Triathlon®
Design Rationale

Don’t just replace the knee. Replace the way the knee moves.¹⁻³
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Experience the difference of our circular, single-radius design.
Design

Since its first use in surgery in 2004, Triathlon has demonstrated what a knee replacement system can offer patients. Triathlon’s distinction as a modern knee with a wealth of clinical support offers surgeons modern advancements in motion with confidence in implant selection.

When Triathlon was designed, Stryker examined the leading reasons why knee replacements require revision and designed the features of Triathlon to address Early and Late Failure modes.

Clinical studies and laboratory studies have demonstrated the potential performance and functional benefits of the Triathlon Knee System.

When evaluating a knee system, the clinical questions to ask are the following:

1. Can it improve implant survivorship?

A 2013 study showed implant survivorship was 99.7% at a final follow-up of 7 years with Triathlon.

2. Can it improve patient recovery and function?

Clinical studies have shown reduction in physiotherapy sessions, more rapid abandonment of crutches, and less anterior knee pain comparing single radius to multi radius knees.

3. Can it introduce any new failure mode?

X3 achieves oxidation resistance without the use of additives. Multiple attempts by manufacturers to combine additives into polyethylene have yielded unfavorable results including additive leaching and polyethylene damage.
Ligament Balance

While femoral components of most knee systems create multiple turning radii during movement, the Stryker Triathlon system is built around a circular, Single Radius design. It’s rotation is designed to mimic natural knee kinematics, allow for constant ligament balance, and offer enhanced stability throughout the active range of motion. Knee replacement has finally come full circle.

Shorter Posterior Condyle

The shorter posterior condyles facilitate the relaxation of the soft tissues to enable deep flexion.

Flared Posterior Condyles

Designed to accommodate 20 degrees of internal/external rotation throughout the range of motion.

Rotary Arc

Precision machined surface facilitates internal/external rotation.

Anatomic Patellofemoral Track

Designed with a deepened trochlear groove to help relax the extensor mechanism, enable deeper flexion, and reduce contact stresses exerted across the patella.
Motion

Hyperextension/Extension

Triathlon is designed to allow for +/- 10 degrees of rotation in hyperextension and extension. In these early degrees of motion, Triathlon has demonstrated less post impingement and torque forces than other designs.

Active Flexion

Stryker’s single radius knee is designed to replace the way the knee moves. Traditional theory used a direct lateral view of knee motion to characterize the shape of the posterior condyles. From that view, the posterior condyles appeared oval in shape. Modern research examined the knee looking along the transepicondylar axis, which revealed that the shapes of the posterior condyles were circular. More specifically, a cadaver study showed that the active flexion radius ranged from 10° to 110°.

Stryker’s virtual bone database of over 1,000 consecutive femurs provides support and rationale for Triathlon. This single radius has been discussed by various researchers, and is apparent in sample images of femurs from the SOMA database.
Deep Flexion

Triathlon is designed to accommodate up to 150 degrees of deep flexion. This is achieved through the interaction of the shortened, flared posterior condyles and rotary arc. The flared posterior condyles and the rotary arc are designed to accommodate up to 20 degrees of internal/external rotation. The shortened posterior condyles facilitate the relaxation of the soft tissues and mitigate the need for additional tibial slope resection.

<table>
<thead>
<tr>
<th>Deep Flexion</th>
<th>Mean</th>
<th>Max</th>
</tr>
</thead>
<tbody>
<tr>
<td>Harwin et al</td>
<td>126°</td>
<td>150°</td>
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</table>

“The Reality of Additional Insert Thicknesses”

Balancing the knee is a principal goal in total knee replacement, and can be impacted by femoral geometry and technique. Some new knee systems offer 1mm incremental insert thicknesses. However, the data from a competitor offers little evidence that these insert options address a clinical need. Zimmer’s own data shows that as loads increase on the knee, the effect of 1mm incremental insert thicknesses on AP and IE laxity is reduced as shown in the chart.

- Zimmer tested up to 112 pounds of force (500 N), and the effect on AP and IE laxity is reduced as force increased. The average weight of a knee replacement patient is 185 pounds.
- Activities like walking, exercising, and golfing can lead to 2-4 times body weight of force.

As the average knee replacement patient engages in these activities, how meaningful are these additional insert thicknesses? Instability is a leading cause for early revision, and one study demonstrated that Triathlon has 99.7% survivorship at 7 years.
Contact Area
Triathlon is designed to exhibit an appropriate contact area throughout the range of motion. Designs, like Triathlon, with smaller contact areas have been shown to wear less than designs with larger contact areas.
Rotation

Triathlon is designed to accommodate up to 20 degrees internal and external rotation. This can be accomplished via the patented rotary arc and the shortened and flared posterior condyles.

