fit:** Tibial base overhang on the posterior medial side of the resected tibial bone can cause irritation of the Medial Collateral Ligament (MCL). Overhang on the posterior lateral side can result in impingement with the popliteal tendon. Femoral component overhang of 3 mm is associated with an almost twofold increased risk of knee pain more severe than occasional or mild at 2 years after surgery.[7] A study with some commonly used knee designs has shown that 40% of men and 68% of women have at least one area of the implant with 3 mm or more of overhang.[7]

2017 VALUE BASED PURCHASING DOMAINS AND PERCENTAGE OF REIMBURSEMENT



VALUE BASED PURCHASING

Comprehensive Care for Joint Replacment (CJR Model)

CJR is a mandatory bundled payment for Medicare fee-for-service knee and hip replacement in 67 selected geographical areas. Hospitals are held accountable for the quality and cost of care for lower extremity joint replacements. This includes the cost during the hospital stay and for 90 days after discharge. The hospital may set up gainsharing or division of risk with partners in their system.[8]

THE ATTUNE KNEE SYSTEM IS DESIGNED TO **REDUCE PAIN, INCREASE STABILITY, AND ADDRESS IMPLANT FIT**

ATTUNE Knee features address unmet needs for hospitals, patients, and surgeons. Each of these technologies was designed to provide function for surgeons in the operating room and for patients after surgery, resulting in over 60 patents granted for the ATTUNE Knee System.[3]

The ATTUNE Knee is Designed for Motion and Stability:

The chart below contains data from a study looking at the ATTUNE Knee and the other named TKA designs in relation to constraint at various degrees of flexion. This data supports that the ATTUNE Knee offers more stability than the other named TKA designs while still allowing rotational freedom in deeper flexion.[9] This is accomplished through a gradually reducing radius (ATTUNE GRADIUS™ Curve) on the femoral component paired with a mating tibial insert. The result is a balanced level of motion and stability that more closely matches that found in the native knee.[10] This aids in patient performance during dynamic activities such as going up and down stairs.[9] The study concluded the other manufacturers' TKA implants named in the chart below have abrupt* changes during the gait cycle (highlighted by the purple arrows in the chart from Fitzpatrick et al.[9]).

FLEXION ANGLE	0°	15°	30°	60°	90°	120°	Abrupt Change*
ATTUNE CR FB Knee Conformity	0.88	0.83	0.77	0.66	0.67	0.35	None
ATTUNE CR RP Knee Conformity	0.99	0.93	0.87	0.74	0.76	0.40	None
Smith & Nephew® Genesis® II CR FB Conformity	0.59	0.32	0.32	0.32	0.21	0.21	11°
Biomet® Vanguard® CR FB Conformity	0.47	0.47	0.30	0.30	0.21	0.21	25°
Zimmer® NexGen® CR FB Conformity	0.54	0.54	0.54	0.31	0.31	0.31	37°
Stryker® Triathlon™ CR FB Conformity	0.38	0.22	0.22	0.22	0.22	0.11	10°

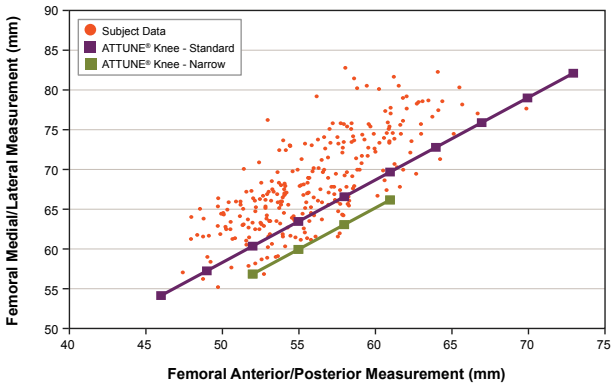
*An abrupt change occurs when the geometry of the TKA implant changes from a large load-bearing distal radius to a smaller posterior radius.[29]

Extensive Size Offering for Diverse Population:

To address sizing challenges, the ATTUNE Knee System sizing is based on extensive research using a global database of patients.[11] Based on this data, DePuy Synthes Companies created an extensive portfolio with 10 femoral and tibial component sizes, plus 4 additional narrow femoral component sizes, to meet the needs of the diverse worldwide population.[11]

The chart below from Fitzpatrick et al.[11] depicts the ATTUNE Knee femoral sizing line overlaid on the measurements of patients studied. The femoral sizes were developed to minimize instances of component overhang (i.e. greater number of patients above the line rather than below).

