ATTUNE® KNEE SYSTEM
VALUE ANALYSIS BRIEF

VALUE SUMMARY
The ATTUNE® Knee System is designed to address the unmet needs of patients, surgeons, and hospital providers 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.

BENEFITS OF TOTAL KNEE ARTHROPLASTY (TKA)
Total knee arthroplasty helps to relieve pain and restore function and mobility for arthritis pain sufferers. It is widely recognized as one of the most performed and successful surgical procedures. A review of 350,000 knees in a recent registry publication found that primary knees had a 93.5% survivorship rate at 12 years.¹

In addition, total knee replacement surgery generates net societal savings of approximately $19,000* per patient lifetime due to reduced disability costs and improved productivity. For all knee replacement surgeries performed in the U.S. in 2009, aggregate lifetime savings was estimated at $12 billion.²

Data has shown that 98% of working patients return to work following total knee replacement.³

UNMET NEEDS IN TKA

Patient Satisfaction:
• Patient dissatisfaction after knee replacement is between 10% and 20%. The leading indicator for patient dissatisfaction is pain.⁴
• Pain management is 1 of 10 Hospital Assessment of Healthcare Providers and Systems (HCAHPS) measures that impact Medicare reimbursement.⁵
• Implant companies have an opportunity to work with hospitals to improve the patient experience and patient satisfaction.

Operating Room (OR) Efficiency:
• Every minute in the OR costs on average $62.⁶* The average knee replacement surgery lasts approximately 1 hour and 12 minutes, equaling $4,464.⁷*
• Data shows that new OR teams are 9% less efficient than teams that have been together for more than 5 years.⁸
• Implant companies have an opportunity to help reduce the learning curve of OR teams and provide more efficient solutions to positively impact OR time and reduce costs.

²⁰¹⁵ Value Based Purchasing measures and percentage of weight impacting reimbursement

In 2015, 1.5% of hospital payments from The Centers for Medicare & Medicaid Services (CMS) will be impacted by the quality measures in the chart above.⁹ Each quality measure carries a slightly different weight. Implant companies can help hospitals address these measures by providing products and services that are designed to improve patient satisfaction and increase system efficiency.

*Note: Cost and Efficiency data is US-specific data and may be different in other geographies.
PATIENT SATISFACTION

Data shows that as recently as 2009, between 10% and 20% of TKA patients were dissatisfied with their results. This dissatisfaction included daily activities such as stair descent and rising from a seated position.4

Limitations of Total Knee Patients 1 Year After Surgery

Patient research from 2007 showed that 58% were “limited a lot” when kneeling, and 38% were “limited a lot” when squatting after knee replacement surgery.9

What Impacts Patient Satisfaction:

• Instability: Data has shown that activities which cause a greater force on the knee after TKA lead to increased problems. This has been attributed to design deficiencies, procedure related challenges, and inadequate soft tissue stability.10 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.11 With commonly used knee designs, data 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.11

• Anterior Knee Pain: One of the most common complaints after total knee replacement is anterior knee pain. Data has shown that up to 25% of patients have anterior knee pain.12

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, as of this writing, there are 17 patents granted for key inventions related to the ATTUNE Implants and Instruments.13

ATTUNE System Options:

• 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™ Polyethylene for all Patella Components and Tibial Inserts

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

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

PMA Supplements: P830055/S121, P830055/S127

† PMA approvals for Class III medical devices require higher levels of research and testing before market introduction. Only 10% of medical devices go through the PMA approval process. Most knee systems in the US are Class II devices and are cleared through a substantially equivalent product process called the 510K.14
The ATTUNE Knee System delivers breakthrough discoveries that make the ATTUNE Knee an advancement for hospitals, patients, and surgeons. Each of these significant technologies was designed to provide function for surgeons in the operating room and for patients after surgery.