Triathlon is also designed to reduce rotational constraint compared to other systems.

Pivot

Komistek et al demonstrated that the normal, healthy knee exhibits a medial pivot 80% of the time. Many traditional knee systems are designed based on this premise and drive a medial pivot. Komistek also demonstrated that patients with various knee replacement designs demonstrated a medial pivot 55% of the time. Given the variability in pivot in knee replacement patients, Triathlon was designed to allow the soft tissues to guide pivot. There are no design features in Triathlon that promote a particular pivot location, giving the patient’s soft tissues the ability to pivot as needed.
Recovery

A study showed that select patients without post-op complications who received Stryker’s single-radius knee replacement abandoned crutches sooner and required fewer physiotherapy sessions than patients with traditional knee replacements.¹

Patients with a single radius knee have also demonstrated less anterior knee pain than patients with a multi radius knee.⁹,²⁶ Triathlon also incorporates the same patellofemoral design as Duracon, which demonstrated <1% patellofemoral complication rates in multiple studies.⁴¹,⁴²
Fit
Femur – Implant Features

Triathlon’s broad range of size offerings are based on an anthropometric measurement study\textsuperscript{10} for improved interplay between implant geometry and anatomic structure for women and men. Triathlon incorporates a variable aspect ratio to adequately fit the female anatomy while still accommodating the male population.\textsuperscript{10} It is designed to address smaller anatomies, often found in female patients, heavily concentrated in the region shown,\textsuperscript{10} while still accommodating larger male patients.

The unique 7-degree anterior flange design of Triathlon is designed to provide the flexibility to downsize the femoral component while avoiding the incidence of notching. This feature culminates in the potential to provide patients with a better fit.
Femur – Instrument Features

How To Accommodate Femoral Bow with the FlexRod

Triathlon also has a unique instrument that works with the patient’s individual anterior femoral bow. Anterior bow of the femur varies widely. The Triathlon FlexRod bends to avoid making distal femoral resection in extension due to a patient’s anterior femoral bow. In a retrospective study, by reducing the likelihood of making the distal resection in extension the FlexRod has been shown to allow more downsizing than the rigid rod.

In a separate prospective study, patients whose procedure included the FlexRod had greater range of motion and higher KSS scores.

<table>
<thead>
<tr>
<th>ROM\textsuperscript{12}</th>
<th>pre-op</th>
<th>6 weeks</th>
<th>3 months</th>
<th>1 year</th>
<th>2 years</th>
<th>% change at 2 years</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rigid</td>
<td>101.1</td>
<td>103.1</td>
<td>113.6</td>
<td>119.0</td>
<td>123.6</td>
<td>22.2%</td>
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<tr>
<td>Flexible</td>
<td>99.7</td>
<td>107.0</td>
<td>118.2</td>
<td>124.3</td>
<td>127.9</td>
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<tr>
<td>% diff</td>
<td>-1.5%</td>
<td>3.8%</td>
<td>4.1%</td>
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<th>KSS Pain/Motion\textsuperscript{12}</th>
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<th>6 weeks</th>
<th>3 months</th>
<th>1 year</th>
<th>2 years</th>
<th>% change at 2 years</th>
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<tr>
<td>Rigid</td>
<td>37.25</td>
<td>73.9</td>
<td>80.31</td>
<td>88.52</td>
<td>90.5</td>
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<td>35.74</td>
<td>76.9</td>
<td>82.75</td>
<td>90.1</td>
<td>92.73</td>
<td>159.5%</td>
</tr>
<tr>
<td>% diff</td>
<td>-4.1%</td>
<td>4.1%</td>
<td>3.0%</td>
<td>1.8%</td>
<td>2.5%</td>
<td>16.5%</td>
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<table>
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<th>KSS Function Data\textsuperscript{12}</th>
<th>pre-op</th>
<th>6 weeks</th>
<th>3 months</th>
<th>1 year</th>
<th>2 years</th>
<th>% change at 2 years</th>
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<tr>
<td>Rigid</td>
<td>53.08</td>
<td>56.84</td>
<td>78.42</td>
<td>86.4</td>
<td>86</td>
<td>62.0%</td>
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<tr>
<td>Flexible</td>
<td>52.87</td>
<td>68.74</td>
<td>82.14</td>
<td>87.86</td>
<td>89.04</td>
<td>68.4%</td>
</tr>
<tr>
<td>% diff</td>
<td>-0.4%</td>
<td>17.3%</td>
<td>4.5%</td>
<td>1.7%</td>
<td>3.4%</td>
<td>6.4%</td>
</tr>
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</table>
Tibial Coverage

Symmetric baseplates have been shown to produce positive clinical results1,3,5,9,17,26,32 and adequate surface coverage in relation to tibial aspect ratio.13 In fact, a study by Incavo, et al. demonstrated symmetric baseplates provided greater coverage in anterior quadrants when compared to asymmetric designs.13 Another study showed an asymmetric tray had higher rates of posterolateral and posteromedial overhang compared to symmetric designs, including Triathlon.68

A clinical study on 287 total knee replacements who received a Triathlon implant demonstrated no tibial component subsidence.67 Triathlon’s rotary arc is designed to provide surgeons with the ability to fine tune tibial rotation for preferred coverage while reducing the effect on motion.

