stryker

# Triathlon® Hinge

## Design rationale

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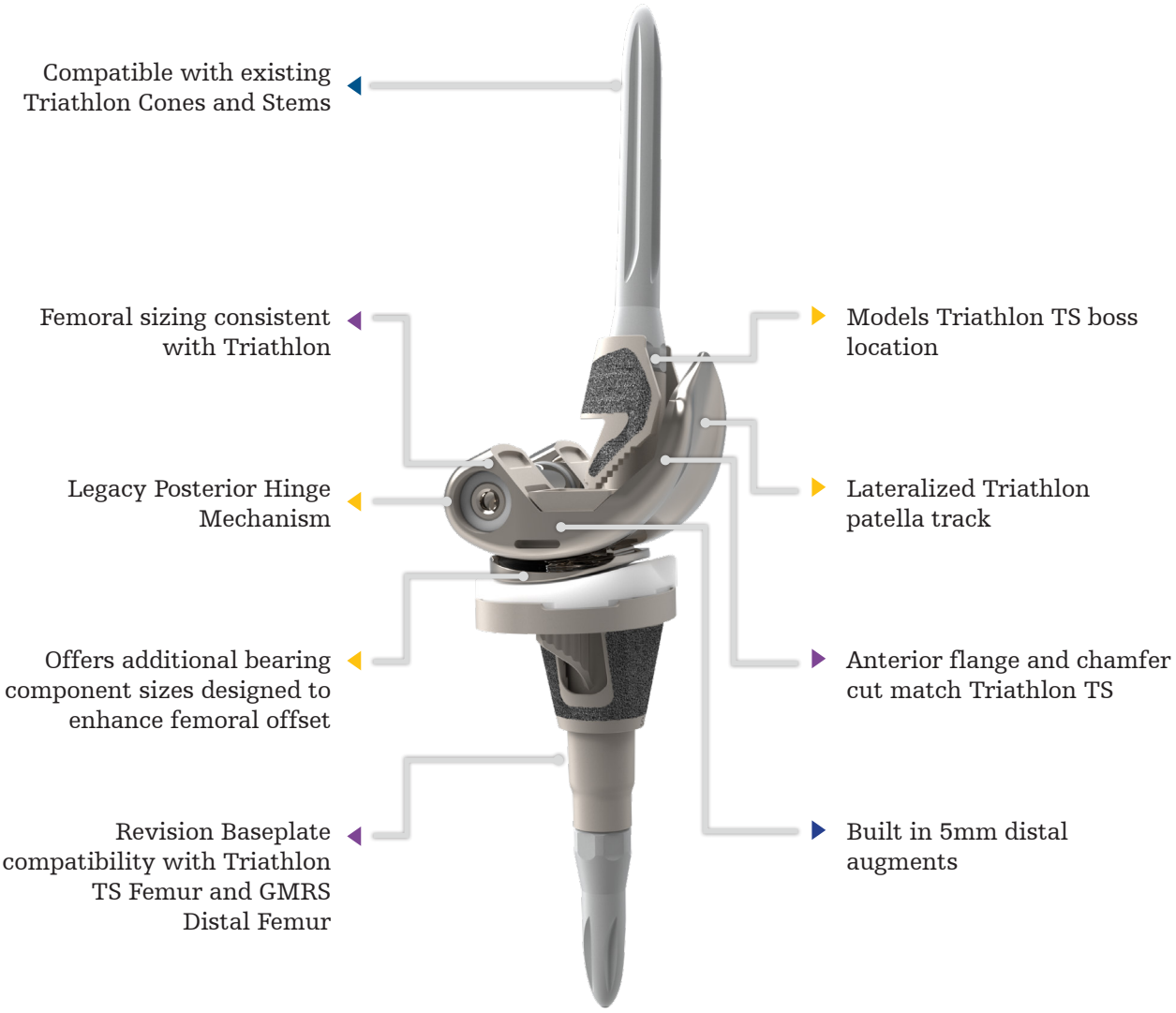
# Introduction

Triathlon Revision is designed to simplify complex revision procedures by offering a versatile baseplate. This system is designed to reduce workflow steps to streamline knee revision procedures.

## Triathlon Hinge

**Revision versatility | Workflow simplicity | Clinical performance**



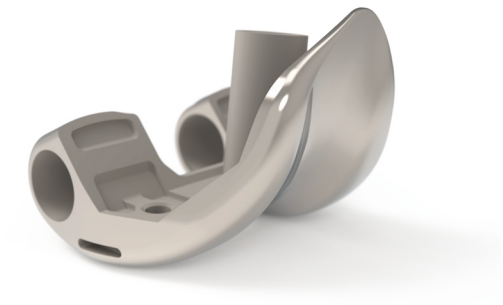
# Design principles

## Revision versatility

- Triathlon Revision Baseplate
- Revision Baseplate design features
- Triathlon Insert and Stabilizer Pin
- Joint line consideration

## Workflow simplicity

- Streamlined surgical workflow
- Triathlon Hinge Trial Cutting Guide
- Trial Bearing Plate and Post
- Alignment Guide
- Built-in 5mm Distal Augment



