Fixed Bearing Knees
Function with Wear Resistance
Today’s surgeons demand a knee system that can react to the needs of the individual patient. The Sigma® Knee System brings together function with wear resistance to match the needs of a diverse patient population. Regardless of the size, shape or activity level of patients, surgeons can feel confident that with the Sigma Knee system, they can choose the procedure and implant to meet their patients’ demands.
The Sigma Knee System offers one of today's most comprehensive, integrated knee systems. It embraces a wide variety of philosophies and surgical techniques and continues to develop with the addition of further implant options and instrumentation.

The Sigma Fixed Bearing Knee Portfolio

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**Sigma Fixed Bearing Knees**
*Function with Wear Resistance*

### Femoral Components
- Rounded coronal geometry maximizes contact area while minimizing contact stresses
- Accommodates high flexion with Sigma CR150

### Highly Polished Cobalt Chrome Tibial Tray
- Reduces backside polyethylene wear (as compared to titanium trays) by providing a smooth surface
- Retrieved CoCr trays show no locking mechanism erosion

### XLK Polyethylene
- Moderately cross-linked to provide increased wear resistance versus standard polyethylene
- Remelted to create an oxidatively stable material

### i2 Locking Mechanism
- Integrity of locking tabs maintained with anterior bumper
- Interference fit between the insert and the tibial tray reduces potential for micromotion
Optimal Function

Sigma Femoral Components

The Sigma femoral components are designed to provide optimal function for high demand patients. The main benefits of the femoral components are:

Rounded Coronal Geometry

By utilizing a round-on-round geometry, the system allows a larger contact area and lower contact stresses, both in neutral alignment and varus or valgus lift-off, compared to flat-on-flat designs. This optimizes the trade-off between maximal contact area and constraint of the implant.¹

In contrast, lift-off of the femoral component in a flatter condylar design can lead to edge loading on the opposite side. This may cause high concentrations of contact stresses on the polyethylene.

High Flexion

The clinically proven Sigma J-curve with extended posterior condyles provides conforming contact through 150 degrees of flexion, reducing the risk of point contact stress.

At 135 degrees of flexion, the Sigma CR150 knee system provides a 31 percent increase in contact area resulting in a 19 percent decrease in contact stress compared to the Sigma CR femoral component. This helps to protect the tibial insert and reduce polyethylene wear.⁶

To increase congruency and conformity in high flexion, the J-curve of the Sigma CR150 is extended beyond 120 degrees. In order to achieve this, Sigma CR150 requires a posterior bone resection of an additional 2 mm when compared to the existing Sigma CR.
A highly polished Cobalt Chrome (CoCr) fixed bearing tibial tray is a unique product from DePuy Orthopaedics with features not offered by any other competitor on the market. The main benefits of this tray are:

**Highly Polished Surface**

The polyethylene friendly, highly polished CoCr tray creates a smooth surface, minimizing abrasion.\(^2\)

The Ra value (a measure of surface roughness) of the CoCr tray surface has been reduced by 95 percent compared to the older Titanium tray.\(^2\)

**Proven Design**

The CoCr tray uses the same design that was used by the original and successful P.F.C.\(^8\) tibial trays. It utilizes the same tray thickness, stem and keel, design as well as the same undersurface finish.

In essence, the highly polished cobalt chrome tray provides a more polyethylene friendly environment than titanium with no compromise in material strength or fixation. It has been demonstrated that:

- Because motion between the insert and metal backing may be inevitable, the wear characteristics of the inner tray surface should be optimized to minimize debris production.\(^7\)
- Polishing the tray has been shown to improve the wear characteristics of the articulation.\(^7\)
The main goal of cross-linking is to improve polyethylene's wear properties. Improving the wear properties of the polyethylene material is important in fixed bearing knees because of the multi-directional stress that the insert experiences.

Gamma irradiation is a proven method for cross-linking the polyethylene. As the dose of gamma radiation increases, the material's wear properties also improve. But higher doses of gamma irradiation have a drawback -- gamma radiation adversely affects polyethylene's mechanical properties. Therefore, it is not advisable to increase the dose indiscriminately. A balance needs to exist between the amount of wear reduction that is achieved and reduction in mechanical properties. Sigma XLK finds that balance with the following characteristics:

GUR 1020 Resin
Sigma XLK polyethylene is made from GUR 1020 resin which has tougher mechanical properties relative to GUR 1050.

Moderately cross-linked
DePuy Orthopaedics uses the 5 Mrads dose as it gives the desired amount of wear reduction without a significant drop in mechanical properties. Moderate cross-linking of the polymer chains provides increased resistance to the multidirectional wear generated by fixed bearing designs.

