Design Rationale

Supporting healthcare professionals
ANTHEM™
Total Knee System

Table of contents

Introduction ............................................................................................. 2
Relevant Feature by Region ................................................................. 3
Anatomic Implant Fit ............................................................................ 4
Femoral Component Design ................................................................ 12
High Flexion PS Tibial Insert Design ................................................. 14
High Flexion CR Tibial Insert Design ................................................ 15
Tibial Component Design ................................................................... 16
Built on Proven Heritage .................................................................... 19
Promoting Efficiency Through Intelligent Design ............................... 20
ANTHEM Total Knee System Design Rationale

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, taking into consideration the anatomical differences among global ethnicities.

- 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 in a study of 89 patients.

- 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
Fit for ALL

Relevant Feature by Region

- Low profile anterior femoral flange
- Optimised ML femoral component
- S-shaped trochlear groove
- High flexion insert
- 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 (TKA) were found between geographical regions relating to

- **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. This means that when addressing patients from different ethnicities, there may be a compromised implant fit.
Anatomic Fit
Anatomic Implant Fit

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. On the opposite side avoiding overhang by downsizing the implant may lead to knee instability. 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.
Aspect ratio provides a measure of relative femoral shape

Aspect ratio is defined as the Medio-Lateral width divided by the lateral 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 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 for different genders have been identified between regional patient groups.

With an optimised trochlear and ML dimension the ANTHEM™ knee facilitates optimal fit for a wider range of shapes and sizes of the knee.

There are differences in the shape of the knee between ethnicities

![Femoral Aspect Ratio Between Ethnicities](image)

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

![Femoral aspect ratio (ML/AP)](image)

- Smaller aspect ratio – smaller ML for constant AP
- Larger aspect ratio – wider ML for constant AP
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.

The medial and lateral plateau have different dimensions across ethnicities.

All patient groups have a larger Medial AP dimension than Lateral AP dimension.³
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 & 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 - Design Definition

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.1

<table>
<thead>
<tr>
<th>Trochlea Dimension of the resected Femur compared to ANTHEM trochlea dimension</th>
<th>ANTHEM Narrow Femoral Size</th>
<th>ANTHEM Standard Femoral Size</th>
</tr>
</thead>
<tbody>
<tr>
<td>India Trochlea</td>
<td>40</td>
<td>60</td>
</tr>
<tr>
<td>European Trochlea</td>
<td>40</td>
<td>60</td>
</tr>
<tr>
<td>China Trochlea</td>
<td>40</td>
<td>60</td>
</tr>
<tr>
<td>African Trochlea</td>
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<td>60</td>
</tr>
<tr>
<td>Middle East Trochlea</td>
<td>40</td>
<td>60</td>
</tr>
</tbody>
</table>
India Condyle

European Condyle

China Condyle

Africa Condyle

Middle East Condyle

Condylar Dimension of the resected Femur compared to ANTHEM condylar dimension
Anatomic Fit

Anatomic Implant Fit - *In vivo* testing of ANTHEM° Fit

**ANTHEM – Optimised implant fit for all patients**

In a further study, intraoperative measurements were taken from 967 TKAs for each critical dimension of the knee. Five regions were included in the sample: Australia, 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.

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

Low profile of the anterior flange
Narrower flange shape than GENESIS™ II, which has been shown to limit bone overhang and soft-tissue impingement in the patello-femoral trochlea region.¹

Suitable for PS and CR
ANTHEM™ is available in both Posterior Stabilised and Cruciate Retaining options.

