ANThEM®
Total Knee System
Design Rationale
ANTHEM®
Total Knee System
Fit for All

The ANTHEM Total Knee System was designed to provide an advanced and globally relevant prosthesis and instrumentation system while being accessible to all arthroplasty surgeons and patients.
• The ANTHEM™ knee system is a total knee prosthesis with advanced femoral and tibial anatomic design to promote improved anatomic implant fit for all patients globally.

• The ANTHEM knee is based upon trusted design pedigree incorporating clinically advanced technology such as the tibio-femoral articulation and patello-femoral function equivalent to the GENESIS II Total Knee System, which exhibits a 98% survivorship at 15 years.

• The ANTHEM Total Knee System coupled with ORTHOMATCH™ Universal Instrumentation Platform has been developed in conjunction with leading surgeons from Emerging Markets and Europe providing benefits by creating efficiency through intelligent design which translates into tangible value for surgeons, patients and healthcare providers.
Fit for ALL

Relevant Feature by Region

- Low profile anterior femoral flange
- Optimised M/L femoral component
- S-shaped trochlear groove
- Tibio-femoral 155° flexion
- Bone conserving PS box
- Asymmetric tibial base, shorter, medial stem
- DURAHONE® Advanced Finishing tibial polished surface
- ORTHOMATCH® instrument platform
Anatomic Implant Fit

Understanding Size and Shape of the Knee

Anthropometry, the study of the measurements and proportions of the human body, is relevant to knee arthroplasty. A better understanding of the significant differences in size and shape of patients’ knees may lead to being able to improve implant fit, and thereby reproduce normal knee anatomy more closely. From a recent systematic review of 30 peer reviewed articles, statistically significant anatomical and morphological differences of the knee joint critical to Total Knee Arthroplasty were found between geographical regions relating to 4:

- **Size:** Antero-Posterior height and Medio-Lateral width of the femur and tibia
- **Shape:** Aspect Ratio between Medio-Lateral width and Antero-Posterior height of femur and tibia

Due to historical and incomplete design data, many contemporary TKA implants do not adequately address these fundamental differences in shape and size. Inevitably this will mean that when addressing patients from different ethnicities, there will be a compromised implant fit.
Implant fit in Total Knee Arthroplasty

Total Knee Arthroplasty (TKA) is a highly successful surgery relieving pain and restoring function, however, the available results of this flagship procedure are largely derived from studies conducted in Caucasian patients. Patients from other regions, with knees of differing shapes and sizes, may be poorly served by contemporary TKA devices, which were primarily designed with Caucasian patients in mind.

Implications of implant fit

Tibial and Femoral implant overhang greater than 3-4mm (implant larger than resected bone surface) has been correlated to a reduced ROM, reduced function, and increased post-operative pain in patients undergoing TKA \(^{5,6,7,8}\). Underhang (implant smaller than resected bone surface) may cause issues such as uncovered cancellous bone leading to increased bleeding and compromised implant fixation \(^2\). Therefore the relationship between the implant and each patient’s individual anatomy may influence the following areas that are relevant to optimising outcomes of TKA:

**Implant fit**
- Femoral and Tibial size options to match the majority of patients
- Correct shape to accommodate regional and gender differences

**Surgical technique**
- Implant size selection to optimize bone cuts
- Ligament stability and balancing

**Function and longevity**
- Improved Kinematics (motion)
- Soft tissue irritation and pain caused by prosthesis overhang
- Sizing conformity to improve tribology and reduce wear

As correct implant fit contributes to clinical outcomes, an implant and instrumentation system that accommodates individual patients reduces clinical compromise and promotes longevity is desirable.
There are differences in the shape of the knee between ethnicities.

Aspect ratio provides a measure of relative femoral shape

Aspect ratio is defined as the Medio-Lateral width divided by the Antero-Posterior height of the femur or tibia. A larger aspect ratio corresponds to a larger ML dimension for a given AP size, while a smaller aspect ratio corresponds to a smaller ML dimension for a given AP size. The benefits of understanding aspect ratio include that the femoral shape can be predicted and can act as a guide to femoral component size. In addition, the aspect ratio provides a measure of the relative dimension of the knee between patients.

The ML width of the distal femur is primarily associated with femur length and ethnicity, not gender. Based on current evidence, ‘gender specific’ designs confer no clinical benefit. However, differences in aspect ratio and femoral shape have been identified between regional patient groups.

East Asian patients have a larger aspect ratio, or wider femoral ML dimension for a given AP dimension, compared to Caucasian patients.

With an optimised trochlear and M/L dimension, the ANTHEM knee facilitates optimal fit for a wider range of shapes and sizes of the knee.
Anatomic Fit

The tibial plateau is asymmetric, with a larger AP dimension medially than laterally.