**ATTUNE GRADIUS™ Curve**
The patented ATTUNE GRADIUS™ Curve is designed with a gradually reducing femoral radius. This curve creates a smooth transition during knee bending and produces high stability of the knee by minimizing unnatural sliding of the femur on the tibia.\(^{15}\)

**GLIDERIGHT™ Articulation**
The patello-femoral interaction is one of the more challenging aspects of total knee arthroplasty.\(^{22}\) 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 provides a smooth engagement for gradual femoral rollback and stability in flexion, while reducing the forces transferred to the tibial spine.\(^{16}\)

**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.\(^{23}\) These innovative instruments work with the advancements in the implant design to help balance the soft tissues and precisely control the implant position and fit for each patient.

**LOGICLOCK™ Tibial Base**
Differentiated to current offerings, 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.\(^{17}\) The LOGICLOCK™ Tibial Base allows surgeons to use a tibial base that can be upsized or downsized two sizes versus the insert. No other Fixed Bearing device provides this insert to femur matching in every case.\(^{18, 19, 20, 21}\)

**AOX™ Polyethylene**
AOX™ Polyethylene has an advanced blend of polyethylene resin and a proprietary COVERNOX™ Antioxidant. AOX Polyethylene is uniquely designed to deliver optimal wear resistance and long term oxidative stability.
Knees become unstable when the femur is able to slide forward on the polyethylene insert, similar to a ball on a flat surface.15

How to Achieve Implant Stability:
Increasing the conformity between the femoral component and insert can help improve implant stability.24 A perfectly stable knee would have a conformity ratio of 1 (the insert would perfectly conform to the femoral like a ball in a socket). A completely unstable knee would have a conformity ratio of 0 (like a ball on a flat surface).

Reduced implant conformity in deeper flexion is necessary to allow the knee to rotate in flexion. Abrupt changes in conformity while the knee is flexing may allow the femoral to slide forward on the tibial insert. For this reason, a gradual reduction in conformity is needed, as it improves implant stability while allowing the freedom to rotate in deeper flexion. A gradual reduction in conformity has been shown improve implant stability while allowing the freedom to move.15

The Goal: The goal of a TKA design is to have a high level of conformity in flexion during gait (0–70 degrees), allow for rotational freedom in deeper flexion, and mitigate any abrupt changes in conformity.

The ATTUNE Knee is Designed for Motion and Stability:
The chart below shows how the ATTUNE Knee provides more stability while still allowing rotational freedom in deeper flexion.17 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.24 This aids in patient performance during dynamic activities such as going up and down stairs.17 Other manufacturers have abrupt changes in their design (highlighted by the purple arrows).

| FLEXION ANGLE17 | 0º 15º 30º 60º 90º 120º 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 | 11º |
| Biomet® Vanguard® CR FB Conformity | 0.47 0.47 0.30 0.30 0.21 0.21 | 25º |
| Zimmer® NexGen® CR FB Conformity | 0.54 0.54 0.54 0.31 0.31 0.31 | 37º |
| Stryker® Triathlon® CR FB Conformity | 0.38 0.22 0.22 0.22 0.22 0.11 | 10º |
THE ATTUNE KNEE SYSTEM IS DESIGNED TO ADDRESS IMPLANT FIT

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. To address this and other sizing challenges, the ATTUNE Knee System sizing is based on extensive research using a global database of patients. From this analysis, DePuy Synthes Companies created a sizing portfolio to meet the needs of the diverse worldwide patient population. There are 10 sizes of femoral and tibial components sizes and 4 additional narrow femoral component sizes.

Maximizing Options and Efficiency:
- The ATTUNE Knee accommodates patient variation by offering a wider breadth of sizes compared with almost all other systems in the market.
- The ATTUNE Knee reduces the number of implant stock keeping units (SKUs) versus Persona™ by 66% (442 vs. 1,312).