## Clinical performance

- Triathlon TS design features
- Predicate Hinge design features
- Assessing hinged knee replacement
- Extensor mechanism efficiency at 90° of knee flexion[1]
- Improved extensor mechanism [1,2,3]
- Triathlon Hinge insert
- Expanded Femoral offset

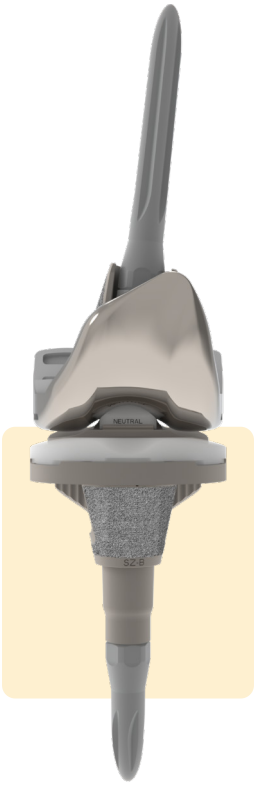
# Revision versatility

## Triathlon Revision Baseplate

Triathlon Revision now offers a single platform for revision and limb salvage surgeries in patients with significant bone loss and/or ligament deficiencies. The Triathlon Revision Baseplate can be utilized in Triathlon TS and Triathlon Hinge procedures and is compatible with the Global Modular Rotating System (GMRS) Distal Femur.

Disclaimer: Refer to relevant device labeling for specific indications for use.

**Triathlon TS Femur**

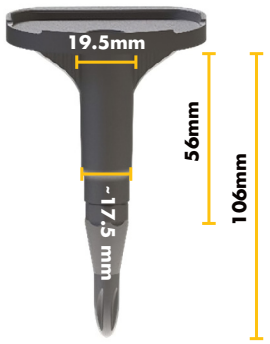


**Triathlon Hinge Femur**

**GMRS Distal Femur**

Note: Refer to relevant device labeling for specific indications for use.

# Revision versatility




## Boss

The boss features a tapered design transitioning from 19.5mm to 17.5mm which may help to conserve bone in the tibial canal.[4] The boss length for the baseplate is 56mm.


## Keel design

Designed to enhance the Triathlon profile, the Keel design on sizes 4 to 7 Revision Baseplates features a shorter keel. This is intended to accommodate the unique positioning of the Revision Baseplate being further down the tibia. Sizes 1 to 3 of the Keel design maintain the same keel length as the Universal Baseplate.

Revision

Universal

## Locking

The locking design incorporates anterior locking barbs that are identical to those found in other Triathlon baseplates. The press-fit mechanism of the locking design of the Revision Baseplate is strategically located along the M/L periphery, rather than the M/L walls of the island to allow for the versatility of going from an index revision procedure to a hinge procedure.

# Revision versatility

## Filler Bushing

The Filler Bushing, made of Cobalt Chrome, is inserted into the Bearing Hole of the Revision Baseplate. It features an Anti-Rotation Tab designed to help minimize unwanted movement or rotation. This versatile bushing is designed to be a one-size-fits-all solution, compatible with all Revision Baseplate sizes. Additionally, it is equipped with a threaded hole that enables streamlined removal using the Filler Bushing Removal Tool.

## Revision Insert X3

The preceding TS Insert's articular surface shape and insert post are maintained by the Revision Insert. However, the Revision Insert's distal and posterior surfaces have been changed to facilitate compatibility with the Revision Baseplate. The Revision Insert is available in sizes 1–7 and thicknesses of 9, 11, 13, 16, 19, 22 and 25mm (excluding 28mm and 31mm ).