- Standard: The standard sizing line (purple) shows coverage without overhang is achieved for approximately 70% of patients.[11]
- Narrow: The narrow femoral sizes (green line) show coverage without overhang is achieved for approximately 30% of patients beyond the standard sizing.[11]



ATTUNE KNEE PATIENTS HAVE BEEN SHOWN TO EXPERIENCE **STATISTICALLY SIGNIFICANT IMPROVEMENTS IN PATELLOFEMORAL OUTCOMES** COMPARED TO ANOTHER LEADING KNEE BRAND [2,5,12,14]

Literature has shown that up to 50% of TKA patients experience anterior knee pain,[5,13] one of the most common complaints after total knee arthroplasty. When compared to a leading knee brand, two studies demonstrated statistically significant reductions in anterior knee pain for patients implanted with ATTUNE Posterior Stabilized Knee at 2 year follow-up[2,5], with one study showing as few as 2% of patients experienced post-operative anterior knee pain.[2] Other recent studies have observed less incidence of symptomatic crepitus for ATTUNE PS Knees compared to a leading knee brand.[12,14]

THE ATTUNE KNEE SYSTEM OFFERS **A WIDE VARIETY OF CHOICES** FOR **EVERY SURGICAL WORKFLOW**

The ATTUNE Knee accommodates patient variation by currently offering a wider breadth of sizes compared with certain other leading knee systems in the market, as outlined in the table below.

	Femoral Sizes	Tibial Sizes	Insert Thickness Increments
ATTUNE Knee	14	10	1-2 mm increments
Zimmer® Persona®[15]	21	9	1-2 mm increments
Stryker® Triathlon™[16]	8	8	2-3 mm increments
Biomet® Vanguard®[17]	10	9	1-2 mm increments
Smith & Nephew® Journey 2™[18]	10	8	1-4 mm increments

The patella components within the ATTUNE System are designed with a dome that is offset medially. This offset is designed to reflect the natural patella shape and enhance patellofemoral function. The chart below shows that the ATTUNE Knee System is one of the few leading TKA systems currently in the market (mentioned below) with both dome and medially offset patella options.

Knee Systems with a Medialized Patella	
ATTUNE Knee	Yes
Zimmer® Persona®[15]	No
Stryker® Triathlon™[16]	Yes
Biomet® Vanguard®[17]	No
Smith & Nephew® Journey 2™[18]	No

ATTUNE KNEE US CLASS III PREMARKET APPROVALS† (PMA):

- PS & CR Femoral Components
- Medialized Dome and Medialized Anatomic Patella Components
- PS & CR Rotating Platform Tibial Inserts with AOX™ Antioxidant Polyethylene
- Rotating Platform Tibial Base

† PMA approval P830055.

ATTUNE KNEE SYSTEM OVERVIEW

The ATTUNE Knee System is designed to deliver a high level of stability and motion. DePuy Synthes Companies has applied for extensive patent protection in countries throughout the world for the ATTUNE System implants, instruments, and surgical methods. In the U.S. alone, there are over 60 patents granted for key inventions related to ATTUNE Knee implants and instruments.[3]

- Available in Rotating Platform (RP) and Fixed Bearing (FB)
- CR and PS implant variants designed to accommodate Posterior Stabilized (PS), Cruciate Retaining (CR) and Cruciate Sacrificing (CS) techniques
- 14 Left and Right Femoral Sizes (includes Standard and Narrow options)
- 10 Tibial Sizes
- 1 mm Tibial Insert Increments for most commonly used thicknesses and 2 mm for remainder
- 0.5 mm Patella Thickness Increments
- Medialized Dome and Medialized Anatomic Patella Options
- Gap Balancing & Measured Resection Techniques
- Advanced materials: AOX Antioxidant Polyethylene for all Patella Components and Tibial Inserts
- Options include stemmed tibia in primary TKA

THE ATTUNE KNEE SYSTEM HAS SHOWN **IMPROVED PATIENT REPORTED OUTCOMES** COMPARED TO CERTAIN OTHER LEADING KNEE BRANDS[1] AND **PERFORMED FAVORABLY TO THE CLASS OF TKR** IN TWO NATIONAL JOINT REGISTRIES

Patient Reported Outcome Measures (PROMs) are pre- and post-operative questionnaires that measure outcomes from the patient's perspective. The Oxford Knee Score (OKS) is a widely used PROM that measures pain and functional outcomes. The Oxford Knee Score is graded on a scale of 0-48, with 48 being the highest score.[20]

Interim results of two worldwide, multi-center prospective studies demonstrated four PROMs that favored the ATTUNE Knee System. OKS data is shown in the table below.[1]

