DePuy Synthes
JOINT RECONSTRUCTION
COMPANIES OF Johnson & Johnson

KNEE REVISION

PORTFOLIO

Revision Solutions

KNEE REVISION PORTFOLIO

The *DePuy Synthes Joint Reconstruction* Knee Revision Portfolio offers surgeons a comprehensive array of implant options for cases that require varying levels of constraint. From moderate soft tissue laxity and minor bone defects through end-stage revision, each system promotes successful patient outcomes through the following areas:

- Reduce loosening forces with rotating platform
- Address instability from bone loss with metaphyseal sleeves
- Provide seamless surgical integration
- Fewer instrument trays could improve OR time

System Options:

PFC® SIGMA® PS RP

PFC® SIGMA® TC3 RP

S-ROM® Noiles™ Hinge

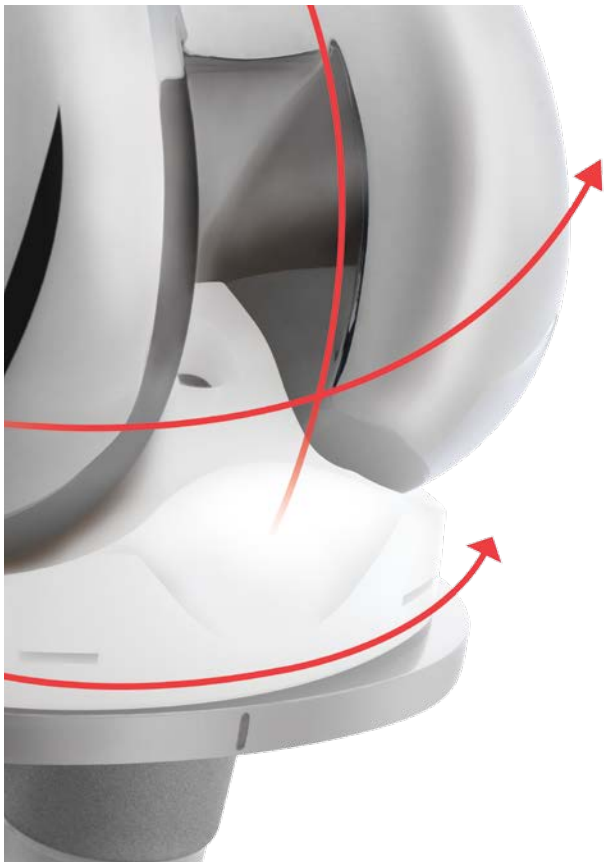
Limb Preservation System (LPS)™

MBT Revision with sleeve and stem

ADDRESSING THE TOP TWO REASONS FOR KNEE FAILURE:

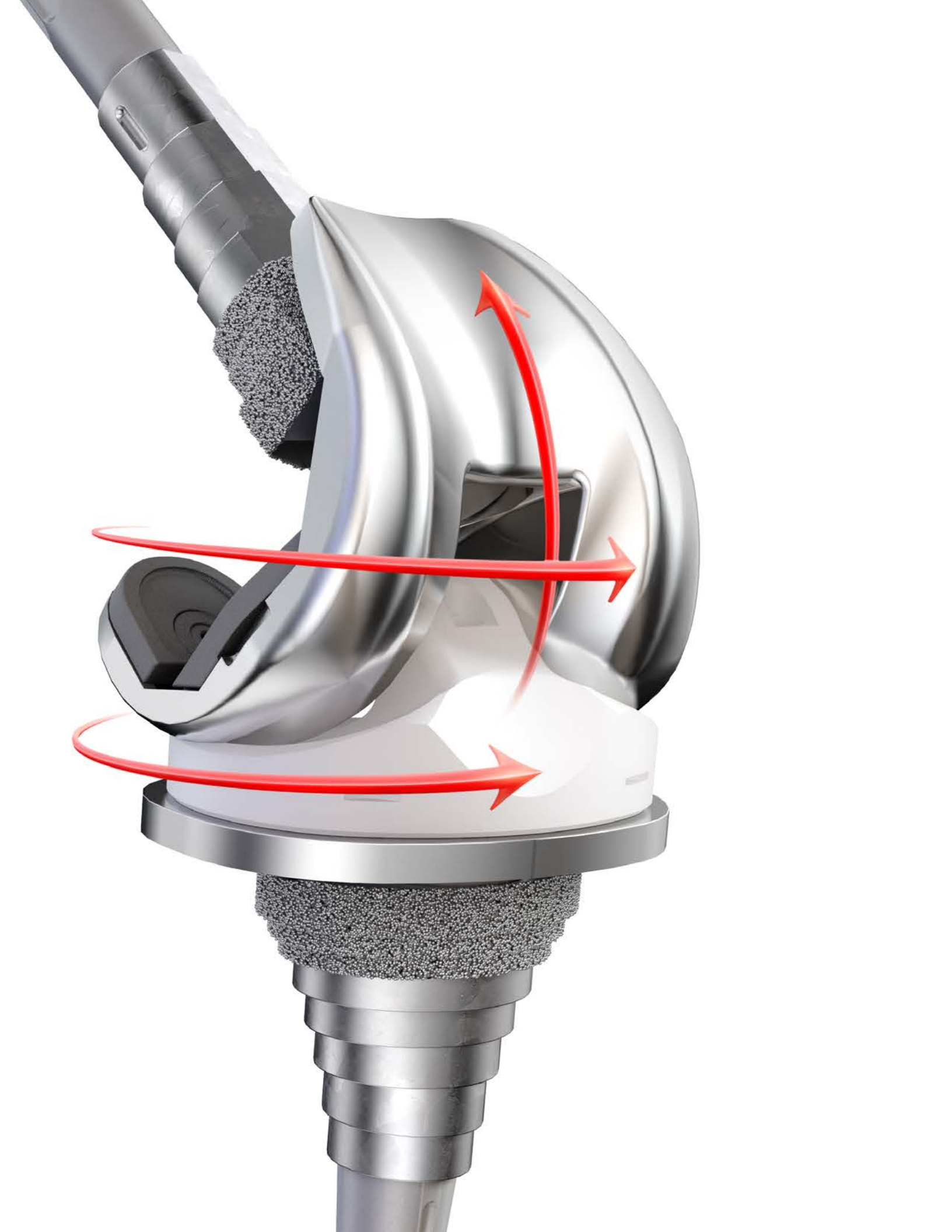
Addressing Loosening

with Rotating Platform



Addressing Instability

with Metaphyseal Sleeves



REDUCE LOOSENING FORCES WITH ROTATING PLATFORM

The only revision knee portfolio with a mobile bearing option for every constraint level.