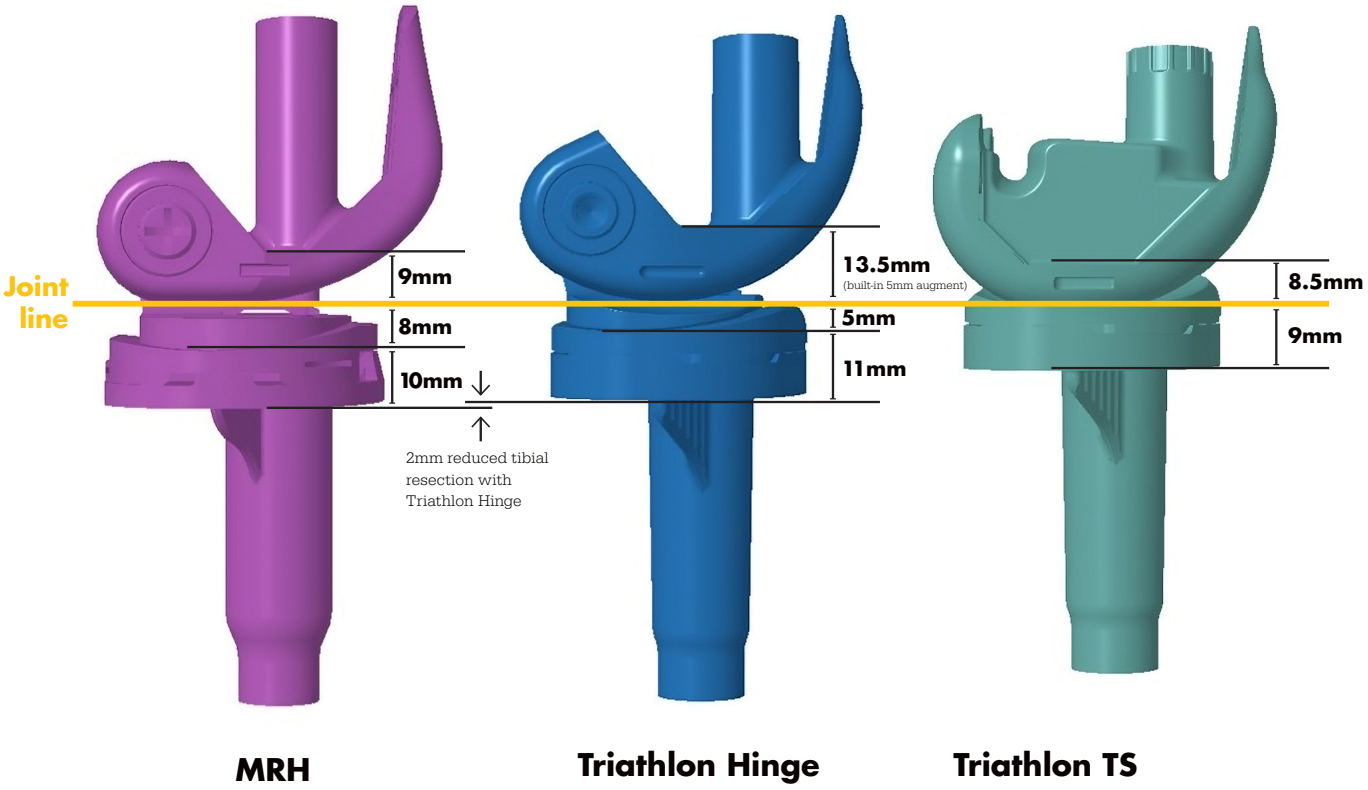
## Stabilizer Pin

The Stabilizer Pin comes in a range of diameters from 9mm to 25mm and is designed to match the thickness of the Revision Insert. It has the same geometry as the preceding Triathlon TS Stabilizer Pin, except for a 4mm longer length to compensate for the absence of an island in the baseplate. The Stabilizer Pin can be installed with the Stabilizer Post Impactor that is currently used to install the TS Stabilizer Pin.

# Revision versatility

## Joint line consideration

Considerations for potential revisions: In a native joint for Triathlon Hinge procedure, to help maintain the joint line, the minimum tibial resection is 16mm. When determining the tibial resection depth for the Revision Baseplate, consider the impact to the joint line and patella tracking in the event a potential revision of the femur to a Triathlon Hinge Femur is required.




**Note:** Offsets are not compatible with Revision Baseplate or Triathlon Hinge Femoral Component. On the femoral side, the built-in femoral offset (i.e., anteriorized boss location) is the same as Triathlon TS. In Triathlon TS, the boss position reduces the need for offsetting to only 8.7%[5] of the time, while other systems require offsetting up to 55.4% of the time.[5,6]

# Workflow simplicity

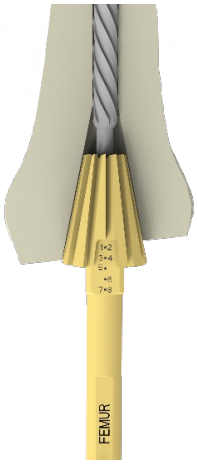
## Streamlined surgical workflow

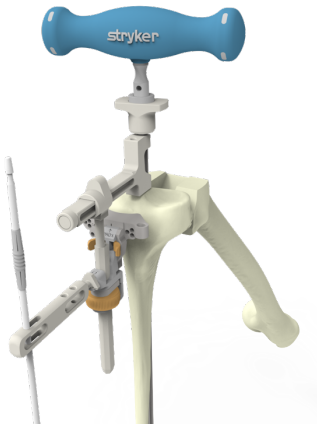
### Optimized tray layouts

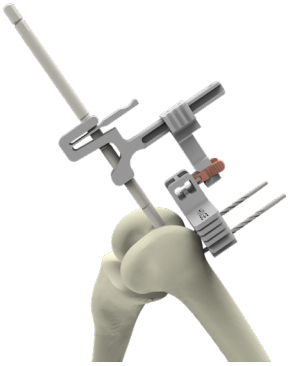
Designed to enhance operating room efficiency, the Triathlon Revision trays were redesigned. Now, +3 additional trays are needed to be brought into the operating room to convert from a Triathlon TS to a Triathlon Hinge (including Cones). This is a 60% reduction in the additional number of trays needed for a Triathlon TS to Hinge conversion compared to legacy Hinge systems.[7]

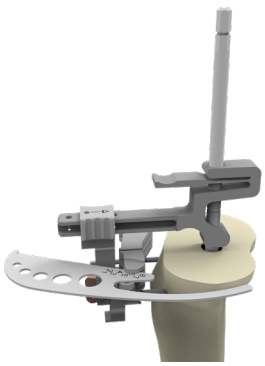
### Triathlon-based instrument platform

The instrumentation required to perform a Triathlon Hinge procedure leverages existing Triathlon instruments and a similar workflow to Triathlon TS, so the procedure resembles a Triathlon case. This may facilitate learning adoption and allow for a streamlined transition throughout the Triathlon portfolio.



