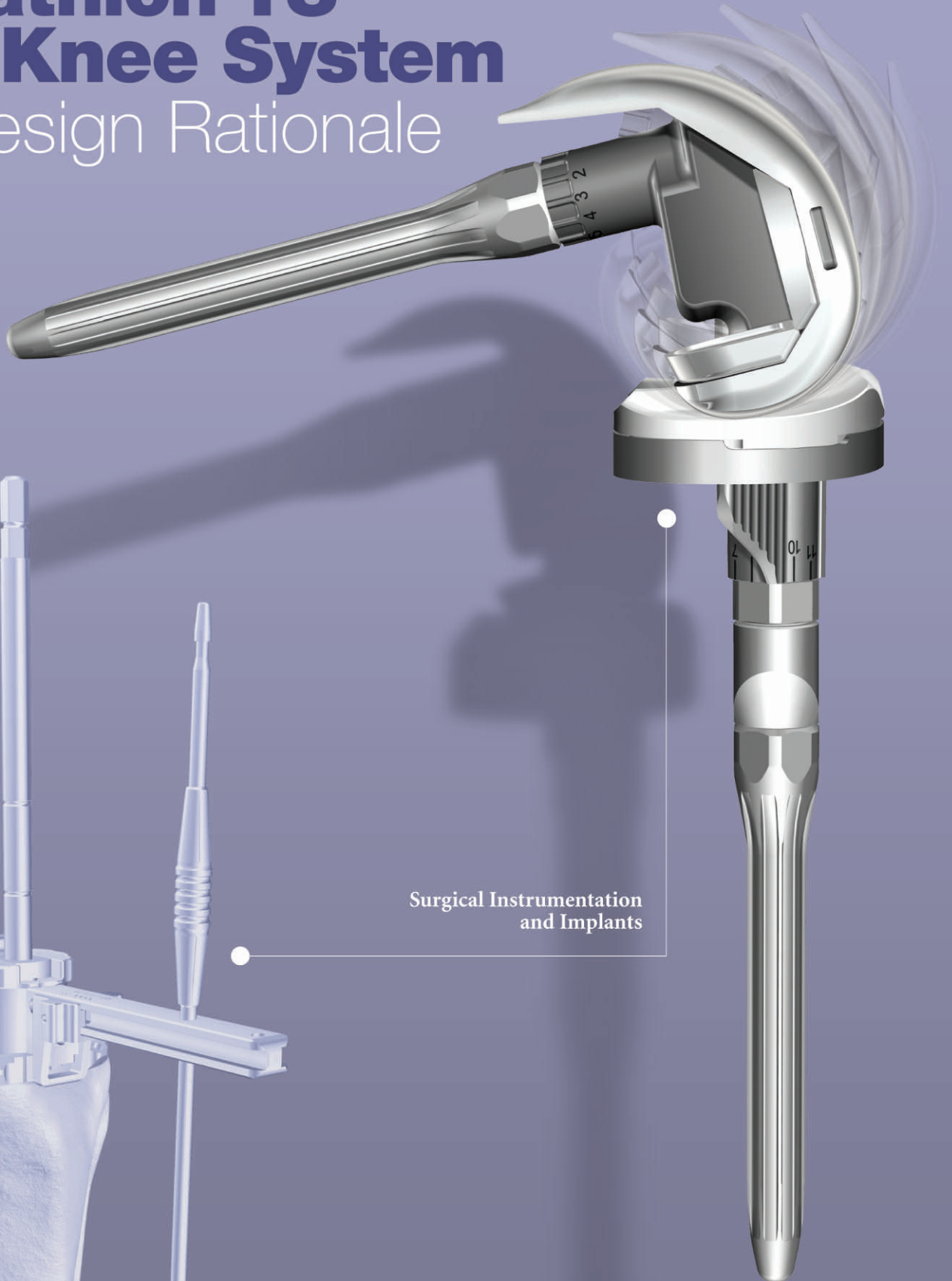


Triathlon TS Knee System

Design Rationale



Surgical Instrumentation
and Implants

Triathlon

Performance

The Triathlon TS Knee System is designed to provide Triathlon performance in a streamlined revision procedure. (A revision system designed to provide stability without compromising performance.) The intuitive and evolutionary design is based on the worldwide clinical success of the Triathlon Primary system and millions of Stryker knee implantations. The Triathlon TS Knee System is designed to provide improved motion²¹, better fit⁴ and the potential for greater implant longevity.^{22,14}

The Triathlon TS Knee is an evolutionary design developed for mobility with stability through 135 degrees of flexion¹.