Fixed bearing tray stress

Fixed bearings allow rotation, but shear and torsional forces also pass through to the fixation interface.

Rotating platform rotational freedom

The rotating platform mobile bearing diffuses loosening forces above the tibial tray.

SIGMA® TC3 RP has been shown to reduce torque stresses by up to 87% versus a constrained fixed bearing device.[1]

Inevitably, as constraint increases, rotation (induced by normal knee function) passes through the joint and loosening forces become stronger at the fixation interface. Optimized, curve-on-curve bearings are designed to accept rotation and for many patients this will be sufficient. However, only the SIGMA Revision Rotating Platform System provided the rotational freedom to actively diffuse loosening forces, making it suitable for increased mechanical constraint within the implant.[1] Freedom to rotate also allows the implant to find its natural alignment post-operatively, bringing the bearing surfaces into congruent, low-wear contact.

ADDRESS INSTABILITY FROM BONE LOSS WITH METAPHYSEAL SLEEVES

Unique stepped sleeves compensate for substantial cavitary defects, compressively load the bone and provide a solid foundation for implant stability.

Case History

Pre-operative X-ray

Post-operative X-ray

With the tibial defects filled, the surgeon is able to restore the patient's natural joint line.

The metaphyseal sleeves can fill type 2 and 3 defects, while bringing the implant into contact with strong, supportive bone. The sleeve is stepped to compressively load the bone and form a strong foundation for reliable implant stability, avoiding excessive bone resection and preserving true joint line restoration. The sleeves provide a variety of sizes and options (both fully porous and distally porous).

PROVIDE SEAMLESS SURGICAL INTEGRATION

Provides simplified surgical approaches to handle a multitude of situations encountered in the OR.

Same canal preparation throughout the systems. Universal Stems on both the tibia and femur allow rotational stability and reduce end-stem pain.

Same broaching technique throughout the various levels of constraint. A simplified surgical flow allows the surgeon to cut directly off the tibial broach and reference femoral cuts.

Same tibial preparation regardless of the level of constraint needed. This eliminates the need for additional instrumentation and OR time. As the MBT Revision Tibial Tray is universal, the surgeon can seamlessly transition to the next level of constraint.

PFC SIGMA PS RP

PFC SIGMA TC3 RP

S-ROM Noiles Hinge

Limb Preservation System (LPS)

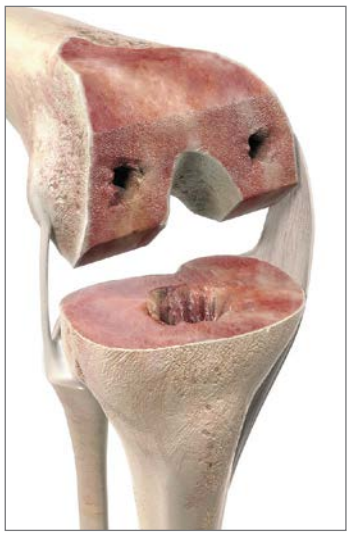
MBT Revision with sleeve and stem

BONE DEFECTS IN REVISION TOTAL KNEE ARTHROPLASTY

The *DePuy Synthes Joint Reconstruction* Revision Knee System allows the surgeon to address T1/F1, T2/F2 and T3/F3 bone defects, taking full account of the soft tissue envelope status from a fully functional joint through the absence of any viable ligaments.[2]

Type 1

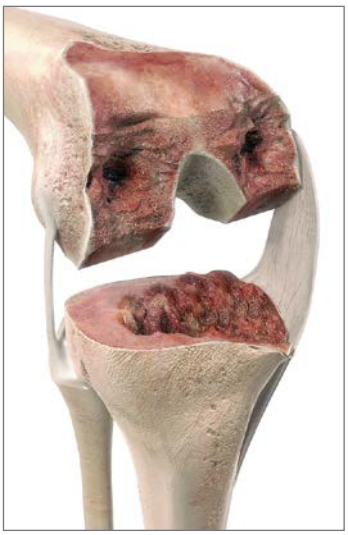
T1 Tibia/F1 Femur

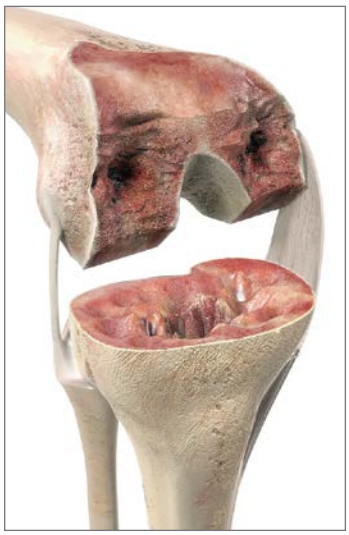


- Localized defect: cortical rim intact
- Near normal joint line
- Often requires small amounts of bone graft

Type 2

T2 Tibia/F2 Femur





- Cortical rim intact
- Central or peripheral metaphysis loss
- Requires cement fill, cancellous bone graft, augments or sleeves to restore joint line

Type 3

T3 Tibia/F3 Femur

- Loss of entire metaphysis and cortex
- Requires structural bone graft, hinged implant or sleeve
- Compromised ligaments

SOFT TISSUE LOSS IN REVISION TKA

Ligament Status:

- Stable
- PCL Absent
- LCL Absent
- MCL Absent
- All Absent

Implant selection for revision TKA is based upon a combination of soft tissue/ligament stability and bone defects. The chart below shows *DePuy Synthes Joint Reconstruction's* recommended implant systems using the Engh Bone Defect Classification System and ligament stability in the patient's joint.[2]

Revision TKA Defect to Prostheses Match

Soft tissue laxity →

Bone defects ↓

	Stable	PCL Absent	LCL Absent	MCL or All Absent
T1/F1	Non-stabilized or stabilized	Stabilized	Stabilized or VVC (Varus/Valgus Constraint)	Hinge
T2/F2	Stabilized or VVC	Stabilized or VVC	VVC or hinge	Hinge
T3/F3		Hinge	Hinge	Hinge or LPS

