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pfc sigma™

Product Rationale

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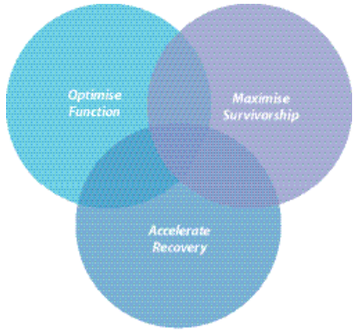
Issued: 03/06



Intelligent **Surgery**

Intelligent surgery is an approach to total knee replacement that places equal importance on:

Optimising function

Maximising survivorship

Accelerating recovery

Its success is founded on leadership in the development of:

Advanced mobile bearing technology

A progressive pathway to Ci™ Minimally Invasive Surgery

Professional education

M. Lehmann, P.F.C.® Sigma™ Rotating Platform Knee Patient, France

DEPUY PATHWAY TO MINIMALLY INVASIVE SURGERY WITH Ci™ GUIDANCE

OPEN CAS.

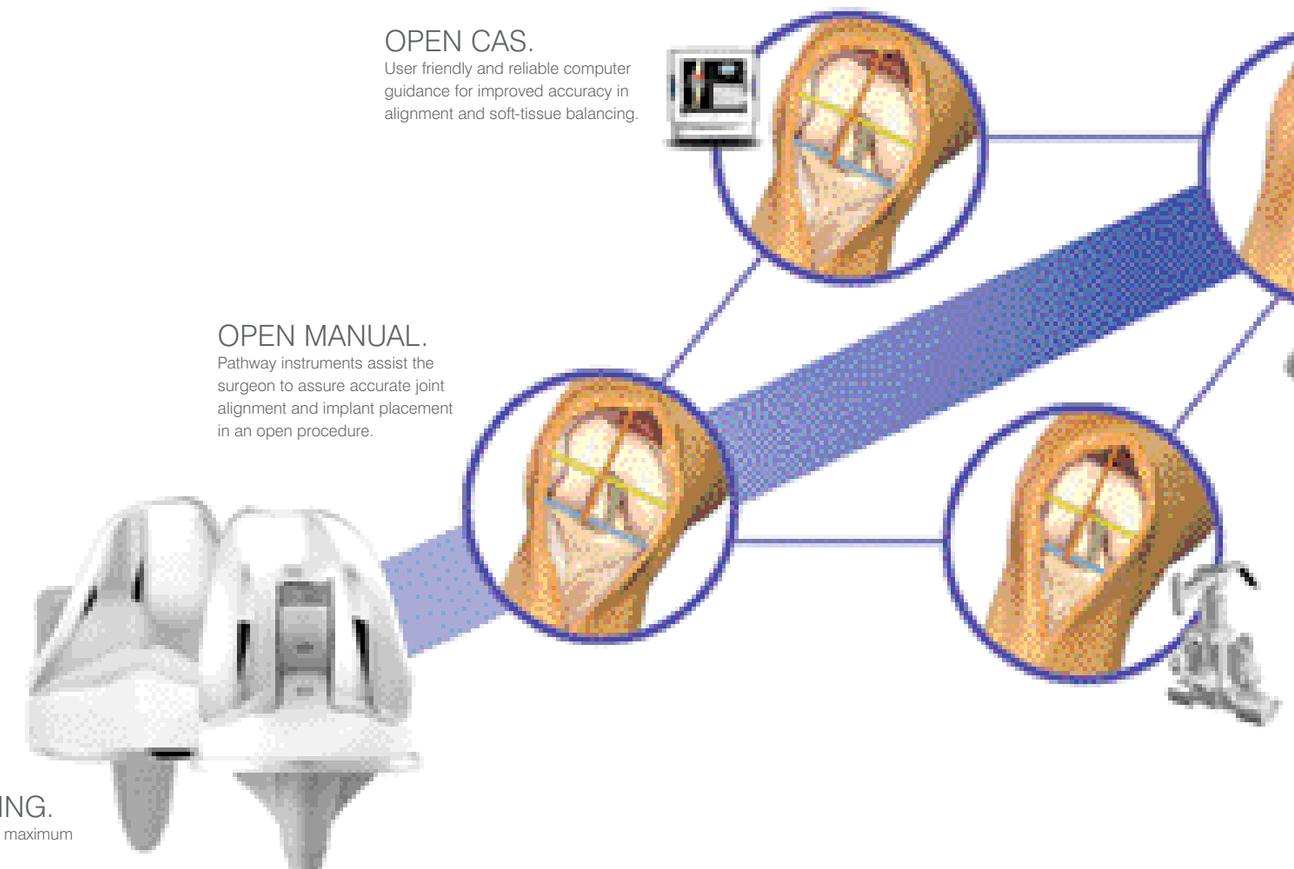
User friendly and reliable computer guidance for improved accuracy in alignment and soft-tissue balancing.