Improved Motion²¹

- ▶ Incorporates all of the enhanced features from the primary Triathlon System with the stability required of a revision knee system.
- ▶ Design features such as a patented single radius, deep flexion radius and flared posterior condyles, as well as an anatomic patellofemoral track allow the Triathlon TS Knee system to maintain substantial contact area throughout the entire Range of Motion.^{2,3}
- ▶ The deep flexion features of the components are designed to allow up to 135 degrees of flexion without sacrificing stability.¹
- ▶ Enhanced Rotary Arc that allows for 7 degrees of internal/external rotation.
- ▶ Improved Quadriceps efficiency that has the potential to facilitate a quicker return to function.^{2,3}

Better Fit⁴

- ▶ The only revision system with size offerings based on an anthropometric measurement study for excellent interplay between implant geometry and anatomic structure.⁴
- ▶ Optimized Femoral Boss position designed to better match femoral canal location.
- ▶ Offers a broad range of tibiofemoral sizing options to meet the anatomic realities of TKR.
- ▶ The forgiving design aspects of the implant helps accommodate surgical realities.
- ▶ 360 degree radial offsetting for both the femur and tibia potentially allowing for more stability, ligament balancing, and optimal bone coverage.

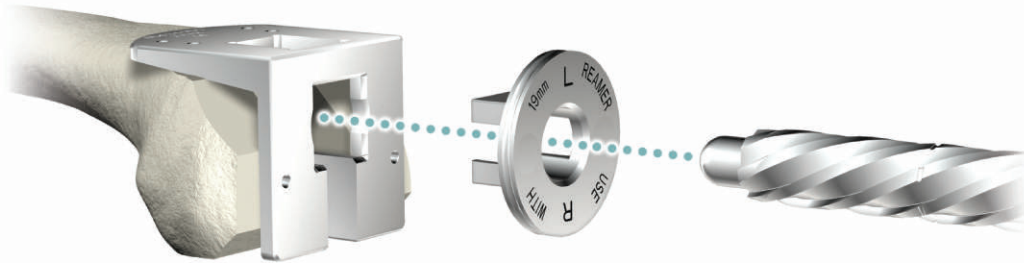
Potential for Greater Implant Longevity^{22,14}

- ▶ The revision system with advanced bearing technology – X3.
- ▶ A high degree of conformity throughout the range of motion is designed to reduce the contact stresses and wear, offering the potential for enhanced long-term component durability.^{2,3,14}
- ▶ Single radius design and early cam engagement provides potential reduction in insert wear.^{5,6,7}
- ▶ A precision insert locking mechanism and Anti-Rotation Island addresses insert micromotion and increases insert/tibial tray contact surface area – all designed to decrease the likelihood of backside wear.³
- ▶ Patent Pending post-preserving features.

Streamlined Procedure

The Triathlon TS Knee System Instrumentation has been developed based on Stryker's 30 year orthopaedic history. The system combines the engineering expertise of Human Factors Engineers along with the experience of surgeons and OR staff worldwide.

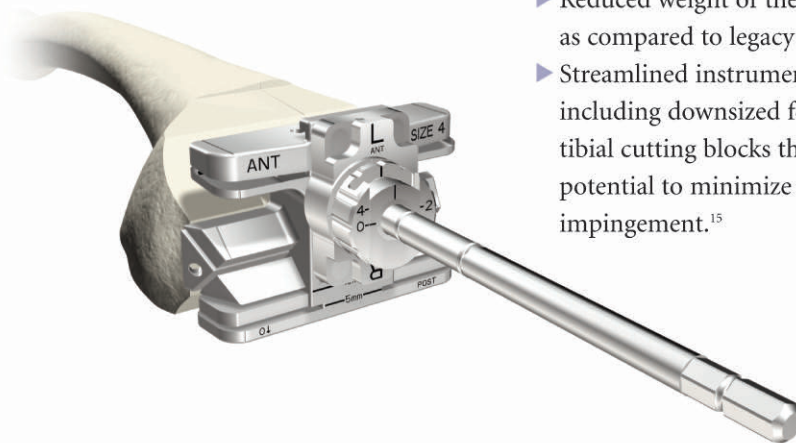
The Triathlon TS Knee system instrumentation provides optimal OR efficiency and intra-operative flexibility with a seamless integration with the primary Triathlon System.