PFC SIGMA TC3

- Provides constraint needed with reduced tibial tray loosening forces
- Compatible with both the rotating platform revision tray and the fixed bearing options
- Addresses the majority of commonly recognized defects

Soft tissue laxity →

Bone defects ↓

	Stable	PCL Absent	LCL Absent	MCL or All Absent
T1/F1	CR or PS Augment or graft	PS Augment or graft	**PS or TC3** Stem always with TC3; Sleeve, augment and/or graft where required	S-ROM Noiles Hinge Sleeve always; Stem, augment and/or graft where required
T2/F2	**PS or TC3** Stems always; Sleeve, augment and/or graft where required	**PS or TC3** Stems always; Sleeve, augment and/or graft where required	**TC3 or S-ROM Noiles Hinge** Stems always; Sleeve, augment and/or graft where required	S-ROM Noiles Hinge Sleeve always; Stem, augment and/or graft where required
T3/F3		S-ROM Noiles Hinge Stems and sleeves always; Augment and/or bone graft where required	S-ROM Noiles Hinge Stems and sleeves always; Augment and/or bone graft where required	S-ROM Noiles Hinge or LPS Stems and sleeves always; Augment and/or bone graft where required

Trays: MBT Revision Tray for mobile bearing revision (recommended), PFC SIGMA Mod+ or PFC SIGMA Offset Tray for fixed bearing.
Stems: Recommend stems for TC3 and S-ROM Noiles Hinge prostheses.
Sleeves: Recommend sleeves for all T3/F3 defects.

S-ROM Noiles Hinge

- Clinically proven hinge design for patients with severe soft tissue instability and/or bone deficiency[3]
- Offers a load-sharing polyethylene insert to reduce stress and wear
- Unique sleeve options for tibial and femoral bone defects
- Compatible with same MBT Revision tray as with less constrained options; providing a seamless surgical flow

Soft tissue laxity →

Bone defects ↓

	Stable	PCL Absent	LCL Absent	MCL or All Absent
T1/F1	CR or PS Augment or graft	PS Augment or graft	PS or TC3 Stem always with TC3; Sleeve, augment and/or graft where required	**S-ROM Noiles Hinge** Stems and sleeves always; augment and/or graft where required
T2/F2	PS or TC3 Stems always; Sleeve, augment and/or graft where required	PS or TC3 Stems always; Sleeve, augment and/or graft where required	**TC3 or S-ROM Noiles** Hinge Stems always; Sleeve, augment and/or graft where required	**S-ROM Noiles Hinge** Stems and sleeves always, augment and/or graft where required
T3/F3		**S-ROM Noiles Hinge** Stems and sleeves always; Augment and/or bone graft where required	**S-ROM Noiles Hinge** Stems and sleeves always; Augment and/or bone graft where required	**S-ROM Noiles Hinge or LPS** Stems and sleeves always; Augment and/or bone graft where required

Trays: MBT Revision Tray with Orthogenesis LPS insert for mobile-bearing revision (recommended): S-ROM Noiles tray available.
Stems: Recommend stems for TC3 and S-ROM Noiles Hinge prostheses.
Sleeves: Recommend sleeves for all T3/F3 defects.

LPS (Limb Preservation System)

- Most comprehensive lower extremity system
- Used for end-stage revision, severe trauma and oncology cases
- Compatible with MBT Revision Trays
- Unique ability to resect bone in 5 mm increments
- Offer a variety of surgical options, including cemented or press-fit stems and metaphyseal sleeves.