Extensive Size Offering for Diverse Population:
The chart below depicts the ATTUNE Knee femoral sizing line overlaid on the measurements of the 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).
- The standard sizing line (purple) shows coverage without overhang is achieved for approximately 70% of patients.
- The narrow femoral sizes (green line) shows coverage without overhang is achieved for approximately 30% of patients.

<table>
<thead>
<tr>
<th>Femoral Sizes</th>
<th>Tibial Sizes</th>
<th>Insert Thickness Increments</th>
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ATTUNE Fixed Bearing Knee: The ATTUNE Knee System was designed with 10 symmetric tibial base sizes to address proper tibial coverage without overhang. In a review of 14,700 tibial bones, the ATTUNE Fixed Bearing Knee resulted in the greatest average coverage of the tibial plateau (84%), followed by, 83% with Genesis®, 81% with Persona™, and 80% with the SIGMA® Knee.

ATTUNE Rotating Platform Knee: The ATTUNE Rotating Platform Knee design was shown to have improved tibial coverage versus the fixed bearing designs. The ATTUNE Rotating Platform Tibial Base had 86% coverage without overhang. Because the polyethylene insert rotates with the femoral, the rotating platform base can be freely rotated on the tibia to maximize tibial coverage without affecting patella tracking.

The native tibia does have slight asymmetry (the medial side is 1.09 times larger on average than the lateral side). However, due to wide variations in patient anatomy, asymmetric designs may result in increased overhang for a number of patients. This is demonstrated by the shading to the left of the average line.

ATTUNE Fixed Bearing Knee: The ATTUNE Knee System was designed with 10 symmetric tibial base sizes to address proper tibial coverage without overhang. In a review of 14,700 tibial bones, the ATTUNE Fixed Bearing Knee resulted in the greatest average coverage of the tibial plateau (84%), followed by, 83% with Genesis®, 81% with Persona™, and 80% with the SIGMA® Knee.

ATTUNE Rotating Platform Knee: The ATTUNE Rotating Platform Knee design was shown to have improved tibial coverage versus the fixed bearing designs. The ATTUNE Rotating Platform Tibial Base had 86% coverage without overhang. Because the polyethylene insert rotates with the femoral, the rotating platform base can be freely rotated on the tibia to maximize tibial coverage without affecting patella tracking.

The colors represent the average amount of bone each tray does not cover on the tibia. Blue is 0 to 1 mm and Red is 4–5 mm.

When proper rotation is set for the tibial base, the ATTUNE Knee Tibial Base provides better coverage without overhang as compared to Zimmer® and Smith & Nephew®. The Rotating Platform Base provides improved coverage compared to the fixed bearing designs.
The ATTUNE Knee System was designed to help address one of the most common complaints after total knee replacement: anterior knee pain. Data has shown that up to 25% of patients experience anterior knee pain.12 Some of the design factors that may impact anterior knee pain include:28

1. The design of the patella component
2. The shape of the trochlear groove
3. The thickness of the femoral component

**Patella Design:** With many current systems, patella implants are designed as a central dome which does not reflect the shape of the native patella. This creates the need to manually offset the implant on the bone during implantation. Offsetting the central dome leaves exposed bone which may cause soft tissue disruption.

![Traditional Patella Design](image)

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 patello-femoral function. The asymmetric design allows for more opportunities to use a larger size patella to provide optimal bone coverage. The small and consistent increments between component sizes give surgeons flexibility to avoid overstuffing the patellar joint.

![ATTUNE Medialized Dome Patella Design](image)

**Patella Options:**

**Unresurfaced Patella:** The ATTUNE Trochlear Groove is designed to be similar to the trochlear groove of the native knee.29 This allows the ATTUNE Knee to be used with an unresurfaced patella.