Intra-operative Flexibility

The proprietary instrumentation design also delivers intra-operative flexibility. The following features accommodate surgical preferences and help surgeons and staff adapt to multiple surgical realities:

- ▶ A common platform that is designed to allow for seamless intra-operative transitions.
- ▶ Limited incision capabilities.
- ▶ 1 step transition from PS to TS.



OR Efficiency

The Triathlon TS Knee System Instrumentation design team focused on identifying ways to increase the **accuracy** and **simplicity** of the surgical procedure; two variables that may affect OR efficiency. The features incorporated include:

- ▶ An IM Reamer referencing based system.
- ▶ Color coding of trials for ease of use and clear identification.
- ▶ Quick attach and release mechanisms to facilitate easy assembly.
- ▶ Streamlined tray layout based on operational sequence.
- ▶ Reduced number and size of trays.
- ▶ Quick offset determination.
- ▶ Simplified implant assembly.
- ▶ Joint line ruler to help restore correct Joint Line.
- ▶ Reduced weight of the instrument set as compared to legacy systems.
- ▶ Streamlined instrumentation, including downsized femoral and tibial cutting blocks that have the potential to minimize soft tissue impingement.¹⁵

Improved Motion²

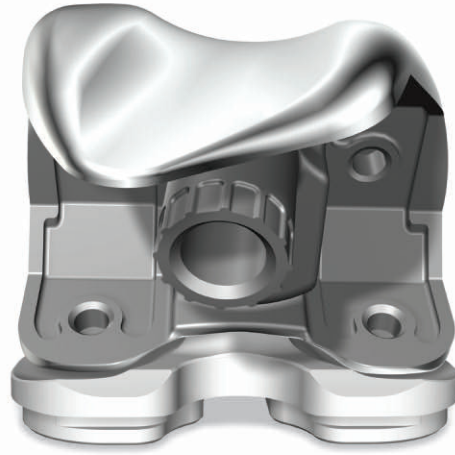
A key design goal of the Triathlon TS Knee System was to optimize stability through deep flexion. The unique design of the Triathlon Knee System replicates proper tracking of the epicondyles, creating natural soft-tissue tension that promotes stability and allows for deep flexion.^{5,6,7} Enhanced patellofemoral mechanics mimics natural knee motion through range of motion.

The Triathlon TS Knee design criteria are realized through component features including a patented single radius, deep flexion radius, flared posterior condyles, anatomic patellofemoral track, and patent pending enhanced rotary arc.⁸

Single Radius

Studies of kinematics and biomechanics have identified a constant radius in natural knee motion centered about the transepicondylar axis.

The Triathlon TS Knee system is designed with a patented single radius. Centering the radius of curvature about the transepicondylar axis provides ligament isometry, not only in full extension and 90 degrees of flexion, but through the entire range of motion. The single radius centered about the epicondylar axis reproduces natural knee movements designed to minimize the quadriceps forces required for extension thereby maximizing muscle efficiency.^{5,6,7}



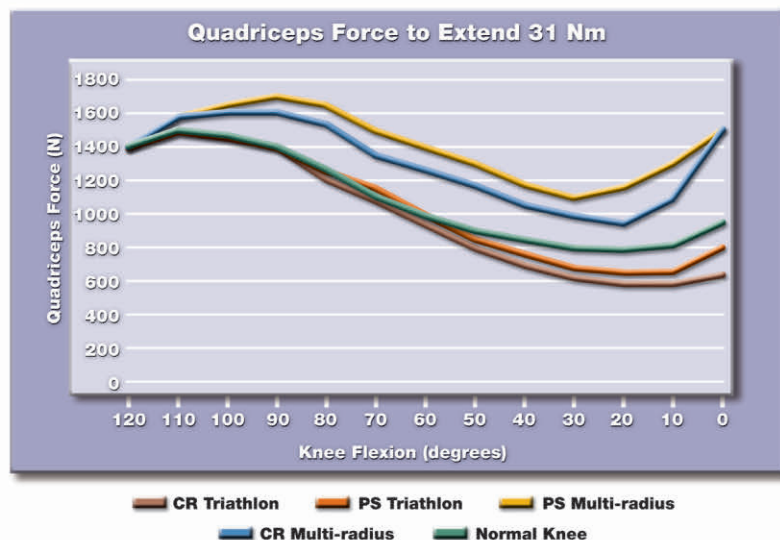
Deep Flexion Radius and Flared Posterior Condyles

The Triathlon TS Knee System is the first of its kind with shorter and flared posterior condyles to facilitate the relaxation of soft-tissues to enable deep flexion. The condylar geometry is designed to allow for rapid flexion and enhanced contact area throughout 135 degrees of flexion. Flaring the posterior condyles accommodates tibial rotation as the knee approaches deep flexion while maintaining excellent contact area.