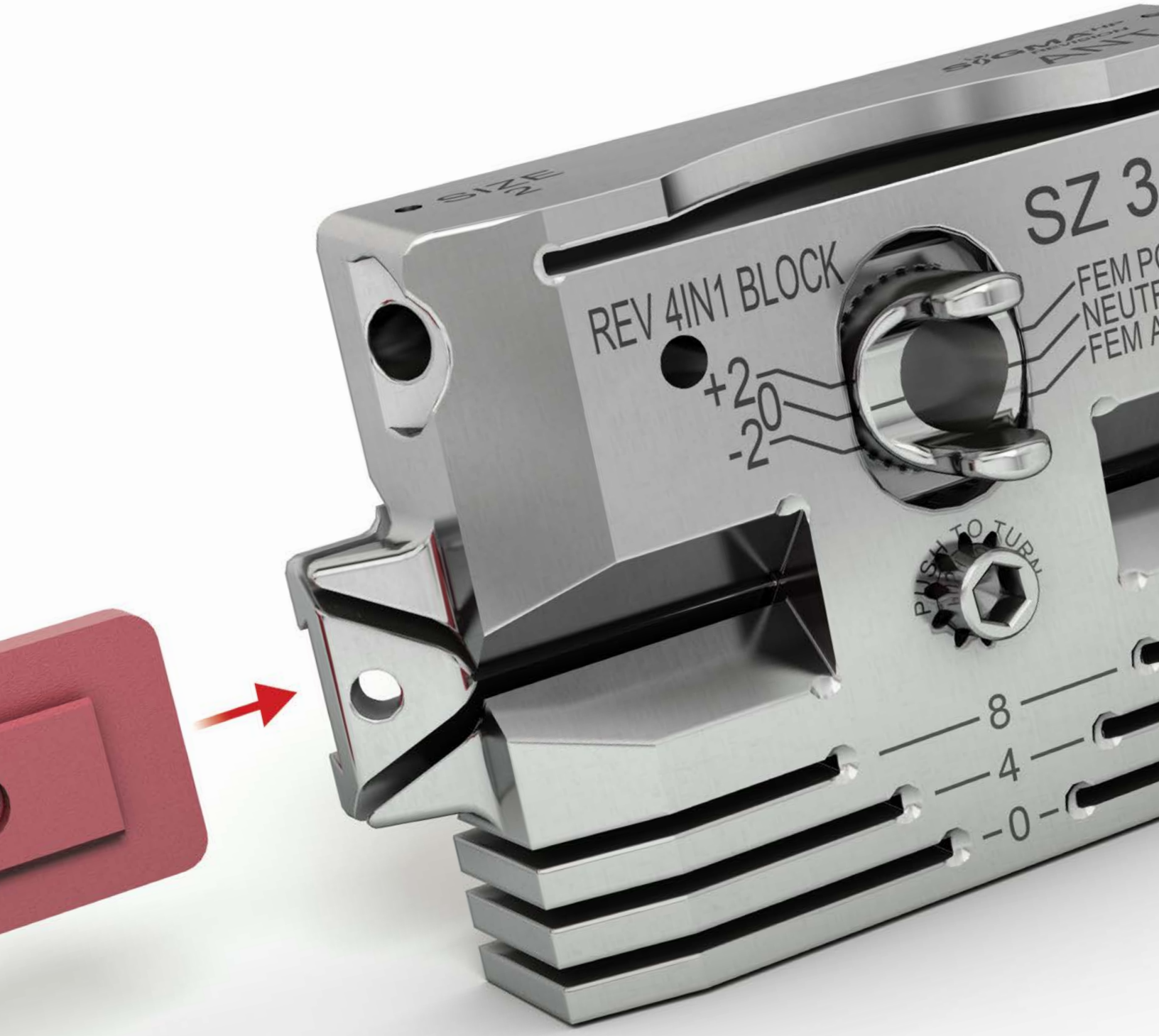
Proximal Femoral Replacement

Total Femoral Replacement

Midshaft Femoral Replacement

Distal Femoral Replacement

Proximal Tibial replacement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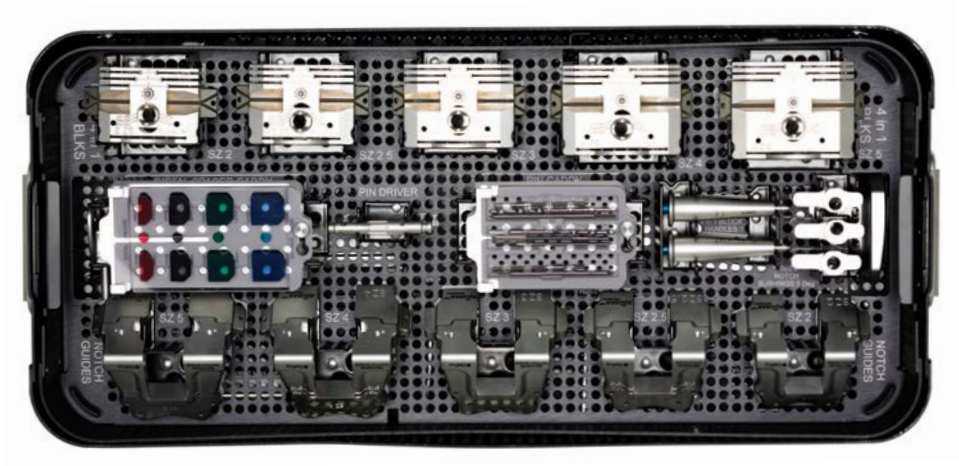
FEWER INSTRUMENT TRAYS COULD IMPROVE OR TIME

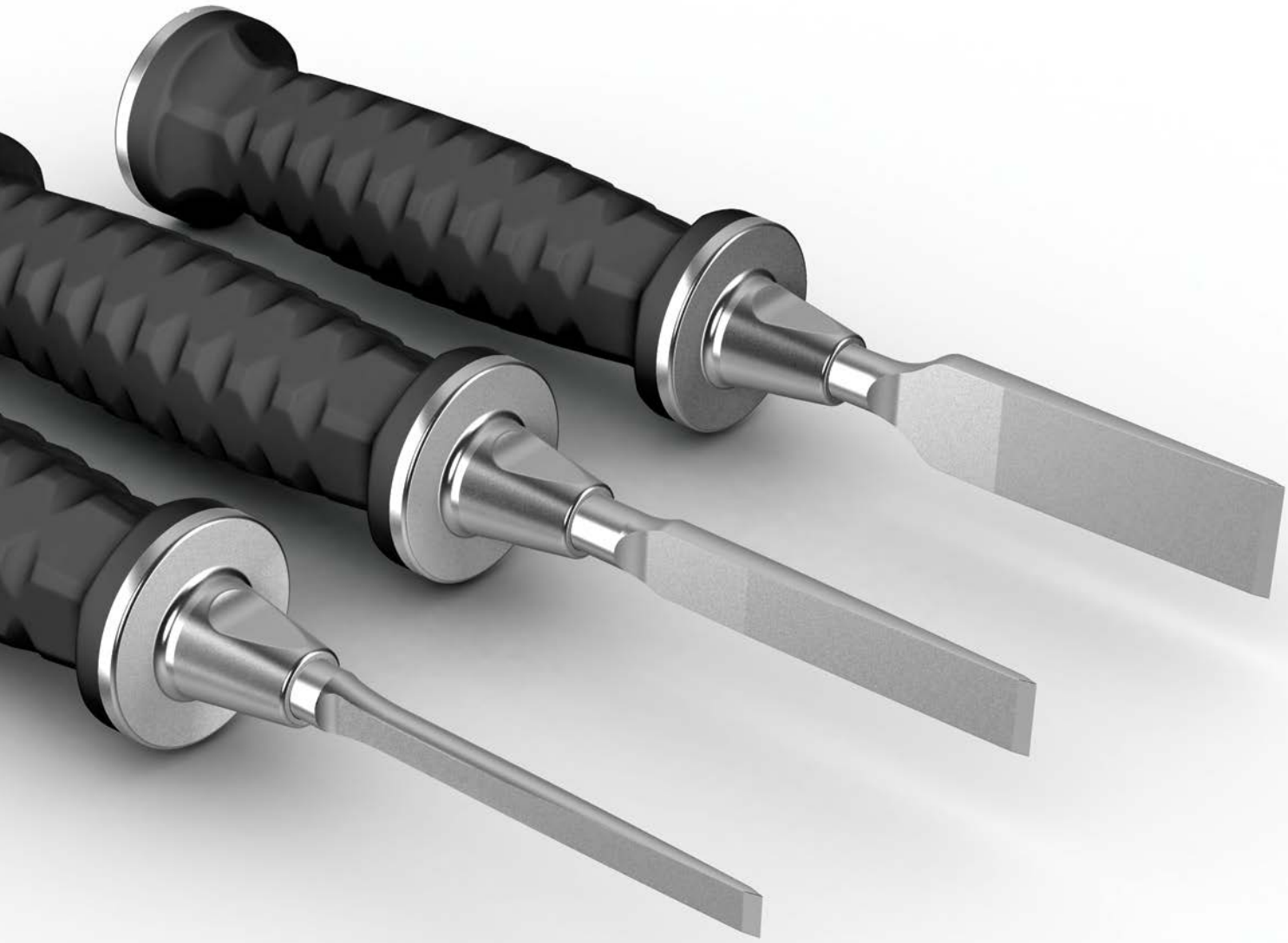
High Performance Revision Instrumentation designed to make complex revisions easier.