OPEN MANUAL.

Pathway instruments assist the surgeon to assure accurate joint alignment and implant placement in an open procedure.

MOBILE BEARING.

Improved knee function for maximum implant survivorship.



OPTIMISE FUNCTION
MAXIMISE SURVIVORSHIP
ACCELERATE RECOVERY

MI.

Ci™ System navigation helps the surgeon achieve accurate implant placement through the minimum possible exposure, where alignment references are not visible.

MANUAL LESS INVASIVE.

Pathway instruments allow a progressive reduction in surgical exposure, without compromising the visibility of the alignment references.

A SYSTEM OF CHOICE
FROM PRIMARY TO COMPLEX REVISION

P.F.C.® Sigma™ Fixed Bearing Knee System

P.F.C.® Sigma™ Rotating Platform Knee System

P.F.C.® Sigma™ RP-F Knee System

P.F.C.® Sigma™ Revision Knee System

The outstanding clinical success[1,2] of the P.F.C.® Sigma™ Knee System is the outcome of a unique collaboration with leading surgeons Richard Scott, Thomas Thornhill and Chitranjan Ranawat. The P.F.C.® Sigma™ offers today's most comprehensive, integrated knee system. It embraces all philosophies and surgical techniques. It offers the surgeon fixed and mobile bearing platforms, with PCL retaining and substituting options. The system continues to develop with the addition of further implant options, instrumentation and Ci™ Guidance computer precision surgery.

LEADERSHIP IN MOBILE BEARING DESIGN

DePuy invented mobile bearing total knee replacement with the introduction of the LCS® Knee System in 1977.
The rotating platform design, with its unrivalled clinical success[3], was integrated into the P.F.C.® Sigma™ Knee System in 2000.

The congruent, articulating surfaces of the rotating platform design maximise contact area
and minimise polyethylene stress, to assure long-term survivorship.[4]

The unidirectional motion pattern, produced by the rotating platform hardens and strengthens the
polyethylene bearing surface and reduces wear.[5]

94%

Wear reduction has been reported for the P.F.C.® Sigma™ rotating platform design compared to a fixed bearing design.[6]

The P.F.C.® Sigma™ rotating platform design allows increased rotation of the knee and therefore more natural knee function.[7]
Clinical results clearly indicate that bearing rotation also plays an important role in assuring long-term fixation,
by transforming shear force into compression.[3]

THE ULTIMATE LOW WEAR PLATFORM

The M.B.T. (Mobile Bearing Tibial) Tray builds upon clinical experience gained with the DePuy rotating platform design.

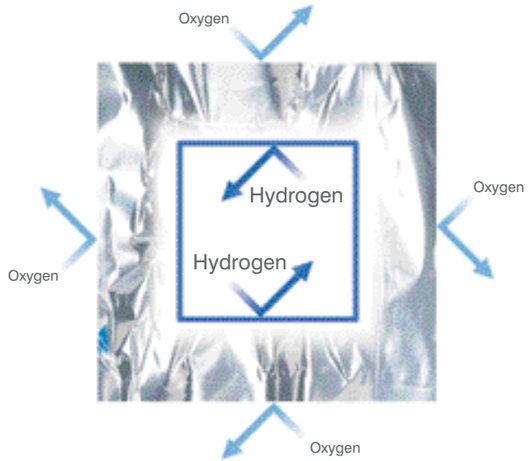
Its long-term success, 97.7% survivorship at twenty years, demonstrates that its bearing rotation effectively reduces wear and loosening forces and so assures maximum implant survivorship.[3]

The highly polished top surface of the M.B.T. Tray allows the insert to articulate smoothly and assures excellent low wear performance.[6]

Bearing rotation allows the surgeon to position the M.B.T. Tray for maximum coverage of strong cortical bone, and so assure even load transfer and secure fixation.

The M.B.T. Revision Tray allows compensation of substantial bone loss in complex primaries as well as revision cases.