Potential for Improved Quadriceps Efficiency

Because of its single radius design, Triathlon has been shown to require 29% less effort at 60° than traditional J-Curve (multi-radius) designs.²³ This has the potential to allow patients to more quickly return to function and mobility.^{25,26}



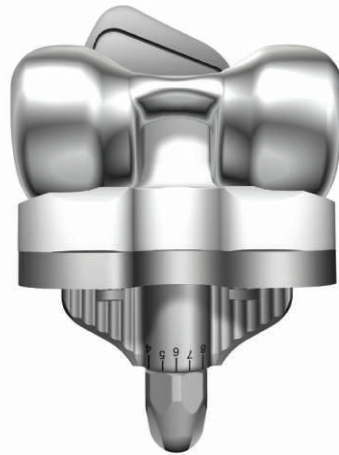
Ability to articulate with PS Insert

If soft tissue allows, the Triathlon TS system is designed to articulate with the PS insert providing capabilities identical to the primary system.

Triathlon Insert Compatibility

	Triathlon PS Insert	Triathlon TS Insert
Triathlon PS Femoral Component	X	X
Triathlon TS Femoral Component	X	X

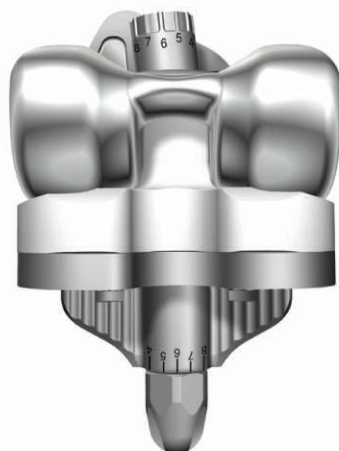
The Triathlon TS Insert must be used with the Universal Baseplate.



Triathlon PS Femoral Component and Triathlon PS Insert



Triathlon TS Femoral Component and Triathlon PS Insert



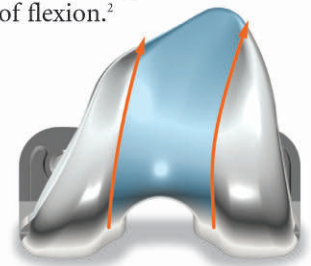
Triathlon TS Femoral Component and Triathlon TS Insert

Varus/Valgus

+/- 2 degrees of varus/valgus constraint. The larger post allows for increased stability throughout the whole range of motion.

Anatomic Patellofemoral Track

The Triathlon TS Knee patellofemoral track shares the same design as preceding Stryker Total Knee Systems, bringing over a decade of excellent clinical performance and which in 1997 had the industry's lowest revision rate (0.3%) to this knee system.⁸ The patellofemoral track has been enhanced with a deepened trochlear groove. This feature relaxes the extensor mechanism and is designed to enable deeper flexion and reduce the contact stresses exerted across the patella in deeper angles of flexion.²

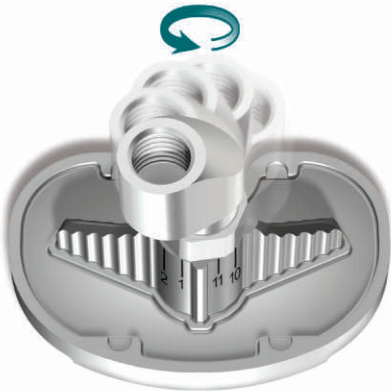


Better Fit⁴

The anthropometrically-based design, unique implant geometry, anatomic boss placement and femoral sizing options provide surgeons the flexibility to respond to anatomical and surgical realities.