Oxidatively Stable
Sigma XLK is remelted above the melting point of polyethylene after it is exposed to gamma radiation to make it oxidatively stable.

Bottom line:
Sigma XLK is remelted to eliminate free radicals and therefore is oxidatively stable – both on the shelf and in vivo.
Wear Resistance
i2 Locking Mechanism

The Sigma i2 locking mechanism plays a pivotal role in reducing the amount of micromotion between the tibial insert and the tibial tray. The two salient features of the i2 locking mechanism include:

**Interference Fit**

The size of the polyethylene insert is 150 microns bigger than the tibial tray pocket. Due to this difference in size, the insert has to ‘squeeze’ inside the tray. Since the insert deforms as it goes in the tray, there is little room for it to move, thus minimizing the rotational micromotion and potential for backside polyethylene wear.

**Integrity**

There is an anterior bumper on the front of the insert between the two locking tabs. This improved design removes the load from the tabs. Since the locking tabs do not experience the stress, it reduces the risk of tabs breaking over time. The bumper will also absorb most of any anteriorly directed force, minimizing the anterior/posterior micromotion and potential for backside polyethylene wear.
This construct delivers the benefits of modularity while approaching the performance of a one-piece tibial design. When compared with the older lock, the i2 lock has reduced the amount of micromotion by 85 percent. In fact, 16 microns of resultant micromotion in the Sigma design is the lowest among a group of implant systems as demonstrated in mechanical testing.

![Graph showing mean R & RT micromotion by manufacturer](image)

**Mean R & RT Micromotion by Manufacturer**

- **R** = \( \sqrt{(AF)^2 + (ML)^2} \)
- **RT**

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>R (MICROMETERS)</th>
<th>RT (DEG)</th>
</tr>
</thead>
<tbody>
<tr>
<td>PFC ∑ i2 XLF</td>
<td>257</td>
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<td>PFC ∑ i2 GVF</td>
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<td>Scorpio</td>
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</table>
Micromotion

Micromotion is the motion that occurs between the polyethylene insert and the tibial tray. It’s a phenomenon that has been recognized as a contributing factor to backside wear of polyethylene and is an unintended consequence of modularity in total knee implant systems.12

Benefits of Modularity

Modularity allows flexibility to customize the thickness of the polyethylene insert after the tibial tray has been fixed in the patient and exchange of polyethylene bearings without revision of the entire tibial component.12

Disadvantages of Modularity

The tray and insert interface can be a source of polyethylene wear debris. In a study by Wasielewski et al, wear on the underside of retrieved modular tibial inserts was associated with radiographic evidence of osteolysis.13

Source and Significance of Micromotion

Micromotion is typically caused by inherent design characteristics of the implant. By definition, modularity requires the two components to be of slightly different size so that they can easily be assembled. The key is to minimize this difference so as to minimize the ‘play’ between the two. At the same time, it should be easy for a surgeon to assemble (and disassemble when required) the two components. Different implant designs in the marketplace have had different levels of success achieving this balance.

Solution

It is not possible to completely eliminate micromotion between the tibial tray and tibial insert in a modular design. Therefore the locking mechanism, material, and the surface finish of the tibial tray assume greater significance. If any amount of motion is taking place, the following is desirable:

- The insert locking mechanism should secure the insert and the tray with a tight fit.
- The surface finish of the tray should be polyethylene friendly. It should be as smooth as possible in order to minimize the friction between the metal and plastic components.
- The tray material should be a friendly articular surface.

Key Message

“The undersurface of the insert is an additional source of polyethylene debris contributing to tibial metaphyseal osteolysis. To lessen polyethylene debris produced at this modular surface, the tibial implant locking mechanism should fix the insert firmly to the metal backing to decrease relative micromotion. Because motion between the insert and the metal backing may be inevitable, the wear characteristics of the inner tray surface should be optimized to minimize wear debris production at this other articulation.”13

The combination of a highly polished cobalt chrome tray, i2 locking mechanism and moderately cross-linked polyethylene has resulted in significant reduction in overall polyethylene wear in the Sigma Knee System. Tests have shown that use of these improved technologies has reduced the polyethylene wear rates in a Sigma Fixed Bearing Knee by 88 percent under standard kinematic loads and 71 percent under high kinematic loads compared to standard polyethylene and titanium trays.14
Oxidative Stability

Polyethylene has been successfully used in orthopaedic implants, including knee systems, for many decades. However it is also often cited as the leading cause of knee revision.\textsuperscript{15}

Oxidative Stability

Oxidative Stability is defined as the material’s ability to resist combining with oxygen molecules. Oxidation eventually leads to breakdown of the polyethylene material and may contribute to implant failure.