When performing a complete knee revision, *DePuy Synthes Joint Reconstruction* High Performance Revision Instrument System (HP) reduces the amount of instrument cases needed by 40% versus leading competitors.* In addition, with enhanced visual cues, easy adjustments on the cutting blocks, and a new simplified trialing system, the HP Revision Instruments allow surgeons to increase efficiency throughout the procedure.



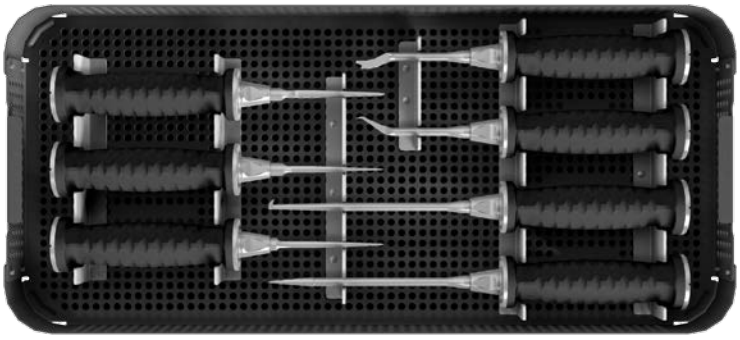
The end result is an instrument system that delivers simplicity and reproducibility to revision challenges encountered in the OR.

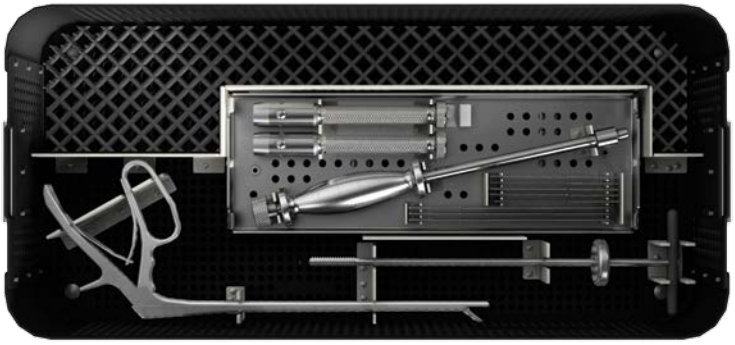
*Comparison between SIGMA TC3 RP and S-ROM Hinge surgical techniques versus Zimmer® LCCK and RHK surgical techniques and Stryker® TS and MRH surgical techniques.

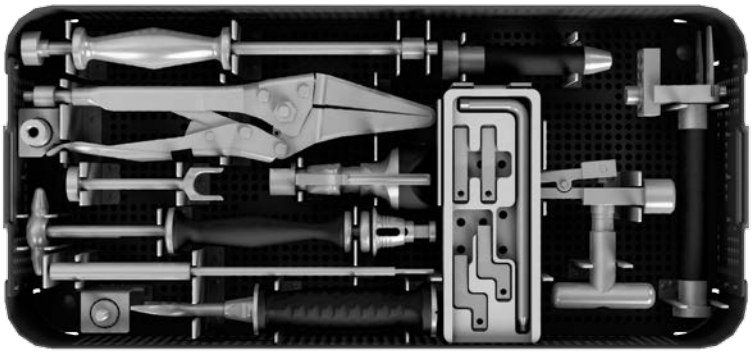


HP Extraction Instruments

- Instruments designed to aid in the removal of any implant system
- Ergonomic handles and easy to use adjustments







IMPORTANT

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DESCRIPTION

The DePuy LPS™ Limb Preservation System is designed for the replacement of the mid-shaft portion of the femur, proximal, distal and/or total femur, and proximal tibia. The DePuy LPS system offers a variety of component options (including, but not limited to, proximal femoral bodies, segmental components, distal femoral components, femoral stems, tibial stems, proximal tibial components, hinged tibial insert bearings, metaphyseal sleeves, and adapters). The components, which can be used in conjunction with certain components from other systems, are for treatment of patients presenting bone loss and deformity associated with bone tumors resection, trauma, infection, and difficult revision arthroplasty. A total femoral replacement is possible in those cases where no part of the femur can be salvaged.

INDICATIONS

The DePuy LPS System is intended for use in replacement of the mid-shaft portion of the femur, proximal, distal and/or total femur, and proximal tibia, especially in cases that require extensive resection and replacement. Specific diagnostic indications for use include:

• malignant tumors (e.g., osteosarcomas, chondrosarcomas, giant cell tumors, bone tumors) requiring extensive resection and replacement;

• patient conditions of noninflammatory degenerative joint disease (NIDJD), e.g. avascular necrosis, osteoarthritis, and inflammatory joint disease (IJD), e.g., rheumatoid arthritis, requiring extensive resection and replacement;

• revision cases for a failed previous prosthesis requiring extensive resection and replacement;

• severe trauma requiring extensive resection and replacement.

The LPS System is also intended for use in bone loss post-infection, where the surgeon has elected to excise the bone and replacement is required.

The S-ROM tibial tray and the non-porous coated straight and bowed stems are intended for cemented use only.

The porous-coated metaphyseal sleeves are intended for either cemented or cementless applications.

CONTRAINDICATIONS

1. Active local or systemic infection.

2. Loss of bone or musculature, osteoporosis, neuromuscular compromise or vascular deficiency in the affected limb in sufficient degree to render the procedure unjustifiable (e.g., absence of musculoligamentous supporting structures, joint neuropathy).

NOTE: Diabetes, at present, has not been established as a contraindication. However, because of the increased risk for complications such as infection, slow wound-healing, etc., the physician should carefully consider the advisability of knee replacement in the severely diabetic patient.