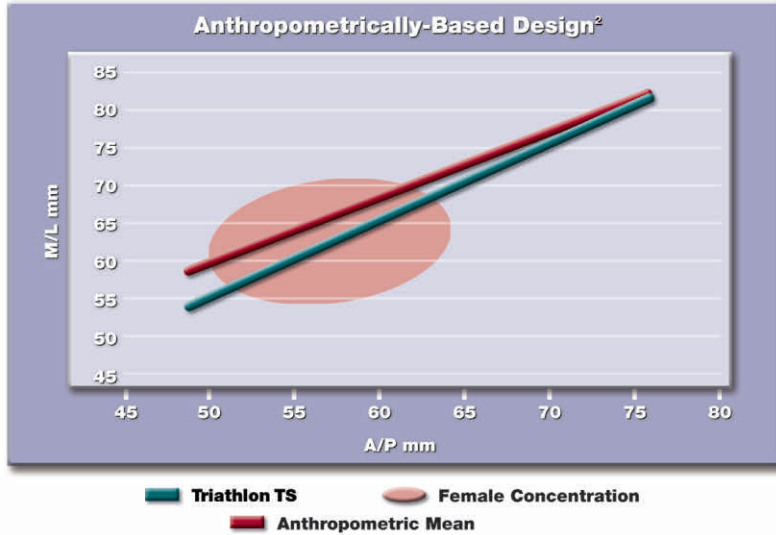
Anthropometrically-based Design

The Triathlon Knee System sizing options are based on an anthropometric study for optimum interplay between implant and anatomic structure. With 8 sizes growing by no more than 3mm in the sagittal plane, the closely linked dimensions of the components offer excellent fit to a wider spectrum of patients.



360 degree radial offsetting

Unique 360 degree radial offsetting, for both the femur and tibia, is designed to optimize fit of implant. It provides the surgeon better control to balance and stabilize the knee, fill flexion gaps, and restore the jointline.¹⁹



The Triathlon Knee System addresses smaller anatomies, often found in female patients, heavily concentrated in the region shown, while still accommodating larger patient sizing requirements.

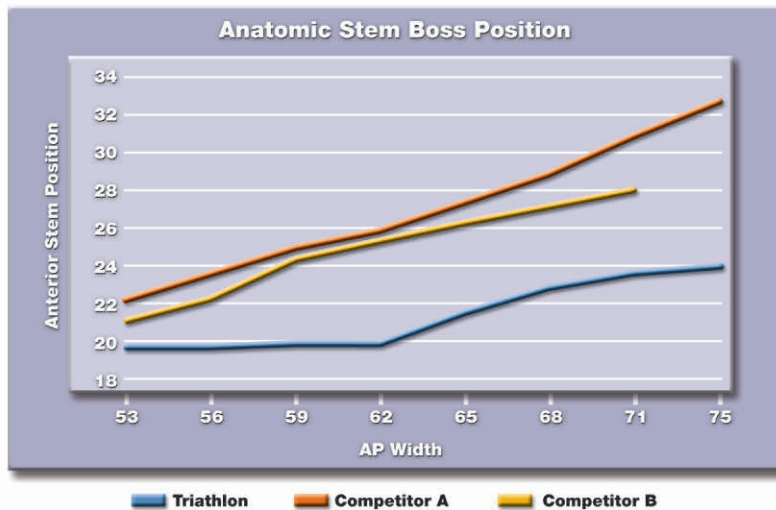
Cam-Post Engagement/Jump Height

The design of the TS's cam/post mechanism allows for cam engagement relatively low on the tibial post in deeper ranges of motion. This has the potential to decrease forces on the tibial-bone interface and keeps dislocation height high. The TS insert allows for 12 degrees of hyperextension.

Anatomic Boss Placement

Femoral: The boss location on the Triathlon TS Femoral implant has been optimized to minimize the amount of off-setting and facilitate more accurate femoral canal alignment.

Tibial: The boss location on the TS Universal Baseplate has been shortened to reduce potential impingement of offset on cortical bone.



The femoral implant boss location has been optimally positioned by A/P dimensions.

Stems

Designed to provide the surgeon with the ability to accurately fit different patient anatomies, Triathlon TS stems are available in 1mm increments.¹⁶

Designed to reduce the instances of Tibial/Thigh pain with cementless stems, larger diameter stems are fluted with variable core diameters to provide a constant modulus of stiffness.

By only tapering the distal tip of the stem, the surface area for fixation is maximized. For cemented stems, the 1 degree taper is also designed to aid in pressurizing the canal and cement absorption in Cancellous bone.

Cemented Stems

- ▶ 9 mm x 50, 100 & 150mm
- ▶ 12 mm x 50, 100 & 150mm
- ▶ 15 mm x 50, 100 & 150mm

Cementless Stems

- ▶ 10 – 25mm x 100mm
- ▶ 10 – 25mm x 150mm

Stem Extenders

In addition to stems, Triathlon TS Stem Extenders are available in 25mm and 50mm lengths to optimize Stem placement within the canal.



Augments

The 10mm tibial as well as posterior femoral augments have tapered sides intended to match patient anatomy, minimize overhang, and potentially reduce the occurrence of tissue impingement.

Tibial

Feature Triathlon TS's unique locking mechanism that eliminates the need to use screws, which reduces the possibility of back out as well as osteolysis.