PROMS favor ATTUNE Knee[1]

PROM	Scale	Brand	1 year	2 years
Oxford Knee Score	0-48	ATTUNE Knee	41.5 ± 6.2	42.3 ± 6.3
		Leading Knee Brands (non-ATTUNE Knee)*	40.2 ± 7.4	41.4 ± 6.9

* Leading brands included SIGMA® Knee, NexGen®, and Triathlon®, n=845

Results from 9,294 ATTUNE Knee System implants have been recorded in two large national joint registries. The National Joint Registry for England, Wales, Ireland, and the Isle of Man (NJR), and the Australian Orthopedic Association National Joint Registry Report (AOANJRR) both demonstrate real world evidence with the ATTUNE Knee System.

Per the 2016 NJR, the ATTUNE Knee estimated cumulative percent revision was 1.39% at three years (98.61% survivorship) for 4,463 knees, comparing favorably to the class of all Cemented TKA that has an estimated cumulative percent revision of 1.50%.[21]

Table 3.28–Cumulative Percentage Probability of a First Revision (95% CI) if Time Elapsed Since Primary Operation is:

Adapted from tables 3.24a, 3.28	Cumulative Percentage Probability of a First Revision (95% CI) if Time Elapsed Since Primary Operation is					
Brand	Number of Knee Joints	1 year	3 years	5 years	7 years	10 years
ATTUNE Knee (Table 3.28)	4,463	0.25 (0.13-0.49)	1.39 (0.64-3.03)			
ALL Cemented Knee (Table 3.24a)	737,759	0.39 (0.38-0.41)	1.50 (1.47-1.53)	2.14 (2.10-2.18)	2.65 (2.60-2.70)	3.37 (3.30-3.45)

Per the 2016 AOANJRR, in which 4,831 ATTUNE Knees are being tracked, the ATTUNE Knee estimated cumulative percent revision was 0.5% (ATTUNE Knee Cruciate Retaining, N=3199), 0.4% (ATTUNE Knee Posterior Stabilized, N=1632) at one year.[22] This compares favorably to the overall class of cemented total knee arthroplasty at one year, which has an estimated cumulative percent revision of 1.0%[22]

Extracted from Table KT9 Cumulative Percent Revision of Primary Total Knee Replacement with Cemented Fixation

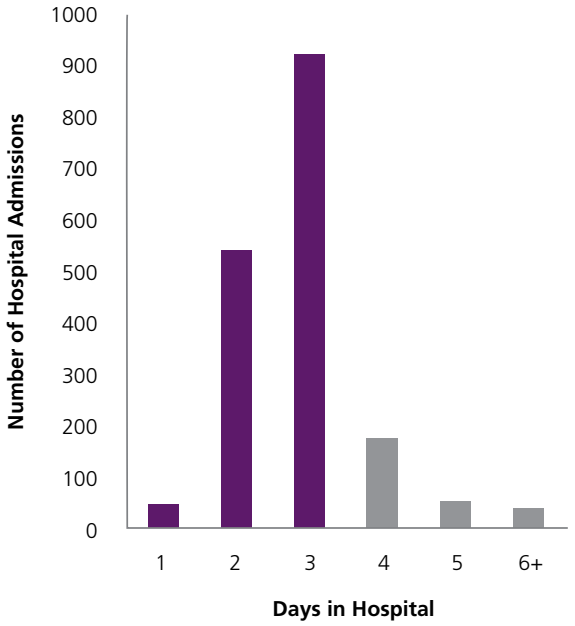
Femoral Component	Tibial Component	N Revised	N Total	1 year	3 years	5 years	7 years	10 years	15 years
ATTUNE CR	ATTUNE	17	3,199	0.5 (0.3, 0.9)					
ATTUNE PS	ATTUNE	7	1,632	0.4 (0.2-0.9)					
Table KT22 Cemented Fixation Class data		8,439	258,789	1.0 (0.9, 1.0)	2.6 (2.5, 2.6)	3.4 (3.4, 3.5)	4.2 (4.1, 4.3)	5.1 (5.0, 5.3)	7.3 (6.9, 7.7)

THE ATTUNE KNEE SYSTEM MAY HELP YOU **ACHIEVE THE TRIPLE AIM GOALS**: IMPROVED PATIENT EXPERIENCE, IMPROVED OUTCOMES, AND REDUCED COSTS