WARNINGS AND PRECAUTIONS

CAUTION: Federal Law (USA) restricts this device to sale by or on the order of a physician.

- DePuy's Single Use devices have not been designed to undergo or withstand any form of alteration, such as disassembly, cleaning or re-sterilization, after a single patient use. Reuse can potentially compromise device performance and patient safety.
- Implants and trial components from different manufacturers or implant systems should never be used together.
- Prosthesis components should never be reimplanted. Even though the implant appears undamaged, the implant may have developed microscopic imperfections, which could lead to failure.
- Always use a trial prosthesis for trial purposes. Trials should not be assembled with any components intended for permanent implantation. Trials must have the same configuration size, etc. as the corresponding components to be permanently implanted.
- Do not alter or modify implants in any way.
- When used with multiple components of the Limb Preservation System, the MR compatibility and safety of the entire system of implants has not been evaluated and the entire system of implants has not been tested together for heating or migration in the MR environment. The risks of exposure to MR include heating and/or displacement of a metallic implant. Image artifacts including dead zones and distortion may occur, especially in the immediate area around the implant, requiring optimization of imaging parameters. In line with the recommendations of the American College of Radiology, DePuy recommends that a professional familiar with the specific MRI apparatus to be used, assess the patient prior to any MRI examination or therapy.

CAUTION: The following conditions, singularly or concurrently, tend to impose severe loading on the affected extremity thereby placing the patient at higher risk of failure of the prosthesis.

1. Obesity or excessive patient weight.
2. Manual Labor.
3. Active sports participation.
4. High levels of patient activity.
5. Likelihood of falls.
6. Alcohol or drug addiction.
7. Other disabilities, as appropriate.

The following physical conditions, singularly or concurrently, tend to adversely affect the fixation of prosthesis:

1. Marked osteoporosis or poor bone stock.
2. Metabolic disorders or systemic pharmacological treatments leading to progressive deterioration of solid bone support for the implant (e.g., diabetes mellitus, steroid therapies, immunosuppressive therapies, etc.).
3. History of general or local infections.
4. Severe deformities leading to impaired fixation or improper positioning of the implant.
5. Tumors of the supporting bone structures.
6. Allergic reactions to implant materials (e.g., bone cement, metal, polyethylene).
7. Tissue reactions to implant corrosion or implant wear debris.
8. Disabilities of other joints (i.e., hips or ankles)

A higher incidence of implant failure has been reported in paraplegics and in patients with cerebral palsy or Parkinson Disease.

WHEN THE SURGEON DETERMINES THAT A PROSTHESIS IS THE BEST MEDICAL OPTION AVAILABLE AND DECIDES TO USE THIS PROSTHESIS IN A PATIENT WHO HAS ANY OF THE ABOVE CONDITIONS OR WHO IS SIMPLY YOUNG AND ACTIVE, IT IS IMPERATIVE THAT THE PATIENT BE INSTRUCTED ABOUT THE STRENGTH LIMITATIONS OF THE MATERIALS USED IN THE DEVICE AND FOR FIXATION AND THE RESULTANT NEED TO SUBSTANTIALLY REDUCE OR ELIMINATE ANY OF THE ABOVE CONDITIONS.

The surgical and postoperative management of the patient must be carried out with due consideration for all existing conditions. Mental attitudes or disorders resulting in a patient's failure to adhere to the surgeon's orders may delay postoperative recovery and/or increase the risk of adverse effects including implant or implant fixation failure.

Excessive physical activity or trauma to the replaced joint may contribute to premature failure of the prostheses by causing a change in position, fracture, and/or wear of the implants. The functional life expectancy of prosthetic implants is, at present, not clearly established. The patient should be informed that factors such as weight and activity levels may significantly affect wear.

IMPORTANT

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INDICATIONS AND USAGE

The NOILES Rotating Hinge Knee is indicated for use with PMMA bone cement in primary or revision cases in patients:

- who have reached skeletal maturity and
- for whom the surgeon has decided to resect both cruciate ligaments or whose cruciate ligaments are absent or incompetent and
- who exhibit insufficiency of lateral/collateral ligaments and other soft supporting tissue due to the following conditions:

o Rheumatoid arthritis, osteoarthritis, post-traumatic arthritis, and arthritis secondary to a variety of diseases and anomalies

o Failure of a previous knee reconstruction procedure

o Trauma

CONTRAINDICATIONS

1. Active infection or history of general infections or local infectious disease.
2. Vascular insufficiency, muscular atrophy or neuromuscular disease in the affected limb.
3. Advanced loss of osteochondral structure that would preclude proper fixation of the prosthesis.
4. Tumors of the supporting bone structure, systemic and metabolic disorders leading to progressive deterioration of solid bone support.
5. Drug or alcohol addiction, or limiting neuropathic disease.
6. Skeletal immaturity.
7. Obesity or very active lifestyle that can produce loads on the prosthesis that can lead to failure of the fixation of the device or device itself.
8. Allergic reaction to the implant materials.
9. Inadequate flexor and extensor mechanism necessary to achieve a functional prosthetic joint.

WARNINGS

Improper prosthesis selection or alignment, inadequate fixation, use where contraindicated or in patients whose medical, physical, mental, or occupational conditions will likely result in extreme stresses to the implant, may result in premature failure due to loosening, fracture, or wear.

Postoperative care is extremely important. The patient should be instructed on the limitations of the device and should be cautioned regarding load bearing, ranges of motion, and activity levels permissible. Early motion and load bearing should be carefully controlled.

The S-ROM tibial base, tibial sleeve, tibial stem extension, and tibial augmentation blocks may not be used with the NOILES Posterior Stabilized Knee.

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.

PRECAUTIONS

The NOILES Rotating Hinge Knee is designed to articulate from 6° hyperextension to 110° flexion. If, due to grossly inadequate soft tissue integrity, flexion beyond 90° causes luxation of the plateau assembly out of the tibial base, the patient must have a knee brace postoperatively to limit flexion to 90°. In such cases, the surgeon should consider closing the wound with the knee in full extension.

The size of the tibial plateau assembly must correspond with the size of the femoral component.

The size of the tibial augmentation block must correspond to the size of the tibial base.

Femoral sleeves are required when using femoral stem extensions.