Virgin polyethylene is a material not exposed to any gamma radiation and is therefore inherently oxidatively stable. However, exposure to gamma radiation is an essential step in the current manufacturing processes. Gamma radiation serves two functions:

- Cross-linking - Improves the wear characteristics of polyethylene\textsuperscript{9}
- Sterilization - Terminal sterilization of some inserts

Oxidation

When polyethylene is exposed to gamma radiation, the gamma energy initially breaks either the carbon-carbon or carbon-hydrogen bonds along the polyethylene chain and forms free radicals. If the polyethylene material with free radicals is exposed to oxygen, oxygen molecules can combine with the free radicals. This can cause the long molecular chains to break, creating even more free radicals in the process. Degradation of the polymer chain continues in the presence of free radicals and oxygen molecules. Polyethylene that is not oxidatively stable has shown mid to long-term clinical mechanical failure and elevated wear rates.\textsuperscript{16}

Thus, it is of crucial importance to either:

- Remove free radicals from the polyethylene material
- Avoid exposure of polyethylene material to oxygen if free radicals are present in the material

It is desirable to remove free radicals from the polyethylene because it is not possible to avoid exposure of the polyethylene insert to oxygen once placed in the body. Therefore, manufacturing techniques like remelting have been developed that allow removal of all free radicals that are generated in the process of gamma irradiation. It has been shown that cross-linking the polyethylene and then remelting above the melt point eliminates free radicals and creates an oxidatively stable polyethylene.\textsuperscript{8}
Technical Details

**Box height of Sigma PS Femoral Components**

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<thead>
<tr>
<th>Size</th>
<th>Height (mm)</th>
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<tbody>
<tr>
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<td>Size 4</td>
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<td>Size 4N</td>
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<tr>
<td>Size 5</td>
<td>18.6 mm</td>
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<tr>
<td>Size 6</td>
<td>19.5 mm</td>
</tr>
</tbody>
</table>

**Sagittal Shape**

*10 mm for size 6

**Coronal Shape**

**Not Available for TC3 Femoral Components**
Amount of rotation allowed by each insert:

- **Posterior Lipped (PLI) Insert**
  - 15°

- **Curved (CVD) Insert**
  - 10°

- **Curved Plus (CVD+) Insert**
  - 20°

- **Stabilized (STB) Insert**
  - 8.0°

- **Stabilized Plus (STB+) Insert**
  - 2.0°

<table>
<thead>
<tr>
<th>Size</th>
<th>Keel Height</th>
<th>M/L Keel</th>
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</thead>
<tbody>
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<td>6</td>
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Sigma High Performance Instruments

Function

HP Instruments deliver Function with Wear Resistance through ease of use and improved alignment. Ease of use, or function, impacts all healthcare providers throughout the surgical pathway including surgeons, scrub techs and surgeon assistants by creating a straightforward and efficient procedure.

Distal Femoral Resection

Efficient - Engineered for fast pinning and easy removal. Adjustments designed to be easy to access and use.

User-Friendly - Designed for comfortable fingertip control.


Fixed Reference

Options - Anterior or Posterior referencing in one system, available in 0, 3, 5, or 7 degrees of rotation. Rotation Guides provide reference points to Whiteside's line and epicondylar axis.

Optimized profile - Cutting blocks minimize soft tissue impingement, enable complete cuts, and are the same M/L width as the implant.

Flexibility - Allows for easy downsizing or upsizing changes, as well as last minute +2 or -2mm adjustments.
Wear Resistance

Wear resistance is a key factor in an implant’s long-term success. It is influenced by implant alignment, which is a combination of surgical skill and precise instrumentation.

Tibial Resection

**Stability** - Blocks are designed to maximize stability against the bone, to promote a more accurate cut.

**Precision** - Instruments provide 1 mm resection adjustment – which allows for optimum gap balancing. Precise calculation sets the exact degree of slope that the surgeon desires based on leg length.

**Versatility** - Multiple alignment checks/tools are available to aid in correct placement and resection.

Tibial Preparation

**Precision** - 1 mm cement mantle produced by instruments provides consistent implant fit.

**Accuracy** - Tray tower is designed for drill and punch to occur at the same spot on the tibia.

**Rotation** - Fixed Bearing instruments allow surgeons to locate optimal implant positioning for rotation.
References


2. Data on File at DePuy Orthopaedics, Inc. WR# 010120.


6. Data on File at DePuy Orthopaedics, Inc.


10. Data on File at DePuy Orthopaedics, Inc. WR# 020159 and 040076.


14. Data on File at DePuy Orthopaedics, Inc. WR# 020085 and 30058.
