

SIGMA[®] Fixed Bearing Knee System

Value Summary

The P.F.C.[®] SIGMA[®] Knee System is the most implanted total knee replacement (TKR) worldwide.¹ It embraces a wide variety of surgeon philosophies and surgical techniques, while providing function, clinical results, and a variety of options for today's patients.

Proven History of Clinical Results

According to The National Joint Registry for England and Wales, 8th Annual Report, 2011, the P.F.C. SIGMA Knee was the market leader for total condylar knee replacements.² The SIGMA Knee System is one of only a few contemporary knee systems on the market for 10 years with a minimum of 7 years of published in-vivo experience.³ Furthermore, the SIGMA Knee is the most implanted total knee replacement worldwide.⁴

- The P.F.C. Total Knee System was launched in 1984, and was widely adopted by many orthopaedic surgeons. Clinical studies have proven the success of the P.F.C. design, with 92.6% survivorship at 15 years.⁵
- Based on this clinical success, the P.F.C. SIGMA System was introduced in 1996. The SIGMA Fixed Bearing Knee System has demonstrated excellent survivorship with 99.6% at 7 years.⁶



SIGMA PS Fixed Bearing

SIGMA CR Fixed Bearing

Variety of Options to Address Patient & Surgeon Needs

The SIGMA Knee System is designed to give surgeons intraoperative flexibility to treat each patient's unique needs, such as solutions for retaining, sacrificing, or substituting the posterior cruciate ligament (PCL). There are also options for patients who desire high flexion components and cementless fixation. The breadth of these implants is supported with today's surgical instruments – High Performance Instruments and TRUMATCH[®] Personalized Solutions.

Background

Reasons for TKR Failure

With the increase in osteoarthritis, the prevalence of degenerative conditions of the knee will rise and contribute to the proliferation of TKR. In fact, the incidence of TKR is significantly increasing in those younger than 65 years. Additionally, implant performance expectations have greatly increased due to factors such as obesity and increasing patient demand for maintenance of activity and lifestyle.⁷ Two of the most common causes of TKR failure are polyethylene wear and instability. A study conducted by Sharkey et al. determined a distribution of reasons of TKR failure stemmed from polyethylene wear 25% of the time and from instability 21.2% of the time.⁸ In another study by Mulhall et al., it was concluded that a distribution of reasons for failure and subsequent revision surgery was caused by polyethylene wear in 24.5% of patients and by instability in 30.2% of patients.⁹ As well, Loughhead et al. collected data from TKR patients 15 years after implantation and identified reasons for revision knee surgery. The two most common reasons for revision TKA were polyethylene wear (32%) and loosening of the components (30%).¹⁰

DePuy Orthopaedics' Implants Address Surgeon & Patient Concerns

DePuy Orthopaedics is the only manufacturer to specifically address the most common TKR failures by offering the combination of femoral components with rounded coronal geometry, oxidatively-stable polyethylene, an i2 locking mechanism, and a highly polished cobalt chrome tray. Additionally, DePuy Orthopaedics is the only orthopaedics company with third-party IACET accredited technical experts who help you pre-plan and integrate innovative technology and techniques to help surgery run more efficiently.

Clinical Benefits

The SIGMA Fixed Bearing Knee System offers a highly polished Cobalt Chrome (CoCr) fixed bearing tibial tray and i2 Locking Mechanism with features not offered by any other competitor in the market. The SIGMA System also features rounded coronal geometry of the femoral components to reduce the potential for excess polyethylene wear.

Highly Polished Cobalt Chrome Surface Reduces the Risk of Wear

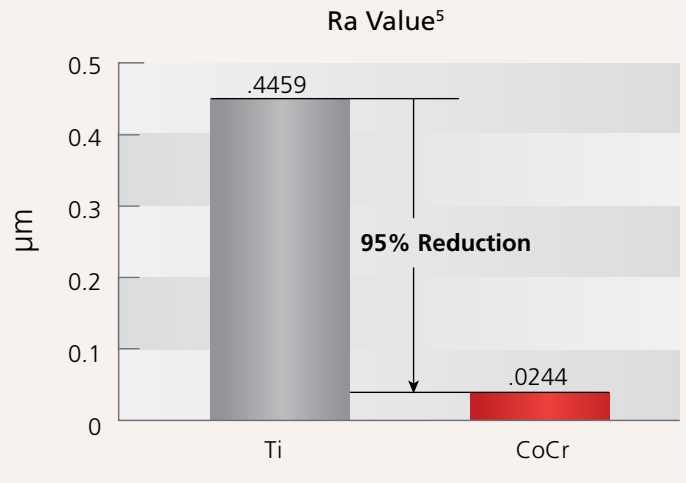
- The highly polished cobalt chrome tibial tray provides a more polyethylene friendly environment than titanium tibial trays with no compromise in material strength or fixation.¹¹
- The surface roughness (measured as Ra Value) of the CoCr tray has been reduced by 95 percent compared to the Titanium tray.¹²
- Polishing the tray has been shown to improve the wear characteristics of the articulation.⁷