A femoral plug is required with the femoral sleeve when a femoral stem extension is not used.

A tibial cap is required with the tibial sleeve when a tibial stem extension is not used.

Tibial augmentation blocks cannot be used when tibial sleeves are being used.

An implant should never be reused. Any implant, once used, should be discarded. Even though it appears undamaged, it may have small defects and/or internal stress patterns that may lead to failure. Likewise, a new implant should be handled carefully to avoid damage that could compromise the integrity of the device and cause early failure or loosening.

The wear rate of prosthesis contact surfaces is greatly accelerated if loose fragments of bone cement become detached and act as an abrasive in the bearing surfaces. When using bone cement, care should be taken to remove all excess cement from the periphery of the implant.

DePuy's Single Use devices have not been designed to undergo or withstand any form of alteration, such as disassembly, cleaning or re-sterilization, after a single patient use. Reuse can potentially compromise device performance and patient safety.

ADVERSE EFFECTS

Fracture may occur due to improper preparation of the implant site or if excessive force is used during seating of the implant. Transient peroneal palsy has been reported following total knee arthroplasty, especially after correction of severe flexion or valgus deformities.

Patients have complained of persistent pain and stiffness following total knee arthroplasty. In addition, patellar tendon rupture, femoral-tibial subluxation or dislocation, and persistent ligamentary laxity have been reported with the use of total knee implants. Infection and loosening have been reported following total joint arthroplasty, as have wear and failure due to fracture of knee prosthesis components.

Histological reactions have been reported as an apparent response to exposure to a foreign material. The actual clinical significance of these reactions is unknown.

Serious adverse side effects may necessitate surgical intervention.

Total and Unicompartmental Knee Prosthesis

IMPORTANT:

This Essential Product Information sheet does not include all of the information necessary for selection and use of a device. Please see full labeling for all necessary information.

INTENDED USE:

Total or unicompartmental knee arthroplasty is intended to provide increased patient mobility and reduced pain by replacing the damaged knee joint articulation in patients where there is evidence of sufficient sound bone to seat and support the components. Total or unicompartmental knee replacement may be considered for younger patients if, in the opinion of the surgeon, an unequivocal indication for total or unicompartmental knee replacement outweighs the risks associated with the age of the patient, and if limited demands regarding activity and knee joint loading can be assured. This includes severely crippled patients with multiple joint involvement for whom a gain in knee mobility may lead to an expectation of significant improvement in the quality of their lives.

INDICATIONS:

Candidates for total or unicompartmental knee replacement include patients with a severely painful and/or severely disabled joint resulting from osteoarthritis, post-traumatic arthritis, rheumatoid arthritis, or a failed previous implant. In candidates for unicompartmental knee arthroplasty, only one side of the joint (the medial or lateral compartment) is affected.

THE SIGMA C/R POROCOAT FEMORAL COMPONENTS ARE INTENDED FOR CEMENTED OR CEMENTLESS USE AS THE FEMORAL COMPONENT OF A TOTAL KNEE REPLACEMENT SYSTEM.

IN THE US THIS POROUS COATED COMPONENT HAS
BEEN CLEARED FOR CEMENTED USE ONLY.

ANY NON-POROUS COATED COMPONENT IS INTENDED FOR CEMENTED USE ONLY.

CONTRAINDICATIONS:

The following conditions are contraindications for total or unicompartmental knee replacement:

1. Active local or systemic infection.
2. Loss of bone or musculature, osteoporosis, neuromuscular compromise or vascular deficiency in the affected limb in sufficient degree to render the procedure unjustifiable (e.g., absence of musculoligamentous supporting structures, joint neuropathy).
3. Severe instability secondary to advanced loss of osteochondral structure or the absence of collateral ligament integrity.
4. Unicompartmental knee replacement is contraindicated in patients with a severe (over 30°) fixed valgus or varus deformity.

NOTE: Diabetes, at present, has not been established as a contraindication. However, because of the increased risk for complications such as infection, slow wound healing, etc., the physician should carefully consider the advisability of knee replacement in the severely diabetic patient.

WARNINGS AND PRECAUTIONS:

CAUTION:

- Implants and trial components from different manufacturers or implant systems should never be used together.
- Knee prosthesis components should never be reimplanted. Even though the implant appears undamaged, the implant may have developed microscopic imperfections which could lead to failure.
- Always use a trial prosthesis for trial purposes. Trials should not be assembled with any components intended for permanent implantation. Trials must have the same configuration size, as the corresponding components to be permanently implanted.
- Do not alter or modify implants in any way.
- Avoid drilling multiple pin holes in the proximal tibia which may affect the compressive strength of the tibia.

CAUTION: The following conditions, singularly or concurrently, tend to impose severe loading on the affected extremity thereby placing the patient at higher risk of failure of the knee replacement:

1. Obesity or excessive patient weight.
2. Manual Labor.
3. Active sports participation.
4. High levels of patient activity.
5. Likelihood of falls.
6. Alcohol or drug addiction.
7. Other disabilities, as appropriate.

In addition to the above, the following physical conditions, singularly or concurrently, tend to adversely affect the fixation of knee replacement implants:

1. Marked osteoporosis or poor bone stock.
2. Metabolic disorders or systemic pharmacological treatments leading to progressive deterioration of solid bone support for the implant (e.g., diabetes mellitus, steroid therapies, immunosuppressive therapies, etc.).
3. History of general or local infections.
4. Severe deformities leading to impaired fixation or improper positioning of the implant.
5. Tumors of the supporting bone structures.
6. Allergic reactions to implant materials (e.g. bone cement, metal, polyethylene).
7. Tissue reactions to implant corrosion or implant wear debris.
8. Disabilities of other joints (i.e., hips or ankles).

A higher incidence of implant failure has been reported in paraplegics and in patients with cerebral palsy or Parkinson Disease.

WHEN THE SURGEON DETERMINES THAT KNEE REPLACEMENT IS THE BEST MEDICAL OPTION AVAILABLE AND DECIDES TO USE THIS PROSTHESIS IN A PATIENT WHO HAS ANY OF THE ABOVE CONDITIONS OR WHO IS SIMPLY YOUNG AND ACTIVE, IT IS IMPERATIVE THAT THE PATIENT BE INSTRUCTED ABOUT THE STRENGTH LIMITATIONS OF THE MATERIALS USED IN THE DEVICE AND FOR FIXATION AND THE RESULTANT NEED TO SUBSTANTIALLY REDUCE OR ELIMINATE ANY OF THE ABOVE CONDITIONS.