- ▶ 5 & 10mm
- ▶ Augments can be stacked

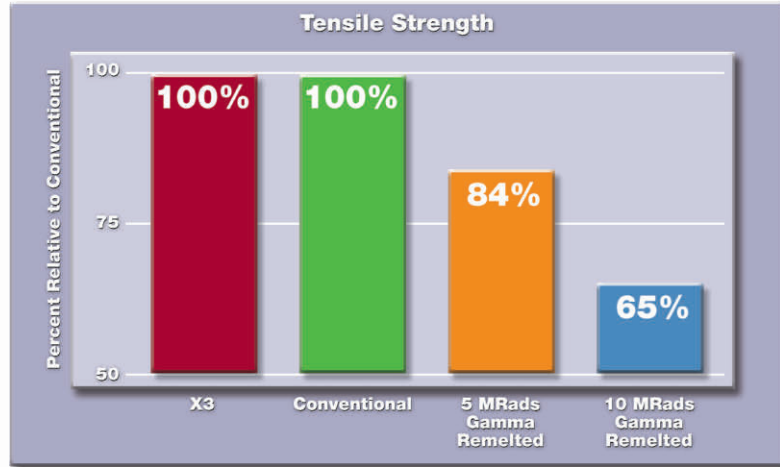
Femoral

- ▶ 5, 10, & 15mm Distal
- ▶ 5 & 10mm Posterior

Through the unique 360 degree offsetting capability, multiple stem options, stem extenders, as well as femoral and tibial augments, the Triathlon TS system provides the surgeon with the ability to tailor the implant to the individual patient's unique anatomy.

Potential for Greater Implant Wear^{22,14}

The Triathlon TS Knee System is designed to offer a high degree of conformity throughout the range of motion, as well as reduce contact stresses and wear, offering the potential for enhanced long term component durability.^{2,3,14} Through the single radius design and anatomic cam engagement as well as precision locking mechanism and anti-rotational island, the system provides the potential to reduce insert wear. The Triathlon TS System is available with X3 advanced bearing technology.



X3

X3 is a breakthrough in advanced bearing technology that results in a polyethylene bearing material that offers excellent wear characteristics while preserving mechanical strength.²⁷⁻³⁴ The result is a bearing surface option with properties ideal for both primary and revision applications.

X3 is sequentially crosslinked using three separate gamma radiation doses with an annealing step, polyethylene is heated below melting temperatures, following each irradiation. The sequential irradiation and annealing process provides a greater percentage of crosslinking while virtually eliminating free radicals.^{32,35,36} Finally, X3 is gas plasma sterilized to avoid additional radiation dosage during sterilization.



Insert Fixation System

The locking mechanism of the Triathlon TS Knee System features a complete peripheral rim-locking mechanism between the tibial baseplate and insert. An anti-Rotation Island is designed to reduce micromotion (A/P and M/L) and increase backside contact area, further enhancing the insert fixation system. These features, in conjunction with reduced articular stresses, work together to minimize the clinical challenges of micromotion that have been shown to lead to backside wear.^{9,10,11,12}

Post-preserving Technology

Improved distribution of forces

Wear in revision knees is a function of forces placed on the implant in an effort to achieve the required stability. Through the Enhanced Rotary Arc design, anatomic radius and flared posterior condyles, the Triathlon TS Knee System balances the way stability is achieved with constraint to mimic natural knee kinematics and potential for enhanced wear. The Triathlon TS Knee System maintains conformity with a high contact area throughout the entire range of motion while reducing the stresses transmitted to the insert post in deep flexion.^{2,3}

The favorable degree of conformity demonstrated by the Triathlon TS Knee System components throughout the range of motion leads to reduced contact stresses and offers the opportunity for enhanced long term component durability without compromising stability.



Load sharing of articulating surface post-preserving features

The enhanced Rotary Arc is designed to reduce insert post wear due to rotational forces by load sharing with the articular surface.

Hyperextension

- ▶ Geometry reduces potential for anterior post wear.²

Stabilizing Post

- ▶ Creates stronger structure.
- ▶ Locking features prevent backout.