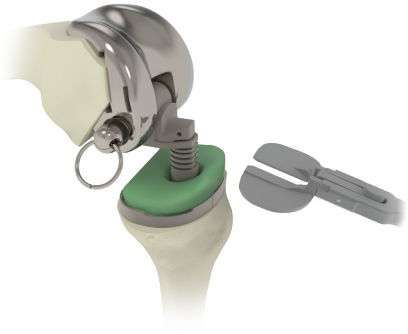


# Workflow simplicity

## Streamlined surgical workflow


### Triathlon Hinge Trial Cutting Guide (TCG)

During a revision case or an intraoperative conversion where femoral resections have already been made, the Hinge TCG allows the surgeon to make the desired distal augment cuts as well as the Hinge anterior and posterior chamfer cuts using a single guide (no anterior flange cut). The Triathlon Hinge TCG assembles to a TCG-specific Bearing Post Trial and allows the user to determine I/E rotation in flexion and assess both joint line and leg length in extension. The cutting guide features an ME and IPP line to help align the guide to anatomical landmarks and compatible valgus adaptor allowing one instrument to work for both left and right orientations.



### Trial Bearing Plate and Post

These instruments allow for streamlined trialing of different insert thicknesses without having to disassemble the entire construct. This is designed to complete the trialing process in fewer steps, while reducing the number of trays in the operating room due to the eliminated need for insert trials with multiple thicknesses.

### Alignment Guide

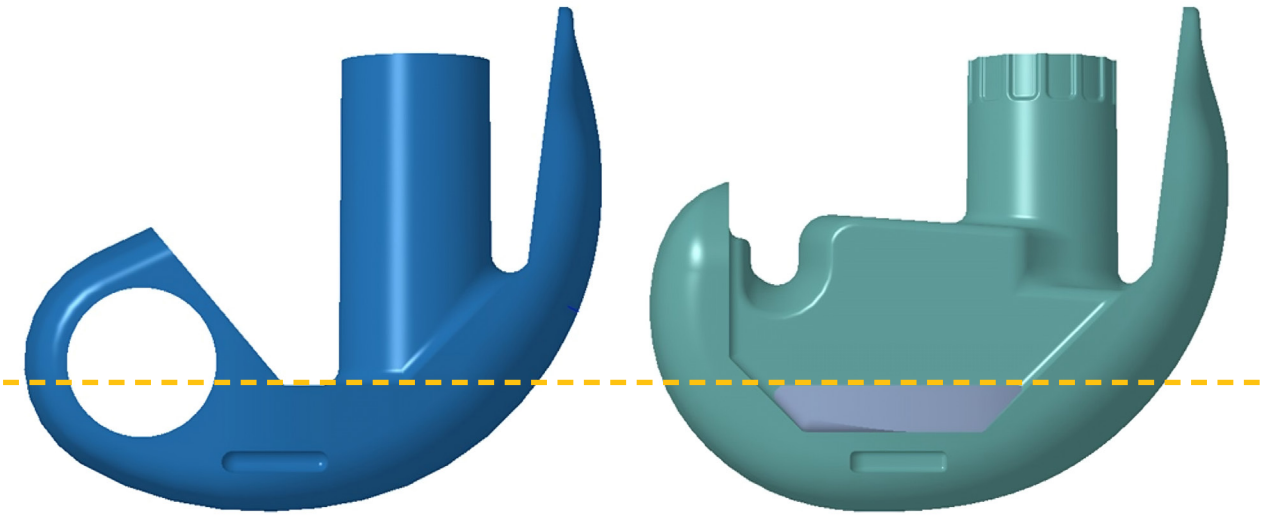
The Alignment Guide can assist in aligning the Bearing Component and Femur coaxially and hold the position until the axle is fully in place and is compatible with both the trialing and implant constructs. The alignment guide may help to relieve the force on the axle within tight joint spaces making it easier to extract.

