25 Reasons to Sell the P.F.C. Sigma® Knee
25 Reasons to Sell the P.F.C. Sigma® Knee System

25 Years of progress and innovation

2,000,000 knees implanted worldwide

10,000 orthopaedic surgeons

95 countries

1 P.F.C. Sigma® Knee System

- No 1 knee replacement in the world
- The most comprehensive and seamless primary and revision knee system
- Extensive long term clinical data
**Around the world success: Most implanted knee in the world**

1. No 1 most implanted knee in the UK National Joint Registry.¹

2. No 1 most implanted knee in the Swedish Knee Arthroplasty Register.²

3. No 1 most implanted cemented knee in the Australian Joint Replacement Registry.³

**Extensive Clinical Heritage**

**Sigma® Knee System**

4. P.F.C. Sigma® Total Knee Arthroplasty: 7-9 year results, 99.7% survivorship.


5. The Wrightington Experience: Excellent clinical results of P.F.C. Sigma® Total Knee Replacement after almost eight years follow-up.


All Poly Tibial Implants

All-poly tibial components can provide excellent performance and survivorship in younger, active patients.


Superior Wear Performance: CoCr Tray, i2 Locking and XLK

A highly polished CoCr tibial tray, oxidatively stable XLK polyethylene and i2 locking mechanism show a significant reduction in wear.

**High Function, Low Wear**

9. **Highly polished CoCr tray:** when compared to the titanium design, it leads to a **47% reduction in volumetric wear** under the same loading conditions – extending implant life especially for active patients. ⁴

10. **i2 Locking Mechanism:** 85% reduction in micromotion compared to the P.F.C.® locking mechanism creating a class leading micromotion level between the modular tibial tray and the tibial insert. ⁵ This results in a **28% reduction in total volumetric wear** when comparing the P.F.C.® locking mechanism and the i2 locking mechanism under the same loading conditions. ⁴

11. **Oxidatively Stable XLK Polyethylene:** moderately cross-linked at 5MRads, leads to high resistance to multidirectional wear ⁶ whilst maintaining the strength and integrity of the polyethylene. ⁷ ⁸ **36% Reduction in total volumetric wear** from GVF to XLK under the same loading conditions. ⁹ Cross-linked and re-melted polyethylenes such as XLK are oxidatively stable both on the shelf and in vivo. ¹⁰

12. Overall combination of the **CoCr Tray, i2 locking and XLK polyethylene** gives an **89% reduction in total volumetric wear** compared to titanium tray, P.F.C.® locking mechanism and GVF under standard kinematic test conditions. ¹¹

13. Sigma® Knee System accommodates the necessity for high function for certain patients with the P.F.C. Sigma® CR150 and RPF femoral components which are designed with an extended J curve to allow safer deep flexion.

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A Complete System

The Sigma® Knee System is a complete system of implant solutions accommodating all surgical and patient needs from early intervention to complex revision surgeries.

Sigma® High Performance Partial Knee: Is the only specifically designed Unicompartmental and Patellofemoral Joint System that has the ability to treat knee arthritis, one compartment at a time, restoring patient’s natural kinematics. The system allows for a variety of component placement scenarios, simultaneous or staged, suited to an individual patient’s anatomy.

Sigma® Primary Knee System: is a completely modular and extensively proven system with high function, low wear mobile and fixed bearing solutions. The range of Sigma® products provide solutions for all types of patients, meaning potential cost savings can be made by matching specific implants to individual patient demand, ranging from the all poly tibia to femurs designed to support high function.

The new Sigma® PS Femoral Component allows you to target competitor surgeons who have concerns about anterior knee pain, patella crepitis and clunk. The evolution of the already successful CS femoral component includes a smoother trochlear groove designed to enhance patella tracking and reduce the risk of soft tissue impingement.
The Sigma® CR150 femur: the design of the posterior condyles has been extended to provide conforming contact up to 150° flexion. This evolution of femoral geometry provides even greater polyethylene protection in deep flexion. At 135° flexion the system provides a 31% increase in contact area resulting in a 19% decrease in contact stress and helping to protect the tibial insert and reduce polyethylene damage.

The TC3 Mobile Bearing Revision System: addresses rotation, fixation and stability in revision surgery.

The Rotating Platform offers rotation in constrained knee replacement designed to minimise polyethylene wear and reduce loosening forces.

Metaphyseal sleeves compensate for substantial bone defects, designed to compressively load the bone resulting in beneficial bone remodelling at the bone-implant interface and providing a strong foundation for implant fixation.

Stability can be achieved with the range of posterior stabilised, varus / valgus constrained or hinged bearing options.
High Performance Instruments

The Sigma® HP Instruments provide the latest and most advanced instrumentation to date from DePuy Orthopaedics. Modern knee replacement demands high performance instrumentation to achieve accurate alignment and a well balanced knee. The cornerstones of the Sigma® HP instrumentation are efficiency, precision and flexibility.

Efficiency: through secure instrument locking, colour coded locking mechanisms and the ‘quick connect’ power pinning system.

Precision: through macro/micro fine tune adjustment, combined componentry and exact instrumentation to create a 1mm cement mantle or line to line fit for uncemented implants.

Flexibility: with femoral preparation available in classic, fixed reference and balanced philosophies. Choice in femoral rotation, femoral referencing and pinning options allow instrumentation to deliver solutions to surgeons regardless of their surgical philosophy.
25 Years of the P.F.C. Sigma® Knee

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2010 is an important year for us at DePuy as it marks 25 years of the P.F.C. Sigma® Knee. Like any modern technology, its success is a result of evolution – a combination of progress and innovation over time to give us what is today a high function, low wear modern knee solution.
There is a major focus on this iconic date with many materials, meetings and opportunities to talk to both existing and competitor surgeons about the evolution and success of the Sigma® Knee brand. The continued success of the P.F.C. Sigma® System is reflected in the volume of Sigma® Knees sold worldwide and the high number of surgeon registrations for the Sigma® High Function Low Wear Symposium in Rome, 18–20th October.
References


4. Data on file at DePuy Orthopaedics, Inc. Data from AMTI knee simulators (WR:010120, 020085 and 030058)


11. Data on file at DePuy Orthopaedics, Inc. Data from AMTI knee simulators (WR030085 & WR030058)


13. Data on file at DePuy International Ltd. DVE-000861-FEA