The ANTHEM™ asymmetric tibial baseplate design facilitates optimal fit for a wider range of shapes and sizes of the knee.

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The medical and lateral plateau have different dimensions across ethnicities.

All patient groups have a larger Medial AP dimension than Lateral AP dimension.
Optimising implant fit for all patients

Previous TKA implant design has focused on basic Medio-Lateral measurements at the widest aspect of the femur. However evidence exists that the position of overhang may be an important contributor to postoperative pain and reduced functional outcome, especially in the Trochlea region. In cases when upsizing of the femoral component is required, such as to restore posterior femoral condylar offset, or to balance a larger flexion gap, a lack of optimized design or size options may lead to clinical compromise.

To facilitate optimal implant fit, the ANTHEM™ knee system was designed based on the anatomical measurements of hundreds of patients globally encompassing all major geographic regions with the assistance of proprietary ADaM (Anatomical Data Mining) protocol. After virtual bone preparation for TKA of Smith and Nephew in-house VISIONAIRE® Patient Matched Technology, each critical dimension of the femur related to implant fit was evaluated and analyzed:

Trochlea dimension: Width of the femur at Trochlea chamfer
Condylar dimension: Width of the femur at Condylar chamfer
Anatomic Fit

**Anatomic Implant Fit**

ANTHEM™ – Optimised implant fit for all patients

The ANTHEM Total Knee System is designed to provide an optimal size range and geometry for patients from all regions, at the Trochlea, Junction, and Condylar areas of the femoral component. The charts illustrate the comparison of Trochlea Dimension of the resected Femur compared to ANTHEM trochlea dimension for various regions: India, European, China, African, and Middle East.
Condylar Dimension of the resected Femur compared to ANTHEM condylar dimension
Anatomic Fit
Anatomic Implant Fit

ANTHEM™ – Optimised implant fit for all patients

In a further study, intraoperative measurements were taken from 982 patients undergoing TKA for each critical dimension of the knee. Four regions were included in the sample: China, India, Japan, Korea. The ANTHEM Narrow and a conventional femoral trial component were compared on the prepared bone to confirm size. Implant overhang was then calculated. Clinically relevant overhang was defined as an implant dimension 3mm or greater than the measured bone dimension at the Trochlea and Condylar regions.

*The sample used Size 3-6 for direct comparison of components.
Advanced Technology
Femoral Component Design

Low profile of the anterior flange
Reduces bone overhang and soft tissue impingement in the patello-femoral trochlea region.

Radiused coronal articulation (Conformity 1:1.05)
Coronal conformity to help decrease wear and improve tolerance to lateral lift off.

Anatomic femoral ML dimension
M/L dimension offered in Standard and Narrow femoral dimensions. All ANTHEM Femoral Components are optimized from anthropometric data from a wide range of patients to improve prosthesis fit.

Tightly radiused symmetrical posterior condyles
Allow deep flexion without the risk of edge loading or excessive collateral ligament tension without the need for additional posterior condylar resection. ANTHEM includes symmetric posterior condyles allowing the surgeon to set external rotation based on patient anatomy. The design includes tibio-femoral geometry equivalent to the GENESIS II design.

S-shaped trochlear groove
Simulates a natural femur in its movement of the patella from a lateral position in extension to midline in flexion, thereby reducing lateral release rates to approximately 3% compared with approximately 14% for some competitive devices.

Bone preserving open PS box design
Removes significantly less bone than some major competitive systems, leaving the anterior bone bridge intact for stability and strength. The PS box design provides improved cement pressurisation, rotational stability, and fixation while still allowing access to medullary canal for nailing procedures.

Low profile anterior flange

Optimized M/L dimension

Patella friendly ‘S’ curve

Bone conserving PS box

Tightly radiused condyles allow up to 155° flexion
Advanced Technology
Femoral Component Design

The ANTHEM® bone bridge preserving PS box removes less bone than most PS designs
Over resection of bone to accommodate PS box may result in an increase in risk of intraoperative intercondylar fractures. Leaving the anterior bone bridge intact may reduce the risk of stress risers and reduce fracture incidence. Intercondylar notch resection volume is reduced by 50-59% compared to competitive systems. The addition of a Bone Bridge Preserving PS Box Design geometry may also assist in cement pressurization and enhanced fixation in the box region.

The ANTHEM Femoral PS Box design reduces bone removal and includes one step ream through femoral trails
High Flexion PS Tibial Insert Design

Anterior chamfered section
Relieves tension on the patellar tendon, allowing a more natural angle of the patella and reduces potential for anterior knee pain.