UNIQUE DEPUY GAMMA VACUUM FOIL (GVF) PACKAGED STERILISATION FOR INCREASED WEAR RESISTANCE

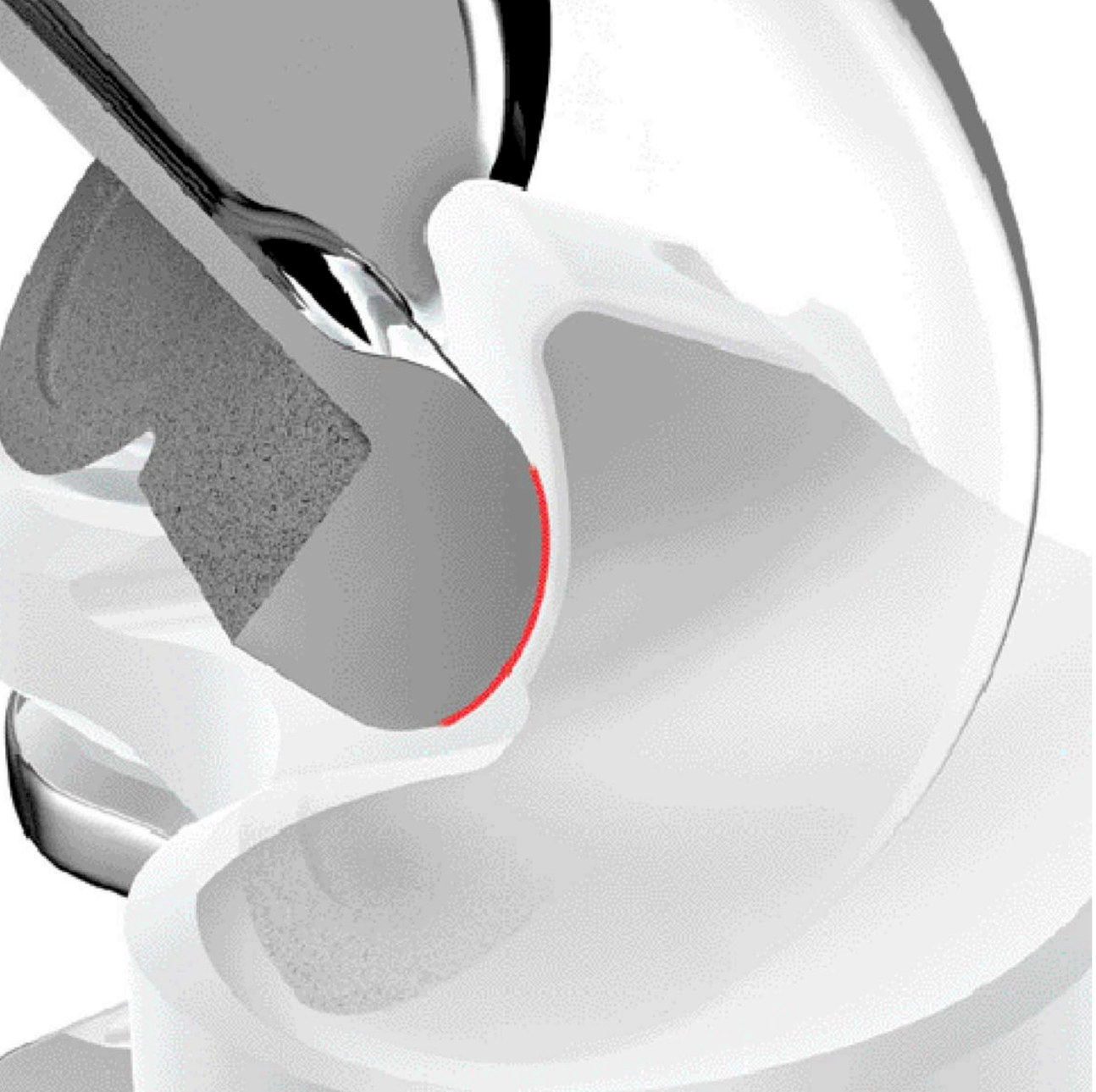


Sterilisation in a **patented vacuum foil pouch** promotes hydrogen recombination to maintain maximum material strength. As a result, wear resistance is significantly increased in comparison with other barrier packaged materials.[8]

Barrier packaging prevents oxidation and therefore maintains material toughness.

Mild crosslinking of the polymer chains, produced by conservative irradiation at 40 kGy (4 Mrad), further increases resistance to abrasive wear without compromising material toughness.