# Workflow simplicity

## Streamlined surgical workflow

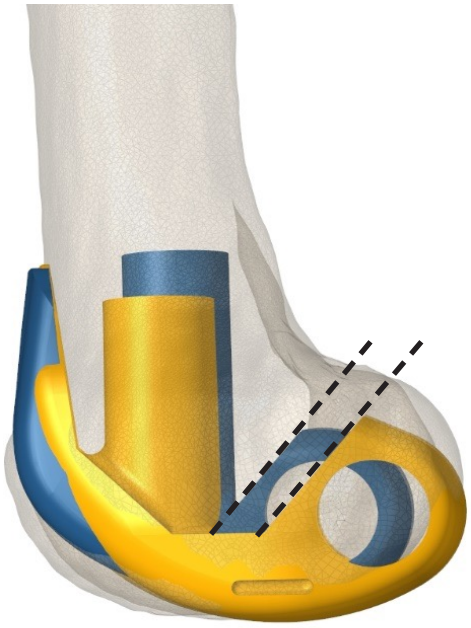
### Built in 5mm Distal Augment

Revision surgery makes up most Hinge Femur usage, with ~90% requiring the use of distal femoral augmentation for joint line restoration.[6] With revision surgery in mind, the Triathlon Hinge Femoral Component offers a built-in 5mm distal augment compared to Triathlon TS femurs. The built-in augments are designed to reduce the number of surgical steps needed and may help minimize the need to use additional stand-alone augments.



- Triathlon Hinge
- Triathlon TS

# Clinical performance



- Triathlon Hinge size 4
- Predicate Hinge size small

## Triathlon TS design features

Triathlon Hinge models Triathlon TS anatomic boss location relative to the anterior flange, which has been shown to reduce the need for offsetting.[5,6,8] The updated boss location is designed to minimize posterior resection.[8] Additionally, the Triathlon Hinge Femoral Component shares Triathlon's broad range of size offerings; offering Sizes 1 through 6 matching Triathlon A/P and M/L, size for size. Because Triathlon Hinge and Triathlon TS share sizing, the anterior bone cuts (Anterior and Anterior Chamfer) are identical. The anterior matchup is designed to allow for streamlined revision surgery by enabling intraoperative conversion and central femoral cone compatibility.

The Patella Track of the Triathlon Hinge Femoral Component matches the Triathlon TS Femur. The lateralized track is designed to be anatomic, which may reduce the risk of patellar subluxation.[8]

# Clinical performance

## Triathlon Hinge femoral sizes

The sizing for the Triathlon Hinge femur has been standardized to match that of our existing Triathlon Femurs. The implants below were precisely aligned, ensuring femoral flexion and varus-valgus were maintained at 0°. The alignment of the femoral component is determined based on the fit between the femoral boss and the canal, while the patellar alignment is carefully adjusted with the intent to restore medialization and maximize coverage. In a validated model,[4] Triathlon Hinge demonstrated improved patellar fixation and tracking within the trochlear groove, mirroring the performance observed in primary systems.[9]

Triathlon Hinge size 4

Predicate Hinge size small (S)

Predicate Hinge size medium (M)

# Clinical performance

## Predicate Hinge design features

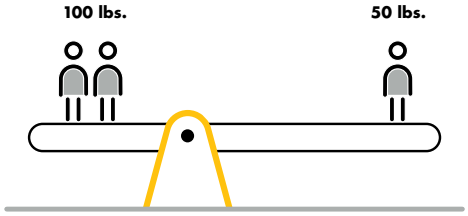
The posterior hinge mechanism of the Modular Rotation Hinge (MRH) knee has a proven track record with **90.2% overall survivorship at a 10-year follow-up**.[1] Additionally, the posterior design of the mechanism may increase the mechanical advantage of the device with a longer moment arm when compared to central hinge designs.[9]

The posterior mechanism can also provide three other key advantages over other hinge designs:

1. No intercondylar box cut is required, eliminating the narrowing of the condyles that may lead to condylar fracture.[10]
2. Intercondylar designs may lack the ability for efficient revision of the hinge mechanism without removing the implant or removing bone to gain access.[10]
3. Intercondylar designs may have a small axle width, which can increase the stress on the component during varus/valgus loading when compared to longer axles across the width of the femur.[10] (see figure below)

**Triathlon Hinge**


**Intercondylar designs**[8]


In the above example, the seesaw is balanced even though the people weigh different amounts because the distance between them and the pivot point is different. Similarly, the further the axle and bushing are from the varus/valgus moment (pivot point), the less force they need to provide to resist that moment (Triathlon Hinge bushings and axle are designed to impart less force to resist varus/valgus loads).[1, 11]

# Clinical performance

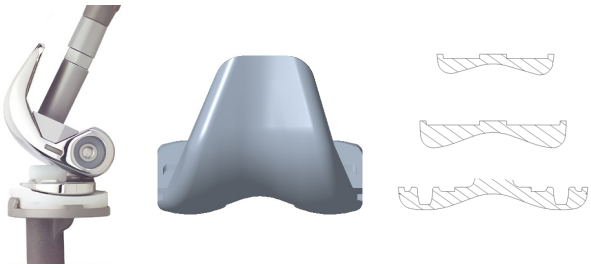
The information presented on pages 15-17 summarize non-clinical testing conducted as a part of the development of the Triathlon Hinge Knee System.