Anatomic femoral ML dimension
ML 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.¹

S-shaped trochlear groove
Simulates a natural femur in its movement of the patella from a lateral position in extension to midline in flexion, with potential to reduce lateral release rates to approximately 3% compared with approximately 14% for some competitive devices.¹⁴,¹⁵

Tightly radiused symmetrical posterior condyles
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 and LEGION™ design.¹⁶

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.¹⁷
Advanced Technology
Femoral Component Design

The ANTHEM™ bone bridge preserving PS box removes less bone than other 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 significantly reduced compared to competitive systems.
High Flexion PS Tibial Insert Design

**Based on clinically successful Heritage**
The ANTHEM™ Insert design is based upon the trusted GENESIS™ II and LEGION™ designs.16

**Chamfered anterior**
Relieves tension on the patellar tendon, allowing a more natural angle of the patella and reduces potential for anterior knee pain.19

**Chamfered anterior post**
Designed to eliminate patellar component impingement in deep flexion; has equivalent fatigue strength to the standard LEGION PS Insert.20

**Modified posterior articulation**
Lowered posterior lip reduces contact stress and avoids edge loading in deep flexion; maintains collateral ligament tension in deep flexion; and moves the flexion contact point anteriorly and distally from the proximal edge of the posterior condyles.19

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**What is the benefit of a high-flex insert?**
Traditional Total Knee Replacement systems have been designed to deliver flexion up to 120°, which has typically been sufficient for the average patient. However, those patients who require deeper flexion because of their culture or an active lifestyle need a system that can safely accommodate flexion up to 155°.19,21 Even daily activities like stair climbing, rising from a chair, or getting out of a bathtub can require flexion greater than those usually delivered by standard TKA systems. The LEGION PS High-Flexion Insert was designed to accommodate flexion up to 155° without additional posterior condyle resection.
Advanced Technology
High Flexion CR Tibial Insert Design

Based on clinically successful Heritage
The ANTHEM™ Insert design is based upon the trusted GENESIS™ II and LEGION™ designs.2,16

Deepened PCL notch
Allows for smoother PCL tracking with minimal insert contact.22

Reduced posterior lip
Modified articulation allows for maximum flexion by minimizing cortical impingement and convexity avoids edge loading in deep flexion.19,21

Anterior conformity
Dished anterior design assists in A/P stability by limiting paradoxical motion (femur driving forward on tibia) during early-mid flexion.23

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.19

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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 $\geq 95\%$ bone coverage.\textsuperscript{14,24-27}

Anatomic Tibial Stem and Keel

Proportionally medialized on the proximal tibia to align with the intramedullary canal.

Fin location and shape were designed to be stress absorbing while providing rotational resistance when the prosthesis is implanted.\textsuperscript{28,29}

Optimal tibial position

A posterior sloped baseplate design allows for optimal loading of the tibial bone and good range of motion.\textsuperscript{30,31}

Cutting the tibia with a posterior slope, as opposed to a 0° cut, provides stronger bone that may help reduce the chance of tibial baseplate subsidence.\textsuperscript{32}
Advanced Technology
Tibial Component Material and Fixation 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.33

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.

Optimised Fixation
The grit blasting has been shown to improve cement interdigitation and bonding strength through its optimized surface roughness.

The cement pocket design has been shown to be optimal for cement penetration into bone and improving tibial baseplate fixation stability.
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.34 Tibial components utilizing DURAHONE polishing, coupled with the a peripheral dovetail locking mechanism, reduces insert micro-motion by 29% compared to manual polishing methods.35
Built on Proven Heritage

The tibial locking mechanism and fixation surface of the ANTHEM™ is using the proven GENESIS™ II technology

Peer Reviewed Article

- Thicker CoCr tibial trays were associated with more medial bone loss than thinner Titanium designs

Peer Reviewed Article

- The mean migration of the tibial component was less than 0.1mm and 0.1° in all planes relative to the postoperative RSA exam.
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.

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:

**Improving implant fit** by offering an optimized design and portfolio of sizes that is inspired by studies looking at the different anatomies of the human knee joint

**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
1. Anatomical Data Mining of CT data utilising sets from Europe, China, India, Middle East and Africa.
   Smith & Nephew internal report: Design control document DHF-INDG-Anatomical Analysis B.