In clinical use since 1996.[9]



P.F.C.® SIGMA™ RP-F: PERFORMANCE IN FLEXION

Patients need to bend their knee into deep flexion for a full and active lifestyle. Deep knee flexion is a global patient requirement.

The P.F.C.® Sigma™ RP-F Knee System has proven to provide a design specific improvement in post-operative range of motion.[10]

DEEP KNEE FLEXION REQUIRES ROTATION

The P.F.C.® Sigma™ RP-F Knee System is designed to accommodate increased loading and rotation in deep knee flexion, to provide high function and long-term survivorship.

EXTENDED POSTERIOR CONDYLES

The posterior curve of the P.F.C.® Sigma™ RP-F Knee System is extended to assure smooth curve-on-curve contact through 155 degrees of flexion to minimise polyethylene wear.

CONFORMING CAM AND SPINE DESIGN

The unique cam and spine design of the P.F.C.® Sigma™ RP-F knee prosthesis becomes fully congruent in deep knee flexion and acts as a third weight bearing surface, which is designed to stabilise the knee in flexion and to minimise polyethylene wear.

Accelerated and predictable posterior rollback, provided by the cam and spine design, facilitates deep knee flexion.[11]

OPTIMAL WEAR PERFORMANCE IN FIXED BEARING KNEES

The P.F.C.® and P.F.C.® Sigma™ fixed bearing knee systems have delivered outstanding clinical results.[1,2]
DePuy has evolved the P.F.C.® Sigma™ fixed bearing knee system to meet
the high expectations of today's young and active patients.

The P.F.C.® Sigma™ knee system offers the choice of the clinically proven[1] Titanium - or the optional Cobalt Chrome tibial tray.

The newly designed i2 locking mechanism reduces micromotion between tibial insert and tray by 85% on all fixed bearing tibial trays.[12]

The highly polished surface of the Cobalt Chrome tray provides an extremely polyethylene friendly
environment and is designed to reduce underside wear for high demand patients.

DePuy offers the choice of the clinically proven[2], mild cross-linked 40 kGy (4 Mrad) GVF polyethylene
as well as the moderate 50 kGy (5 Mrad) cross-linked tibial insert for its fixed bearing P.F.C.® Sigma™ product range.

Moderate crosslinking 50 kGy (5 Mrad) of the polymer chains provide increased resistance to the multidirectional
wear generated by fixed bearing designs.

89%

DePuy moderately crosslinked polyethylene - in combination with the Cobalt Chrome tray - delivers an 89% reduction in wear.[13]

BEARING ROTATION TAKES THE STRESS OUT OF REVISION

True modularity and intra-operative flexibility made the clinically successful P.F.C.® Sigma™ fixed bearing knee revision system the implant of choice for many teaching hospitals around the world.[14]

With the introduction of the M.B.T. Revision Tray, DePuy offers further benefits to the surgeon in complex primaries as well as revision cases:

ROTATION

The M.B.T. Revision Tray offers bearing rotation in constrained revision knee replacement to minimise polyethylene wear and reduce loosening forces.

FIXATION

Unique stepped sleeves compensate for substantial bone defects, compressively load the bone and provide an immensely strong foundation for implant fixation.

STABILITY

The P.F.C.® Sigma™ revision knee system allows compensation of the patient's individual soft tissue deficiencies, with cruciate retaining, posterior stabilised or varus / valgus constrained bearing options.