DePuy Synthes Companies queried the Premier Perspective™ Database in late 2015. The Premier Perspective™ Database, which includes billing, cost, device, medication, diagnosis, and procedure data from more than 670 hospitals in the United States, was analyzed to identify trends in TKA. The data was analyzed for the ATTUNE Knee's performance (single-arm) and a comparison of the ATTUNE Knee compared to the Triathlon™ Knee (comparative arm).[24]

The objective of the single-arm analysis was to evaluate hospital length of stay (LOS) and discharge status for patients who received TKA with the ATTUNE Knee. 1,766 patients received the ATTUNE Knee within a total of 55 hospitals over the observation period. The study concluded that 85% of ATTUNE Knee patients in the study were discharged in 3 days or less.[23]

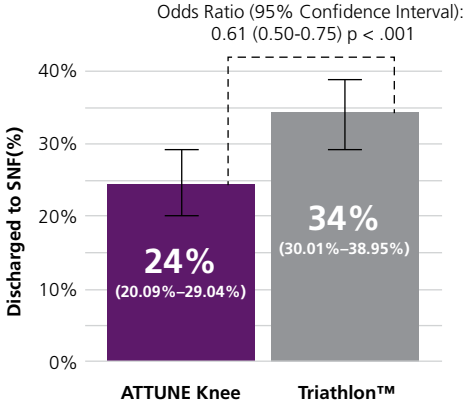
Eighty-five percent of patients (1,506/1,766) were discharged in three days or less



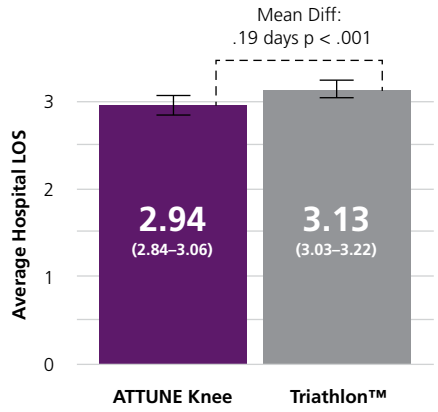
Using the same Premier Perspective™ data, a retrospective, comparative review of real world claims demonstrated that patients in the study who received a TKA with the ATTUNE Knee had statistically shorter length of stay (2.94 vs. 3.13; p<0.001) compared to the patients in the study implanted with Triathlon™ Knee.[24] The comparative study included 38 hospitals in the U.S., representing 1,178 primary, unilateral TKAs with the ATTUNE Knee System and 5,707 primary, unilateral TKAs with Triathlon™. Small improvements in hospital length of stay and reduced total hospital costs are becoming increasingly relevant, as the shift to value based care places more financial burden on providers for the episode of care.[24]

Patients in the study who received TKA with the ATTUNE Knee had a slightly shorter Length of Stay (LOS) and were less likely to be discharged to a skilled nursing facility (SNF) and more likely to be discharged home versus patients in the study who received a Triathlon™ Knee.[24] Sensitivity analyses suggest that these effects could not be explained by patient factors including age, insurance or marital status.[24]

Adjusted Proportion of Patients Discharged to Skilled Nursing Facility (SNF), Mean (95% Confidence Interval)



Adjusted Hospital Length of Stay, Mean (95% Confidence Interval)



INNOVATIVE DESIGN PROVIDES **INCREASED STABILITY AND IMPROVED PATELLOFEMORAL FUNCTION** COMPARED TO ANOTHER LEADING KNEE BRAND [2,5,12,14]

ATTUNE Knee features address unmet needs for hospitals, patients, and surgeons. Each of these technologies was designed to provide function for surgeons in the operating room and for patients after surgery, resulting in over 60 patents granted for the ATTUNE Knee System.[3]

ATTUNE GRADIUS™ Curve

The patented ATTUNE GRADIUS™ Curve is designed with a gradually reducing femoral radius. This curve potentially creates a smooth transition during knee bending and produces high stability of the knee by reducing unnatural sliding of the femur on the tibia.[25]

GLIDERIGHT™ Articulation

The patellofemoral interaction is one of the more challenging aspects of total knee arthroplasty.[27] The GLIDERIGHT™ Articulation encompasses a trochlear groove designed to accommodate patient variation and soft tissue interaction, and patella components designed to optimize patella tracking while maintaining bone coverage.

SOFCAM™ Contact

For the Posterior Stabilized design, the interaction between the cam and spine, the articular surface geometry, and the collateral ligaments is complex and essential to the function of the knee in deep flexion. The proprietary s-curve design of the SOFCAM™ Contact is designed to provide a smooth engagement for gradual femoral rollback and stability in flexion, while reducing the forces transferred to the tibial spine.[26]

INTUITION™ Instruments

The INTUITION™ Instruments were developed to deliver efficiencies for all stakeholders and an intuitive surgical process. Advanced composite materials and modular designs allow lighter instruments, less trials, and less instrument trays while providing intra-operative flexibility for the surgeon.[28] These innovative instruments work with the advancements in the design to help balance the soft tissues and precisely control the implant position and fit for each patient.