Post-Cam Engagement

- ▶ The Triathlon TS Knee System is designed for post-cam engagement to occur at 40-45 degrees of flexion mimicking what studies have shown occurs in the natural knee.¹⁸

The Triathlon TS Knee System is designed so the cam rides down the post as the knee goes into flexion. Thereby, reducing the potential for dislocation by increasing the dislocation height, in addition to reducing the forces on the insert locking mechanism.²⁰

Streamlined Revision Procedure

The Triathlon TS Knee System Instrumentation has been developed based on Stryker's 30 year orthopaedic history. Triathlon TS combines the engineering expertise of Human Factors Engineers with the experience of surgeons and OR staffs worldwide. The Triathlon TS Knee system instrumentation has the potential to provide OR efficiency and intra-operative flexibility with a seamless integration with the primary Triathlon System.

OR Efficiency and Intraoperative Flexibility

The Triathlon TS Knee System Instrumentation is designed to increase the accuracy and simplicity of the surgical procedure.

Accuracy

IM Based Instrumentation

The Triathlon TS Knee System is an Intramedullary Reamer based system potentially leading to more anatomic alignment and more accurate resections.



Reproducible Alignment and Resection

Assemblies are designed to translate towards the bone. Decreasing this distance reduces pin and blade skiving and allows for more accurate fixation and resections.

Attachments and Assemblies

Traditional mechanisms used for attachment and release resulted in the inadvertent malpositioning of the instruments. The Triathlon TS Knee System is designed to eliminate uncontrolled inertia, allowing assemblies and guides to be placed and used with precision.



Streamlined Instrumentation

Downsized femoral and tibial cutting blocks that have the potential to minimize soft tissue impingement.¹⁶



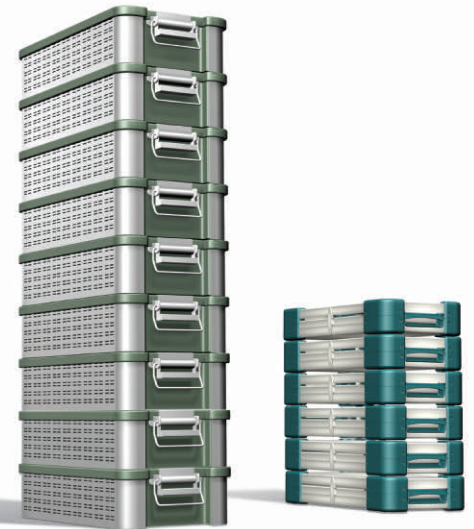
Simplicity

The Triathlon TS Knee System is designed to increase OR efficiency by simplifying trial assembly, off-set determination and instrument case configuration.



Instrumentation Case Configuration

Cases and the instrumentation layout within have been optimized based on operative usage patterns. Triathlon TS Knee Instrumentation is configured in modules that correspond to the surgical procedure, optimizing surgical flow while accommodating surgeon preference. Instruments used with less frequency are available in optional trays, reducing the number of required instruments and simplifying hospital operation. The system requires 45% less trays compared to competitive systems.³⁷

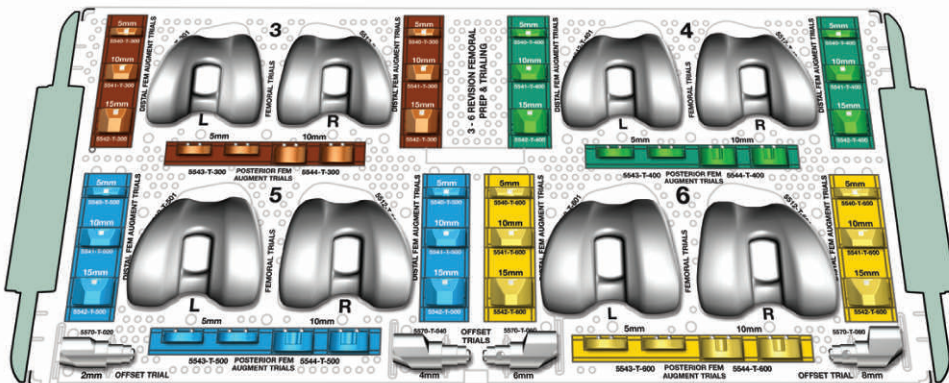


Off-Set Determination

Patent-pending instrumentation enables surgeon to quickly determine off-set positioning and ensure optimal bone/implant coverage.

Trial Assembly

Trial assembly is made easy with color-coded trials that identify sizes. Augment trials are magnetic, off-set trials are quick-connect and thread couplings have been shortened, resulting in quicker trial assembly.