What Effect Does Gender and Race Have on Femoral Sizing?

Images from SOMA, Stryker’s virtual bone database, demonstrate that accommodating for femoral bow can reduce the incidence of overhang in bone types with anterior bow.

Anterior Femoral Bow (Asian Female)

Flexed Femoral Component

Extended Femoral Component (Oversized)
Polyethylene

Research has shown that the main objective for polyethylene in orthopedics is to reduce wear through crosslinking without sacrificing strength or oxidation resistance. X3’s patented sequential irradiation and heat process has been shown to achieve this objective without the use of additives.
Wear Resistance

Sequential irradiation provides a greater degree of crosslinking versus a single dose as demonstrated in the chart below. The X3 process is a proprietary three step process of irradiation with 3MRads (total 9MRads) of gamma radiation and annealing.\textsuperscript{14}
Oxidation Resistance

Multiple laboratory tests have confirmed that X3 virtually eliminates free radicals.19,33 X3 oxidation resistance is similar to that of virgin polyethylene.33

Some researchers have published on the presence of oxidation on polyethylene retrievals.57,58 The test methods used by these retrieval centers have been called into question.47 Data supports that the test methods used by institutions like Dartmouth58 and Massachusetts General Hospital57 leave residual body fluid containing oxygen, or can even induce oxidation itself.47 Polyethylene retrievals that show signs of discoloration may actually be due to residual body fluids.65

In an effort to reduce the residual free radicals that could lead to oxidation, many traditional polyethylenes were remelted. Remelting has been shown to improve oxidation resistance, however remelting has also been shown to decrease strength.34

Today, some polyethylenes are manufactured with antioxidant additives.35,36 In doing so, these polyethylenes avoid the remelting process that reduces mechanical strength.34 Polyethylenes with antioxidant additives are attempting to address concerns over the reduced mechanical strength of remelted polyethylenes.46 There is no clinical evidence to support that new antioxidant additive polyethylene provides superior oxidation resistance.

“What Issue Are Antioxidants Trying to Solve?”

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Here are results of competitors’ historic attempts to incorporate additives to polyethylene:

- Carbon fiber38 – A carbon fiber additive was intended to improve wear and mechanical strength characteristics. It was later discovered that the additive was associated with polyethylene damage including fibers pulled from the surface, broken fibers, and polyethylene removed from the surface fibers.
- Calcium stearate51 – One study showed that a calcium stearate additive in polyethylene induced bone resorption and promoted inflammation.
- Vitamin E57 – In a lab test, Vitamin E was confirmed to leach from inside of vitamin E-blended polyethylene.
Mechanical Strength

X3 is annealed, allowing it to maintain its mechanical strength.\textsuperscript{33}

Fracture Toughness

A published study showed that wear and mechanical integrity of X3 PS inserts was unaffected by accelerated aging, even after a rigorous stair climbing test.\textsuperscript{16} Furthermore, the fracture toughness of X3 is double the ASTM minimum requirement.\textsuperscript{18} There have been zero reported material-related fractures for X3 tibial and patella inserts.\textsuperscript{69}
References

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7. Stryker test data RD-03-041
18. Stryker test report: RD-03-081 Rev 2. 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 32, 1014 spins/gram) was found when compared to N2Vac gamma sterilized UHMWPE.
27. Stryker Test Data RD-06-013.
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36. E1 Antioxidant Infused Technology. Biomet. Form No. BOII0314.1 • REV103109.


40. Stryker Test Report RD-13-005


43. Stryker Test Data RD-09-088


47. Le, K-P; Song, L; Longaray, J; Carlos, A; Herrera, L; Yau, S-S; Essner, A. Can We Trust Oxidation Measurements from Retrieved UHMWPE? ORS 2013 POSTER No. 1235

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64. FDA 510K K101433

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A surgeon must always rely on his or her own professional clinical judgment when deciding whether to use a particular product when treating a particular patient. Stryker does not dispense medical advice and recommends that surgeons be trained in the use of any particular product before using it in surgery. The information presented is intended to demonstrate the breadth of Stryker product offerings.

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TRIATH-SS-13 Rev-1
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