## Assessing hinged knee replacement designs using a Biomechanical Knee Simulator[3]

The purpose of the bench test was to compare the extensor efficiency in terms of quadriceps force, quadriceps effective moment arm, patellofemoral force, and patellar flexion between clinically successful Stryker MRH[12] and the Stryker Triathlon Hinge implants.[9]

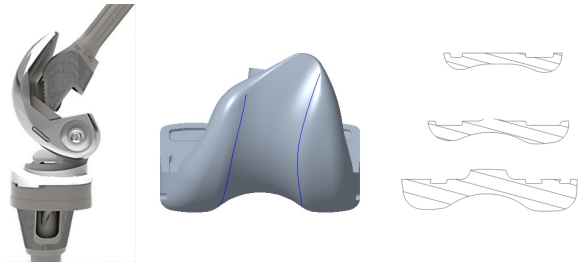
### Stryker Predicate Hinge

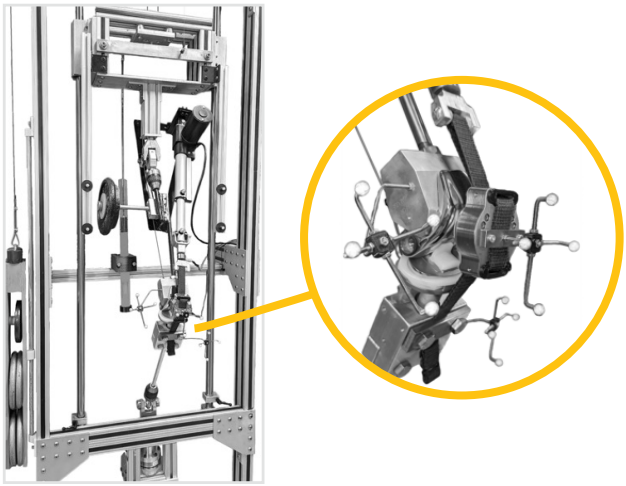
Symmetric "V-groove" Patella Track



### Stryker Triathlon Hinge

Anatomical Patella Track[1]



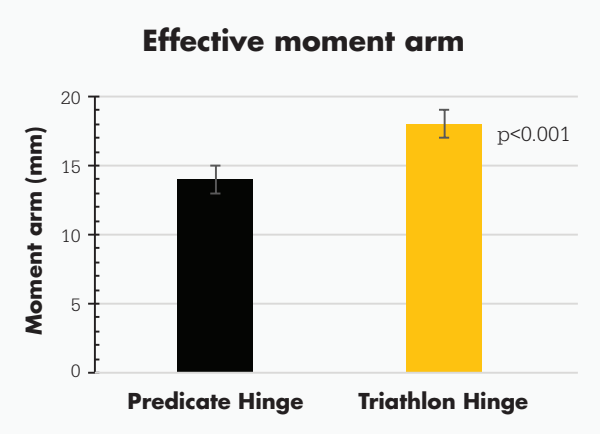


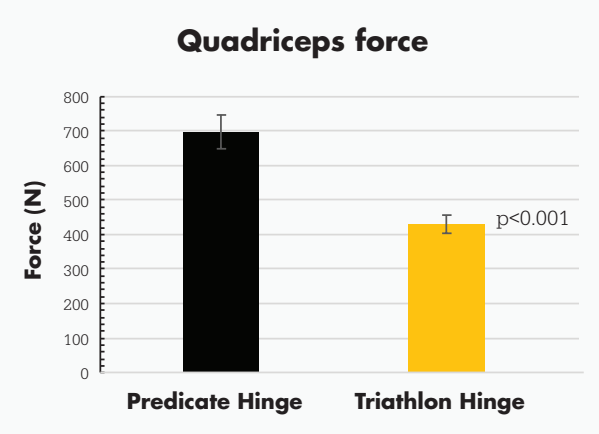
The methods involved the use of the Penn State Knee Simulator (PSKS), a non-cadaveric knee simulator based on the Oxford Rig design. The simulator was instrumented with load cells to track tibiofemoral and patellofemoral motions, and the implants were repeatedly trialed to gather data.

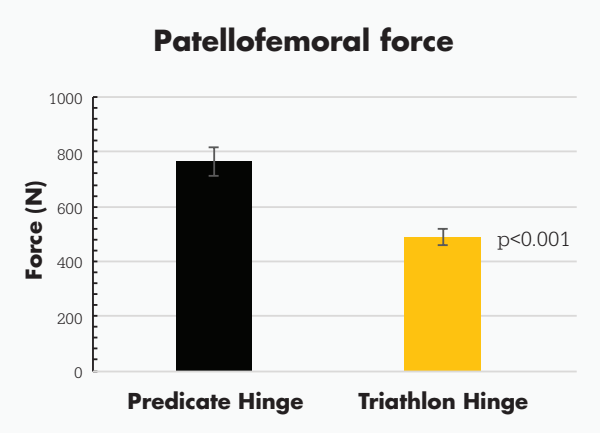
# Clinical performance

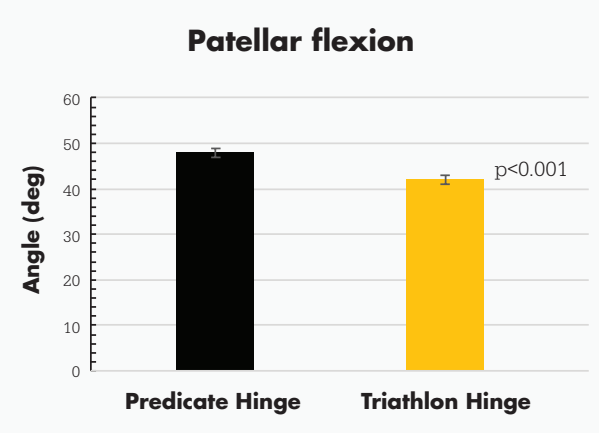
## Extensor mechanism efficiency at 90° of knee flexion