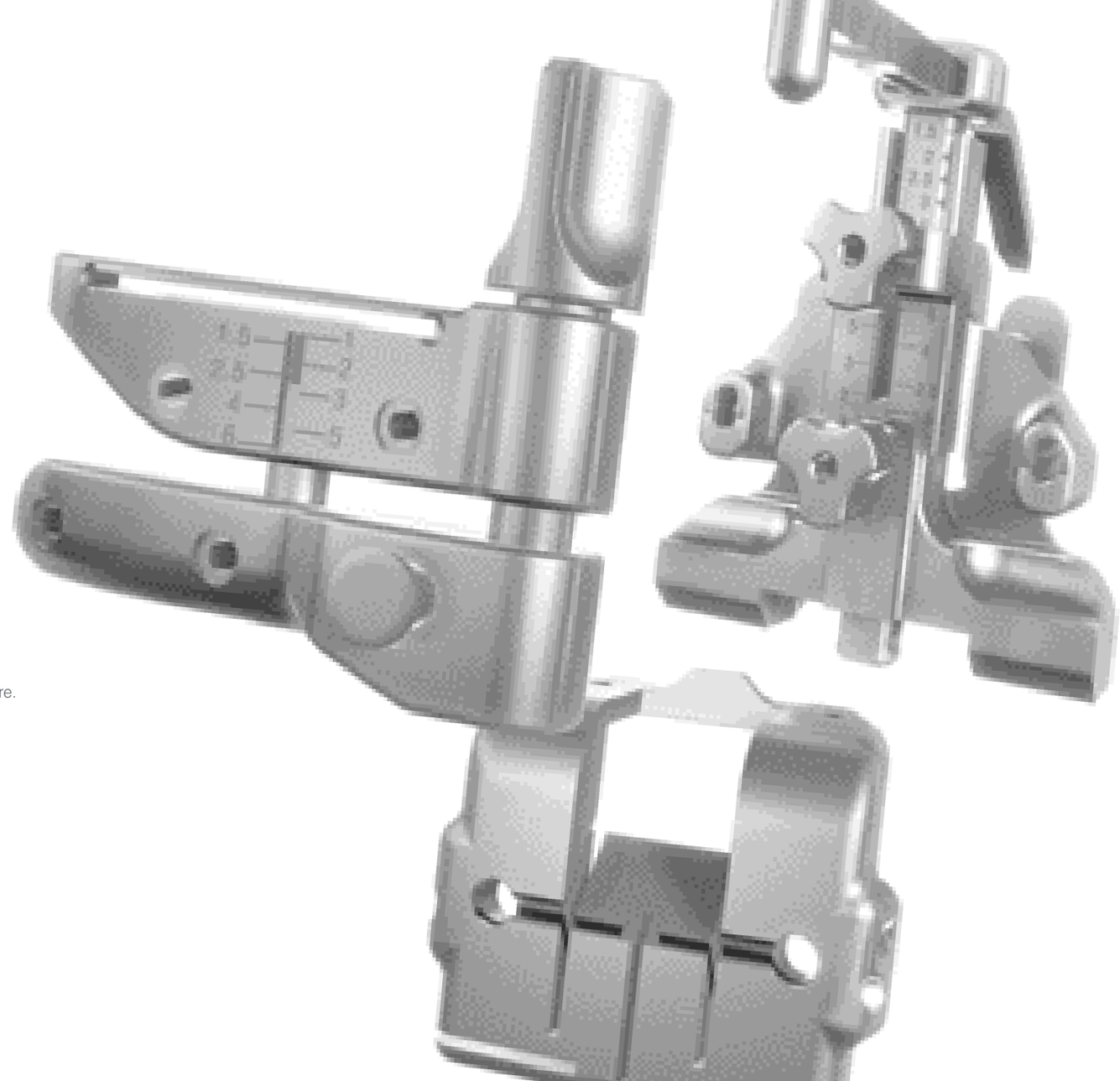
A SINGLE SET OF PATHWAY INSTRUMENTS FOR ALL SURGICAL APPROACHES

One set of Pathway instruments supports open manual, open CAS, manual less invasive and minimally invasive CAS techniques.

Short, front - to - back bone cuts follow a familiar surgical technique and avoid the variation produced by long medial / lateral cuts in minimally invasive surgery. This assures precise bone preparation for accurate implant placement.

Pathway instruments are significantly smaller than conventional TKR instruments, with reduced profiles. The sequence of the bone cuts creates space within the soft tissue envelope and makes it easier to operate through a reduced exposure.

A single set of instruments for all approaches reduces hospital inventory and allows maximum intra-operative flexibility and choice.



Ci™ GUIDANCE FOR PRECISE IMPLANT PLACEMENT

Ci™ Guidance brings a new level of precision and control to open and minimally invasive knee replacement.
The Ci™ System with Pathway instruments assists the surgeon to align the implant within 1 mm and 1 degree of its planned position.

The visualisation provided by the Ci™ System assists accurate placement of the P.F.C.® Sigma™ implant in minimally invasive knee replacement with Pathway instruments. Clinical results of navigated and manual minimally invasive procedures show significantly better alignment with CAS.[15]

The combination of the Ci™ System and the CAS ligament tensor allows the surgeon to accurately balance the joint.

The intuitive workflow and clear virtual imagery makes Ci™ guided surgery simple, easy to learn and reproducible.