i2 Locking Mechanism Reduces Micro Motion

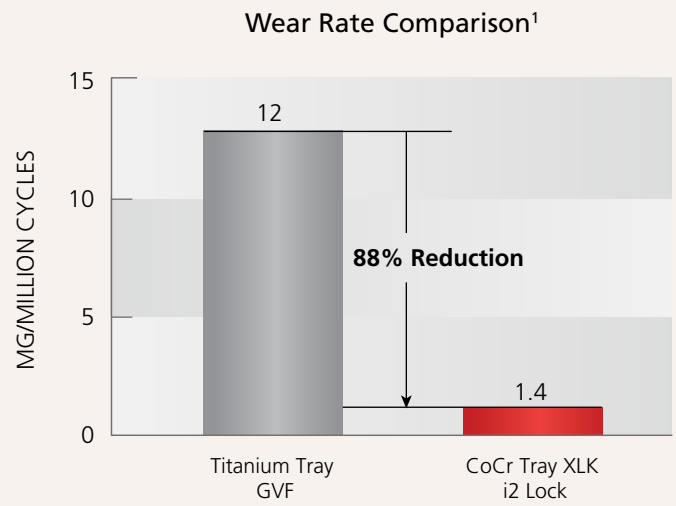
- Because micromotion between the insert and metal tray may be inevitable, the wear characteristics of the inner tray surface should be optimized to minimize debris production.¹³
- The SIGMA i2 Locking Mechanism has reduced the amount of micromotion by 85 percent when compared with the previous locking mechanism.¹⁴
- The SIGMA Knee design demonstrated 16 microns of resultant micromotion and is the lowest amount of motion among a group of implant systems studied, as demonstrated by mechanical testing.¹¹

Rounded Femoral Components Are Polyethylene Friendly

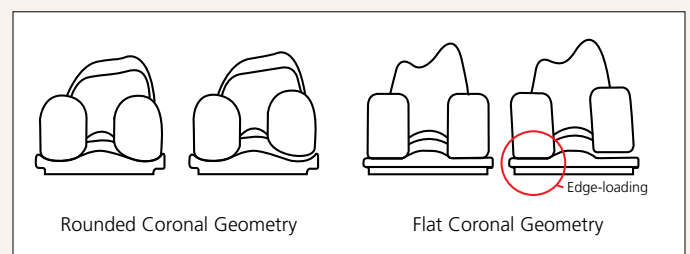
- The SIGMA Knee Systems rounded coronal geometry, as compared to the flat-on-flat design reduces the potential for “edge-loading.”¹⁵
- Since polyethylene wear is one of the leading causes of TKR failure, reducing high concentrations of contact stresses on the polyethylene may reduce the incidence of TKR failure.¹⁶



Measurement of tibial tray surface roughness between SIGMA Titanium & Cobalt Chrome tibial trays



Comparison of wear rates in SIGMA Titanium & Cobalt Chrome tibial trays



Surgical Precision & Efficiency

Economic Benefits

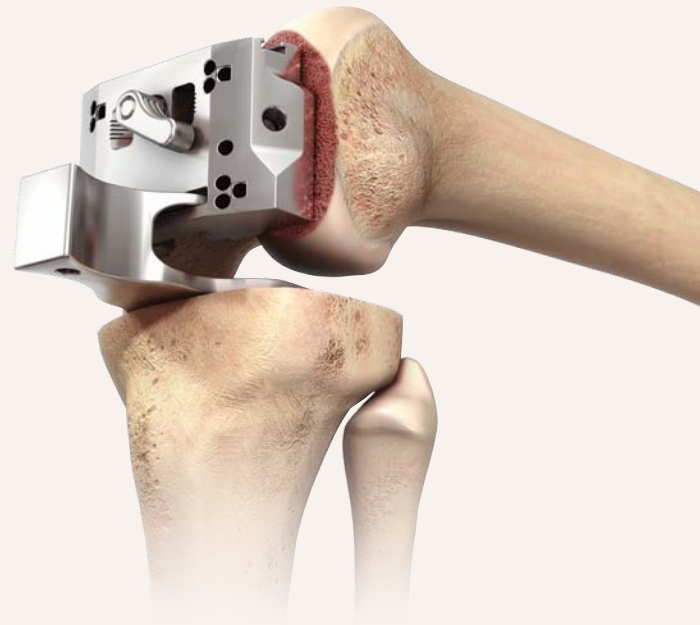
The SIGMA Knee System Instrumentation offers more implant options and more surgical flexibility – all with one efficient instrument system.