The surgical and postoperative management of the patient must be carried out with due consideration for all existing conditions. Mental attitudes or disorders resulting in a patient's failure to adhere to the surgeon's orders may delay postoperative recovery and/or increase the risk of adverse effects including implant or implant fixation failure.

Excessive physical activity or trauma to the replaced joint may contribute to premature failure of the knee replacement by causing a change in position, fracture, and/or wear of the implants. The functional life expectancy of prosthetic knee implants is, at present, not clearly established. The patient should be informed that factors such as weight and activity levels may significantly affect wear.

DePuy's Single Use devices have not been designed to undergo or withstand any form of alteration, such as disassembly, cleaning or re-sterilization, after a single patient use. Reuse can potentially compromise device performance and patient safety.

ADVERSE EVENTS:

The following are the most frequent adverse events after knee arthroplasty: change in position of the components, loosening, tibial subsidence, bending, cracking, fracture, deformation or wear of one or more of the components, infection, tissue reaction to implant materials or wear debris; pain, dislocation, subluxation, flexion contracture, decreased range of motion, lengthening or shortening of leg caused by improper positioning, looseness or wear of components; fractures of the femur or tibia.

LCS® COMPLETE™ – PFC® SIGMA® RP Mobile Bearing Total Knee System

IMPORTANT

This Essential Product Information sheet does not include all of the information necessary for selection and use of a device. Please see full labeling for all necessary information.

INDICATIONS

CEMENTED USE:

The LCS® COMPLETE™ – PFC® SIGMA® RP Mobile Bearing Total Knee System is indicated for cemented use in cases of osteoarthritis and rheumatoid arthritis. The RP-F insert and femoral component are indicated where a higher than normal degree of postoperative flexion is required. The rotating platform prosthesis and modular revision components are indicated for revision of failed knee prostheses.

UNCEMENTED USE:

The porous coated Keeled and Non Keeled MBT™ (Mobile Bearing Tibial) Tray configurations of the LCS Total Knee System are indicated for noncemented use in skeletally mature individuals undergoing primary surgery for reconstructing knees damaged as a result of noninflammatory degenerative joint disease (NIDJD) or either of its composite diagnoses of osteoarthritis and post-traumatic arthritis pathologies. The Rotating Platform device configuration is indicated for use in knees whose anterior and posterior cruciate ligaments are absent or are in such condition as to justify their sacrifice. The PFC SIGMA RP Curved bearings when used with the PFC SIGMA Cruciate Retaining Femoral Component can be used in posterior cruciate ligament retaining procedures.

CONTRAINDICATIONS

The use of the LCS COMPLETE – PFC SIGMA RP Mobile Bearing Total Knee System is contraindicated in:

- the presence of osteomyelitis, pyrogenic infection or other overt infection of the knee joint;
- patients with any active infection at sites such as the genitourinary tract, pulmonary system, skin or any other site. Should a patient have any infection prior to implantation,
  the foci of the infection must be treated prior to, during and after implantation.
- patients with loss of musculature or neuromuscular compromise leading to loss of function in the involved limb or in whom the requirements for its use would affect recommended rehabilitation procedures.
- patients with severe osteoporosis or other metabolic bone diseases of the knee.
- patients with any of the following conditions:
  - lesions of the supporting bone structures (e.g. aneurysmal or simple bone cysts, giant cell tumor or any malignant tumor),
  - systemic and metabolic disorders leading to progressive deterioration of solid bone support,
  - the presence of severe instability secondary to advanced loss of osteochondral structure or the absence of collateral ligament integrity, fixed deformities greater than 60° of flexion, 45° of genu varus or valgus,
  - known drug or alcohol addiction,
  - skeletally immature individuals and the presence of allergic reaction to implant metals or polyethylene are also contraindications for the noncemented, porous coated, MBT and LCS COMPLETE – PFC SIGMA RP Mobile Bearing device configurations, and for the cemented use of all device configurations of the LCS COMPLETE – PFC SIGMA RP Mobile Bearing Total Knee System.

CONTRAINDICATIONS FOR USE WITHOUT CEMENT

Noncemented use of the Porous Coated Keeled or Non-Keeled MBT Tray device configurations is contraindicated in patients with sufficient loss in quantity or quality of bone stock (as determined on x-ray) such that successful noncemented fixation is unlikely. Additional contraindications may become apparent at the time of surgery. These include:

- vascular deficiency at the bone site;
- inadequate bone stock to assure both a firm press fit and close apposition of the cut bone surfaces to the prosthesis;
- the inability to make bone cuts so as to assure both correct component position and intimate apposition of bone and prosthetic surfaces;
- inadequate bone quality (e.g. severe osteoporosis) and lack of stability of the implanted components.

In the presence of any of the above conditions the components should be fixed with cement.

WARNINGS AND PRECAUTIONS

Components labeled for "Cemented Use Only" are to be implanted only with bone cement. The following conditions tend to adversely affect knee replacement implants: excessive patient weight, high levels of patient activity, likelihood of falls, poor bone stock, metabolic disorders, disabilities of other joints.

ADVERSE EVENTS

The following are the most frequent adverse events after knee arthroplasty: change in position of the components, loosening, bending, cracking, fracture, deformation or wear of one or more of the components, infection, tissue reaction to implant materials or wear debris; pain, dislocation, subluxation, flexion contracture, decreased range of motion, lengthening or shortening of leg caused by improper positioning, looseness or wear of components; fractures of the femur or tibia.

References:

1. Souchen, D. (2011). Rotating platform total knee prosthesis reduce axial rotational constraint torque.
2. Engh, G.A., et. al. (1997). Revision total knee arthroplasty. *Williams and Wilkins, Co.*
3. Jones, R.G. (2005). Mobile bearings in revision total knee arthropplasty. *AAOS Instructional Course Lectures, 54*.

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WARNING: In the USA, this product has labeling limitations. See package insert for complete information.

CAUTION: USA Law restricts these devices to sale by or on the order of a physician.

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0612-00-506 (Rev. 6) 2M 01/14