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28. Stryker® Orthopaedics Triathlon® PS Tibial Inserts made of X3® UHMWPE, 5532-G-409 show a 64% reduction in volumetric wear rate versus the same insert fabricated from N2\Vac™ gamma sterilized UHMWPE, 5532-P-409. The insert tested was Size 4, 9 mm thick. Testing was conducted under multiaxial knee simulator (multi-station MTS knee joint simulator) for five million cycles using a size 7 CoCr counterfaces, a specific type of diluted calf serum lubricant and literature or fluoroscopy based motion and loading conditions representing stair climbing. b, c Volumetric wear rates were 3.6 ± 0.61 mm³/106 cycles for standard polyethylene inserts and were 1.3 ± 0.44 mm³/106 cycles for test samples. Test inserts were exposed to a gas plasma sterilization process. In vitro knee wear simulator tests have not been shown to quantitatively predict clinical wear performance.
29. Stryker® Orthopaedics Scorpio® CR Tibial Inserts made from X3® UHMWPE, 72-22-0708, show a 79% reduction in volumetric wear rate versus the same insert fabricated from N2\Vac™ gamma sterilized UHMWPE, 72-2-0708. The insert tested was Size 7, 8 mm thick. Testing was conducted under multiaxial knee simulator (multi-station MTS knee joint simulator) for five million cycles using appropriate size CoCr counterfaces, a specific type of diluted calf serum lubricant and the motion and loading conditions, representing normal walking, outlined in ISO/DIS 14243-3. Volumetric wear rates were 34.6 ± 1.5 mm³/106 cycles for standard polyethylene inserts and 7.3 ± 0.7 mm³/106 cycles for test samples. Test inserts were exposed to a gas plasma sterilization process. In vitro knee wear simulator tests have not been shown to quantitatively predict clinical wear performance.

30. Stryker® Orthopaedics Scorpio® PS Tibial Inserts made from X3® UHMWPE, 72-23-0708, show a 77% reduction in volumetric wear rate versus the same tibial insert fabricated from N2\Vac™ gamma sterilized UHMWPE, 72-3-0708. The insert tested was Size 7, 8 mm thick. Testing was conducted under multiaxial knee simulator (multi-station MTS knee joint simulator) for five million cycles using appropriate size CoCr counterfaces, a specific type of diluted calf serum lubricant and literature or fluoroscopy based motion and loading conditions representing stair climbing. b, c Volumetric wear rates were 35.8 ± 1.7 mm³/106 cycles for standard polyethylene inserts and were 8.2 ± 0.7 mm³/106 cycles for test samples. Test inserts were exposed to a gas plasma sterilization process. In vitro knee wear simulator tests have not been shown to quantitatively predict clinical wear performance.
31. Stryker® Orthopaedics Trident® Acetabular Inserts made of X3® UHMWPE (unsterilized), 721-00-32E, show a 97% reduction in volumetric wear rate versus the same insert fabricated from N2\Vac™ gamma sterilized UHMWPE, 620-00-32E. The insert tested was 7.5 mm thick with an inner diameter of 32 mm. Testing was conducted under multiaxial hip joint simulation for 5 million cycles using a 32 mm CoCr articulating counterface and calf serum lubricant. X3® UHMWPE Trident® acetabular inserts showed a net weight gain due to fluid absorption phenomena but yielded a positive slope and wear rate in linear regression analysis. Volumetric wear rates were 46.39 ± 11.42 mm³/106 cycles for N2\Vac™ gamma sterilized UHMWPE inserts and 1.35 ± 0.68 mm³/106 cycles for X3® UHMWPE (unsterilized) Trident® Acetabular Inserts. Although in-vitro hip wear simulation methods have not been shown to quantitatively predict clinical wear performance, the current model has been able to reproduce correct wear resistance rankings for some materials with documented clinical results. d, e, f.
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35. X3® UHMWPE maintains mechanical properties for Tensile Yield Strength and Ultimate Tensile Strength of N2\Vac™ gamma sterilized UHMWPE as measured by ASTM D638. Tensile Yield Strength was 23.2 ± 0.4 MPa and 23.5 ± 0.3 MPa for N2\Vac™ UHMWPE and X3® UHMWPE, respectively. Ultimate Tensile Strength was 54.8 ± 2.5 MPa and 56.7 ± 2.1 MPa for N2\Vac™ UHMWPE and X3® UHMWPE, respectively.
36. X3® UHMWPE virtually eliminates free radicals, as measured by Electron Spin Resonance (ESR). A very low (noise level, near instrument detection limit) concentration of residual free radicals was detected in the X3® UHMWPE. A 99% reduction of free radicals (14 ± 2 versus $1550 \pm 32, 1014$ spins/gram) was found when compared to N2\Vac™ gamma sterilized UHMWPE.
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