High Performance Instruments facilitate a more precise and reproducible surgery. These advanced instruments enable correct implant alignment and surgeon confidence. Unique to DePuy Orthopaedics, the Gap Balanced Surgical technique and instruments provide another highly sought-after option in establishing accurate implant positioning.

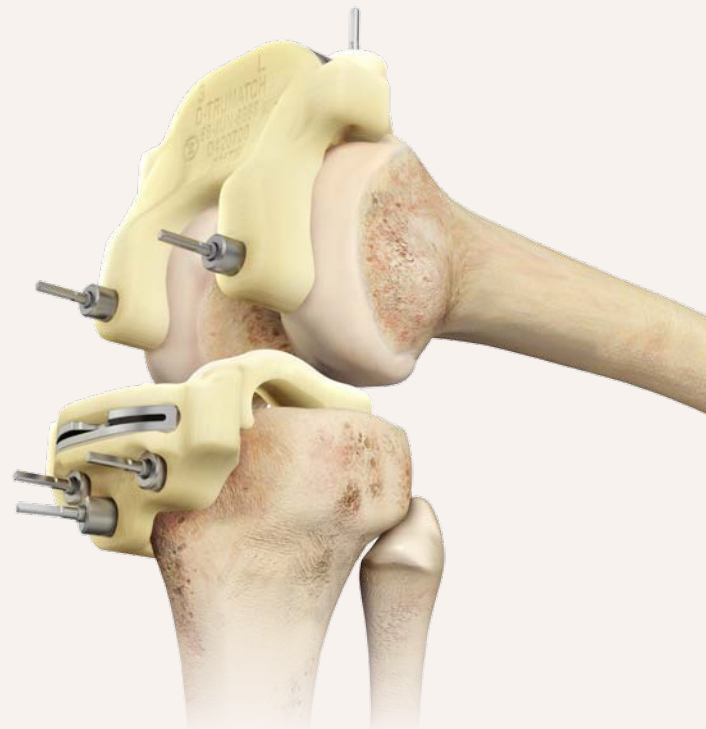
TRUMATCH Personalized Solutions is an advanced technology with preoperative planning that brings patient specific femoral and tibial cutting blocks to the surgeon and a personalized knee replacement surgery to the patient.

Using TRUMATCH Solutions brings a new level of Total Knee Replacement surgery into your OR by:

- Reducing up to 9 surgical steps
- Utilizing as few as 2 trays in the OR
- Simplifying OR set-up and turnover
- Delivering sterile and surgery ready instrumentation
- Providing less invasive instrumentation with integrated metal saw slots and pin guides



High Performance Instruments featuring Gap Balancing Surgical Technique



TRUMATCH Personalized Solutions femoral & tibial cutting blocks

The DePuy Orthopaedics Difference

Trusted quality and innovation

- The most orthopaedic products receiving premarket approval (PMA) in the United States of any major manufacturer¹⁸
- A century of breakthroughs that create value with a broad range of hip, knee, trauma, and shoulder products
- More than 20 years of published clinical success based on DePuy Orthopaedics Rotating Platform technology¹⁹

Proven efficiency

- Enhanced surgical efficiency with High Performance Instrumentation and TRUMATCH Personalized Solutions²⁰
- Strong evidence demonstrating value – with case studies, value dossiers, and data from centers of excellence

Technical expertise and best practices

- The only orthopaedics company with third-party, IACET-accredited technical experts* who help you pre-plan and integrate innovative technology and techniques
- Surgical training that helps you optimize skills
- Community patient education and outreach to help meet higher levels of patient demands

Customer rewards program that offers efficient, consolidated purchasing opportunities

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* Program accredited and certified by Pfiedler Enterprises, an authorized provider for the International Association for Continuing Education and Training (IACET).

For more information, contact your DePuy Orthopaedics representative today.

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