LOGICLOCK™ Tibial Base

Surgeons are able to match the femoral size to the insert size every time to achieve the highest conformity and optimized stability in early flexion.[9] The LOGICLOCK™ Tibial Base is designed to allow surgeons to use a tibial base that can be upsized or downsized two sizes versus the insert. The ATTUNE Knee is differentiated from Fixed Bearing competitive designs (Persona®, Vanguard®, Triathlon™, NexGen®) which currently do not provide this insert to femur matching in every case.[15-18]

aox™
ANTIOXIDANT
POLYETHYLENE

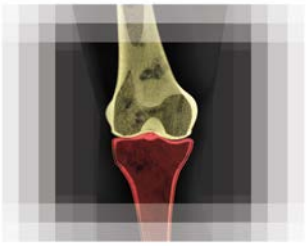
AOX™ Antioxidant Polyethylene

AOX Antioxidant Polyethylene has an advanced blend of polyethylene resin and a proprietary COVERNOX™ Antioxidant. AOX Polyethylene is designed to deliver optimal wear resistance and long term oxidative stability.

COMBINED WITH OTHER DEPUY SYNTHES COMPANIES PROGRAMS, THE ATTUNE KNEE SYSTEM MAY **REDUCE COSTS AND INCREASE EFFICIENCIES**

Efficiency

Digital Templating: Digital Templating is a pre-operative templating tool that can help size the implant and potentially reduce the number of instruments needed in the operating room on the day of surgery.



ATTUNE Knee Primary Size Specific Trays

The ATTUNE Knee features Size Specific trays that can help potentially reduce the number of trays from eight to two full & two half trays. Combined with digital templating, significant efficiencies may be realized with reduced sterilization costs, reduced set up and tear down time, and less space required to store instruments in the facility.

TRUMATCH® Personalized Solutions:

TRUMATCH® Personalized Solutions is the DePuy Synthes Companies Patient Specific Instrumentation System. TRUMATCH Personalized Solutions delivers personalized patient cutting blocks or pin guides based on CT scans of a patient's knee.

DATA Tracker App

This tablet based application can be used to record start and stop times for set up, anaesthesia, surgery, and room turn over. This data is compiled into charts to demonstrate where efficiencies are being realized and lost.

Health Partner for Knees

The Health Partner for Knees patient app is a 24/7 personal coach that is designed to help prepare patients for surgery and recovery, from 4 weeks pre-operatively up to 12 weeks post-operatively. Using proven behavioral science and energy management techniques along with relevant health information, the app aims to motivate patients on their path to recovery, while potentially reducing readmissions and post-surgical complications.

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Extracted from: Table KT9 - Cumulative Percent Revision of Primary Total Knee Replacement with Cemented Fixation

Femoral Component	Tibial Component	N Revised	N Total	1 Yr	3 Yrs	5 Yrs	7 Yrs	10 Yrs	15 Yrs
Attune CR	Attune	17	3199	0.5 (0.3, 0.9)					
Attune PS	Attune	7	1632	0.4 (0.2, 0.9)					

Extracted from: Table KT22 - Cumulative Percent Revision of Primary Total Knee Replacement by Fixation (Primary Diagnosis OA)

Fixation	N Revised	N Total	1 Yr	3 Yrs	5 Yrs	7 Yrs	10 Yrs	15 Yrs
Cemented	8439	258789	1.0 (0.9, 1.0)	2.6 (2.5, 2.6)	3.4 (3.4, 3.5)	4.2 (4.1, 4.3)	5.1 (5.0, 5.3)	7.3 (6.9, 7.7)
Cementless	4612	103903	1.2 (1.1, 1.3)	3.2 (3.1, 3.3)	4.3 (4.2, 4.4)	5.0 (4.9, 5.2)	6.1 (5.9, 6.3)	8.1 (7.7, 8.6)
Hybrid	3964	119262	0.9 (0.9, 1.0)	2.5 (2.4, 2.6)	3.3 (3.2, 3.5)	3.9 (3.8, 4.1)	4.8 (4.7, 5.0)	6.6 (6.2, 7.0)
TOTAL	**17015**	**481954**						

Note: Excluding cementless Genesis Oxinium and Profix Oxinium femoral prostheses

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