The bench test found the Triathlon Hinge implant provided enhanced extensor mechanism efficiency compared to the clinically successful legacy design.[3] The anatomical patellofemoral geometry of the Triathlon Hinge implant[1] was suggested to potentially provide desired postoperative functional performance and enhanced stability of the knee with biomechanically efficient movements.



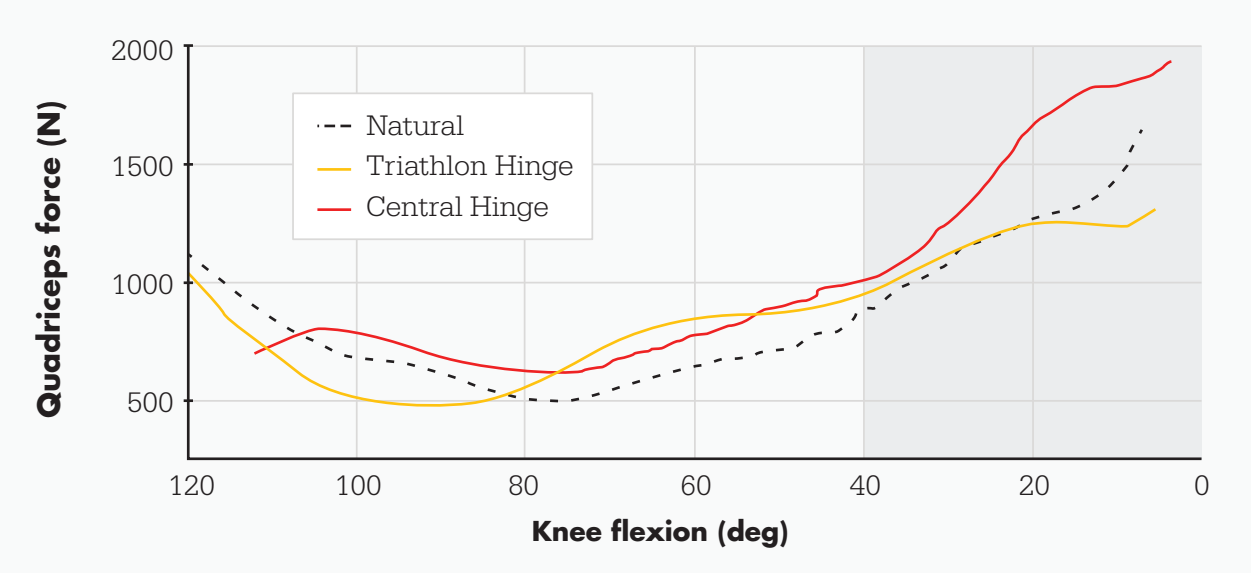



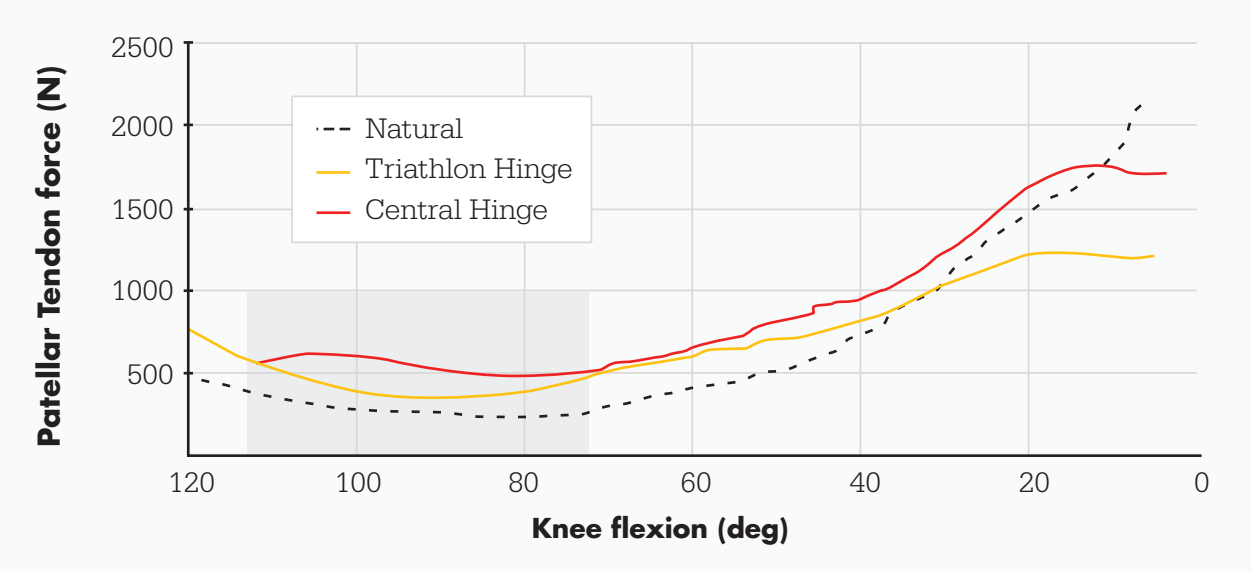

Overall, the assessment provides valuable insights into the comparative performance of hinged knee replacement designs and suggests potential benefits of the Triathlon Hinge implant in terms of functional recovery after revision knee arthroplasty.[3]