Anterior chamfered post
Designed to eliminate patellar impingement in deep flexion; in retrieval studies High Flexion inserts have shown no difference to Standard PS inserts.

Reduced posterior lip
Reduces contact stress and avoids edge loading. Maintains collateral ligament tension and moves the flexion contact point anteriorly and distally.

Highly conforming cam and post engages during flexion
By utilising a highly conforming cam and post geometry, contact area is increased while providing gradual engagement and tibio-femoral stability during flexion. In related retrieval studies no difference was found in the articular surface or post between PS and Hi Flexion inserts.
Advanced Technology
High Flexion CR Tibial Insert Design

Deepened PCL notch
Allows for smoother PCL tracking with minimal insert contact.

Reduced posterior lip
Modified articulation allows for maximum flexion by minimizing cortical impingement and convexity avoids edge loading in deep flexion.

Anterior conformity
Dished anterior design assists in A/P stability by limiting paradoxical motion (femur driving forward on tibia) during early-mid flexion.

Anterior chamfer
Minimizes patellar tendon/implant impingement and allows for a more natural angle of the patella to facilitate deeper flexion and reduce the potential for anterior knee pain.

Highly congruent tibial insert design promotes conformity throughout range of motion
The ANTHEM Total Knee System incorporates a highly congruent design that distributes load evenly and allows for higher contact areas during flexion and under varus/valgus stress 24, 25. The ANTHEM design exhibits a tibiofemoral conformity ratio of 1:1.05 in the coronal plane and the same kinematic contact throughout the range of motion for all sizes of compatible inserts. Articular inserts in the ANTHEM Total Knee System have a minimum polyethylene thickness of 6.7mm (9mm combined tibial component) and have been tested to provide up to 155° range of motion 26.

Schematic demonstrating conformity in the coronal plane for all compatible inserts. Both Standard and Narrow Femoral components are shown.

Compatibility chart for Hi Flexion PS and CR Inserts for each femoral size

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Compatibility chart for Hi Flexion PS and CR Inserts for each femoral size.
Tibial Component Design

Asymmetric tibial base
Provides less risk of overhang, improved cortical coverage and optimal rotation compared to symmetric designs.

Shorter, medialised tibial stem
Removes less bone than designs with longer stems and prevents impingement in smaller or deformed tibial anatomies.

Titanium material
Biocompatible and improved fatigue strength compared to Cobalt Chrome.

Patent pending DURAHONE® polishing process
Provides a more consistent manufacturing process, while maintaining proven locking mechanism and highly-polished titanium surface. Highly polished tibial baseplates have demonstrated lower wear than unpolished versions.

Asymmetric tibial design allows for optimal coverage and rotation
The asymmetric shape closely matches the anatomy of the tibia for optimal cortical rim coverage and even stress distribution. This minimizes tibial rotational errors, baseplate overhang and achieves ≥95% bone coverage. 3 degrees of posterior slope is built into the tibial implant to ensure the tibial stem is centralized in the canal and reduces the risk of impingement on the anterior cortex.
Advanced Technology
Tibial Component Design

Titanium tibial baseplate delivers improved biocompatibility and biomechanical properties

Titanium is used due to its elastic properties and relative lack of stiffness, to better match the elasticity of bone. Reducing stiffness of the implant enhances stress resistance which minimizes stress shielding, reducing the risk of bone resorption and atrophy, potentially prolonging the life of the implant.

The ability to forge Titanium allows for a thin yet strong tibial baseplate with a maximum thickness of 2.3mm, both increasing the minimum thickness of polyethylene and improving bone conservation.

Compared to cobalt chrome, the titanium alloy used in the ANTHEM™ tibial component has lower levels of nickel, chromium and cobalt (≤ 0.1% nickel, < 0.01% cobalt and < 0.02% chromium).

ANTHEM tibial baseplate is made of Forged Titanium with baseplate of 2.3mm, allowing optimal insert thickness and bone conservation.
Tibial Component Design

DURAHONE® polishing produces a visibly smoother surface and reduces insert micro-motion

Polished tibial baseplates reduce the incidence and rate of backside polyethylene wear. Tibial components utilizing DURAHONE polishing, coupled with a peripheral dovetail locking mechanism, reduces insert micro-motion by 29% compared to manual polishing methods.