**Medialized Dome:** This patella component provides optimal bone coverage and improved tracking compared to central dome designs.30

![Unresurfaced Patella, Medialized Dome Patella, Medialized Anatomic Patella](image)

**Medialized Anatomic:** This patella features a conforming lateral facet and a domed medial facet. This results in decreased patella tilt and improved extensor mechanism efficiency.31

**Trochlear Groove:**

The shape of the ATTUNE Knee Femoral Component is designed to complement the patient’s natural anatomy. The ATTUNE Knee System has a proportional trochlear groove angle that changes based on femoral size. In addition, the trochlear groove allows the patient’s soft tissues to control patella tracking for the first 30° and then it funnels the patella into the center of the groove after 30°. This is similar to how the native knee functions.22

**Reduced Implant Thickness/Bulk:**

To accommodate the native soft tissues surrounding the anterior portion of the knee, the ATTUNE Knee has a reduced femoral component profile.32 This, in addition to 0.5 mm patella thickness increments, helps keep the patella from being overstuffed, which may lead to anterior knee pain.

The ATTUNE Knee (Gray) has less metal than other predicate knee systems (Yellow).
THE ATTUNE KNEE IS DESIGNED TO ADDRESS EFFICIENCY WITH INTUITION INSTRUMENTS

The INTUITION Instruments Reduce the Effort From Start to Finish:
DePuy Synthes Companies set out to create a new set of innovative tools based on unmet needs, which required a new way of thinking about instrument designs.

Efficient Path:
With the inclusion of highly engineered polymers, weight was reduced by 51% as compared to current instrumentation. This reduction was designed to help hospitals comply with requirements for manual handling of heavy objects. By minimizing the number of instruments and trays, the effort and cost associated with the management of instruments are reduced.

Precise Control:
The INTUITION Instrumentation combines the surgical process with implant options to allow the surgeon to balance the soft tissues and precisely control the implant position and fit for each patient. With the 4-in-1 cutting block, the surgeon has precise control to fine tune the implant position through 1.5 mm A/P adjustments with a removable posterior saw capture for flexion gap assessment. In combination with the consistent 3 mm increments between femoral sizes and the 1 mm increments in tibial insert thicknesses, the INTUITION Instruments help deliver stability and motion.

Designed Clarity:
Orthopaedic instruments should provide clear and accurate information to reduce confusion and shorten the learning curve for OR teams. Design features including red actuators, high-contrast markings, and quick set/release functions make the INTUITION Instruments clear and easy to use from the moment the user picks them up.

Single layer trays and composite materials help reduce instrument weight by 51% compared to current instrumentation

High contrast markings to increase visibility
Red actuators indicate key surgical functions
Engineered polymers to reduce overall weight

Efficient path through fewer and lightweight instruments

Engineered polyme...
TRUMATCH® Personalized Solutions:
TRUMATCH® Personalized Solutions is DePuy Synthes Companies patient-specific instruments that are designed from a patient’s CT scan. TRUMATCH Personalized Solutions instruments are designed to uniquely fit a patient’s anatomy and must be ordered separately from the ATTUNE Knee.

- TRUMATCH Solutions was designed to increase procedural efficiency by reducing the number of instrument trays, eliminating up to nine surgical steps compared with traditional knee replacement, and delivering the guides sterile and ready to use, which may decrease hospital costs.35
- TRUMATCH Cutting Guides and TRUMATCH Pin Guides are less invasive than standard instrumentation and do not puncture the Intramedullary (IM) canal. Not puncturing the IM canal has been associated with decreased blood loss and reduced OR costs.36, 37*

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

- Digital templating eliminates the need to generate x-ray films, potentially reducing costs.
- Digital templating increases OR efficiencies through reduced trays and instruments and decreases OR complexities.

These intra-operative efficiencies can reduce the surgery cycle time.38*

*Note: Cost and Efficiency data is US-specific data and may be different in other geographies.
DePuy Synthes Companies offer additional programs and services that compliment the ATTUNE Knee Replacement System. This offering is known as the DEPUY SYNTHES ADVANTAGE™ Program.

DePuySynthes Advantage™

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