# Clinical performance

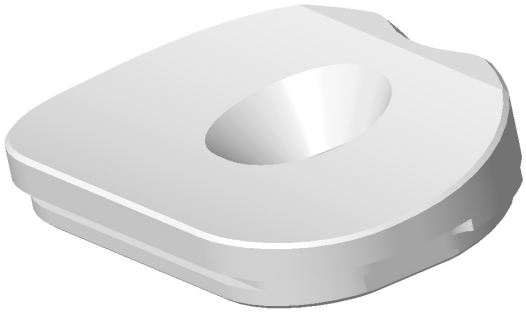
## Improved quadriceps efficiency

The combined effect of the Triathlon deepened trochlear groove, increased moment arm and bearing component femoral offsetting has demonstrated that extensor mechanism efficiency improves with a **32.5% reduction in quadriceps force**[9,12] **and 39% reduction in patellar tendon force.**[9,12]



# Clinical performance



## Triathlon Hinge Insert

The Triathlon Hinge insert is N2VAC, a ultra-high molecular weight polyethylene that is sterilized using Gamma radiation. This material was chosen intentionally due to its shear loading and compressive strength polyethylene.[11, 13, 14]

In designing the Triathlon Hinge Knee (THK), a wear assessment was performed under the most severe conditions for the Triathlon Hinge Insert. Results demonstrated that THK wear was under the clinical threshold.[14]

The Triathlon Hinge inserts are available in a variety of sizes, ranging from 1 to 7, and thickness options of 11, 13, 16, 19 and 22mm. It features a ramp designed to aid in joint distraction and resist internal/external rotation.

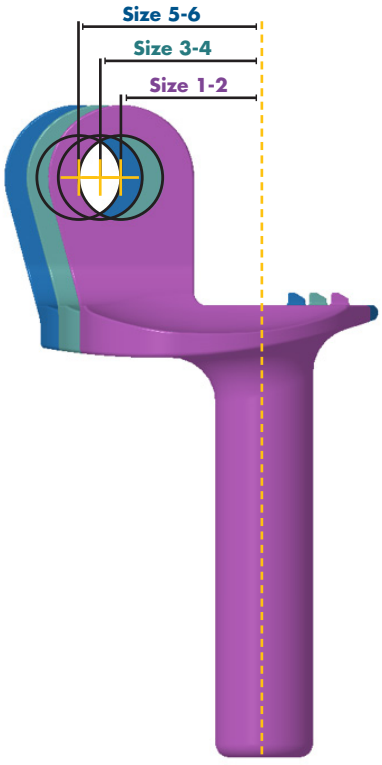
# Clinical performance

## Expanded Femoral offset

The Triathlon Hinge Femoral component incorporates Triathlon's deepened trochlear groove, designed to relax the extensor mechanism, enable deeper flexion and reduce contact stresses exerted across the patella.[1,9,15] Femoral offset is expanded across all femur sizes by offering 3 sizes of tibial bearing components with varying distances between the Bearing Component Post and Hinge Axle Hole for patellofemoral kinematics. All Bearing Component Posts offer a "jump height" of 46mm, regardless of insert thickness.

| Revision Baseplate size | Hinge Femur size | Compatible Bearing Component part number |
|---|---|---|
| 1 | 1-2 | 5612-0-001 |
| 2 | 1-2 | 5612-0-001 |
| | 3-4 | 5612-0-003 |
| 3 | 1-2 | 5612-0-001 |
| | 3-4 | 5612-0-003 |
| 4 | 1-2 | 5612-0-001 |
| | 3-4 | 5612-0-003 |
| | 5-6 | 5612-0-005 |
| 5 | 1-2 | 5612-0-001 |
| | 3-4 | 5612-0-003 |
| | 5-6 | 5612-0-005 |
| 6 | 1-2 | 5612-0-001 |
| | 3-4 | 5612-0-003 |
| | 5-6 | 5612-0-005 |
| 7 | 1-2 | 5612-0-001 |
| | 3-4 | 5612-0-003 |
| | 5-6 | 5612-0-005 |

**Compatibility table indicating appropriate Bearing Component implant for each tibial and femoral implant size.**




Bearing Component Posterior Offset increases by ~2.5mm for each size:

Size 1-2 = 16.7mm

Size 3-4 = 19.25mm

Size 5-6 = 21.8mm

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