ANTHEM® Tibial Baseplate utilizing DURAHONE polishing process

ANTHEM Tibial Baseplate peripheral dovetail locking mechanism

*Competitive products consist of DePuy Synthes SIGMA®, Wright Advance™ and Stryker Scorpio™ utilizing Scanning Electron Microscope (SEM) at 650 times magnification.
Efficiency
Promoting Efficiency Through Intelligent Design

The global healthcare system is currently under increasing pressure. While in the past enjoying rapid technological development and uptake, public healthcare systems in developed markets are now being expected to improve efficiency, reduce spending, and ultimately ‘achieve more with less’. Similarly private funders are under pressure to maximise profits and maintain competitiveness. An aging population and increase in developed world disease will continue to add further stress to already stretched surgical resources. After nearly a decade of generous increases, health-care spending across the 34 countries of the OECD has not significantly increased since 2010 46.

Conversely there is an opportunity for emerging economies to set their health systems on a path to sustainability, with an estimated one third of all global health expenditure occurring in emerging economies by 2022 47. Emerging economies are generally less burdened by legacies and enjoy a greater degree of freedom to design efficient and cost-effective systems. This allows them to leverage technological advances more easily and to learn from the experiences of developed economies. However with spiralling population growth, market volatility, and variable healthcare infrastructure many challenges exist to provide world class medical care.

It has been proposed that 60-70% of all admissions are caused by surgical interventions, the operating theatre is one of the most critical and expensive resources within a hospital. It has been estimated that 40% of the total hospital expenses arise from the operating theatre suite 48.

The ANTHEM™ Knee System and ORTHOMATCH™ Universal Instrumentation platform have been developed to reduce activities that add unnecessary cost into the orthopedic healthcare system through dedication to the following principles:

- **Streamline operative flow** by reducing the number of surgical steps and simplifying procedure flow
- **Maximize productivity** by reducing tray weight through the use of using space age polymers, combined functionality, and modularity within instrument design
- **Optimise asset utilization** by reducing comprehensive instrument set to three trays* without sacrificing functionality
- **Advanced delivery and logistics** channels are included within the Syncera operating model

The resultant breakthrough improvements result in system that that provide quantifiable gains in efficiency for knee replacement surgery and measureable cost saving potential in the global orthopedic healthcare delivery system.
Simplify Surgical Flow
Maximize Productivity
Optimize Asset Utilization
Provide Value and Access
Efficiency
Streamlining Operative Flow

The following features of the ORTHOMATCH™ Universal Instrumentation system promote efficiency through design, reducing the number of surgical steps and simplifying the procedure flow. This helps to ensure clinical benefits to achieve optimal component placement and management of soft tissue without compromise.

**Femoral sizing**
- Femoral sizer allows 0-9° of femoral external rotation to match the majority of femoral anatomies
- Satisfies both Anterior or Posterior referencing philosophies with the same femoral sizer

**Femoral design and preparation**
- Simplified femoral upsizing and downsizing protocol
- Consistent femoral A/P box resections between CR and PS options
- Ream through Femoral trials reduce the number of steps and ensure accurate M/L femoral placement
- Single femoral trial to access either Standard or Narrow femoral implants
- Ability to translate femoral cutting block position anterior or posterior before committing to chamfer cuts

**Tibial preparation**
- Provides either central or MIS utilizing same cutting block
Maximizing productivity
The following features of the ORTHOMATCH™ Universal Instrumentation system reduce tray weight and working instrument footprint to deliver cost saving for both hospital and healthcare system.

- Modular and multi-purpose instruments to reduce number of instruments in working space
- State of the art low weight, durable polymers reducing weight by up to 60%
- Reduction of instrument footprint
- Multi stack connectivity of trays to improve shipping and storage
- Highly visible instrument markings for critical steps

Optimizing asset utilisation
By consolidating the complete instrument set into three trays significant costs saving can be achieved for the hospital. For an orthopaedic unit undertaking 100 TKA cases per year this may equate to saving of over $18,000 - $36,000 USD in sterilization costs alone.

By minimizing the number of trays additional cost reduction can be generated by space saving, and reduction of effort and cost associated with management of complex instrumentation systems.
Syncera, the brand for a new business unit powered by Smith and Nephew, offers quality, life-changing healthcare solutions for orthopedic reconstruction surgery by providing access to value-based care to more patients globally.

Syncera draws on the Smith & Nephew heritage, trust and expertise, and combines this with local insights and a focus on greater efficiency through innovation. Syncera is a new way of thinking that supports healthcare systems to achieve higher standards while reducing unnecessary costs.

Syncera aims to deliver the following benefits:

- An intuitive range of solutions to bring greater efficiencies to healthcare professionals and healthcare systems
- Product alternatives that are tailored to suit a broad range of geographies and demographics
- Offerings to complement Smith & Nephew’s years of expertise and knowledge to meet healthcare needs through value-based, quality solutions
- Intuitive workflow and digital teaching tools to reduce staff learning curve
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